Case Study

# LNC for the Defense in a Medical Malpractice Case

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KEY WORDS
Negligence, Duodenal Perforations, Case Evaluation, Liability

*This case study details the medical care given to a patient after an ERCP induced duodenal perforation, giving an overview of the six days of treatment. Also reviewed is the subsequent case evaluation by the legal nurse consultant and details of the trial.*

## *The Medical Care Rendered After ERCP Induced Duodenal Perforation Was There Negligence?*

Jane Doe, a 58-year-old female, was admitted to the hospital for an elective laparoscopic cholecystectomy due to chronic cholecystitis (inflammation of gall bladder) and cholelithiasis (gallstones) on September 20, 2000. The procedure was uneventful and the plaintiff was discharged on September 21, 2000. Four days later, she presented to the emergency room complaining of sudden onset of epigastric pain and right upper quadrant tenderness. Other symptoms were shaking, chills, dark urine, and nausea. Mrs. Doe described the pain as being similar to a gallstone attack. The plaintiff was admitted to the hospital under the care of the general surgeon who had performed the cholecystectomy. The plaintiff was given nothing by mouth and a nasogastric tube was placed to low suction. IV fluids and antibiotics were started, and a work-up to ascertain the underlying cause of the symptoms was begun. The differential diagnoses were: retained stones, bile leak, and common bile duct injury or duct obstruction.

### Past Medical History

Hiatal hernia, gastric reflux, diverticulitis x2, status post umbilical hernia repair and status post laparoscopic cholecystectomy. The plaintiff had no known allergies and neither smoked or drank alcohol.

### Physical Examination in the Emergency Room

Negative except for epigastric and right upper quadrant pain with tenderness but no guarding or rebound.

### Initial Diagnostics

An abdominal sonogram on the evening of admission and a hydroxy iminodiacetic acid (HIDA) scan the following morning were both negative effectively serving to rule out a bile leak or collection. Chest x-ray was negative. Electrocardiogram (EKG) showed normal sinus rhythm. Vital signs were stable.

### Emergency Department Relevant Blood Work Results

Elevated liver function tests and elevated pancreatic enzymes were noted (see Table 1).

### Hospital Course

By the morning after admission (September 26), Mrs. Doe was having less abdominal pain and less epigastric tenderness. However, liver function tests and pancreatic enzymes remained elevated. The most likely diagnosis being considered by the afternoon of September 26 was a stone (choledocholithiasis) which was preventing the flow of bile from the liver and/or pancreas into the duodenum. At that point in time, a consult was requested of a gastroenterologist to determine whether Endoscopic Retrograde Cholangiopancreatography (ERCP) should be the next step. The gastroenterologist agreed with the plan for ERCP and explained the risks of the procedure to Mrs. Doe. The procedure was scheduled for September 28. A consent for ERCP with general anesthesia was obtained. Because of the decrease of the abdominal pain after admission, it was thought that a stone may have passed on its own or was "ball-valving" thereby creating an intermittent obstruction. The plaintiff continued to be pain free on September 27.

### Endoscopic Retrograde Cholangiopancreatography

On September 28 at 3:45 p.m., the plaintiff was taken to the procedure room. The duodenoscope was passed and several attempts to enter the duodenal papilla (mouth to the conjoined pancreatic/common bile duct) were made. Finally, the pancreatic duct was entered and appeared normal in size, shape and contour. A pancreatic stent (#5 F 5 cm.) was placed and a sphincterotomy was done. A gush of bile was noted which was followed by bleeding. The papilla became covered with blood and 15 c.c.s of 1:10,000 epinephrine was injected all around the entire area. The bleeding ceased. An attempt to enter the spincterotomy with a catheter was made and dye was

injected which outlined the duodenum (duodenal perforation). The procedure was immediately stopped and an x-ray was obtained which revealed retroperitoneal air in the right upper quadrant and a small amount of free intraperitoneal air under the right hemidiaphragm.

The plaintiff was taken to the Perianesthesia Care Unit (PACU) at 6:30 p.m. A nasogastric tube was placed and returned blood tinged reddish-brown material. Antibiotics were re-instituted. The abdomen was firm with bowel sounds. The plaintiff was alert and oriented. Another abdominal film was repeated two hours later and was unchanged. Vital signs remained stable. The plaintiff complained of severe abdominal pain while in the PACU and was given Demerol three times (see Table 2). The plaintiff was transferred to the ICU for close observation.

