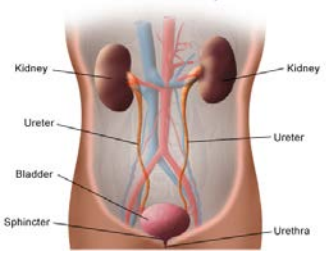
Medical Records Reviewed:

- Surgery Specialists (Drs. Cohen and McGeorge) – 12/17/2010-07/12/2011
- Medical Specialists (Dr. Munez) – 06/27/2011-01/19/2012
- Regional Medical Center miscellaneous records 04/14/2010 – 01/19/2012

Statement of Merit:

This case has merit based upon adverse surgical outcomes involving both Dr. Crutchfield and Dr. Winston. Dr. Crutchfield performed the initial abdominal hysterectomy on 12/17/10 which was found to have resulted in a torn right ureter requiring placement of a nephrostomy tube. Dr. Winston performed a repair of the ureter on 06/24/2011 and while opening the abdomen, tore the small bowel in two places. There was also found to be a tear of the rectum during the repair of the bowel.

Figure 1 – Ureter (Medicine)



Breach of Standard of Care – Dr. Crutchfield (transection of the ureter): Dr. Crutchfield performed an abdominal hysterectomy on 12/17/10. Exploratory laparotomy on 12/22/10 (Bate #6) showed a transected (torn or cut) right ureter (tube that drains urine from the kidney to the bladder) which required placement of a nephrostomy tube (a tube inserted in the kidney to drain the urine outside the body preventing urine from draining into the abdomen and allowing the ureter to heal before surgical repair). There was also noted to be a bleeder of the pelvic ligament that required suturing.

The identification of the injury was timely from the perspective of the symptoms that presented after the abdomen was closed. However, because of the frequency of ureter injuries during abdominal hysterectomy, there are sources that recommend direct visualization of the ureters during the initial course of the surgery (to avoid injury) and prior to closing the abdomen (to inspect for injury) (Hoffman, MD, 2008). If this is accepted as the standard of care in the current venue, delay in identification of the transected ureter may be an argument.

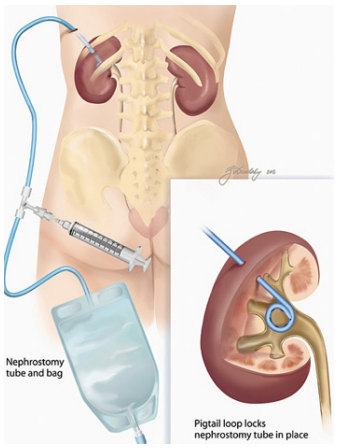


Figure 2 - Nephrostomy Tube (Tour2India4Health)

Breach of Standard of Care – Dr. Winston (bowel lacerations): Dr. Winston performed surgery on 06/24/2011 to repair the torn ureter. During the opening of the abdomen, two enterotomies (cuts of the intestines) occurred in two separate loops of the bowel (Bate #20). One enterotomy involved greater than half the circumference of the bowel requiring bowel resection (cutting out the injured piece of bowel and suturing the ends back together). The second laceration was repaired directly by suturing it. In addition, there was noted to be a serosal tear of the anterior portion of the rectum that was repaired. It is not clear when or how the rectal tear occurred.

Breach of Standard of Care – Nursing Staff Regional Medical Center (heparin protocol not administered): The records indicate (Bate #248) that an incident report was ordered on 06/20/2011. It had been ordered that Ms. Tomas be placed on a heparin drip on 06/17/2011 due to her prior history of pulmonary emboli as a precaution against the formation of blood clots. On 06/20/2011 it is noted that the drip was never started and it was determined to be too close to her surgical date to initiate at that point. There is no apparent adverse outcome as a result of this omission.

