

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

ARMS#

12871



5 - SUMMARIES

000001

DISCHARGE SUMMARY REPORT

ADMISSION DATE: 04/02/98

DISCHARGE DATE: 04/06/98

HOSPITAL COURSE:

The patient was admitted with a massive left hemispheric CVA based on clinical exam. The CT scan initially was unremarkable, but subsequently demonstrated a large left hemispheric CVA with early edema. On April 4, the patient was noted to be increasingly agitated with respect to his respirations. His blood pressure was labile. He was felt to have early herniation on the basis of this as well as his anisocoria. He was intubated, hyperventilated, given Mannitol, and repeat CT showed increasing degree of edema and herniation. Despite aggressive Mannitol and hyperventilation, the patient continued to have a declining neurologic status.

It was quite clear from the patient's family that he would not have wanted this type of existence, and, therefore it was elected to discontinue life support. Also, it was quite clear that the patient had desired donation of his organs prior to his death, and therefore, the people from [REDACTED] have assisted in arranging the harvesting. Cerebral blood flow study was done prior to this time, which was entirely without cerebral blood flow, and thus, that combined with his clinical exam were consistent with brain death.

The patient was harvested on April 6, 1998.

[REDACTED] M.D.

D: 04/06/98

T: 04/13/98 15:58

cc: [REDACTED] M.D.

000002

Dictating: [REDACTED] M.D.
Attending: [REDACTED] M.D.

DISCHARGE SUMMARY
PAGE 1

HISTORY & PHYSICAL

DATE OF ADMISSION: 04/02/98

REASON FOR ADMISSION:

Stroke.

HISTORY OF PRESENT ILLNESS:

This is a 46-year-old gentleman with a history of talking on the telephone at approximately 3:05 p.m. on the afternoon of April 2 to a business partner. The story as related to us by his parents is that the business partner noted there was an abrupt cessation of the conversation and that the patient, immediately preceding that cessation of conversation, complained of dizziness. The business partner evidently called the patient's brother or his parents, who went to the patient's office and found the patient. Subsequently the patient was taken to [REDACTED] emergency department where he was found to have a dense right hemiparesis and expressive aphasia, and he was felt to have had an acute ischemic event in the left hemisphere.

He was seen in consultation in the emergency room by Dr. [REDACTED] and he was entered into the stroke protocol. He was started on TPA and being considered for the _____ study.

In talking with the patient's parents, the patient has evidently been very healthy. He has been very active. He exercises three times a week. He has no underlying medical problems. There is no history of IV drug abuse or other illicit drug abuse. He has been very active in general.

PAST MEDICAL HISTORY:

Significant for no major medical illnesses. There is no history of hypertension or hypercholesterolemia. There is no history of previous TIA or stroke. No history of diabetes or underlying cardiac disease. No history of abdominal disorders or renal disorders.

CURRENT MEDICATIONS:

None.

ALLERGIES:

NONE.

FAMILY HISTORY:

Significant for stroke in the patient's grandmother at age 49. There

000003

DICTATING: [REDACTED] M.D.
ATTENDING: [REDACTED] M.D.

HISTORY & PHYSICAL
PAGE 1

HISTORY & PHYSICAL

is no history otherwise of bleeding or clotting diatheses. The family history is otherwise negative.

SOCIAL HISTORY:

He is a nonsmoker and a nondrinker. He is a businessman.

REVIEW OF SYSTEMS:

Unobtainable from the patient.

PHYSICAL EXAMINATION:

GENERAL: This gentleman is alert and does follow verbal commands but has an expressive aphasia. He is no acute distress.

VITAL SIGNS: Blood pressure 113/85, pulse 72, respiratory rate 18 to 20. He is afebrile.

HEENT: Pupils equal, round and reactive to light. Extraocular muscles are noted to be abnormal with abnormal gaze to the right. No evidence of hemorrhage, exudates or papilledema on funduscopic exam. Oropharynx is negative.

NECK: Supple. Carotids diminished somewhat bilaterally. There is no adenopathy, tracheal deviation or thyromegaly.

CHEST: Clear to auscultation and percussion. Symmetric breath sounds bilaterally.

CARDIOVASCULAR: Regular rate and rhythm. There is no S3, S4 or murmur. No rub.

ABDOMEN: Soft, nontender, not distended, no masses, megaly, bruit, distention, rebound, guarding or ascites.

EXTREMITIES: Without cyanosis, clubbing or edema. Distal pedal pulses 2+. Radial pulses 2+.

NEUROLOGIC: Dense right hemiparesis, expressive aphasia and probable right homonymous hemianopia.