## Intensive Care Unit

The plaintiff arrived in the Intensive Care Unit at 9:15 p.m. Vital signs were essentially stable. Oxygen therapy was begun via nasal cannula. The abdomen was soft but tender with hypoactive bowel sounds. The plaintiff complained of increased abdominal pain upon transfer from gurney to bed and was medicated.

## September 29

In the morning an abdominal x-ray was done and again showed a large amount of retroperitoneal air and evidence of a small amount of free intraperitoneal air. Various physicians evaluated the plaintiff's abdomen several times in the morning. There appeared to be little, if any, improvement in the distension and tenderness aspects but there was also no guarding or rebound. **Analgesia was needed at regular intervals** (see Table 2). X-rays were done and compared with the previous films. Evidence of pneumo-retroperitoneum as well as a small quantity of free intraperitoneal air was found. Both findings appeared somewhat decreased from the prior film. A computerized tomography (CT) abdominal scan without IV contrast was done in the afternoon and revealed a large amount of retroperitoneal air extending into the mediastinum and a small amount of free fluid in the paracolic gutters. A small amount of oral contrast was given and was seen within the fundus of the stomach but never reached the duodenum, and therefore was **non-diagnostic in terms of evaluating the perforation**.

Another surgeon was brought in for a second opinion. He found the abdomen to be moderately distended and diffusely tender in the lower quadrants. He noted hypoactive

## Table 1: Laboratory Data

| Date | Amy-lase (53-123) | Lipase (.12-1.0) | T. Bili (0.2-1.0) | GGTP (1-94) | ALT (SGOT) (7-37) | AST (SGPT) (0-48) | Alk. Phos. (50-160) | LDH (79-179) | Ca (8.5-10.5) |
|---|---|---|---|---|---|---|---|---|---|
| 9/25 | 97 | 0.6 | 1.2 | 238 | 452 | 261 | 243 | 471 | 9.5 |
| 9/26 | 146 | | 2.7 | | 1463 | 1142 | 294 | | |
| 9/27 | 127 | 2.1 | 1.7 | 335 | 708 | 1048 | 415 | 551 | 8.8 |
| 9/28 Pre-ERCP | 68 | | | | | | | | |
| Post ERCP | 303 | | 1.1 | | 680 | | 420 | | 8.5 |
| 9/29 7:00 a.m. | 378 | 6.2 | | | | | | | 8.0 |
| 9/29 6:00 p.m. | 443 | | | | | | | | 7.5 |
| 9/30 6:00 a.m. | 469 | | 1.2 | | 153 | 81 | 233 | 200 | 6.2 |
| 9/30 6:00 p.m. | 414 | | | | | | | | 5.8 |

- Amylase/Lipase typically elevated with acute pancreatitis but level does not predict whether disease is mild, moderate or severe
- T. Bilirubin measures obstruction to bile outflow, liver damage
- GGTP-markedly elevated with obstruction of bile ducts
- ALT (SGOT) and AST (SGPT) increased in liver damage
- Alkaline Phosphatase increased in liver damage
- LDHG elevated in acute pancreatitis
- Calcium-decreased in acute pancreatitis

bowel sounds. His impressions were that the plaintiff had a retroperitoneal duodenal/common bile duct perforation with pancreatitis secondarily. His recommendations were to continue conservative treatment over the next 12 to 24 hours and to do an exploratory laparotomy if there was no improvement or if the plaintiff's condition worsened.

In the evening, the plaintiff was again evaluated and complained of increased pain especially in the lower abdomen. Bowel sounds were rare, and the abdomen was distended and diffusely tender. At 7:00 p.m. the plaintiff was experiencing a **back spasm** at the right flank which was thought to be related to a pre-existing back problem. The spasms were treated with Valium. Her abdomen was firmly distended with faint hypoactive bowel sounds. Her urine output was tea colored and adequate in quantity but was markedly decreased from earlier quantities. The plaintiff was evaluated again at 10:00 p.m. by the surgeon. Four 500 cc normal saline boluses were given from 10:00 p.m. to 6:00 a.m. The fluid intake over the previous 24 hours was far exceeding output.

