

Food and Drug Administration
Center for Food Safety and Applied Nutrition
Office of Special Nutritionals

ARMS#

13167



5 - SUMMARIES

000001

HOSPITALIZATION #1

000002

[REDACTED]

HISTORY AND PHYSICAL

PATIENT NAME: [REDACTED]
PATIENT NUMBER: [REDACTED]
ROOM: [REDACTED]

DATE OF ADMISSION: 09-09-98

HISTORY: We have a 45-year-old, well-developed, well-nourished, white female who complained of increased blood pressure after taking some over-the-counter Metabolife. This contains ephedrine. The substance is called Ma Haung. This is an oriental herb which has natural-occurring ephedrine. She took this for two doses and she went to the emergency room complaining of extremely high blood pressure. She was seen in our emergency room and evaluated by the emergency room doctor and admitted to the hospital under hypertensive crisis. A nitroprusside medication was started intravenously to decrease the blood pressure and controlled it very well.

ALLERGIES: No known medical allergies.

CURRENT MEDICATIONS: Metabolife, Estradiol one per day.

PAST SURGICAL HISTORY: Gallbladder surgery, appendectomy, total abdominal hysterectomy and bilateral salpingo-oophorectomy, plantar fascial surgery bilaterally in June of 1998, a vaginal cyst, and history of fibroid tumors.

PAST MEDICAL HISTORY: Positive for hepatitis B. Blood pressure medications in the early 1980's but none since. Questionable transient ischemic attack in 1989. History of hemorrhoids. Also exposure to battery fumes during the years 1991 to 1994 while working in a chemical company (I think it was called [REDACTED]). Also denies any genitourinary, gastrointestinal, neurological, pulmonary, or cardiac problems. There is a history of tunnel vision with fainting spells as a child, though, and occasional blurred vision. Eyes have recently been checked by an ophthalmologist and found to be normal.

GYN HISTORY: She had a mammogram which was normal and a Pap smear which was normal in less than six months. Her index is gravida 2, para 1, A 1. She had tubal ligation before her miscarriage.

FAMILY HISTORY: There is a positive history of cancer for mother and father, with colon cancer and liver cancer which was the demise of both of them. There is no history of thyroid problems in the family. There is diabetes in an uncle and a half-brother. Stroke is noted in a full brother, glaucoma in a half-sister, drug use in one of the half-brothers which was alcohol abuse, hypertension in one of the brothers, and also heart disease in one of the brothers with a triple bypass. She denies any blood disorders or mental disorders in the family.

IMMUNIZATION HISTORY: She had hepatitis B vaccination. She also had a flu shot in 1993, a tetanus shot less than seven years ago, but never had a Pneumovax shot.

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[REDACTED]
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HISTORY AND PHYSICAL

PATIENT NAME: [REDACTED]
PATIENT NUMBER: [REDACTED]

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SOCIAL HISTORY: She has been divorced now for six years with one child, a 23-year-old female, who is very healthy. She works as a cashier on third shift on a regular basis but has difficulty sleeping in the daytime. She wears seat belts. She does not smoke or drink alcohol. There are no weapons in the house. She denies any abusive relationship or any AIDS contacts or any "Living Will" but does have a donor card.

PHYSICAL EXAMINATION:

VITAL SIGNS: Weight 254 lb., blood pressure 127/82, pulse 71, respirations 18, pulse ox 99% on room air.

HEENT: Pupils are equal and reactive to light and accommodation. Extraocular muscles are intact. Funduscopic examination reveals no AV nicking or hemorrhages or exudates. Sclerae white, conjunctivae pink. Tympanic membranes are clear. External auditory canals are patent. There is some pressure to the supraorbital and infraorbital sinuses to palpation. Transillumination of the supraorbital sinuses was unobtainable at this time. The throat is clear, with a little bit of PND in the posterior oropharynx but no signs of any petechiae on the soft or hard palate and no signs of any significant yellow or pustular exudates. There are no oral lesions. The patient has a partial upper plate. There are no signs of gum disease or gingivitis.

NECK: Is soft and supple. No bruits and no jugular venous distention, and there are no nodes palpable. The head is normocephalic. Full range of motion at AO and AA. There are no supraclavicular lymphadenopathy.

HEART: The heart rate is regular and rhythmic, without murmurs. There is no S3, S4, clicks, rubs, or heaves or thrills. The point of maximal impulse is at the fifth intercostal space, lower left sternal border.

LUNGS: Clear to auscultation. No rales, rhonchi or wheezes. No hyperresonance, crepitus, flatness, or dullness to percussion.

EXTREMITIES: There are no signs of peripheral cyanosis or clubbing. Capillary return is less than two seconds bilaterally.

ABDOMEN: Is distended with increased adipose tissue, but bowel sounds are present in all quadrants, but there is no pain to palpation, no rebound tenderness, no organomegaly, no flank pain, and no bruits.

