SODIUM CHLORIDE, POTASSIUM CHLORIDE

Vol. 1

VOLUME 1

GRAS MONOGRAPH SERIES
SODIUM CHLORIDE, POTASSIUM CHLORIDE

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Table of Contents

SUMMARY

SODIUM CHLORIDE

CHEMICAL INFORMATION

		Page
I.	Nomenclature	1
II.	Empirical Formula	1
III.	Structural Formula	1
IV.	Molecular Weight	1
V.	Specifications	1
VI.	Description	7
VII.	Analytical Methods	8
VIII.	Occurrence and Levels	8

BIOLOGICAL DATA

I.	Acute Toxicity	10
	A. Fish	10
	B. Chickens	10
	C. Mice	14
	D. Rats	15
	E. Guinea Pigs	16
	F. Rabbits	16
	G. Cats	16
II.	Short-term Studies	17
	General Toxic Effects	17
	A. Fowl	17
	B. Mice	22
	C. Rats	22
	D. Rabbits	24
	E. Dogs	25
	F. Pigs	28
	G. Human Toxicity	32
	Dangers of Salt as an Emetic Agent	36
	Toxic Effects from Hypertonic Saline for Intractable Pain	37
	Dangers of Hypertonic Saline for Abortion	38
	Salt and Hypertension	38
	Chickens	38
	Rats	39
	Rabbits	45
	Dogs	46
	Humans	49
	Salt in Infant Foods	85
	Rats	85
	Humans	86

III. Long-term Studies 94
A. Mice 94
B. Rats 94
C. Rabbits 108
IV. Special Studies 109
A. Chick Embryos 109
B. Mice 112
C. Rats 113
D. Rabbits 113

BIOCHEMICAL ASPECTS

I. Effects on Enzymes and Other Biochemical Parameters 115
A. Mice 115
B. Rats 115
C. Dogs 117
D. Humans 119
II. Drug Interactions 120
A. Microorganisms 120
B. Rats 120
III. Consumer Exposure Information 123

POTASSIUM CHLORIDE

CHEMICAL INFORMATION

I. Nomenclature 127
II. Empirical Formula 127
III. Structural Formula 127
IV. Molecular Weight 127
V. Specifications 127
VI. Description 130
VII. Analytical Methods 130
VIII. Occurrence and Levels 131

BIOLOGICAL DATA

I. Acute Toxicity 132
A. Mice 132
B. Rats 132
C. Guinea Pigs 135
D. Rabbits 135
E. Sheep 136
F. Goats 137
II. Short-term Studies 137
A. Mice 137
B. Rats 138
C. Rabbits 139
D. Dogs 139
E. Sheep 141
F. Monkeys 142
G. Human toxicity 143

III. Special Studies 148
A. Amphibians 148
B. Human Toxicity 148

BIOCHEMICAL ASPECTS

I. Drug Interactions 149
A. Guinea Pigs 149
B. Dogs 149
C. Humans 149
II. Effects on Enzymes and Other Biochemical Parameters 150
Humans 150
III. Consumer Exposure Information 151

SODIUM CHLORIDE AND POTASSIUM CHLORIDE

BIOLOGICAL DATA

I. Special Studies 153
Chick Embryos 153

BIOCHEMICAL ASPECTS

I. Breakdown 154
II. Absorption-Distribution 154
A. Sheep 155
B. Humans 155
III. Metabolism and Excretion 156
Humans 159
IV. Effects on Enzymes and Other Biochemical Parameters 163

SUMMARY

Acute Toxicity

Sodium chloride has an oral MLD in chickens of 4000 mg/kg BW (2234). In mice, the oral LD_{50} is 6441 mg/kg BW (0258). Orally in rats, an LD_{50} value of 3750 mg/kg BW has been found (0361). In the guinea pig, an intravenous LDL_0 of 2910 mg/kg BW was reported (0056).

Potassium chloride has an oral LD_{50} in rats of 3020 mg/kg BW (0362). For the guinea pig, an oral ALD of 2500 mg/kg BW has been reported (3343). The oral MLD for rabbits is 2000 mg/kg BW (3292); intravenously in this species, the MLD is 80 mg/kg BW (2600). In sheep, an oral MLD value of 4000 mg/kg BW was found (3292). For goats, an oral LD of 4000 mg/kg BW was reported (3292). (The other acute toxicity data for sodium chloride and potassium chloride are listed in Tables 1 and 72, respectively.)

Short-term Studies

Saline infused i.v. into rabbits caused toxic effects similar to the usual neurologic signs at hypertonic dehydration in infants and children (0812). Salt accidentally used in place of sugar in a hospital nursery formula resulted in the death of 6 of 14 infants and neurologic symptoms in 5 others. A unique and distinctive kidney lesion was found also (0908). The literature reveals that the use of salt as an emetic agent has caused many deaths, but recommendations for its use are still found on labels of common household products. Directions are vague and ambiguous and do not carry warnings that excess salt is a poison (0742).

Rats genetically-resistant to hypertension (R), united in parabiosis with genetically-susceptible animals and placed on an 8% NaCl diet, rapidly developed chronic hypertension. R + R parabionts, on the other hand, remained normotensive (1600).

High blood pressures in benign hypertensive dogs were reduced to normal by drastic chronic salt depletion; pressures of normotensive controls remained the same with this treatment (1067).

The role of salt as an etiologic agent in essential hypertension in man is a controversial subject (1017); there is a considerable body of evidence both pro and con in the medical literature (1600). In one survey of salting habits and hypertension, a large percentage of the subjects (61/105) always salted food at the table (0705); in another study, however, salt intake by 563 normal individuals and 437 hypertensives were approximately the same (0143). Some families show a history of high blood pressure indicating an hereditory factor in hypertension (0257). In one population study, hypertension was more prevalent in an area where the salt intake was very high than in areas where it was more moderate (0682); in another part of the world, on the other hand, pressures of the high salt intake study-group were found to be essentially the same, or even lower, than the pressures in the low salt intake group (2190). Low salt diets in many instances have brought about dramatic blood pressure reductions in essential hypertension patients (1668). Other investigations, however, have concluded that salt does not affect blood pressure (2274). Certain data have indicated the possibility of two types of hypertension in certain conditions: a "salt-dependent type" (majority) and a "renin-dependent type" (minority) (0551).

There is some difference of opinion today concerning the safety of added salt to infant foods (1017). Most of the experts agree, however, that the amount of added salt should be reduced in commercial preparations which contain much more than the estimated requirement of 2-5 mEq/day (1017). A limit of 0.25% added salt has been

recommended (1017). Some believe that salt should be omitted entirely wherever possible (1600) in view of the possibility that essential hypertension may be due first and foremost to the combined effects of ingested salt and genetic factors (0688). Hypertension (100%) and death (50%) in rats have been produced by feeding certain commercial baby foods (0704). Newborn or premature infants are unable to excrete excess water and solutes, particularly during the first week of life (0416). As little as 0.7% sodium chloride in the formula caused premature infants to become edematous and sick in a very short time; a normal diet and water intake corrected the condition (2117). The earlier an infant is started on solid foods, the higher the sodium content of his diet will be all through his life (1296).

A potassium hazard may exist with stored blood bank blood due to leakage of K ions from red blood cells into the plasma (1083).

Labels on KCL gargle preparations should include a warning as to toxic effects; levels as low as 167 mg/kg BW are toxic, and 250-334 mg/kg BW are lethal for adults (1815).

Long-term Studies

Rats fed high sodium chloride diets had a shortened life span and an increased incidence of hypertension, kidney and heart failure, edema and abnormal lipid metabolism; these changes are also characteristic of hypertensive cardiovascular kidney disease in humans (0197). Two strains of Sprague-Dawley rats differing genetically in susceptibility to salt-induced hypertension to a high degree have been developed by selective in-breeding. On normal diets, however, high blood pressure does not develop in either strain, thus indicating that salt and heredity play roles in the hypertension in these animals (0699). A genetic strain of spontaneously hypertensive Wistar rats, where salt is not a factor, has been produced also by repeated selective in-breeding (2431).

Special Studies

High salt and low protein diets increased the incidence of stomach cancer in mice treated with 4-nitroquinoline 1-oxide (1702). Teratogenic effects in mice followed large doses of NaCl injected s.c. (2376).

Biochemistry

Sodium, potassium and chloride ions in the right concentration and balance are indispensable for a number of normal physiologic processes (0269). Osmotic pressure, body-fluid balance, heart action, nerve-impulse conduction and transmission, are typical examples (2474). Sodium and potassium chloride are the main extracellular ions in the body; potassium is the major intracellular ion (1010). Urinary excretion of added dietary sodium was found to be markedly lower in newborn infants than in older children (0115). Several investigators have obtained data indicating the danger of high solute feedings to infants undergoing increased water loss (0590).

Drug Interaction

Marked impairment of vitamin B_{12} absorption was detected in a controlled study of hospitalized patients on KCL therapy (2852). Camphor was found to have a strong protective effect against KCL cardiac toxicity in animals (1911).

Consumer Exposure

Sodium chloride is used in the food industry and in the home as a nutrient, a flavoring agent, and as a preservative (0598). Average possibly daily intakes range from 591 mg for the 0-5 months age group to 7090 mg for the 2-65+ years group (1012); maximum daily intakes for these groups are estimated to be 1427 and 13599 mg, respectively (1012).

Potassium chloride is used in the food industry as a nutrient, dietary supplement, gelling agent, salt substitute, and yeast food (0598). Daily intakes range, on the average, from 244 mg (0-5 months) to 1719 mg (2-65+ years) (1012). Maximum daily intakes are estimated as 453 to 3039 mg, respectively, for the above-mentioned groups (1012).

SODIUM CHLORIDE

CHEMICAL INFORMATION

I. **Nomenclature**

A. Common name:

Sodium Chloride (Salt; common salt, table salt)

B. Chemical name:

Sodium Chloride

C. Trade names:

Sterling Table Salt
Morton Salt
Morton Lite Salt
Sterling Brine Buttons

D. Chemical Abstracts Unique Registry Number:

007647145

II. **Empirical formula**

NaCl

III. **Structural formula**

NaCl

IV. **Molecular Weight**

58.44

V. **Specifications**

A. Chemical Grade (1558)

Primary Listing: Sodium Chloride, 'Baker Analyzed' REAGENT, Crystal
Secondary Listing:
Formula: NaCl FW: 58.44
Specifications: Meets A.C.S. Specifications

Assay (NaCl)	99.5	%	Calcium, Magnesium and R_2O_3 Precipitate	0.005	%
Insoluble Matter	0.005	%	Heavy Metals (as Pb)	0.0002	%
pH of 5% Solution at 25°C	5.0-7.0		Iron (Fe)	0.0001	%
Iodide (I)	0.002	%	Potassium (K)	0.005	%
Bromide (Br)	0.005	%			
Chlorate and Nitrate (as NO_3)	0.003	%			
Nitrogen Compounds (as N)	0.0005	%			
Phosphate (PO_4)	0.0005	%			
Sulfate (SO_4)	0.001	%			
Barium (Ba)	0.001	%			

Primary Listing: * Sodium Chloride, C. P., Crystal (1558)

Secondary Listing:

Formula:	NaCl	**F W**	58.4428

Specifications:

Assay (NaCl)	99.0	%
Insoluble Matter	0.005	%
pH of 5% Solution at 25°C	5.0-8.0	
Iodide (I)	0.005	%
Bromide (Br)	0.010	%
Phosphate (PO_4)	0.001	%
Sulfate (SO_4)	0.005	%
Barium (Ba)	0.002	%
Calcium, Magnesium and R_2O_3 Precipitate	0.010	%
Heavy Metals (as Pb)	0.0005	%
Arsenic (As)	0.0004	%

* **Change Style** Label to show maximum limits of impurities.
GEW/jkk

Sodium Chloride, USP, Crystal (1558)
Comm. No. 3628

Assay (NaCl)	99.5-100.5%
Description, solubility, identification	passes test
acidity or alkalinity	passes test
loss on drying	o.5% max.
Iodide or Bromide	passes test
calcium & magnesium	0.05%
Sulfate (So_4)	0.015% 150 ppm
Sodium Ferrocyanide	0.0013
Arsenic	0.0003% ppm

B. Food Grade

Food Chemicals Codex, 2nd edition (0598) gives the following specifications for food grade sodium chloride:

SODIUM CHLORIDE

NaCl Mol. wt. 58.44

DESCRIPTION

Sodium chloride is a transparent to opaque white crystalline solid of variable particle size. It is odorless and has a characteristic saline taste. It remains dry in air at a relative humidity below 75 percent, but becomes deliquescent at relative humidities above this value. It may contain not more than 2 percent of suitable anticaking or crystal-modifying agents approved for these purposes by the federal Food and Drug Administration. One gram is soluble in 2.8 ml. of water at 25°, in 2.7 ml. of boiling water, and in about 10 ml. of glycerin. A 1 in 20 solution of sodium chloride in water gives positive tests for *Sodium*, page 928, and for *Chloride*, page 926.

SPECIFICATIONS

Assay. Not less than 97.5 percent of NaCl after drying.

Sodium ferrocyanide. Not more than 13 parts per million (0.0013 percent) of $Na_4Fe(CN)_6$.

Limits of Impurities

Arsenic (as As). Not more than 3 parts per million (0.0003 percent).

Heavy metals (as Pb). Not more than 5 parts per million (0.0005 percent).

Loss on drying. Not more than 1 percent.

C. Pharmaceutical Grade

The U. S. Pharmacopoeia XVIII (3333) gives the following specifications for pharmaceutical grade sodium chloride:

Sodium Chloride
NaCl 58.44

Sodium Chloride contains not less than 99.5 percent and not more than 100.5 percent of NaCl, calculated on the dried basis. It contains no added substance.

Description: Colorless, cubic crystals or white, crystalline powder. Has a saline taste.

Solubility: Freely soluble in water, and slightly more so in boiling water; soluble in glycerin; slightly soluble in alcohol.

Identification - A solution (1 in 20) responds to the tests for Sodium, page 893, and for Chloride, page 892.

Acidity or alkalinity - Dissolve 50 g in 200 ml of carbon dioxide-free water, and add 10 drops of bromothymol blue pH indicator. If the solution is yellow, it requires not more than 1.0 ml of 0.02 N sodium hydroxide to produce a blue color. If the solution is blue or green, it requires not more than 2.0 ml of 0.02 N

hydrochloric acid to produce a yellow color.

Loss on drying, page 935 - Dry it at 105° for 2 hours; it loses not more than 0.5 percent of its weight.

Iodide or bromide - Digest 2 g of finely powdered Sodium Chloride for 3 hours with 25 ml of warm alcohol, cool the mixture, and remove the undissolved salt by filtration. Evaporate the filtrate to dryness, dissolve the residue in 5 ml of water, add 1 ml of chloroform, and cautiously introduce, dropwise, with constant agitation, 5 drops of dilute chlorine T.S. (1 in 3): the chloroform does not acquire a violet, yellow, or orange color.

Calcium and magnesium - Dissolve 20 g in 200 ml of water, add 0.1 ml of hydrochloric acid, 5 ml of a pH 10 buffer solution, and 5 drops of eriochrome black T.S. Titrate with 0.05 M disodium ethylenediaminetetraacetate to a pure blue end-point. Each ml of 0.05 M disodium ethylenediaminetetraacetate is equivalent to 2.004 mg of Ca. Not more than 0.05 percent of calcium and magnesium (as Ca) is found.

Sulfate, page 895 - A 6.25 g portion shows no more sulfate than corresponds to 0.15 ml of 0.02 N sulfuric acid (150 parts per million).

Sodium ferrocyanide - Dissolve 25 g in 80 ml of water in a glass-stoppered, 100 ml graduated cylinder or flask. Add 2 ml of ferrous sulfate T.S. and 1 ml of diluted sulfuric acid, dilute with water to 100 ml, and mix. For a control, dissolve another 25 g in 80 ml of water, dilute with water to 100 ml, and mix. Transfer 50 ml portions of the respective solutions to matched color-comparison tubes: the solution to which ferrous sulfate T.S. was added shows no blue color when compared with the control.

Assay - Weigh accurately about 250 mg of Sodium Chloride, dissolve in 50 ml of water in a glass-stoppered flask, and add 50.0 ml of 0.1 N silver nitrate, 3 ml of nitric acid, 5 ml of nitrobenzene, and 2 ml of ferric ammonium sulfate T.S. Shake well, and titrate the excess silver nitrate with 0.1 N ammonium thiocyanate. Each ml of 0.1 N silver nitrate is equivalent to 5.844 mg of NaCl.

Packaging and storage - Preserve in well-closed containers.

Category: Electrolyte replenisher; also see Dextrose and Sodium Chloride Injection, Mannitol and Sodium Chloride Injection, Ringer's Injection, and Lactated Ringer's Injection.

Usual Dose: Oral, 1 gram three times a day.
Intravenous infusion, 1 liter of a 0.9 percent solution.
Topically to wounds and body cavities, as a 0.9 percent solution for irrigation.

Usual Dose Range: Oral, 3 to 6 grams daily.

Sodium Chloride Injection (3333)

Sodium Chloride Injection is a sterile, isotonic solution of sodium chloride in water for injection. It contains no antimicrobial agents. It contains not less than 0.85 percent and not more than 0.95 percent of NaCl.

Identification - It responds to the tests for Sodium, page 893, and for Chloride, page 892.

Pyrogen - It meets the requirements of the Pyrogen Test, page 886.

pH, page 938 - between 4.5 and 7.0.

Arsenic, page 894 - Use 35 ml of Injection. The limit is 0.08 part per million.

Heavy metals, page 897 - To 20 ml of Injection add 2 ml of diluted acetic acid, then dilute with water to 25 ml: the heavy metals limit is 0.3 part per million.

Other requirements - It meets the requirements of the test for Ferrocyanide under Dextrose and Sodium Chloride Injection, page 181, except that 40 ml of Injection is used, and it meets the requirements under Injections, page 797.

Assay - Pipet 25 ml of Sodium Chloride Injection into a glass-stoppered flask, add 50 ml of water, mix, and add 50.0 ml of 0.1 N silver nitrate, 3 ml of nitric acid, 5 ml of nitrobenzene, and 2 ml of ferric ammonium sulfate T.S. Shake well, and titrate the excess silver nitrate with 0.1 N ammonium thiocyanate. Each ml of 0.1 N silver nitrate is equivalent to 5.844 mg of NaCl.

Packaging and storage - Preserve in single-dose containers, preferably of Type I or Type II glass.

Injections available - Injection is usually available in the following volumes: 100, 150, 250, 500, and 1000 ml.

Category:	Fluid and electrolyte replenisher; irrigating solution.
Usual Dose:	Intravenous infusion, 1 liter. Topically to wounds and body cavities, for irrigation.

Sodium Chloride Tablets (3333)

Sodium Chloride Tablets contain not less than 95.0 percent and not more than 105.0 percent of the labeled amount of NaCl.

Identification - A filtered extract of Tablets responds to the tests for Sodium, page 893, and for Chloride, page 892.

Iodide or bromide - Digest 2 g of powdered Tablets for 3 hours with 25 ml of warm alcohol, cool, and filter. Evaporate the filtrate to dryness, dissolve the residue in 5 ml of water, filter if necessary, and add 1 ml of chloroform. Cautiously introduce, dropwise, with constant agitation, dilute chlorine T.S. (1 in 3): the chloroform does not acquire a violet, yellow, or orange color.

Barium - Digest 4 g of powdered Tablets with 20 ml of water, filter, and divide the solution into two equal portions. To one portion add 2 ml of diluted sulfuric acid and to the other add 2 ml of water: the solutions are equally clear after standing for 2 hours.

Calcium and magnesium - Digest 1 g of powdered Tablets with 50 ml of water, and filter. Add 4 ml of ammonia T.S. to the filtrate, and divide the mixture into two equal portions. Treat one portion with 1 ml of ammonium oxalate T.S. and the other portion with 1 ml of sodium phosphate T.S.: neither mixture becomes turbid within 5 minutes.

Disintegration, page 932 - 30 minutes.

Weight variation, page 950 - meet the requirements for Tablets.

Assay - Dissolve not less than 20 Sodium Chloride Tablets in about 100 ml of water, filter into a 500 ml volumetric flask, and wash the original container and the filter with 100 ml of water in divided portions, adding the washings to the original filtrate. Dilute with water to volume. Pipet a volume of solution, equivalent to about 250 mg of sodium chloride, into a glass-stoppered flask, and dilute with water to about 50 ml. Add 50.0 ml of 0.1 N silver nitrate, 3 ml of nitric acid, 5 ml of nitrobenzene, and 2 ml of ferric ammonium sulfate T.S. Shake well, and titrate the excess silver nitrate with 0.1 N ammonium thiocyanate. Each ml of 0.1 N silver nitrate is equivalent to 5.844 mg of NaCl.

Packaging and storage - Preserve in well-closed containers.

Tablets available - Tablets usually available contain the following amounts of sodium chloride: 600 mg and 1 and 2.25 g.

Category: See Sodium Chloride.

Bacteriostatic Sodium Chloride Injection (3333)

Bacteriostatic Sodium Chloride Injection is a sterile, isotonic solution of sodium chloride in water for injection, and it contains one or more suitable antimicrobial agents. It contains not less than 0.85 percent and not more than 0.95 percent of NaCl.

Note - Use Bacteriostatic Sodium Chloride Injection with due regard for the compatibility of the antimicrobial agent or agents it contains with the particular medicinal substance that is to be dissolved or diluted.

Description - Clear, colorless solution, odorless or having the odor of the bacteriostatic substance.

Pyrogen - It meets the requirements of the Pyrogen Test, page 886, the test dose being 5 ml per kg, injected very slowly.

Other requirements - It responds to the Identification Test and meets the requirements for pH, Arsenic, Heavy metals, and Assay under Sodium Chloride Injection, page 616. It meets the requirements of the test for Ferrocyanide under Dextrose and Sodium Chloride Injection, page 181, except that 40 ml of Injection is used. It meets also the requirements under Injections, page 797.

Packaging and storage - Preserve in single-dose or in multiple-dose containers, of not larger than 30 ml size, preferably of Type I or Type II glass.

Labeling - Label it to indicate the name(s) and proportion(s) of the added antimicrobial agent(s).

Injections available - Injection is usually available in the following volumes: 2, 5, 10, 20, and 30 ml.

Category: Sterile vehicle

Sodium Chloride Solution (3333)

Sodium Chloride Solution is a solution of sodium chloride in purified water. It contains not less than 0.85 percent and not more than 0.95 percent of NaCl.

Caution - Do not use Sodium Chloride Solution for parenteral administration or for irrigations that may result in absorption of the Solution into the blood. For such purposes use Sodium Chloride Injection (see page 616).

Sodium Chloride	9 g
Purified Water, a sufficient quantity, to make . . .	1000 ml

Filter the prepared solution until clear.

Description - Clear, colorless solution.
Identification - It responds to the tests for Sodium, page 893, and for Chloride, page 892.
Sterility - Sodium Chloride Solution that has been rendered sterile meets the requirements under Sterility Tests, page 851.
Other requirements - It meets the requirements for pH and Assay under Sodium Chloride Injection, page 616.
Packaging and storage - Preserve in tight containers. Preserve Sodium Chloride Solution that has been rendered sterile in single-dose containers, preferably of Type I or Type II glass.
Labeling - The designation "non-sterilized" or "not sterilized" appears prominently on the label unless the Sodium Chloride Solution has been rendered sterile.

Category: Isotonic vehicle.

VI. Description

A. General characteristics

Sodium chloride is a white crystalline solid. The large cubic crystals may be colorless and transparent or translucent (3156). It is odorless and has a characteristic saline taste (0598).

B. Physical Properties

Soluble in water (1 g/2.8 ml H_2O at 25° C) and in glycerol but only slightly soluble in alcohol (3156).

Density:	2.17
Melting Point:	804°C
Boiling Point:	1413°C
Freezing Point:	-20.5°C

C. Stability

Sodium chloride becomes deliquescent at relative humidities above 75%. Suitable anti-caking agents approved by the Food and Drug Administration may be added in amounts up to 2% (0598).

VII. Analytical Methods

Food Chemicals Codex, 2nd edition (0598) gives the following analytical methods for sodium chloride:

> **TESTS**
>
> **Assay.** Weigh accurately about 250 mg., previously dried at 105° for 2 hours, and dissolve it in 50 ml. of water in a glass-stoppered flask. Add, while agitating, 3 ml. of nitric acid, 5 ml. of nitrobenzene, 50.0 ml. of 0.1 *N* silver nitrate, and 2 ml. ferric ammonium sulfate T.S. Shake well, and titrate the excess silver nitrate with 0.1 *N* ammonium thiocyanate. Each ml. of 0.1 *N* silver nitrate is equivalent to 5.844 mg. of NaCl.
>
> **Sodium ferrocyanide.** Dissolve 9.62 grams of the sample in 80 ml. of water in a 150-ml. glass-stoppered cylinder or flask. Prepare a standard solution containing 125 mcg. of $Na_4Fe(CN)_6$ in each ml. by dissolving 99.5 mg. of $Na_4Fe(CN)_6 \cdot 10H_2O$ in 500.0 ml. of water, then transfer 1.0 ml. of this solution into a similar 150-ml. container for the control. To each container add 2 ml. of ferrous sulfate T.S. and 1 ml. of diluted sulfuric acid T.S., dilute to 100 ml. with water, and mix. Transfer 50-ml. portions of the respective solutions into matched color-comparison tubes. The sample solution shows no more blue color than the control.
>
> **Arsenic.** A solution of 1 gram in 10 ml. of water meets the requirements of the *Arsenic Test*, page 865.
>
> **Heavy metals.** A solution of 4 grams in 25 ml. of water meets the requirements of the *Heavy Metals Test*, page 920, using 20 mcg. of lead ion (Pb) in the control (*Solution A*).
>
> **Loss on drying, page 931.** Dry at 105° for 2 hours.

VIII. Occurrence and Levels

A. Plants

Sodium is not an essential element for plants and most members of the plant kingdom contain only relatively small amounts. Indeed, for some plants sodium is actually a trace element. Herbivorous animals do not obtain enough NaCl from natural foods and require added salt in the diet. Wild animals, such as deer, will travel long distances to obtain salt at a salt lick (0257).

B. Animals

In contrast to plants, sodium chloride is widely distributed in animals. Carnivores obtain adequate amounts of salt in the diet. Sodium chloride makes up about 0.9% of the blood and body fluid of mammals (0257).

C. Natural Inorganic Sources

Sodium chloride occurs abundantly in nature in the form of large underground deposits in various parts of the world, in sea water, salt lakes, mineral

springs, and other natural waters. In North America, large deposits are found in Newfoundland, central New York, Michigan, and the Gulf Coast. The mineral form is called Halite. The Great Salt Lake in Utah also contains a large amount of NaCl (1384).

Commercial salt is obtained by direct mining from underground and surface deposits, by evaporation and crystallization from natural brines, and from sea water.

D. Synthetics

Sodium chloride is widely used industrially in the manufacture of chlorine compounds, glazes, soaps, dyes, in the metallurgy of tin and other metals, in photography, in freezing mixtures, for de-iceing highways, as an herbicide, for curing hides, in fire extinguishers, and in home water softeners (1384, 3156). One salt company estimated that there are 14,000 uses for its product. In the food industry, salt is widely employed in seasoning and as a preservative (1384, 3156). Sodium chloride is used also in human medicine for the treatment of Addison's disease, heat exhaustion, to relieve intractable pain, and for therapeutic abortions (1384, 3156).

SODIUM CHLORIDE

BIOLOGICAL DATA

I. Acute Toxicity

A. Fish

1. Ghosh (1153) determined the LC_{50} of sodium chloride for the fry of Indian carp in a study designed to ascertain safe concentrations of various compounds for the chemotherapy of fish diseases.

Small fry of the Indian major carps, Catla catla, Labeo rohita, or Cirrhinus mrigala, 22-49 mm long, weighing 0.2 to 1.3 grams, in groups of 2 to 10, were subjected to varying concentrations of sodium chloride or the other chemicals under controlled conditions of pH, dissolved oxygen, and total alkalinity, in duplicate experiments at 26°C and 32°C, in soft water. Observations on survival and mortality were recorded after 24 and 48 hours and the LC_{50} concentration determined for both temperature conditions. The results are presented in Tables 1, 2, and 3. The data obtained indicate that sodium chloride is somewhat more toxic for small carp fry than for more mature Bluegills (see this section).

2. Trama (3303) subjected Bluegills (Lepomis macrochirus), 5 to 9 cm long, weighing 1 to 9 g, ten per group, to varying concentrations of NaCl or KCl at 20°C under controlled conditions of pH, dissolved oxygen, and mineral balance. Ten control fish were included for each 100 test fish. All tests were run in duplicate. The animals were observed for toxic signs and mortalities over a period of 96 hours. The LD_{50} data are presented in Tables 1 and 4. (See original article for results of individual tests).

The LD_{50} value obtained - 12,946 mg/liter - indicates that sodium chloride is quite a bit less toxic for Bluegills than potassium chloride (See this section, Potassium Chloride, A). The relative toxicity of cations used in this study was K > Ca > Na.

B. Chickens

1. Quigley et al. (2635) administered dry sodium chloride orally to 5-day-old S.C.W. Leghorn chicks, 27-39 g BW, 4 to 6 per group, in single doses of 1000, 2000, 3000, 4000, 5000, 7000 or 10,000 mg/kg BW in a Minimum Lethal Dose determination. Additional experiments in which the above-mentioned amounts were administered in divided doses over a period of 24 hours were conducted also. All animals were on a standard diet containing 1% salt and water ad libitum throughout. The results are presented in Tables 5, 6, and 7.

Table 1

Acute Toxicity Table

(by substance or constituent thereof)

SUBSTANCE	ANIMAL (Species)	SEX & No. (M or F)	ROUTE (p.o.,i.v.,s.c., i.p.,i.m., other)	DOSAGE mg/kg body wt.	MEASUREMENT (LD50, ED50 or other)	Ref. Bibliogr. No.
Sodium Chloride	Fish	10/group	Immersion	12,946[a]	LD_{50}	Trama (3303)
Sodium Chloride	Fish	2-10/group	Immersion	6,000[b]	LC_{50}	Ghosh (1153)
Sodium Chloride	Chicks	35	p.o.	4,000	MLD	Quigley (2635)
Sodium Chloride	Chickens	30	p.o.	4,000	MLD	Mitchell (2234)
Sodium Chloride	Mice	-	p.o.	6,441	LD_{50}	Behrens (0258)
Sodium Chloride	Rats	168 (M & F)	p.o.	3,750	LD_{50}	Boyd (0361)
Sodium Chloride	Rats	5F/group	s.c.	3,500	MLD	Main (2018)
Sodium Chloride	Rats	11	i.p.	5,000	ALD	Ullrich (3343)
Sodium Chloride	Rats	-	i.v.	1,800	MLD	Loeser (1947)
Sodium Chloride	Rats	-	i.v.	6,000	MLD	Richter (2723)
Sodium Chloride	Guinea Pigs	-	i.v.	2,910	LDL_0	Amberg (0056)
Sodium Chloride	Cats	1-4/group	i.v.	4460-8500	MLD	Cutting (0674)

[a] mg/liter [b] ppm

Table 2

Toxicity of Four Therapeutic Compounds to Catla, Rohu and Mrigal at 26°C (1153)

COMPOUND	Catla LC_{50}		Mrigal LC_{50}		Rohu LC_{50}	
	At 24 hrs	at 48 hrs	at 24 hrs	at 48 hrs	at 24 hrs	at 48 hrs
Sodium chloride	7500 ppm	6000 ppm	7500 ppm	6000 ppm	7500 ppm	6000 ppm
Potassium dichromate	125 ,,	110 ,,	110 ,,	110 ,,	100 ,,	95 ,,
Potassium permanganate	48 ,,	40 ,,	48 ,,	40 ,,	48 ,,	40 ,,
Acriflavine	60 ,,	50 ,,	65 ,,	55 ,,	80 ,,	70 ,,

Table 3

Toxicity of Four Therapeutic Compounds to Catla, Rohu and Mrigal at 32°C (1153)

COMPOUND	Catla LC_{50}		Mrigal LC_{50}		Rohu LC_{50}	
	At 24 hrs	at 48 hrs	at 24 hrs	at 48 hrs	at 24 hrs	at 48 hrs
Sodium chloride	7250 ppm	5500 ppm	7250 ppm	5500 ppm	7250 ppm	5500ppm
Potassium dichromate	120 ,,	105 ,,	105 ,,	97.5 ,,	95 ,,	92.5 ,,
Potassium permaganate	45 ,,	37.5 ,,	45 0 ,,	37.5 ,,	45 ,,	37.5 ,,
Acriflavine	55 ,,	47.5 ,,	60 ,,	52 5 ,,	70 ,,	65 ,,

Table 4

Concentrations of Salts (including both cations and anions) Producing 50 percent Mortality in 96 Hours (3303)

Chemical	Salt		Cation		Anion	
	mg./l.	molar concn.	mg./l.	molar concn.	mg./l.	molar concn.
NaCl	12,946	0.221	5,100	0.222	7,846	0.221
Na_2SO_4	13,500	0.095	4,372	0.095	9,128	0.095
$NaNO_3$	12,000	0.141	3,247	0.141	8,753	0.141
KCl	2,010	0.027	1,054	0.027	956	0.027
K_2SO_4	3,550	0.020	1,593	0.020	1,957	0.020
KNO_3	3,000	0.030	1,160	0.030	1,840	0.030
$CaCl_2$	10,650	0.096	3,846	0.096	6,804	0.096
$CaSO_4$	----	----	----	----	----	----
$Ca(NO_3)_2$	10,000	0.061	2,442	0.061	7,558	0.061

Errata in Table 4 In column under "Cation—molar concn." Second figure from top—for 0.095 read 0.190; fifth figure from top—for 0.020 read 0.041. In last column on right, under "Anion—molar concn." Seventh figure from top—for 0.096 read 0.192; last figure in column—for 0.061 read 0.122.

Table 5

Acute Toxicity of Sodium Chloride for Baby Chicks (2635)
(Single Oral Dose)

Dose (mg/kg BW)	Number of Chicks	Deaths
1,000	5	0
2,000	5	0
3,000	5	0
4,000	5	4
5,000	5	3
7,000	6	5
10,000	4	4

Table 6

Acute Toxicity of Sodium Chloride for Baby Chicks (2635)
(two equal doses at 4-hr. intervals)

Total Dose (mg/kg BW)	Number of Chicks	Deaths
4,000	3	0
5,000	3	1
7,000	3	2
10,000	3	3

Table 7

Acute Toxicity of Sodium Chloride for Baby Chicks (2635)
(three equal doses at 4-hr. intervals)

Total Dose (mg/kg BW)	Number of Chicks	Deaths
4,000	5	0
5,000	5	0
6,000	11	0
7,000	10	4
8,000	5	3
9,000	5	4
10,000	5	4

The MLD (single) of dry salt for the baby chicks was found to be 4000 mg/kg BW. When the total dose was divided into two equal portions, the MLD was 5000 mg/kg BW; when given in 3 divided doses at 4 hour intervals, it was 7000 mg/kg BW. The results obtained in this study are in close agreement with those of previous workers.

2. Mitchell et al. (2234) gave White Wyandotte and White Leghorn chickens, 3 to 5 lbs BW, 4 or 6 per group, sodium chloride solution orally in single doses of 2000, 3000, 4000, 5000 or 6000 mg/kg BW, and determined mortality ratios over 24- and 72-hour periods. The data are presented in Table 8. The MLD for 3-5 pound chickens, 4000 mg/kg BW, is approximately the same as that for baby chicks (2635).

Table 8

Acute Toxicity of NaCl for Chickens (2234)

NaCl Dose (mg/kg BW)	Number of Birds	Observation Period (hrs)	Number of Deaths
2,000	4	24	0
4,000	4	24	2
6,000	4	24	4
3,000	6	72	0
4,000	6	72	0
5,000	6	72	5

C. Mice

Behrens (0258) gave mice weighing 16-19 g (other specifications not given), by stomach tube, varying volumes of 2, 3, 4, or 5 molar sodium chloride solution containing 105 mg and observed the animals for toxic symptoms and death time. In a second experiment, the solutions were injected directly into the duodenum after tying off the pylorus. In both studies the animals were fasted for 2 hours before salt administration.

The oral LD_{50} value of 5 M sodium chloride administered orally was 6441 mg/kg BW with death times ranging from 3 1/2 to 9 hours. 2.5 M saline was considerably more toxic causing 67% mortality at levels of 5700-6600 mg/kg BW, with death times as low as 1/2 hour. When injected directly into the duodenum, doses of 5500-7000 mg/kg BW caused 100% mortality with death

times of 1 to 1 3/4 hours. Somnolence, exhaustion, decreased respiratory rate, and convulsions preceded death which was caused by respiratory paralysis.

D. Rats

1. Boyd et al. (0361) determined the oral (by stomach tube) LD_{50} value of sodium chloride using 168 albino rats (Wistar strain), half males (202 ± 42 g) and half female (167 ± 27 g), which had been fasted for 16 hours before dosing. Doses of 0, 0.8, 3.0, 3.2, 3.5, 3.8, 4.0, 5.0, 10.0 or 16.0 g/kg BW of sodium chloride in distilled water were then given to groups of 12 to 44 animals. The rats were observed for toxic signs and mortalities during the acute phase. Food consumption, water intake, bodyweight, urine volume and pH, glucose, protein, and colonic temperature were determined on survivors during the first three days of the test. Fatalities, and survivors after 15 days, were autopsied and examined for gross and microscopic pathologic changes.

The authors pointed out that the LD_{50} value found, 3750 ± 430 mg/kg BW, was approximately equivalent to the total body content of sodium chloride. The mean ± standard deviation hours to death was 8.6 ± 5.3 (see Table 1). Convulsions, diarrhea, muscular rigidity and prostration preceded death which was caused by respiratory failure with acute encephalopathy. Major pathologic findings were vascular congestion, particularly in meninges and brain, dehydration, and lysis of columnar epitheli of the gastro-intestinal tract. Survivors suffered a brief anorexia, polyuria, fever and acidosis.

2. Main (2018) injected 21-day-old female rats, 30 g average weight (other specifications not given), five per group, subcutaneously with 10% sodium chloride solution and determined the Minimum Lethal Dose (MLD). He found that the maximal safe dose (no deaths) was 3000 mg/kg BW in comparison with the MLD of 3500 mg/kg BW (see Table 1). The death time was approximately 5 hours.

3. Ullrich et al. (0343) injected 11 large healthy albino rats of 220 g average weight (other specifications not given) intraperitoneally with M/1 sodium chloride and determined the average lethal dose. The results are given below and in Table 1. Marked convulsions (non-asphyxial type) followed by twitching of limbs and body musculature, depression of respiration and of heart, preceded death.

4. Loeser et al. (1947) determined the intravenous Miminum Lethal Dose (MLD) of sodium chloride in young white rats (other specifications not given) to be 1800 mg/kg BW (see Table 1).

5. Ritcher et al. (2723) administered sodium chloride to domesticated Norway rats intravenously in the form of a 25% solution in graded doses and observed the animals for mortalities. The MLD was 6000 mg/kg BW (Table 1). Death occurred within a few minutes.

E. Guinea Pigs

Amberg et al. (0056) determined the intravenous Fatal Dose of sodium chloride for guinea pigs to be 2500-3333 mg/kg BW (see Table 1). The authors observed that the lenses became cloudy and that a precipitate formed following i.v. injection of the fatal dose.

F. Rabbits

Ravasini (2672) injected rabbits weighing 1.0 to 1.55 kg intravenously with increasing amounts of sodium chloride in water and observed the animals for toxic signs and mortalities. Death times were recorded and the minimum distant lethal dose (smallest amount which caused death within a specified time) was calculated from the mortality data. All animals were autopsied and studied grossly and microscopically.

High doses of NaCl (equivalent grams 0.0515/kg BW, and higher) caused death through effects on the central nervous system. Nervous excitement (tonic-clonic contraction, opisthotonos) followed by a deep depression with flaccid paralysis of the muscles preceded death which occurred in 9-12 hours. Cerebral edema with hyperemia and hemorrhage of the meningeal vessels was noted at autopsy. Survivors manifested nervous excitement but not depression and remained perfectly normal after recovery. The minimum distant lethal dose was eq. grams 0.0500 per kg.

Lower doses of NaCl (equivalent grams 0.0500 - 0.5010/kg BW) caused no symptoms worthy of note except extreme emaciation for a period of about 10 days. Death occurred in 7-9 days without significant pathlogic changes. The authors concluded that the cause of death was "a profound effect on the trophic centers leading to a disorder in the mechanism of saline balance".

G. Cats

Cutting et al. (0673, 0674) infused cats weighing 1.5 to 3.5 kg (other specifications not given), one to four per group, intravenously with 1, 2, 5, or 10% saline solution at a rate of 5-8.5 ml of NaCl/kg BW/min. until death occurred (see Table 9). Effects on blood pressure, water content of tissues, excretion, and other parameters were studied also with lethal and

sublethal infusions administered at various rates.

The Minimum Lethal Dose (MLD) varied from 4460 to 8500 mg/kg BW according to the concentration of salt in the infusion (see Table 9). The authors pointed out, however, that it was the combination of water and salt that represented the toxic principle rather than either alone. They concluded that cats tolerate tremendously large amounts of sodium chloride solution at a rapid rate if the salt concentration is not greater than 2%. Cats are able to eliminate by the kidneys all of the salt and 80% of the water within 24 hours after massive infusions of 1% sodium chloride solution in an amount just under the lethal dose (see original article for sodium, chloride, and water content of various tissues).

Table 9

Lethal Doses of 1 Percent Sodium Chloride Solution (0674)

Animal Number	Weight in Kilograms	Rate of Infusion, Cc./Kg./Min.	Total Amount Infused, Cc./Kg.	Retained Fluid, Cc./Kg. Including Peritoneal Fluid	Retained Fluid, Cc./Kg. Not Including Peritoneal Fluid
S 25	2.10	3.7	670	575	468
S 26	1.70	5.6	727	495	423
S 27	1.90	5.8	686	522	450
S 28	1.70	4.8	742	519	446
S 29	1.70	5.7	717	606	540
Mean		5.1	706.2	553.5	465.4
Mean variation			7.2 per cent	9.4 per cent	6.7 per cent

II. Short-term Studies

General toxic effects

A. Fowl

1. Quigley et al. (2635) placed S.C.W. Leghorn chicks, 14 per group, on a basal ration containing sodium chloride at levels of 1, 3, 5, 8, 10 or 15%, with water available at all times, for a period of 9 weeks and observed the animals for weight gain, toxic signs, and mortalities. Food consumption and salt intakes were determined also. The major results are presented in Figure 1 and Table 10 (see original article for detailed tabular data).

The mortality data in Table 10 indicate that chicks can tolerate sodium chloride in the diet at levels as high as 5% when water is constantly available. Weight gains at 5% levels were somewhat lower, however, then at 3% or 1%. The present chick feeding formulas containing 0.5% to 1% NaCl in the mash are perfectly safe, according to the authors.

