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APPLICATION OF UROLOGIC TECHNIQUES TO NONURINARY CALCULI

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Technologic innovations have revolutionized the treatment of human calculi. Urologists were the first to apply minimally invasive techniques to stones, first with intracorporeal lithotripsy and subsequently with extracorporeal shock-wave lithotripsy (ESWL). Open surgery for urolithiasis is now rarely performed. In contrast, surgery is still the main therapy for patients with symptomatic gallstones or with chronic pancreatitis associated with calculi and intractable pain.

Recently, several minimally invasive treatments have been applied to biliary and pancreatic calculi: dissolution with oral agents, topical application of solvents, gallbladder mucosal ablation, intracorporeal lithotripsy via endoscopic or percutaneous access, laparoscopic cholecystectomy, and ESWL. The urologist familiar with percutaneous techniques and ESWL can be of great service assisting in their application to nonurinary calculi. We present an outline of minimally invasive treatment options, including representative case reports from our institution, and discuss the role of the urologist in these situations. To provide a complete overview of minimally invasive therapy of biliary and pancreatic stones, even those options in which the urologist's expertise may not be applicable are included.

Biliary Calculi

Gallstones are present in 15–20 percent of adults in the United States.[1] Forty to 60 percent of patients are asymptomatic; of the remaining, 20 percent present with acute cholecystitis, 10 percent with complicated cholecystitis (jaundice, cholangitis, or pancreatitis), and 60–70 percent with chronic cholecystitis (biliary colic).[1] At cholecystectomy, approximately 15–20 percent will have common bile duct stones. Calculi proximal to the common duct are seen in a few patients.

Seventy-five percent of patients with cholelithiasis have calculi composed predominantly of cholesterol (70–90%). Pigment stones, the other type of biliary calculi, are a mixture of calcium bilirubinate, complex bilirubin polymers, and bile acids.[2] Fifty percent of pigment stones and 5–10 percent of cholesterol stones are radiopaque. The majority of radiolucent stones are therefore cholesterol; they are "soft" compared with most urolithiasis.

Although the clinical magnitude of biliary calculi is certain, the optimal treatment is undefined. Cholecystectomy is the gold standard for symptomatic gallstones and endoscopic sphincterotomy with extraction is the present treatment of choice for retained common bile duct stones. Other ductal calculi usually require open surgery. New technology and pharmaceuticals are changing the management of biliary calculi. The minimally invasive treatments presented herein may become standard in the coming decade.

Oral agents

Chenodeoxycholate, a naturally occurring human bile salt, and ursodeoxycholate, a chenodeoxycholate epimer, alter the composition of bile by decreasing biliary cholesterol secretion and expanding the bile salt pool. The net effect is desaturation of bile with cholesterol and subsequent resolubilization of the cholesterol component of cholelithiasis. Oral agents alone can achieve gallstone dissolution in selected patients, requiring six months to four years of daily medication.[3] Their efficacy is greatly enhanced by lithotripsy.

Topical solvents

Mono-octanoin and methyl tert-butyl ether solubilize cholesterol directly. Instilled through an intrabiliary catheter, these agents can dissolve cholesterol-containing biliary stones in hours to days.[4] An infusion set-up with an interposed manometer as a pressure safety valve is used to prevent cholangiovenous reflux.

Gallbladder mucosal ablation

Following percutaneous cholecystolithotomy, cystic duct occlusion and gallbladder mucosal ablation may provide relief of biliary symptoms and prevention of stone recurrence. After years of animal studies, this technique has recently been applied to humans.[5] Eight patients underwent cholecystostomy and cystic duct obliteration with catheter-delivered radiofrequency electrocoagulation. Gallbladder mucosal sclerotherapy with 95% ethanol and 3% sodium tetradecyl sulfate was subsequently performed in 5 of these patients. Cystic duct occlusion was achieved in 6 patients. Hepatic iminodiacetic acid scan showed no activity in the gallbladder in the patients treated with sclerotherapy. There were no complications, but long-term follow-up is not yet available.

Intracorporeal lithotripsy

Access to the biliary system can be achieved through four means. First, a T-tube placed during common bile duct exploration provides a stable tract after six weeks.[6] Baskets or lithotrites (mechanical, electrohydraulic, ultrasonic, laser) can be used to fragment and extract ductal stones. Second, transhepatic puncture of an intrahepatic duct provides access for similar instrumentation. Third, endoscopic sphincterotomy of the ampulla of Vater with subsequent balloon or basket extraction of common duct calculi is successful in the majority of cases.[7] Endoscopic mechanical and electrohydraulic lithotripsy of larger duct stones has met with success, but ultrasonic and laser applications are still investigational. The length of instruments necessary for intestinal endoscopy precludes the use of the urologist's standard probes, which can be used via transhepatic or T-tube routes. The three aforementioned approaches are limited, for the most part, to ductal stones. The fourth, percutaneous cholecystostomy, can provide access to the gallbladder and biliary ducts.

Sonography, fluoroscopy, or laparoscopy guides the cholecystostomy. Fluoroscopy requires gallbladder opacification by oral cystography or injection of contrast media from an endoscopically placed nasobiliary catheter. Percutaneous gallbladder entry may be gained in a transperitoneal (subhepatic) or transhepatic fashion. Dilation of the tract is accomplished with standard techniques, including coaxial dilation with a peel-away sheath, Amplatz-like dilating systems, or balloon dilators. The gallbladder is mobile, especially in comparison to the kidney. Tract dilation into the gallbladder lumen may be difficult if the unfixed gallbladder wall is pushed away rather than pierced by the dilator.[8] Transhepatic access risks hepatic hemorrhage,[8] but transperitoneal entry may chance upon bowel.[9] Laparoscopic cholecystostomy entails the use of a periumbilical laparoscope to directly visualize the placement of either an introducer needle[9] and/or a cholecystoscope[10] into the gallbladder. This visualization decreases the likelihood of injury to surrounding structures.

