

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

ARMS#

12979



5 - SUMMARIES

000001

CHIEF COMPLAINT:

Chest pressure for the last 10 hours with shortness of breath and sweating.

HISTORY OF PRESENT ILLNESS:

The patient is a 61-year-old female with a benign past medical history but elevated cholesterol, who developed hypertensive response after trying Metabolife for weight loss. The medication was stopped one month ago, but she has continued to have problems with severe hypertension ever since. She was initially tried on atenolol 50 mg up to 100 mg twice a day. Recent check in the office approximately one week ago was sustained elevated blood pressures. She was begun on hydrochlorothiazide 50 mg a day in addition to atenolol. However, the patient discontinued the atenolol. For the past week, she has been getting substernal chest pressure whenever she walks. She stops and this goes away. This morning at 2:00 a.m. she awoke with heaviness in her chest and a tingling sensation in her left arm. She also felt short of breath and sweaty. There was no nausea. Despite this, she ate her breakfast and went off to work but continued to feel poorly. She was seen in the office and then sent to the emergency room where aspirin, Ativan and sublingual nitroglycerin x 3 has produced some relief in her chest pressure; however, she continues to have it.

ALLERGIES:

NKA.

MEDICATIONS:

Hydrochlorothiazide 50 mg p.o. q.day, b.i.d. She recently stopped ibuprofen 800 mg twice a day for left lateral epicondylitis.

PAST MEDICAL HISTORY:

Benign. Negative for hypertension until just recently. She has had three vaginal deliveries without problems.

PAST SURGICAL HISTORY:

None.

FAMILY HISTORY:

The father died in a motor vehicle accident. Mother currently has hypertension. Brother, sister and children are all without medical problems.

SOCIAL HISTORY:

She works at [REDACTED] Chocolate Factory lifting boxes of chocolate. She does not smoke cigarettes or drink alcohol or use recreational drugs. Her husband died approximately six years ago of malignant melanoma.

REVIEW OF SYSTEMS:

Negative for headaches. Positive for some dizziness with this episode of chest pain. Negative for abdominal pain, dyspepsia, melena, hematochezia.

CONTINUED

NAME: [REDACTED]

MRN: [REDACTED]

DATE: 06/22/98

HISTORY & PHYSICAL

000002

REVIEW OF SYSTEMS (CONTINUED):

Negative for hematuria, dysuria, urgency, frequency. Negative for vaginal discharge. Positive for arthralgias in the DIP joints occasionally but no swelling. She has also had lots of pain in her left elbow which is being currently seen as a Worker's Compensation injury with Dr. [REDACTED]

PHYSICAL EXAMINATION:

VITAL SIGNS: Initial exam in the office revealed blood pressure 180/100 which is now down to 112/78 with nitroglycerin. Pulse was initially 80 and is now up to 120. Weight 168 pounds. Respirations 18.

GENERAL: Middle-aged female in no acute distress.

HEENT: The tympanic membranes are clear. Fundi are flat. Discs are sharp and flat. Vessels are normal. No AV nicking. No silver wires. No papilloedema. Pupils are equally round at 3-4 mm and reactive. Extraocular muscles are intact. Sclerae anicteric. Oropharynx - palate rises symmetrically. No lesions. Dentition is good. Tongue is midline.

NECK: No adenopathy. Carotids without bruits. Thyroid normal size.

LUNGS: Clear to auscultation.

CARDIAC: Regular rate and rhythm. S1, S2 without murmurs, clicks, rubs, gallops or heave.

ABDOMEN: Soft. Nontender. Normoactive bowel sounds. No hepatosplenomegaly. No bruits.

GU: Bimanual exam of the uterus is mid position, slightly enlarged uterus to approximately 6-8 weeks size. Adnexa without masses.

RECTAL: Soft. Guaiac-negative stool.

EXTREMITIES: Radial pulses 2+. Dorsalis pedis and posterior tibial pulses 2+. No cyanosis, clubbing or edema. There is slight swelling of the DIP joints of the fingers which are nontender. No erythema.