DIAGNOSTIC STUDIES:

White blood count 13,400, hematocrit 43.7, platelet count 225,000. Sed rate pending. Sodium 138, potassium 4.2, initial creatinine on chemistry panel 2.5, repeat 1.1. Drug screen pending.

000004

Dictating: [REDACTED] M.D.
Attending: [REDACTED] M.D.

HISTORY & PHYSICAL
PAGE 2

HISTORY & PHYSICAL



Electrocardiogram is a normal sinus rhythm and is a normal tracing. Chest x-ray is without abnormality.

IMPRESSION:

Left hemispheric cerebrovascular accident, question etiology. The history in the family of previous cerebrovascular accident at a young age suggests possible underlying hypercoagulable condition. The status of his carotid arteries at this point is not known. Likewise, consideration of possible occult cardioembolic events needs to be considered.

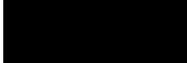
RECOMMENDATIONS:

1. Admit.
2. Medical stabilization.
3. Stroke protocol per Dr. [REDACTED]
4. Hypercoagulable workup.
5. Echo of the heart.
6. Carotid duplex study.
7. Follow up pending the above.



M.D.

D: 04/03/98 09:10
T: 04/04/98 04:27



000005



Dictating: [REDACTED] M.D.
Attending: [REDACTED] M.D.

CONSULTATION REPORT

DATE: 04/02/98

REASON FOR CONSULTATION:

Stroke code consult.

REASON FOR EVALUATION:

"Cannot talk or move his side."

HISTORY OF PRESENT ILLNESS:

The patient is a 46-year-old right-handed man brought in by his parents this afternoon at 1620, with new stroke symptomatology. He was on the phone talking to a business associate at 3:05 p.m., when abruptly his speech became garbled. His parents were called by 3:15, went over to his house and brought him to the emergency room. They note that he initially was able to speak a little, was able to use his right arm and leg some, and in fact, was able to climb into their Land Rover and walk into the emergency department. Here, he was noted to be aphasic and paralyzed on the right, and was assessed as having an acute ischemic stroke.

A stroke code was appropriately called. I was notified at 1700. He had already undergone a head CT scan which was read by the radiologist as showing possible cortical edema on the right. He has continued with similar severity of deficits, unable to speak or move his right side. A stroke code consultation has now been requested.

PAST MEDICAL HISTORY:

This was reviewed with his parents and is very benign. He does have a history of back injury from which he had apparently fully recovered and he has, in fact, been working with a personal trainer to control his weight. He watches his diet carefully, does not smoke, and drinks wine in moderation occasionally. There is no history of elevated cholesterol, elevated blood pressure, diabetes, clotting disorders, or any sort of trauma.

To their knowledge, he uses no medications or street drugs. No history is available from the patient.

CURRENT MEDICATIONS:

To their knowledge, he uses no medications.

ALLERGIES:

No known drug allergies.

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CONSULTANT:
ATTENDING:

M.D.
M.D.

CONSULTATION
PAGE 1

CONSULTATION REPORT

FAMILY HISTORY:

The patient's grandparents apparently had strokes or heart attacks at older ages but there is no family history of young age cardiovascular disease.

SOCIAL HISTORY:

The patient is self-employed as a computer engineer and

PHYSICAL EXAMINATION:

VITAL SIGNS: The blood pressure is 124/62, heart rate is 76, respiratory rate is 18 and he is afebrile.

HEENT: Normocephalic and atraumatic.

NECK: Supple. There are no cranial or cervical bruits.

LUNGS: Clear to auscultation.

CARDIAC: Regular rate and rhythm. No audible murmurs or gallops.

ABDOMEN: Soft and nontender. No masses or hepatosplenomegaly.

EXTREMITIES: No clubbing, cyanosis or edema.

NEUROLOGIC: The patient appears alert, occasionally yawning, but fully attentive to what is going on. He is essentially mute without verbalization, though occasionally there is a soft grunt or sound. He follows about 50-70% of simple one-part commands but follows no two-part or more complex commands. He has right neglect and a left gaze preference. Cranial nerves: The pupils are 3 mm, round and reactive. He appears to have a right homonymous field cut to threat. The disks are flat. The extraocular movements are full, although as noted above, he has a left gaze preference that can be overcome with pursuit of my face. He grimaces to supraorbital pressure but has a moderately severe right central facial weakness. The tongue protrudes in the midline. The palate elevates symmetrically. The gag is intact.

