Legal Issues in Hemodialysis Access

Larry A. Scher, M.D.
Division of Vascular Surgery
Montefiore Medical Center
Albert Einstein College of Medicine
Bronx, New York
Problems are frequently seen with dialysis access in hemodialysis patients.

If you or someone you know has been the victim of an error in dialysis care or treatment call.....
Patient E.L.

- 66 year old diabetic female with ESRD
- left forearm AV graft with 4-7 mm. tapered PTFE
- postop pain, numbness and difficulty moving fingers
- good capillary refill, monophasic doppler signal, motor decreased
- **Ischemic monomelic neuropathy**
- AV graft ligated POD # 4
- minimal improvement in weakness and pain
Patient E.L.

- Ischemic monomelic neuropathy
- Not true arterial steal – neurologic deficit without significant clinical signs of ischemia
- Despite recommendation for early intervention, delay in diagnosis of more than 24 hours common 2° minimal tissue ischemia (+ pulse or Doppler signal)
- Response to therapy unpredictable, most patients with residual neuropathy
Malpractice Lawsuit
Patient E.L. vs. J. Hospital and Dr. E.M.

• Carrier thought case not defensible – offered $500K
• Defendant doctor refused to settle
• Concerns regarding defense:
  – Sympathetic plaintiff with significant deficit
  – Too early (5/29) / Too early (5/30) / Too late (5/31)
  – Graft subsequently placed in opposite extremity without complications
Malpractice Lawsuit (continued)

Patient E.L. vs. J. Hospital and Dr. E.M.

- Jury can’t possibly understand these issues!!!
- Defense
  - Graft is lifeline for patient with ESRD
  - If removed, would require placement elsewhere with same potential for complications
  - Surgery performed appropriately
  - Management of complication: clinical judgment vs. negligence
  - Ischemic monomelic neuropathy – diagnosis is difficult and often delayed
Malpractice Lawsuit (continued)

Patient E.L. vs. J. Hospital and Dr. E.M.

Result – defense verdict

But system of justice is very arbitrary!
“Law is supposed to provide deliberate judgments of right and wrong, so people know where they stand. America’s legal system today is more like a free-for-all.”

“Sensible judgments will be possible only when doctors, hospitals and other providers feel that justice will reliably distinguish between right and wrong and make predictable judgments about fair compensation. A trusted system of justice is the key.”

Philip K. Howard, chair, Common Good, a legal reform coalition
Legal Issues in Hemodialysis Access

• Catheter complications
• Ischemic complications
• Hemorrhage
• Hyperkalemia
• Dialysis incidents
Case Analysis

- Facts of case
- Lawsuit
- Expert report (if available)
- Outcome
- Discussion
Case Analysis

- **Cases reviewed (59)**
  - Most cases NY (27)
  - Other states: TX (8), CA (5), IL (3), OH (3), GA (2), MD, NC, VA, PA, MI, NJ, LA, NH, MA, NM

- **Issues**
  - *Ischemia, steal, gangrene* (20)
  - *Catheter related complications* (17)
  - Dialysis incidents (8)
  - Miscellaneous (9)
Analysis of cases

*Ischemia, steal, gangrene (20)*

- Major issues
  - Informed consent
  - Ischemic monomelic neuropathy
  - Preoperative vascular testing
  - Inadvertent arterial ligation
- 6 defense verdicts, 14 plaintiff verdicts or settlements
Analysis of cases
Catheter related complications (17)

- Venous perforation, hemorrhage 11
- Arterial puncture 3
- Miscellaneous catheter complications 3

- 2 defense verdicts
- 15 plaintiff verdicts or settlements
Analysis of cases
Dialysis incidents (8)

Issues

- Improper supervision – hemorrhage, hypotension
- Dislodged needle, disconnected catheter
- Nerve injury during needle insertion
- Defective dialyser ( $8 million settlement)
- Injection of disinfectant acid on hemodialysis ( $5.2 million settlement)
- Broken catheter ( $3 million settlement 1° against manufacturer – catheter brittle 2° cleaning with iodine)
Analysis of cases

Miscellaneous (9)

Issues

– Infection of catheters
– Negligent catheter removal (fractured)
– Hemorrhage after surgery
– Hemorrhage 2° skin erosion over access
  (failed to diagnose and treat chronic ulceration)
Case Report # 1

- 40 year old with intermittent bleeding AV shunt
- Referral to vascular surgeon delayed 2 weeks
- Attempted to clean scab covering access day before appointment
- Uncontrollable bleeding – expired
- Negligence in failing to appreciate significance of problem resulting in arterial bleed
- Plaintiff verdict - $1.85 million
Case Report # 2

