

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

ARMS#

13085



5 - SUMMARIES

000001

Attachment 1

12/10-17/98 PJP



DISCHARGE SUMMARY

PATIENT: [REDACTED]
MEDICAL RECORD #: [REDACTED]
PATIENT ID#: [REDACTED]
ADMISSION DATE: 07/20/98
DISCHARGE DATE: 07/25/98

ADMISSION DIAGNOSES:

1. Hypokalemia.
2. Metabolic alkalosis.
3. Possible urinary tract infection.
4. Dehydration.

DISCHARGE DIAGNOSES:

1. Hypokalemia.
2. Metabolic alkalosis.
3. Possible urinary tract infection.
4. Dehydration.
5. Breast lesion, probably infectious in nature.
6. Rhabdomyolysis probably secondary to dietary supplement use.

CONSULTS THIS ADMISSION: Endocrinology, Dr. [REDACTED]

PROCEDURES THIS ADMISSION: Mammography performed on July 23, 1998

PRESENT ILLNESS: This is a 31-year-old white female who presented to the ER complaining of a two to three day history of generalized weakness. She had some nonspecific abdominal pain in the left rib cage area and some questionable left flank pain. She was seen in the ER two days prior to admission for an injury to her right knee which she sustained after a fall. She was given some Lodine in the ER that day and was doing

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CONTINUATION OF DISCHARGE SUMMARY

fairly well until the day prior to admission. She did have two episodes of vomiting just prior to coming to the ER on the day of admission.

PAST HISTORY: Her medical history is notable only for allergic rhinitis. She has never had any surgeries.

MEDICATIONS: Her medications at the time of admission included a dietary supplement called "H.E.L.P." The active ingredients included in this supplement include B12, Chromium and desert T extract (Ephedra). She was taking this formulation twice a day for weight loss. She denied diuretic abuse, induced vomiting or laxative abuse.

ALLERGIES: She claims no drug allergies.

SOCIAL HISTORY: She smokes a little more than a pack a day for 10 years, but denies alcohol or drug abuse.

FAMILY HISTORY: Family history is positive for asthma and diabetes in her mother, hypertension in grandmother and father with coronary artery disease.

PHYSICAL EXAMINATION:

General: A well-developed, well-nourished, mildly overweight white female in moderate distress. She appears quite dehydrated.

Vital Signs: Weight 166 pounds, temperature 99.2°F, pulse 88, respirations 20, blood pressure 135/71.

HEENT: Normocephalic, atraumatic. Pupils are equal and reactive to light. Extraocular muscles are intact. Oral cavity and oropharynx show tacky mucosa.

Neck: Supple with no JVD or thyromegaly.

Chest: Clear to auscultation.

Heart: Regular rate and rhythm, no murmur, rub or gallop.

Abdomen: Soft, nontender, nondistended. Positive bowel sounds.

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[REDACTED] *Attachment 1*
[REDACTED]
CONTINUATION OF DISCHARGE SUMMARY
[REDACTED] *12/10-17/98 PJP*

Extremities: No cyanosis, clubbing or edema.
Neurologic: She is alert and oriented times and has no focal deficits.

LABORATORY DATA: Initial laboratory data was notable for a potassium of 1.6, a CO₂ of 40, creatinine of 0.3. The CBC was normal. The urinalysis was borderline with 2+ occult blood, 4 to 8 white blood cells, numerous epithelial cells and 3+ bacteria. The ABGs showed metabolic alkalosis with a pH of 7.528, PCO₂ 48, PO₂ 151, bicarbonate 38, saturation 99% on 4 liters by nasal cannula. The EKG showed normal sinus rhythm, flattened T-waves and questionable ST depression.

HOSPITAL COURSE: She was admitted with the diagnosis of severe hypokalemia. Her potassium on recheck was 1.5. She was sent to the Unit and given aggressive potassium replacement with 60 mEq in 1 liter of fluid given over one hour which she tolerated without difficulty. We utilized continuous cardiac monitoring. We also gave her some p.o. K-Dur to help replace her potassium. We also started her on antibiotics for a possible UTI. We stopped her dietary supplement. We slowly were able to replace her potassium over the next few days.

On the second hospital day, we noticed that her liver functions were elevated with elevated LDH, SGPT and SGOT. We drew a hepatitis panel and obtained a CT of the abdomen that showed a simple liver cyst. Hepatitis panel eventually returned negative for any type of viral hepatitis. She was transferred to the floor in stable condition with a potassium of 3.9. Her potassium replacement was decreased.