## September 30

At 7:00 a.m. Jane Doe's abdomen remained firm, distended, and diffusely tender without rebound or guarding. Urine remained tea colored. The white blood cell count was 13.9, amylase remained elevated, and calcium was decreased significantly. Both the gastroenterologist and the consulting surgeon indicated that the plaintiff was slowly improving with less abdominal pain and less distension than the previous evening. However, she continued to complain about back spasms.

At 2:30 p.m., the gastroenterologist again evaluated her. Amylase remained high, while liver chemistries decreased. The impression at that time was retroperitoneal perforation with slightly improved symptoms, ileus and pancreatitis. The plaintiff again needed IV boluses to increase the urine output. By 6:00 p.m. the plaintiff's abdomen remained distended and firm but less tender. The plaintiff was complaining of less pain. The urine output continued to decrease and become more concentrated. IV fluids were given to counteract the imbalance. The plaintiff started to run a fever in the evening.

## October 1

Fluid balance, hypocalcemia, intermittent abdominal pain, distension and tenderness (without guarding or rebound), fever, increased heart rate, and decreased oxygen saturation were all noted to be problematic. The plaintiff was prepped with contrast via a nasogastric tube for the abdominal CT scan. At 10:30 a.m. she was transported to radiology. The plaintiff was noted to have an expiratory wheeze during the procedure. The oxygen saturation remained at 93%. **The CT scan revealed some extravasation of contrast in the retroperitoneum** and increasing retroperitoneal air. The unopacified pancreas was unchanged. There was no bowel obstruction.

The plaintiff was taken to surgery in the afternoon where an exploratory laparotomy was done to repair the retroperitoneal duodenal perforation found at the junction of the duodenum and pancreas. There was spillage of bile into the retroperitoneum. The surgery included a T-tube insertion into the duodenal perforation and closure around it, gastrojejunostomy and a duodenal exclusion. Because the bowel was distended the abdomen could not be closed and was therefore left open.

Shortly after surgery the plaintiff developed adult respiratory distress syndrome and her pulmonary condition further deteriorated, resulting in respiratory and cardiac failure. Death ensued the following day.

## Role of the LNC

The LNC was asked to summarize the records as done above, to research the management of duodenal perforations and to analyze the care rendered based on the prevailing research.

## Duodenal Perforations and ERCP

ERCP with sphincterotomy has a complication rate of approximately 10% and includes pancreatitis, infection, bleeding, and perforation of the duodenum. (Cotton et al., 1991) Perforations occur in about 1% of patients, and such an injury has a death rate of 16% to 18%. (Stapfer et al., 2000) A consensus, as to the care of the patient with a perforated duodenum during ERCP, is lacking. (Chung et al., 1993) Failed non-surgical management has carried a very high mortality rate, yet surgical exploration has its associated risks. The decision to medically manage versus surgically intervene seems to have "evolved toward a more selective approach" (Stapfer et al., 2000). The decision to take a patient to surgery or to wait is an on-going process of evaluation of the clinical features and radiological findings. In the case at hand, the perforation was a small retroperitoneal perforation caused by a guide-wire or catheter that was expected to seal itself. If the perforation were to seal, the clinical picture would find a patient with diminishing symptoms. However, this could only be ascertained from meticulous clinical evaluation coupled with imaging studies (UGI, double-contrast CT scan) to confirm that the leak sealed.

## LNC Case Evaluation

There was no question that a duodenal perforation had occurred as reported by the gastroenterologist who performed ERCP. In addition, it was seen on contrast study at the close of the procedure. The series of abdominal x-rays reporting retroperitoneal air along with a small amount of free intraperitoneal air supported the existence of a perforation. The perforation was considered small because the equipment that caused the perforation was either a guidewire or catheter with measurements of 1.7 mm to 6 mm.

Historically, many small retroperitoneal duodenal perforations caused by ERCP will spontaneously seal within the first 24 to 36 hours. (Stapfler et al., 2000) Therefore, case

evaluation centered on whether the records would lead our defendant surgeons to conclude that the perforation had sealed. However, a confounding aspect to case evaluation and to medical evaluation was the possibility that pancreatitis, a not unexpected complication of ERCP, was responsible for the clinical symptoms. A table of various chemistries revealed increased pancreatic enzyme production (see Table 1) .