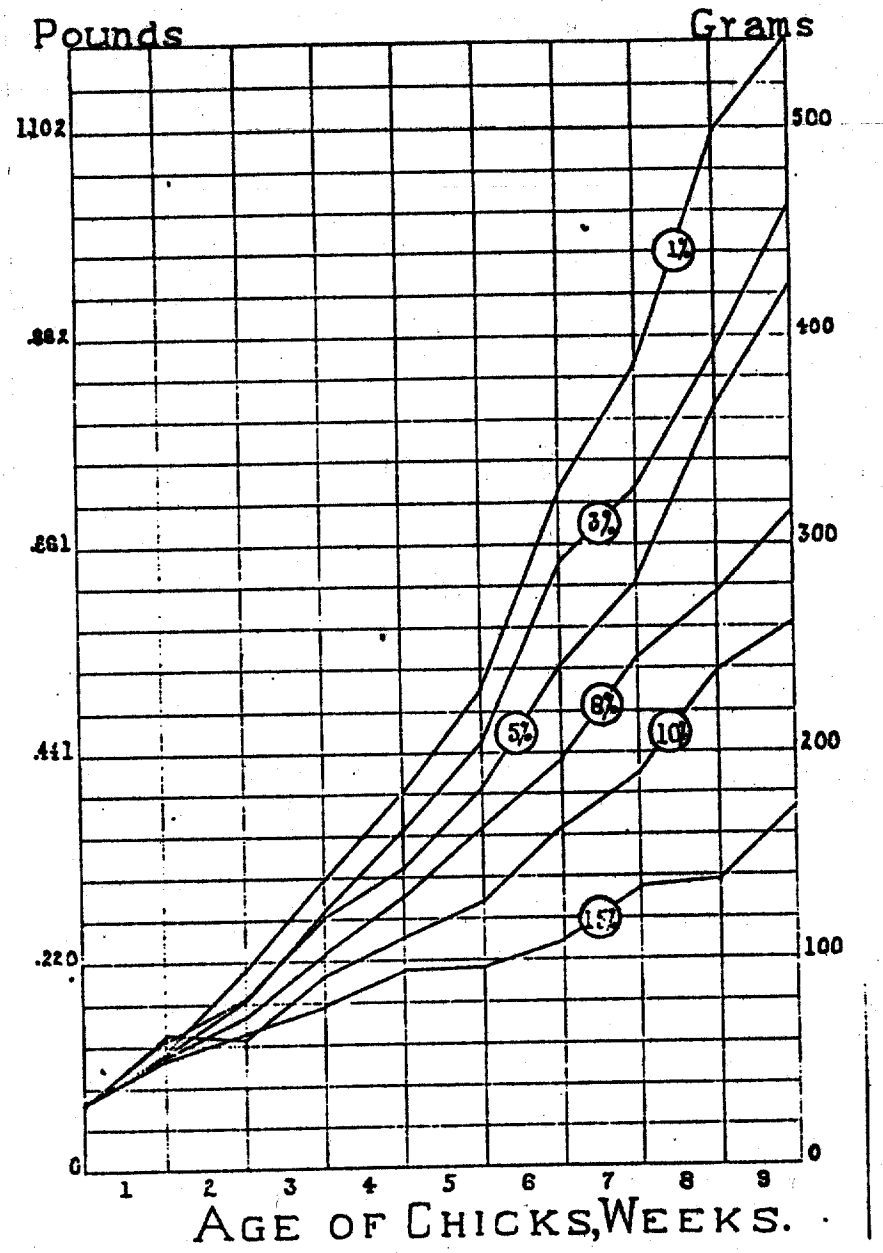


Figure 1

Growth curves of S.C.W. Leghorn Chicks Fed 1%, 3%, 5%, 8%, 10%, 15% of Salt in Ration. (2635)

Table 10

Mortality During Nine Weeks in the Salt Fed Lots (2635)

Pen No.	Per Cent Salt in Ration	Number Chicks	Number Died	Per Cent Loss
1	1	14	1	7.14
2	3	14	1	7.14
3	5	14	0	0.00
4	8	14	5	35.71
5	10	14	7	50.00
6	15	14	11	78.57

2. Whitehead et al. (3509) fed broiler chicks 1, 7, 14 and 21 days of age, a mash containing sodium chloride at a level of 1.13% for a period of 3 weeks after which the birds were sacrificed and the testes examined grossly and microscopically for lesions. The data are presented in Table 11.

Sodium chloride at the level fed caused testicular cysts in a relatively high percentage of chicks during the second and third weeks of life. Control chicks on a ration with the normal salt concentration of 0.13% showed no evidence of cyst formation after 3 weeks or more. The authors discussed possible mechanisms of cyst formation.

Table 11

The Incidence of Cystic Lesions in Chicks Fed 0.13 and 1.13 Percent Sodium for Different Lengths of Time (3509)

No. of weeks (0·13 per cent sodium)	No. of weeks (1·13 per cent sodium)	No. of birds	Age at examination (weeks)	No. of birds having cystic testes		Total incidence (%)
				Macro.*	Histo.†	
0	1	44	1	2	0	4·5
0	2	26	2	4	3	27
0	3	43	3	13	5	42
1	1	32	2	1	5	19
1	2	36	3	3	7	28
1	3	31	4	4	5	29
2	1	26	3	0	1	4
2	2	29	4	0	4	13
2	3	24	5	1	0	4
3	3	33	6	0	0	0

* Macroscopically discernible.
† Recognizable only by histological examination.

3. Mohanty et al. (2245) studied in detail the pathologic changes in experimental sodium chloride poisoning in chicks. Twenty-six one-day-old chicks of the Babcock strain were given 1% sodium chloride in distilled drinking water for 10 days, followed by an increase to 1.5% for the remainder of the 6-week experimental period. Six control chicks were given distilled water to drink throughout. Both groups were maintained on a non-medicated pellet-type feed containing 0.25% NaCl. The animals were observed for toxic symptoms, weight change, feed consumption, and water intake. Detailed histopathologic studies were made of the major organs at death or sacrifice (see Figure 2 and Table 12).

All experimental chicks on the 1-1.5% NaCl ration died or became moribund and were sacrificed by the sixth week. Twelve of the 26 animals died during the first two weeks. The main clinical symptoms of sodium chloride toxicity were: increased water intake, lowered feed consumption, anorexia, marked weight loss, edema and nervous signs (see Table 12). Major histopathologic findings were: degenerative changes in kidneys, liver, spleen, pancreas, adrenals, heart, lungs, central nervous system, small intestine, proventriculus, crop, and esophagus (Figure 2) [See original article for details].

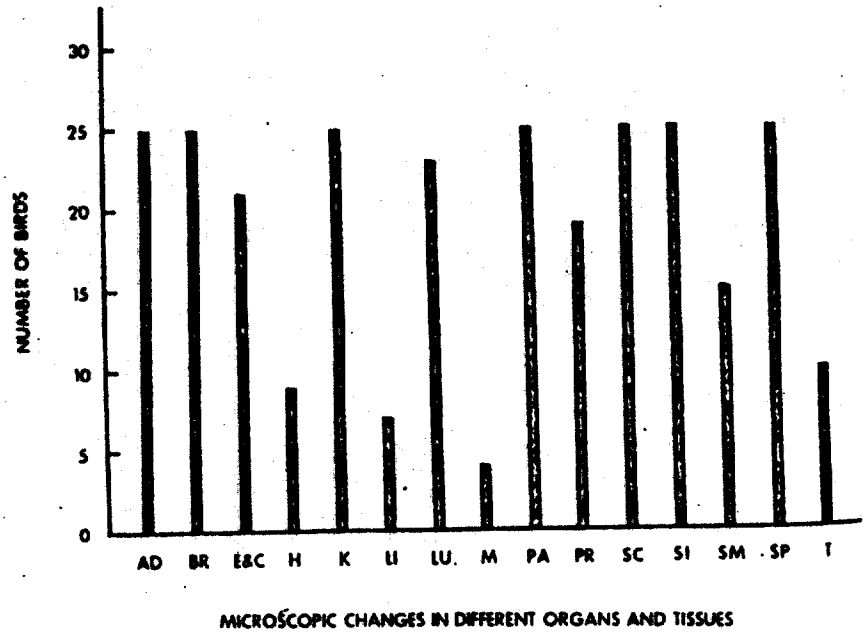


Figure 2

Graphic Representation of Birds with Microscopic Changes in Indicated Organs and Tissues (2245)

Key: AD, adrenals; BR, brain; E & C, esophagus and crop; H, heart; K, kidneys; LI, liver; LU, lungs; M, meninges; PA, pancreas; PR, proventriculus; SC, spinal cord; SI, small intestine; SM, skeletal muscles; SP, spleen; T, trachea.

Table 12

Weight and Hematocrit Values of Experimental and Control Chicks (2245)

Sl. no.	Weight (g) 2 weeks old	Weight (g) 4 weeks old (2 weeks PE[A])	Hematocrit value 4 weeks old (2 weeks PE)
Experimental group			
1	122	115	30%
2[B]	130	122	50%
3	127	115	38%
4	125	126	36%
5	113	135	36%
6	124	131	41%
7	123	112	32%
8	119	133	40%
9	115	136	35%
Mean av.	125	122	37.55%
Control group			
1	120	262	36%
2	121	229	37%
3	132	219	39%
4	117	264	39%
5	128	274	37%
6	116	257	35%
Mean av.	122.66	219.5	37%

[A]PE (postexperimental period).
[B]Comatosed state.

4. Matterson et al. (2093) placed one-day-old Bronze turkey poults (Conn. Agr. Exp. Sta. Strain), 12 or 13 per group, on a basal "salt-free" diet to which NaCl was added at levels of 0.5%, 1%, 2%, or 4%. In a second series, 1% KCl was added to each of the test diets. The mortality data over a 23-day period are given in Table 13. The Minimum Lethal Concentration of NaCl in the diet was found to be 4%. KCl at a level of 1% had no protective effect on NaCl toxicity.

Table 13

Toxicity of NaCl for Turkey Poults (2093)

Salt Conctn. in diet (%) NaCl	KCl	No. of Birds	Deaths
0.5	0	12	0
1.0	0	12	0
2.0	0	12	0
4.0	0	12	3
0.5	1	13	1
1.0	1	13	1
2.0	1	13	1
4.0	1	13	4

B. Mice

Davis et al. (0737) studied the effect of physiological saline administered intraperitoneally on the locomotor activity of six inbred strains of mice with three very sensitive photocell activity devices. Inbred males of the C57BL/6, DBA/2, C3H/An, CBA, and BALB/c strains, and Swiss-Webster NLW, 8 to 12 weeks of age, were injected intraperitoneally with 0.9% saline in distilled water at a level of 0.09 mg/kg BW and observed for locomotor activity over a period of 30 minutes. Sixty mice from each strain, including controls, were employed in the study.

The authors concluded from the data presented in Table 14 that sodium chloride at the level injected had a significant depressant effect on locomotor activity in the six strains of mice used. They pointed out that although the strains differed significantly in activity levels, there was no difference in the degree of effect of saline on activity. The results obtained are in general agreement with those obtained by several other investigators.

Table 14

Effects of Saline Injection on Locomotor Activity of Six Strains of Mice Tested Singly or in Groups of Four (0737)

Mean 30 min. Activity Count[a] (Log Transformed)

Single Mice			Grouped Mice		
Strain	No. Inject.	Saline	Strain	No. Inject.	Saline
NLW	2.990	2.810	NLW	3.522	3.409
C57BL 6	2.948	2.904	C57BL 6	3.452	3.360
DBA/2	2.934	2.855	C3H/An	3.381	3.331
BALB/c	2.913	2.905	CBA	3.335	3.353
C3H/An	2.847	2.796	DBA/2	3.324	3.235
CBA	2.778	2.714	BALB/c	3.322	3.300

[a] N = 12 in all cases.

C. Rats

1. Boyd et al. (0364) determined the oral chronic toxic, 50% end point, LD_{50} (0.1L), of sodium chloride in rats by ascertaining the daily dose which killed 50% of the animals after administration for 100 days, i.e., 1/10 of the animal's normal life span (0.1L).

Young male CBL Wistar albino rats (150-200 g) in groups of 14-40, were given 2570-6140 mg/kg BW NaCl in H_2O by stomach tube once daily for 100 days, or until 50% of the animals died, whichever occurred first. Control groups of 6-16 rats, given distilled water only, were included for each dosage. The rats were maintained on Purina Laboratory Chow and water ad libitum.

In addition to continual observation for toxic signs, the following clinical measurements were made on each rat before administration of NaCl, and at weekly intervals after the first dose: bodyweight, food consumption, water intake, colonic temperature, urinary volume, and urinary glucose, protein and pH.

Survivors were sacrificed at 100 days or after 50% of the animals had succumbed, whichever occurred first, and subjected to a detailed gross and microscopic pathologic study. The LD_{50} (0.1L) value of sodium chloride for the animals employed was calculated to be 2690 ± 120 mg/kg BW. [The authors determined the acute oral LD_{50} to be 3750 ± 430 mg/kg BW, in a previous experiment].

Hypothermic cachexia preceded death which was caused by bronchopneumonia associated with hepatitis, nephritis, arteriolitis. Some animals showed signs of encephalopathy which was accompanied by degeneration of the thymus, adrenals, and testes. During the first month, the rats developed a slight fever, proteinuria, and alkalinuria. Survivors were underweight and exhibited dose-dependent polydipsia and polyuria. A slight hypothermia and aciduria were noted also during the last month.

2. Heller et al. (1420) studied the effect of sodium chloride and several other common, naturally-occurring salts, administered in the drinking water, on the general health, reproductive capacity, etc. of rats, in a study prompted by the paucity of information in the literature on the physiologic effects of natural saline drinking waters. The authors pointed out that salt concentrations in excess of 20,000 ppm have been found in water from streams, springs, and wells in the southeastern United States and that concentrations of 5,000 to 50,000 ppm are common.

Reproduction was adversely affected by sodium chloride at a level of 10,000 ppm; growth retardation occurred when the concentration was increased to 20,000 ppm, and 25,000 ppm caused a rapid decline in weight. The chloride ion was found to be more toxic than either the carbonate or the sulfate ion. Calcium and magnesium ions, on the other hand, were more harmful than the sodium ion. The authors pointed out the dangers of the continual use of saline drinking waters.

3. Ritcher et al. (2723) studied the relationship between salt intake and thirst in wild and domesticated Norway rats. Twelve groups of the animals consisting of both sexes, weighing 155-563 g, were placed on a basal low-salt

diet plus 0, 2, 4, 6, 8, 10, 15, 20, 25, 35, 50, or 70%, respectively, of added salt (as percentage of the diet). Food consumption, water intake, body-weight, were determined regularly and the animals were observed throughout the feeding period of 72-92 days for toxic signs. At the conclusion of the observation period, the animals were sacrificed and the adrenals, thymus, pituitary, spleen, and kidneys weighed and preserved for histochemical and histopathologic examination.

All rats, wild and domesticated, on the 35, 50, and 70% salt diets died in 9 to 42 days despite full access to water. Only 3 sporadic deaths occurred in the other groups, however. NaCl levels of 3000-4000 mg/kg BW killed the domesticated rats in a few hours if the animals were deprived of water. With free access to water, on the other hand, the rats freely consumed rations containing up to 35% salt, and ate moderate amounts of diets containing as much as 50-70% salt. The data indicated that the animals were able to handle salt loads up to 15,000-20,000 mg NaCl/kg BW per day, if sufficient water was available. Domesticated rats required 50-60 cc of water per gram of salt ingested to maintain health. The authors suggested that difficulties encountered by man in using salt may result from his failure to drink enough water for excreting the excess salt ingested.

D. Rabbits

1. Behrens (0258) investigated the effect of sodium chloride (oral) on blood volume and erythrocyte concentration in the rabbit in a study on the mechanism of sodium chloride intoxication. Rabbits weighing 1600-3200 g (other specifications not mentioned) were given NaCl orally in doses of 3960 to 6250 mg/kg BW and erythrocyte concentrations determined initially and after 8 hours.

All animals succumbed in 1 to 3 days following a significant decrease in the erythrocyte count. The authors concluded that acute lethal sodium chloride poisoning was accompanied by a dilution of the blood (hydremia) with the resultant reduction in the red blood cell concentration.

2. Dodge _et al_. (0812) studied neurologic disturbances in rabbits during hypertonic dehydration induced with sodium chloride, urea, or sucrose. Thirty-seven adult New Zealand rabbits (other specifications not mentioned), were given NaCl, urea, or sucrose solutions (2,000 m Osm/liter) i.v. over a period of one to several hours to induce maximum tonicity. In addition to clinical symptom observations, polygraphic recordings of electroencephelograms, electro-

myograms from fore and hind limbs, blood pressure and respiratory pattern measurements were made.

Death due to respiratory failure occurred with a mean osmolality of 435 m Osm/kg with NaCl and sucrose. Tonic spasms or trembling of the limbs occurred when the osmolality exceeded 400. Nystagmus, ataxia and tremulous movements of the trunk and limbs appeared in the 375-400 range. Restlessness, startle responses, and licking of the lips appeared in the 350-375 m Osm/kg range.

EEG changes noted above 400 m Osm/kg indicated disturbance in function of the cerebral hemispheres. Other changes were attributed to involvement of the vestibular-cerebellar mechanisms, respiratory center and spinal cord. The data indicated that hypertoxicity of the body fluids had a profound influence on all levels of the nervous system in the rabbit. The authors mentioned that the clinical symptoms observed in this study were similar to the usual neurological signs of hypertonic dehydration in infants and children.

3. Michalska (2196) examined kidneys from 48 rabbits and 25 swine suffering from acute or chronic sodium chloride poisoning for histopathologic manifestations and changes in acid and alkaline phosphatase reactions. Six normal animals of each species were included as controls.

Chronic sodium chloride poisoning caused severe damage to the collecting tubules of the nephrons which are actively engaged in electrolyte exchange. Breakdown of epithelia and cystic dilation of the lumen of damaged tubules was noted. A greatly intensified reaction for alkaline phosphatase together with a simultaneous increase in the reaction for acid phosphatase was detected indicating an increased permeability of the cell membrane and impairment of the renal tubules. Acid phosphatase reaction data suggesting damage to the juxtaglomerular aparatus was obtained also.

E. Dogs

1. Rowe et al. (2809) determined the systemic and coronary hemodynamic effects in 10 mongrel dogs, 19-29 kg, after the intravenous administration of sodium chloride solution (30%) at a level of 300 mg/kg BW during a period of 30 minutes.

The data presented in Table 15 indicate significant increases in heart rate, cardiac output, stroke volume, and cardiac efficiency. Significant decreases occurred in arterial hematocrit, hemoglobin, peripheral and pulmonary vascular resistance. Systemic blood pressure was not affected. Other

workers, however, have shown that this species is resistant to salt-induced hypertension (2450). The authors pointed out though that salt administration to hyponatremic human subjects produces a rapid rise in blood pressure.

Table 15

Hemodynamic Effects of Hypertonic Sodium Chloride Solution (2809)

Parameter	Control ± so	Study ± so	% Change	P Value
Heart rate, beats/min	73±16	85±17	+16.4	<0.01
Mean arterial blood press, mm Hg	130±20	127±15	−2.3	<0.4
Mean pulmonary arterial blood press, mm Hg	18±2	19±3	+5.6	>0.9
Mean right atrial blood press, mm Hg	5.3±2.1	5.3±1.6	0	0
Oxygen consumption, ml, min	122±21	127±22	+4.1	<0.2
Arterial oxygen content, ml/100 ml blood	17.5±1.8	15.4±1.8	−12.0	<0.001
Arterial-venous oxygen diff, ml/100 ml blood	4.3±1.0	3.0±0.6	−30.2	<0.01
Arterial hematocrit, %	42±5	35±4	−16.7	<0.001
Coronary sinus oxygen content, ml/100 ml blood	6.7±1.9	5.5±2.1	−17.9	<0.01
Cardiac output, liters/min	2.97±0.88	4.41±1.30	+48.5	<0.001
Stroke vol, ml	40±6	51±8	+27.5	<0.001
Left ventricular work, kg-m/min	5.3±2.1	7.8±3.0	+47.2	<0.01
Right ventricular work, kg-m/min	0.8±0.3	1.1±0.4	+37.5	<0.001
Total peripheral resistance, cgs units	3707±1064	2417±428	−34.8	<0.01
Total pulmonary resistance, cgs units	530±143	363±119	−31.5	<0.01
Coronary blood flow, ml/100 g per min	111±46	123±52	+10.8	<0.5
Coronary vascular resistance, units	1.33±0.56	1.16±0.37	−12.8	<0.4
Left ventricular oxygen usage, ml/100 g per min	12.1±4.9	11.8±5.0	−2.5	<0.9
Index of efficiency, LVW/LVO₂ usage	0.45±0.06	0.68±0.19	+51.1	<0.01

2. Youmans (3617) placed 24 littermate pedigreed male Beagle dogs in groups of 4 on diets containing 0.2% (low), 1.4% (control), 6.0%, and 12% sodium chloride[a] for a period of 26 weeks and observed the animals for increase in blood pressure and other toxic effects.

The higher levels of dietary NaCl (6 and 9-12%) markedly reduced the growth rate with differences of 5-7 pounds per animal when compared with dogs on the low and control concentrations (see Figure 3). Hemoglobin, packed cell volume, erythrocyte and leucocyte counts, were considerably reduced in dogs on the 9% NaCl diet (Tables 16 and 17), but not at the other levels. There was little difference in average arterial blood pressure after 26 weeks on the high salt diets but the author points out that this is not unusual

[a]Salt content reduced to 9% after 4 weeks of feeding due to extreme adverse effects at the higher level.

because hypertension usually does not occur until around the end of the first 1/3 of the life span. Serum cholesterol values were within normal limits at this time also.

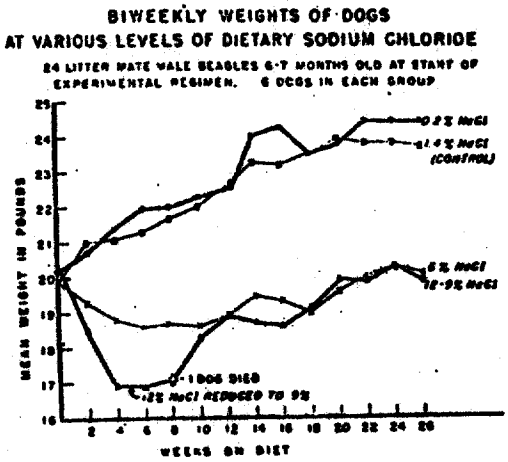


Figure 3

Weight Curves of Dogs Eating Various Levels of Sodium Chloride (3617)

Table 16

Hemoglobin and Packed Cell Volume After 26 Weeks on Diet (3617)

% of NaCl in the diet	No. of dogs	Average hemoglobin concentration (gms. per 100ml. blood)	Average packed cell volume
0.2%	6	15.6	46.3
1.4%	6	14.9	44.0
6.0%	6	15.0	44.8
9.0%	5	13.4	41.2

Table 17

Erythrocytes and Leucocyte Counts After 26 Weeks on Diet (3617)

NaCl content of diet	No. of dogs	RBC per cmm. blood x 10^6	WBC per cmm. blood
0.2%	6	6.00	13,200
1.4%	6	5.57	13,600
6.0%	6	5.50	13,400
9.0%	5	5.18	12,600

3. Finberg et al. (0979) found that a steady-state experimentally-induced (artificial kidney) hypernatremia in dogs resulted in kidney lesions and impaired renal function to the extent that sodium was not excreted in sufficient quantity to alleviate the condition and restore a normal physiologic state. The authors pointed out that the same situation obtains in salt poisoning in infants who are able to excrete only dilute urine in the face of a heavy salt excess.

Ten large female mongrel dogs (18-22 kg) and the Kolff artificial kidney were used to maintain the steady-state hypernatremia by extracorporeal dialysis in the animals with functioning intact kidneys. (See original article for details and tabular data).

F. Pigs

1. Cameron et al. (0470) studied the clinical and histopathologic toxic effects of sodium chloride injected intraperitoneally into the pig in a study prompted by the view that deaths during hypertonic saline abortions are due to the severe hypernatremia resulting from seepage of saline into the peritoneal cavity or inadvertent injection into this area.

Fifteen 5-to-6-week-old pigs of average weight were injected intraperitoneally with 32.5% sodium chloride solution at levels of 1500 to 8900 mg/kg BW and observed for toxic signs and mortalities over a period of 9 days. All animals were studied histopathologically following death or sacrifice (see Table 18).

All of the pigs injected intraperitoneally with hypertonic saline exhibited symptoms of motor disturbance, convulsions, and coma similar to those observed in women who died after saline abortions. Brain lesions, although widespread, differed somewhat however, from those found in women dying from saline abortion attempts.

2. Todd et al. (3290) studied the toxic effect of sodium chloride on young pigs subjected to restricted water as compared with water ad libitum. Sixteen young pigs (just after weaning) weighing 26 to 35 pounds, were divided into four treatment groups as follows;

Group 1 ($C+H_2O$) - Controls - Basal diet, H_2O ad libitum
Group 2 ($C-H_2O$) - Basal diet, water restricted
Group 3 ($NaCl+H_2O$) - High salt, water ad libitum
Group 4 (NaCl-water) - High salt, water restricted

Pigs on the high salt diet (Groups 3 and 4) were given daily oral doses of salt, 2500 mg/kg BW in 8 oz of water, with the aid of a drenching gun. Animals on the basal diet, water restricted, received 8 oz of water only each day. The basal diet contained 0.5% NaCl.

When an animal in group 4 died, one animal from each of the other groups was sacrificed for comparative study. Sodium, potassium, and chloride determinations were made on the blood, cerebrospinal fluid, cerebrum, cerebellum, liver, kidney, heart, and spleen. The NaCl content of the stomach and small intestine was determined also. The brain and other tissues were studied microscopically for pathologic effects.

All pigs in group 4 (high salt, water restricted) died 26, 33, 36, and 48 hours after receiving the first dose of NaCl; all had also received a second dose. Death was preceded by muscular tremors, incoordination, convulsions, prostration, and coma. The chloride and sodium contents of the blood, brain, liver, kidney, spleen, and heart were significantly higher than in the other groups. (See tabular data in original article).

One animal in group 2 (basal diet, water restricted) had clinical symptoms and histopathologic lesions similar to the fatalities but tissue levels of sodium and potassium were normal. None of the animals in the other groups, including the high-salt, water ad libitum group, showed any abnormal clinical symptoms or microscopic lesions.

3. Done et al. (0823) studied the effect of salt loading with restricted water in swine. Large white, or large white cross pigs, purchased from commercial sources were fed 3.0, 5.3, or 9.4% NaCl in the diet with water restricted to about 2 1/2 times the weight of the dry food for 2-11 days. (In one experiment a combination of 3% NaCl and 7.5% urea was fed). The following observations were made: toxic signs, death time, salt intake (g/kg BW/day), white blood cell counts at time of death, plasma chloride urine chloride, and microscopic changes in the brain tissue. The results are presented in Tables 19, 20 and 21.

The LD_{50} with the 9.4% dietary NaCl and water restricted was 4300-4800 mg/kg BW (Table 2). With 3 and 5% NaCl, no deaths occurred in 5-11 days. All animals on the 9.4% NaCl diet and 4 of 7 on the 5.3% diet, showed typical lesions of meningoencephalitis eosinophilica as well as the usual clinical signs. Feeding 3% NaCl with the same allowance of water did not cause any significant clinical or histologic abnormality.

Table 19

Experiment I. Effects of Feeding Meal Containing 5:3 Percent NaCl (0823)

Number of pigs	Mode of death	Days to death	Salt eaten, gm. per kilo. bodyweight per day	White blood cell counts at time of death: Total	L per cent.	N per cent.	E per cent.	M per cent.	B per cent.	Plasma chloride mg. per cent.	Lesions: Perivascular eosinophile infiltration	Malacia
1397	K	5½	4·7	19,750	34·0	53	4·0	9	0	505	++++	—
1400	K	8½	3·3	12,200	65·0	27	1·0	7	0	480	—	—
1402	K	8½	1·8	24,300	63·0	25	6·0	6	0	575	+++	—
1403	K	8½	2·4	22,600	74·0	17	2·0	7	0	482	+	—
1398	K	9½	2·1	25,150	64·5	29	1·5	5	0	502	—	—
1399	K	9½	2·3	20,200	50·5	33	5·5	11	0	475	+	—
1401	K	9½	2·4	19,100	48·5	36	5·5	10	0	535	—	—

Table 20

Experiment II. Effects of Feeding Meal Containing 9.4 Percent NaCl (0823)

Number of pig	Days to signs	Days to death	Mode of death	Salt eaten gm. per kilo. bodyweight per day	White blood cell counts at time of death: Total	L per cent.	N per cent.	E per cent.	M per cent.	B per cent.	Urine chloride mg. per cent.	Serum chloride mg. per cent.	Lesions: Perivascular eosinophile infiltration	Malacia
1634	2	2	D	4·8	Not done						Not done		[illegible]	[illegible]
1631	2	2	D	4·3							615	Not done	[illegible]	—
1632	2	5	K	4·9	4,050	12	79	2	7	0	142	425	[illegible]	[illegible]
1636	4	6	K	3·7	15,600	40	50	2	8	0	1,133	473	[illegible]	[illegible]

Table 21

Experiment III. Effects of Feeding Meal Containing (A) 15 Percent Urea; (B) 3 Percent NaCl + 7.5 Percent Urea; (C) 3 Percent NaCl (0823)

	Number of pigs	Days to signs	Days to death	Mode of death	Lesions: Perivascular eosinophile infiltration	Perivascular lymphocytic infiltration	Vascular endothelial proliferation	Microgliosis of cerebrum	Malacia of cerebrum	Serum chloride mg. per cent.	Remarks
A. 15 per cent. urea	4194	2	3½	D/K	—	+	+	—	[illegible]	Not done	
	4189	2	4	D	—	+	[illegible]	[illegible]	[illegible]	[illegible]	
	4174	3	5	K	—	+	[illegible]	—	[illegible]	445	
	4180	2	5	K	—	+	±	—	[illegible]	500	
B. 3 per cent. NaCl 7·5 per cent. urea	4183	2	2	D	—	—	[illegible]	[illegible]	[illegible]	490	Malacia irregularly distributed
	4192	3	4	K	++	—	[illegible]	—	[illegible]	500	
	4188	2	5	D	—	—	+	[illegible]	[illegible]	Not done	
	4193	2	5	K	+	+	[illegible]	[illegible]	[illegible]	490	
C. 3 per cent. NaCl	4106	—	11	K	—	+	—	—	[illegible]	Not done	
	4107	—	11	K	—	±	—	[illegible]	—	"	
	4108	—	11	K	—	—	—	[illegible]	—	"	

D = Died. K = Killed. ± = Doubtful. — = Negative. + to ++++ = ascending degrees of severity

The authors stated that the pronounced eosinophile infiltration in meningoencephalitis eosinophilica is a characteristic sign of the toxic effect of the sodium ion. It is recommended that sodium chloride should not be added to commercial pig rations and that unrestricted water should be available at all times.

G. Human toxicity

Although widely employed as a food seasoning and preservative, sodium chloride is moderately toxic for man (0123, 1188). Actually, in ancient times it was used in certain cultures as a suicide potion. Lethel levels, of course, are not encountered in commercial foods but fatalities have occurred in several hospital nurseries where salt was accidentally used in place of sugar in preparing formulas. Deaths have resulted also from its use as an emetic where vomiting did not occur, and in instances where young infants have surreptitiously consumed lethal amounts of table salt over a short period of time. The use of hypertonic saline injections to induce abortion has caused many deaths too. Toxic effects sometimes occur following intraspinal injections of saline for the relief of intractable pain. Finally, an excessively high concentration of sodium ions (Hypernatremia) resulting from sodium bicarbonate therapy in salicylate poisoning or from excessive diarrhea and vomiting in infants has produced permanent brain damage and other pathologic effects.

Representative studies in each of these areas are described in the following section.

1. Calvin et al. (0467) reported an instance of salt poisoning in 14-month-old twins who consumed an undetermined amount of salt without vomiting or diarrhea and were admitted to the hospital 36 hours later with hypernatremic dehydration. Serum sodium and chloride concentrations were 182 mEq/liter and 149 mEq/liter for Marla and 179 and 143 mEq/liter for Marta. Parenteral fluid therapy (water and electrolytes) brought about prompt and apparently complete recovery.

2. Finberg (0977) warned of the danger of salt poisoning and brain damage in cases of infant diarrhea where salt-sugar-water mixtures or skim cow's milk are prescribed, and in sodium bicarbonate therapy for salicylate poisoning. Infants who have died of salt poisoning have all shown extensive hemorrhage in the brain.

3. Luttrell et al. (1987) described the clinical, laboratory, and pathological findings in three fatal cases of dehydration and hypernatremia in infants (1-8 months of age) resulting from severe diarrhea and/or vomiting. Lethargy, tremulousness, muscle twitchings, and frank convulsions were the major clinical symptoms. Hemorrhagic encephalopathy was the prominent pathological lesion. Gross subarachnoid hemorrhage, as well as intradural, intracerebral, and intraventricular bleeding were observed also. The authors stated that factors other than vascular damage are involved in the devastating effects of hypernatremia.

4. Elton et al. (0908) described the first known accidental mass salt poisoning of infants in a hospital population when 14 infants were given one or more feedings of a prepared formula in which salt was accidentally used in place of sugar (1 1/2 tablespoons/21 ounces of milk and water). Eleven of the infants showed neurologic symptoms and six died. Eight of the babies were saved by intensive peritoneal dialysis.

In addition to the characteristic central nervous system lesions of salt poisoning (intracerebral, subarachnoid and intraventricular hemorrhage, sinus thromboses and thromboses of small intracerebral vessels and subependymal vessels), the authors found a unique and distinctive kidney lesion attributable solely to acute salt poisoning, i.e., "a diffuse or lobular shrinkage of the proximal and distal convoluted tubules in the cortex, owing to dehydration induced by the hyperosmolarity of the extracellular fluid". (See original article for case histories and details of the pathologic findings).

5. Gauthier et al. (1128) described five cases of accidental salt poisoning in a recent hospital nursery tragedy in Australia. Five babies, one to four weeks old, received feedings from a formula in which salt was accidentally used instead of sugar with a resultant sodium concentration of 2,000 to 2,500 mEq per liter. Four of the infants died in less than two days after the feeding; the fifth baby made a complete recovery. Vomiting, diarrhea, periphery circulatory failure, and respiratory depression preceded death.

The main pathologic findings were: subarachnoid hemorrhages and multiple small intracerebral hemorrhages. Kidneys showed shrinkage of the convoluted tubular cells from the basement membrane. The stomach and small intestine showed diffuse reddening of the mucosa. The authors pointed out

that these findings were not significantly different from those previously reported in children who had died of hypernatremia or hypernatremic dehydration. The authors recommended that salt not be stored in the formula room in order to prevent recurrence of such a tragedy.

6. Bostand et al. (0346) described 18 non-fatal cases of accidental salt poisoning in the maternity ward of a hospital in Oslo, Norway, where salt mixed with sugar was used instead of sugar in preparation of formulas. The sodium chloride content of the mixture ranged from 2 to 10% in different parts of the storage bag. Fifteen of the infants were 2 to 6 days old; two others were 28 and 58 days of age.

The onset was acute with respiratory symptoms predominating. Many of the infants became critically ill with dyspnea, cyanosis, and fever. Vomiting was prominent in six cases. Four infants showed signs of cerebral irritation and one had convulsions. Leucocytosis exceeding 15,000 was found in five cases. There were no deaths and most of the prominent symptoms disappeared after transfer to the pediatric ward; all of the infants were clinically well after five days. The authors stated that the respiratory symptoms were probably caused by hydremia, circulatory failure, and pulmonary edema.

7. Finberg (0978) described seven cases of hypernatremic dehydration in infants with resultant significant moderate to severe neurologic damage. Only one of these infants was an accidental salt poisoning victim (see Table 22). Subdural effusions and bleeding were common symptoms in all, and permanent brain damage resulted in three cases. The author pointed out that several earlier investigators found central nervous system damage in cases of hypernatremia. The dangers of dehydration and hypernatremia in infants were discussed.

8. Arena (0123) stated that the early symptoms of salt poisoning are referable to the gastrointestinal tract with nausea, vomiting, and refusal of feeding. Later, there is evidence of central nervous system involvement either by frank convulsions or muscular twitchings. Temperature elevation is common. Severe respiratory distress with tachypnea and dyspnea may be the predominant finding. Renal damage often occurs in hypernatremia.

In infants, redistribution of water causes brain damage. Victims show extensive hemorrhage in the central nervous system as well as in the kidney tubules. The author pointed out that a level teaspoonful of table salt contains more sodium and chloride ions (about 350 mEq) than does a 5 kg baby and that this amount for the newborn is equivalent to about a pound for an adult.

Table 22

Cases of Subdural Effusion or Hemorrhage Accompanying Hypernatremic Dehydration (0978)

Case No. Initials	Age and Sex	Prior Status	Etiology or Underlying Disease Process	Maximum Concentration of Sodium in Serum (meq/l)	Clinical Features	Concentration of Protein in Cerebrospinal Fluid (mg/100 ml)	Results of Subdural Tap or Exploration	Remarks
1. M.B.	5 wk male	Thought to be normal; no convulsions	Salt poisoning (see text)	193	Stupor, convulsions (details in text)	100	Right 15 ml, left 6 ml; conc. protein 252 mg/100 ml; conc. Na 195 meq/l	Convulsive disorder requiring medication; permanently and severely damaged (see text)
2. C.T.	11 mo male	Normal development; no convulsions	Diarrhea with dehydration	161	Coma, convulsions	60	4 or 5 ml of grossly bloody fluid; exploration showed no membrane or large hematoma	Convulsive disorder requiring medication; spastic quadriplegia; institutionalized at 7 years of age
3. M.A.	9 mo male	Motor development slow; did not sit up at 9 mo; no convulsions	Fever and anorexia	154	Convulsions	65	Subdural hygroma containing 60 ml, found after tap revealed fluid	Convulsive disorder requiring medication; did not sit up until after 18 months of age; seems probable that damage to central nervous system present before hypernatremic episode and was then aggravated
4. I.P.	8 mo male	Normal development; no convulsions	Diarrhea with dehydration	168	Hyperpyrexia, somnolence, spasticity of muscles, brief convulsion	126	12 ml of clear fluid by tap	Two subsequent convulsions; development "low average" at 2 years of age
5. R.I.	6 mo male	Motor development a little slow; could sit alone for an instant only; no convulsions	Fever and anorexia	154	Hyperpyrexia, convulsion	58	10 to 15 ml of clear fluid; no membrane found on exploration	No convulsions subsequently; slightly retarded but possibly unrelated to hypernatremic episode in view of limited intellectual capacity of others in family
6. M.A.B.	2 mo female	Thought to be normal; no convulsions	Diarrhea with dehydration	176	Somnolence, hemiparesis	72	5 ml of clear fluid by tap bilaterally	No convulsions, hemiparesis persists at 2 years of age
7. M.G.*	6 mo* male	Normal development; no convulsions	Diarrhea and vomiting. Received vigorous intravenous therapy with one sixth molar sodium lactate and saline during first day in hospital	182	Became lethargic and convulsed on third day in hospital	68	15 to 20 ml of xanthochromic fluid; no membrane on exploration	Patient reported to appear normal at time of discharge; no follow-up information can be obtained

*The data concerning this patient were supplied by Dr. Samuel P. Bessman of the University of Maryland who gave permission to include it in this publication. The first six patients were all treated and followed at the Baltimore City Hospitals.

9. Gleason et al. (1188) assigned sodium chloride a toxicity rating of 3, i.e., moderately toxic, the probable lethal dose (human) being 500 to 5000 mg/kg BW or between one ounce and one pound for a 150 pound (70 kg) man.

Dangers of Salt as an Emetic Agent

Human Toxicity

1. DeGenaro et al. (0742) warned of the dangers attending the use of salt as an emetic agent. The authors pointed out the wide use of salt to induce vomiting in suspected poisoning and that recommendations for its use are found on labels of common household products, in first aid manuals, and in the pediatric literature. They decried the vague and ambiguous directions concerning dosage and lack of warnings of the dangers of excessive salt ingestion. They believe that the use of salt as an emetic is contraindicated. Details of fatal cases of salt poisoning following its use as an emetic are given.

2. Robertson (2748) reported four recent deaths following the use of salt as an emetic agent and lauded DeGenaro's (0742) condemnation of the practice.

3. Ward (3458) reported a case of fatal sodium chloride poisoning in an adult after two doses of 30 g each of salt as an emetic in a case of perphenazine-imipramine overdose. The patient died from pulmonary edema secondary to hypernatremia 32 hours after admission to the hospital.

4. Barer et al. (0215) described a typical case of fatal poisoning resulting from sodium chloride (table salt) used as an emetic in a small child. A three-year-old was given an unknown amount of salt at home after accidental ingestion of aspirin. The emetic was unsuccessful and the patient was transferred to a hospital where gastric lavage with saline solution was carried out. Fluid therapy, peritoneal dialysis, and mechanical ventilation were instituted in an unsuccessful attempt to save the child. Ten hours after dialysis, the patient died from cardiac arrest. The salicylate blood level had decreased to the asymptomatic level 6 hours after ingestion and was not a major factor in the outcome. Cause of death was attributed to the effect of an extremely high level of NaCl on the central nervous system.

5. Schatz (2904) reported the first successful treatment of salt poisoning following ingestion of a known lethal amount. A young female subject, 17 years of age, weighing 102 pounds, drank four glasses of salt

water at 20 minute intervals, on the advice of a friend, to induce vomiting for relief of menstrual cramps. Two heaping dessertspoonsful of salt were used in each glassful so that the total amount ingested within 2 hours was approximately 150 g (3261 mg/kg BW). (The author stated that 3 g is regarded as lethal and that smaller amounts have been known to kill).

The patient exhibited typical symptoms of salt poisoning shortly after drinking the last dose with retching but failure to vomit. Treatment was begun shortly thereafter in a physician's office with a procedure that had been used successfully with domesticated animals, i.e., massive gastric and intraperitoneal lavage with distilled water followed by physiologic salt solution administered subcutaneously. Large volumes of urine were voided after the treatment was begun and continued over a period of ten hours. The patient recovered completely within three to four days and exhibited no after-effects over a period of several years.

Toxic Effects from Hypertonic Saline for Intractable Pain

Human Toxicity

1. Thompson (3264) warned of the potential danger in the use of hypertonic saline injections for the relief of intractable pain. Severe pulmonary edema followed injection of 40 ml of 5% saline (0°C) intrathecally in a 47-year-old cancer patient. The patient responded to correction therapy without residual damage, however.

2. Hitchcock et al. (1450) studied 108 patients with intractable pain from cancer or benign diseases after intrathecal injection of 20 ml of 15% sodium chloride for symptomatic relief. Severe parathesia associated with hyperventilation occurred when the injection was done under local anesthesia but not under general anesthesia. A rise in blood pressure followed injection and fasiculation together with piloerection and some venostasis and faint cyanosis in dependent parts of the body were observed also. Most of the reactions subsided in about 30 minutes. The majority of the patients reported immediate relief of the pain which continued for 3 months in 50% of the cancer patients. Sphincter disorders in 8% of the cases and muscle weakness in 3% of those treated were the most important complications.

Dangers of Hypertonic Saline for Abortion

Human Toxicity

1. Cameron et al. (0469) described three fatalities in young women (20-23 years of age) following intra-amniotic injection of hypertonic saline to induce abortions. Death preceded by convulsions occurred 22-45 hours after the injections. Autopsy findings indicated acute hemorrhagic infarction of the amygdaloid nuclei and adjacent structures and a Y-shaped infarct in the pons as the cause of death.

The authors attributed the cerebral damage to excessive dehydration of the brain caused by the strong hypertonic NaCl solution injected into the amnion. They suggested that the amniotic-fluid replacement technique for inducing abortions should be used with caution until more information is available on the potential dangers to the mother by the hypertonic state of the body fluids which it may induce. Cameron stated that although they have received reports from other physicians who have used the above-mentioned technique in several thousand patients without fatalities, reports have been received of many deaths from its use abroad.

2. In a recent study of mortality associated with hypertonic saline abortion in New York City, Schiffer et al. (2911) gave the mortality rate over the period 1970-1972 as 20.2 per 100,000 abortions, in data from 49,474 saline mid-trimester attempts. The cause of death was not hypernatremia except in one case. The authors concluded that despite risks and complications, the hypertonic saline procedure remains the most satisfactory method for inducing mid-trimester abortion.

Salt and Hypertension

The scientific literature regarding the relationship of sodium chloride to hypertension is truly voluminous. Some aspects are controversial. Typical studies and interpretations are summarized in the following pages and in Long-term Studies.

A. Chickens

Lenel et al. (1893) induced arterial hypertension in chickens (8-week-old White Leghorns) by substituting 0.9 or 1.2% saline for the drinking water. Average systolic and diastolic blood pressures increased steadily during salt feeding from 132/117 to 182/154 mm Hg on the average. The degree of hyper-

tension produced seemed to be proportional to the salt intake. Discontinuance of salt feeding caused a prompt return of the blood pressure to normal levels. Pathologic findings were: hyperplasia and proliferation of glomerular tufts and Bowman's capsule with compression of the capillaries. Hyperplasia, like blood pressure, was reversible.

B. Rats

1. Dahl et al. (0694) investigated blood pressure changes in various parabiotic combinations of rats from genetically-resistant (R) and genetically-susceptible (S) strains on a high sodium chloride diet.

R+R and S+S parabionts on high sodium chloride diets (8%) behaved like single animals of either strain, i.e., blood pressures of the (S) parabionts rose rapidly and all succumbed by the end of 3 months; (R) parabionts, on the other hand, remained healthy with little change in blood pressure (Table 23).

When R+S rats were united in parabios and placed on an 8% NaCl diet, however, the (R) animals rapidly developed chronic hypertension whereas the rate of development and level of hypertension as well as the mortality rate were significantly lower than usual in the (S) rats of the R+S parabiotic union (see Table 24).