Motor: Strength on the left side appears normal. His right side is completely flaccid and plegic. There is a flicker of movement in his leg at most. **Sensory:** There is diminished grimace to noxious stimuli on the right. He appears to appreciate pinprick and touch fairly normally as best I can tell on the left. There is no sign of ataxia on

CONSULTANT: M.D.
ATTENDING: M.D.

CONSULTATION
PAGE 2

000007

CONSULTATION REPORT

the left, as noted above, he is flaccid and plegic on the right. The reflexes are symmetric and normal. There is an easily elucidible right Babinski while the left plantar response is flexor.

LABORATORY DATA:

The head CT scan films were reviewed in detail. There was no evidence of sulcal flattening, significant loss of gray white matter distinction, ventricular asymmetry, edema, hemorrhage or mass. EKG showed sinus rhythm without acute ST or T-wave changes. Metabolic panel showed a glucose 126, BUN 17, creatinine 2.5, and the protime 13.1, PTT 22, and sedimentation rate 2. CBC was pending.

IMPRESSION:

This patient presents rapidly with signs and symptoms of ischemic stroke involving the left hemisphere appearing to represent a left middle cerebral artery occlusion or possibly a complete left internal carotid artery occlusion. In this context, I would be concerned about possible dissection, although there is no history of trauma. Coagulation disorder remains a possibility as does some underlying as yet undisclosed cardiac arrhythmia or structural cardiac anomaly. His cardiac examination is normal and history for this is completely benign. More conventional stroke etiology such as atheroembolus is relatively improbable in this context and there is no history of drug abuse from which he might be developing vasospasm.

He has presented rapidly and following full discussion with the family as well as their written consent, tPA has been initiated at a total dose of 68 mg based on his body weight of 75 kg with an initial loading dose of 6.8 mg and the balance given over one hour.

In addition, following full review of the inclusion and exclusion criteria, he is appropriate for the [REDACTED]. I have discussed the trial in detail with his parents, who are here in the emergency department, including all of the potential risks, potential benefits and alternatives. Following this discussion and their review of the informed consent statement, they agreed to his participation and have signed for him as he is unable to sign both because of his hemiplegia and his aphasia. Consequently, he is randomized as patient [REDACTED] on the [REDACTED]. The protocol as appropriate to the trial will now be initiated including study of appropriate laboratory assessments and administration of the medications.

He will need intensive care unit admission and I have discussed this

CONSULTANT: [REDACTED] M.D.
ATTENDING: [REDACTED] M.D.

CONSULTATION
PAGE 3

000008

CONSULTATION REPORT

[REDACTED]

already with Dr. [REDACTED] who will be the attending and admitting physician. Further evaluation for the etiology of his stroke will be pursued aggressively, including initial carotid duplex and transthoracic echo as well as appropriate hypercoagulation laboratories and if necessary, transesophageal echocardiogram. A 24-hour head CT will be ordered as is routine following tPA administration.

He will be followed quite closely and once he is fully stable neurologically, then transfer to [REDACTED] can be considered at that point.

I thank you for the opportunity to assist in the evaluation of this gentleman.

[REDACTED], M.D.

D: 04/02/98 18:35
T: 04/03/98 20:45

[REDACTED]

cc: [REDACTED] M.D.

000009

[REDACTED]

CONSULTANT: [REDACTED] M.D.
ATTENDING: [REDACTED] M.D.

ADMITTED

EMERGENCY DEPARTMENT REPORT

DATE: 04/02/98

CHIEF COMPLAINT:

Unable to talk.

HISTORY OF PRESENT ILLNESS:

The parents of this 46-year-old man state that he has been unable to talk and has had right-sided weakness since 3 p.m. They state that he was talking with a friend on the telephone when suddenly he could not continue the conversation at 3:03 p.m. today. His friend summoned help, and the parents brought him to the E.D. via private car.

He saw his physician at [REDACTED] today and received a "hepatitis shot" for a trip that he is planning to [REDACTED]. The parents state that the patient is in excellent health and has no medical problems of which they know.

PAST MEDICAL HISTORY:

Negative per the parents.

SOCIAL HISTORY/REVIEW OF SYSTEMS:

Information cannot be obtained from the patient.

PHYSICAL EXAMINATION:

VITAL SIGNS: Temperature 96.9 degrees, pulse 96, respiratory rate 16, blood pressure 142/66 **GENERAL:** The patient is awake and cooperates with the physical examination, such as when requested to squeeze the examiner's hand, etc. He cannot verbalize intelligible words. **HEENT:** PERRL. Pharynx clear. **NECK:** Supple. No Kernig or Brudzinski sign. **LUNGS:** Clear. **HEART:** Regular rhythm. No murmur, rub or gallop. **ABDOMEN:** Soft, bowel sounds normal, nontender. No rebound, guarding, spasm or mass. **EXTREMITIES:** Nontender. **NEUROLOGIC:** Right hemiparesis, upper extremity greater than lower extremity. Right facial weakness. Right hyperreflexia. Babinski sign present on the right.