BREASTS: The breasts are pendulous. The patient deferred examination at this time.

VAGINAL: Vaginal examination is deferred at this time.

RECTAL: Deferred by patient at this time.

NEUROLOGIC: Cranial nerves II through XII are grossly intact with a normal gait and normal station. Deep tendon reflexes are equal in upper and lower extremities, 2/4 bilaterally. There are no signs of peripheral vascular disease or signs of clubbing or cyanosis distally.

MUSCULOSKELETAL: Major motor muscle groups are intact with full range of motion to shoulders, wrists, fingers, toes, knees, hips and elbows. No signs of subluxation or deformities, angulation or nodularity noted. No signs of effusion. No signs of cyanosis. No signs of major motor muscle group wasting. Bilateral grip strength is equal in both active and passive range of motions.

PSYCHIATRIC: We note that the patient is well oriented to time, place, and circumstance. She has good insight and judgment, and memory is excellent. A very jovial, pleasant person to talk to.

Adverse Event Project # 13167

[REDACTED]
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[REDACTED]
HISTORY AND PHYSICAL

PATIENT NAME: [REDACTED]
PATIENT NUMBER: [REDACTED]

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- ASSESSMENT:
1. Acute sinusitis.
 2. Hypertensive crisis, iactogenically caused by the ephedrine in Metabolife (an over-the-counter medicine).
 3. Rule out hypothyroid disease.
 4. Morbid obesity, weight greater than 100 lb. above ideal body weight.

PLAN: The patient is to be admitted to the hospital, closely observed in the intensive care unit, and we will gradually taper off the nitroprusside to control the blood pressure and start Norvasc 5 mg one per day and will start Biaxin 500 mg one twice a day for 10 days for any sinus infection. We will stop the Metabolife and any type of over-the-counter antihistamines or decongestants at this time. The patient will monitor her blood pressure upon discharge and we will follow with laboratory results in the morning. Laboratories drawn today were T3, T4, TSH, CBC with differential. Urinalysis was evaluated and a full chemistry profile and a liver profile. The patient will be followed closely. Dr. [REDACTED] was consulted for internal medicine for intensive care unit.

[REDACTED]
[REDACTED] M.D.

D: 09-10-98
T: 09-10-98

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[REDACTED]
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[REDACTED]

CONSULTATION

PATIENT NAME: [REDACTED]
PATIENT NUMBER: [REDACTED]

DATE OF CONSULTATION: 09-09-98

REQUESTING PHYSICIAN: [REDACTED] MD

CONSULTING PHYSICIAN: [REDACTED] MD

REASON FOR CONSULTATION: Hypertensive crisis.

RECOMMENDATIONS: 1. The patient is currently being controlled well with a Nipride drip at .6 mcg per kg. Would recommend starting Norvasc 5 mg PO now and weaning Nipride off, with a target blood pressure in the 140 to 150 systolic/80 to 90 diastolic range. Would not attempt to be more aggressive with lowering at this time due to the possibility for some adverse hemodynamic consequences. If blood pressure is difficult to control within this target with the Norvasc would add an ACE inhibitor beginning with Lotensin 10 or 20 mg. The patient will probably end up needing combination therapy for adequate control.

2. Nonspecific ST-T wave changes with some T wave inversion noted on EKG probably related to the acute effects of the profound hypertension. Would, however, repeat an EKG in the a.m. The patient has no evidence of ongoing poorly controlled hypertension. I believe this is an acute crisis related to the ephedrine component of the herbal preparation for weight loss that she has been taking.

3. Obesity. Would recommend considering Glucophage as a potential weight loss adjunct in addition to her continuing the Weight Watcher's program that she is doing as well and encourage exercise. However, the patient is unable to exercise aggressively at this time due to bilateral lower extremity plantar fascial surgery three months ago.

HISTORY OF PRESENT ILLNESS: This is a 45-year-old, obese, white female currently weighing 250 lb. who presented to the emergency department with severe headache, nausea, and some diplopia worsening over the past 24 hours. She started Metabolife weight loss over-the-counter preparation five days ago prior to developing these symptoms. She had a history of hypertension approximately 10 to 12 years ago that was treated for a time with medications, but she was taken off medications at that time and has had no problems with hypertension until the current episode.

In the emergency department she was evaluated and CT scan was ordered, showing no evidence of infarction or cerebral bleed, and the patient's headache improved markedly with decrease in blood pressure with Nipride. There were some abnormal EKG findings, showing some T wave inversion and nonspecific ST wave changes; however, the patient denied any chest pain, shortness of breath, palpitations, lower extremity edema, paroxysmal nocturnal dyspnea, orthopnea, or other symptoms. She reports a recent 17-lb. weight loss with Weight Watcher's diet program but states that her weight gain has been slowly progressive over many years but has increased dramatically with her decreased activity levels that have accompanied her recent plantar fascial surgery of the lower extremities.