The authors pointed out that it is estimated that about 0.5 to 1.0% of the blood volume of each rat in parabiotic union is exchanged per minute. They believe that the data obtained indicate that a humoral factor, genetically determined, plays a role in the development of the hypertension observed in the animals employed in this study.

2. Barsanti et al. (0224) compared the effect of salt ingestion over a period of 7 months on spontaneously hypertensive and normal rats. Two groups of spontaneously hypertensive rats (SHR), Okamoto-Aoki strain, 4 females and 3 males, of matching average systolic blood pressures and body weights, constituted the test groups. One group received 1% NaCl in tap water ad libitum; the other was given plain tap water. Two control groups of 3-month-old normal Wistar rats (Non-SH) were included also. One control group (3 males and 3 females) received 1% NaCl in tap water ad libitum; the other (1 female and 2 males) was given plain tap water. All groups were fed Wayne chow.

Systolic blood pressure and body weight were determined every two weeks. Water consumption over the first 21 weeks was recorded daily in terms of ml/rat/day. The animals were observed for toxic signs and mortalities throughout. Results are presented in Tables 25 and 26.

Table 23

Parabionts from Same Strain* (0694)

Strain	R + R				S + S				
Diet (% NaCl)	0.38		8		0.38		8		
	Left	Right	Left	Right	Left	Right	Left	Right	Died‡ (months)
Systolic B.P. of individual parabionts (mm Hg)	122	110	108	122	124	150	198	220	3
	120	110	116	106	140	116	202	210	3
	118	98	112	120	128	114	221	218	3
	124	130§	100	114	124	140	172	211	2
	104	128	122	123	120	132	172	210	2
	130	112	122	106	124	122	184	212	2
	122	124	114	106	150	120	184	170	2
	118	111	102	109	124	120	198	193	3
			110	120	114	130	224	162	3
No. rats in group	8	8	9	9	9	9	9	9	
Mean B.P. of group (±S.E.)	118.5 (2.20)	115.4 (3.87)	111.8 (2.99)	113.0 (2.58)	127.6 (3.63)	132.7 (4.18)	195.0 (6.33)	200.7 (7.05)	
Median B.P.	120	112	112	114	124	132	198	210	

Analysis of variance of mean B.P.: In all four parabiont groups, left = right ($P > 0.05$) and S (8%) >** all others.

* Blood pressures of female rats from same strain united in parabiosis.

Results at end of study (6 months) or last B.P. before death (see Materials and Methods).

‡ Pair died during month indicated.

§ Animal died during 3rd month, B.P. of both parabionts at 2½ months.

Table 24

Parabionts from Opposite Strain* (0694)

Strain	R + S			
Diet (% NaCl)	0.38		8	
	R	S	R	S
Systolic B.P. of individual parabionts (mm Hg)	108	122	154	128
	112	118	169	132
	134	130	204	212‡
	110	112	174	170
	124	122	172	184
	102	130	144	157
	122	116	174	128
	110	128	192	150
	110	134	164	204
No. rats in group	9	9	9	9
Mean B.P. of group (±S.E.)	114.7 (3.32)	123.6 (2.47)	171.8 (6.02)	162.8 (10.7)
Median B.P.	110	122	172	157

Analysis of variance of mean B.P.: In both paraboint groups, R = S, but R (8%) or S (8%) >** R (0.38%) or S (0.38%).

* Blood pressures of female rats from both strains united in parabiosis. Results at end of study (6 months).

‡ Died during final week of experiment.

Table 25

Effect of 1% NaCl in Drinking Water on Normal and Spontaneously Hypertensive Rats (0224)

Group	Number	Deaths
SHR-1% NaCl	7	5
SHR-Tap H_2O	7	0
Non-SHR-1% NaCl	6	1
Non-SHR-Tap H_2O	3	0

The death time was 14-21 weeks. Prior to death, bloating, edema, decreased motor activity, rhythmic twitching, and dyspnea, were observed. The rapid acceleration of hypertension in the SH rats due to salt ingestion in comparison with the controls is shown in Table 26.

Water consumption of the SH rats receiving salt increased with time until the majority had died. This group drank 2 to 3 times more water than their counterparts on tap water alone and 1 to 3 times more than the normotensive rats on 1% NaCl in the drinking water.

Table 26

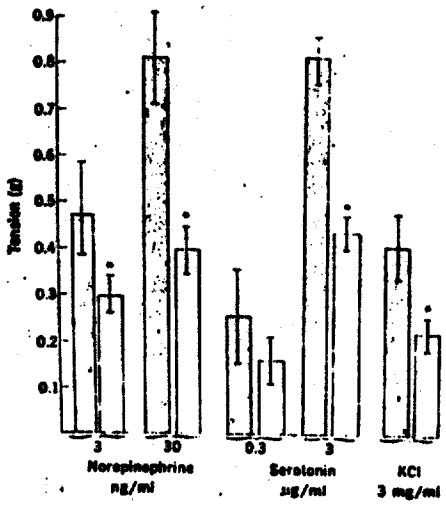
Blood Pressure Changes in Various Groups of Rats (0224)

	Systolic blood pressure (mm Hg)			
	SHR		Normal	
Time in study (weeks)	Controls (tap water)	1% NaCl	Controls (tap water)	1% NaCl
0	121 ± 17	120 ± 23	107 ± 8	106 ± 15
1	136 ± 14	129 ± 14		
3	142 ± 23	144 ± 25	111 ± 12	104 ± 18
5	152 ± 28	160 ± 26		
7	152 ± 20	167 ± 23		
9	148 ± 14	184 ± 31	91 ± 5	105 ± 16
15	155 ± 20	196 ± 14	106 ± 11	103 ± 19
20	153 ± 19	186 ± 3	104 ± 8	103 ± 10
24	146 ± 19	176 ± 12		
26	172 ± 18	179 ± 6		
28	160 ± 26	185 ± 33		

3. Catalanotto et al. (0495) discovered recently that spontaneously hypertensive Wistar rats (SH) demonstrated a persistent increased preference for sodium chloride (0.15 M and 0.30 M) over water in comparison with either Wistar or Holtzman normotensive controls when given a free choice between saline and water. Total fluid intake was increased also in the SHR group.

4. Spector et al. (3136) found that spontaneously hypertensive rats differ from normotensive animals in vascular smooth muscle reactivity in a study prompted by the fact that increased peripheral resistance of the vascular system is characteristic of hypertension in humans. Blood pressure of spontaneously hypertensive - SHR (174 ± 6 mm Hg) and normotensive Wistar rats (122 ± 6 mm Hg) were determined and the animals then sacrificed by a blow on the head. Spirally cut thoracic aortic strips were then subjected to varying levels of K Cl, serotonin, norepinephrine, or isoproterenol, in a constant temperature bath at 37.5°C and reactivity determined under controlled conditions.

The tissue strips from SHR animals were less responsive than those from normotensive rats to the contractile effects of potassium chloride, serotonin, and norepinephrine but more reactive to the beta receptor drug, isoproterenol (Figures 4 and 5). The relationship of these findings to hypertension mechanisms is discussed (See original article for details).



A comparison of the contractile responses of thoracic aortic strips from five normotensive and nine spontaneously hypertensive rats to norepinephrine, serotonin, and KCl. Data given as means ± standard errors. The asterisks indicate statistically significant differences, $P < .05$. Shaded bars, normotensive animals; open bars, SHR.

Figure 4 (3136)

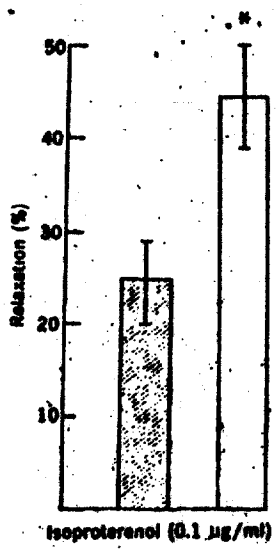


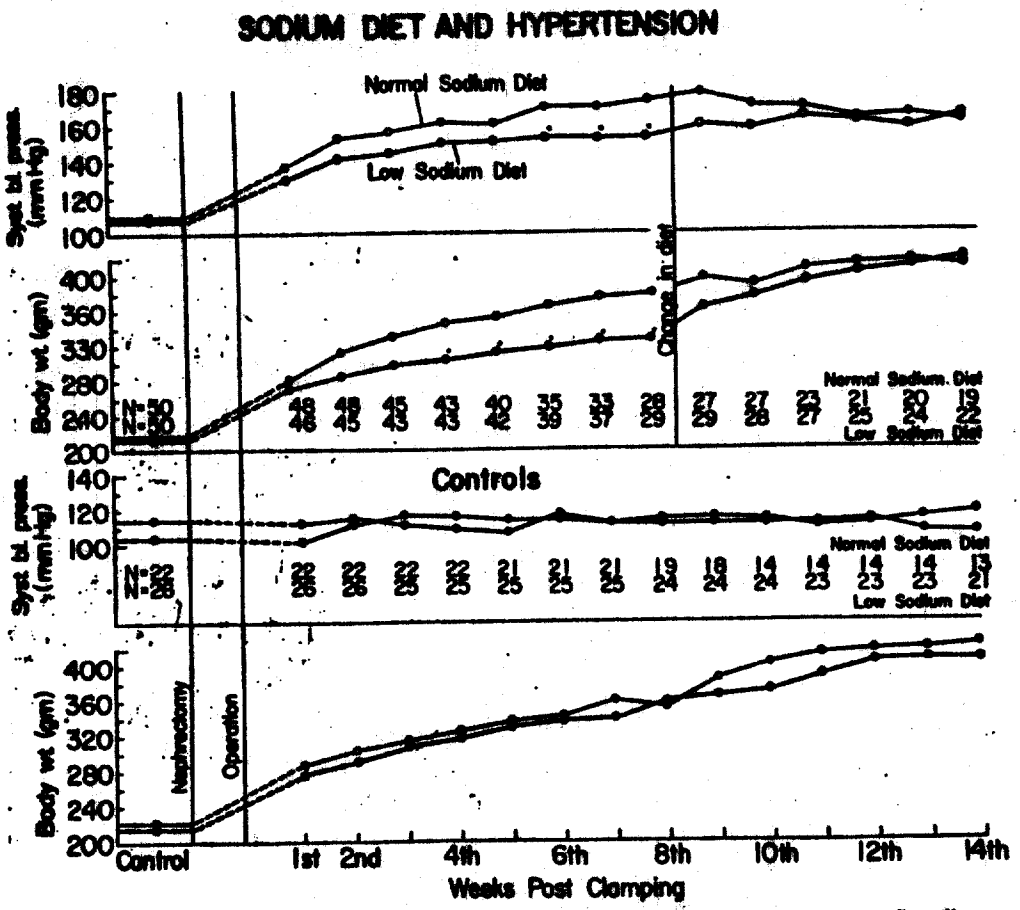
Figure 5 (3136)

A comparison of the relaxant beta responses of thoracic aortic strips from four normotensive and seven spontaneously hypertensive rats to isoproterenol. The aortic tissue was made to contract with 3 µg of scrotonin per milliliter. Data given as means ± S.E. The asterisk indicates a statistically significant difference, $P < .05$. Shaded bar, normotensive animals; open bar, SHR.

5. Conway (0607) studied the effect of sodium restriction on experimental renal hypertension in rats with a clipped renal artery. One hundred young Wistar rats weighing approximately 200 g with a silver clip applied to one renal artery, with contralateral nephrectomy, were employed in the study. Fifty animals were placed on a low sodium diet (50 mg/kg); the other half were fed the same diet with 0.6% sodium chloride added. Distilled water was provided ad libitum for both groups. After 8 weeks the diets were reversed for an additional 5 weeks.

Forty-eight control rats, subjected to a sham operation in which a unilateral nephrectomy operation was performed and a clip placed on the opposite renal artery and then removed, were included in the study also. Twenty-six of these rats were placed on the low sodium diet and 22 on the higher sodium intake. Blood pressure measurements were made at regular intervals on all groups. The results are presented in Figure 6.

Hypertension developed in both groups of test rats over a period of 4-6 weeks but its onset was more gradual and the extent was lower (18 mm Hg) in rats on the low sodium diet. Blood pressure and weight gain of control rats were not influenced in any way by differences in the sodium intake.



Evolution of hypertension in animals fed on diets differing in sodium content. Systolic blood pressure and weight gain in rats on a normal (O) or a low sodium intake (●). All animals were subjected to nephrectomy; (upper), a clip was applied to the opposite renal artery; and (lower), a sham operation on that side; *N* indicates the numbers of animals in the study during each week of observation; *Indicates a "significant difference" $p<0.05$ between rats on the sodium deficient diet as compared to those on a normal diet.

Figure 6 (0607)

6. Selye et al. (2994) determined the pathologic changes in the kidneys and other organs accompanying malignant hypertension produced in the rat by desoxycorticosterone acetate (DCA) and sodium chloride.

Four groups of young albino rats, consisting of 4 males and 4 females weighing 30-46 g were treated as follows: Group 1 animals received two daily subcutaneous injections of 3 to 5 mg of DCA and were given tap water to drink; Group 2 was treated in the same manner except that 1% NaCl solution was given instead of tap water; Group 3 animals received injections of cholesterol in the same manner and amount as DCA was administered to Groups 1 and 2; Group 4 rats on tap water received no medication. All groups were fed "Purina fox chow". Food and fluids were available at all times. The animals were observed

for toxic signs and mortalities over a 53-day period. Blood pressure was measured on the 52nd day. All rats were sacrificed on the 53rd day and their organs prepared for detailed histologic examination.

Two animals in Group 2 died from hemorrhagic lung edema. Survivors showed a pronounced elevation in blood pressure (187/130 ave.) and most had symptoms of severe circulatory failure. Marked diuresis, increased excretion of sodium and chloride, and proteinuria were noted also. Pathologically, the kidneys showed signs of malignant nephrosclerosis with glomerular damage. Pancreas and adrenal capsule were affected also. The authors stated that the disease produced bore a striking resemblance to the hypertensive heart disease of renal origin in man.

One animal in Group 1 died. No deaths occurred in Groups 3 and 4. The average blood pressure of animals in Groups 1, 3, and 4 was 110/80. The kidneys of Group 1 animals were only slightly affected; those of the other groups were normal.

7. Fadeva et al. (0941), Institute of General and Communal Hygiene, Mowcow, USSR, found that rats given sodium chloride in the drinking water for one year at a level of 10 g/liter exhibited a statistically-significant increase in arterial pressure (from 67.3 ± 6.3 to 83.7 ± 1.4 mm) as compared with control animals given tap water for drinking.

On the basis of some comparisons of results between the effect of NaCl and Na_2SO_4, the authors concluded that sodium is capable of causing an hypertensive effect only when combined with a chloride ion (See original article for details). The safety of standardizing the content of chlorides in drinking water at a level of 350 mg/liter on the basis of an "organoleptic hazard symptom" was confirmed.

3. Rabbits

Fujii et al. (1083) investigated the effect of sodium intake on hypertensive vascular lesions in the rabbit. Two groups of 21 male rabbits, 2.0-2.5 kg BW, were fed as follows: Group A - low sodium diet (7 mEq of sodium and 26 mEq of potassium/100g of diet); Group B - high sodium diet (28 mEq of potassium per 100 g of diet). Each animal was given 100 g of the diet each day and water ad libitum. After a control period of 2 weeks, hypertension was produced by applying a silver clip on the left renal artery. Blood pressure was measured daily and plasma renin activity on the last day of the experiment. Seven days after clipping, the animals were sacrificed and the hypertensive

vascular lesions studied microscopically.

Increase in blood pressure and incidence of hypertensive lesions were significantly greater in rats on the high salt diet ($P < 0.05$). Vascular lesions were found in 6 or 29% of animals on the low-sodium diet and in 13 or 62% of those on the high-level ration. There was no significant difference in plasma renin between the two groups. The authors pointed out that the sodium levels employed were not excessive but rather were actually within the high physiological range.

D. Dogs

1. Dahl (0687) fed 17 pure-bred Beagle dogs (16 females and 1 castrated male), in groups of 4 or 5, diets yielding daily average NaCl intakes of 2.5 g (control), 5.5 g (2% NaCl in food), 11.5 g (1% NaCl in water), and 12.5 g (6% NaCl in food) over a period of 4 years and determined the effect of the varying salt levels on blood pressure, plasma cholesterol, and blood urea nitrogen. The data are presented in Table 27 and Figure 7.

Excess salt feeding definitely caused an increase in blood cholesterol, but blood pressure was unaffected. Rats employed in the same study experienced a rise in blood pressure as well as elevated cholesterol levels.

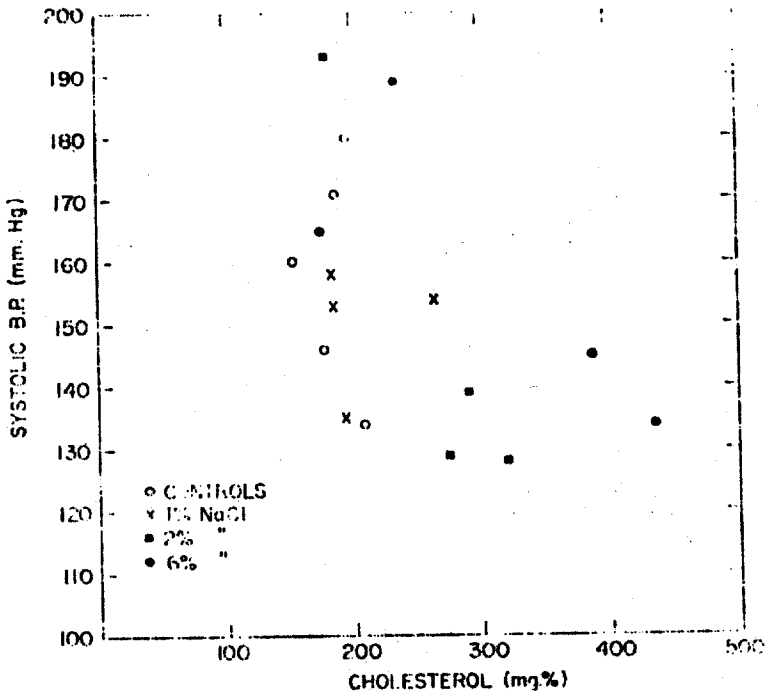


Figure 7 (0687)

Effect of chronic salt feeding on blood pressure and plasma cholesterol levels in female dogs. Results after 4 years.

The concentration of plasma sodium was not altered by overloading with salt but the total exchangeable sodium was approximately doubled. Peripheral resistance was not affected in contrast to essential hypertension in man where peripheral resistance is increased with a normal cardiac output.

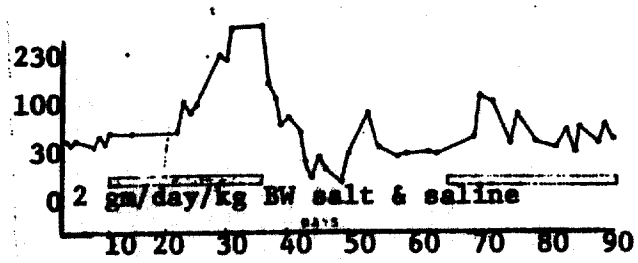


Figure 8 (3643)

Effect of dietary sodium chloride on the systolic blood pressure of four dogs. Pressures were determined every 2-3 days by sphygmomanometry. Salt and saline were administered during days covered by hatched bar

3. Frieden et al. (1067) demonstrated that elevated blood pressures in benign hypertensive dogs could be reduced to normotensive levels by severe chronic salt depletion which had no effect on the normal pressures of normotensive control animals. Five dogs (specifications not given) with benign renal hypertension of 1/2 to 6 months duration responded to two peritoneal lavage treatments with a decrease in blood pressure from 195/115 - 230/135 to 155/90 - 210/115. Plasma sodium levels were reduced to 115-120 mEq/liter (see Table 28). A low sodium diet alone was without significant effect on elevated blood pressures in the dogs studied.

The authors pointed out that the blood pressure reduction achieved by decreased sodium was directly associated with the hypertensive process per se, since sodium depletion had no effect on normal blood pressures in normotensive control animals.

4. Haddy et al. (1303) investigated the effect of acute selective sodium chloride depletion, with body water held constant, in anesthetized dogs. Dogs of average weight, 18.5 kg, were injected intravenously with Furosemide (diuretic), 20 mg/kg BW, and then immediately thereafter with 500 ml of replacement solution to start urine flow. Urine was then replaced, as excreted, with an isosomotic Ringer's solution in which mannitol was substituted for sodium chloride. The following measurements and observations

were made: blood pressure, plasma and urine osmolality, plasma sodium, potassium, calcium, magnesium, blood pH, and hematocrit.

The data obtained showed that sodium chloride depletion per se had no appreciable influence on blood pressure when test and control animals were compared. It was suggested that blood pressure changes which occurred with changes in the plasma sodium chloride content were produced indirectly by associated changes in extracellular osmolality. The authors stated that their results were in agreement with those of other studies in perfused vascular beds which indicated that sodium chloride per se is not vasoactive and that its effect seems to result indirectly from osmotic shifts of water.

Table 28

Effect of Low Sodium Diet and Sodium Depletion on Blood Pressure of Renal Hypertensive Dogs (1067)

1	2	3	4	5	6	7
DOG NO.	SEX	PRE-LONALAC BLOOD PRESSURE	PRE-Na DEPLETION BLOOD PRESSURE EFFECT OF LONALAC DIET	BLOOD PRESSURE DURING CHRONIC Na DEPLETION, mm. Hg: Plasma Na, 130-135 mEq/l.	BLOOD PRESSURE DURING CHRONIC Na DEPLETION, mm. Hg: Plasma Na, 115-120 mEq/l.	BLOOD PRESSURE AFTER RETURN TO NORMAL DIET AND RECOVERY FROM Na DEPLETION
		mm. Hg	mm. Hg			mm. Hg
Z 158.....	♂	225/140	230/135	220/120	185/95	210/115
Z 160.....	♂	190/115	195/115		165/100	Deceased
Z 185.....	♀	205/125	—[1]	200/110	155/90	170/105
Z 189.....	♀	—[2]	220/115	210/120	170/100	185/100
Z 202.....	♀	205/130	210/125		155/90	190/115
Duration....		½-6 months	1-6 months	2-3 weeks	2-3 weeks	1-3 months

[1] Lonalac feeding was instituted simultaneously with peritoneal lavage. [2] On Lonalac prior to Goldblatt operation.

5. In a study designed to explore the anatomical site of the enzyme for the conversion of angiotensin I to angiotensin II, Franklin et al. (1032), found that dogs maintained on a high salt diet (6 g twice daily) and treated with 25 mg of deoxycorticosterone acetate (DOCA) once a day, had a reduced rate of conversion of angiotensin I to angiotensin II (19% to 10%) over a period of seven to ten days. Experiments carried out with perfused canine kidney in situ indicated that the kidney contains the enzyme for the above-mentioned conversion as well as the enzyme rennin.

E. Humans

1. Dahl et al. (0705) studied the relationship of salt intake to hypertension in 1346 healthy adults in an attempt to shed more light on the possible role of sodium chloride in the etiology of essential hypertension in man. One hundred and five or 7.8% of the group studied had hypertension.

Sixty-one of the hypertensives had a high salt intake (always salted food at the table), 43 had an average salt intake (salted food at the table only after tasting it and finding it unpalatable), and only one had one had a low salt intake (never salted food at the table). The author pointed out that when these data were analyzed by the chi-square method, the probability that such a distribution between hypertension and salt intake occurring by chance would be less than 1 in 1,000.

The relationship between obesity, hypertension and salt intake revealed the following statistically-significant information: (1) individuals of normal weight on a high salt diet have several times the incidence of hypertension than similar subjects on a low-sodium diet ($P < 0.01$); (2) individuals with a high salt intake who are overweight will have significantly more hypertension than those who are not overweight; (3) persons who are overweight on a high salt diet will have a much greater incidence of hypertension than will individuals not overweight and on a low-sodium diet. The author stated that clinical evidence indicates that it is the sodium ion and not the chloride ion that is important in hypertension.

2. Fishbein (0983) in a brief article on salt and hypertension stated that, "modern man's habitual daily salt intake probably is well in excess of normal needs and that an abnormally high sodium intake may induce or exacerbate some forms of hypertension in humans".

3. McDonough et al. (2131) administered 865 g of salt to a young healthy normotensive male over a period of 23 days (average of 37-38 g/day) and studied the effect on systolic and diastolic blood pressures, bodyweight, fluid characteristics, hematocrit, blood volume, and total plasma volume. Salt loading was then abruptly stopped and measurements continued for another 25 days.

The data presented in Figure 9, according to the authors, indicate a gradual, progressive highly-significant increase in systolic and diastolic pressures with a precipitous drop when salt was discontinued and a leveling off to almost normal (pre-salt) values during the ensuing 25 days. Bodyweight increase coupled with swelling of tissues of the face, arms, and legs occurred during the period of high salt ingestion. Pitting edema, however, did not occur. Heart weight changes were not significant.

4. McQuarrie et al. (2144) discovered that oral administration of sodium chloride at a level of 1000 to 2000 mg/kg BW daily diminished glycosuria and increased systolic and diastolic blood pressures significantly in

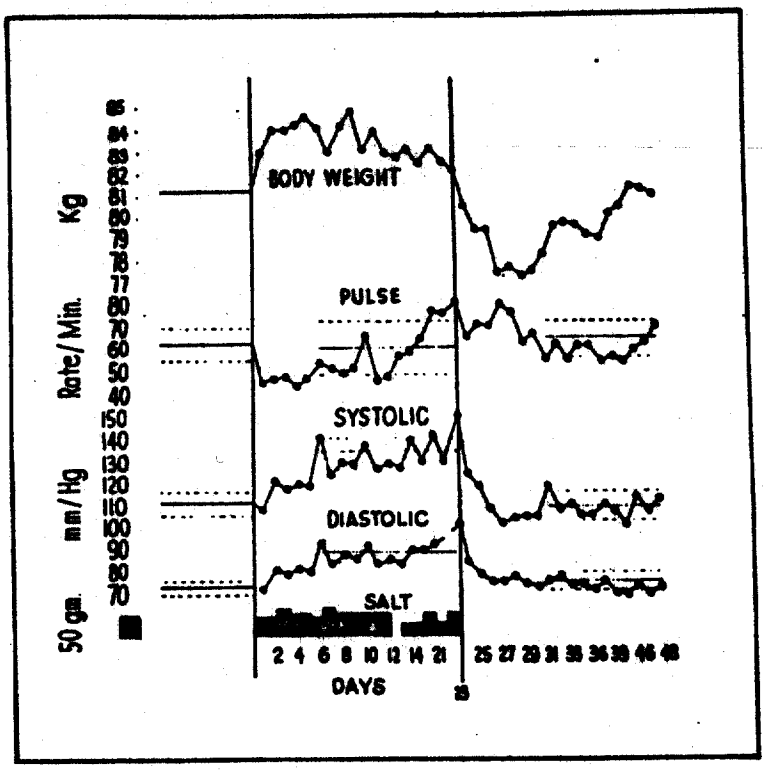


Figure 9 (2131)

Broken Lines Represent Standard Deviation from the Mean

diabetic and normal children.

Repeated studies carried out on four diabetic patients and one non-diabetic subject, 13 to 15 years of age, revealed that both systolic and diastolic blood pressures increased to plateaus between 30 and 50% above control levels and remained so as long as excess salt was ingested. The sodium rather than the chloride ion appeared to be chiefly responsible for both effects. Discontinuance of insulin therapy had no influence on either sodium chloride effect. Diets high in potassium, or administration of 10 to 20 g of KCl per day, caused a slight drop in blood pressure and a significant increase in glycosuria. When sodium chloride and potassium chloride were given simultaneously, one part of potassium was found to completely abolish the effect of at least three chemically equivalent parts of sodium. The main findings are presented in Table 29 and Figures 10, 11, and 12. (See original article for other details.) The authors stated that the mechanisms involved in blood pressure elevation and better utilization of carbohydrates by increased salt ingestion are obscure.

Table 29

The Effects of Ingesting 60 gm of NaCl Daily on L.R. Age 15 Years. Severe Diabetic. Diet Contained Protein 64, Fat 132 and Carbohydrate 168 gm. Insulin 32 Units Daily. No Ketosis. (2144)

DAY	INTAKE (GRAMS)				OUTPUT (GRAMS)					WEIGHT (KILOGRAMS)	BLOOD PRESSURE
	Na	Cl	K	N	Na	Cl	K	N	Glucose		
1	1.57	2.43	1.48	10.36	1.86	2.37	0.86	12.40	73	38.3	116/80
2	25.16	38.84	1.48	10.36	14.26	13.38	0.86	11.10	83	38.2	116/76
3	25.16	38.84	1.48	10.36	24.17	42.28	0.86	7.87	13	40.8	140/88
4	25.16	38.84	1.48	10.36	23.55	38.16	1.40	9.23	14	40.3	150/98
5	25.16	38.84	1.48	10.36	26.56	43.06	0.93	9.63	33	40.3	174/110
6	25.16	38.84	1.48	10.36	24.38	33.58	1.56	9.67	31	40.2	166/108
7	25.16	38.84	1.48	10.36	24.83	40.36	1.40	9.78	26	40.4	164/112
8	25.16	38.84	1.48	10.36	27.28	41.85	1.21	10.87	26	40.4	176/118
9	1.57	2.43	1.48	10.36	4.99	7.88	1.44	8.78	30	40.4	164/98
10	1.57	2.43	1.48	10.36	1.86	2.41	0.82	8.91	49	39.2	130/88
11	1.57	2.43	1.48	10.36	2.57	3.80	1.13	9.47	57	39.1	112/80
12	1.57	2.43	1.48	10.36	1.75	2.24	1.05	10.87	72	38.7	106/74

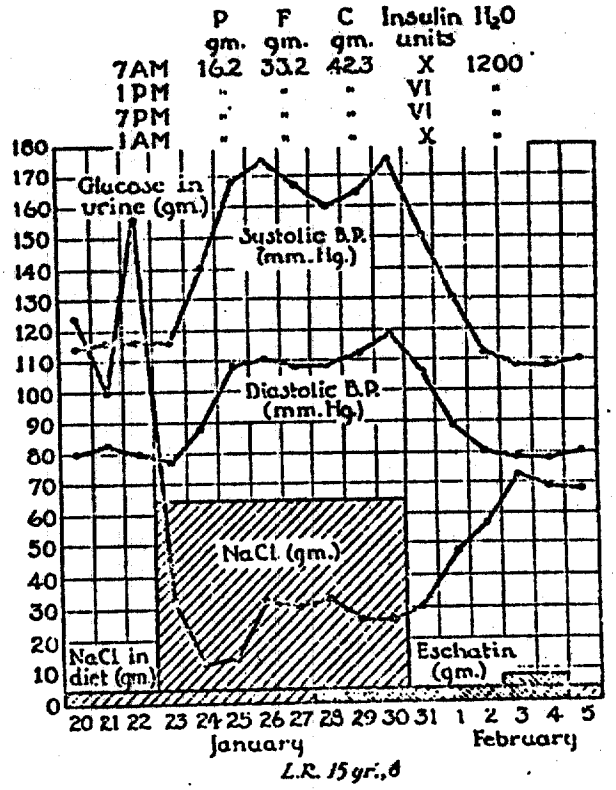


Figure 10 (2144)

Effects of sodium chloride on glycosuria and blood pressure. Non-effect of extract of adrenal cortex. L.R. severe diabetes.

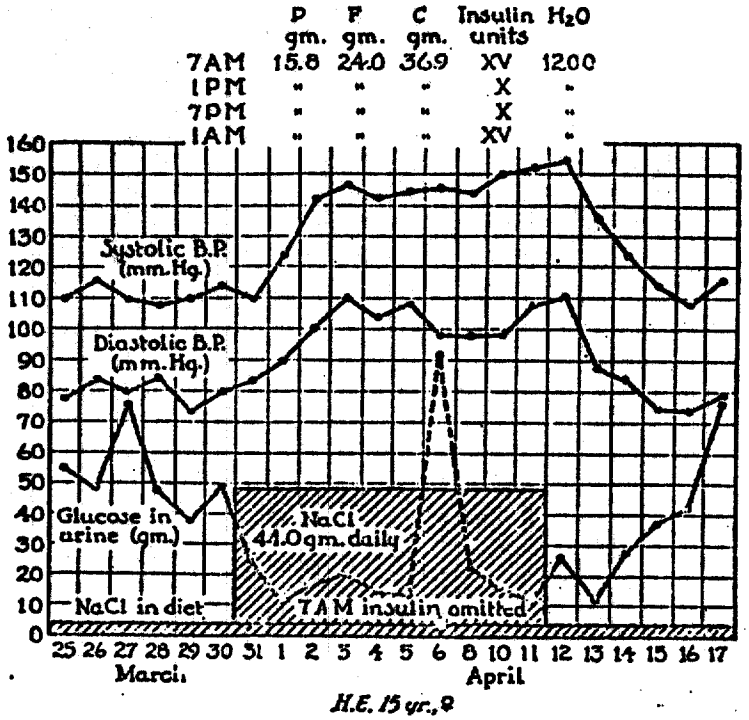


Figure 11 (2144)

Effects of sodium chloride ingestion on glycosuria and blood pressure. Dotted line shows effect on glycosuria of omitting insulin for 12 hours. H.E. severe diabetes.

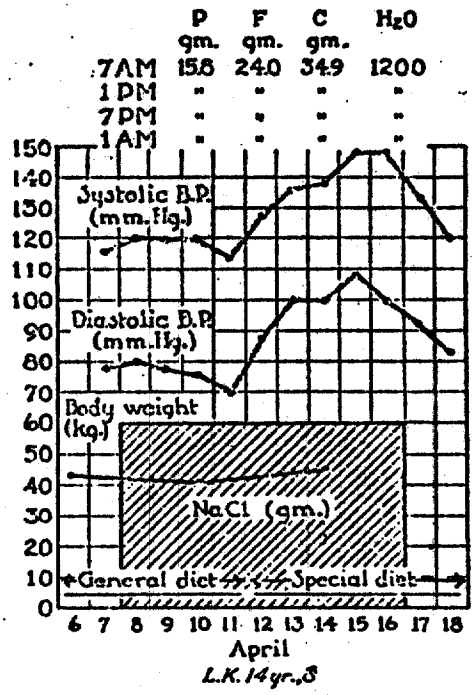


Figure 12 (2144)

Response of blood pressure to high-sodium, low-potassium intake in normal subject, L.K.

5. Sollmann (3126) stated that prolonged consumption of excessive salt tended to cause edema, degenerative changes in the kidneys, and chronic arterial hypertension. Restriction of salt intake, on the other hand, lowered the excessive systolic and diastolic blood pressures, and symptoms improved in many patients with chronic hypertension.

6. Schechter et al. (2905) determined sodium chloride preference in 10 essential hypertension patients and in 12 normal volunteer controls. All exhibited normal taste thresholds for table salt. Both groups were placed on a dry diet containing 9 mEq of Na^+ and given a choice of drinking either distilled water or 0.15 M sodium chloride solution. The following daily observations and determinations were made: food, fluid and NaCl intakes; urine volume and concentrations of sodium, potassium, and creatinine; bodyweight. The data were subjected to statistical analysis for significance. Results are shown in Table 30 and Figure 13.

The hypertensive patients consumed a significantly greater amount of their total fluid intake as saline (38.2%) over one week, as compared with the controls (10.6%) and also had a greater total fluid intake (1269 ml) than the controls (668 ml). The salt intake of the hypertension patients was more than 4 times that of the normotensive controls.

Table 30

Comparative Data (2905)

	Subject No.	Sex/Age/Race	Body Weight, kg	Admission Blood Pressure, mm Hg	Sodium Chloride Thresholds, mM*†	Average Daily Na^+ Intake, mEq‡	Average Daily Na^+ Intake/Body Weight, mEq/100 kg
Hypertensives	1.	F/43/W	81.00	160/100	30/30	92.8	114.6
	2.	M/39/N	89.02	150/100	12/12	54.8	64.6
	3.	F/25/W	73.32	170/130	30/60	51.6	70.4
	4.	M/51/N	100.75	190/110	6/6	61.7	61.2
	5.	F/44/W	84.44	150/108	60/60	250.8	297.0
	6.	M/56/W	76.78	180/120	30/60	84.5	110.0
	7.	M/50/N	56.92	170/102	60/60	34.7	60.9
	8.	M/42/N	84.40	140/100	30/30	62.2	73.7
	9.	M/47/N	70.42	156/112	30/30	11.0	15.7
	10.	M/54/N	73.40	162/108	60/60	39.1	53.3
Mean			79.05		30/45‖	74.3±21.0§¶	92.1±24.4§¶
Volunteers	1.	M/19/W	72.20	128/72	12/60	10.2	14.2
	2.	M/19/W	69.60	120/72	30/60	2.2	3.2
	3.	F/43/W	54.58	130/78	12/12	0	0
	4.	M/19/W	71.02	100/60	60/60	2.6	3.7
	5.	M/19/W	72.04	132/70	60/60	0	0
	6.	M/21/W	61.72	136/84	60/60	43.1	73.6
	7.	M/23/W	80.82	124/80	30/30	45.8	56.6
	8.	M/21/W	65.40	110/70	12/12	63.6	97.2
	9.	M/19/W	73.46	120/80	30/30	1.8	2.4
	10.	M/19/W	58.68	120/70	30/30	0	0
	11.	M/21/W	78.66	118/80	30/30	3.7	4.8
	12.	F/19/W	61.10	118/70	6/6	0	0
Mean			68.27		30/30‖	14.4±6.5§	34.2±9.9§

*Numerator of fraction is detection threshold, denominator of fraction is recognition threshold.
†Normal values according to Henkin et al[14] 12/30 mM (range, 8 to 60/6 to 60 mM).
‡Excluding daily 9 mEq of Na^+ intake in constant diet.
§Mean ± S.E.
‖Median values (not significant, Wilcoxson rank sum statistic).
¶$P < .02$ (two-sided t test) compared to normal volunteers.

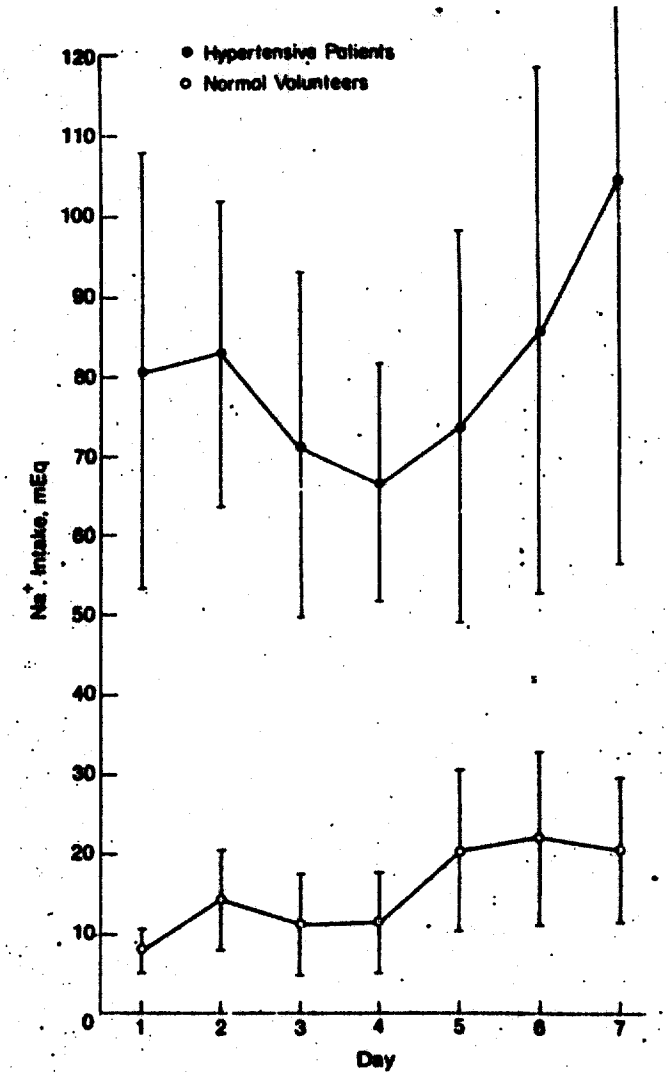


Figure 13 (2905)

Daily intake of Na^+ of hypertensive patients (solid circles) and normal volunteers (open circles). Na^+ intake is plotted on ordinate, days of study on abscissa. Each point and vertical bars represent group mean ± 1SE.

7. Coleman et al. (0589) in a recent review of salt and hypertension concluded that salt and water play a very important role in determining blood pressure, particularly, in cases of normal plasma renin activity.

Data from patients (including anephrics where the renin-angiotensin system is not a factor) and experimental animals indicated the following, according to the authors:

a. In uncomplicated hypertension, increased salt intake and decreased salt excretion, will increase arterial pressure. Decreased salt intake and increased excretion, on the other hand, will lower pressure.

b. Low salt diets and diuretics are very effective in lowering blood pressure in many instances.

c. Two possible mechanisms of increased blood pressure are:

(1) An increase in peripheral resistance brought about circulation vasoconstriction as those of the renin-angiotensin system.

(2) Fluid retention and increased cardiac output in the presence of kidney dysfunction and absence of plasma renin activity which leads to increased peripheral resistance by auto-regulation of blood flow.

8. Dahl (0682) in a survey of dietary habits, salt intake, and incidence of hypertension and cerebrovascular disease in population groups found that these diseases were more prevalent in the northern part of Japan, where the salt intake is approximately 27 g per day, as compared with an average consumption of about 17 g per day in the central and southern parts of the country (American (male) intake is about 10 g per day). The Japanese diet - low fat (largely unsaturated), average protein, and high carbohydrate - is fairly uniform throughout the country.

9. Sasaki (2867) also studied the relationship of salt intake to hypertension in Japan and found that the incidence of high blood pressure was 30 to 40% in inhabitants of Akita farm villages of northeastern Japan where the daily salt intake is about 27 g per day compared to the national average of 13 g daily. Deaths from cerebral apoplexy also paralled salt intake (see Table 31 and Figure 14). Salt excretion of the above group averaged about 27.3 g per day with a maximum of 61.4 g.

10. Isaacson et al. (1541) studied the relationship of sodium intake, hypertension, and sodium excretion in 100 healthy adult Bantu miners and found that the data agreed well with Dahl's hypothesis that a linear relationship exists between dietary sodium intake and the communal incidence of hypertension. The results in comparison with Dahl's findings are given in Figure 15.

Table 31

Systolic Blood Pressure of Inhabitants in Northeastern District of Japan (averages and standard deviations) (2867)

Age	Males: All Japan*	Males: I**	Males: II***	Females: All Japan*	Females: I**	Females: II***
6-11			109±13 (287)			110±15 (299)
12-14		118±13 (185)	122±15 (291)		123±13 (151)	123±16 (283)
15-19		131±14 (610)	139±13 (72)		127±13 (1176)	133±13 (111)
20-24	126±15	131±15 (998)	142±15 (167)	120±13	128±15 (688)	127±12 (308)
25-29	127±16			121±15		
30-34	127±16	131±17 (706)	142±19 (201)	120±15	127±17 (802)	133±19 (350)
35-39	127±17			122±17		
40-44	129±18	137±23 (752)	148±27 (285)	127±19	137±25 (871)	141±21 (176)
45-49	131±20			132±23		
50-54	137±25	148±27 (657)	160±28 (309)	138±24	147±28 (795)	157±30 (140)
55-59	146±28			142±28		
60-64	150±30	158±31 (359)	171±30 (203)	150±28	158±29 (466)	169±30 (275)
65-69	155±29			156±30		
70-74	158±27	170±32 (98)	185±35 (66)	161±30	171±30 (122)	177±30 (98)
75-79						
80-84		173 (6)	197 (6)		175 (6)	185 (13)
85-89						

Numbers in parentheses refer to numbers of persons in each age sex group.

* National Nutrition Survey in November 1959.