Case Summary:

Ms. Tomas is a 51 year old female who is admitted to the hospital 12/17/2011 for an elective hysterectomy following a reported seven month history of excessive menstrual bleeding and anemia. Hysterectomy is performed by Dr. Crutchfield on that date. Post-operatively, Ms. Tomas complains of abdominal pain, distention and is not passing gas or having bowel movements. X-rays of the abdomen on 12/19/2010 show findings consistent with an ileus (lack of motility in the bowel which can occur after a surgical procedure). CT of the abdomen is performed on 12/20 showing partial small bowel obstruction and possible right hydronephrosis (swelling of the kidney due to backing up of urine). A surgical consult with Dr. Cohen shows an impression of a probable ileus, doubt small bowel obstruction. A definitive diagnosis was not made at that time because the CT was done without contrast. This may have resulted in a delay in the identification of the injury but does not appear to have altered the outcome. A repeat CT with contrast on 12/21/2010 shows increasing fluid collections in the abdomen and no apparent contrast in the right ureter.

Exploratory laparotomy was conducted on 12/21/2010 by Dr. Cohen and Dr. Crutchfield and the operative report (Bate #6) notes, “Obvious ureteric injury with dilation of the proximal ureter and spillage of urine.” Examination of the bladder and ureter by cystoscopy was performed 12/22/2010 by Dr. Winston (Bate #1109) and he was unable to pass a catheter up through the ureter so placement of a nephrostomy tube was completed on 12/23/2010. Ms. Tomas was discharged home with the nephrostomy tube in place.

On 01/18/2011, she returned to the ER with complaints of abdominal pain. She was found to have a urinary tract infection and was discharged with antibiotics. CT of the pelvis was also performed and she was called back to the hospital on 01/19/2011 due to findings of right middle and lower lobe pulmonary emboli (blood clots in the lungs). The CT also showed (Bate #775) pelvic vein thrombosis (blood clots in the pelvic veins) which would be the probable source of the clots in the lungs. She was started on anti-coagulation drugs and discharged.

Interim records show recurrent bladder infections and changes of the nephrostomy tube.

On 06/17/2011, she is admitted to have her medications for the pulmonary emboli stabilized prior to surgery to repair the lacerated ureter. As noted above, the heparin protocol was not initiated as ordered. She also developed another urinary tract infection that required treatment prior to surgery.

On 06/24/2011, she was taken to surgery by Dr. Winston. During the opening of the abdomen and dissection of adhesions (scar tissue from the prior surgeries), he noted damage to the bowel and called Dr. McGeorge. Dr. McGeorge noted (Bate #15) large, thick adhesions of the small bowel which were adhered to the undersurface of the prior surgical scar. There were two inadvertent enterotomies or cuts to separate loops of the bowel. There was also a tear of the outer layer of the rectum. The main tear was repaired by removing the damaged portion of the bowel and sewing the ends back together. The second tear and the rectal tear were sutured. Dr. Winston then repaired the ureter by reimplanting the upper portion from the kidney into the bladder utilizing a stent (piece of plastic). He was unable to find the section of the ureter that ran into the bladder itself so an artificial opening was made. Ms. Tomas was discharged on 07/01/2011.

On 09/07/2011, an outpatient procedure was performed to remove the stent.

Issue: Hysterectomy – Necessity of Surgery: An initial question in cases involving hysterectomy is the medical necessity of the surgical procedure itself since there is a long history of concerns related to unnecessary procedures in the United States (Larson, 2008) (National Women's Health Network, 2005) (Nazar, RN, 2011). The surgery is noted to have been performed due to a fibroid uterus (benign tumors of the uterine muscles that can cause pain and bleeding) resulting in excessive bleeding and anemia.

In my opinion, medical necessity for the hysterectomy is likely established based upon the size of Ms. Tomas's uterus at 15 cm (bate #1187) and the bleeding pattern documented in the records (Bate #1189) although a detailed history of her menstrual patterns is not documented. One concern is that Ms. Tomas remained anemic after the hysterectomy suggesting that this is not the sole cause of that condition. The records do not indicate how much this condition was worked up prior to deciding to perform the surgery.

Also, the American Congress of Obstetricians and Gynecologists recommends vaginal hysterectomy as the safest and most cost effective approach for performing hysterectomy (American Congress of Obstetricians and Gynecologists, 2009). The medical rationale for performing an abdominal hysterectomy is not documented. Additional review by an expert may be warranted to establish whether the abdominal approach was a breach in the standard of care.