LABORATORY DATA: Potassium 3.6, sodium 140, glucose 122, CK 234, MB 5.4, MB% 2.3, LDH 159. LFTs within normal limits. Uric acid 7.8. Cholesterol 274, triglycerides 268. Hemoglobin 16, hematocrit 48, platelets 289, INR .99. Chest x-ray normal. EKG sinus tachycardia, nonspecific lateral ST-T wave changes, poor R wave progression. Compared to EKG done two months ago, the nonspecific ST-T wave changes are new.

CONTINUED

NAME: [REDACTED]

MRN: [REDACTED]

DATE: 06/22/98

HISTORY & PHYSICAL

000003

ASSESSMENT/PLAN:

Probable subendocardial myocardial infarction. The patient is being admitted to ICU as she has continued to have pain and pressure in her chest. Will start Tridil drip along with heparin. She has been given aspirin. Will restart atenolol and if blood pressure can tolerate, Vasotec will be given. Question whether these effects are still the lingering effect of the Metabolife which contains Mahuang ephedra. The patient strongly denies having taken any of this for the past month.

██████████ M.D.
d: 06/22/98 1:16 p.m.
t: 06/23/98 11:10 a.m. ██████████
██████████

NAME: ██████████

MRN: ██████████

DATE: 06/22/98

HISTORY & PHYSICAL

000004

Patient:
Unit:
Acct:
Type:
Location:
Room:

HISTORY AND PHYSICAL EXAMINATION

Date of Admission: 02/11/99

cc: [REDACTED] MD

copy: [REDACTED]

PATIENT IDENTIFICATION: The patient is a 61-year-old, widowed, white female packager in a chocolate factory, who is admitted to the hospital for diagnostic cardiac catheterization.

HISTORY OF PRESENT ILLNESS: This patient was evaluated by me, in June 1998, when she began having symptoms of substernal heaviness and pressure, which actually awakened her from sleep at night.

She had previously been documented to have significant hypertension, for which she had already been placed on beta blockade.

She was then admitted to [REDACTED], was cooled off with use of heparin, and did show a very slight CK elevation.

She subsequently was transferred for cardiac evaluation via angiography, and that study, which I performed on 6/24/98, revealed a high-grade ostial stenosis of the left main trunk. There was also minimal narrowing of the mid-segment of the LAD, with the lumen narrowed by 30%, distal to the origin of the first diagonal, and there was a mid-third stenosis of the large diagonal, with the lumen narrowed by 25%. The circumflex coronary artery was essentially normal, and there was minimal narrowing of the RCA proximally, not greater than 20%.

The patient subsequently underwent CABG, performed by Dr. [REDACTED] on 6/24/98.

At the time of surgery, she had emplacement of a LIMA graft to the LAD, and a saphenous vein graft to the larger ramus intermedius branch.

She did well in the early postoperative stage, and I thought she was essentially doing well.

However, she was re-referred by Dr. [REDACTED] because of the recurrence of exertional heaviness in the chest.

Apparently, she completed a cardiac rehabilitation session with Dr.

HISTORY AND PHYSICAL EXAMINATION 1

000005

Patient:
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and was actually back to work. The patient indicates that when she is working, particularly in the afternoon, and when she has her arms extended, packaging chocolates, she would experience a heavy sensation, felt throughout the entire precordial region.

At other times, as she is carrying a heavy object, she will also experience anterior chest discomfort. At times, the discomfort will come on, without any physical activity.

For further evaluation of her problem, she underwent standard treadmill exercise testing, on 1/26/99. However, the patient could only exercise to the third minute of Stage II of the Bruce protocol, at which time she achieved only 75% of her predicted maximum heart rate, at a maximum heart rate of 120. At peak heart rate achieved, she experienced very mild substernal pressure discomfort, but the test was discontinued primarily because of leg fatigue. At the submaximal heart rate achieved, there was no induction of ST-segment changes, but again this was only 75% of predicted capacity.