** Warmer season (May to Oct): males (4671), females (5375)

*** Colder season (Nov to April): males (1891), females (2656)

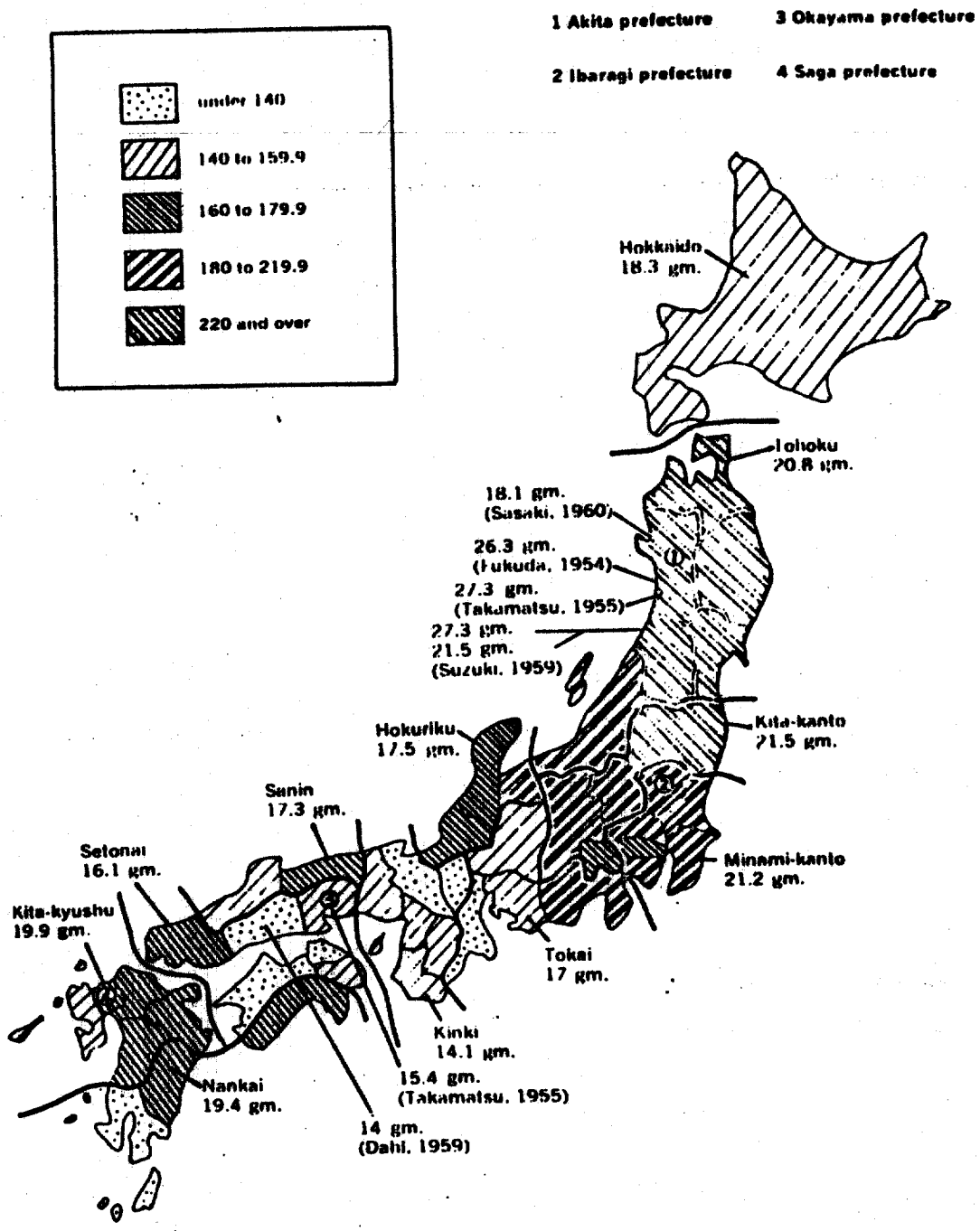


Figure 14 (2867)

Distribution of age-adjusted death rate per 100,000 males from cerebral apoplexy (B22) by 46 prefectures (1960). Average daily salt intake in grams per day of farmers in 11 farm districts (1953-58).

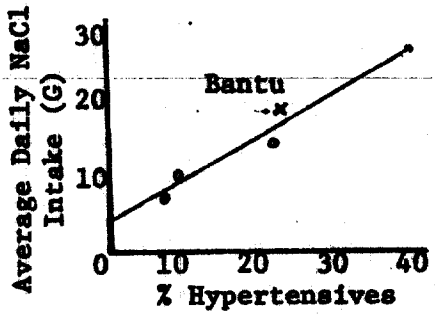


Figure 15 (1541)

11. Prior et al. (2627) investigated the relationship between blood pressure and salt intake in two Polynesian populations of the Cook Islands. One group consisted of the entire adult population of the atoll, Pukapuka; the second group was made up of 455 adults who represented 98% of the town of Avarua on the island of Rarotonga.

Amongst the Pukapukans, systolic blood pressure ranged from 108-129 mm Hg; sodium intake varied from 50 to 70 mEq/day; urinary sodium levels averaged 63 mEq/day. Twenty-eight percent of the Rarotongan men, and 47% of the women, on the other hand, had systolic blood pressures above 159 mm Hg; salt intake ranged from 120 to 140 mEq/day; urinary sodium levels averaged 108 mEq/day.

A Nutrition Review editorial (0098) commenting on this study stated that the findings constitute strong evidence for the relationship between sodium intake levels and blood pressure differences between the two groups.

12. Truswell et al. (3318) reported recently on a study of the relationship of salt, and sociologic, anthropometric, medical, biochemical factors to blood pressure in a population where arterial pressure in general declines with advancing age. The subjects of this investigation, the !Kung bushmen of Northwestern Ngamiland, Botswana, are isolated by a surrounding waterless zone 60 to 100 miles wide and live a stressless life, mainly as hunter-gatherers. Blood pressures were measured in 152 of the subjects (79 men and 73 women) aged 15 to 83 years, and analyzed in comparison with other parameters of the study.

Systolic and diastolic pressures of the men declined with age. In the female group, diastolic pressure decreased with age also but there was a slight rise in the systolic pressure after the menopause.

The subjects eat a low salt diet which the authors pointed out contains little more sodium than diets that were actually used to treat essential hyper-

tension patients before the advent of oral diuretics. Lack of obesity and freedom from mental stress were two other factors postulated as explanations of the lack of hypertension in the subjects. Other population groups where blood pressures do not increase with advancing age are discussed also.

13. Kemper (1668) determined the effect of a rice-fruit-sugar diet (not more than 150 mg of sodium and 200 mg of chloride) on 500 patients with serious hypertensive vascular disease and noted definite improvement in 322 patients with respect to blood pressure, cardiac improvement, or disappearance of severe retinopathy.

In 311 patients, hypertension was definitely improved with a reduction in mean arterial pressure of 34 mm Hg; in 163 patients where the hypertension was not improved, there was a decrease of 11 mm Hg. Fifty-two percent of heart conditions improved; 71% of retinal hemorrhages cleared up.

14. Harrison's Principles of Internal Medicine (3562) states:

> "In the past, diets low in sodium and protein have in some hands unquestionably resulted in striking amelioriation of hypertensive vascular disease. The low sodium content of the diet appears to have been the effective factor. The multitude of effective oral natriuretic agents available today, however, make unnecessary diets rigidly restricted in sodium, such as the rice diet. Moderate sodium restriction and judicious use of oral diuretic agents are equally effective in the control of hypertension in individuals with normal renal functions. Both rigid sodium restriction and the use of diuretics, however, may further impair kidney function in the patient with renal failure. A diet effectively low in sodium, may potentiate the effect of other forms of treatment of hypertension, both surgical and pharmacologic."

15. Allen (0047) obtained dramatic results in the treatment of 20 cases of hypertension in patients ranging from 25 to 69 years of age with a low salt diet. The data presented in Table 32 show that all of the patients responded to treatment with a marked decrease in blood pressure and in the concentration of the blood chloride level.

16. Dahl et al. (0690) studied the effect of reduction of sodium and caloric intake on eleven obese patients with essential hypertension of 2 to 14 years duration, in a controlled hospital study. During control periods of approximately 4 to 7 weeks duration, all patients were placed on a "high sodium" intake (10 g per day) with sufficient calories to maintain initial weight. After stabilization of blood pressure and weight, either salt or caloric intake was reduced. The low-sodium diets provided 85 to 105 mg of sodium per day; the low-calorie diets, 600 to 800 calories per day. The new

Table 32

Effects of Dietetic Treatment in Twenty Cases of Hypertension (0047)

Case No.	Phenolsulphone-phthalein Excretion in 2 Hrs., %	Before Treatment: Plasma Chlorides Mg per 100 C.c.	Before Treatment: Blood Urea Mg per 100 C.c.	Before Treatment: Blood Pressure Sys-tolic	Before Treatment: Blood Pressure Dias-tolic	After Treatment: Plasma Chlorides Mg per 100 C.c.	After Treatment: Blood Urea Mg per 100 C.c.	After Treatment: Blood Pressure Sys-tolic	After Treatment: Blood Pressure Dias-tolic
1	....	624	29.2	208	...	569	28.0	166	98
2	54.5	610	27.1	(300) 215	170	588	20.0	134	70
3	54.0	620	21.8	210	110	541	24.5	140	80
4	42.8	610	19.8	210	120	586	21.2	160	95
5	36.0	620	20.5	240	110	590	10.4	166	75
6	....	620	23.5	220	140	556	23.5	178	98
7	46.0	608	32.2	195	92	591	26.9	162	80
8	48.0	613	30.7	220	98	570	28.5	110	80
9	....	611	32.6	220	70	576	16.2	130	66
10	41.3	612	47.0	220	110	555	31.4	154	80
11	4.0	556 (625)	69.4	212	104	556	52.6	156	80
12	30.2	664	94.4	210	120	598	26.4	172	100
13	....	659	104.5	198	100	545	62.5	90	60
14	5.0	648	124.0	214	170	537	42.2	140	100
15	....	597	27.1	190	92	597	....	108	70
16	38.2	569	36.4	190	90	595	14.6	165	100
17	....	534	46.7	210	100	553	56.2	180	95
18	27.4	576	55.0	235	145	543	23.7	170	98
19	12.1	548	58.2	(305) 215	170	505	18.0	180	130
20	64.8	565	21.0	234	160	559	19.4	180	120

*Parentheses in the systolic pressure column indicate that the pressure in these cases was repeatedly near 300 mm, but the actual pressure on beginning dietetic treatment was 215. In Case 19 this reduction had been accomplished by heavy bleeding in another hospital.

regimen was usually maintained for several months. The patients were ambulatory in the hospital throughout the study. Bodyweights were determined daily and blood pressures were measured six mornings each week. The data were analyzed for statistical significance by the student's "t" test.

Eight of the 13 patients studied had a significant decline in both systolic and diastolic pressures after salt limitation ($P < 0.01$); four showed no decline or a fall in the systolic or diastolic pressure only. One patient attained a normal pressure prior to salt restriction. Three of 4 patients on a low-calorie but normal-sodium diet failed to achieve a reduction in blood pressure despite a marked weight loss (11 to 25% of control weight). Data on the 4th patient were inconclusive. All of these subjects had significant declines in blood pressure (systolic and diastolic) after salt intake was restricted. The authors concluded that salt restriction rather than caloric reduction was the effective agent in lowering blood pressure in obesity.

17. McLester (2141) studied the effect of salt-poor diets (1 or 2 g NaCl/day) in 10 hypertensive patients, on blood pressure, urea nitrogen, creatinine nitrogen, sugar, and chloride contents of the blood and chlorides, albumin, and casts in 24-hour urine specimens, over periods of 15 to 79 days.

The data obtained indicated that salt restriction resulted in decreases of 15 to 43 mm Hg in the systolic pressure of 6 of the patients; four subjects showed an increase ranging from 20 to 40 mm Hg. The patients found the food unappetizing, according to the article, and usually ate but little. Urine chlorides were very low but blood chlorides varied only slightly. The author concluded that "the almost complete elimination of chlorides from the diet of patients with nephritis and vascular hypertension accomplishes little if anything more that does the salt-poor diet ordinarily prescribed".

18. Dole _et al_. (0817) studied the effect of a low sodium diet (7 mEq/day of Na^+) on five patients with uncomplicated hypertension.

Statistically-significant reductions in blood pressure were observed in all five patients when the sodium intake was reduced from 180 mEq per day to 7 mEq/day. Three patients became normotensive; two with the highest initial blood pressures remained in the hypertensive range. Weight losses were observed in all five patients and there was a decrease in the heart size in four patients. Loss of exchangeable sodium amounted to 14-20% during the first month. The reverse effects were noted following re-administration of salt.

19. Blair-West et al. (0283) in a review of sodium homeostasis, salt appetite, and hypertension, pointed out that although some factors involved in sodium metabolism control have yet to be discovered (see Figure 16), there is abundant evidence that essential hypertension in man is ameliorated by restricted salt in the diet and, conversely, that a high sodium intake aggravates the condition, although its role as an etiologic factor in hypertension has not been proven.

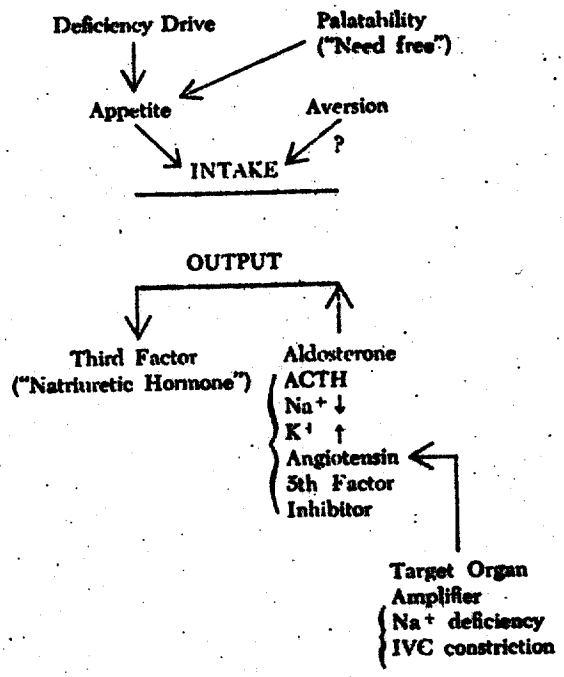


Figure 16 (0283)
Physiological Control of Salt Homeostasis

20. Doyle et al. (0836) studied the effect of dietary sodium depletion and of Frusemide (diuretic) on plasma renin concentration in hypertensive patients and normotensive controls.

Fifty essential hypertension patients and 30 normotensive controls were selected for the study. After 5 days on a normal diet and salt loading (100 mEq of sodium per day), the subjects were admitted to the hospital and placed on a low-sodium diet containing about 10 mEq of sodium, for a period of 4 days. Blood pressure, bodyweight, plasma urea, sodium, potassium, renin, steroid levels, and urinary sodium, potassium, and aldosterone concentrations were measured at definite intervals.

In a second experiment, hypertensive patients and normotensive controls, 8 to 15 per group, were given 40 or 60 mg of the diuretic drug Frusemide intravenously. Plasma renin and urinary sodium concentrations were then determined. The main findings are depicted in Figures 17 and 18 and summarized below.

Hypertensive patients had significantly lower levels of plasma renin (PRC) than the control group during salt loading, and lower levels and a smaller rise after sodium depletion (Figures 17 and 18). Frusemide diuretic (1 mg/kg BW intravenously) induced a rise in PRC in only 6 of 14 hypertensive patients in comparison with an increase in 11 of 12 normotensive control subjects. There was no significant difference between either peripheral plasma aldosterone levels or renal sodium excretion between the two groups during salt loading or after sodium depletion (dietary or diuretic).

The authors pointed out that in most normal animals, including man, dietary sodium restriction or diuresis leads to a rise in plasma renin concentration, a rise in plasma and urinary levels of aldosterone, and a decrease in urinary sodium excretion. Their data, as well as those of previous workers, indicated that hypertensive patients behave in a different manner. It was concluded that aldosterone secretion in essential hypertension patients is either controlled to a lesser extent by the renin-angiotensin system than in normotensive subjects, or that different mechanisms may actually be involved for aldosterone control as well as sodium conservation.

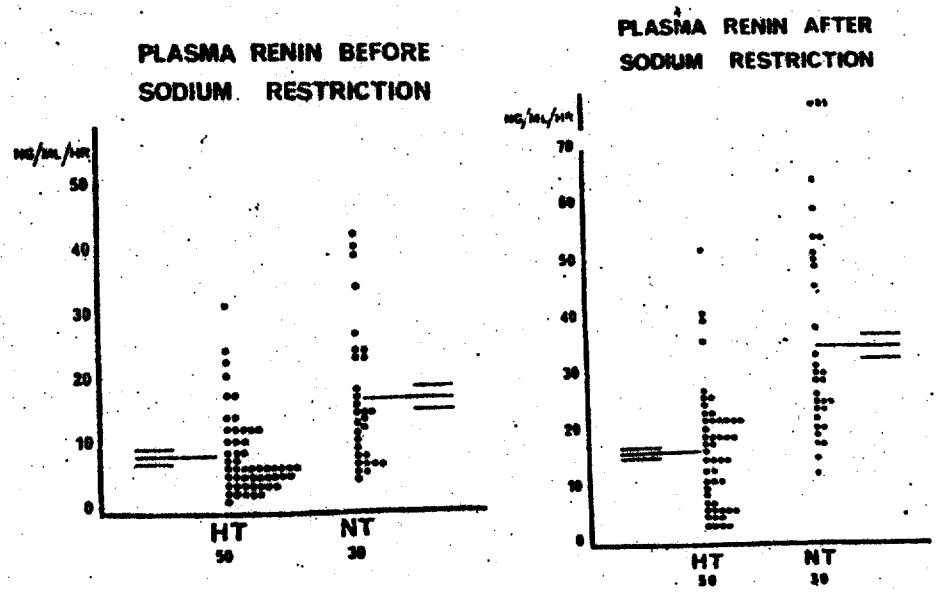


Figure 17 (0836)

Plasma renin concentration in hypertensive (HT) and normotensive (NT) patients before sodium restriction (left) and after 4 days of sodium restriction and 2 hr of upright posture (right).

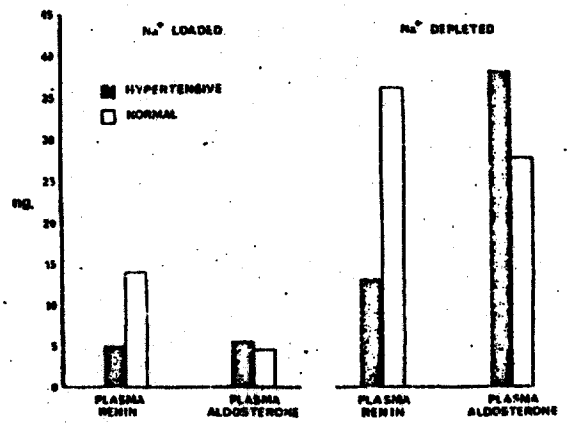


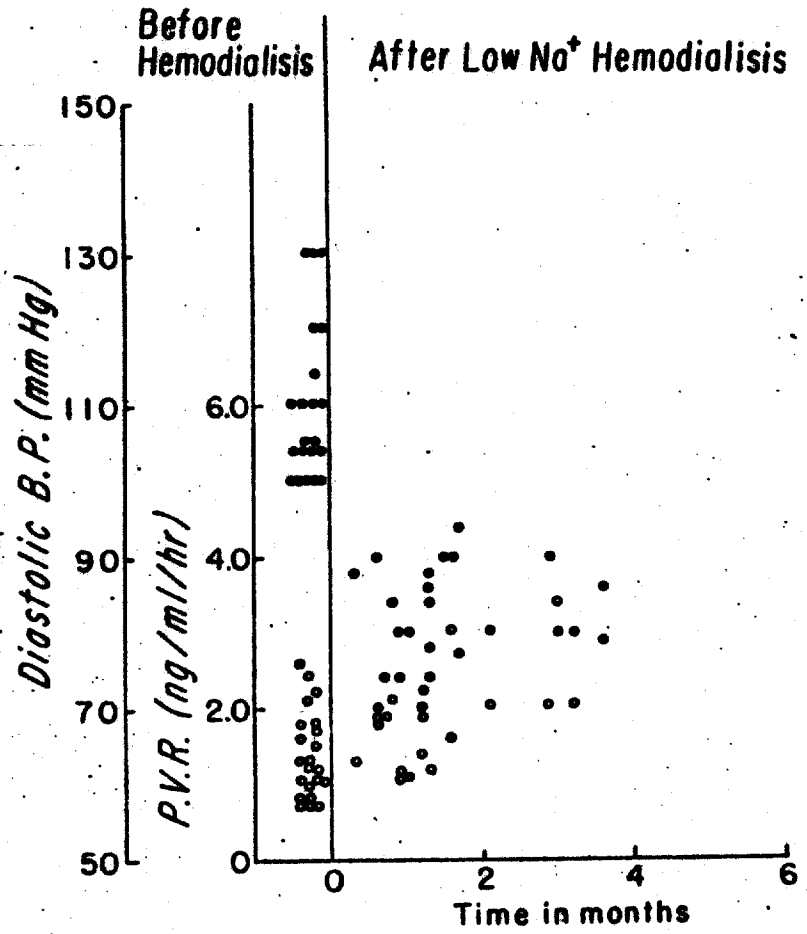
Figure 18 (0836)

The mean levels of PRC and peripheral plasma aldosterone in 15 hypertensive patients (shaded columns) and nine control patients (open columns) during sodium loading and sodium depletion.

21. Chrysanthakopoulos et al. (0551) recently studied the effect of low salt diet and ultrafiltration with low sodium dialysate on the blood pressure of 27 patients with end-stage renal disease and hypertension. Twenty-one patients responded favorably to the treatment with a return of blood pressures to normal. Renin activity was normal or only slightly elevated in most (see Figure 19). The 6 patients who did not respond to treatment all had very high peripheral vein renin activity; four required bilateral nephrectomy for reduction of the hypertension (Figure 20). The authors concluded that there are two types of hypertension in patients with end-stage renal disease: (1) the "salt-dependent type" (majority) and (2) the "rennin-dependent type" (minority) (see Figure 21).

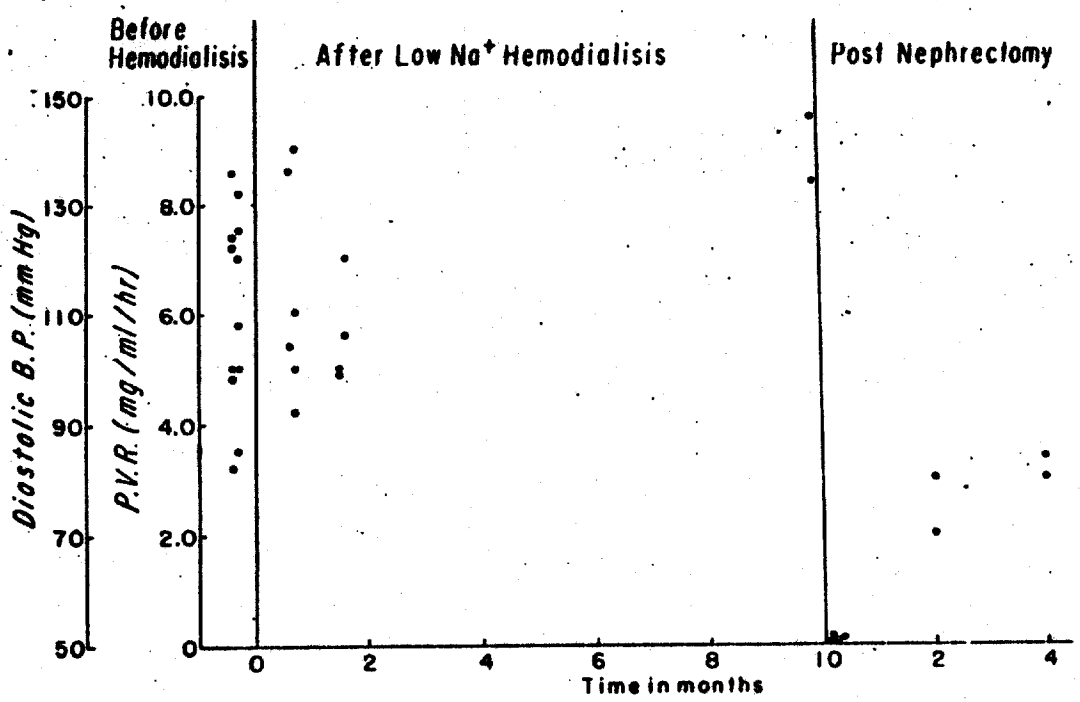
22. Kirkendall et al. (1707) made a very detailed study of the effect of varying salt intakes on the blood pressures of four normotensive male prison volunteers (27-47 years of age) over four week periods. A basic low-sodium, low-potassium diet was supplemented with KCl to bring the K content to 100 mEq in each of the test diets which contained sodium levels of 10 mEq (low sodium), 210 mEq (moderate sodium), or 410 mEq (high sodium). The potassium:sodium ratio varied from 10 to 1 in the low sodium diet to 1:4.1 in the high sodium diet. Each subject received a different test diet every four weeks. In addition to blood pressure measurements, excretion of sodium, potassium, and creatinine were determined each day. Urinary excretion of calcium, magnesium, and phosphorus as well as serum sodium, potassium, chloride, creatinine,

Figure 19 (0551)

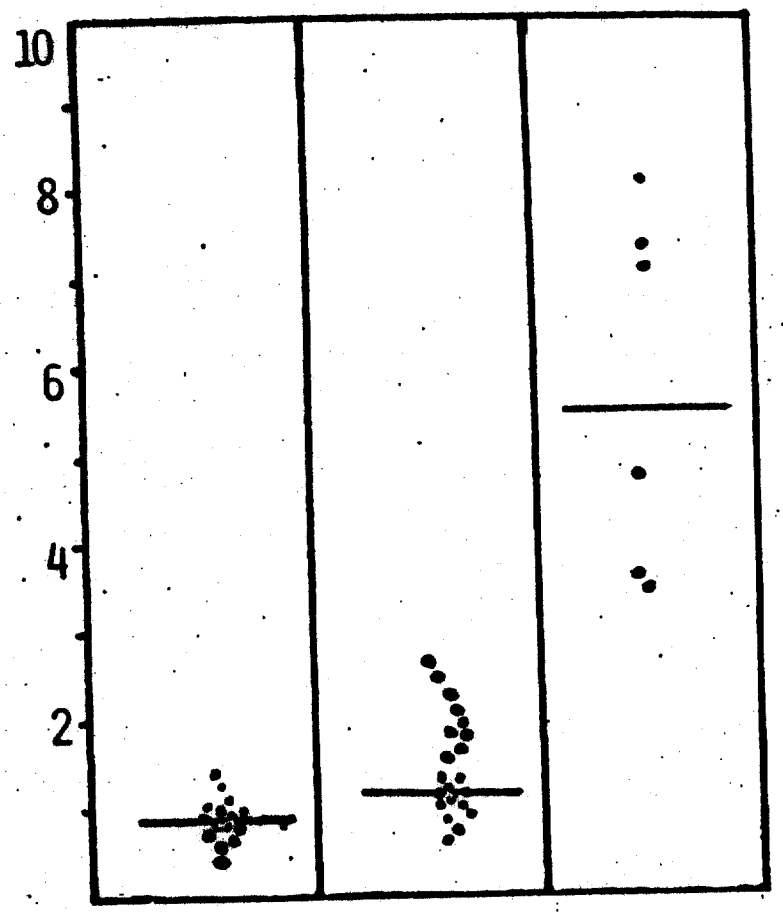


Effect of dialysis on diastolic BP and PVR values in patients whose hypertension was controlled by dialysis alone. Closed circles = diastolic BP. Open circles = PVR values.

Figure 20 (0551)



Effect of dialysis and bilateral nephrectomy in diastolic hypertension and PVR values in patients whose hypertension was not controlled by dialysis alone. Closed circles = diastolic BP. Open circles = PVR values.



NORMAL	GROUP I	GROUP II
N = 15	N = 21	N = 6
Mean = 0.9	Mean = 1.3	Mean = 5.7

Figure 21 (0551)

Renin values in ng/ml/hr in normal controls and hypertensive patients on maintenance hemodialysis.

cholesterol, triglycerides, blood urea nitrogen, and creatinine clearance were measured weekly. During the final week of each dietary period, total body water, exchangeable sodium, total body potassium, inulin clearance, inulin space, plasma renin, and aldosterone were determined.

There was no change in blood pressure with any of the salt intakes when the subjects were at rest, supine or upright. Two of the patients, however, showed higher intra-arterial pressures with increased dietary sodium at the time of the vascular reactivity studies. Periphereal plasma renin and urinary aldosterone decreased in all four patients as the sodium level of the diet increased from 10 to 410 mEq. Extracellular fluid and total body water increased

in parallel with increased salt intake. Potassium excretion increased also as the sodium intake increased but excretion of calcium, phosphorus, and magnesium were unaffected.

The authors concluded that white normotensive males on a high salt diet respond after about a month with a new steady state which is conducive to the development of higher blood pressures, but whether arterial hypertension actually develops may depend on genetic factors, time of exposure, and other variables such as neurogenic and hormonal stimuli which "apparently cause exaggerated vascular responses when excess salt is present". The authors called attention to the great change in the K:Na ratio - 10 to 0.24 - during the study and stated that the ratio of these two major cations may be more important than the level of sodium alone in producing cardiovascular changes.

23. Hartroft (1373) in a review of nutritional aspects of hypertension reported that a brief period of choline deficiency during infancy could lead to hypertension in later life. Weanling rats fed a diet low in choline and other lipotropic agents for a period of less than one week and then given a normal diet (stock laboratory chow) for the remainder of the experimental period developed hypertension. Added protein and sodium chloride increased the degree of blood pressure elevation and their reduction in the diet tended to reduce the hypertension. The author believed that the effect of dietary sodium chloride on blood pressure probably involved the juxtaglomerular cells of the kidney and thus the renin-angiotensin-aldosterone system, and he presented histologic data in support of the theory.

24. A leading article in the British Medical Journal (0104) stated that on the basis of observations that high blood pressure in early adult life is statistically correlated (although only very roughly) with that observed in the fourth decade or later, screening children for elevated blood pressure might be wise in view of the possible benefits of prophylactic measures such as reduced salt intake, prohibition of the contraceptive pill, and so forth. This would be especially true where there is a very definite familial tendency towards hypertension such as both parents, for example, on medication for high blood pressure.

25. Concerning the role of heredity in hypertension, Cecil's Textbook of Medicine (0257) states that many factors, mainly environmental but also inherited, lead to similar arterial pressures in members of certain families,

and that the inherited tendency seems to be greater in some families than in others.

According to the authors, the tendency to develop high blood pressure certainly appears to be present at an early age and long before high arterial pressure itself is present. The example is given of certain young women in whom high blood pressure suddenly appears for the first time during pregnancy, falls to normal after the baby is born, and then recurs later in life. Medical records reveal that these individuals usually come from families with a history of high blood pressure.

26. Londe et al. (1958) noted that 44% of children with elevated blood pressures detected in a screening program had a family history of hypertension and that 53% were obese. Several thousand children were involved in the program which was designed to establish normal blood pressure values for children of various ages. The authors recommended weight reduction, reduced salt intake, and annual physical examinations for the obese hypertensive child.

27. Overturf et al. (2482) studied the medical records of 200 white hypertensive patients (male and female) in an effort to determine possible interrelationships between renin activity, dietary sodium and potassium, and a number of other clinical and chemical parameters, and hypertension. Included in the study were serum cholesterol creatinine, fasting blood glucose, uric acid, carbon dioxide determinations, creatinine clearance test, intravenous pyelography, radioactive renography, aortography, renal arteriography, and electrocardiographic data. Drug treatments were taken into consideration also. A group of normal subjects with average blood pressures and no evidence of renal or cardiovascular disease were included as controls.

In the essential hypertension (EH) group (137 patients - 80 males and 57 females), renin activity levels were within normal limits. Increased uric acid (6.6-7.2 mg%, normal 2-6 mg%) and fasting blood glucose levels (105.8 mg%, normal 65-100 mg%) were the only clinical chemical variations from the normal found in this group. Approximately 30% however, had evidence of left ventricular hypertrophy and 54% had other cardiac abnormalities such as st-t changes. Approximately half of these patients were overweight (see Tables 33 and 34).

In the renovascular hypertension group (RVH), plasma renin levels were higher than in the EH group and significant negative correlations between serum potassium levels and renin activity, and between serum potassium levels and

blood pressure were found. Seventy percent of these patients had some form of cardiac abnormality.

The authors suggested that the renin-angiotensin system may plan an important role in renal vascular hypertension.

Table 33

Summary of Essential and Renovascular Hypertensive Patients (2482)

	Essential hypertensive patients* N=137		Renovascular hypertensive patients N=50	
	No drug $\bar{x}\pm$S.D. (n)	Diuretics $\bar{x}\pm$S.D. (n)	No drug $\bar{x}\pm$S.D. (n)	Diuretics $\bar{x}\pm$S.D. (n)
Systolic pressure (mm Hg)	159.3±3.6 (66)	155.3±4.1 (49)	166.1±6.6 (18)	168.0±6.0 (23)
Diastolic pressure (mm Hg)	98.5±2.2 (66)	98.1±3.1 (49)	102.1±3.2 (18)	102.5±2.9 (23)
Age (yr)	41.8±1.6 (70)	47.2±1.6 (50)	47.2±3.7 (18)	46.9±2.5 (23)
Weight (lb)	160.6±5.0 (68)	176.8±5.0 (50)	153.5±6.8 (17)	140.0±6.4 (22)
Chemistry				
BUN (mg %)	16.1±0.6 (64)	19.3±1.1 (46)	17.9±1.6 (17)	20.0±1.9 (22)
Fasting glucose (mg %)	105.8±5.1 (43)	103.0±5.0 (40)	99.3±4.2 (8)	108.6±8.7 (15)
Cholesterol (mg %)	239.5±7.3 (45)	240.0±7.0 (37)	227.0±10.0 (14)	261.1±16.3 (21)
Creatinine (mg %)	1.1±0.1 (65)	1.2±0.1 (50)	1.6±0.4 (18)	1.5±0.3 (23)
Potassium (mEq/l)	4.1±0.1 (62)	4.0±0.1 (50)	4.0±0.1 (18)	3.8±0.2 (22)
Sodium (mEq/l)	140.3±0.6 (54)	140.2±0.6 (31)	138.4±0.9 (18)	139.1±0.9 (23)
Uric acid (mg %)	6.6±0.6 (31)	7.2±0.4 (35)	7.1±1.3 (5)	6.1±0.5 (12)
Carbon dioxide (mM/l)	24.9±0.5 (59)	25.1±0.5 (48)	25.9±0.9 (17)	25.2±0.8 (22)
Chloride (mEq/l)	100.7±0.9 (45)	101.9±1.4 (24)	98.0±1.4 (16)	98.1±1.5 (20)
Creatinine clear (ml/min)	88.9±5.4 (24)	86.8±8.4 (14)	75.0±14.0 (9)	64.8±5.9 (16)
Renin activity (ng/ml)	3.2±0.4 (70)	5.1±0.9 (50)	5.8±1.2 (18)[a]	12.2±2.5 (23)[b]

* Tests of significance between groups are designated [a], [b]; Essential hypertensives are denoted as EH, Renovascular hypertensives denoted as RH.

[a] RH no drugs significantly ($P<0.01>$) higher than EH no drugs.

[b] RH taking diuretics significantly ($P<0.1>$) higher than RH no drugs, also significantly higher than EH no drugs and EH diuretics.

Table 34

Means and Standard Error and No. of Subjects (2482)

	ng of angiotensin/ml of plasma*		
	Male	Female	Both
Normal subjects	2.9±0.5 (20)	3.2±0.8 (10)	3.0±0.5 (30)
Essential hypertension (No drugs)	2.8±0.3† (39)	3.9±0.7† (31)	3.2±0.4 (70)
Essential hypertension (Anticatecholamines)	5.2±1.0† (28)	3.6±0.7† (11)	4.7±0.8 (39)
Essential hypertension (Diuretics)	5.1±0.9 (34)	5.0±2.0 (16)	5.1±0.9 (50)
Renovascular hypertension (No drugs)	4.6±0.9 (34)	7.0±2.2 (9)	5.8±1.2 (18)
Renovascular hypertension (Anticatecholamines)	8.4±3.3 (9)	16.4±3.7 (15)	13.4±4.4 (24)
Renovascular hypertension (Diuretics)	12.3±2.5† (23)	14.0±3.4† (15)	12.2±2.5 (38)

Contraceptive status of essential hypertensive women	Age	Blood pressure	Renin value
No birth control pills	33.9±2.5 (18)	157/99.4±6.9/5.0 (18)	3.8±0.6 (18)
Birth control pills	33.5±2.4 (16)	160/101±8.4/5.9 (16)	4.1±0.8 (16)

*Statistical evaluation of significance between means was done only within drug group, and only when N > 10 for both males and females.

†$P = < 0.05$ between males and females within a drug group.

28. Although considerable research has been conducted concerning the possible etiologic relationship of the renin-angiotensin system in human essential hypertension, Pickering (2572) stated that "the only function that can be ascribed to them with reasonable certainty is that of regulating the renal excretion of sodium by the kidney through the secretion of aldosterone by the zona glomerulosa of the adrenal gland".

29. In a recent review and evaluation of information on the safety and suitability of salt for use in baby foods, a special National Academy of Sciences subcommittee concluded that although salt may lead to hypertension in certain kinds of rats, the evidence relating salt intake to hypertension in man is inconclusive. The authors pointed out that while a high intake of sodium chloride can lead to hypertension in young rats and that the hypertensive effect is greater the earlier in life a continuous high salt intake is begun, genetic factors are involved as well. (1017)

With respect to man, the subcommittee stated that although a number of studies have shown a correlation between average daily salt intake and the

incidence of hypertension in different populations (see Table 35), other surveys failed to reveal any significant correlation in this respect (1017). Moreover, they indicated that other factors such as dietary, genetic, cultural, and social, may be involved in population study results like those reported in Table 35. Furthermore, several surveys on salt habits revealed that the normotensive subjects used as much, or more, salt than the hypertensive patients (1017).

Table 35

Correlation of Hypertension with Salt Intake (1017)

Group	Average Salt Intake gm/day	% with Hypertension B.P. > 140/90
Alaskan Eskimo	4	0
Marshall Islander	7	6.9
United States	10	8.6
Japan (Southern)	14	21
Japan (Northern)	26	39

Adopted from Dahl[8]

30. Mosenthal (2274) in a treatise on high blood pressure presented data on 38 cases showing the relationship between blood sodium chloride levels and systolic and diastolic blood pressure values (see Tables 36 and 37). The author concluded that sodium chloride does not affect blood pressure. In nephritis, he stated that the salt intake must be adjusted to the excretory ability of the kidney but the height of the arterial pressure can be ignored.

31. Gros et al. (1273) investigated the effect of added sodium chloride, and NaCl-KCl mixtures, on the blood pressure of patients with mild essential hypertension (treated and untreated) in comparison with normal subjects. In the first experiment (1A), 6 g of NaCl as a supplement to the normal diet were given to seven patients with milk hypertension and 3 normal control subjects over a period of 2 to 9 weeks. The same ten subjects were then given 6 g of NaCl and 6 g of KCl over a subsequent 4 week period. Blood pressure measurements (diastolic) were made each morning and evening and bodyweights were recorded daily. In the second experiment, eight blood pressure patients on hydrochlorothiazide therapy (50 mg daily) were given 5 g of NaCl as a dietary

Table 36 (2274)

Cases demonstrating the lack of relationship between blood-pressure and concentration of sodium chlorid in the blood. These were consecutive cases of hypertension. There are fewer cases exhibiting a sodium chlorid concentration greater than 500 mg. per 100 c.c. than a lower level.

Case.	Sodium chlorid, mg. per 100 c.c. whole blood.	Blood-pressure, mm. mercury.
1	627	226/90
2	588	181/110
3	557	208/94
4	538	221/120
5	519	180/76
6	500	214/136
7	500	200/82
8	500	212/130
9	494	224/120
10	494	221/106
11	488	206/126
12	482	156/100
13	478	216/132
14	478	210/114
15	475	210/116
16	462	216/120
17	450	210/145
18	429	201/128
19	429	170/110
20	429	224/136

Table 37 (2274)

Consecutive cases exhibiting an increased concentration of salt in the blood. There is no direct relationship between the sodium chlorid and the arterial tension. About one-half the cases exhibit a normal blood-pressure in the presence of a raised blood chlorid concentration.

Case.	Sodium chlorid, mg. per 100 c.c. whole blood.	Blood-pressure, mm. mercury.
1	676	105/52
2	627	226/90
3	625	98/80
4	588	140/84
5	588	184/110
6	562	150/86
7	557	208/194
8	550	130/70
9	550	104/78
10	544	148/90
11	538	224/120
12	538	108/82
13	532	108/74
14	530	148/86
15	529	120/66
16	519	180/76
17	513	170/86
18	511	136/70

supplement each day and the effect on bodyweight and blood pressure determined as before over a period of 4 weeks.

Five patients from Group 2 with normal or slightly elevated blood pressures on thiazide therapy were later given a mixture of NaCl and KCl (5 g of each) for 2 weeks followed by 5 g of NaCl only for 2 weeks and then the NaCl-KCl mixture again for a two-week period. Blood pressures and bodyweights were determined as before. The results are presented in Table 38 and Figure 22.

Six grams of salt daily in the diet of the 7 hypertensive patients and 3 normal control subjects over a period of 2-9 weeks had no effect on diastolic blood pressure or bodyweight nor did it cause edema. A mixture of 6 g each of NaCl and KCl over a period of 4 weeks was likewise without effect on blood pressure or bodyweight in these same patients. Five g of NaCl given daily to 8 hypertensive patients over a period of 4 weeks did not nullify the anti-hypertensive effect of hydrochlorothiazide therapy.

Table 38

Maximal Change in Early Morning Lying Diastolic Blood Pressure Values with Added NaCl and with Added NaCl-KCl Mixture (1273)

Patient	Change in diastolic blood pressure	
	With 6 g NaCl	With 6 g each NaCl and KCl
	mm Hg	mm Hg
ON	+8	−1
CM	−9	+6
McL	−3	+5
HH	−11	−8
VB	+4	+1
TB	−1	+1
WS	−4	+3
BS	−8	−5
JK	0	0
McG	+2	+6
Mean	−2.2	+0.8

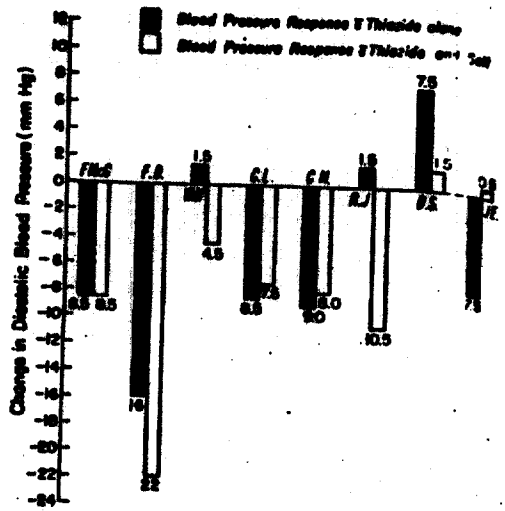


Figure 22 (1273)

Change from mean control value of the early morning lying diastolic blood pressure after 4 weeks on hydrochlorothiazide (solid bars) and after an additional 4 weeks on hydrochlorothiazide plus 5 g added sodium chloride (open bars).

32. O'Hare et al. (2407) studied the effect of alternate low (0.5 g/day) and high (4.0 g/day) NaCl intakes on the systolic and diastolic blood pressures and serum chloride levels of 18 hypertension patients, kept at bed rest, over periods of 4 to 46 days. Fourteen of the 18 patients showed decreases in the average systolic pressure of 1 to 40 mm Hg when salt was restricted (0.5 g/day); four patients had elevations of 3 to 4 mm Hg. The authors concluded that these data indicated that salt plays little part in vascular hypertension.

33. Ashe et al. (0143) stated that analysis of data on 1,000 New York City residents who came in for a "check up" revealed the following concerning diet, salt, and hypertension:

a. Salt intake of 563 normal individuals and 437 hypertensives was approximately the same. 94% of both groups ate from 4 to 8+ g per day. Excessive salt intake (> 8 g/day) was actually higher in the normal group (57%) than in the hypertension group (42-50%). (See Tables 39, 40, and 41.)

b. Most of the individuals studied had a low protein (42 g or less) ration, moderately high salt intake (4-8+ g), and moderate fluid consumption (1,000 ml or more) per day.

c. Normal individuals on low protein diets tended to have a low blood pressure and a low Hb percentage but there was no evidence that high protein diets produced high blood pressure.

d. Hypertensive subjects do not habitually eat more protein or salt than normotensive individuals.

e. There was no evidence that a low protein diet would reduce blood pressure in a hypertensive subject.