Issue: Transection of the Ureter (Dr. Crutchfield): Accidental damage or cutting to the bladder or ureter occurs in 1-4.3% of hysterectomies (Ibeanu, MD, Chesson, MD, Echols, MD, Nieves, MD, Busangu, & Nolan, MD, 2009) (Santucci, MD & Schwartz, 2012). This may occur from direct cutting, crushing with forceps or hemostats, cauterization, etc. Injuries to the bladder and ureter are the most common cause for legal actions against gynecologists (Vasavada, MD & Schwartz, DO, 2011). There is also an increased chance of this type of injury with increased uterine size as Ms. Tomas had. This incident required multiple additional surgeries including the exploration of the abdomen on 12/21/2010, cystoscopy on 12/22/2010, placement of a nephrostomy tube on 12/23/2010, replacement of the nephrostomy tube on 04/20/2011, reimplantation of the ureter on 06/24/2011 and removal of the ureteral stent on 09/07/2011. In addition, there were multiple treatment and ER visits for urinary tract infection as well as the need to wear the nephrostomy collection bag for 6 months.

In my opinion, the transection of the right ureter is a known risk of the hysterectomy performed on 12/17/2011 and in itself is not a breach in the standard of care. The operative report does not indicate any unusual circumstances or difficulties with visualization during surgery that might have contributed to the injury. Although the condition was detected within 3 days, it lead to multiple additional surgeries and medical treatments. It is also noted that the incidence of ureteral injury is significantly higher in patients having abdominal hysterectomy (1.3-2.2%) vs. vaginal hysterectomy (.03%) which raises question as to whether vaginal hysterectomy was an option in this patient and therefore the transected ureter may have been a preventable consequence (Ibeanu, MD, Chesson, MD, Echols, MD, Nieves, MD, Busangu, & Nolan, MD, 2009) (Vasavada, MD & Schwartz, DO, 2011)**.**

Issue: Pulmonary Emboli: Ms. Tomas was found on 01/18 and 01/19/2011 to have pulmonary emboli (blood clots) in the right lungs. CT of the abdomen showed the presence of pelvic vein thrombosis (blood clots in the pelvic veins). Pelvic thrombosis may occur after pelvic injuries such as infections, malignancy and surgery. When clots form in the pelvic veins, they may break off and flow to the lungs where they can lodge and form pulmonary emboli. Ms. Tomas will be required to stay on anti-coagulation medications for at least a year per the recommendation of her physicians.

In my opinion, abdominal surgery is a contributing event to the development of pelvic vein emboli as is prolonged immobilization. In this case, the need for additional abdominal surgery due to the transection of the ureter likely contributed to the development of the pelvic vein clots as well as increasing Ms. Tomas's period of immobility thus increasing the risk of pulmonary emboli. Therefore, the pulmonary embolism and the risks and treatment associated with it should be included in the damages assessment.

Issue: Inadvertent Enterotomies (Dr. Winston): When abdominal surgeries are performed, it is likely that adhesions (scar tissue) will develop at the surgical site inside the abdomen. Ms. Tomas having two abdominal surgical procedures would increase the likelihood of adhesions developing over time. During the surgery of 06/24/2011, Dr. Winston noted the presence of adhesions upon opening the abdomen and while attempting to dissect the adhesions, cut two loops of the small bowel. The surgeon who performed the repair (Dr. McGeorge) noted that one loop was cut more than 50% through. He also noted an additional tear of the rectum was found. The operative report does not clarify how the rectal tear occurred. These injuries required a more complicated surgical procedure including a resection of the bowel and repair of the other two lacerations, would have resulted in a prolonged recovery time and increased the risk of infection post-operatively.

In my opinion, the development of adhesions from the initial surgeries should have been anticipated along with the need for careful dissection. The depth of the laceration in the loop of bowel involving 50% of the circumference raises concern as to whether due care was exercised. Consideration could have also been given to having a surgical assistant present to assist with the dissection.