At this point in time, the patient is stating that the chest discomfort interferes with her being able to function and work, and so since she is status post recent bypass graft surgery, it was elected to perform coronary angiography, to document the status of her graft.

PAST HISTORY

MEDICAL

1. She has had recent episodes of significant hypertension, which are presently well-controlled with low-dose atenolol.
2. Hypercholesterolemia has been documented, and is now well-controlled with Lipitor 20 mg daily.
3. She has had episodes of bladder infections in the recent past.
4. Carpal tunnel syndrome.

SURGICAL

1. Tubal ligation, performed at [REDACTED], 30 years ago.
2. CABG, 6/98, as above.

DRUG ALLERGIES: None known.

CURRENT MEDICATIONS

1. Lipitor 20 mg daily.
2. A.S.A. 325 mg daily.
3. Atenolol 25 mg daily.
4. Sulfamethizole one tablet b.i.d.
5. Allegra b.i.d.

FAMILY HISTORY: Her father died of accidental causes. The mother is alive, at age 81, and has high blood pressure. Two sisters and two brothers are alive and well.

HISTORY AND PHYSICAL EXAMINATION 2 [REDACTED]

000006

Patient:
Unit:
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HABITS

SMOKING: She has never smoked.
ALCOHOL: None.
CAFFEINE: None.
OTHER: There also is no history of drug abuse.

REVIEW OF SYSTEMS: Noncontributory, except for HPI.

PHYSICAL EXAMINATION

VITAL SIGNS: Afebrile. The apical pulse is 70 and regular, respirations 16, blood pressure 120/80.
HEIGHT: 5 feet, 7 inches.
WEIGHT: 156 pounds.
GENERAL APPEARANCE: The patient is a pleasant, middle-aged white female, in no acute distress.
HEENT: Normocephalic. Pupils are equal and react to light. Extraocular movements intact. No arcus senilis or xanthelasma. The oral mucosa is benign.
NECK: No neck vein distention or carotid bruits. Thyroid not enlarged.
LUNGS: Clear to auscultation.
HEART: Precordium is quiet. The rhythm is regular. M1 and S2 are within normal limits. No gallop, rub, or murmur audible.
ABDOMEN: Soft, obese and slightly protuberant. No organomegaly. No epigastric bruits.
EXTREMITIES: No peripheral edema, cyanosis or clubbing. Peripheral pulses are intact and equal. No femoral artery bruits.
NEUROLOGIC: Physiologic.

CLINICAL IMPRESSION

1. Arteriosclerotic heart disease.
 - a. Recently documented ostial left main trunk stenosis and status post coronary artery bypass graft surgery, with LIMA to LAD, and SVG to ramus intermedius.
 - b. Recurrent symptoms suggestive of angina pectoris.
2. Hypercholesterolemia.
3. Systemic hypertension.

PLAN: The patient has been admitted to the hospital, specifically for coronary angiography. The risks of that procedure, which the patient is well aware of, include the possibility of death, heart attack, stroke, femoral artery thrombosis, bleeding, infection, and complications not restricted to the above, have been explained to, and accepted by, the patient.

STATE DOCUMENTATION REQUIREMENT

I have provided the patient with a copy of the State Department of

HISTORY AND PHYSICAL EXAMINATION 3

000007

Patient: [REDACTED]
Unit: [REDACTED]
Acct: [REDACTED]
Type: [REDACTED]
Location: [REDACTED]
Room: [REDACTED]

Health Services information pamphlet, If You Need Blood: A Patient's Guide to Blood Transfusions, concerning the advantages, disadvantages, risks and benefits of autologous blood and of directed and non-directed homologous blood from volunteers. I have also allowed adequate time prior to surgery for the patient or another person to predonate blood for transfusions purposes, except where there is a life-threatening emergency, there are medical contraindications, or the patient has waived this right.