Table 39

Salt Eaten by Group A: 563 Normal Individuals (0143)

	Cases	Percent
Less than 4 gm.	27	5
4 to 8 gm.	211	27
Over 8 gm	325	57

Table 40

Salt Eaten by Group B: 298 Individuals Who Were Found to Have Hypertension Which They Did Not Suspect (0143)

	Cases	Percent
Less than 4 gm.	15	5
4 to 8 gm.	133	44
Over 8 gm.	150	50

Table 41

Salt Eaten by Group C: 139 Subjects Who Were Found to Have Hypertension and Blood Urea Nitrogen of from 20 to 40 Mg. (0143)

	Cases	Percent
Less than 4 gm.	8	6
4 to 8 gm.	72	52
Over 8 gm.	50	42

34. In a study of factors affecting blood pressure in a group of 1,575 Negro villagers of St. Kitts, West Indies, aged 20 to 29 years, Schneckloth et al. (2927) found that the intake of sodium and output in the urine showed no definite association with arterial pressure. These results are in agreement with the author's conclusion that salt intake is not a determinant in the high prevalence of hypertension in North American Negroes.

35. Miall (2190) in a follow-up study of arterial pressure in the population of a Welsh mining village found that the women in the high salt intake group actually had lower blood pressures and smaller pulse pressures than those of the low salt intake set. Differences between the men of the two groups were not significant. (See Figure 23).

36. Dawber and Paul (0739) also failed to find a significant relationship between salt and blood pressure.

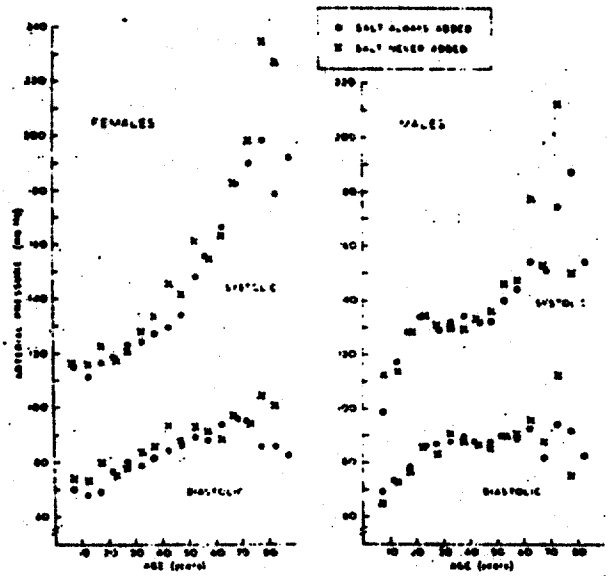


Figure 23 (2190)
Mean systolic and diastolic pressures by age and salt habits in the 1958 survey.

37. Berger et al. (0264) studied the effect of salt withdrawal and salt loading in 13 essential hypertension patients, 3 men and 8 women, 31 to 57 years of age, in a carefully-controlled hospital study over an average period of 44 days (range 20-81 days). Very low salt intakes (< 1.0 g per day) as well as salt loading (5, 10, 15, 20, 25, or 30 g/day) failed to produce

any unequivocal modification of the blood pressure curve definitely attributable to sodium chloride, according to the authors.

38. Perera et al. (2545) investigated the effect of rigid salt restriction and increased salt intake on resting and casual blood pressures in six patients with uncomplicated hypertensive vascular disease. Weekly electrocardiograms and a number of clinical chemical determinations were made also (see original article for details).

Rigid restriction of sodium chloride in the diet over a period of 2 weeks resulted in a slight decrease in the resting blood pressure of the six subjects, but apparently did not influence the casual (normal daily activity) readings (Figure 24 and Table 42).

Addition of sodium chloride to the salt-poor basal diet at levels of 4 g or 15 g per day over an 8-day period caused a rise in the resting blood pressure of 5 of 6 hypertensive patients, but was without effect on the casual readings (Figure 24 and Table 43). Resting blood pressure was increased by salt feeding (4 g daily) in 5 hypertensive patients treated with desoxycorticosterone acetate (5 mg twice daily). Rigid salt restriction eliminated the pressor response (Figure 25).

The authors were of the opinion that the small decreases in resting blood pressure observed in their hypertensive patients following rigid sodium chloride withdrawal were not of therapeutic significance. They suggested that vasoconstrictive factors, at least in part neurogenic, in hypertensive patients are independent of the influence of salt.

39. Swaye et al. (3224) analyzed a large number of patients in an investigation of the relationship between dietary salt intake, genetic factors (family history), and hypertension. Of the 1,536 patients in the study, 717 had essential hypertension and 819 were normotensive. The results are summarized in Tables 44, 45, 46, 47 and 48.

In the normotensive group, 174 (21.2%) added salt to food before tasting it (Group B) while 163 (22.7%) of the hypertensive patients had this habit. In the entire group, including both normotensive and hypertensive persons (Table 48), a significantly greater percentage of hypertensive patients had a family history of high blood pressure than did normotensives ($P<0.0005$ to $P<0.005$). Moreover, this difference was independent of salt intake (Table 48). In the hypertensive group, women who added salt before tasting (Group B) had higher diastolic pressures and a high incidence of retinopathy than those who did not salt before tasting (Group A). (Tables 49 and 45). Hypertensive men who

Table 42

Clinical and Laboratory Data of 6 Hypertensive Patients Before and After Rigid Sodium Chloride Restriction (2545)

Case	Mean "resting" B.P.		Mean "casual" B.P.		B.P. response to cold pressor test		Before and after 2 weeks of rigid NaCl restriction								
							Urine*		Serum						
	week before	2nd week of	week before	2nd week of	before	after	Sodium	Chloride	CO_2 content	Chloride	Sodium	Potassium	Proteins	Urea nitrogen	Volume
	NaCl restriction						m.eq. per 24 hrs.	m.eq. per 24 hrs. as NaCl	m.eq. per liter	m.eq. per liter	m.eq. per liter	m.eq. per liter	grams per 100 cc.	mgm. per 100 cc.	cc.
1	164/106	148/92	182/114	180/112	196/116	200/120	86– 9	88–11	26.4–29.6	104.1–103.1	139.1–140.5	4.3–4.2	6.4–6.6	13–16	2460–2420
2	168/110	152/96	178/116	180/116	194/122	190/120	82–13	94–14	29.0–28.6	102.4–100.3	138.4–139.3	4.2–4.0	6.1–7.0	8–14	2710–2680
3	182/104	160/92	—	—	—	—	68–13	90–16	27.7–24.2	104.6–104.1	142.5–135.7	4.4–5.4	6.7–6.9	7– 9	
4	160/98	140/90	174/104	170/100	182/110	188/112	69– 8	64–20	33.5–30.1	97.5– 99.0	140.1–139.8	4.4–4.8	6.7–6.8	12–14	2360–2280
5	162/110	146/100	176/120	172/118	—	—	68– 9	70–14	27.9–29.7	100.4– 98.1	138.5–138.5	4.5–4.5	7.3–7.2	14–18	
6	182/116	168/108	204/110	208/114	216/120	206/118	66–14	76–15	27.3–28.5	100.8– 99.2	137.5–137.7	4.4–4.4	7.2–7.4	11–10	2000–2000

* Mean values for each period.

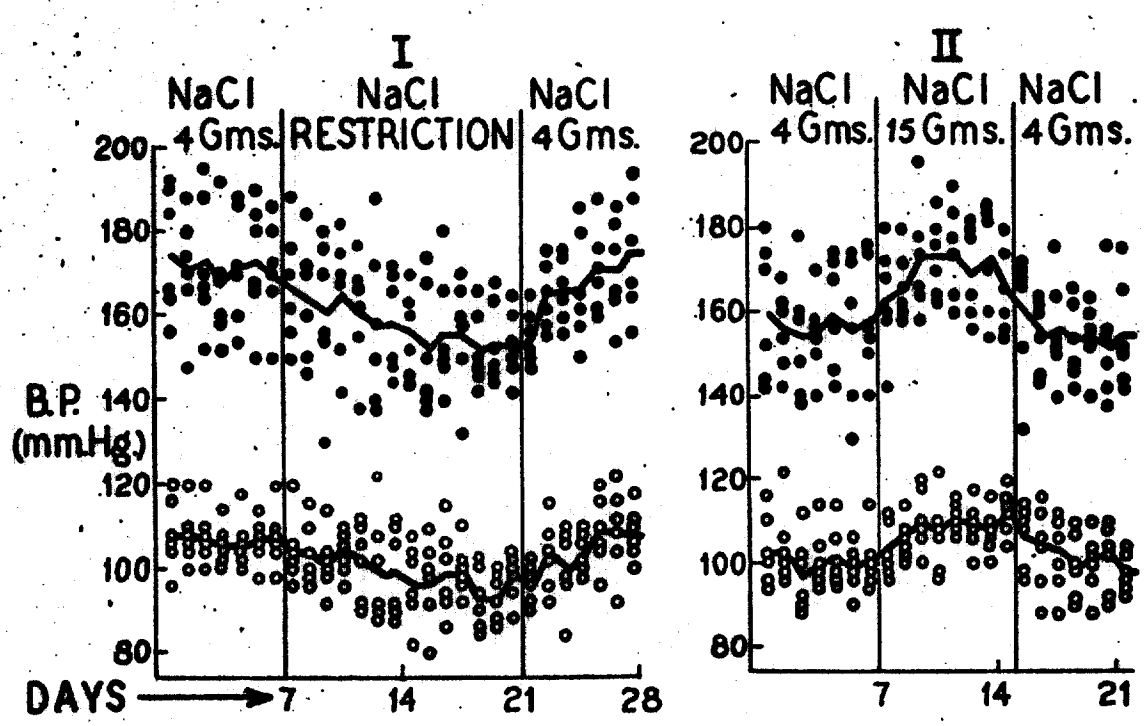


Figure 24 (2545)
Effect of Rigid Sodium Chloride Restriction and of Increased Sodium Chloride Intake on 6 Patients with Hypertension.

Table 43

Clinical and Laboratory Data of 6 Hypertensive Patients Before and After Increased Sodium Chloride Intake (2545)

Case	Mean "resting" B.P.		Mean "casual" B.P.		B.P. response to cold pressor test		Before and after 8 days of increased NaCl intake								
							Urine*		Serum						
	week before	8 days of	week before	8 days of	before	after	Sodium	Chloride	CO_2 content	Chloride	Sodium	Potassium	Proteins	Urea nitrogen	Volume
	Increased NaCl intake						m.eq. per 24 hrs.	m.eq. per 24 hrs. as NaCl	m.eq. per liter	m.eq. per liter	m.eq. per liter	m.eq. per liter	grams per 100 cc.	mgm. per 100 cc.	cc.
1	140/96	158/108	160/110	160/112	178/120	174/118	57–190	74–176	31.4–32.8	99.4– 99.0	140.0–140.8	4.4–4.2	6.4–6.4	13–11	2440–2500
2	166/100	180/112	210/120	206/120	220/120	220/120	72–204	80–200	27.4–28.0	100.4– 99.6	138.4–138.4	4.9–4.6	6.0–5.9	18–18	2620–2580
3	162/112	164/116	176/122	174/120	—	—	66–210	74–210	26.3–27.0	101.9–101.9	138.1–138.9	4.6–4.9	7.0–7.2	14–17	
4	146/92	160/102	162/104	162/100	180/118	182/118		90–216							2480–2520
5	162/102	178/110	186/114	188/114	196/118	200/120	86–204	68–178	29.9–30.4	104.4–103.3	140.9–138.0	4.9–4.9	6.2–6.0	14–16	2840–2920
6	172/102	184/110	196/116	194/118	—	—	65–186	74–230	24.4–26.1	106.3–108.0	140.7–140.0	5.2–4.7	6.1–6.0	9–13	

* Mean values for each period.

Table 44

Dietary Salt Habits of Normotensive and Hypertensive Patients (3224)

Dietary Salt Group	Normotensive				Hypertensive			
	no. of Men	no. of Women	Total	%	no. of Men	no. of Women	Total	%
Group A (salt not added before tasting)	297	348	645	78.8	229	325	554	77.3
Group B (salt added before tasting)	135	39	174	21.2	120	43	163	22.7
Total	432	387	819	100.0	349	368	717	100.0

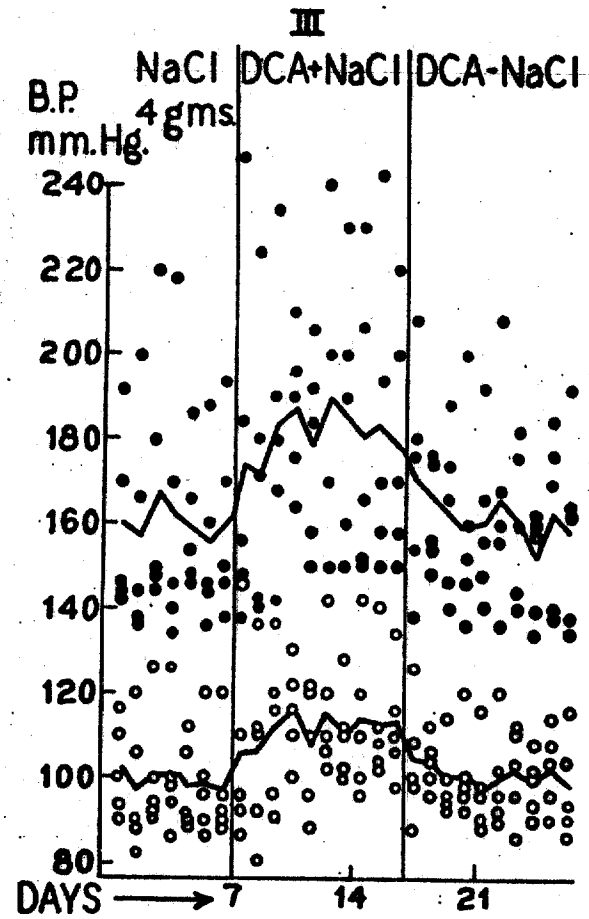


Figure 25 (2545)

Effect of Rigid Sodium Chloride Restriction on Pressor Action of DCA in 5 Hypertensive Subjects.

Table 45

Relation Between Dietary Salt Habits and Diastolic Blood Pressure in Patients with Essential Hypertension (3224)

Dietary Salt Group	no. of Patients	Patients with Diastolic Blood Pressure > 120 mm. Hg.	
		no.	%
Group A	554		
Women	325	56	17.2*
Men	229	52	22.7
Group B	163		
Women	43	17	39.5*
Men	120	32	26.6

* Difference is statistically significant (P <0.0006).

Table 46

Relation Between Dietary Salt Habits and Either or Both the Presence of Cardiomegaly and Electrocardiographic Changes of Left Ventricular Hypertrophy in Patients with Essential Hypertention. (3224)

Dietary Salt Group	no. of Patients	Patients with Cardiomegaly and/or ECG Changes of LVH	
		no.	%
Group A	554		
Women	325	71	21.8
Men	229	51	22.3*
Group B	163		
Women	43	11	25.6
Men	120	47	39.2*

* Difference is statistically significant (P <0.0008).

ECG = electrocardiographic; LVH = left ventricular hypertrophy.

Table 47

Relation Between Dietary Salt Habits and Family History of Hypertension in Patients with Essential Hypertension (3224)

Dietary Salt Group	no. of Patients*	Patients with Family History of Hypertension	
		no.	%
Group A	381	231	60.6
Women	219	139	63.5†
Men	162	92	56.8
Group B	117	70	59.8
Women	32	26	81.3†
Men	85	44	51.8

* Patients for whom adequate information on family history was recorded.

† Difference is statistically significant (P <0.05).

b. The efficacy of Kemper's rice and fruit diet in lowering blood pressure is due to its low sodium content.

c. All diuretics act as hypotensive agents and the common denominator in all cases is natriuresis.

d. A number of population studies indicate a direct relationship between salt intake and hypertension.

e. Salt causes hypertension in genetically-predisposed rats.

The main arguments against the role of salt in arterial hypertension, according to the author are:

a. The effect of salt on blood pressure in man seems to vary from one individual to another. It is possible for many individuals to eat large quantities of salt, remain normotensive, and live to a ripe old age.

b. There is considerable variation between blood pressure and urinary sodium levels (indication of salt intake) within a population.

c. It is possible to induce chronic hypertension in rats by giving them water containing 5 mg/liter of cadmium. Three out of four human autopsy surveys have shown that there is more cadmium in the kidneys of hypertensives than normotensives.

d. Stress can cause elevation of blood pressure, according to experimental results.

e. There is an inverse relationship between water hardness and cardiovascular deaths (including those due to hypertension).

Salt in Infant Foods

There is some difference of opinion amongst the experts today concerning the safety of added salt to infant foods. The following studies are representative of opinions on both sides of the controversy.

A. Rats

Dahl *et al*. (0704) produced hypertension (100%) and death (50%) in rats by feeding commercial baby foods consisting of processed meats and vegetables purchased on the open market. Twenty-five weanling rats (14 males and 11 females) of a hypertension-prone strain (other specifications not given) were placed on the commercial baby food for a period of 8 months. A control group

of litter-mates (7 males and 8 females) were placed on chow pellets containing 0.4% NaCl. (The baby foods contained 150-500 mg % as sodium). Both groups of animals were given their respective diets and tap water ad libitum. Blood pressures were measured at 2-4 week intervals and the animals were observed throughout for toxic signs.

The experiment was terminated at the end of 8 months because all of the rats on the processed baby food diet had developed hypertension (180-190 mm Hg) and about half were dead! All control animals were alive and well with normal blood pressures of 141.4 mm Hg on the average.

The author pointed out that the NaCl requirement of the normal infant is met by milk, making addition of salt to meats, vegetables, or cereals unnecessary. In spite of this, however, salt is added to practically all processed infant foods and it is difficult to obtain a low sodium diet even on prescription. He warned that the added salt in present baby foods may initiate hypertension in infancy or later in life in genetically predisposed individuals.

B. Humans

1. McCance et al. (2117) demonstrated the marked effect of added salt on water balance in the premature infant. Addition of sodium chloride to a level of 0.7% in the formula caused the babies to become edematous and sick in a very short time. Putting them back on a normal diet and water intake corrected the condition. The authors pointed out that a very small amount of added salt in the formula of the newborn can cause the ingestion of more salt per unit of body weight than an adult would normally take because of the large fluid intake of babies. The authors stated that the kidney of some newborn animals is so immature that it can keep the proportion of water, sodium, and potassium, within normal limits only if its requirements are met by a perfect diet, and growth is unrestricted.

2. Dean et al. (0746) obtained additional evidence of the dangers of high salt in infancy in a study on the response of newborns to hypertonic solutions of sodium chloride and urea. Newborn infants with inoperable meningo-myeloceles and healthy adults as controls, were given sufficient NaCl to raise the serum level to 147 mEq/liter in the infants and 135 mEq/liter in the adults (Both groups were deprived of water for 12 hours before administration of salt).

Salt loading caused a diuresis in both infants and adults. The rate of sodium chloride excretion per unit of body surface, however, was 8 times

greater in adults than in infants. The results are in accord with previously established facts that the glomerular filtration rate of infants and their clearance of sodium chloride are considerably less than those of adults.

3. Stanincova et al. (3152) investivated the relationship between excess sodium intake and salt fever in babies as part of a long-term general study of sodium metabolism in infant nutrition. Twenty full-term healthy breast-fed infants weighing 3748 ± 690 g and 15 babies (4004 ± 557 g) fed dried buttermilk were employed in the study. The age range in both groups was 15 to 42 days. On the first day of the experiment, both groups were given an added 80 mg of NaCl per 100 g of milk. Rectal temperature was then measured twice daily before each feeding and salt administration was stopped immediately when the temperature reached 38.5°C. After administration of a suitable amount of tea, the temperature invariably dropped within a few hours. The data were evaluated statistically with the student "t" test (see Figure 26).

Typical salt fever with an average maximum temperature of 38.4 ± 0.6°C developed within 42 days in the infants fed buttermilk with added salt but not in the breast-fed group ($P < 0.003$) (see Figure 26). The authors pointed out that the osmo regulatory function of the infant kidney is not yet fully developed and consequently babies are incapable of maintaining water and salt homeostasis adequately so ingestion of excess salt leads to salt fever and other effects.

All artificial baby foods, including cow's milk, contain more sodium than the infant requires. The authors called attention to the fact that babies on a diet of whole dried cow's milk ingest relatively more sodium than the average adult; if a salted commercial vegetable soup is added to the diet, the infant is called upon to deal with the highest level of ingested Na per kg BW that he will ever face in his entire life.

4. Puyau et al. (2632) estimated the daily sodium intake of 103 well infants, 1 to 14 months of age, at the Vanderbilt University Hospital Well Baby Clinic. At one month, the mean sodium intake was 4.6 mEq/kg/day. At one year of age, it had risen to 6.3 mEq/kg/day. The "normal" requirement for a rapidly growing infant would be 2.3 mEq/day. The higher sodium intakes found in the survey were near levels which produce hypertension in experimental animals. Most of the sodium overload came from commercially processed meat, eggs, and vegetables.

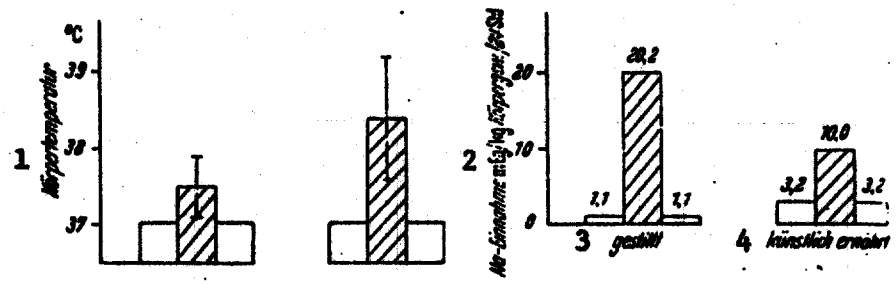


*Figure 26 (3152)

Relationship between body temperature and Na ingestion in a group of 20 breast-fed and 15 artificially fed infants aged 15-42 days. Individual columns: Days of observation, white columns; normal NaCl uptake, striated columns; increased NaCl uptake. Key: 1. Body temperature. 2. Na uptake/kg bodyweight/24 hours. 3. Breast-fed. 4. Artificially fed.

*Abb. 2 of article

5. The Subcommittee on Safety and Suitability of MSG and Other Substances in Baby Foods, Food Protection Committee, Food and Nutrition Board, National Research Council, National Adademy of Sciences (1017) stated that they found no evidence that the current load of sodium chloride in baby foods is either harmful or beneficial to the healthy infant (1017). The premises that the added salt contributes to the development of hypertension or other diseases in adulthood, or that present salt intake by infants overburden excretory mechanisms, are without valid scientific evidence, according to the subcommittee (1017). They stated further, however, that there is no valid evidence that the practice is not harmful (1017). In clarification of the problem, the subcommittee states:

a. The infant can ordinarily excrete an acute sodium load up to 250 mEq/m^2/day, if sufficient water is available (1017).

b. The highest sodium intakes, according to recent surveys, range between 50 and 60 mEq/day, representing an acute sodium load of 175 mEq/m^2/day (1017). Almost any modern combination of milk and infant food, therefore, could be tolerated from the standpoint of the sodium load. The authors pointed out, however, that diets such as these may contain large loads of solutes other than sodium which must be excreted by the kidneys (1017).

In further consideration of the problem, the subcommittee stated that one must be concerned with the capacity of the infant to excrete the amount of sodium in current diets which contain so much more than the estimated requirement of 2-5 mEq/day (see Tables 50 and 51) (1017). They recommended, therefore, that no more than 0.25% salt be added in the commercial preparation of infant food. This would result in a reduction of sodium intake of 33 to 46% on the basis of present infant foods (see Table 52) (1017).

Table 50

Sodium Content of Some Infant Foods (1017)

Food	Kilocalories/ 100 ml or 100 g (1)	Sodium		
		mg/100 g	mg/100 Kcal	mEq/100 Kcal (approx.)
Cow's Milk	70	58 (2)	83	3.5
Cereal (dry)	308	400 (3)	130	6
Meat	84	250 (3)	300	15
Vegetables	24	250 (3)	1000	44

(1) Calculated from G.H. and E.W. McHenry (Eds.) 1966. Nutrition, Vol. III, Table V. p. 33. Academic Press, New York.

(2) H.J. Heinz Co. 1965. Heinz Handbook of Nutrition, p. 173.

(3) Average data, provided by manufacturers of infant foods.

Table 51

Sodium and Potassium Content of Representative Infant Foods and Formulas (1017)

Type of Food	Sodium	Potassium	Na/K Ratio
	mg/jar		
Juices	5	156	0.03
Fruits	37	109	0.34
Meats	212	184	1.15
Vegetables	290	218	1.33
Desserts	177	101	1.75
Cereals	143	74	1.93
High Meat Dinner	388	152	2.56
Dinners	342	101	3.39
	mg/L		
Breast Milk	150	550	0.27
Cow's Milk	410	1810	0.23
Commercial Formulas reconstituted to 20 cal/oz	253	800	0.32

Table 52

Sodium Content of Representative Infant Foods Salted at Present Levels, Unsalted, and with 0.25 Percent Added Salt (1017)

Variety of Food	Sodium mEq/100 Kcal		
	Salted	Unsalted	0.25% NaCl Added
Mixed Cereal with apples and bananas	6.1	0.3	5.2
Peaches*		0.5	
Applesauce*		0.9	
Bananas	3.1	0.4	1.0
Vegetables and Beef	36.0	10.7	18.9
Carrots	52.5	12.2	44.0
Green Beans	35.8	0.8	1.9
Chicken and Vegetables	12.9	1.6	5.3

Caltulated from Fomon et al. J. Pediat. 76:242, 1970, and data supplied by H.J. Heinz Co.

*Not salted as generally produced

6. Lowe (1966) has calculated that an average adult on a 2800 kcal/day diet would ingest 10.5 g of sodium chloride if he consumed salt at the same rate as do infants on the highest salt intake (6.4 mEq/100 kcal). The author pointed out that this is significantly below the average adult intake of 12 g/day on a mixed diet. Moreover, since the vegetables and fruits first given to infants have relatively large amounts of potassium but practically no sodium, the author believed that foods should be salted. However, Lowe emphasized the fact that the sodium:potassium ratio should be maintained in the range of 0.5 to 1.0. Finally, after reviewing the various arguments regarding the safety of added salt in infant foods, the author reached the conclusion that there is just as much justification for maintaining the status quo as for imposing regulations limiting manufacturing practices (1966). Lowe believes that intra-uterine malnutrition predisposes to hypertension (1966).

7. Dahl (0686) is strongly of the opinion that added salt in baby foods is neither necessary nor beneficial and that it can be harmful. He contended that there is no metabolic need for the high salt levels in present day infant

foods since intakes of 4-8 mEq of sodium suffice for growth requirements during the first year of life. Analyses of 16 different samples of common baby foods indicated that sodium contents exceeded that of the natural unsalted foods by factors of approximately 5-6 for meats, 6-60 for vegetables, and more than 100 for dried cereals.

8. Joossen's review (1600) of the literature on salt and hypertension found much in favor of Dahl's hypothesis (0686) that essential hypertension is first and foremost due to the combined effects of ingested salt and genetic factors. The author suggested that salt should be omitted in food wherever possible. He pointed out that the nutritionally-adequate mother's milk contains only 0.4 g of salt per liter which is 4 times less than cow's milk which is so widely used today in infant nutrition.

9. Guthrie (1296) investigated the sodium content of the diets of 89 urban and rural infants at 3-13 weeks of age (see Table 53). By the 13th week, they were receiving 230 mg or 10 mEq of sodium per day from solid food alone. The median sodium intake from milk in the diet was 300-350 mg. In addition, there was an undetermined amount of sodium in the water used to reconstitute the formulas; estimates are that this could range from 0.4 to 1900 mg/liter.

The author estimated that infants in some areas could be taking in sodium at a level greater than 6.2 mEq/kg/day which was characteristic of the diets of certain hypertensive adults. Since there is considerable evidence that diets high in sodium predispose to hypertension in young animals, the author suggested that manufacturers should be encouraged to reduce the amount of salt added to infant foods.

Table 53

Sodium Intake From Solid Foods by Infants Fed on Solid Foods Beginning at Different Ages (1296)

Age solid food feeding begun, weeks	<3		<5		<7		<9	
Subgroup	U	R	U	R	U	R	U	R
Number of infants	15	20	23	15	7	2	4	1
Age, weeks	Sodium Content of Solid Foods, mg							
3	23	48						
	37							
5	53	99	48	39				
	80		44					
7	113	142	65	106	26	9		
	129		81		22			
9	113	152	93	210	40	20	57	61
	135		139		30		59	
11	144	191	120	255	76	36	101	41
	170		171		67		75	
13	213	251	145	272	120	128	106	32
	235		189		122		72	

U = urban, R = rural.
Underlined values represent average values from total of rural and urban groups.

10. Mayer (2103) pointed out that an intake of sodium of 1 mEq/kg BW is sufficient for the infant from birth to one year and that human breast milk is nutritionally adequate in this respect. In a recent survey on a large group of healthy American babies, 1 to 14 months of age, on cow's milk, the average daily intake of sodium was 4.6 mEq/kg BW with the highest value 8 mEq/kg BW, or 8 times the intake of a breast-fed infant of the same age. (Cow's milk is much higher in sodium (30 mEq/liter) as compared with human milk (7 mEq/liter). The author stated that on the basis of the relationship of salt to hypertension, additional sodium should not be added to the diet by using salted baby foods.

11. Fomon et al. (1009) studied the acceptance of salted as compared to unsalted strained baby foods with 40 infants (both sexes) of the age range 4 to 7 months over a period of 3 to 4 weeks.

Table 54

Sodium Content of Some Salted and Unsalted Strained Baby Foods (1009)

Food	Sodium (mg)/100 grams of Food	
	Salted	Unsalted
Mixed cereal with banana & apples	125	7
Peaches	9	9
Apple sauce	12	12
Bananas	60	7
Vegetables & Beef	440	130
Carrots	194	45
Green Beans	223	5
Chicken with Vegetables	353	45

Consumption of the strained foods offered was not influenced by whether or not salt had been added.

The authors pointed out that since unsalted foods supply more salt than does human breast milk, plus the fact that by 4 months of age most infants are on cow's milk which supplies more than 3 times as much sodium as does human milk, there is no nutritional justification for adding sodium chloride to infant foods.

12. Harrison et al. (1368) in a review of hypernatremia (serum sodium levels of 150 mEq/liter or higher) warned of the danger of high protein and electrolyte intakes in normal infant feeding and prescribed corrective measures.

They pointed out that the feeding of undiluted and unmodified cow's milk to a 2-month-old infant in a hypernatremic state may cause a water deficit.

In addition to the usual causes of hypernatremia (vomiting, diarrhea, profuse sweating, and so forth), the authors pointed out neglect to offer water to the infant as a cause. Lethargy or hyper-irritability, tremors, exaggerated deep tendon reflexes, and muscle rigidity are prominent symptoms of the condition. Rupture of capillaries and venules secondary to reduction of cerebrospinal fluid pressure and subdural effusion may cause severe residual brain damage or death.

13. Bruck (0416) warned that infants have less reserves of body water and electrolytes than adults and that newborn or premature infants, in addition, may lack mechanisms which protect older children and adults from the toxic effects of abnormal loss or administration of electrolytes. During the first week of life particularly, the kidneys are not able to excrete excess water and solutes. The Average Daily Requirements of sodium, potassium, and chloride, for the infant and child, are 12-30, 15-25, and 12-20 mEq per M^2 of body surface area. (see Table 55).

Table 55

Average Daily Requirements of Water and Electrolyte for Maintenance (0416)

INFANT AND CHILD PER M^2 OF BODY SURFACE AREA		NEWBORN INFANT, 3 KG. ABSOLUTE VOLUME	
Water	1500 ml.	Age	ml.
Sodium	12-30 mEq.	2 days	100
Potassium	15-25 mEq.	3 days	180
Chloride	12-20 mEq.	4 days	240
Glucose	100-150 gm.	5 days	300
		10 days	400

14. Droese et al. (0841) surveyed commercial infant foods in West Germany for salt content and found that pre-cooked and other cereals contained 4 to 740 mg Na/100 g as compared to 1 to 5 mg/100 g in the original cereal. Strained vegetables contained 100 to 250 mg Na/100 g which is 2 to 5 times that of unprocessed vegetables. The sodium content of strained fruits was 2 to 40 mg Na/100 g or up to 10-fold that of the original fruits. The authors estimated that the sodium intake may double by 2 months and triple by 6 months if commercial infant foods are fed. They suggested that sodium salts should not be added to infant food.

15. Denton (0100) of Australia in a review article stated that the salt content of many commercial infant food mixtures was as high as concentrations ingested by adults in northern Japan where the incidence of hypertension is probably higher than in any other part of the world. The recommendation was made that manufacturers lower the salt content in their infant foods.

16. Blair-West et al. (0283) believe that manufacturers should be persuaded to stop the practice of highly salting infant foods since the infant's daily sodium requirement is only 4 to 8 mEq/day (1-2 mEq/kg).

III. Long-term Studies

A. Mice

Blount et al. (0295) determined the effect of genetic differences and aging on salt toxicity in mice. Approximately 1700 animals were employed in the feeding experiment which extended over a period of 18 months. Groups of resistant (IHB) and susceptible (NH) mice were placed on 4% sodium chloride in the drinking water in parallel with control groups of each strain given distilled water to drink. All four groups were fed a standard pellet diet. The animals were weighed at intervals and observed throughout for toxic signs and mortalities.

The data presented in Tables 56, 57, and 58 show the marked effects of genetic factors and aging on salt toxicity. Significant numbers of the resistant strain survived for more than a year on 4% NaCl in the drinking water whereas all members of the susceptible group were dead within 3 months. Mice started on salt at a very young age (< 30 days) were very susceptible to salt toxicity, often dying in less than 10 days; beyond that age, however, older animals of both strains were more susceptible than the younger animals.

B. Rats

1. Dahl (0687) investigated the effect of chronic excess salt feeding on plasma lipids in rats and dogs in a study prompted by possible interrelationships between salt, hypertension, and atherosclerosis. Ninety-three Sprague-Dawley female rats were divided into three groups fed a basal diet of Ralston Purina fox chow pellets and sodium chloride at levels of 0.51 - 0.74% (controls), 8%, or 11.6%.

Blood pressure measurements were made at monthly intervals. Cholesterol and blood urea nitrogen (BUN) were determined on blood samples from the tail vein at various intervals during the experimental period. The major results

Table 56

Comparison of the Survival of the Two Strains of Mice (0295)

Placed on 4% NaCl between 22 and 40 days of age

Number of Animals — Resistant Strain (HHB)—160; Susceptible Strain (NH)— 50

Days on Salt	Survival in % HHB	Survival in % NH	Days on Salt	Survival in % HHB	Survival in % NH
5	99	80	210	61	0
10	95	38	240	53	0
15	93	34	270	46	0
20	93	18	300	35	0
25	93	14	330	28	0
30	91	12	360	18	0
40	89	8	390	9	0
50	89	6	420	7	0
60	87	6	450	1	0
90	84	0	480	1	0
120	75	0	510	1	0
150	70	0	540	0	0
180	66	0	570	0	0

Table 57

Age and Susceptibility of the Resistant Strain (0295)

Days Age at Start	21–30	31–60	61–90	91–180	181–270	271–360	361–450	451–540	541–630	631–[illegible]
Number Started (1154)	90	345	81	156	147	183	101	45	2	2
Days after Start	Number Surviving									
10	59	341	67	126	82	102	36	16	0	0
20	52	321	50	54	25	24	5	1		
30	51	296	41	37	17	11	3	1		
60	49	281	38	28	12	2	3	0		
90	47	253	35	16	10	1	0			
120	44	240	34	14	8	0				
150	39	205	34	12	6					
180	38	176	30	5	6					
210	37	156	24	2	5					
240	31	138	23	2	2					
270	29	121	18	1	1					
300	29	85	10	1	0					
330	26	58	7	1						
360	17	37	5	0						
390	11	16	4							
420	8	7	4							
450	2	2	0							
480	1	1								
510	1	0								
540	0									
Median Survival Time	240	225	195	135	105	25	20	15		

Control Median Survival Time on H_2O 547 Days

Table 58

Age and Susceptibility of the Susceptible Strain (0295)

Rats Age at Start	27–40	41–50	51–60	61–70	71–80	81–90	91–120	121–150	151–210	211–270
Number Started (299)	43	45	34	37	35	31	31	20	15	8
Days after Start					Number Surviving					
10	17	26	22	25	24	19	21	11	6	3
20	9	15	10	11	10	1	1	1	0	0
30	6	11	9	6	7	1	1	1		
40	4	4	6	0	4	1	0	0		
50	3	0	1	.	1	0				
60	3	.	0	.	1					
70	1	.	.	.	0					
80	0									
Median Survival Time	35	20	25	15	30	20	15	15	6	3

Control—Median Survival Time on distilled H_2O—118 Days

are presented in Figures 27 and 28. The data obtained indicated that excess salt feeding (8.0 and 11.6%) increased the blood pressure and plasma cholesterol levels over a period of 6 months to a year. The possible relationship of this phenomenon to atherogenesis is discussed by the author.

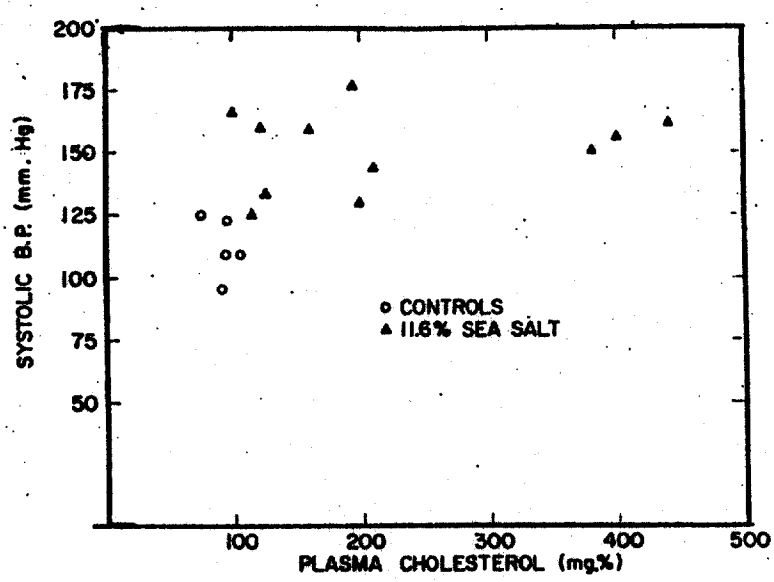


Figure 27 (0687)

Effect of chronic salt feeding on blood pressure and plasma cholesterol levels in female rats. Results after 15 1/2 months.

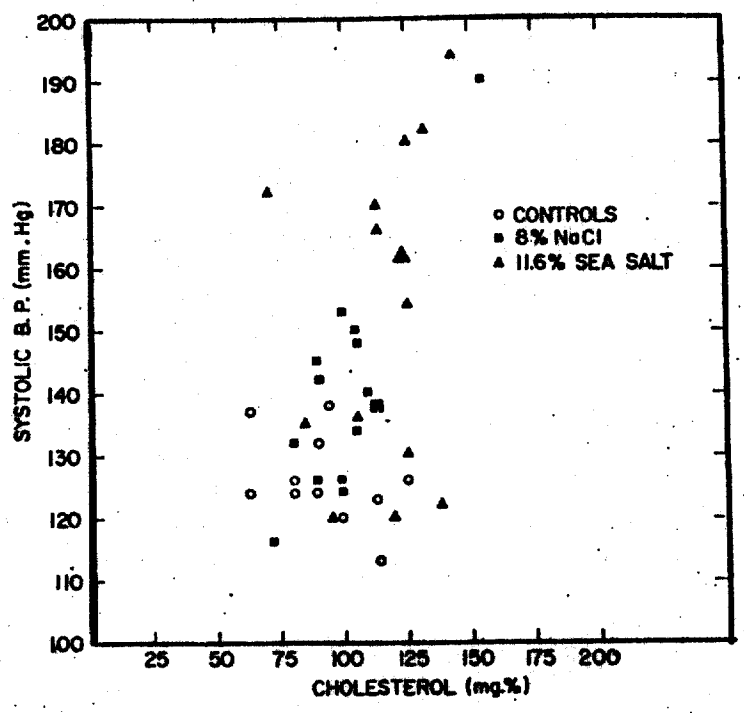


Figure 28 (0687)

Effect of chronic salt feeding on blood pressure and plasma cholesterol levels in female rats. Results after 6 1/2 months.

2. Meneely et al. (2163, 2164) studied the effect of sodium chloride on rats when administered at various levels in the diet over a period of 14 months. Male Sprague-Dawley albino rats, 33-40 days old, and weighing 86-154 g, 30-31 per group, were placed on a purified diet containing NaCl at a level of 0.01, 0.15 (control), 2.8, 5.6, 7.0, 8.4, or 9.8%, and demineralized water ad libitum. The animals were observed daily for symptoms of toxicity and weighed weekly for growth rate calculations. Food and water consumption were determined at regular intervals. Systolic blood pressure measurements were made by the cuff method. Fatalities and sacrificed animals were examined histologically. The data are presented in Figures 29 and 30 (2164).

Massive edema and renal failure occurred in 18% of the animals on diets containing 7.0 to 9.8% NaCl. Lipemia, anemia, hypoproteinemia, and azotemia were other aspects of the syndrome. Severe damage was found in all parts of the kidney at autopsy. The authors pointed out the similarity of this condition to nephrosis in man.

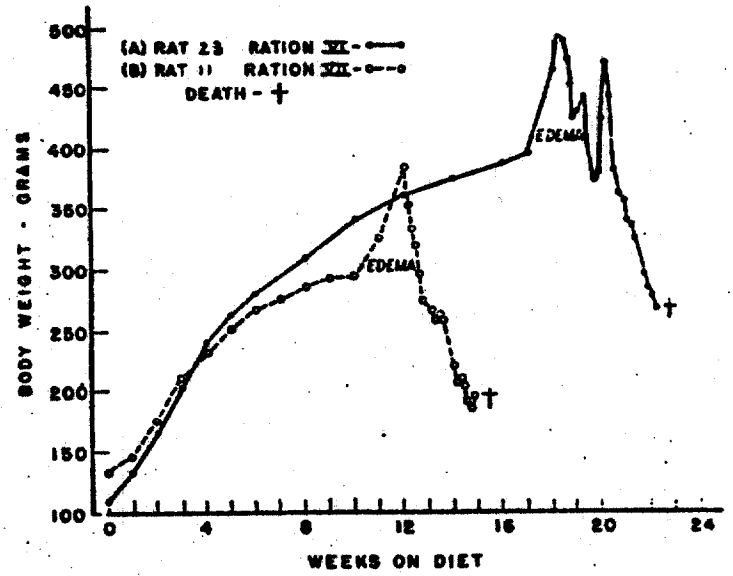


Figure 29 (2164)

Growth curves for two rats which developed massive edema.
A. Solid line. Rat 23 on ration VI (8.4 percent NaCl).
B. Broken line. Rat 11 on ration VII (9.8 percent NaCl).
† Death.

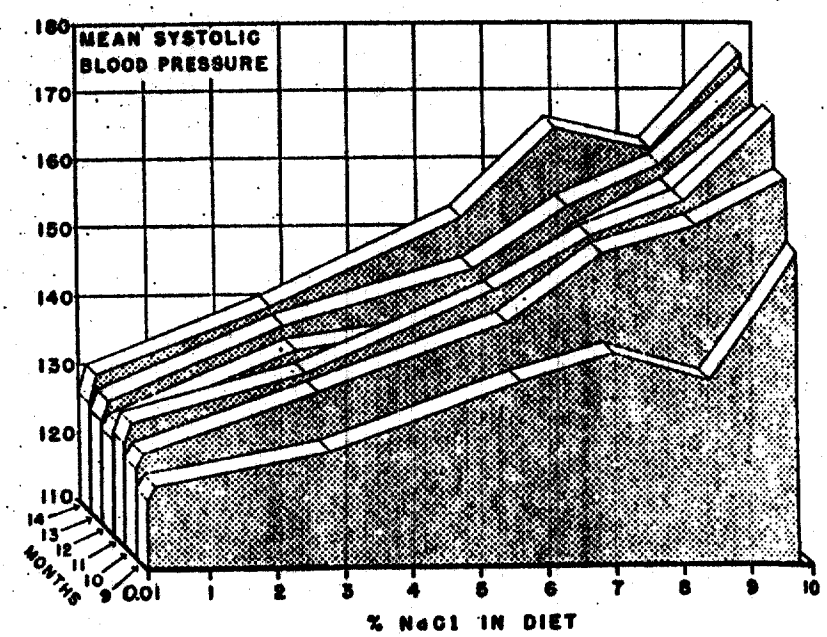


Figure 30 (2164)

The oblique lines represent the means of the systolic blood pressures of the seven different groups at monthly intervals.

