

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

ARMS#

12452



7 - PROCEDURES

000001

19 JUN-1997 19:22

ID: [REDACTED]

Heart rate	106	BPM
PR interval	152	ms
QRS duration	80	ms
QT/QTc	335/422	ms
P-R-T axes	63 - 6	84

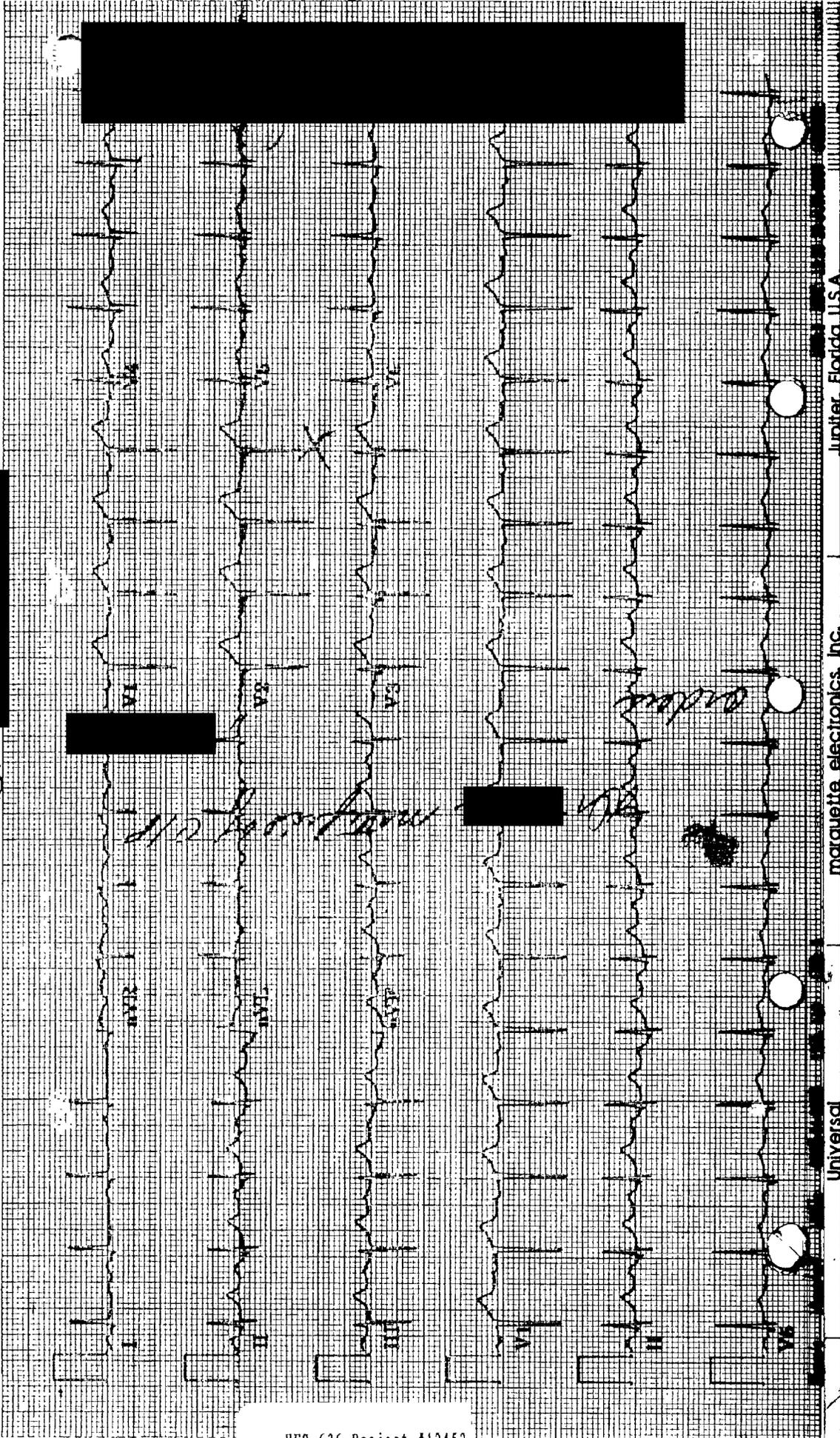
59 yr
Female
Caucasian
Race
Location
Oxycodone 17

SINUS TACHYCARDIA
LEFTWARD AXIS
ANTEROSEPTAL INFARCT, AGE UNDETERMINED
ST ELEVATION, CONSIDER EARLY REPOLARIZATION
ABNORMAL ECG
NO PREVIOUS ECGS AVAILABLE

CC: [REDACTED]

Referred by [REDACTED] M.D.