Discussed with patient: Yes ___ No ___ Emergency ___
Does not apply in this case ___.

[REDACTED], MD

[REDACTED] D: 02/03/99 5:46P PST T: 02/03/99 6:38p PST

CHARTED:

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RECEIVED
CLINICAL RECORDS
& REVIEW DEPARTMENT
'99 JUL 14 P3:10

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Patient:
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Type:
Location:
Room:

12979

DISCHARGE SUMMARY

Date of Discharge: 06/27 98
Date of Admission: 06/23 98

cc: [redacted] MD
cc: [redacted] D
cc: [redacted]

copy: [redacted]

99 JUN 13 P 3:58

RECEIVED
CLINICAL RESEARCH
& REVIEW/OSN HFS-432

FINAL DIAGNOSIS: Left main coronary artery disease with angina.

SECONDARY DIAGNOSES:

1. Subendocardial myocardial infarction.
2. Hypertension.
3. Hyperlipidemia.
4. Carpal tunnel syndrome.

OPERATION AND PROCEDURES PERFORMED:

1. Coronary artery bypass grafting on 6/24/98.
2. Insertion of central venous catheter on 6/24.
3. Cardiac catheterization on 6/24/98.

REASON FOR ADMISSION: This is a 61-year-old woman admitted with several weeks of unstable chest pressure.

HOSPITAL COURSE: The patient was admitted 6/23. There was suggestion of unstable angina, and she was admitted to the coronary care unit on Heparin. She was taken to catheterization laboratory on 6/24 and found to have ostial left main stenosis greater than 50%. She was recommended to undergo urgent revascularization which was performed later in the day on 6/24. The patient underwent two-vessel coronary bypass. Postoperatively, she did well. There were no difficulties. The patient remained in a sinus rhythm. She has been ambulated and is tolerating activity without difficulty.

Laboratory show hematocrit of 26% today. The patient is asymptomatic. BUN and creatinine were 24 and 1.0, potassium is 4.4. Wounds are healing nicely and pacing wires have been removed.

DISPOSITION AND FOLLOW UP: The patient will be discharged home tomorrow 6/28/98. Follow up will be with Dr. [redacted] in four weeks, Dr. [redacted] in one week.

DISCHARGE MEDICATIONS: The patient will be discharged home on Ecotrin one PO daily, Darvocet-N 100 1-2 PO q4h p.r.n. pain, Peri-Colace one PO b.i.d. and iron sulfate 325 mg PO t.i.d.

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DISCHARGE DIET AND DISCHARGE ACTIVITY: The patient will be instructed in activity and dietary regimen.



2:03P PST T: 06/29/98 1:09p PST

CHARTED:

7/1

000010



Patient:
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Type:
Location:
Room:

HISTORY AND PHYSICAL EXAMINATION

Date of Admission: 06/23/98

cc: [REDACTED] MD

copy: [REDACTED]

HISTORY OF PRESENT ILLNESS: The patient is a 61-year-old widowed white female who is admitted in transfer from [REDACTED] for urgent cardiac catheterization.

The patient indicates that her problems began several weeks ago when she apparently underwent an insurance physical examination and was found to have high blood pressure.

At that time she had been taking Metololife, which is a preparation which contains ephedrine. She was taking this essentially for weight loss. However, at the time of her insurance exam she was found to be significantly hypertensive.

Ultimately she was referred to Dr. [REDACTED] who documented systemic hypertension and then started the patient on atenolol 100 mg b.i.d.

She had some adverse effects with the atenolol in the sense that she then began noticing chest pressure occurring both at rest and sometimes with walking. When she was reexamined by Dr. [REDACTED] her blood pressure was still elevated and hydrochlorothiazide was added. By misunderstanding the situation the patient then discontinued her atenolol and was taking hydrochlorothiazide 50 mg daily.