On the third hospital day, the patient noticed she had a lesion on her right breast approximately 9 o'clock in regard to the nipple approximately 2 cm from the center of the nipple. It was an excoriated lesion with a firm base. We obtained a culture and mammogram. Mammogram was negative for any sign of malignancy. Culture eventually returned with a finding of *Staphylococcus lugdunensis* that was sensitive to Keflex which we kept her on. The TSH was 1.9. A 24-hour urine and electrolytes were mildly abnormal with a 24-hour protein of 284 mg per 24 hours. Urine myoglobin was positive. We checked a CK and it was 28,010 with mostly MM fraction. We continued aggressive

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[REDACTED]
CONTINUATION OF DISCHARGE SUMMARY
[REDACTED]

Attachment 1

12/10-17/98 PJP

hydration for this presenting rhabdomyolysis. The patient remained stable throughout the hospitalization.

On the fifth hospital day, she was on the floor. Her potassium had been stable off potassium replacement. She was afebrile. Her vital signs were stable. Her CK had declined to a level of 6966. She was tolerating p.o. and having no shortness of breath. At that time, she seemed stable and ready for discharge.

DISCHARGE INSTRUCTIONS: She went home on a regular diet. She was instructed to discontinue her dietary supplement. Activity will be as tolerated.

Medications will include Keflex for 14 days. She was to follow up with me in the clinic at [REDACTED] for a recheck of her potassium and review of some laboratories that were still pending. She will also need a follow up ultrasound as recommended by radiology to assess her liver cyst. Otherwise, her follow up will be with her primary care physician who is Dr. [REDACTED]

[REDACTED] M.D.

Dictated by [REDACTED], M.D.

D: 10/06/98

T: 10/08/98

cc [REDACTED]

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Attachment 1

12/10-17/98 AJP

HISTORY & PHYSICAL

PATIENT: [REDACTED]
 MEDICAL RECORD NUMBER:
 PATIENT ID#: [REDACTED]
 ADMISSION DATE: 7-20-98
 ROOM:
 ATTENDING PHYSICIAN: Dr. [REDACTED]

CHIEF COMPLAINT: Weakness.

HISTORY OF PRESENT ILLNESS: This is a 31 YO WF who came to the ER with a 2-3 day history of generalized weakness which began on Sat. She still had some non-specific abdominal pain in the left rib cage area and questionable left flank pain. She was seen in the ER Sat. for injury to her right knee which she sustained when she fell.

PAST MEDICAL HISTORY: She is a patient of Dr. [REDACTED] and he has been treating her for allergic rhinitis symptoms.

PAST SURGICAL HISTORY: None.

MEDICATIONS: She takes an OTC diet pill "H.E.L.P." Active ingredients listed include Vitamin B12 and ^{Chromi}Acromion, also dessert tea extract among others. She takes this twice a day for weight loss. She was given Lodine in the ER on Sat. and has been taking that for the last 2 days. *Denies diuretic abuse*

ALLERGIES: None known.

SOCIAL HISTORY: She smokes a little more than a pack a day and has done so for 10 years. Denies alcohol or drug abuse.

FAMILY HISTORY: Mother has asthma and diabetes. Grandmother has hypertension. Father has coronary artery disease.

REVIEW OF SYSTEMS: Positive for generalized weakness. She denies dysuria, fever, chills or vomiting. She does have some nausea. Otherwise, she has no chest pain, SOB, dysuria or peripheral edema.

PHYSICAL EXAMINATION:

GENERAL: This is a WD, WN, mildly overweight white female in moderate distress.

VITAL SIGNS: Wt. 166. Temp. 99.2°. Pulse 88. Resp. 20. BP 135/71.

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Attachment 1

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CONTINUATION OF HISTORY & PHYSICAL

HEENT: Normocephalic, atraumatic. PERRL. EOMI. Oral cavity and oropharynx show tachy mucosa.

NECK: Supple with no JVD.

CHEST: Clear to auscultation.

CARDIOVASCULAR: Regular rate and rhythm. No murmur, rub or gallop.

ABDOMEN: Soft, non-tender, non-distended. Positive bowel sounds.

EXTREMITIES: No clubbing, cyanosis or edema.

NEUROLOGICAL: She is alert and oriented X3. No focal deficits.

LABORATORY DATA: Initial Chem-7 showed sodium 145, potassium 1.6, chloride 95, CO2 40, BUN 14, creatinine .3, glucose 94. CBC: White count 8.5, HCT 35.2, platelets 314. UA shows cloudy urine with 2+ occult blood, 4-8 WBC's, numerous epithelial cells and 3+ bacteria. ABG's: PH 7.528, PCO2 48, PO2 151, bicarb. 38, sat. 99% on 4 liters by nasal cannula.

EKG: Normal sinus rhythm. Flattened T-waves. Some questionable ST depression.

ASSESSMENT:

1. HYPOKALEMIA.
2. METABOLIC ALKALOSIS.
3. POSSIBLE UTI.

PLAN:

1. We will admit her to the ICU for cardiac monitoring while we replace her potassium. Check serial potassium levels to insure that we are correcting at a slow and steady rate. Will start her on antibiotics for UTI and also workup her metabolic alkalosis and try to ascertain the etiology of her severe hypokalemia.

M. D.

dictated by M. D.

D&T: 7-20-98

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