REVIEW OF SYSTEMS: As per present illness.

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[REDACTED]
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HOSPITALIZATION #2

000008

[REDACTED]
[REDACTED]
NAME OF PATIENT: [REDACTED]
HOSPITAL NUMBER: [REDACTED]
MEDICAL RECORD NUMBER: [REDACTED]
ROOM NUMBER: [REDACTED]
DATE OF ADMISSION: 03/15/99

HISTORY AND PHYSICAL

CHIEF COMPLAINT: Left arm pain.

HISTORY OF PRESENT ILLNESS: This is a 46-year-old white female who has been having left arm pain. The left arm pain was severe. It was relieved with sublingual nitroglycerin. The pain lasted more than 30 minutes. There were no palpitations, dizziness, or syncope. There was no shortness of breath, nausea, vomiting, or diaphoresis. She denied history of paroxysmal nocturnal dyspnea or orthopnea.

PAST MEDICAL HISTORY: The patient denied history of any cardiac problem. There was no history of angina, myocardial infarction, rheumatic fever, or heart murmur. She has history of hypertension and hypothyroidism. She also had hypercalcemia. She is known to have history of obesity.

PAST SURGICAL HISTORY: Cholecystectomy, foot surgery, and surgery for vaginal cyst.

ALLERGIES: No known allergies.

CURRENT MEDICATIONS: Norvasc, Levoxyl, quinine, and diuretics.

FAMILY HISTORY: Positive for coronary artery disease. Patient's brother had myocardial infarction.

REVIEW OF SYSTEMS:

HEENT: No complaints.

PULMONARY: No cough or pleuritic chest pain.

CARDIOVASCULAR: As mentioned in History of Present Illness.

GASTROINTESTINAL: No history of nausea, vomiting, hematemesis, or melena.

CENTRAL NERVOUS SYSTEM: No history of headaches, seizures, or paralysis.

MUSCULOSKELETAL: Denies any musculoskeletal problems.

ENDOCRINE: Has history of hypothyroidism. There was no history of diabetes mellitus.

SIGNED ORIGINAL MAINTAINED AT HOSPITAL
[REDACTED] HISTORY AND PHYSICAL

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PT: [REDACTED]
MRNO: [REDACTED]
HISTORY AND PHYSICAL
PAGE 2

PHYSICAL EXAMINATION: Well-developed, moderately obese white female. She was in no acute distress. Blood pressure 139/67. Pulse 72 per minute. Respiration 18 per minute. She was afebrile.
HEAD: Normocephalic. Ears, nose, and throat were normal.
EYES: Conjunctivae did not show any pallor. Sclerae did not show any icterus. Pupils equal, react to light and accommodation.
NECK: Neck showed trachea was in the midline. There was no goiter or lymphadenopathy. Jugular venous pressure was not elevated. Carotid pulsations were equal without any bruit.
LUNGS: Clear to auscultation and percussion.
HEART: Heart showed PMI was within the midclavicular line. On auscultation cardiac rhythm was regular. There was a 1/6 systolic murmur best heard in the apical area. There was no diastolic murmur, click, or rub heard.
ABDOMEN: Abdomen was soft and nontender.
EXTREMITIES: Extremities did not show any edema or cyanosis.
CENTRAL NERVOUS SYSTEM EXAMINATION: Did not show any focal motor weakness.

ASSESSMENT:

1. Rule out acute myocardial infarction.
2. Arterial hypertension.
3. Obesity.
4. Hypothyroidism.
5. Family history of coronary artery disease.
6. Hypercalcemia.

PLAN: The patient will be admitted to the telemetry floor where she will be monitored. Serial EKGs and enzymes will be done. She will be treated with aspirin, nitrates, and beta blockers. Further plan will depend on the clinical course.

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[REDACTED]
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SIGNED ORIGINAL MAINTAINED AT HOSPITAL
HISTORY AND PHYSICAL
[REDACTED]

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PT: [REDACTED]
MRNO: [REDACTED]
HISTORY AND PHYSICAL
PAGE 3

In determining the plan of care for this patient , I have evaluated the risks and benefits of any planned procedure(s). The risks and options have been discussed with the patient and/or his or her representative.

Yes No Procedure Planned At This Time

In determining the plan of care for this patient, I have evaluated the risks and benefits of any planned use of blood or blood components. The likelihood of, risks of, and alternate options to the use of blood or blood components have been discussed with the patient and/or his or her representative.

Yes No Blood/Blood Component Use Planned At This Time

[REDACTED] M.D.

[REDACTED]
D: 03/15/99
T: 03/16/99
L: [REDACTED]

Adverse Event Project # 13167

[REDACTED]
3/26/99 HRB

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SIGNED ORIGINAL MAINTAINED AT HOSPITAL
[REDACTED] HISTORY AND PHYSICAL

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