On the morning of 06/22/98 the patient awakened from sleep at 0200 hours and felt fairly exceptional substernal heaviness and pressure which did radiate to the left arm and was associated with dyspnea as well as diaphoresis. She had a poor night sleeping but did attempt to go to work the next morning. While at work her co-workers noted that she did not feel well and subsequently referred her to Dr. [REDACTED] who then admitted the patient to the hospital.

While in the hospital the patient had an exacerbation of chest discomfort and had to be started on intravenous heparin. With morphine and sedation the chest discomfort gradually abated. However, her EKG was abnormal due to nonspecific ST segment changes principally in the inferolateral leads.

In addition her cardiac enzymes were mildly elevated with a total CK of 234 with the upper limit of normal being 139.

In addition she was found to have an elevated total cholesterol of 274,

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Patient:
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Elevated triglycerides of 268.

With the use of heparin the patient's discomfort abated and when she was stable she was then transferred to [REDACTED]

At this time she is completely pain-free. However, repeat enzymes here have continued to show minimal elevation of CK. Her EKG shows flattened T waves in leads I, aVL, II, III, and aVF as well as V5 and V6 which are nonspecific changes.

Because of the patient's risk factors and recurrence of discomfort, it has been elected to perform coronary angiography.

POTENTIAL CORONARY ARTERY DISEASE RISK FACTORS:

1. Recent discovery of significant hypertension which has been resistant to early medical therapy.
2. Hypercholesterolemia.
3. Negative family history.
4. She is a nonsmoker.
5. No evidence of diabetes mellitus.

PAST HISTORY:

MEDICAL:

1. She apparently does have prior evaluations for carpal tunnel syndrome.
2. Episode of cystitis about five months ago.
3. Hypercholesterolemia and hypertension, as above.

SURGICAL: Tubal ligation performed here at [REDACTED] 30 years ago.

DRUG ALLERGIES: None known. Specifically denies allergies to iodine or shellfish.

FAMILY HISTORY: The father died of accidental causes. The mother is alive at age 81 and is said to have hypertension. She has two sisters and two brothers who are alive and well.

HABITS:

SMOKING: Denied.

ALCOHOL: None.

DRUGS: No history of drug abuse.

CAFFEINE: Negative.

SOCIAL HISTORY: The patient works as a packer for a chocolate company in [REDACTED]. She has been widowed for six years after husband died of disseminated melanoma. She has two boys and one daughter and lives with her son in [REDACTED].

REVIEW OF SYSTEMS: Essentially noncontributory except for HPI.

PHYSICAL EXAMINATION:

VITAL SIGNS: Afebrile, apical pulse 72 and regular, respirations 16,

Patient:
Unit:
Acct:
Type:
Location:
Room:

blood pressure 150/92.

GENERAL APPEARANCE: The patient is an obese, pleasant white female who does not appear in acute distress.

HEENT: Normocephalic. No arcus senilis or xanthelasma. The oral mucosa is benign.

NECK: No neck vein distention or carotid bruits. Thyroid not enlarged.

LUNGS: Clear to auscultation.

HEART: Precordium is quiet. The rhythm is regular. M1, S2 are within normal limits. No gallop, rub, or murmur audible.

ABDOMEN: Soft, obese, and protuberant. No organomegaly. No epigastric bruits.

EXTREMITIES: No peripheral edema, cyanosis, or clubbing. Peripheral pulses intact and equal. No femoral artery bruits.

NEUROLOGIC: Physiologic.

IMPRESSION:

1. Probable coronary artery disease.
 - a) Clinical evidence of unstable angina with minor CK elevation.
2. Hypercholesterolemia.
3. Systemic hypertension.
4. Exogenous obesity.

PLAN: The patient has been admitted for coronary angiography. The risks of that procedure which include the possibility of death, heart attack, stroke, femoral artery thrombosis, bleeding, infection, and complications not restricted to the above have been explained to and accepted by the patient.