Issue: Laceration of the Aorta: A nick of the aorta is noted in the admission history and physical by Dr. Brooke on 06/17/2011 (Bate #173). It appears that this is a typo and should have read "ureter" as there is no other mention of this injury in the records.

Damages:

The following should be considered in the damage assessment for this case:

- Exploratory laparotomy to identify the transected ureter.
- Placement, wearing and maintaining of the nephrostomy tube.
- Pulmonary emboli.
- Recurrent urinary tract infections and replacement of the nephrostomy tube.
- Surgical repair of the transected ureter.
- Surgical repair of the small bowel and rectal lacerations.
- Surgical removal of the ureteral stent.

List of Defendants to be Named:

- Dr. Lacy Crutchfield
- Dr. Thomas Winston
- Regional Medical Center
    - Nurses responsible for removing and implementing the orders on 06/17/2011.

Recommendations:

- RFP Ms. Tomas's records from Dr. Barston for 2 years prior to the hysterectomy to identify presenting symptoms necessitating surgery.
- RFP outpatient clinic records of Dr. Crutchfield to identify medical necessity for surgery, medical necessity for abdominal approach and documentation of counseling regarding possible complications. RFP outpatient clinic records of Dr. Winston to further identify course of treatment and complications following placement of nephrostomy tube and any counseling regarding potential complications for the surgical repair on 06/24/2011.
- RFP policies and procedures from Regional Medical Center regarding processing of physician orders and pharmacy orders.
- RFP incident report from Regional Medical Center (ordered on 06/20/2011).
- Review and testimony by a board certified gynecologist regarding the necessity of the hysterectomy, vaginal vs. abdominal approach, contribution to the development of the pulmonary emboli, and possible breach of standards of care related to the ureteral and small bowel injuries.
- UPLNC applicable services:
    - Review and preparation of records including record organization and fact chronology for expeditious and cost effective expert review.
    - Locate and prepare an expert for testimony including a line of questioning.
    - Prepare a line of questioning for treating providers.

Thank you for the opportunity to work with you on this case. Please don't hesitate to contact me if you have any questions or concerns.

For questions pertaining to this case, or for any other information, including referrals and initial reviews, contact University Park LNC at 707-968-5060 or info@universityparklnc.com

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Notes & Impressions

Summary of Opinions:

Possible Defense Theory: The defense is likely going to argue that the injury to the ureter and the lacerations of the small bowel are known potential complications with abdominal surgery and that the presence of an enlarged uterus and later, adhesions, complicated the surgeries. While that argument is true, they still reflect events that should not occur during a normal surgery and are adverse outcomes. During the hysterectomy, it was chosen to take an abdominal approach which carries a higher rate of complications. The rationale for this is not described in the current records. Nor is it described how much discussion there was with Ms. Tomas regarding the different options for surgery and the potential for complications. The operative report from this surgery does not describe any complicating conditions or difficulties in visualizing the operative site that would have made the hysterectomy more complicated than normal.

During the repair of the ureter, it was probable that adhesions would have developed after two prior abdominal surgeries so the need for meticulous and cautious dissection should have been anticipated. Of greatest concern is the fact that three separate tears were found and the significance of the one that involved 50% of the circumference of the bowel.

To further evaluate the potential for defensibility, it may be helpful to obtain additional records from Dr. Barston as well as the office records from Dr. Crutchfield and Dr. Winston to assess whether documentation is present supporting counseling pre-surgery regarding potential complications. The records from Crutchfield may also help to clarify the decision to perform an abdominal instead of a vaginal hysterectomy (which carries a lower potential for complications). This may also be an area to further discuss with Ms. Tomas.

At that point, expert review may be beneficial to address the medical necessity of the hysterectomy, the decision to perform an abdominal hysterectomy instead of a vaginal approach, the probability of a second surgery contributing to the development of the pulmonary emboli and the standards of care related to the adverse events of both surgical procedures.

Thank you for the opportunity to work with you on this case. Please don't hesitate to contact me if you have any questions or concerns.

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