A sustained arterial hypertension was the second major toxic effect noted. All rats on rations with levels of 7.0 - 9.8% NaCl, and most animals on the 2.8 - 5.6% diets, had significant elevations of the blood pressure. The authors stated that a positive, linear correlation (r=0.91) was found between systolic blood pressure and the concentration of sodium chloride in the diet.

3. Koletsky (1743) placed 25 young adult male, white rats weighing about 180 g on a diet of pellets and 1% sodium chloride solution for drinking over a period of 16-17 months in a study of hypertension, vascular disease, and salt. A group of 28 control rats maintained on pellets and tap water was included. The following observations and determinations were made: blood pressure measurements at weekly intervals, and fluid intake, urinary output, blood urea nitrogen, and quantitative albuminuria determinations at various intervals. All animals were autopsied and the organs examined microscopically.

Seventy-two percent of the rats on 1% salt became hypertensive (170-190 mm Hg) and 68% had vascular disease, with lesions of the polyarteris type, often severe. Kidney damage was present in 16 of the 25 animals given salt. A progressive glomerulitis, severe in 7 animals, moderate in 5, and slight in 4 others, was found. Four of the animals with hypertensive vascular disease showed myocardial lesions. Control animals remained normotensive throughout the course of the experiment and exhibited no pathologic changes attributable to the effect of salt.

4. Ball and Meneely (0197) studied the chronic toxicity of sodium chloride in rats from 5 weeks of age throughout life at ten different levels of added dietary salt in a series of seven experiments with results that the authors pointed out were remarkably reproducible.

Five hundred and forty-six male and 21 female Sprague-Dawley rats, five weeks old at the beginning of the experiment, were fed purified diets containing from 0.15% to 21% sodium chloride (the basic diet had approximately 0.01% NaCl). The animals were weighed and examined weekly. Systolic blood pressures were determined at monthly intervals. Serum cholesterol was determined on young (< 10 months), middle-aged (19-21 months), and old (23+ months) rats. Electrocardiograms were taken on all surviving animals after 19 months. All animals were autopsied. Total body sodium and sodium space (using radioactive sodium) were determined on selected male rats at 4 and 8-10 months. The results are presented in Figures 31 and 32 and Table 59.

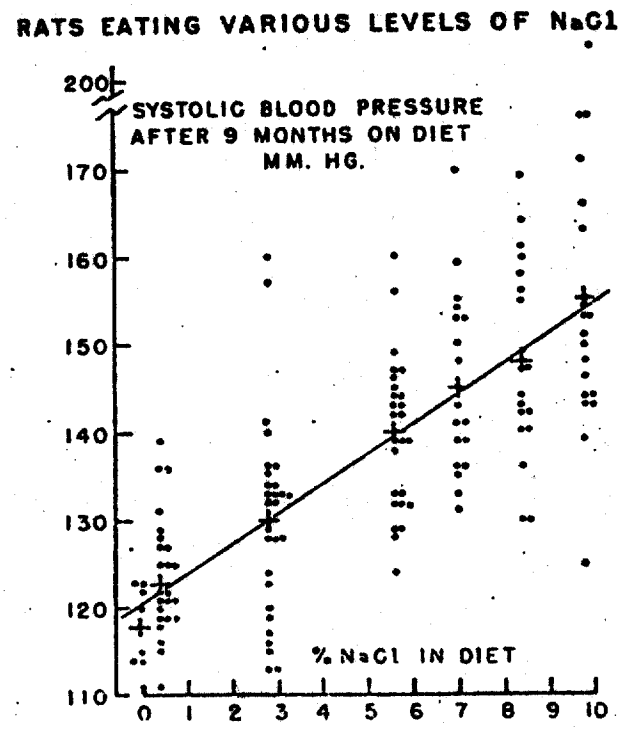


Figure 31 (0197)

Hypertensive action of dietary sodium chloride in male rats.

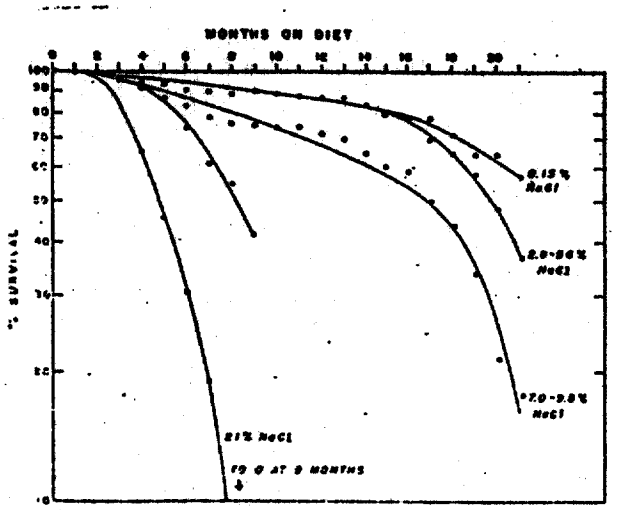


Figure 32 (0197)

Survival curves at twenty-one months, Experiment 1, and at nine months, Experiment 2.

Table 59

Hypertensive Action of Dietary Sodium Chloride on Female Rats After Ten Months Experiment (0197)

Ration	Sodium Chloride	Systolic Blood Pressure Mean	S. D.*
Purified control	0.15 %	124.2	2.1
Purified	5.6 %	139.3	0.4
Purified	9.8 %	149.8	1.3
Commercial	5.6 %	140.1	1.2

* Standard deviation.

In general, high sodium chloride diets resulted in a shortened life span and an increased incidence of hypertension, kidney and heart failure, edema and abnormal lipid metabolism - changes which are characteristic of hypertensive cardiovascular renal disease in man (0197). Concerning life span, the authors drew attention to the fact that animals on 2.8 to 5.6% salt diets (levels comparable to human consumption) did not show excessive mortality rates until after the 17th month (early fifties in man), although blood pressure measurements indicated development of hypertension in the third or fourth decade of life. Additional experiments indicated that increased NaCl intakes by young rats caused more serious after-effects than in older animals and that KCl had a remarkably protective effect against NaCl toxicity.

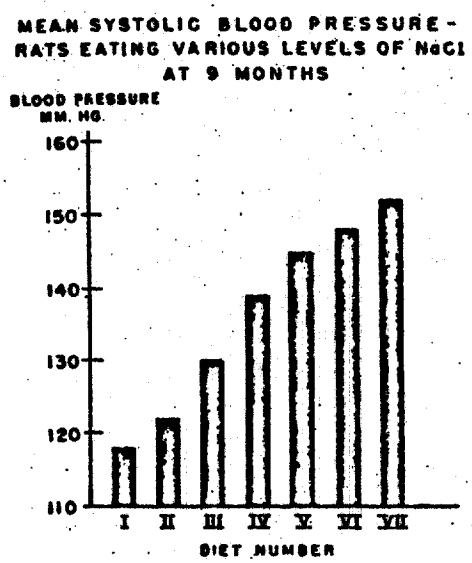
5. Meneely et al. (2159, 2165) recently summarized results of their long-term chronic salt toxicity studies in rats. Three levels of NaCl were used for the most part in these studies: control diet (0.15 - 2.0% NaCl) which would compare roughly to a daily intake of 0.75 to 10 g for man; the "moderate" excess range, (2.8 - 5.6%) would compare to a 14 to 28 g per day human intake; the "high" excess salt level (7.0 - 9.8%), equivalent to 35 to 49 g daily for man, which obtains only in a few parts of the world, notably in northern Japan.

The most significant adverse effect of salt noted was the increased mortality rate with excess sodium. Differences in this respect were not apparent, however, until the 17th month of life (approximately age 51 in man), but then they became very marked. For example, rats on an 8.4% NaCl diet died

8 months earlier, on the average, than the controls; the authors pointed out that this would correspond to a span of approximately 32 years in man.

Hypertension, essentially proportional to the sodium chloride content of the diet, was established by the ninth month in rats eating above the control levels of salt (see Figure 33) (2165). A very considerable scatter of individual values was observed, however, indicating substantial individual differences in susceptibility to hypertension. Pathologic lesions in the kidneys involving especially the arterioles and small arteries were noted. At high levels of salt feeding these lesions were similar to those observed in malignant hypertension in man. The weight of the kidneys and heart increased also in proportion to dietary salt and blood pressure. Increased serum cholesterol values were associated with increases in dietary sodium chloride and a strong positive correlation between the former and blood pressure level was noted. Massive edema developed in approximately 20% of the rats on the highest salt ration (7.0 - 9.8%).

Amongst the hypertensive animals, definite abnormalities of the electrocardiogram were observed which were quite similar to those seen in human hypertension patients - a high incidence of t wave abnormalities, s-t segment abnormalities, left axis deviation, left ventricular strain pattern, and prolonged duration of the QRS complex. The growth rate also was reduced by excess sodium chloride. Potassium chloride added to the diet protected rats against the toxic effects of chronic excess sodium chloride ingestion, increasing the life span by as much as 7 to 8 months; hypertension, however, was reduced only at the higher NaCl levels.



Mean systolic blood pressure at nine months.

I	- 0.01% NaCl
II	- 0.15% NaCl
III	- 2.8% NaCl
IV	- 5.6% NaCl
V	- 7.0% NaCl
VI	- 8.4% NaCl
VII	- 9.8% NaCl

Figure 33 (2165)

6. Dahl et al. (0699) demonstrated the role of heredity in salt-induced hypertension in rats when they developed two strains of Sprague-Dawley rats by selective in-breeding which differed genetically in susceptibility to salt-induced hypertension to a marked degree. The susceptible strain (S) was exceptionally sensitive to induction of hypertension by excess salt ingestion showing blood pressures of 180 mm Hg and greater. The resistant strain (R) animals, on the other hand, were refractory to the effect of excess salt feeding on blood pressure, maintaining levels in the range of 140 mm Hg. Neither strain, however, developed high blood pressure on a normal diet thus heredity and salt played roles in hypertension in these animals. (See Section 8 for the role of heredity alone in hypertension in rats). The results on blood pressure of 130 siblings of these groups are presented in Table 2 of original article. The authors stated that it is possible that similar genetic factors may operate in man.

7. Knudsen, Dahl et al. (1729) investigated inheritance of salt-induced hypertension in rats further with the (S) and (R) strains in an effort to determine the number of genes involved. Approximately 2000 animals were used in the study extending over a period of six years.

The authors reported that both resistant (R) and susceptible (S) strains thrived and developed normally on low sodium diets with blood pressures developing slowly and leveling off at about 120 and 140 mm Hg, respectively. On an 8% NaCl diet, however, blood pressures of the (S) rats rise rapidly to as high as 200 mm Hg and more, and most of the animals died between 6 and 12 weeks of age. (R) strain animals, by contrast, usually showed only a moderate increase in blood pressure although there was a greater fluctuation amongst the males than the females. By cross-breeding and back-breeding, inheritance of susceptibility and resistance to salt-induced hypertension in the F_1 and F_2 (first and second) generations of cross-bred rats and in back-crosses between parent and first filial (F_1 x R, F_1 x S) generations were studied (See original article for details).

The authors concluded from the data obtained that regulation of blood pressure in the rat is multigenic, the probable number of genes involved being two to four. "The simplest model compatible with the data consists of two non-linked, autosomal, diallelic loci with a sex-modified expression of the genes at one locus".

8. Okamoto and Aoki (2431) developed a genetic strain of spontaneously hypertensive rats where salt is not a factor by repeated selective in-breeding of two spontaneously hypertensive Wistar rats (150-175 mm Hg ♂, and 130-140 ♀) from normal stock. Blood pressure rose from generation to generation from F_1 through F_6. At present, 100% of the animals develop spontaneous hypertension within 15 weeks of age. The average systolic pressure at 25 weeks of age is 206 mm Hg in male and 193 mm Hg in female F_5 rats. Values greater than 200 mm Hg were found in 56% of the males and 37% of the females. Blood pressure increased with age. In the normotensive control animals blood pressures remain at 131 to 136 mm Hg in the male and 130-135 mm Hg in female rats after ten weeks of age. Growth rates are comparable in the hypertensive and control rats.

9. McConnell et al. (2127) studied blood pressure and preference for salt in spontaneously hypertensive (SH) male rats and normotensive Wistar/Kyoto (WI/KY) controls from weaning through 20 weeks of age (adulthood) in a two-bottle preference test between 0.3 M NaCl solution or distilled water. The results are presented in Figure 34.

The authors pointed out that the spontaneous hypertensive rat shows an increased preference for salt at the time it becomes hypertensive, as does man. In the SH group, increased preference for salt and hypertension reached a peak at 14 weeks of age and remained so thereafter.

When SH rats first developed a preference for salt at 14 weeks of age, the preference was just as great as those given saline from weaning; blood pressures of the two groups were the same also. The growth rates of SH rats decreased after 17 weeks of age as compared with the controls although food intake was comparable. SH rats did not increase their water intake in spite of the increased salt load.

The authors pointed out that in all other studies on rats made hypertensive by various means, a decrease in preference for salt was found in contrast with the definite increased preference by the spontaneously hypertensive rats used in the present study.

10. Youmans et al. (3617) investigated the effect of seven different dietary levels of NaCl (0.01, 0.15, 2.8, 5.6, 7.0, 8.4, and 9.8%) in a long-term study in rats (193) over a period of 21 months. Food and demineralized water were provided ad libitum. The animals were weighed and examined carefully

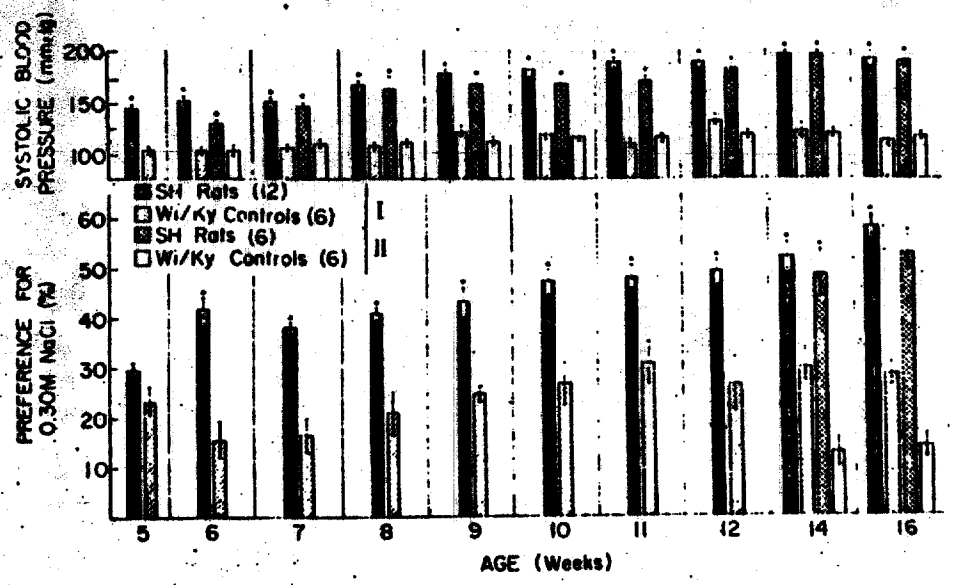


Figure 34 (2127)

for toxic effects each week. Relationship of the salt level to body water, blood pressure, serum cholesterol, electrocardiogram, reproductive capacity, and survival was also determined. Fatalities and survivors were autopsied and examined for gross and microscopic pathologic effects. The results are presented in Figures 35, 36, 37, 38 and 39.

Although only 17 animals died during the first 5 months from effects attributable to salt, by the end of the experimental period, approximately 85% of the rats on the 7.0 - 9.8% NaCl diets were dead and approximately 60% of those on the 2.8 and 5.6% diets had succumbed also. The fatality rate was less than 40% for animals on the control (0.15% NaCl) diet. (See Figure 38.)

During the period from the 2nd to the 6th month, about 15% of the 90 rats on the higher salt diets (7.0 - 9.8%) developed a syndrome consisting of edema, hypertension, anemia, lipemia, hypoproteinemia, and azotemia with pathologic lesions resembling those of nephrosis in man. Hypertension appeared in most rats on salt levels of 5.6% and above, and significant elevation was found in some of the animals at the 2.8% level also. After the 12th month, there was a direct linear relationship between the elevation of systolic blood pressure and the concentration of salt in the diet (See Figure 35). Hypercholesterolemia also correlated positively with high blood pressure and increased dietary NaCl. Electrocardiogram abnormalities were found in many animals and the incidence was found to be directly proportional to the amount

of salt in the ration. Approximately 80% of rats on the 9.8% diet were affected (see Figure 37).

Excess salt caused enlargement of the adrenals and kidneys as well as the heart. Some of the animals exhibited symptoms of congestive heart failure. Although a small percentage (15%) of rats ingesting excess salt develop severe kidney disease during the first six months, most of the animals survive and grow (although not normally) until later in life when they come down with a chronic glomerular nephritis with lesions in the arterioles which sometimes resemble malignant hypertension in man.

The authors pointed out that the 2.8% NaCl diet employed in their study compares roughly with the average human intake in this country (12-15 g NaCl per day).

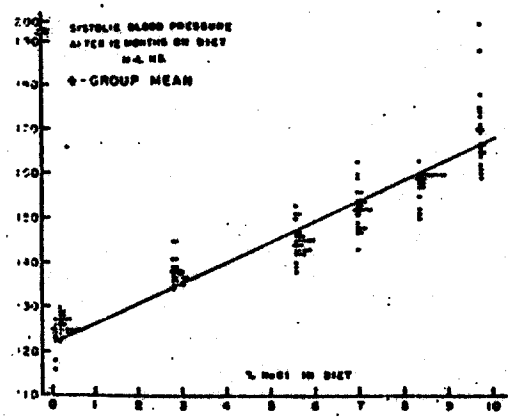


Figure 35. Systolic blood pressure after 12 months (3617)

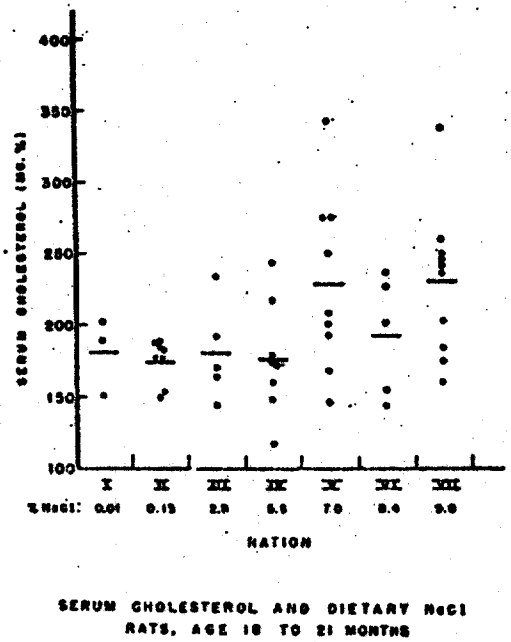


Figure 36. Relation of serum cholesterol to percent of NaCl in ration (3617)

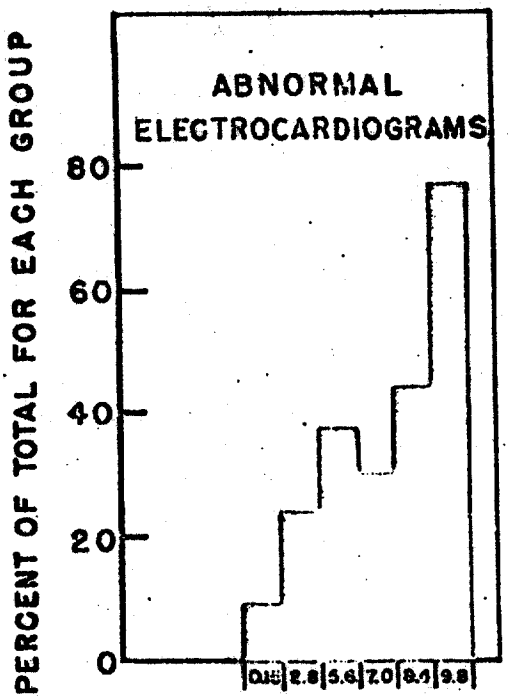


Figure 37 (3617)

Relation of incidence of ECG abnormalities and percent of NaCl in ration.

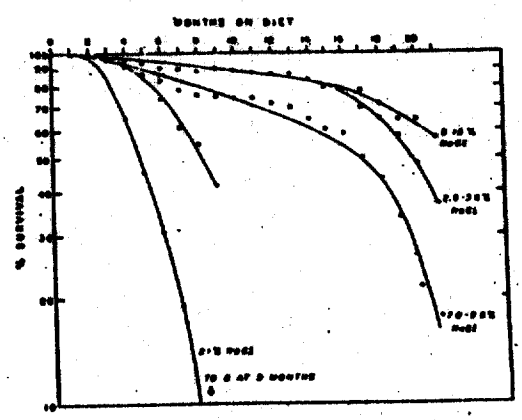


Figure 38 (3617)

Longevity % survival of rats eating 0.15 (control) 2.8, 5.6, 7.0, 8.4, 9.8, 14.0 and 21.0% NaCl. The slope of the line indicates mortality rate.

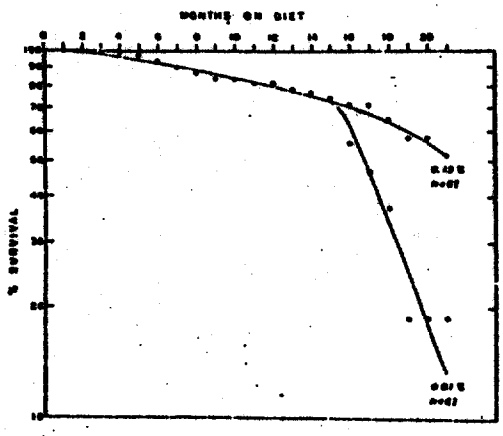


Figure 39 (3617)

Percent survival of low NaCl (0.01%) and control (0.15% NaCl) rats.

C. Rabbits

Goldblatt (1198) determined the effect of high salt intake (5 g daily) - 1250 mg/kg BW/day - together with a normal rabbit chow diet on blood pressure in a large number of young giant female Chinchilla rabbits (6 months old, 3.75 - 4.25 kg BW) over a period of 5 years. The sodium chloride was administered in the drinking water.

The maximal rise in blood pressure found ranged from 0-14 mm Hg in rabbits on the high salt intake as compared with a range of 4-24 mm Hg in the control group (Table 60). Rabbits subjected to unilateral nephrectomy and high salt intakes likewise did not show great increases in blood pressure when compared with controls over the same time interval (Table 61).

Table 60. Blood Pressures in Rabbits on Normal and High Salt Diets (1198)

Rabbit	Normal salt intake		High salt intake	
	Time	Maximal rise of blood pressure	Time	Maximal rise of blood pressure
	weeks	*mm. Hg*	*weeks*	*mm. Hg*
54	39	16	42	4
176	38	8	65	14
182	26	12	34	12
185	24	10	24	2
187	24	24	31	8
184	16	4	17	0

Table 61. Blood Pressures in Rabbits Subjected to Unilateral Nephrectomy and High Salt Intake (1198)

Rabbit	Control period: normal salt intake		Period after unilateral nephrectomy: normal salt intake		Period after unilateral nephrectomy: high salt intake	
	Time	Maximal rise of blood pressure	Time	Maximal rise of blood pressure	Time	Maximal rise of blood pressure
	weeks	*mm. Hg*	*weeks*	*mm. Hg*	*weeks*	*mm. Hg*
42	12	2			53	16
44	12	6			94	20
61	28	18			52	12
40	14	16	4	8	82	28
34	12	10	9	12	76	10
45	9	2	18	2	18	10

IV. Special Studies

A. Chick embryos

1. McLaughlin et al. (2139) noted that hypertonic sodium chloride had a marked embryocidal action on the developing chick embryo when injected into the embryonating chicken egg. Amounts as low as 0.1 ml of a 5% solution (5 mg) reduced hatchability by 60% when compared with isotonic saline (0.45 mg/egg).

2. Ridgway et al. (2727) found that the LD_{50} of sodium chloride for the 4-day-old chick embryo, when administered via the yolk sac, was somewhat greater than 50 mg per egg. When administered via the chorio-allantoic membrane, however, the value calculated was 145 micro-atoms[a]/egg (See Table 62).

3. Conti et al. (0604) in a study of the effect of different diluents and solvents on the developing chick embryo, injected embryonated eggs via the albumin before incubation, and at varying intervals after incubation, with increasing amounts of 8.5% sodium chloride solution[b] (0.05, 0.1, 0.5, and 1.0 cc) and observed the embryos for toxic effects, malformations, and mortalities. A total of 1000 eggs, including controls, were used in the study. The results are presented in Tables 63, 64 and 65.

The data obtained indicated that 8.5% NaCl solution is surprisingly toxic for the developing chick embryo in doses greater than 0.5-1.0 ml per egg, the lethal effect being greatest prior to incubation, or 5 days after incubation, than at intervening periods (Tables 63 and 64). Unstability of the unincubated

[a] $\text{a microatom/egg} = \dfrac{\text{LD50 in mg/egg} \times 1000}{\text{mol. wt. of the salt in g}} \times \text{number of atoms of element in salt}$

[b] Note: The authors speak of a "physiologic solution of sodium chloride" and of "Physiologic saline". However, the article clearly states 8.5% NaCl solution rather than 0.85%.

Table 62

Toxicity of Salts of Various Elements in Four- and Eight-Day Chick Embryos (2727)

Element	Formula of Salt	Estimated LD_{50}			
		Mg/egg	Microatoms/egg*		
		4-day	4-day	8-day	8-day CAM route
		Yolk sac route			
Arsenic	$KAsO_2$	0.02	0.10	0.34	0.07
Arsenic	$Na_2HAsO_4 \cdot 7H_2O$	0.30	0.96	2.60	0.32
Arsenic	As_2O_3	0.16	1.40		
Cadmium	$CdCl_2$	0.02	0.13	0.22	0.09
Selenium	H_2SeO_4	0.03	0.17	0.55	0.11
Platinum	$PtCl_4 \cdot 2HCl \cdot 6H_2O$	0.13	0.25	>19.0	0.17
Lead	$Pb(NO_3)_2$	0.10	0.30	4.50	3.00
Mercury	$HgCl_2$	0.08	0.30	3.10	0.21
Chromium	$Na_2Cr_2O_7 \cdot 2H_2O$	0.06	0.40	0.30	1.02
Chromium	$Cr(NO_3)_3 \cdot 9H_2O$	0.80	2.00	>50.0	7.50
Antimony	$SbCl_3$	0.10	0.44	2.20	0.08
Silver	$AgNO_3$	0.10	0.59	0.50	0.50
Nickel	$NiCl_2 \cdot 6H_2O$	0.20	0.84	10.0	1.40
Vanadium	$VO(CH_3COO)_2$	0.20	1.10	0.65	0.24
Tungsten	Na_2WO_4	0.78	2.60	8.50	6.30
Molybdenum	$Na_2MoO_4 \cdot 2H_2O$	0.80	3.30	2.90	14.0
Copper	$CuCl_2 \cdot 2H_2O$	0.60	3.50	29.0	0.71
Strontium	$Sr(NO_3)_2$	0.80	3.80	>94.0	54.0
Cobalt	$CoCl_2$	0.50	3.80	7.70	2.30
Tellurium	Na_2TeO_3	1.00	4.50	18.0	0.12
Osmium	OsO_4	1.20	4.70	9.90	0.99
Thallium	Tl_2SO_4	1.30	5.20	5.50	2.80
Lanthanum	$LaCl_3 \cdot 7H_2O$	6.00	16.0	54.0	2.80
Zinc	$ZnSO_4 \cdot 7H_2O$	5.00	17.0	>69.0	1.20
Cerium	$Ce(NO_3)_3 \cdot 6H_2O$	8.00	18.0	>46.0	3.00
Manganese	$MnSO_4 \cdot 4H_2O$	5.00	21.0	>86.0	1.50
Uranium	$UO_2(C_2H_3O_2)_2 \cdot 2H_2O$	15.0	22.0	>29.0	0.44
Indium	$InCl_3$	5.00	23.0	>91.0	21.0
Ruthenium	$RuBr_3$	7.00	27.0	>76.0	9.50
Iron	$FeSO_4 \cdot 7H_2O$	8.0	29.0	25.0	2.00
Iron	$FePO_4 \cdot 2H_2O$	15.0	80.0	75.0	2.90
Thorium	$Th(NO_3)_4 \cdot 4H_2O$	20.0	38.0	>38.0	14.0
Fluorine	NaF	1.75	42.0	71.0	30.0
Iridium	$IrCl_3$	14.0	47.0	13.0	1.30
Iodine	KI	8.0	48.0	60.0	78.0
Tantalum	K_2TaF_7	20.0	51.0	36.0	6.40
Tin	$SnCl_2$	10.0	53.0	>105.0	7.40
Tin	$SnCl_4$	20.0	77.0	77.0	5.40
Gallium	$GaC_6H_9O_7$	15.0	58.0	77.0	2.70
Magnesium	$MgSO_4 \cdot 7H_2O$	15.0	61.0	>121.0	105.0
Lithium	$LiSO_4 \cdot H_2O$	8.0	62.0	78.0	64.0
Zircon	$ZrOH(C_2H_3O_2)_3$	18.0	63.0	>70.0	18.0
Boron	H_3BO_3	5.0	81.0	113.0	81.0
Aluminum	$AlCl_3$	15.0	112.0	>150.0	16.0
Silicon	$Na_2Si_2O_7$	20.0	247.0	>247.0	31.0
Germanium	GeI_2	>10.0	>31.0	31.0	3.10
Gold	$AuCl_3HCl \cdot 4H_2O$	>20.0	>41.0	>41.0	1.20
Rhodium	$RhCl_3$	>10.0	>48.0	72.0	4.30
Bismuth	$BiCl_3$	>20.0	>63.0	>63.0	11.0
Yttrium	$Y(NO_3)_3 \cdot 6H_2O$	>30.0	>78.0	>52.0	2.90
Barium	$BaCl_2 \cdot 2H_2O$	>20.0	>82.0	45.0	3.30
Palladium	$PdCl_2 \cdot 2H_2O$	>20.0	>94.0	>94.0	19.0
Titanium	$Ti_2(SO_4)_3$	>20.0	>104.0	89.0	29.0
Beryllium	$BeSO_4 \cdot 4H_2O$	>20.0	>113.0	>113.0	5.60
Cesium	$CsCl$	>20.0	>119.0	>119.0	77.0
Rubidium	$RbCl$	>30.0	>248.0	>248.0	124.0
Calcium	$CaCl_2$	>30.0	>270.0	270.0	23.0
Potassium	KCl	>50.0	>671.0	>537.0	134.0
Sodium	$NaCl$	>50.0	>855.0	>685.0	145.0

* Microatoms, egg = $\frac{\text{LD}_{50} \text{ in mg/egg} \times 1000}{\text{Mol. wt. of salt in gms.}} \times$ no. atoms of element in salt. The LD_{50} in mg/egg for each salt for the eight-day embryos is calculated easily from the relationship between the mg/egg and microatoms/egg data presented for the four day embryo.

embryo, and development of the vascular system and increased absorption capacity after the 5th day, are believed to be responsible for the pronounced toxic effects at these times. The overall incidence of malformed embryos was not significantly higher in the treated groups than in the controls (See Table 65).

The authors concluded that where 8.5% NaCl is to be used as a diluent for substances in chick embryo studies, injections between 24-48 hours minimize complications due to toxic effects of the diluent alone.

Table 63

Number of Embryo Deaths (%) in the First Three Days After Treatment (0604)

Date of Treatment	Control	Injection of Physiologic Solution (NaCl 8.5%)			
		0.05 cm^3	0.1 cm^3	0.5 cm^3	1 cm^3
Before incubation	10.2	26.1	20.0	17.1	43.2
After 24 hours		8.0	14.3	4.5	32.5
After 48 hours		12.8	9.3	27.0	61.8
After 3 days		8.7	4.7	43.7	50.0
After 4 days		12.0	16.3	37.8	73.3
After 5 days		10.0	56.0	26.7	82.2

Table 64

Number of Embryos (%) at the 21st Day (0604)

Date of Treatment	Control	Injection of Physiologic Solution (NaCl 8.5%)			
		0.05 cm^3	0.1 cm^3	0.5 cm^3	1 cm^3
Before incubation	75.8	56.4	57.8	37.1	10.8
After 24 hours		76.0	71.4	61.4	32.5
After 48 hours		76.6	86.0	54.1	23.5
After 3 days		84.7	84.4	40.6	14.8
After 4 days		68.0	67.3	44.4	14.1
After 5 days		10.0	30.0	68.9	17.8

Table 65

Number (%) of Malformed Embryos (0604)

Date of Treatment	Control	Injection of Physiologic Solution ($NaCl_3$ 8.5%) 0.05 cm^3	0.1 cm^3	0.5 cm^3	1 cm^3
Before incubation	6.3	10.9	8.9	25.7	5.4
After 24 hours		2.0	7.1	4.5	2.5
After 48 hours		4.3	6.9	2.7	8.8
After 3 days		2.2	4.5	3.4	2.9
After 4 days		10.0	4.1	4.4	2.2
After 5 days		8.0	2.0	4.4	2.2

B. Mice

1. Nishimura et al. (2376) demonstrated teratogenic effects in mice following large doses of sodium chloride injected subcutaneously. The study was prompted by previous reports of similar effects caused by a number of normal body constituents, nutrients, and drugs commonly used in man, when administered in excessive amounts. Pregnant Japanese dd strain mice, 10 per group, were injected subcutaneously with 1900 or 2500 mg/kg BW of sodium chloride (aqueous solution) at 10 or 11 days of gestation, and maintained on a mouse pellet diet and fresh water ad libitum until sacrificed on the 18th day of gestation. [Control groups of the same number of animals were included for each dose level of NaCl.] After sacrifice, all embryos were removed, weighed, and examined for malformation. The data are presented in Table 66.

Both levels of NaCl caused embryocidal and/or teratogenic effects in up to 18% of the embryos (Table 66). Club foot and certain other abnormalities of the foot or toes were the most prevalent malformations found. The authors postulated that the teratogenic effects observed were associated with the increased osmotic pressure of the blood in the embryonic circulation.

2. Morgareidge et al. (2265) reported that sodium chloride (FDA 71-70) was negative for significant teratologic effects in mice orally at a level of 480 mg/kg BW/day for 10 consecutive days; likewise, there was no adverse effect on nidation, or on maternal or fetal survival.

Table 66

Embryocidal and Teratogenic Effects of 25% Sodium Chloride Solution on Mouse Offspring (Subcutaneous Injection) (2376)

Treatment			Condition of offspring				
Day of gestation	Dose (mg/kg)	No. of mothers	Total implants	Dead or resorbed (%)	Body weight of survivors (g)	Survivors malformed (%)	Type and No. of malformations***
10	2500	10	77	48*1	1.23*2	18*1	1Ad, 2Cf, 1Dd, 1Pd, 1St, 2Sl
	1900	10	75	8	1.33	12*1	8Cf, 1Dd
	Control**	10	73	5	1.36	0	-
11	2500	10	68	37*1	1.23*2	16*1	5Cf, 1Mw
	1900	10	76	45*1	1.30	2	1Cf
	Control**	10	73	4	1.31	0	-

*1 Significantly different from the control ($P < 0.01$). *2 Significantly different from the control.
** The nape was pricked once with a needle on the respective day.
*** Ad = adactyly, Cf = clubfoot, Dd = deviation of digit(s), Mw = maldirected wrist joint, Pd = polydactyly (toe), St = shortness of foot, Sl = shortness of forelimb.

3. Kinosita (1702) discovered that high salt and low protein diets increased the incidence of stomach cancer in 4-nitroquinoline 1-oxide (4-NQO) treated mice. When 4-week-old mice were fed 0.5 ml of 10% NaCl 5 hours before administration of the carcinogen (0.5 ml of 1% 4-NQO in 10% ethyl alcohol) once a week for 10 weeks (or twice a week for 8 weeks), 6 out of 17 animals (35.3%) had stomach cancer while only 1 out of 13 (8%) developed cancer on 4-NQO alone. Stomach cancer developed in 50% of mice maintained on a diet containing only 8% protein, when sodium chloride was given before 4-NQO; metastases were present in one of the cases. The author stated that these data suggest why the incidence of stomach cancer is so high in rural Japan.

C. Rats

Morgareidge et al. (2265) stated that sodium chloride (FDA 71-70) was negative for significant teratologic effects in rats orally at a level of 368 mg/kg BW/day, for 10 consecutive days. The substance was negative also for adverse effects on nidation, maternal, and fetal survival.

D. Rabbits

1. Collier et al. (0593) studied the effect of sodium chloride and lime on development of the Brown-Pearce rabbit carcinoma in vivo. Ten rabbits (specifications not given) were injected intraperitoneally with a fine suspension of the carcinoma cells and then treated daily with 10% NaCl solution

subcutaneously at a level of 150 mg/kg BW for a period of 4 to 6 weeks. (The total dose was a maximum of 6.5 g per animal.) Ten additional infected animals were held as untreated controls. At the end of the experimental period, all survivors were killed and autopsied. The experiment was repeated four times.

Amongst the NaCl-treated rabbits, only 16% were negative for tumors as compared with 33% negatives in the control group. Moreover, 28% of the NaCl group had extensive tumor development whereas only 13% of the controls showed strong cancer growth. The authors concluded that the data indicate that a relatively small amount of sodium chloride strongly predisposes rabbits to malignancy with the Brown-Pearce rabbit carcinoma.

2. Morgareidge et al. (2265) concluded that sodium chloride (FDA 71-70) was negative for significant teratologic effects in rabbits orally at a level of 363 mg/kg BW/day for 13 consecutive days; no adverse effects on nidation, maternal or fetal survival were noted.

SODIUM CHLORIDE

BIOCHEMICAL ASPECTS

I. Effects on Enzymes and Other Biochemical Parameters

A. Mice

Isler, Axelrad *et al.* (1548) investigated the effect of salt (acute and chronic) on the metabolism of radioiodine in the mouse in an effort to determine the mechanism of NaCl stimulation of the thyroid gland. C_3H/Jax male mice, 2 to 6 1/2 months of age, were used throughout. In one experiment, the influence of NaCl on the pituitary was studied with the use of thiouracil in the presence and absence of salt. In a second experiment, the influence of sodium chloride on thyroid iodine metabolism was compared with that of propylthiouracil. In a third experiment, the effect of salt on renal iodine excretion was determined with nephrectomized, thyroidectomized, and control mice (See original article for details of methodology).

Chronic salt feeding (1% NaCl for 2 months) caused enlargement of the thyroid, reduction in iodine content, and increase in urinary iodine excretion. In acute studies, a single oral dose of 30 mg of NaCl increased the urinary excretion of radioiodine by 10- to 20-fold in 2-3 hours while lowering the blood iodine level moderately.

The authors suggested that the mechanism involved in stimulation of the thyroid gland involves increase in the renal excretion of iodine resulting in reduced iodine uptake by the thyroid causing a decrease in the amount of hormone produced and released into the circulation; this in turn causes an increase in the secretion of the thyrotrophic hormone by the pituitary gland resulting in thyroid stimulation.

B. Rats

1. Dahl (0684) studied the effect of chronic excess salt feeding on blood cholesterol levels in rats over a period of approximately one year. Two groups of female Sprague-Dawley rats, 15 per group, were given excess sodium chloride in the diet at levels of 8% or 11.6%. A control group of 11 animals was maintained on the basal ration without excess salt. Both control and experimental animals had free access to food and water at all times.

Plasma cholesterol, blood urea nitrogen, and systolic blood pressure determinations were made at regular intervals. The results are presented in

Table 67. Forty percent (40%) of the rats given excess salt in the diet had markedly elevated blood cholesterol values ranging from 150 to 516 mg % after 9 or 10 months on excess salt feeding. Blood pressures were also significantly higher than in the control group.

Table 67

Female Rats, Seven and One-Half Months of Age at Time of Bleeding for Plasma Cholesterol (0684)

Rat	Food	Months on Diet	Body Weight (gm.)	Systolic Blood Pressure (mm. Hg)	Total Cholesterol (mg. per cent)
16	Control	7	297	111	113
17	Control	7	297	124	63
18	Control	7	232	124	81
19	Control	7	268	126	81
20	Control	7	242	120	99
21	Control	7	269	126	125
22	Control	7	255	123	113
23	Control	7	292	132	90
24	Control	7	263	124	89
25	Control	7	260	137	63
26	Control	7	285	138	94
Average (and S.D.)			*269.1 (±21.8)*	*126.2 (±7.1)*	*91.9 (±19.9)*
27	11.6 per cent sea salt	6½	262	151(3)*	175
28	11.6 per cent sea salt	6½	249	122	138(2)
29	11.6 per cent sea salt	6½	263	180(3)	125
30	11.6 per cent sea salt	6½	239	120	119
31	11.6 per cent sea salt	6½	283	166(3)	113
32	11.6 per cent sea salt	6½	249	172(3)	71
33	11.6 per cent sea salt	6½	281	162(3)	175
34	11.6 per cent sea salt	6½	245	182(3)	132(2)
35	11.6 per cent sea salt	6½	263	136	106
36	11.6 per cent sea salt	6½	275	162(3)	133
37	11.6 per cent sea salt	6½	265	170(3)	113
38	11.6 per cent sea salt	6½	239	135	85
39	11.6 per cent sea salt	6½	271	194(3)	143(2)
40	11.6 per cent sea salt	6½	264	120	96
41	11.6 per cent sea salt	6½	256	130	125
Average (and S.D.)			*260.3 (±11.0)*	*153.7 (±24.6)*	*115.8 (±19.5)*
42	8 per cent NaCl	6½	277	140(2)	109
43	8 per cent NaCl	6½	270	199(3)	155(3)
44	8 per cent NaCl	6½	254	145(2)	90
45	8 per cent NaCl	6½	270	148(3)	106
46	8 per cent NaCl	6½	258	138	113
47	8 per cent NaCl	6½	263	142(2)	90
48	8 per cent NaCl	6½	253	150(3)	101
49	8 per cent NaCl	6½	271	138	113
50	8 per cent NaCl	6½	247	124	99
51	8 per cent NaCl	6½	268	116	73
52	8 per cent NaCl	6½	268	134	106
53	8 per cent NaCl	6½	223(2)	126	90
54	8 per cent NaCl	6½	245	126	99
55	8 per cent NaCl	6½	262	133	94
56	8 per cent NaCl	6½	229(2)	153(3)	99
Average (and S.D.)			*262.2 (±16.5)*	*140.1 (±17.3)*	*101.8 (±18.6)*

Systolic blood pressures are those for the last month of the experiment.

* Differs from mean value in control group by 2 or 3 S.D., respectively. Both salt fed groups had higher mean blood pressure (sea salt < 0.01, NaCl < 0.05 > 0.01) than control group. Sea salt group only had higher ($p < 0.01$) mean plasma cholesterol than control group.

FROM: DAHL, L. K. *J. Exper. Med.*, 112: 635, 1960.[3]

pressure or kidney disease nor was there any evidence that excess salt consumption was or was not related to atherogenesis.

2. Omen et al. (2450) investigated thyroid function in salt-induced hypercholesterolemia in the dog in a study prompted by the suggestion that this lipid abnormality may be secondary to hypothyroidism. Seventeen pure-bred Beagles (16 females and 1 castrated male) were used in the study. Twelve of the animals had been on high salt diets, consuming 12-21 g of sodium chloride per day for more than 5 years. Five control dogs received approximately 2.5 g of sodium chloride daily for the same period. Each animal was given 0.25 μCi of carrier-free ^{131}I in the form of NaI intravenously and thyroid uptake determined 24 and 48 hours after administration of the radioactive isotope. Protein-bound iodine (PBI), urea nitrogen, and plasma cholesterol were determined also. Biopsies of thyroids of six representative dogs were performed and examined microscopically. The data were analyzed statistically using the "t" test.

