Stroke Treatment Legal Issues

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Objectives

- Cover medical issues related to diagnosis and treatment of stroke in the ED
- Cover the legal implications of those issues

And….

- **Ruin your morning**

Issues

- Diagnosis
- Treatment--Thrombolysis
  - Yes or no (AHA Class I, 8/2000)
  - Protocols
- Informed consent
- Back-up–Neurology/Neurosurgery
- Transfer

A Little Legal Overview

- Lawsuits require
  - A breach of the *standard of care*
  - That is the *proximate cause* of
  - *Injury or damages*
- Strokes have great potential for high damages
- The higher the damage potential, the higher the incentive for patients, family (and attorneys) to bring a case

Case 1

- TC--2000 Michigan
  - 70 yr old man collapsed on court while refereeing a basketball game
    - Time of event known to 0.1 sec
  - Immediate R hemiparesis/aphasia
  - Transferred to hospital via EMS
    - Arrived within less than 40 min of event
  - Found to have R hemiparesis (dominant) and aphasia

Case 1

- CT scan and TPA available
  - Protocol for MI, not stroke
  - MD had used TPA many times for MI
  - tPA had been used (by other MDs) at hospital for stroke
- Family present
- CT scan performed within 90 min of event
- Patient admitted to hospital
- Hemiparesis/aphasia persisted
- Confined to institution

Case 1

- Family filed suit
- Issues
  - Lack of treatment or offer of treatment
  - Lack of information about options
- OPINIONS
  - Met standard?
  - Did not meet standard?

Case 1

- Outcome
  - Verdict--Emergency MD failed to meet standard of care for failing to discuss options with family
  - No $$$ awarded because Michigan rule of >50% likelihood of improvement required for damage award

Case 1

"The question in this case is that the physicians actively or passively made a unilateral decision not to offer an FDA approved on-label drug that is the only drug that has any proven benefit, regardless of whether it's a massive benefit or a minor benefit or whether there's ups and downs or pluses or minuses, which there are; there is no question about that. There is some controversy about this drug. But it is not within the standard of care for a physician to simply say it's my opinion, although I'm not telling you about my opinion, that I'm not even going to mention this."

"The Food and Drug Administration of the United States says this is a proven effective on label nonexperimental drug. The physician may disagree with that, and he should tell the family: "This is what's available. I don't think you should get it." And if the family says "Fine, we don't want it," fine. Nobody did any of that. That is the issue in this case. But it didn't happen, and that's really the issue. And it goes far beyond whether it's tPA for MI or stroke or anything else. Patients deserve the right to be told what their options are.

And we have passed the '60s and '70s. Marcus Welby is no longer our family doctor, and this is not how practice is done in the United States, by the standard of care. Doctors do not have that right. And I think that's fairly well known by most practicing physicians."

Case 1

- Discussion

Case 1

- Legal
  - What impact age of patient?
- Any different standard of care?
  - Different risks
  - Juries treat geriatric cases differently
- Counter-intuitive impact on "damages"

Case 2

- Reed v. Granbury (TX--date unknown)
  - Stroke sx--taken to hospital 10 min away
    - Protocol for tPA (available) for MI only
  - Wife (nurse) wished tPA rx
  - MD refused
  - Wife initiated transfer to 2nd hospital
    - Arrived > 3 hr from onset--no rx

Case 2

- Suit re: failure to treat with tPA
- Summary judgment for defendants
  - "No showing that a common or universal standard of care for administering tPA to stroke patients applied to both MDs and hospitals"
- Appealed
  - Affirmed above decision
- Discussion

Case 2

- Legal:
  - Depends upon individual state standards
  - Some states would only require an expert to say it was *reasonable and prudent*
  - Then case would proceed to trial
  - There may also be a "judgment call" defense or a "schools of thought" defense if multiple options

    (documentation of consideration is helpful and informed consent to course of Tx still probably necessary)

Case 3

- Fernandez vs U Penn (PA ? date)
  - Sudden H/A, dizziness, weakness
    - Dx--"vertigo"
    - Discharged
  - Admitted with slurred speech, inability to walk
    - Dx--Stroke

Case 3

- Suit for failure to diagnose stroke and loss of opportunity to give tPA
  - Loss of chance in PA/NJ
- Verdict $5M
- Discussion

Case 3

- "Loss of chance" cases
  - Not in all states (in WA, PA and others)
- For where chance of survival or good result starts <50%
  - This would normally fail for lack of proximate cause
- Paradigm: failure to diagnose cancer cases

Case 3

- "Loss of chance" cases, continued
- Should require scientifically based statistical evidence
- The claim is for the % reduced chance of a good result (i.e., a loss of 10% of a $1m claim = $100,000)

Case 4

- Brooks vs SSM Healthcare et al (MO, ?date)
  - tPA for stroke
    - No discussion of bleeding complications in consent
    - Cervical epidural hematoma
    - Quadriplegia
  - Plaintiff verdict
    - $315,000
- Discussion

Case 4

- Legal:

Informed consent lawsuits:

- ED not exempt (although there are exceptions for emergencies w/o ability to obtain consent)
- An "objective subjective" standard
  - The reasonably prudent patient would want to have known
- Risks, benefits and alternatives

Case 4

- Informed consent
- A process not a document
- But....
  - We need the process documented
  - We need a credible basis for you testimony, and,
  - The consent form itself is evidence
    (and may create a presumption in some states)

Case 5

- Harris vs Oak Valley Hospital (Cal., ?date)
  - tPA for stroke (Hx HBP)
    - ICH (survived)
  - Suit alleging tPA not indicated and BP high
- Defense argued that informed consent appropriate and BP controlled
- Defense verdict
- Discussion

Case 6 (a composite)

White female, late 20s, presents at ED with family members

- Severe headache
- Uncooperative
- Limited Hx given before leaving AMA
  - Smoker

Case 6

- Case 6 (a)
  - Departure w/o signing anything
  - No follow up contact
- Case 6 (b)
  - Husband signs AMA form

Case 6

- Other facts
  - + family Hx
  - On birth control
- Both cases result in suits

Case 6

- 6(a) settled
- 6(b) dismissed on early summary judgment
- Discussion

Case 7

- 57 yr old WM early retired mechanic (IL, 2003)
  - Physically active
  - 1/12/03: wife noted driving started to weave, totally blank stare, couldn't get seat belt off
  - Assessed as potential brain tumor
  - 2/17/03: major stroke with hemi-paralysis
- Jury trial started late Oct 2007

Case 7

- Discussion

Weekends

- 2007 Canadian study:
  - Stroke patients presenting to ED are 14 times more likely to die if presenting on a weekend vs. weekday

Conclusion

- You are damned if you do and damned if you don't
  - However.....
    - Inform patient/family of options, risks, benefits
- **DOCUMENT WELL**