Dr. [REDACTED]



REPORT OF RADIOLOGICAL CONSULTATION

M.D.

To _____ M.D.
Attending Physician

Patient _____

Age 59 DOB _____

Address _____

Ward or Clinic _____

X-Ray No. _____

Date of Examination 06-19-97

Registration No. _____

ERECT PORTABLE AP CHEST AT 8:10 PM:

Clinical History: Chest pain.

Prior radiographs are not available for comparison. The patient has had a right mastectomy and lymph node dissection. The heart and mediastinum are within normal limits. The lungs are clear.

IMPRESSION: Negative chest post right mastectomy.

D: 6/19/97
T: 6/19/97 9:15 pm

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REPORT OF RADIOLOGICAL CONSULTATION

To: [Redacted] M.D.
Attending Physician

Patient [Redacted]

Age 59 [Redacted]

Address [Redacted]

Ward or Clinic [Redacted]

X-Ray No.

Date of Examination 06/24/97

Registration No. [Redacted]

AP CHEST: 4:00 P.M.

CLINICAL HISTORY: Chest pain. Recheck.

Since the previous exam performed on 06/19/97 a median sternotomy has been performed. An endotracheal tube has been placed and is adequately positioned above the level of the carina. A Swan-Ganz catheter has been placed and the tip is positioned fair peripherally on the right. Mixed interstitial and alveolar infiltrates involving the right lung. A more confluent infiltrate is present in the left perihilar region. There is no evidence of pneumothorax or pleural effusion.

- IMPRESSION:
- 1) Suboptimal positioning of the Swan-Ganz catheter. Suggest retracting approximately 4 cm.
 - 2) Probable mild congestive heart failure. Probable left perihilar atelectasis.

[Redacted]
D: 6/24/97
T: 6/24/97 5:14 pm

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To _____ M.D.
Attending Physician

Patient _____

Age 59 DOB _____

Address _____

Ward or Clinic _____

X-Ray No. _____

Date of Examination _____

Registration No. _____

PORTABLE AP UPRIGHT CHEST: 03:15

CLINICAL HISTORY: Recheck.

Comparison made to prior studies.

ET tube apparently has been removed. There is subsequent hypoventilation.

There is increased density in the left hemithorax which appears to be in large part due to technical differences. I suspect there has been no significant interval change.

The Swan-Ganz catheter has been repositioned with the tip in the area of the right main pulmonary artery.

Pulmonary vascularity now appears essentially within normal limits.

IMPRESSION: Continued increased density in the left hemithorax felt in major part due to atelectasis possibly associated with effusion. There does not appear to be any significant interval change when allowing for technical differences.

Note made of right sided mastectomy.

D: 6/25/97
T: 6/25/97 8:49 am

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HOSPITAL CHART

000005

REPORT OF RADIOLOGICAL CONSULTATION

To [redacted] M.D.
Attending Physician

Patient [redacted]

Age 59 [redacted]

Address [redacted]

Ward or Clinic [redacted]

X-Ray No. [redacted]

Date of Examination 06/20/97

Registration No [redacted]

DOPPLER ULTRASOUND OF THE KIDNEYS AND ULTRASOUND OF THE ABDOMINAL AORTA:

CLINICAL HISTORY: Chest pain.

The abdominal aorta tapers towards the bifurcation. No evidence for aneurysm. The inner wall of the abdominal aorta appearing somewhat irregular suggesting plaque formation.

No evidence for hydronephrosis, suspicious mass, or calculi in either kidney. Both kidneys were very difficult to visualize, especially on the left side. The left renal cortex appears to be diffusely thinned. Two very small simple appearing cysts present in the left kidney, one in the mid and one in the superior aspect of the kidney. Both of these measuring approximately 1 cm in diameter. The right kidney measuring 10.1 x 3.8 cm and the left kidney 10.5 x 4.6 cm.