DIAGNOSTIC STUDIES:

CT of the head: Possible edema on the left, otherwise negative. No hemorrhage. Oxygen saturation 97% in room air, interpreted as showing normal oxygenation. Chest x-ray negative per the radiologist. ECG interpretation: Normal sinus rhythm, rate 80, normal ECG. Metabolic panel: Sodium 138, potassium 4.2, BUN 17, creatinine 2.5, glucose 126. CBC: White count 13,400, hemoglobin 14.9, hematocrit 43.7, 80.2% segs. Urinalysis and urine rapid toxicology pending.

DICTATING: [REDACTED] M.D.
ATTENDING: [REDACTED] M.D.

ED REPORT
PAGE 1

000010

EMERGENCY DEPARTMENT REPORT

IMPRESSION:

Cerebrovascular accident.

EMERGENCY DEPARTMENT COURSE:

The patient was immediately seen on presentation and CT scan was ordered stat. When the results were obtained, and it was found that there was no intracranial hemorrhage, the situation was discussed with the patient's parents concerning TPA. Informed consent was obtained, and the parents were informed of the risk of TPA, specifically intracranial hemorrhage, and the parents wished to proceed with TPA.

The patient was discussed with Dr. [REDACTED] who was also at the bedside, who also recommended the patient receive TPA. The patient has been stable hemodynamically. Dr. [REDACTED] will admit the patient to the intensive care unit for further evaluation and treatment.

The patient was discussed with Dr. [REDACTED], who gives number [REDACTED]

MEDICAL DECISION-MAKING:

This 46-year-old man had the sudden onset of inability to speak and right hemiparesis. There is no hemorrhage on CT. The most likely etiology is an ischemic CVA. At this time, there are no apparent, underlying risk factors for ischemic CVA at the patient's young age, and this will be investigated as an inpatient.

[REDACTED], M.D.

D: 04/02/98 18:03

T: 04/03/98 04:14

[REDACTED]

Dictating: [REDACTED] M.D.
Attending: [REDACTED] M.D.

ED REPORT
PAGE 2

000011

Admission Date 04-02-98	DISPOSITION	Home	AMA	SNF	Rehab.	Other			
Discharge Date		Expired 04-06-98	Autopsy NO	Coroner's Case NO	Coded 2	Assembled	Analyzed	SMS	Admitting Dx Code

PRINCIPAL DIAGNOSIS - The condition established after study to be chiefly responsible for occasioning the admission of the patient to the hospital for care.	Code Number
	✓

SECONDARY DIAGNOSIS (NO ABBREVIATIONS)	Code Number

PRINCIPAL PROCEDURE (NO ABBREVIATIONS)	Code Number
4/5	■

SECONDARY PROCEDURES	Code Number
4/5	■
4/4	■
4/4	■
4/5	■

CONSULTANTS:	DRG Number
■	■

COMPLICATIONS:

"I certify that the narrative description of the principal and secondary diagnoses and the major procedures performed are accurate and complete to the best of my knowledge.

Attending Physician Signature: _____ Date _____

SUMMARY SHEET

■

000012

■

[REDACTED]
Gender : Male
Age : 46
Disposition: Expired (20)
Disch Date : 04/06/1998

DRG

[REDACTED] SPECIFIC CEREBROVASCULAR DISORDERS EXCEPT TIA
wt 1.1889 A/LOS 6.8 G/LOS 5.1

Principal Diagnosis

[REDACTED] OCCLUSION AND STENOSIS OF CAROTID ARTERY WITH CEREBRAL
INFARCTION

Secondary Diagnoses

[REDACTED] RESPIRATORY FAILURE
APHASIA
UNSPECIFIED HEMIPLEGIA AND HEMIPAREISIS AFFECTING UNSPECIFIED
SIDE
SYMBOLIC DYSFUNCTION
COMPRESSION OF BRAIN

Principal Procedure

[REDACTED] CONTINUOUS MECHANICAL VENTILATION FOR LESS THAN 96 CONSECUTIVE
HOURS

Other Procedures

[REDACTED] CEREBRAL SCAN
LEFT HEART CARDIAC CATHETERIZATION
CORONARY ARTERIOGRAPHY USING TWO CATHETERS
VENOUS CATHETERIZATION
ARTERIAL CATHETERIZATION

[REDACTED]

000013