An evaluation of clinical status included the complaints offered by the plaintiff, plaintiff's physical examination, especially of the abdomen, and the level of analgesia required to diminish the plaintiff's pain. The abdominal examination revealed a tender, distended abdomen without guarding or rebound. These findings never seemed to improve to the extent that one would expect if the perforation had sealed. In addition, an analgesia table showed that the level of pain never abated to the level of what would be expected if the perforation had sealed. However, the abdominal findings and complaints of pain could also be associated with pancreatitis. Lastly, imaging studies did not seem to show improvement.

Abdominal x-rays continued to show retroperitoneal air and free intraperitoneal air. The abdominal CT scan that was done the day after ERCP showed extensive retroperitoneal air and a small amount of free fluid but was **non-diagnostic in terms of evaluating for a perforation**. In addition, it showed a normal appearing pancreas. **The surgeons were not able to definitively make any conclusions as to the status of the perforation based on the scan, and no attempt to elicit the status of the perforation was made until two days later when an upper gastointestinal abdominal CT scan showed extravasation**. These findings resulted in an emergency laparotomy on a patient who had deteriorated considerably after the first CT scan.

In conclusion, the weaknesses of the defense case were the level of pain, the continued abdominal complaints, the continued findings on abdominal examination, the existing imaging studies, and the **failure to obtain diagnostic studies to prove the leak had sealed**. The strengths of the defense case were the location of the perforation, which would lend itself to self-sealing; the small size of the perforation, as evidenced by the equipment used and the probability of pancreatitis as evidenced by the laboratory data which could account for the abdominal findings and complaints of abdominal pain.

## Case Claims

Claims were made against the general surgeon and consulting surgeon. The jury was asked to answer the following questions. Did the surgeon and consulting surgeon depart from accepted medical practice in not operating on or before the morning of September 30? And, if so, was it a substantial factor in causing the plaintiff's death?

## Plaintiff's Expert

The plaintiffs called an expert surgeon with experience in ERCP duodenal perforation who testified as to the care rendered by the defendant surgeons. He agreed that it was acceptable for the surgeons to allow a period of observation to see if the perforation had sealed itself before submitting the plaintiff to surgery. The plaintiff exhibited typical signs and symptoms during the first 24 hours associated with this type of injury. However, the surgeon indicated that he would expect improvement thereafter, and his

### Table 2: Medication Data

| Date | Time | Medication | Comments |
|---|---|---|---|
| 9/28 Post ERCP | 7:20 p.m. | Demerol 25 mg. | |
| | 7:35 p.m. | Same | |
| | 8:20 p.m. | Same | PACU |
| | 8:45 p.m. | Same | |
| | 9:30 p.m. | Demerol 75 mg. w/ Vistaril | ICU |
| 9/29 | 12:50 a.m. | Same | |
| | 4:00 a.m. | Same | |
| | 11:00 a.m. | Codeine 30 mg. | |
| | 2:15 p.m. | Valium 2 mg. IVP | Back spasms |
| | 2:55 p.m. | Codeine 30 mg. IM | |
| | 5:15 p.m. | Morphine 5 mg. | |
| | 7:30 p.m. | Same | |
| | 9:00 p.m. | Valium 2 mg. IVP | Back spasms |
| | 10:30 p.m. | Morphine 5 mg. | |
| 9/30 | 2:30 a.m. | Same | |
| | 9:30 a.m. | Same | |
| | 10:00 a.m. | Valium 2 mg. IV | Back spasms |
| | 11:30 a.m. | Morphine 5 mg. | |
| | 1:30 a.m. | Same | |
| | 8:00 p.m. | Same | |
| | 10:00 p.m. | Valium 2 mg. IV | Back spasms |
| | 12 midnight | Morphine 5 mg. | |
| 10/1 | 5 a.m. | Same | |
| | 10:30 a.m. | Same | Post CT scan |
| | 2:30 p.m. | | To surgery |

review of the records did not support continued improvement. The plaintiff developed pain and tenderness in areas previously not complained of. She developed more abdominal distension. She also began to complain of back spasms which could be interpreted as consistent with increased retroperitoneal inflammation. The plaintiff's witness also indicated that the first CT scan revealed a normal pancreas.