Doppler evaluation of the renal vasculature reveals a peak velocity of 1.1 in the aorta, 0.9 in the right renal artery, and 0.22 in the left renal artery. The peak velocity, especially in the left renal artery is significantly lower than the aorta. However, the renal artery was very difficult to identify and these measurements are thought to be essentially nondiagnostic. Certainly, renal artery stenosis cannot be excluded.

- IMPRESSION:
- 1) No evidence for abdominal aortic aneurysm.
 - 2) Diffuse cortical thinning of the left kidney. Two small simple appearing cysts present in the left kidney.
 - 3) Nondiagnostic Doppler study of the renal arteries. If clinically indicated, a Captopril augmented nuclear renogram may be helpful in further evaluation.

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D: 6/21/97 T: 6/21/97 9:41 am

HOSPITAL CHART [redacted]

NAME : [REDACTED]
AGE : 59
NO : [REDACTED]
UNIT :

DATE OF OPERATION: 06-23-97

OPERATIVE PROCEDURE: Left heart catheterization, left ventriculography, selective coronary angiography.

SURGEON: [REDACTED], M.D.

ANESTHESIA: Local.

INDICATIONS: The patient is a 59-year-old white female admitted to the hospital with unstable angina.

DESCRIPTION OF PROCEDURE: The patient was brought to the catheterization laboratory. The right groin was prepped and draped appropriately for a Judkins left heart catheterization. Local anesthesia was obtained with 1% Lidocaine. Access to the right femoral artery was obtained using an 18 gauge thin walled needle. A guide wire was passed through the needle and the needle was removed. A #6 French dilator and introducer were passed over the guide wire and the dilator and guide wire removed. The #6 French catheter was used for a left heart catheterization. A Pigtail catheter was used to measure pressures in the left ventricle and perform a left ventriculogram in the 30 degrees right anterior oblique projection. A Judkins left and right coronary catheter was used for selective coronary angiography. The catheters and introducers were removed. Hemostasis was obtained with 10 minutes of pressure to the right groin.

RESULTS:

1. Pressure data: Intra-aortic pressure: Systolic 161, diastolic 72. Left ventricular pressure: Systolic 169. Left ventricular end diastolic pressure 28. There was no gradient on the pullback across the aortic valve.
2. Left ventriculography: The left ventricle is of normal size. There was mild apical hypokinesia. The overall ejection fraction was within the normal limits measured at 68%. There was 2+ mitral regurgitation.
3. Coronary angiography: A) The left main coronary artery is a short vessel with no significant lesions. B) The left anterior descending was a small vessel. There was an 80% stenosis proximally and distally the vessel was very small. C) The circumflex was a non-dominant vessel that had an 80% proximal stenosis with three obtuse marginal branches, all of which had 70% stenoses in their proximal portion. D) The right coronary artery is a very large, dominant vessel. It had two areas of 70% stenosis in it's mid descending portion with a 90% stenosis at the bifurcation into a large posterior L/V branch and posterior descending coronary artery.

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CARDIAC CATHETERIZATION REPORT

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[REDACTED]

[REDACTED]

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IMPRESSION: The patient has diffuse disease but has significant three vessel coronary disease. Bypass surgery should be considered.

[REDACTED]

CC: [REDACTED]

D: 06/30/97
T: 07/07/97
[REDACTED]

CARDIAC CATHETERIZATION REPORT

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[REDACTED]

Name : [REDACTED]
DOB : [REDACTED]
No : [REDACTED]
Unit : [REDACTED]

DATE OF OPERATION: June 24, 1997.
PREOPERATIVE DIAGNOSIS: Coronary artery disease.
POSTOPERATIVE DIAGNOSIS: Coronary artery disease.
OPERATIVE PROCEDURE: SAPHENOUS VEIN HARVEST
SURGEON: [REDACTED] M.D.
ASSISTANT: [REDACTED]
ANESTHESIA: General endotracheal
PREPARATION: Betadine

DESCRIPTION OF PROCEDURE: After the patient was prepped and draped in the usual fashion, the 7 leg was used for saphenous vein harvest. Scalpel and sharp dissection were used to dissect out the saphenous vein. Side branches were clipped with hemoclips. The vein was removed and flushed with iced heparinized saline. Large side branches were clipped with small hemoclips and leakage sites were repaired with 7-0 Prolene. After the vein was deemed suitable for bypass, the leg was inspected and found to be hemostatic. The wound was closed with running layers of 3-0 Vicryl with running subcuticular suture being used for the skin. Sterile dressings were applied.