• 4 year old – insertion of hemodialysis catheter
• Difficulty threading guidewire, reinserted after several failed attempts
• During passage of guidewire severe hypotension and cardiac arrest
• Cardiac surgery called – thoracotomy and repair of vena cava perforation
• Postoperative disability including paraplegia
Case Report # 2 (continued)

- Plaintiff – vena cava perforation below standard of care and delay in calling cardiac surgeon
- Defendant – known risk of procedure and informed consent obtained from parents
- Plaintiff – if known risk of procedure defendants should have prepared for risk of perforation by having cardiac surgeons on hand
- Settlement $2 million
The American College of Surgeons’ Closed Claims Study: New Insights for Improving Care

- Review of 460 closed files kept by liability insurance companies from 2004-2006 against general surgeons
- 20% cholecystectomy, 7% vascular, 4% placement or removal of central venous access devices
- Assess quality of preoperative, and postoperative care and surgeon’s operative skills
- Useful tool to identify unsafe practices in the delivery of surgical care.

Griffen et al, J Am Coll Surg 2007;204:561-569
Central Line Complications From the ASA Closed Claims Project

• Majority of claims accounted for by three classes of problems
  – Perforation of heart with cardiac tamponade
  – Catheter or wire embolism
  – Injury to veins or arteries

• Most problems preventable by paying meticulous attention to technique.

Bowdle TA: Central line complications from the ASA Closed Claims Project. ASA Newsletter 60 (6):22-25, 1996.
Steal Syndrome
Prediction, Prevention, Treatment

• **Can steal be predicted preoperatively?**
  – Role of preoperative vascular testing

• **Do tapered grafts prevent steal?**
  – Conflicting data but probably not

• **What is the optimal treatment of steal?**
  – Banding - DRIL
  – Proximalization - Ligation
Can the standard of care be defined?

- **Central Venous Catherization**
  - Is the use ultrasound or flouroscopy mandatory?

- **Steal Syndrome**
  - Can preoperative vascular testing predict steal?
  - Do tapered grafts prevent steal?
  - What is the optimal treatment of steal?
    - Banding - DRIL
    - Proximalization - Ligation
What impact do K/DOQI guidelines have on legal issues regarding hemodialysis access?

• prevention and management of ischemia
• placement of central venous catheters
• indicator of risk for graft rupture
Guideline 2.4: evidence is sufficient to recommend that ultrasound be used for all (catheter) insertions because it minimizes inadvertent arterial cannulation

Guideline 5.6: diagnosis of monomelic ischemic neuropathy is a clinical diagnosis and immediate closure of the AV fistula is mandatory

Guideline 6.2: any changes in the integrity of the skin overlying an AV graft should be urgently evaluated
Additional issues impacting outcome in malpractice litigation

- Informed consent
- Expert witness
- Life expectancy of dialysis patients
Informed Consent

• Inform in great detail regarding every possible risk of procedure

• Document discussion or risks with informed consent note in chart

ACKNOWLEDGEMENT OF POTENTIAL RISK FACTORS OF FISTULA / GRAFT SURGERY IN THE UPPER EXTREMITY

Please read the information below in regards to the Risk Factors of Fistula / Graft Surgery.

Patients may experience the following problems:

• Numbness and/or coolness in forearm, and/or hand, and/or fingers (this is usually mild and may resolve by itself)
• Pain and/or burning sensation
• Loss of use of hand either temporary or permanent (although very rare)
• Multiple surgeries of fistula/graft to increase blood flow to hand
• Loss of dialysis access and need for further evaluation eg: ultrasound, and/or need for dialysis catheter
• Bleeding, infection, and/or injury to adjacent structures
• If patient has a slight or unnoticed carpal syndrome, this surgery may exacerbate the problem resulting in the possibility of Carpal Tunnel surgery
• If patient has any neuropathy, this surgery may exacerbate the problem.

I understand that if I experience any of the above problems that I will notify my surgeon immediately.

By signing below, I agree that I have reviewed and understand the information above and that I have received a copy of the Potential Risk Factors of Fistula / Graft Surgery.
What guidelines should be used to determine qualifications for physicians serving as expert witnesses?
The physician expert witness who provides testimony for a plaintiff or defendant in a case involving a specific surgical procedure should hold current privileges to perform those same procedures in a hospital that is accredited ...
Disciplinary actions taken

• A plastic surgeon from Paoli, PA (and a thoracic surgeon from Woodbridge, CT) were admonished following charges that these surgeons had violated the ACS *Bylaws*, Article VII, Sections 1(f) and (I), when providing testimony as an expert witness in a malpractice lawsuit.