The mean plasma cholesterol of the 12 salt-fed dogs (242 mg/100 ml) was significantly higher than that of the control group (179 mg/100 ml), $P < 0.01$. Renal function, bodyweights, and blood pressure were normal for both groups. Radioactive iodine uptake and protein-bound iodine levels were not significantly different between hypercholesterolemic salt-fed dogs and those with normal cholesterol values. Likewise, no histologic differences were detected in thyroid tissue biopsy specimens of the two groups.

The authors stated that their data indicated that there was no evidence in support of the suggestion that development of hypercholesterolemia in salt-fed dogs was due to hypofunction of the thyroid.

3. Davis (0735) studied the relationship of electrolytes and oxygen consumption on water metabolism in the dog. Twenty-five animals (specifications not given) were injected intravenously with 0.9% sodium chloride solution or 5% glucose solution intravenously in amounts ranging from 2500 ml to 4000 ml, and the amounts of oxygen consumed before, during, and after the injections were determined at regular intervals.

An increase in oxygen consumption from 100 to 500% above the basal level occurred in all but three of the animals. The amount of water lost was proportional to the increase in oxygen consumption and metabolic rate. The three animals in which oxygen consumption did not occur during injection died. The increase in O_2 consumption resulting from 5% glucose was greater than that

produced by 0.9% sodium chloride solution. The author concluded that one of the fundamental factors involved in water regulation of the body is the oxygen consumption rate of the tissues.

D. Humans

1. Elsbach et al. (0907) found marked and prolonged positive sodium balances indicative of an abnormal salt and water metabolism in seven hospitalized obese patients undergoing weight reduction. Water retention was so great in some patients that they failed to lose weight even when the caloric intake was reduced to 600. The authors' results are in agreement with those of other workers who concluded that obesity is associated with abnormalities in homeostatic mechanisms regulating the distribution and excretion of salt and water.

2. Clarkson et al. (0566) reported on the use of slow-release sodium tablets with patients and athletes for treatment or prevention of acute and chronic sodium chloride deficiency. The tablets are prepared from a wax sponge substance which disintegrates in the gastro-intestinal tract in such a manner as to release slowly the sodium chloride content of 600 mg (10 mEq Na^+ and Cl^-). The authors pointed out that preparations of this type have been used successfully for a number of years for slow K release in potassium therapy.

3. Colle et al. (0590) determined the plasma levels of sodium, potassium, chloride, bicarbonate, and urea, in 17 infants with gastro-enteritis (non-microbial) admitted to the hospital with hypertonic dehydration. All of the infants had serum sodium levels above 150 mEq/liter or chloride concentrations above 125 mEq/liter. Four patients in the hypernatremic group (172, 160, 173 mEq/liter[a]) died in spite of attempted corrective therapy.

Analysis of feedings given during the initial stage of diarrhea revealed that those who developed hypernatremia had been given formulas in which the ratio of solutes to water was higher than that in the high fluid loss through stools, urine, skin, and lungs. The formulas varied from 42.5 to 64 mEq/liter of sodium. The softened water that had been used in the home for formula preparation had sodium levels ranging from 6 to 14.6 mEq/liter. (A home water softener of the exchange resin type charged with sodium chloride had been used). The authors warned against the danger of high solute feedings to

[a]Value not reported for one fatal case.

infants undergoing increased water loss.

4. Markley et al. (2054) reported that 110 burned children and 83 burned adults, treated orally with isotonic saline solution, equivalent to 10% of the bodyweight during the first 24 hours, and half the amount during the second day after burn injury, showed no toxic effects, in spite of marked water and sodium retention.

In an experimental study, 16 healthy Peruvian males, 20 to 28 years of age, treated with isotopic saline orally, (equivalent to 10% bodyweight), over a period of 21 hours, showed that the glomerular filtration rate increased 32% on the average over that of the controls; effective renal plasma flow did not change significantly. Fifty-eight percent (58%) of the administered sodium and 51% of the administered water were excreted by the kidneys during the period of administration. The total excretion of potassium decreased during sodium loading. No important changes in plasma concentrations of red blood cells, total protein, or electrolytes were observed.

II. Drug Interaction

A. Microorganisms

1. Gooding et al. (1212) reported that although sodium chloride lowers the solubility of sorbic acid in preservative brines, the salt has a marked synergistic effect on the fungistatic action of the agent. Sorbic acid fungistasis is increased by a high sugar content also. (The authors pointed out that "sorbic acid is unique among food additives, being a metabolizable food added for protective purposes to another food".)

2. In a study on the preservation of chapaties (puffed wheat-flour products) under tropical conditions, Rao et al. (2666) found that addition of 1.25% sodium chloride to the dough not only improved the taste but also enhanced the preservative action of sorbic acid. Chapaties packages in paper-foil-polyethylene pouches kept satisfactorily for 6 months under varied tropical conditions when a mixture of sorbic acid (0.18%) and NaCl (1.25%) was incorporated in the dough (0.3% and 2%, respectively, in the flour). Without NaCl, concentrations of sorbic acid as high as 0.3% in the dough (0.48% in the flour) were ineffective in preventing spoilage.

B. Rats

Morrison et al. (2271) determined the effect of B vitamin deficiency on the toxicity of excess salt added to the diet of rats. Twelve comparable groups of weanling male rats (McCollum-Wisconsin strain), 10 per group and weighing

45-48 g were employed. Five groups were fed a basal ration containing various levels of salt (3-8%) but without adequate B vitamins; five other groups were fed the same diets but supplemented with an adequate amount of B vitamins. A salt-free diet control was included for each vitamin group (see Table 68). Food and tap water were provided ad libitum. The following observations were made over a period of 17 weeks: toxic symptoms, survival, weight changes, food consumption, water intake, and caloric efficiency (gram gain per 1000 calories). All animals were fasted for 24 hours at the conclusion of the study and sacrificed for chemical and histopathologic studies. The data were analyzed for statistical significance. The results are presented in Figure 40 and Tables 69 and 70.

B vitamin deficiency definitely enhanced the toxicity of excess dietary sodium chloride as evidenced by a decreased weight gain and lower caloric efficiency, as well as by cardiac, renal, and adrenal hypertrophy (see Figure 40 and Tables 69 and 70). The authors stated that addition of 2% KCl in the diet to a large extent reduced cardiac hypertrophy caused by 6% NaCl in normal animals.

Table 68

Data on Weight Gains, Ad Libitum Food and Water Intakes and Caloric Efficiencies of Male Weanling Rats Fed Otherwise Adequate Diets Containing Different Levels of B Vitamins, Sodium Chloride, Potassium Chloride and Sea Salt for 17 Weeks (2271)

Diet No. and Description	No. of Survivors [1]	Initial Weight	Gain in Weight	Food Intake	Water Intake		Calorie Efficiency [2]
		gm	gm	gm	ml	ml/100 gm food	
Inadequate B vitamins							
1 Control	10	45	149 ± 42 [3]	1057	1331	126	32.2 ± 7.1
2 + 3% NaCl	9	45	118 ± 54	930	1997	215	30.1 ± 10.8
3 + 6% NaCl	10	45	92 ± 33	941	2861	304	25.2 ± 8.5
4 + 4% sea salt	9	45	78 ± 31	760	1675	220	25.3 ± 7.9
5 + 8% sea salt	8	45	111 ± 68	975	3854	395	28.3 ± 9.8
6 + 6% NaCl + 2% KCl	6	45	92 ± 35	972	3221	331	24.9 ± 9.5
Adequate B vitamins							
7 Control	10	47	320 ± 32	1753	2068	118	44.0 ± 5.0
8 + 3% NaCl	10	48	307 ± 37	1776	4181	235	42.9 ± 3.5
9 + 6% NaCl	10	47	305 ± 62	1806	6166	341	42.8 ± 8.8
10 + 4% sea salt	9	47	319 ± 28	1686	3872	230	47.0 ± 2.4
11 + 8% sea salt	10	47	290 ± 34	1783	7391	415	42.9 ± 5.8
12 + 6% NaCl + 2% KCl	10	48	294 ± 27	1859	6746	363	41.3 ± 4.3

[1] Each group contained 10 animals initially.
[2] Grams gain per 1000 Cal.
[3] Standard deviation.

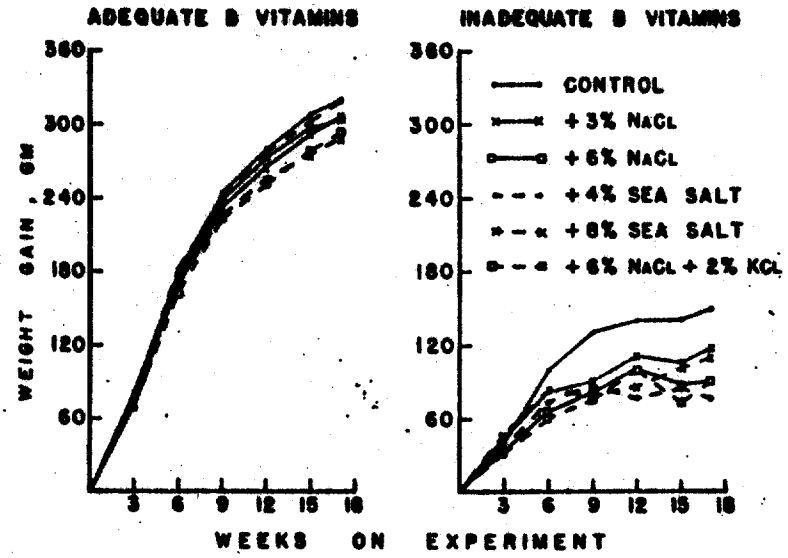


Figure 40 (2271)

Effect of excess salt on weight gains of male weanling rats fed diets containing adequate or inadequate levels of B vitamins.

Table 69

Data on Liver, Heart, Kidney and Adrenal Weights of Male Weanling Rats Fed Otherwise Adequate Diets Containing Different Levels of B Vitamins, Sodium Chloride, Potassium Chloride and Sea Salt for 17 Weeks (2271)

Diet No. and Description	No. of Survivors[1]	Liver		Heart		Kidney		Adrenal	
		gm	gm/100 gm body weight	mg	mg/100 gm body weight	gm	gm/100 gm body weight	mg	mg/100 gm body weight
Inadequate B vitamins									
1 Control	10	5.3	2.9 ± 0.2[2]	612	337 ± 33	1.65	0.90 ± 0.11	35.8	20.1 ± 4.2
2 + 3% NaCl	9	4.8	3.2 ± 0.5	576	392 ± 59	1.68	1.12 ± 0.23	31.2	22.2 ± 6.1
3 + 6% NaCl	10	4.2	3.3 ± 0.3	512	409 ± 46	1.53	1.23 ± 0.13	27.6	22.5 ± 4.8
4 + 4% sea salt	9	3.7	3.3 ± 0.6	479	426 ± 70	1.38	1.24 ± 0.19	27.9	25.5 ± 6.8
5 + 8% sea salt	8	4.8	3.3 ± 0.3	598	411 ± 47	1.63	1.17 ± 0.17	28.9	21.6 ± 5.7
6 + 6% NaCl + 2% KCl	6	4.1	3.4 ± 0.6	504	414 ± 81	1.49	1.23 ± 0.21	25.4	21.5 ± 6.5
Adequate B vitamins									
7 Control	10	9.3	2.7 ± 0.3	995	286 ± 27	2.35	0.68 ± 0.09	42.4	12.2 ± 1.7
8 + 3% NaCl	10	9.1	2.7 ± 0.3	1028	298 ± 34	2.38	0.75 ± 0.07	43.2	13.1 ± 2.0
9 + 6% NaCl	10	9.3	2.8 ± 0.3	1156	361 ± 93	2.71	0.83 ± 0.09	44.8	14.4 ± 6.5
10 + 4% sea salt	9	9.2	2.7 ± 0.2	1020	298 ± 31	2.52	0.73 ± 0.07	39.9	11.6 ± 0.8
11 + 8% sea salt	10	9.3	3.0 ± 0.4	1256	402 ± 77	2.52	0.80 ± 0.08	40.6	13.1 ± 3.5
12 + 6% NaCl + 2% KCl	10	8.4	2.6 ± 0.2	993	311 ± 31	2.56	0.80 ± 0.06	39.7	12.4 ± 1.2

[1] Each group contained 10 animals initially.

[2] Standard deviation.

Table 70

Data on Fasting Weight Losses and Carcass Composition of Male Weanling Rats Fed Otherwise Adequate Diets Containing Different Levels of B Vitamins, Sodium Chloride, Potassium Chloride and Sea Salt for 17 Weeks (2271)

DIET NO. AND DESCRIPTION	NO. OF SURVIVORS[1]	CARCASS COMPOSITION				
		MOISTURE		Ash	Fat	Protein
		Wet weight	Fat-free weight			
		%	%	%	%	%
Inadequate B vitamins						
1 Control	10	65.7 ± 1.8[2]	71.0 ± 0.7	4.8 ± 0.4	7.5 ± 2.6	23.5 ± 1.0
2 + 3% NaCl	9	66.7 ± 1.2	70.9 ± 0.7	5.1 ± 1.0	5.9 ± 2.3	24.4 ± 0.6
3 + 6% NaCl	10	67.2 ± 1.0	70.9 ± 1.1	5.2 ± 0.7	5.3 ± 1.4	23.9 ± 0.7
4 + 4% sea salt	9	67.4 ± 1.1	70.7 ± 1.6	5.6 ± 0.6	4.8 ± 1.4	24.2 ± 0.6
5 + 8% sea salt	8	66.4 ± 2.1	70.8 ± 1.5	5.3 ± 0.8	6.2 ± 3.3	23.9 ± 0.9
6 + 6% NaCl + 2% KCl	6	66.1 ± 1.1	70.8 ± 0.9	5.3 ± 0.7	6.1 ± 2.0	23.9 ± 1.0
Adequate B vitamins						
7 Control	10	61.7 ± 2.7	71.2 ± 0.7	3.7 ± 0.3	13.4 ± 3.3	22.7 ± 0.9
8 + 3% NaCl	10	61.7 ± 1.3	71.0 ± 0.4	3.8 ± 0.2	13.1 ± 1.7	23.0 ± 0.6
9 + 6% NaCl	10	62.2 ± 3.0	71.0 ± 0.4	4.0 ± 0.6	12.3 ± 4.5	23.1 ± 1.3
10 + 4% sea salt	9	60.0 ± 2.5	71.1 ± 0.4	3.7 ± 0.4	15.6 ± 3.4	22.2 ± 1.0
11 + 8% sea salt	10	63.5 ± 2.0	71.1 ± 1.0	3.8 ± 0.2	11.0 ± 2.3	23.0 ± 0.7
12 + 6% NaCl + 2% KCl	10	61.0 ± 1.8	70.9 ± 0.5	3.7 ± 0.2	14.0 ± 2.1	22.7 ± 0.5

[1] Each group contained 10 animals initially.

[2] Standard deviation.

III. Consumer Exposure Information

A. Intakes, usage levels, poundage and import data

The possible daily intake of sodium chloride - all food catagories - is on the average, as follows (1012):

Age	Mg
0-5 months	591
6-11 months	2740
12-23 months	3888
2-65+ years	7090

The possible daily intake of sodium chloride - all food categories - at the highest, found in the literature search is (1012):

Age	Mg
0-5 months	1427
6-11 months	8121
12-23 months	8286
2-65+ years	13599

Foods in which there is the maximum use of sodium chloride, and the amount, according to the literature search are (1011):

Food Category	Wtd Mean, %
Sea Flavrs (R)	81.5
Reconst veg (R)	8.6
Condm Relsh (R)	6.1

Maximum usage levels reported for sodium chloride in infant formula products and baby foods are (1013):

Food Category	Wtd Mean, %
Baked goods	0.75
Most Others	0.25

The total 1970 poundage of sodium chloride reported to National Academy of Sciences together with Food Extracts Manufacturer's Association was 1,832,824,642 (1015).

The amount of sodium chloride or salt imported in 1968 was 5,884,706 (1,000 pounds, shipping weight); in 1970, the amount was 6,512,384 (1,000 pounds, shipping weight) (3331).

B. Other Information

Sodium chloride is used in the home and in the food industry as a nutrient, as flavoring agent, and as a preservative (0598). The main food categories in which it is employed together with quantitative data on the amounts used and intakes therefrom are listed in the Comprehensive GRAS Survey tables (1011, 1012, 103).

1. Corley (0610) pointed out that sodium in the drinking water, natural as well as artificially-softened, may add a significant and unsuspected amount of sodium to the diet.

A survey of Nebraska communities revealed sodium contents as high as 460 mg/liter and hardness levels up to 2600 (as mg $CaCO_3$/liter). Fifty-five communities had sodium contents in excess of 50 mg/liter (see Table 71). Lime-soda ash and ion-exchange resin procedures for softening water both add considerable sodium since 1 mg of hardness as calcium carbonate is equal approximately to 0.46 mg of sodium according to the author. The importance of these findings in connection with the preparation of low sodium diets is discussed.

Table 71. Sodium Contents in Drinking Water of Nebraska Communities (0616)

Community	Sodium mg/liter	Hardness mg $CaCO_3$/liter
*Alliance	78	294
Ansley	53	740
Bridgeport	112	292
Burchard	85	2600
Clarks	58	324
Craig	70	392
Culbertson	59	528
†*Dakota City	78	556
Dawson	53	516
DeWitt	175	260
Eagle	60	350
Elm Creek	63	364
†*Fairbury	62	203
*Filley	53	403
Garland	92	192
Gering	150	262
Haigler	300	1420
Harly	57	256
Henry	63	320
Hershey	110	426
Hordville	53	372
Kearney	68	423
Leigh	73	392
†*Lincoln	26	196
Lodgepole	101	232
Louisville	55	350
McCook	63	304
*Macy	103	402
Maskell	102	640
Minatare	112	150
*Monowi	460	80
Morrill	87	338
Naponee	71	572
‡*Nebraska City	50	196
‡‡*Nehawka	110	76
North Loup	65	434
†Oakland	69	476
†*Omaha	48	153
Overton	61	454
Panama	63	300
Paxton	270	568
Plymouth	60	452
Raymond	52	304
Scottsbluff	138	328
†South Sioux City	80	600
Steinauer	78	548
Syracuse	52	200
†Talmage	52	152
Terry Town	110	568
Trenton	70	304
*Verdel	300	72
Waverly	110	316
*Whitney	270	380
Winnebago	122	644
Winside	62	492

* — samples from distribution system
† — water treatment plant used
‡ — water treatment plant used with lime softening
‡‡ — water treatment plant used with ion-exchange softening

2. Bills et al. (0273) determined the sodium and potassium concentrations in approximately 500 foods and 150 municipal water supplies in a study prompted by the increased interest in low-salt diets for therapeutic purposes.

The data presented (see original article, Table 1) are in accord with the general rule that animal tissue contains much more sodium than plant tissue. Plants, on the other hand, are rich in potassium. The authors pointed out that in food processing, some sodium is usually added. Two popular infant foods - a cereal and a formula - contained 620 and 840 mg/100 g, respectively. Sharply salted foods may contain several thousand milligrams of sodium per 100 grams.

The average sodium content of unprocessed fruits, grains, nuts, and legumes was found to be about 2 mg/100 g whereas fresh meats, fish, and fowl contain from 50-100 mg per 100 grams.

Most fresh vegetables and fruits contained several hundred milligrams of potassium per 100 grams, with values as high as 780 (spinach), 680 (buckwheat) and 690 (almonds).

Drinking water ranged from 0.1 to 34 mg/100 cc of sodium and from 0.1 to 3 mg/100 cc of potassium. (See original article, Table 2). The authors pointed out that on the basis of the average daily consumption of 2.5 liters in food and drink, 500 mg of sodium from water alone would be ingested from a supply containing 20 mg/100 cc.

3. Frank et al. (1029) have suggested sodium chloride-potassium chloride mixtures (1:1) in place of salt for patients with diseases where NaCl restriction is beneficial such as edematous heart disease, congestive heart failure, renal diseases, cirrhosis of the liver, toxemias of pregnancy, and Meniere's disease, as well as hypertension, where NaCl restriction is claimed to be of value. The extra potassium intake from use of KCl-NaCl (1:1) as table salt would present no nutritional or physiologic problems[a], according to the authors, since it would be well within the normal range and the new Na:K ratio would approximate 0.97 of typical diets as purchased before being salted in the home.

Sodium and potassium chloride mixtures (1:1) are palatable, according to the authors, and similar in saltiness to equal weights of sodium chloride; they can be used in food processing - baking, meat curing, etc. - as well as in the home.

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[a] Patients with severe nephritis excepted

POTASSIUM CHLORIDE

POTASSIUM CHLORIDE

Chemical Information

I. **Nomenclature**

A. Common Name

Potassium Chloride

B. Chemical Name

Potassium Chloride

C. Trade Names

Kaleorid; Kalitabs; Potavescent; Rekawan; Slow-K Tablets; Span-K (3156)

D. Chemical Abstracts Services Unique Registry Number:

007447407

II. **Empirical Formula**

KCl

III. **Structural Formula**

K-Cl

IV. **Molecular Weight**

74.55

V. **Specifications**

A. Chemical Grade

Potassium Chloride, VSP-FCC (1550)
#3046 Crystal of
#3052 Powder

Assay (KCl)	99.0-100.5%
Description, identification. solubility	passes test
acidity or alkalinity	passes test
loss on drying	1% max
Iodide or bromide	passes test
Arsenic	0.0003%
Calcium & Magnesium	passes test
Heavy metals	0.001%
Sodium	passes test

B. Food Grade

Food Chemicals Codex, 2nd edition (0598) gives the following specifications for food grade potassium chloride:

POTASSIUM CHLORIDE (0598)

KCl Mol. wt. 74.56

DESCRIPTION

Colorless, elongated, prismatic, or cubical crystals, or a white, granular powder. It is odorless, has a saline taste, and is stable in air. Its solutions are neutral to litmus. One gram dissolves in 2.8 ml. of water at 25°, and in about 2 ml. of boiling water. It is insoluble in alcohol. A 1 in 20 solution gives positive tests for *Potassium*, page 928, and for *Chloride*, page 926.

SPECIFICATIONS

Assay. Not less than 99.0 percent of KCl after drying.

Limits of Impurities

Acidity or alkalinity. Passes test.

Arsenic (as As). Not more than 3 parts per million (0.0003 percent).

Heavy metals (as Pb). Not more than 10 parts per million (0.001 percent).

Iodide or bromide. Passes test.

Loss on drying. Not more than 1 percent.

Sodium. Passes test.

C. Pharmaceutical grade

The U. S. Pharmacopeia XVIII (3333) gives the following specifications for pharmaceutical grade potassium chloride:

Potassium Chloride (3333)

KCl 74.56

Potassium Chloride contains not less than 99.0 percent and not more than 100.5 percent of KCl, calculated on the dried basis.

Description: Colorless, elongated, prismatic, or cubical crystals, or white, granular powder. Is odorless, has a saline taste, and is stable in air. Its solutions are neutral to litmus.

Solubility: Freely soluble in water and even more so in boiling water; insoluble in alcohol.

Identification—A solution (1 in 20) responds to the tests for *Potassium*, page 893, and for *Chloride*, page 892.

Acidity or alkalinity—To a solution of 5 g. in 50 ml. of carbon dioxide-free water add 3 drops of phenolphthalein T.S.: no pink color is produced. Then add 0.3 ml. of 0.02 *N* sodium hydroxide: a pink color is produced.

Loss on drying, page 935—Dry it at 105° for 2 hours: it loses not more than 1 percent of its weight.

Iodide or bromide—Dissolve 2 g. in 6 ml. of water, add 1 ml. of chloroform, and then add, dropwise, with constant agitation, 5 ml. of a mixture of equal parts of chlorine T.S. and water: the chloroform is free from even a transient violet or a permanent orange color.

Arsenic, page 894—Dissolve 500 mg. in 35 ml. of water. The limit is 3 parts per million.

Calcium and magnesium—To 20 ml. of a solution (1 in 100) add 2 ml. each of ammonia T.S., ammonium oxalate T.S., and sodium phosphate T.S.: no turbidity is produced within 5 minutes.

VI. Description

A. General characteristics

Potassium chloride is a white solid consisting of colorless elongated, prismatic, or cubical crystals (0598, 3156). It is odorless and has a saline taste (0598).

B. Physical properties

Potassium chloride is soluble in water and glycerol, slightly soluble in alcohol, but insoluble in ether and acetone (3156).

Physical constants:

Density: 1.98

Melting point: 773°C

Boiling point: 1500°C (sublimes)

C. Stability in containers, animal foods, etc.

Potassium chloride is stable in air (0598).

VII. Analytical Methods

Food Chemicals Codex, 2nd edition (0598) gives the following analytical methods for potassium chloride:

TESTS (0598)

Assay. Dry about 250 mg. at 105° for 2 hours, weigh accurately, and dissolve in 50 ml. of water in a glass-stoppered flask. Add, while agitating, 50.0 ml. of 0.1 *N* silver nitrate, 3 ml. of nitric acid, and 5 ml. of nitrobenzene, shake vigorously, add 2 ml. of ferric ammonium sulfate T.S., and titrate the excess silver nitrate with 0.1 *N* ammonium thiocyanate. Each ml. of 0.1 *N* silver nitrate is equivalent to 7.456 mg. of KCl.

Acidity or alkalinity. To a solution of 5 grams in 50 ml. of recently boiled and cooled water add 3 drops of phenolphthalein T.S. No pink color is produced. Then add 0.3 ml. of 0.02 *N* sodium hydroxide. A pink color is produced.

Arsenic. A solution of 1 gram in 35 ml. of water meets the requirements of the *Arsenic Test*, page 865.

Heavy metals. A solution of 2 grams in 25 ml. of water meets the requirements of the *Heavy Metals Test*, page 920, using 20 mcg. of lead ion (Pb) in the control (*Solution A*).

Iodide or bromide. Dissolve 2 grams of the sample in 6 ml. of water, add 1 ml. of chloroform, and then add, dropwise and with constant agitation, 5 ml. of a mixture of equal parts of chlorine T.S. and water. The chloroform is free from even a transient violet or permanent orange color.

Loss on drying, page 931. Dry at 105° for 2 hours.

Sodium. A 1 in 20 solution, tested on a platinum wire, does not impart a pronounced yellow color to a nonluminous flame.

Packaging and storage. Store in well-closed containers.

Functional use in foods. Nutrient; dietary supplement; gelling agent; salt substitute; yeast food.

VIII. Occurrence and levels found in:

A. Plants

Potassium, in contrast to sodium, is found in abundance in plants. Most fresh fruits and vegetables contain several hundred milligrams per 100 grams, with values as high as 700-800 mg for spinach, buckwheat, and almonds (0257).

B. Animals

Potassium is abundant also in the animal kingdom where it is the principal intracellular cation as sodium is the major extracellular cation (1010). The total amount of exchangeable potassium in the average male (70 kg BW) ranges from 109 to 136 g (2474).

C. Synthetics

Potassium chloride is used in therapeutic preparations in human medicine, as a dietary supplement, in "salt substitutes", as a gelling agent, etc.

D. Natural inorganic sources

Potassium chloride occurs in nature as the mineral Sylvine (Sylvite or Sylvinite) which contains 42.7% KCl and 56.6% NaCl). Large deposits occur in Texas and southwestern New Mexico. Sylvinite is the source of about 85% of potassium salts produced in the United States (0944).

POTASSIUM CHLORIDE

Biological Data

I. Acute Toxicity

A. Mice

Pope (2600) injected mice weighing 16-24.5 g (other specifications not given), five per group, intraperitoneally, with graded doses of KCl ranging from 715 to 2740 mg/kg BW, and determined the LD_{50} value by the method of probit to be 1300 mg/kg BW (see Tables 72 and 73).

Death was preceded by general muscular weakness, paralysis of hind legs, dyspnea, and convulsions. At autopsy, the heart was seen to be in diastole. Extracts of the edible mushroom *Psalliota xanthoderma* were shown to produce the same symptoms as KCl due to their high concentration of the salt.

B. Rats

1. Boyd *et al*. (0362) determined the oral (by stomach tube) LD_{50} of potassium chloride using 109 adult female albino rats (Wistar strain), fasted 16 hours before administration of the salt. Doses of 0, 2.1, 2.4, 2.7, 3.3, 3.6, and 3.9 g/kg BW, dissolved in distilled water, were given. The animals were observed then for signs of toxicity at hourly intervals during the acute toxicity phase of the study. Bodyweight, food consumption, water intake, urine volume, urinalysis values, and colonic temperature were recorded on survivors until recovery was assured. Thirteen survivors and the controls were sacrificed at the end of 2 weeks and examined for gross and histopathologic changes, as were the mortalities. All data were subjected to the t test for statistical significance.

The LD_{50} was found to be 3020 ± 140 mg/kg BW. Death time varied from 2 to 12 hours (standard deviation interval to death was 3.3 ± 3.2 hours). Gastro-enteritis, tonic-clonic convulsions, and prostration preceded death which was caused by respiratory failure. At autopsy, the heart was dilated with blood, respiratory alveoli were frequently collapsed, most organs were dehydrated, and there was evidence of early renal tubular necrosis. Survivors manifested anorexia, polydipsia, polyuria, fever, convulsive movements, and gastro-intestinal disburbances, but they quickly returned to normal after the first day.

Table 73

Toxicity for Mice of Potassium Chloride: Intraperitoneal Injection (2600)

Mouse No.	Weight gm.	Dose level gm /kg.	Vol. injected ml.	Death time mins.
1	20·0		*0·14	S
2	21·0		0·15	S
3	19·5	0·715	0·14	S
4	20·0		0·14	25½
5	20·0		0·14	S
6	20·0		0·10	24
7	23·0		0·115	S
8	19·5	1·0	0·097	22
9	20·0		0·10	S
10	22·5		0·113	1
11	22·0		0·154	S
12	22·0		0·154	S
13	18·0	1·4	0·126	S
14	18·0		0·133	63
15	21·0		0·147	S
16	20·5		0·20	S
17	20·0		0·198	11
18	21·0	1·96	0·21	S
19	18·0		0·176	S
20	16·0		0·157	7
21	19·0		0·26	7
22	21·0		0·29	113
23	21·0	2·74	0·29	10
24	21·0		0·29	6
25	16·5		0·25	4
26	22·5		*0·62	S
27	21·0		0·58	5½
28	22·0		0·60	6
29	20·5	2·74	0·56	4
30	24·0		0·66	5½
31	24·5		0·67	6
32	23·0		0·63	4½
33	22·5		0·62	4
34	24·0		0·66	207

* 1·0 p.c. aqueous solution used. S survived.

2. Ullrich et al. (3343) determined the oral Average Lethal Dose (ALD)[a] of potassium chloride for albino rats using 12 large healthy animals of 184 g average weight (other specifications not given). The results are given below and in Table 72.

In acute poisoning, fatal doses caused increased respiration and heart action, difficulty in breathing, asphyxial convulsions, and a comatose state before death. In sub-acute poisoning, extreme depression of the CNS and a long comatose state preceded death.

3. Main (2018) injected 21-day-old female rats, 30 g average weight (other specifications not given), five per group, subcutaneously, with 5% potassium chloride solution and determined the Minimum Lethal Dose (Table 72). The maximal safe dose (no deaths) was 1000 mg/kg BW in comparison with the MLD of 1200 mg/kg BW. The time of death was approximately 1 hour after administration.

[a] 90-95% deaths within one hour

4. Ullrich et al. (3343) determined the intraperitoneal Average Lethal Dose (ALD) of potassium chloride for rats using 12 animals of the same specifications described in the oral toxicity test 2, this section (see Table 72). Symptoms were similar to those resulting from poisoning with KCl by the oral route. The time until death varied from several hours to several days.

5. Loeser et al. (1947) determined the intravenous Minimum Lethal Doses (MLD) of sodium chloride and potassium chloride in young white rats (other specifications not given). The values obtained, 90 mg/kg BW for KCl and 1800 mg/kg BW for NaCl, indicate the considerably greater toxicity of the potassium salt.

C. Guinea Pigs

1. Ullrich et al. (3343) gave 14 large healthy guinea pigs, average weight 649 g, (other specifications not given) potassium chloride per os in an Average Lethal Dose (ALD) determination. The value obtained, 2500 mg/kg BW, was very close to that for rats (see Table 72). Symptoms and death time were the same as those observed in these animals (see this Section, B., 2).

2. The same authors (3343) injected 14 guinea pigs (same specifications as in preceding study) intraperitoneally with M/1 potassium chloride solution and calculated the Average Lethal Dose (ALD) (see Table 72).

Symptoms and death time were the same as those for rats in the studies described above. The authors stated that the toxicity of sodium and potassium chlorides is evidently due to the depression which they eventually produce, particularly of the nervous system.

3. Levy et al. (1911) determined the intramuscular MLD of potassium chloride in the guinea pig (510-800 g BW) to be 950 mg/kg BW. Death occurred in 78% of the animals 10 to 15 minutes after onset of dyspnea, cardiac arhythmia, convulsions, paralysis of the anterior quarters, and decreased respiration.

4. Amberg et al. (0050) injected guinea pigs, 200-240 g in weight (other specifications not given) intravenously with potassium chloride, and observed the animals for toxic effects and mortality. The Fatal Dose (FD) was 80-87 mg/kg BW.

D. Rabbits

1. Topchyan et al. (3292) determined the oral Minimum Lethal Dose (MLD) of potassium chloride for the rabbit to be 2000 mg/kg BW. Death time ranged from 7 to 36 hours. A single dose of 1000 mg/kg BW caused toxic symptoms but

the animals recovered. Nine rabbits (specifications not given) were used in the study with doses of 1000, 2000, and 3000 mg/kg BW.

2. Truscoe et al. (3316) injected male New Zealand white rabbits (Natl. Naval Med. Res. Inst. strain), weighing 750-2400 g, intraperitoneally with doses of KCl of 550, 575, 600, 625, or 650 mg/kg BW, in a study of the relationship between blood plasma levels and toxicity. Plasma potassium concentrations were determined at 5 minute intervals following injection as the animals were observed for toxic signs and mortalities.

The Minimal Lethal Dose proved to be 575 mg/kg BW with a death time between 14 and 30 minutes. Terminal plasma potassium values ranged from 58 to 85 mg/100 ml for fatalities. Sublethal doses caused only slight elevations in the plasma level. Repeated injections of sublethal doses of KCl after 24 or 72 hours raised plasma K to much higher levels than the initial injection.

The authors concluded that their findings were consistent with the view that potassium is rapidly taken up from the plasma into cells, where it is retained. Intracellular potassium is then slowly released so that the protoplasm becomes saturated and the cells are then unable to deal efficiently with later increases in plasma potassium.

3. Pope (2600) injected six rabbits (specifications not given) with KCl intravenously at levels of 40, 56.6, and 80 mg/kg BW in an acute toxicity study. Three animals of the same specifications were included as untreated controls (see Table 72). The Minimum Lethal Dose (MLD), 80 mg/kg BW, killed the animals in 1 1/4 to 1 1/2 minutes. Death was preceded by dyspnea and convulsions. Dose levels of 40 and 56.6 mg/kg BW caused dyspnea, but the animals recovered.

E. Sheep

Topchyan et al. (3298) administered KCl orally, to sheep maintained on a normal ration, in single doses of 2000, 3000, and 4000 mg/kg BW and observed the animals for toxic signs and mortalities. Six animals (specifications not given) were used in the study.

The MLD in the non-fasted animals was 4000 mg/kg BW with a death time ranging from 40 to 85 minutes. Salivation, vomiting, heart throbbing, accelerated breathing, mydriasis, staggering walk, spasms, and finally coma, preceded death. Sublethal doses caused depression, refusal to eat, polyuria, increased respiration rate, and rapid pulse for a period of 4 to 6 hours, but the animals recovered without any further signs of toxicity.

F. Goats

Topchyan et al. (3292) studied the acute oral toxicity of potassium chloride for goats on a salt-poor diet (no added salt for 1 1/2 months) as compared with animals on a normal ration. A single oral dose of 4000 mg/kg BW caused death within 32 to 85 minutes in the salt-deficient animals whereas those on a normal feed ration survived, although there were some clinical signs of toxicity the first day. The following toxic effects were observed in the animals given lethal amounts of KCl: vomiting, polyuria, tetanic spasms of muscles of the extremities, accelerated respiration and pulse. At autopsy, the kidneys were swollen with strongly congested capillaries, the heart muscle was flabby, and the rumen, reticulum, abomasum, and duodenum mucosae were hyperemic.

II. Short-term Studies

A. Mice

Mescherskaya-Steinberg (2170) obtained very illuminating results in an investigation of the relationship between age level and toxicity of potassium chloride in mice. Three hundred and sixty-four experiments, in replicates of ten at least, were carried out on mice at different life periods injected subcutaneously with potassium chloride at a level of 1000 mg/kg BW. The effect of atropine treatment on KCl toxicity was determined also. The major findings during early life were as follows:

Table 74

Relationship of Age of Mice on KCl Toxicity (2170)

Age (days)	Mortality
0 - 3	0
3 - 7	20 - 25
8	80
9 - 42	100

After the 6th week of age, the mortality rate gradually decreased to a low of 21% at the onset of sexual maturity (13-16 g BW). Pregnancy raised the death rate to 100% but the embryos were not killed. (There was no statement concerning fetal abnormalities.) Atropine, 500 mg/kg BW, decreased KCl mortality from 100% to 28% after the 8th day of age. From age 1-8 days, however, atropine was without effect on KCl toxicity.

B. Rats

1. Drescher et al. (0838) administered excess potassium chloride in the diet of healthy male Sprague-Dawley rats, 150-200 g BW, over a period of several weeks and determined toxic effects and influence on body potassium stores. The potassium load was increased stepwise from a normal intake of 1.6 to 36.8 mEq per 100 g BW per day.

One-half of the animals died within a 3-day period at a calculated LD_{50} of 60 mEq/rat/day. Toxic symptoms observed were rough coat, irritability, lethargy, and generalized weakness. Adrenal enlargement was noted at autopsy. Survivors showed pathologic elevations of plasma potassium levels and characteristic electrocardiographic changes together with a significant decrease in cardiac intracellular potassium concentration but no significant change in total carcass potassium. Intakes below 25.6 mEq per 100 g BW per day were not toxic.

2. In a study of the effect of potassium chloride on the heart, Baccheus (0163) discovered that excess dietary KCl caused a decrease in cardiac mass in the rat. Fourteen female Wistar rats weighing 206 g were placed ad libitum on Purina laboratory chow and 2.5% aqueous potassium chloride as the sole source of fluid. Six control animals received the same diet with tap water in place of KCl solution. Food consumption and fluid intake were determined at 2 to 3 day intervals for 105 days. At that time, 10 of the test animals and six of the controls were killed for histologic study; four test animals were placed on tap water instead of KCl for an additional month and then sacrificed for pathologic study. The heart and paired kidneys were weighed. Ascorbic acid, cholesterol and other lipids were determined in the adrenals. Water content of the heart and left gastrocnemius muscle of some animals in each group was determined. Adrenals and kidneys were examined microscopically for pathologic changes.

The major findings in the study were that excess dietary potassium chloride over a period of 3 1/2 months caused a decrease in the weight of the heart, an increase in the weight of the kidneys, and hypertrophy of the glomerular zone of the adrenals. Results following discontinuation of KCl flooding indicated that the changes were reversible.

C. Rabbits

Underhill et al. (3340) intravenously injected rabbits suffering from tartrate nephritis and normal control animals with potassium chloride and determined the effect on urinary nitrogen, chloride, and systemic toxic effects. In normal rabbits, doses of 240, 310, and 330 mg/kg BW of potassium chloride caused death in from 10 to 23 minutes. In nephritic animals, doses of KCl of 230, 310, and 430 mg/kg BW, caused death in 12 to 21 minutes. Sodium chloride, on the other hand, was tolerated by nephritic animals at levels of 750-900 mg/kg BW intravenously. Results on nitrogen and salt excretion are given in Tables 1, 2, and 3 of original article. The authors concluded that nephritis does not render rabbits more susceptible than normal animals to the toxic effects of KCl which is commonly used as a diuretic.

D. Dogs

1. Schamp (2901) injected 6 dogs (specifications not given) intravenously with 6% or 8% potassium chloride by a continuous method at a rate of 6 cc per hour until death occurred. In addition to observation for toxic signs and mortalities, the following blood serum and urine determinations were made: potassium, sodium, chloride, urea, and glucose. Hematocrit and rectal temperature measurements were made also in some instances.

Death occurred in 3-12 days at the 6% KCl level. The single dog injected with 8% KCl died within 2 days. Since the primary purpose of the study was investigation of the relationship between potassium poisoning and adrenal insufficiency, injections were made at a very slow rate and potassium toxicity relationships per se were difficult to estimate because of excretion over a period of 2 to 12 days.

The authors pointed out that an increase in urine sodium was the only symptom of adrenal insufficiency observed. There was no anorexia, asthenia, or convulsions in any of the animals. They concluded, therefore, that potassium poisoning was probably not the cause of adrenal insufficiency in the dogs (See original article for details).

2. Boley et al. (0328) compared the effects of potassium citrate and potassium gluconate with that of potassium chloride on the intestinal mucosa of the dog. The authors pointed out that the mechanism of ulceration and stenosis due to therapeutic KCl tablets is believed to be due to the rapid release and absorption of KCl in high concentration over small areas of the intestine causing venous spasm in the submucosal and mural veins. "The

resultant venous stasis causes segmental hemorrhagic infarction of varying severity with ulceration and stenosis."

Preliminary studies indicated that the citrate and gluconate salts of potassium would be less likely to be absorbed rapidly enough to cause intestinal lesions. Consequently, tablets of potassium chloride, potassium gluconate, and potassium citrate in combination with hydrochlorothiazide were fixed within the ileum or distal jejunum of mongrel dogs. The animals were observed and sacrificed after 5 to 7 days and the implantation sites studied microscopically. The authors concluded that potassium citrate and gluconate salts, especially in slow release form, appear to be safe for oral administration.

3. Chou et al. (0548) determined the effect of KCl, KCl-hydrochlorothiazide, and control tablets on intestinal blood flow, contraction, luminal pressure, and intestinal lesions in the dog, in a study of the mechanism of KCl-induced intestinal ulcers. Mongrel dogs (15 to 18 kg) were anesthetized and a loop of ileum or jejunum exteriorized and divided into two segments so that the blood flow from each was drained by a single vein (See original article for details). Tablets containing varying concentrations of KCl (572-975 mg), with or without hydrochlorothiazide, were placed into the lumen of one segment and glass beads into the other. The venous outflow from each segment, plasma K or Na concentration, and osmolality of the venous plasma were determined. After the experiment, the intestinal segments were examined grossly and microscopically for lesions. Six or seven animals were used for each test substance and the data were examined statistically by means of the student's "t" test.

Potassium chloride or hydrochlorothiazide-KCl tablets caused a short initial rise followed by a progressive decrease in blood flow and a steady rise in K concentration of the venous plasma from the segment. Tonic contractions of the segment, an increase in luminal pressure and edema, hemorrhage and superficial corrosion of the tissue were noted also. Glass beads or hydrochlorothiazide alone caused little or no effect (See Figures 41 and 42 and original article for details).

The authors suggested that ulcers produced during therapy with KCl tablets might arise from a combination of local mucosal damage by hyperosmolality, reduced blood flow, and increased tonic contractions of the intestine. In a chronic study, dogs given KCl tablets (975 mg) twice daily for 2-3 weeks did not develop ulcers although several showed hemorrhage, hyperemia and edema of the duodenum and ileum at necropsy (See original article for details).