[REDACTED] M.D.
D: 06/24/97
T: 07/01/97/[REDACTED]
T:

OPERATIVE REPORT

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NAME : [REDACTED]
AGE : 59
NO : [REDACTED]
UNIT :

DATE OF OPERATION: 06-24-97

PREOPERATIVE DIAGNOSIS: Coronary disease, unstable angina, acute myocardial infarction.

POSTOPERATIVE DIAGNOSIS: Coronary disease, unstable angina, acute myocardial infarction.

OPERATIVE PROCEDURE: Coronary artery bypass grafting times four, LIMA, LIMA to LAD, saphenous vein graft D1, saphenous vein graft to PDA and PLB.

SURGEON: [REDACTED], M.D.

ASSISTANT: [REDACTED], M.D., CFA.

ANESTHESIA: General endotracheal.

INDICATIONS: The patient is a 59-year-old woman who has known coronary artery disease and who presented with chest pain, ruled in for myocardial infarction. She underwent cardiac catheterization which revealed very severe coronary artery disease and underwent angioplasty and was referred to me for revascularization. I explained the possible risks and complications, up to and including stroke, death, bleeding, infection and non-healing wounds to the patient, she agreed to and requests to proceed as planned.

FINDINGS: LIMA is good quality, as was saphenous vein. Coronary arteries were very calcified and would make her a very poor operative candidate for a redo operation. LAD was 1 to 1 1/2 mm in diameter with very severe diffuse distal disease. PDA, PLB and D1 were 1 1/2 mm in diameter with very severe diffuse distal disease.

DESCRIPTION OF PROCEDURE: After the obtainment of general endotracheal anesthesia and placement of monitor lines the patient was prepped and draped in the usual sterile fashion. The saphenous vein was harvested and prepared from the right leg. Median sternotomy was created and the left internal mammary artery was taken down. The patient was systemically heparinized. The pericardium was opened and the heart suspended in a pericardial cradle. Purse strings were placed in the ascending aorta and right atrial appendage following placement of aortic and right atrial cannula. A purse string was placed in the ascending aorta for placement of the cardioplegia cannula. The patient was placed on cardiopulmonary bypass and cooled. A cross clamp was applied and diastolic arrest was achieved by the administration of 1,000 cc of blood cardioplegic solution in an antegrade fashion bathing the heart in topical iced saline solution throughout the remainder of the case. The heart was vented through the aortic root and was re-pledged times one with 500 cc of cardioplegic solution.

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[REDACTED]

[REDACTED]

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DESCRIPTION OF PROCEDURE (CONTINUED FROM PAGE 1): The above mentioned vessels were identified, the saphenous vein was anastomosed to PDA in an end to side fashion, the saphenous vein was anastomosed to OM-1 in an end to side fashion and the saphenous vein was anastomosed to the PLB in an end to side fashion. LIMA was anastomosed to the LAD in an end to side fashion. All distal anastomosis were created with running 7-0 Prolene. During the creation of the last anastomosis the patient was rewarmed. The side biting clamp was removed, the patient returned to normal sinus rhythm. A cross clamp was applied and two proximal vein grafts were anastomosed to the ascending aorta using running 5-0 Prolene and a 4.4 mm punch. The side biting clamp was removed, vein grafts were de-aired. All distal anastomosis were checked and hemostasis was assured. The left chest tube, two mediastinal tubes and right ventricular pacing wire were placed and brought out through separate stab wounds and secured to the skin. The patient was weaned from cardiopulmonary bypass initially requiring a .02 of epinephrine and then this was discontinued and the patient had indices greater than 2. The patient was then de-cannulated without difficulty. Pledget and sutures had to be used at the right atrial cannula for reinforcement. Hemostasis was obtained with electrocautery and suture ligation as needed. The sternum was then approximated with six #6 wires and the wound was closed in layers with Vicryl and subcuticular Vicryl skin stitch. Sponge, needle and instrument count was reported as correct times two to the surgeon. There were no complications. The patient was stable on no inotropic support to the SICU. Cardiopulmonary bypass time: 88 minutes. Cross clamp time: 47 minutes.

[REDACTED]

[REDACTED] M.D.

D: 06/24/97
T: 06/30/97

[REDACTED]

OPERATIVE REPORT

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