• *Admonition*: a written notification, warning or serious rebuke.
Life Expectancy of Dialysis Patients

OR

How long would the patient have lived anyway?
### Expected remaining lifetimes (years) of the general U.S. population, by age, gender, & race

Table 6.d

<table>
<thead>
<tr>
<th>General U.S. population, 2002</th>
<th>ESRD patients, 2004</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>All races</td>
</tr>
<tr>
<td></td>
<td>All M F</td>
</tr>
<tr>
<td>0-14</td>
<td>70.9 68.2 73.4 71.3 68.7 73.7 66.4 62.9 69.7</td>
</tr>
<tr>
<td>15-19</td>
<td>61.1 58.4 63.6 61.4 58.9 63.9 56.7 53.3 59.9 53.7 15-19 16.3 17.2 15.3 41.1 40.9 41.5</td>
</tr>
<tr>
<td>20-24</td>
<td>56.3 53.8 58.7 56.7 54.2 59.0 52.0 48.7 55.0 20-24 14.0 14.9 13.0 37.4 37.2 37.9</td>
</tr>
<tr>
<td>25-29</td>
<td>51.6 49.1 53.9 51.9 49.5 54.2 47.4 44.3 50.2 25-29 12.3 13.0 11.5 33.7 34.2</td>
</tr>
<tr>
<td>30-34</td>
<td>46.8 44.4 49.0 47.1 44.8 49.3 42.8 39.8 45.5 30-34 10.7 11.0 10.3 29.8 29.4 30.4</td>
</tr>
<tr>
<td>35-39</td>
<td>42.1 39.8 44.2 42.4 40.1 44.5 38.3 35.4 40.8 35-39 9.1 9.3 8.9 26.3 25.9 27.1</td>
</tr>
<tr>
<td>40-44</td>
<td>37.5 35.2 39.5 37.7 35.6 39.7 33.9 31.1 36.3 40-44 7.9 8.0 7.7 23.0 22.5 24.0</td>
</tr>
<tr>
<td>45-49</td>
<td>33.0 30.8 34.9 33.2 31.1 35.1 29.7 26.9 32.0 45-49 6.9 7.0 6.8 20.0 19.4 20.9</td>
</tr>
<tr>
<td>50-54</td>
<td>28.6 26.6 30.4 28.8 26.8 30.5 25.7 23.1 27.8 50-54 6.0 6.1 5.9 17.1 16.6 18.1</td>
</tr>
<tr>
<td>55-59</td>
<td>24.4 22.5 26.0 24.5 22.7 26.1 22.0 19.6 23.9 55-59 5.1 5.2 5.1 14.5 13.9 15.4</td>
</tr>
<tr>
<td>60-64</td>
<td>20.4 18.7 21.9 20.5 18.8 21.9 18.5 16.4 20.1 60-64 4.4 4.4 4.4 12.1 11.6 12.9</td>
</tr>
<tr>
<td>65-69</td>
<td>16.8 15.2 18.0 16.8 15.2 18.0 15.3 13.5 16.7 65-69 3.7 3.7 3.8 10.1 9.7 10.9</td>
</tr>
<tr>
<td>70-74</td>
<td>13.4 12.0 14.4 13.4 12.0 14.4 12.4 10.8 13.5 70-74 3.2 3.1 3.2 8.5 8.1 9.3</td>
</tr>
<tr>
<td>75-79</td>
<td>10.4 9.3 11.1 10.3 9.2 11.1 9.9 8.6 10.7 75-79 2.7 2.6 2.7 7.1 6.7 7.7</td>
</tr>
<tr>
<td>80-84</td>
<td>7.8 6.9 8.3 7.7 6.9 8.2 7.8 6.8 8.3 80-84 2.3 2.2 2.3</td>
</tr>
<tr>
<td>85+</td>
<td>4.3 3.8 4.5 4.2 3.7 4.3 4.6 4.2 4.8 85+ 1.8 1.7 1.9</td>
</tr>
<tr>
<td>Overall</td>
<td>25.0 23.2 26.4 25.1 23.4 26.5 22.8 20.6 24.5 Overall 5.6 5.6 5.5 15.7 15.2 16.5</td>
</tr>
</tbody>
</table>
Conclusions 1 – (lessons learned)

• Steal / ischemia and catheter related complications are most frequent causes of litigation regarding hemodialysis access.
• Informed consent documenting potential complications is important.
• Availability of ultrasound and fluoroscopic guidance for catheter placement is recommended.
Conclusions 2 – (lessons learned)

- Ligation of access is most predictable treatment of steal syndrome – this is often a poor choice but all alternative treatment options should be discussed with patient.
- Ischemic monomelic neuropathy is difficult condition to treat
- USRDS mortality statistics may be useful in predicting life expectancy if faced with litigation
Conclusions 3 – (lessons learned)

• Beware of itinerant expert witnesses
• Beware of lawyers advertising on the internet
• Continued data collection sharing experiences and insights of attorneys and physicians may be helpful in dealing with current malpractice crisis.
Insanity: doing the same thing over and over again and expecting different results.

- Albert Einstein

www.quotesworthrepeating.com