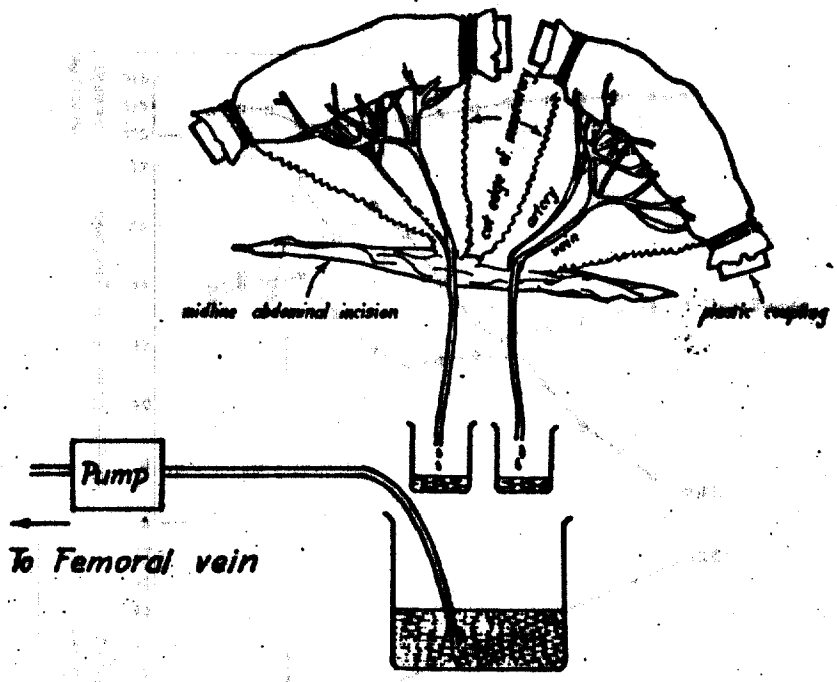

Figure 41 (0548)

Schematic drawing of the preparation. The veins were cannulated, but the arteries and nerves remained intact.

E. Sheep

Topchyan et al. (3292) administered repeated oral doses of KCl (1000 or 2000 mg/kg BW daily) to salt-deficient sheep over a period of 10 days and observed the animals for clinical signs of toxicity and blood dyscrasies. Four animals maintained on a salt-poor ration for three months were used in the study.

All animals survived but experienced depression, temporary loss of appetite, and accelerated respiration and pulse rate during the first half day. Hematologic studies disclosed leucocytosis and a lowered alkali reserve. It was suggested that changes in the leucocyte count might be used to follow the course of KCl poisoning in the species.

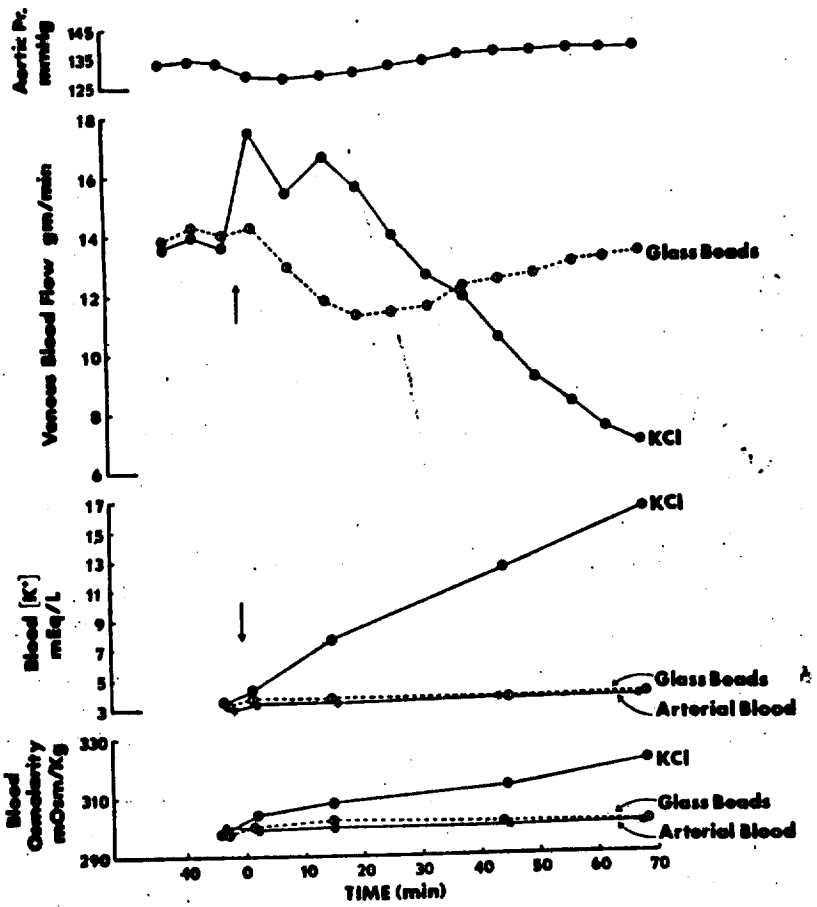

Figure 42 (0548)

Average effects over 70 min. when KCl tablets and glass beads were placed in the 2 segments. Arrows indicate time of placement of tablets (N = 6).

F. Monkeys

Diener et al. (0796) gave rhesus monkeys (Macaca mulata), weighing 4-6 kg, enteric-coated tablets containing varying amounts of KCl with and without thiazides, in parallel with enteric-coated placebos and enteric-coated thiazide without KCl as controls, in an effort to find a counterpart of the lesions produced in humans by these medications. Doses of KCl ranging from 100 mg to 2000 mg were administered twice daily for 4 1/2 days. The animals were then sacrificed on the fifth day and the entire gastrointestinal tract examined in minute detail for lesions.

Intestinal ulcers, similar to those observed in humans, developed in the animals within 5 days after administration of 1000 mg of KCl in enteric-

coated tablets twice daily; 250 mg doses produced lesser lesions; 100 mg tablets caused no disturbance. Commercial thiazide-KCl diuretic tablets caused effects ranging from hyperemia to perforating ulceration. Gradual release tablets (72% release in 2 hours) produced gross lesions mainly in the stomach or duodenum. Enteric-coated placebo and/or enteric-coated thiazide produced no lesions.

G. Human toxicity

1. Bostic et al. (0347) described a fatal case of hyperkalemic cardiac arrest during transfusion of stored blood attributed to high levels of potassium in the plasma. A 9-year-old boy with pulmonary lacerations resulting from being struck by an automobile was given 1500 ml of blood bank blood which was 12 days old or over and contained 7.5 to 13 mEq/l of K^+. Electrocardiographic findings, as his condition worsened, were suggestive of hyperkalemia. The boy died in spite of corrective therapy.

The author warned of the potassium hazard that may exist with stored blood bank blood resulting from leakage of potassium ions from the red blood cells into the plasma. Pressure pumping adds to the hazard. Fresh blood should be used for rapid transfusions.

2. Campbell (0475) investigated plasma potassium levels in newborn infants undergoing blood transfusions for hemolytic disease. A number of deaths led to the suspicion that the stored blood may have contained excess potassium in the plasma.

Three of twenty infants died suddenly following transfusion and all had potassium levels between 32-40 mg per 100 ml. (A fourth death of a premature infant - 4 lb 6 oz - was excluded). Potassium concentrations in the blood used for the transfusions were 22.3, 29.7, and 43.5 mg/100 ml (see Table 75).

In an effort to reduce the danger of hyperpotassemia in subsequent transfusions, the author administered 2 units of insulin into the umbilical vein of 17 infants after the first 100 ml of blood had been exchanged. Fourteen of the 17 infants had blood potassium levels below 32 mg/100 ml and there was only one death (a 6-lb child with intense jaundice who died from hernicterus). The blood bank blood had potassium concentrations of 23.5, 29.9, and 36.9 mg/100 ml (see Table 76). The blood used in all transfusions had not been in storage for more than one week.

The authors stated that hyperpotassemia is not uncommon in the course of exchange transfusions for hemolytic disease of the newborn and that lethal levels may be reached. They concluded, however, that results of their study did not indicate that the potassium levels in the infants were directly related to those in the stored blood used in the transfusions.

Table 75

Potassium Levels (mg. per 100 ml.) in Control Group (0475)

Maximum in Bottle	Mean in Bottle	Maximum in Child						Mean of Maximum Levels in Children
		-20	24	28	32	36	40	
Below 26	22·34	1	2	1*	2	1*	..	25·83
26–32 ..	29·66	1	1	3	—	—	1*	26·3
Over 32	45·3	1	3	2	1	1*	—	25·95

* Indicates deaths.

Table 76

Potassium Levels (mg. per 100 ml.) in Insulin Group (0475)

Maximum in Bottle	Mean in Bottle	Maximum in Child						Mean of Maximum Levels in Children
		−20	−24	−28	−32	−36	−40	
Below 26	23·48	2	3	2	—	—	—	21·91
26–32 ..	29·94	3	—	1*	1	—	2	26·6
Over 32	36·86	1	—	1	—	—	1	27·66

* Indicates deaths.

3. Shapiro et al. (3013) recently reported on five fatal cases of hyperkalemia in 27 deaths from drug reactions in a series of 6,199 consecutively monitored patients on drug therapy. All patients were receiving potassium chloride, alone or in combination with other drugs, up to the time of death. The results are summarized in Table 77.

Table 77

Deaths Due to Hyperkalemia in Patients on Potassium Chloride Therapy (3013)

Case No.	Disease	KCl Dosage (mEq/day)	Serum K level at death (mEq/liter)	Cause of Death
1	Cirrhosis	90	8.8	Hyperkalemia
2	Carcinoma of Breast	60	7.2	Hyperkalemia
3	Mitral Stenosis	45	7.1	Hyperkalemia
4	Cirrhosis	45	7.7	Hyperkalemia
5	Congestive Heart Failure	90	8.0	Hyperkalemia

The authors call attention to the high percentage of deaths due to hyperkalemia in this group of drug reaction fatalities (16%). (See original article for case histories.)

4. Chambers (0508) reported a fatal case of potassium chloride poisoning where an ampoule of 15% KCl solution was injected into the tubing of a drip bottle instead of into the bottle itself; the patient died from irreversible cardiac arrest. The author warned also about the dangers inherent in rapid infusions of standard maintenance fluid for intravenous therapy. The rate of infusion of KCl solution should never be greater than 20 mEq per hour.

5. According to Kwasniewski (1815) potassium chloride levels as low as 167 mg/kg BW produce serious symptoms of poisoning and 250-334 mg/kg BW are lethal for adults. KCl gives rise to chloric acid in the body which converts hemoglobin to methemoglobin and hematin which may cause thromboses and embolisms. Death results from cyanosis since methemoglobin is incapable of releasing oxygen to the tissues.

Since potassium chloride is used as a gargle in cases of sore throat, the author pointed out that its labeling should include a caution as to toxic effects. Potassium chloride is used internally also in human medicine as a diuretic and for other purposes, and its dosage must be carefully regulated.

6. Schwartz et al. (2951) described the electrocardiographic changes which occur at different levels of serum potassium, from normal levels of 3.5-5.3 mEq/liter to fatal concentrations of 14-16 mEq/liter which cause cardiac arrest. The manifestations in a case of transient hyperkalemia due to an

inadvertently rapid infusion of a therapeutic KCl solution are presented and described. (See original article for details.)

7. Brown et al. (0414) described a case of paroxysmal cerebral dysrhythmia in a patient with Ménière's syndrome treated for a period of two years with doses of KCl ranging from 2 to 12 g per day in addition to a low sodium diet. The authors concluded that the cerebral dysrhythmia was related to the large doses of KCl administered.

8. With human volunteers, Keith et al. (1664) studied the effects of relatively large doses of potassium chloride administered orally and parenterally on renal clearance, sensory nerve endings, and heart action. Doses of 9.5 g intravenously over 90 minutes and a single dose of 12.5 g orally (60-100 mg/kg BW of K) were tolerated without evidence of toxic effects by two subjects. The potassium clearance rose from the normal fasting level of 6 to 14 cc/1.73 sq. m./minute to 58 cc and 49 cc, respectively.

In another experiment, however, one individual given 12.5 g of KCl orally, and a second subject fed 17.5 g of $KHCO_3$ (80-100 mg/kg BW of K) showed evidence of disturbed renal function. The authors concluded that a single dose of a potassium salt containing 80-100 mg of potassium per kg of body-weight may have a toxic action on the kidney in man. General paresthesia in hands and feet occurred also after ingestion of 12.5 g of KCl.

Two normal subjects and a patient with diffuse cardiovascular disease and hypertension given single oral doses of 12.5 g KCl showed different effects on the electrocardiogram. The concentration of potassium in the serum and the T-waves in the electrocardiogram rose steadily in all three subjects until a maximum was reached in approximately two hours. In the normal volunteers, there was a gradual decline in serum potassium and T-waves to control values in 4 to 6 hours. In the vascular disease patient, however, the fall in serum potassium was much slower, and the T-waves of the electrocardiogram were still normal after 12 hours.

The authors warned that although normal individuals may tolerate a considerable amount of several potassium salts, their use is contraindicated in patients with renal disease and adrenal insufficiency. They pointed out that a warning symptom indicating toxic concentrations is the development of paresthesia in the hands and feet.

9. Ulcers and stenosis have been observed in a large number of patients receiving enteric-coated tablets containing potassium chloride (0095). In most instances the potassium salt was incorporated with one of the thiazide drugs prescribed for control of hypertension. KCl (500 or 1000 mg) is incorporated in the medication to replenish potassium lost through increased urinary excretion. The authors pointed out that although a large number of patients receiving this form of medication have experienced intestinal lesions, it is still a small percentage of the total number treated. One estimate is that only one in 35,000 patients given the enteric-coated KCl tablets show evidence of lesions. Ulcer-formation was found to be due to the release of a large amount of KCl as the tablet disintegrates and the absorption of the entire dose in a small area of the gastrointestinal tract.

10. Wynn (3582) described results with the use of a wax-base, sugar-coated tablet for KCl therapy. Unlike enteric-coated tablets which disintegrate and are virtually dissolved in 15 minutes, the KCl is dissolved out of the new tablet gradually over a period of 4 hours leaving the wax as a spongy matrix. Since ulceration due to conventional enteric-coated tablets is due to the rapid release of a large amount of KCl over a very small area of the intestine, this hazard is eliminated by the slow release from the new preparation. No intestinal disturbances have been observed over a period of 6 months.

11. Winkler et al. (3554) studied the response of patients with varying types of renal impairment to oral doses of potassium chloride ranging from 67 mEq to 134 mEq of K. Serum potassium levels, rate and amount of potassium excreted in the urine, and urea clearance, were determined at varying intervals over a period of 6 1/2 to 7 hours.

The authors concluded from the results obtained that the relatively slow gastrointestinal absorption of potassium tended to prevent high concentrations in the serum. The clearance of potassium, even in severe renal diseases, rose above the fasting level and the increased excretory rate resulted in elimination of extra ingested potassium after some hours.

According to the authors, it is difficult to administer amounts of potassium too great to be regulated by storage and excretory processes without causing nausea and vomiting. Studies with dogs, however, have indicated that if urinary excretion is interfered with, severe toxicity and death can result from the toxic effect of ingested potassium.

12. Haddy (1302) in an editorial on potassium deficiency and heart function, pointed out that sodium salts sensitize the myocardium to experimental necrosis in association with potassium and magnesium deficiency. Prolonged incubation of isolated cardiac muscle in a potassium-free medium is harmful to contractility; the electrical abnormalities are reversible but the tension change is not. It has been found that these increases in contracticle tension are associated with major changes in the cellular membrane potential: (1) increase or decrease in the resting potential, (2) increase in amplitude of the action potential, (3) increase or decrease in the overshoot, and (4) accelerated early repolarization and prolongation of late repolarization.

Decreased extracellular potassium concentration may also increase norepinephrine efflux from sympathetic nerve endings. Reduction of the potassium level by 50% in coronary arterial blood causes an almost immediate 82% increase in contractile force. The author pointed out that contracticle changes associated with reduced potassium in experimental studies is complicated by the prolonged K deficiency which also induces other electrolyte abnormalities.

III. Special Studies

A. Amphibians

Lehmann (1882) found that potassium chloride enhanced the teratogenic effect of lithium chloride on the salamander (*Triton alpestris*) and the frog (*Rana fusca*). Frog embryos treated as blastulae with a mixture of KCl (1:160) and LiCl (1:200) for 17 hours at 18°C, developed without eyes, had an abnormal brain structure, and a very defective anterior portion. "A neural tube with a sagital cleft situated inside a partially bilateral band of somatic substance was found in the anterior portion of the trunk. The chorda was completely absent from the anterior end of this region but appeared in a further caudal direction." Potassium chloride (1:80) and lithium chloride (1:200) alone, did not cause any abnormalities.

The abnormalities found in the frog resembled those observed in the salamander after lithium treatment with the exception that a stronger necrotization of all tissues was evident.

B. Human toxicity

Golberg (1195) and Shaw (3018) reported that an excess of potassium ions leads to damage in human chromosomes stemming from attenuation and exaggeration of the hetero-chromatin regions.

POTASSIUM CHLORIDE

Biochemical Aspects

I. Drug Interaction

A. Guinea pigs

Lévy et al. (1911) found that camphor has a marked protective effect against KCl cardiac toxicity in the guinea pig and in the dog. In guinea pigs injected with 200 mg of camphor and then with 1000 mg/kg BW of KCl, 67% of the animals survived whereas all of the control animals injected with the same amount of KCl alone, died in 60-65 minutes.

The authors pointed out that potassium causes cardiac diastolic arrest by directly paralyzing the cardiac muscle fibers rendering them unable to contract. Camphor, on the other hand, in small amounts, improves the amplitude and rhythm of heart movements and has been shown to protect it from injury by certain other drugs and poisons such as chloral hydrate, digitalis and chloroform. In large doses, however, camphor acts as a cardiac depressant.

B. Dogs

1. Lévy et al. (1911) also found that dogs given intravenous injections of the salts of camphocarbonic and camphosulfonic acids tolerated intravenous injections of 2 cg/kg BW of KCl repeated 13 to 15 times, and doses of 3 cg/kg BW repeated from 2 to 7 times. Untreated animals, on the other hand, succumbed to 2 cg/kg BW of KCl after 4 or 5 intravenous injections.

2. Brandfonbrener et al. (0375) found that high levels of serum potassium, 6-9 mEq/liter (hyperkalemia), decreased survival time in mongrel dogs (10-17 kg) poisoned with quinidine. Hypokalemia (3.22 - 3.32 mEq/liter of serum potassium), on the other hand, protected against the prolongation of the intraventricular conduction disturbance due to quinidine but did not prolong survival significantly.

The authors pointed out that it has been established that an increase in potassium in the medium potentiated the action of quinidine on isolated rabbit atria in vitro; i.e., it increases the refractory period and depresses the rate and amplitude of the beat. Decreased concentrations of potassium antagonize this quinidine effect.

C. Humans

1. Salokannel et al. (2852) studied vitamin B_{12} absorption in 30 hospitalized patients on potassium chloride therapy (500 mg KCl in a slow

release tablet) by means of the Schilling test using 0.5 μg of CoB_{12}. None of the patients suffered from pernicious anemia or other known reasons for vitamin B_{12} malabsorption.

The data obtained clearly indicated the marked impairment of vitamin B_{12} absorption due to KCl in 11 of the 30 patients (4.8 av.) as compared with control values in the same patients without KCl (11.4 av.). In the other 19 patients, test values were normal with KCl (15.4%) and without the medicant (15.5%). In some patients, pH measurements in the ileum indicated malabsorption of vitamin B_{12} at values below 6 but not above that level even with potassium treatment.

2. Gershberg et al. (1149) discovered that potassium chloride potentiates the hypoglycemic effect of acetohexamide in diabetic patients. Daily administration of 30 ml of a 25% KCl solution in conjunction with acetohexamide therapy to 11 patients increased the reduction of fasting glucose concentrations by 23 mg/100 ml over values without KCl supplementation. The authors stated that the results suggest KCl either aided glucose utilization or provoked insulin secretion.

3. Sidon et al. (3053) found that KCl (1.5%) in combination with 2% lidocaine produced local anesthesia of longer duration than that of lidocaine alone, in two groups of dental patients and one group of volunteer control subjects. The authors proposed that the mechanism involved is that the injected KCl increases the K^+ concentration on the outside of the nerve membrane thus reinforcing and prolonging the blockage produced by lidocaine. The authors noted that it has been established that an accumulation of K ions on the outside of a neuron can effectively block a nerve impulse. It was suggested that KCl in combination with lidocaine would be less hazardous for use with cardiac patients than the more effective combination of lidocaine and the vasoconstrictor, epinephrine.

II. Effects on Enzymes and Other Biochemical Parameters

Humans

In a review on the biochemistry and therapeutic applications of potassium, Talbott et al. (3257) discussed the following uses of potassium chloride in human medicine:

(a) In edema caused by renal, hepatic, or cardiac failure, doses of 5 g have been found to be effective as a diuretic in some cases, but not in others.

(b) Hayfever and urticaria patients have responded to treatment (1-6 g daily) with improvement or complete relief of symptoms within 3 days.

(c) In Familial Periodic Paralysis, daily oral doses of 2-5 g have been effective in preventing paralytic episodes.

(d) Myasthenia gravis responds well to treatment with potassium chloride, according to the authors. Daily doses of 5 to 15 g are used along with prostigmine. However, some cases have been found where 30 to 40 g per day were needed.

(e) In Ménière's syndrome, doses of 2-10 g daily relieve symptoms.

III. Consumer Exposure Information

A. Intakes, usage levels, poundage and import data

The possible daily intake of potassium chloride - all food categories - is on the average, as follows (1012):

Age	Mg
0 - 5 months	244
6 - 11 months	509
12 - 23 months	866
2 - 65+ years	1719

The possible daily intake of potassium chloride - all food categories - at the highest, found in the literature search is (1012):

Age	Mg
0 - 5 months	453
6 - 11 months	1408
12 - 23 months	1776
2 - 65+ years	3039

Foods in which there is the maximum use of potassium chloride, and the amount, according to the literature search are (1011):

Food Category	Wtd Mean, %
Seas Flavrs (R)	22.9
Baked goods (R)	0.8
Soups (R)	0.8

The maximum usage level reported for potassium chloride in infant formula products and baby foods is 0.06 (Wtd mean, %) for formulas (1013).

The total 1970 poundage of potassium chloride reported to National Academy of Sciences together with Food Extracts Manufacturers Association (NAS & FEMA) was 795,146 (1014).

The amount of potassium chloride imported in 1971 was 4,549,098 (STN)[a]; in 1973, the amount was 5,898,988 (STN) (3331).

Potassium chloride is used in the food industry as a nutrient, dietary supplement, gelling agent, salt substitute, and yeast food (0598). See Comprehensive GRAS Survey tables for the amount of KCl in various food categories and intake data related to age groups (1011, 1012, 1013).

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[a] STN = Short ton (2000 lb)

SODIUM AND POTASSIUM CHLORIDE

SODIUM CHLORIDE AND POTASSIUM CHLORIDE

Biological Data

I. Special Studies

A. Chick embryos

1. Grabowski (1236) detected marked $Na^+:K^+$ imbalances in chick embryos treated with trypan blue and several other teratogenic agents and attributed certain malformations observed to an edema syndrome which resulted from the serum and fluid electrolyte imbalance.

2. In a study involving 600 chick embryo tissue cultures, Rumyantsev (2822) noted that an excess of either NaCl or KCl in the medium caused pathologic effects in the cytoplasm and nuclei of the embryonic cells.

In the first series of experiments (I), slide cultures were prepared with bits of myocardium tissue from 6 to 8 day old chick embryos suspended in one drop of the chloride test solution and the smallest possible drop of plasma. In the second series (II), the medium consisted of 1 part of plasma and 2 parts of chloride solution. The cultures were examined after 2-3 days in the dark-field, and in passing light, unstained and after staining with vital dyes. Two hundred and fifty (250) test cultures and 50 controls were used in each series.

Excess sodium chloride caused vacuolization in the cytoplasm, alterations in the chondriosomes, and changes in the nucleus; the effects were more pronounced in medium I than in II. Excess potassium chloride produced essentially the same kind of changes as noted with NaCl but the effects were more severe.

The authors concluded that the vacuolization observed was a result of swelling and compression of protoplasm due to its pronounced hydration and a great increase of the "hydrous phases".

SODIUM CHLORIDE AND POTASSIUM CHLORIDE

Biochemical Aspects

I. Breakdown

Sodium chloride and potassium chloride are stable salts under most conditions. When melted or dissolved in water, however, they ionize in accordance with the laws of physical chemistry:

$$NaCl \rightleftharpoons Na^{+} + Cl^{-}$$

$$KCl \rightleftharpoons K^{+} + Cl^{-}$$

II. Absorption-Distribution

Parsons (2512), in a review of salt and water absorption by the intestinal tract, indicated that these processes resemble transcellular Na transport, widely distributed in other epithelial cells in nature, which appear to be dependent upon a system of "pumps" and passive "leaks" located in the limiting membranes of the cells (2512). In the dynamic steady state, it is believed that there is a constant exchange of the ions between the cell interior and environment, in which the rate of ionic movement in one direction through the leaks is equal to that through the pumps in the opposite direction. The electrochemical potential of Na inside the cell is less than that outside whereas that of K is the reverse.

According to Parsons, most of the ion movement detected across many epithelia is active sodium transport and more moles of Na than any other ion are absorbed by the renal tubules of mammals. The author goes on to say that, in man, the amount of water and salt presented to the intestine each day by the gastrointestinal secretions, is considerably greater than the dietary intake.

In the duodenum and jejunum, salt moves from the blood into the intestine when hypotonic solutions enter the latter while in the lower small intestine, a net absorption of NaCl occurs from hypotonic solutions (2512). There is evidence, according to the author, that Na is subjected to active transport from the lumen across the ileal intestinal mucosa into the blood and that the process is dependent upon cellular metabolism and membrane ATPases (2512). Transport of amino acids and certain sugars, as well as perhaps K and Cl appear to be associated closely with the transport of sodium, according to Parsons (2512).

Potassium is found in most foods and is absorbed readily in the gastro-intestinal tract (2474).

With regard to distribution, sodium and chloride are the main extra-cellular ions in the body and potassium is the major intracellular ion (1010). The concentration of sodium in man is 41 to 43 milliequivalents per kilogram of bodyweight; in blood serum the range is 134 to 141 milliequivalents per liter; approximately 25% of the total body sodium is distributed in the bony structure of the body (2474). The total exchangeable potassium in the normal human male is 40 to 50 milliequivalents per kilogram bodyweight and 97% is intracellular; blood serum contains only about 5 milliequivalents per liter (2474).

Bor, Flexner, Janovsky, and co-workers have investigated absorption-distribution of sodium chloride in the fetus and newborn.

A. Sheep

Bor et al. (0335) injected eight pregnant ewes, (specifications not given), in the last month of confinement, intra-amniotically with radiosodium chloride (25 to 40 microcuries) and determined the levels of the radionuclide in various organs of the fetus in an effort to find the transfer site of amniotic fluid constituents. The data obtained clearly indicated that the fetal membranes are the most important tissues involved in the exchange of sodium.

B. Humans

1. Flexner et al. (0999) investigated the permeability of the human placenta to sodium in twenty-seven women, using radio-active sodium, from the ninth week of gestation until term. A considerable increase in permeability of the placenta to sodium occurred as gestation proceded with a peak at the 36th week when it was approximately 70 times as great as at the 9th week; a rapid decline in permeability to term followed.

According to the authors, at the 12th week of pregnancy, the fetus receives across the placenta 160 times as much sodium as is incorporated into the growing tissues, and at the 40th week, 1100 times that incorporated. Chronic hypertension in five patients studied had no effect on the rate of sodium transfer.

2. Janovsky et al. (1574) studied the distribution of fluid, sodium, and chloride in the body of young infants given milk with excess sodium chloride.

Four newborns (14 days of age) and 2 infants (42 days old) were given 750 mg of NaCl for every 100 ml of milk consumed until the increase in body-weight was at least 170 g (2 to 3 days). Urine, stools, and sweat, as well as blood samples, were collected and analyzed for sodium, potassium, and chloride. The volume of extra-cellular fluid was determined by the distribution space of thiosulfate method. Water and electrolyte balances for 24 hour periods were calculated.

The urine flow decreased, and the excretion of sodium and chloride in urine, feces, and sweat increased, during feeding of excess salt in milk. A gain in bodyweight occurred simultaneously with expansion of the extracellular fluid volume. Retention of sodium and chloride in tissues was higher than in the extracellular fluid; some of the excess was present in the erythrocytes (Table 78 and 79).

Fifty-eight to 68% of the sodium consumed, and 63-75% of the chloride, was retained (Table 79). Fifty-one to 57% of the sodium, and 34-40% of the chloride, was dissolved in the extracellular fluids. Sweat losses were not an important factor. The potassium concentration of the blood was unchanged. The decreased urine flow observed was believed to be due to increased reabsorption of water rather than to a fall in the glomerular filtration rate.

The authors concluded from the data obtained that osmoregulation in young infants is imperfect since both the volume and the osmolality of the extra-cellular fluid (ECF) are unchanged and since a large amount of excess electrolytes consumed is stored outside the ECF. The results obtained are in agreement with those of other workers who have demonstrated that the regulation of water and salt homeostasis in infants is less precise than in adults. The new-born kidney does not react, even to hypertonic NaCl or Urea, with osmotic diuresis as effectively as does the adult.

III. Metabolism and Excretion

Electrolyte metabolism is a vast subject and regarded by experts in the field as one of the most complex in all of physiology. Unfortunately, much of it is only imperfectly understood at present.

Sodium, potassium, and chloride ions in proper concentration and balance are indispensable for a number of normal physiologic processes (0269, 1255, 2281). Sodium is the most important ion in maintenance of proper osmotic pressure, body-fluid balance and hydration of tissues (1010, 2474). Sodium must be restricted in the treatment of edema (cardiac, renal, or hypoproteinemic) (2474).

Table 78

The Effect of Increased Intake of NaCl on Bodyweight and Extracellular Fluid/ECF/Volume (1574)

Infant	C.	H.	K.	R.	M.	S.	Mean 15 days	Mean 42 days	Mean of all infants
Age in days	15	15	15	15	42	42			
Body weight 1 (grams)	3.000	3.200	3.330	3.220	4.340	4.500	3.187	4.420	3.598
Body weight 2	3.170	3.370	3.500	3.450	4.510	4.470	3.372	4.640	3.795
ECF_1 volume in % of body weight	42.6	43.5	39.7	41.2	38.8	38.6	41.7	38.7	40.7
ECF_2 volume in % of body weight	45.0	46.2	42.0	44.3	40.3	41.4	44.4	40.8	43.2
Increment of body weight in grams	170	170	170	230	170	270	185	220	197
Increment of ECF in ml	150	170	176	201	136	242	174	189	179
Period of increased NaCl intake (ECF_1–ECF_2) in hours	24	27.5	48	48	24	24			
Na and Cl serum concentration									
Na_1 meq./kg serum	142.1	136.0	140.0	144.1	141.0	132.0	140.5	136.5	139.2
Na_1 meq./l serum H_2O	152.4	145.6	152.0	154.0	151.8	141.6	151.0	146.7	149.5
Na_2 meq./kg serum	144.3	145.0	142.0	142.0	141.7	134.3	143.3	138.0	141.5
Na_2 meq./l serum H_2O	153.6	153.8	152.5	150.2	151.7	142.9	152.5	147.3	150.7
Cl_1 meq./kg serum	114.4	110.6	107.2	109.8	110.0	104.5	109.7	107.3	108.9
Cl_1 meq./l serum H_2O	119.5	118.4	116.4	117.0	118.5	113.2	117.8	115.9	117.2
Cl_2 meq./kg serum	112.1	119.1	109.0	109.2	112.0	104.5	112.3	108.3	110.9
Cl_2 meq./l serum H_2O	119.4	126.4	117.1	115.5	119.9	111.8	119.6	115.8	118.4
Serum dry weight$_1$	6.76	6.61	7.90	6.23	7.16	6.76	6.87	6.96	6.90
Serum dry weight$_2$	6.10	5.78	6.91	5.50	6.60	6.0	6.07	6.30	6.15
Total ECF_1 Na_1 meq.	194.8	200.9	196.7	200.4	255.5	245.7	199.2	250.6	216.3
Total ECF_2 Na_2 meq.	219.3	238.4	224.2	229.5	275.9	282.5	227.9	279.2	245.6

Table 79

The Distribution of Na and Cl in the Body (1574)

Infant	C.	H.	K.	R.	M.	S	Mean 15 days	Mean 42 days	Mean of all infants
Sodium intake total meq. in period ECF_1 to ECF_2	51.7	82.6	108.6	134.7	72.6	91.6	95.2	82.1	90.8
Sodium excretion total meq. in period ECF_1 to ECF_2	15.1	20.3	48.9	96.0	17.8	36.6	45.1	27.2	39.1
Na retention in the period ECF_1—ECF_2 in meq.	36.6	65.8	59.7	38.7	54.8	55.0	50.2	64.9	51.8
in % of Na intake	70.8	76.4	55.0	28.7	75.5	60.0	57.7	67.8	59.4
Na retained within ECF space in meq.	24.5	37.5	27.5	25.1	20.4	36.8	28.7	28.6	28.6
in % of total Na retained	62.0	55.7	45.9	64.5	36.5	66.5	57.0	51.5	55.2
Na retained outside ECF space in meq.	15.0	29.8	32.4	13.8	35.5	18.2	22.8	26.9	24.5
in % of total Na retained	38.0	44.3	54.1	35.5	63.5	33.5	43.0	44.8	44.8
Cl intake total in meq. in period ECF_1 to ECF_2	52.9	87.6	110.0	137.2	74.3	93.9	97.2	84.1	92.6
Cl excretion total in meq. in period ECF_1 to ECF_2	9.9	19.1	49.1	85.1	11.2	32.9	40.8	22.1	34.5
Cl retention in the period ECF_1—ECF_2 in meq.	43.0	68.5	61.9	52.1	63.1	61.0	56.4	62.1	58.3
in % of Cl intake	81.2	78.2	55.8	38.0	84.9	65.0	63.3	74.0	67.2
Cl retained within ECF space in meq.	17.7	32.5	21.5	21.2	18.7	24.6	23.2	21.7	22.7
in % of total Cl retained	39.7	46.9	33.6	40.8	29.2	40.3	40.2	34.8	38.5
Cl retained outside ECF space in meq.	26.9	37.1	42.5	30.7	45.3	36.4	35.0	40.9	36.9
in % of total Cl retained	60.3	53.1	66.4	59.2	70.8	59.7	59.8	65.3	61.5

Heart action is vitally affected by the sodium-potassium balance (0269, 1255, 2281). Excess potassium causes a decrease in muscle excitability and the heart beat slows and may stop in diastole (2474). With insufficient potassium, excitability of the heart muscle becomes exaggerated and the heart stops in systole (2474). Too little sodium causes heart contraction to be abnormally rapid but weak; a very low level of sodium brings about a marked supression of the pacemaker (0269, 1255, 2281).

Nerve-impulse conduction and transmission is determined by the differential concentration of sodium and potassium across the cell wall as it affects the electrical potential of the cell membrane and thus cellular excitability (1010). Exceedingly high concentrations of potassium, however, lower conductivity in the voluntary nervous system and produce a local anesthetic effect (2474).

The sodium-potassium balance or antagonism also affects certain enzyme systems. Potassium apparently is essential for carbohydrate metabolism and has a stimulating effect on glycolysis (0269, 1255, 2281). Sodium, on the other hand, tends to inhibit glycolysis (0269, 1255, 2281).

Acidosis results if the intake of NaCl is too high, due to a loss of K and bicarbonate as electrolyte excretion is increased in an attempt to maintain normal osmotic pressure (2474).

The chloride ion is the most important anion in the maintenance of the proper fluid-electrolyte balance in the body. The daily turnover in man (adults) is between 85-250 milliequivalents (1010). An insufficiency at the chloride ion leads to a relative increase in the blood bicarbonate level causing alkalosis and a failure of the stomach to form HCl (2474).

Potassium has three main physiologic functions: (1) regulation of the acid-base balance of the body (it is the principal base in tissues and blood cells), (2) in intermediary carbohydrate metabolism, it acts as an insulin-antagonist and epinephrine-like substance, (3) in transmission of nerve impulses to the muscle fiber and contractility of muscle, it is a choline esterase antagonist (3257). Potassium also has a protective effect against the hypertensive action of high sodium intakes in man and experimental animals; the mechanism involved here, however, is not known (1017).

The amount of sodium in the body and its concentration in body fluids is under homeostatic control (1010).

The metabolism of sodium is controlled primarily by the kidney, and by hormones of the adrenal cortex which act upon the kidney and perhaps other tissues (0977).

Regulation of the balance between sodium and potassium is principally a function of the distal portion of the renal tubule (1017). Potassium and hydrogen ions inside the cells of the tubule are exchanged for sodium ions that are inside the lumen of the tubule, therefore the rate at which hydrogen and potassium ions are excreted is determined by the amount of sodium available for exchange (1017).

At the cellular level, the "sodium pump", which is probably under the influence of hormones from the adrenal cortex, maintains the proper balance between sodium and potassium inside the cell (0269, 1255, 2281).

Excess sodium is usually excreted promptly under normal conditions; if the body suffers a sodium deficiency, the excretion rate decreases to a very low level (1010). Excessive losses of sodium occur with severe diarrhea, vomiting, sweating, following long use of diuretics, in chronic kidney disease, and in adrenal insufficiency (1010).

Potassium excretion differs from that of sodium in two important respects. First, large oral intakes of potassium are excreted so rapidly that the concentration in the blood is hardly affected. Potassium enters the urine not only via glomerular filtration but also by way of tubular excretion (2474).

Conservation of potassium is influenced by testosterone and the anterior pituitary growth hormone. The 11-oxysteroid adrenal hormones, on the other hand, cause a loss of potassium from the tissues (2474).

Excessive sodium chloride intakes cause increased excretion of potassium along with other crystalloids as the body attempts to maintain normal osmotic pressure (2474).

Excretion and retention of sodium and potassium appear to be regulated in the main by adrenal cortical hormones although the pituitary also influences electrolyte balance in the body (0269, 1255, 2281).

A. Humans

1. Janovsky et al. (1575) administered sodium chloride by stomach tube at a level of 700 mg/kg BW to 50 mature healthy infants from 16 days to 6 months of age and determined the anti-diuretic activity of the plasma. The sodium chloride load increased the plasma sodium concentration by 11.2 mEq and the chloride level by 9.2 mEq/liter on the average.

Anti-diuretic activity (ADA) was not discernible in untreated controls under 4 1/2 months of age. Administration of NaCl caused ADA in infants as early as the third month.

2. Berliner et al. (0267) pointed out that it is generally accepted that something other than glomerular filtration and adrenal steroids is involved in the regulation of sodium excretion; the term "third factor" has been coined for this variable. In a review of the nature of "third factor", the authors concluded that although certain physical factors - changes in the pressures and flows in the peritubular capillaries and plasma protein concentration - in all probability play a role, there is doubt that they are responsible for the entire phenomenon. Experimental data in support of this view are presented. The authors postulate that it is highly probable that "third factor" is multiple; the evidence for various hormonal factors is discussed but they concluded that none of these have been definitely determined.

3. Aperia et al. (0115) studied the sodium excretion of 31 full-term babies, 1 to 15 days of age, in an investigation prompted by reports that the renal filtration rate, as well as the concentrating and acidifying capacity of the kidney, are restricted in the newborn infant. In Group I (20 babies), an oral sodium load of 95 mEq Na^+ per 1.73 m^2 body surface was given in the formula. In Group II (5 babies), the sodium load was 190 mEq Na^+ per 1.73 m^2 body surface. Group III (6 babies), the control group, was given no added sodium. All of the infants were fed a standard diluted formula ('Allomin' 1:3) which provided an adequate caloric intake. The glomerular filtration rate (GFR) of the babies in Group I was determined by ascertaining disappearance of inulin following a single intravenous dose. Urine was obtained by spontaneous voidings at approximately hourly intervals. Diarrhea was not encountered and one baby who vomited was withdrawn from the study. The following chemical determinations were made: sodium concentration in serum and urine, osmolality in blood and urine and the hematocrit (Tables 80 and 81; Figures 43 and 44).

Urinary excretion of added sodium was found to be markedly lower in newborn infants than in older children (Table 80). The authors estimated the maximal sodium excretory capacity of the newborn baby, for a high sodium load, to be about 12 mEq/kg BW/day. No correlation between sodium excretion and the glomerular filtration rate was observed. Results with 1% and 2% saline indicated that the ability to excrete sodium did not seem to be dose dependent.

The authors stated that although results obtained "do not indicate the exact mechanism of the relative inability of the kidney tubules of the newborn infant to reject reabsorption of sodium adaptively, changes in physical forces brought about by the high hematocrit are partially responsible at least for the enhancement of tubular sodium reabsorption".

Table 80

Sodium Excretion mEq Per Hour Per 1.73 m^2 Body Surface Following an Oral Load of Water or Saline Chloride Solution (0115)

The average hourly urine Na^+ excretion ± one S.D. in infants during high fluid intake with and without an oral salt load. The urinary NA^+ excretion following an oral salt load in older children is given as a reference.

Load	High fluid intake only	High fluid intake + 95 ml q NA^+	High fluid intake + 190 ml q Na^+
Infants 1 - 15 days	0.53 ± 0.09	1.51 ± 0.28	1.11 ± 0.52
Children 8 - 14 years	6.0 ± 2.1	16.0 ± 1.8	25.7 ± 3.5

Table 81

Glomerular Filtration Rate, Urinary Sodium Excretion and Urine Osmolality in 5 Infants Following a 1% Saline Load (0115)

Sex	Age (days)	GFR (ml/min/ 1.73 m^2)	Na-excretion (mEq/hour/ 1.73 m^2)	Average diuresis[a] (ml/min)	Average urine osmolality[a]	Average Na^+ clearance (ml/min)
Male	3	31	2.8	0.75	61	0.056
Female	9	20	1.1	0.24	70	0.016
Male	11	24	3.2	1.07	43	0.054
Male	13	34	0.3	0.30	55	0.005
Male	15	20	0.5	0.52	47	0.003

[a] Average value from 2–6 urine collection periods.

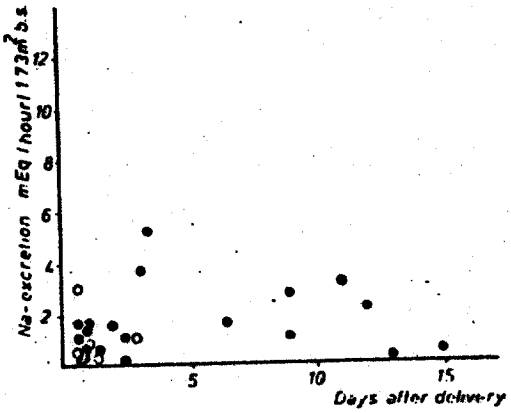

Figure 43 (0115)

The average hourly Na^+ excretion following the administration of a 1% (filled circles) or a 2% (unfilled circles) saline load to infants aged 1 - 15 days.

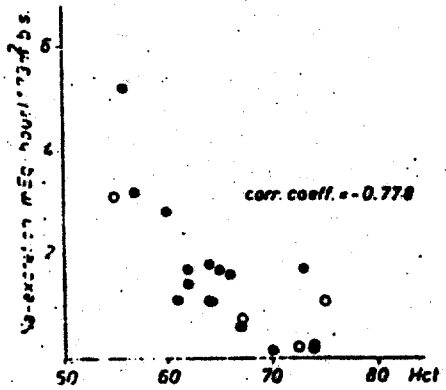

Figure 44 (0115)

The relationship between the hematocrit and the average hourly Na^+ excretion following a 1% (filled circles) or a 2% (unfilled circles) saline load. The correlation coefficient, -0.778, was statistically significant.

4. Quintero-Atencio et al. (2636) studied the relationship between blood pressure and the concentration of sodium and potassium in the sweat in 40 normal young adult volunteers and 38 hypertensive patients (See original article for details). The data obtained showed less sodium in the sweat of subjects with higher blood pressures, and the authors concluded that the results suggest a significant correlation between the arterial blood pressure and the ability of the sweat glands to concentrate sodium in normal and hypertensive subjects.

5. Siegenthaler et al. (3056) reported that the sweat electrolyte excretion in adults is variable. Levels as high as 140 mEq/liter of sodium have been found but only 10% of the population have levels above 80 mEq/liter. Seasonal fluctuations, age, and salt intake levels are the main factors responsible for variations. In children, the upper normal limits are 70-80 mEq/liter for sodium and 50-60 mEq/liter for chloride. In cystic fibrosis of the pancreas, however, sodium values of 120 mEq/liter and higher are found.

IV. Effects on Enzymes and Other Biochemical Parameters

Dogs

Barker (0220) noted that dogs made edematous by reduction of serum proteins responded to added salt in the diet with marked water retention amounting to as much as 40% of the animals weight in five days. When salt was omitted, the edema gradually receded. When potassium chloride was substituted for salt at any period during fluid storage, a prompt and marked diuresis occurred. The edema disappeared and bodyweight fell below control levels even though serum proteins remained at the same levels. In clinical studies, twelve of sixteen patients with edema placed on a full general diet of low sodium:potassium ratio and given 5 g of KCl daily were cured of the edematous condition without toxic effects over a period of 1 1/2 years.

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