STATE DOCUMENTATION REQUIREMENT

I have provided the patient with a copy of the State Department of Health Services information pamphlet, **If You Need Blood: A Patient's Guide to Blood Transfusions**, concerning the advantages, disadvantages, risks and benefits of autologous blood and of directed and non-directed homologous blood from volunteers. I have also allowed adequate time prior to surgery for the patient or another person to predonate blood for transfusions purposes, except where there is a life-threatening emergency, there are medical contraindications, or the patient has waived this right.

Discussed with patient: Yes ___ No Emergency ___
Does not apply in this case .

CHARTED: D: 06/23/98 7:14P PST T: 06/23/98 8:29p MST

000013

Patient:
Unit:
Acct:
Type:
Location:
Room:

HISTORY AND PHYSICAL EXAMINATION

Date of Admission: 06/23/98

cc:
cc:

Copy:

CHIEF COMPLAINT: A 61-year-old female with severe ostial left main stenosis.

HISTORY OF PRESENT ILLNESS: The patient developed rest angina on June 22, 1998, and was admitted for rule out myocardial infarction. Her enzymes indicated a subendocardial infarct. She continued to have pain at rest in the hospital and was transferred to [REDACTED] where Dr. [REDACTED] performed cardiac catheterization, showing good left ventricular function and essentially normal dominant right coronary artery. However, the left main ostium was quite tight. The LAD and diagonal appeared free of significant disease.

The patient is recommended to undergo double coronary artery bypass grafting with left internal mammary to LAD and saphenous vein to obtuse marginal. She understands the risks include death, bleeding, infection, stroke, myocardial infarction, graft failure and virus from blood transfusion. She also understands the medical alternatives and she agrees with the risk and wishes to proceed.

MEDICATIONS

1. Atenolol 100 mg PO b.i.d.
2. Hydrochlorothiazide.

PAST MEDICAL HISTORY

ILLNESSES: Coronary artery disease as above. Subendocardial myocardial infarction June 22, 1998, hypertension, hyperlipidemia, carpal tunnel syndrome, recent history of cystitis.

OPERATIONS: Tubal ligation in 1968.

ALLERGIES: None.

SOCIAL HISTORY: She denies smoking and she denies alcohol ingestion.

SYSTEMIC REVIEW: The patient denies diabetes, CVA, TIA, blood per urine, stool or sputum, or claudication.

PHYSICAL EXAMINATION

GENERAL: A pleasant white female in no acute distress.

HEENT: Normal. Pupils equal and react to light.

NECK: No masses. No carotid bruits.

000014

Patient:
Unit:
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Type:
Location:
Room:

LUNGS: Clear.
CARDIAC: There is no murmur, gallop, rub.
ABDOMEN: Benign.
GENITALIA: Grossly normal.
RECTAL: Deferred.
EXTREMITIES: Lower extremities: No venous varicosities, no skin ulcerations.
PULSES: The radial, carotids, femorals and posterior tibials are 3+/3+.
NEUROLOGIC: She is oriented to time, person, place. Cranial nerves are intact. Motor and sensory are intact.

IMPRESSION

1. Unstable angina secondary to tight ostial left main stenosis.
2. Subendocardial myocardial infarction on June 22, 1998.
3. Hypertension.
4. Hyperlipidemia.
5. Carpal tunnel syndrome.
6. Recent history of cystitis.

DISPOSITION: The patient is scheduled for urgent double coronary artery bypass grafting.

STATE DOCUMENTATION REQUIREMENT

I have provided the patient with a copy of the State Department of Health Services information pamphlet, **If You Need Blood: A Patient's Guide to Blood Transfusions**, concerning the advantages, disadvantages, risks and benefits of autologous blood and of directed and non-directed homologous blood from volunteers. I have also allowed adequate time prior to surgery for the patient or another person to predonate blood for transfusions purposes, except where there is a life-threatening emergency, there are medical contraindications, or the patient has waived this right.

Discussed with _____ No _____ Emergency _____
_____ does not apply in this case _____.

4/98 12:11A PST T: 06/24/98 12:16p PST

CHARTED:

000015