If the plaintiff had anything but a mild case of pancreatitis, the CT scan would show some pancreatic enlargement or fluid. The expert opined that pancreatitis, if there was any, was caused by the exposure of the pancreas to the leaking digestive enzymes through the perforation and not from the pancreas itself. In addition, the CT scan showed that retroperitoneal air had spread out from the initial perforation and some free fluid was now present. Clinically, after this CT scan, the plaintiff continued to develop new symptoms such as back pain and fluid sequestration that was evidence of an on-going progressive inflammatory process.

**The plaintiff's expert disclosed that it was incumbent upon the surgeons to either do further diagnostics to prove the leak had sealed, and to do so promptly, or to take the plaintiff to surgery to perform an exploratory laparotomy to evaluate the duodenal perforation. Waiting two days longer increased the inflammation, increased the pressure in the abdomen, increased fluid accumulation and caused additional tissue destruction.** Furthermore, it resulted in a more complex surgical procedure to close the perforation. Had surgery been performed earlier there would have been less inflammation and there would have been a greater likelihood that the perforation could have been closed with a few sutures. There would have been no need to exclude the duodenum or to do a gastrojejunostomy.

## Defense Expert

A surgeon was called in as an expert witness for the defendants. His opinion was that the laboratory data (elevated lactate dehydrogenase, amylase, WBC, and decreased calcium), imaging studies and clinical symptoms pointed to an underlying pancreatitis which led to the development of a systemic inflammatory response syndrome (SIRS). In his view, SIRS was responsible for the hospital course that the plaintiff endured. He indicated that if pancreatitis were caused by digestive juices leaking onto the pancreas through a perforation, as asserted by the plaintiffs, the organ would have shown inflammation mainly on the organ's surface (peripancreatitis) which was not found at autopsy.

The microscopic examination of the pancreas showed signs of necrosis, hemorrhage, and inflammation all of which were consistent with pancreatitis. Furthermore, the surgical report described the pancreas as appearing inflamed in its entirety. He also indicated that it was reasonable for the physicians to expect a small duodenal perforation to seal itself. He described the nature of the retroperitoneum as composed of tissues that adhere to one another creating a compressive force on any small perforation. The expert witness also believed that the type of surgery that was done on September 30 would not necessarily have been any different if the surgery was done a day or two earlier and such an assertion was speculative.

As to the first abdominal CAT scan showing a small amount of fluid, the surgeon believed this finding to be the body's reaction to pancreatitis and not leakage of fluid through the perforation. He concluded his testimony supporting the actions of the surgeons based on the presenting clinical, laboratory and imaging studies.

## Jury's Decision

The jury took two and a half days to return a verdict. They decided that both physicians departed from accepted medical practice in not operating on or before September 30 and this departure was a substantial factor in the death of the plaintiff. The amount awarded for pain and suffering, past economic loss, and future economic loss amounted to slightly less than a $2,000,000 verdict.

## LNC Conclusions

The role of the LNC was, first, to summarize the records. Next, the LNC gathered research on ERCP including the complications thereof and the treatment options and analyzed the records in comparison to the research. The LNC then pointed out the strengths and weaknesses of the care rendered to the plaintiff by the defendant surgeons in comparison to the prevailing research on how to handle duodenal perforations. It was clear from the research obtained, that even if surgical intervention occurred prior to September 30, the end result to the plaintiff might, very well, have been the same because of the pancreatitis. However, the conclusions that could be drawn from scrutinizing the care rendered to the plaintiff, was that the physicians waited too long and did not obtain enough diagnostic information to warrant their continued waiting.

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Marjorie Berg Pugatch, BS MA, has been a practicing legal nurse consultant for five years and has an independent consulting business. She specializes in medical malpractice and personal injury cases and has worked for both defense and plaintiff firms. Her nursing experience in pediatrics, pediatric cardiology, neonatology and adolescent medicine has provided her with a broad knowledge base that has translated well in all types of medical and personal injury cases.