With established percutaneous access, standard endourologic instruments may be utilized. Stones can be directly visualized, fragmented, extracted, or dissolved. In one series, 42 of 46 patients with gallstones were rendered stone-free by percutaneous cholecystolithotomy via transperitoneal puncture with sonographic and fluoroscopic imaging.[8] Two patients required a second lithotripsy session to remove all of the calculi. Two others experienced biliary leaks managed with percutaneous peritoneal drains, and 2 patients suffered inadvertent puncture of the transverse colon. Of the 2 patients with colonic injury, one was asymptomatic and the other required parenteral feeding because of the resultant enterocutaneous fistula. In both cases the fistulas closed immediately upon removal of the cholecystostomy catheters. In the 4 patients without successful stone removal, failure was due to an inability to gain percutaneous access because of a mobile and/or shrunken gallbladder.

Seven to ten days after treatment the self-retaining cholecystostomy catheter may be removed. The delay is necessary to allow maturation of the tract and decrease the likelihood of an intraperitoneal bile leak. A method of laparoscopic incisional cholecystostomy that obviates the need for post-procedure biliary drainage has been described.[11] A periumbilical laparoscope guides the placement of a second operating laparoscope that is used to incise the gallbladder, remove calculi, and then close the incision with clips. The inconvenience of a temporary indwelling biliary catheter is exchanged for the increased complexity of the procedure.

The timing and choice of percutaneous maneuvers is critical. A patient suffering from biliary colic without acute cholecystitis can undergo cholecystostomy with cholecystolithotomy at the same sitting. The patient with acute cholecystitis in whom traditional cholecystectomy is contraindicated may undergo percutaneous cholecystostomy. Subsequent manipulation, however, should be delayed until percutaneous decompression and antibiotics have allowed the inflammatory response to subside.[12] If the patient converts to a reasonable surgical candidate, delayed cholecystectomy is an option. In the chronically ill patient continuing with significant surgical risk, or a patient refusing open surgery, cholecystolithotomy (or topical application of solvents), with or without gallbladder mucosal ablation, can be the definitive treatment.

Patient 1. A sixteen-year-old boy with Oriental cholangiohepatitis suffering from numerous intrahepatic stones was unimproved following cholecystectomy with common bile duct exploration. He underwent four attempts of Dormia basket and balloon catheter extraction of calculi via an established T-tube tract. Many stones remained, including a 3.5-cm calculus in the superior left intrahepatic ductal system. Using peel-away catheters, the T-tube tract was dilated up to 16 F and directed toward the left hepatic stone. An 11.5 F rigid ureteroscope with an ultrasonic lithotrite was used to visualize, fragment, and evacuate the bulk of the stone. Two subsequent extractions via the established T-tube tract, using baskets and balloons, removed all but a small amount of debris. Additionally, a high-grade stricture was dilated with a balloon catheter. Cholangitis resolved and three months later he had remained asymptomatic.

ESWL

Several studies have documented the efficacy of ESWL in conjunction with oral dissolution therapy for the treatment of selected patients with cholelithiasis.[13,14] ESWL is best considered an adjuvant to oral dissolution therapy. ESWL dramatically increases the surface area of gallstones with effective fragmentation, thus allowing more rapid dissolution than would otherwise be possible. The endpoint of therapy is therefore eventual clearance of the stones by dissolution. Eligible candidates are those with biliary colic, three or fewer radiolucent or minimally calcified gallstones with a total diameter less than 30 mm, and visualization of the gallbladder by oral cholecystogram. Complicated cases (acute cholecystitis, pancreatitis, cholangitis, or bile duct obstruction) and patients with certain medical or anatomic conditions are excluded.[15] Approximately 20 percent of patients with symptomatic gallstones are candidates for ESWL.[16]

Both first and second generation lithotriptors have been used; roughly 2,000 discharges at approximately 20 kV are delivered at each treatment session and patients can safely undergo more than one session (necessary in 5–14% of patients). Radiolucent stones are imaged by sonography. General or epidural anesthesia, or intravenous sedation and analgesia, can be used in an inpatient or outpatient setting. Complications to date are minor: cutaneous petechiae; rare gross hematuria; transient rises in amylase, liver enzymes, or leukocyte counts. Thirty-five to 58 percent of patients suffer one or more episodes of biliary colic during passage of stone fragments. Rarely, subsequent cholecystectomy or endoscopic sphincterotomy with stone extraction is necessary. In a large Munich study, 91 percent of patients had complete disappearance of gallstones in twelve to eighteen months.[13]

ESWL also has been applied to bile duct calculi (common, cystic, hepatic, and intrahepatic ducts). Large, proximal, or impacted stones may be resistant or inaccessible to intracorporeal instrumentation. In the Dornier U.S. Bile Duct Lithotripsy Study,[17] 57 ESWL treatments using Dornier HM-3 lithotriptors (Marietta, GA) were applied to 42 patients with bile duct calculi refractory to intracorporeal techniques. A mean of 1,924 discharges were delivered at a mean of 18.5 kV. Stone fragmentation occurred in 95 percent of patients and complete duct clearance at the time of hospital discharge in 74 percent. Patients with fewer calculi were more likely to be rendered stone-free. Location of the calculi did not impact upon results. Adjunctive treatments including endoscopic extraction and biliary lavage were necessary in 50 percent of the patients to remove fragments. Hemobilia, biliary colic, gross hematuria, and biliary sepsis were infrequent complications.

Unlike the ureter, the common bile duct has no peristaltic activity except in its most distal portion, so spontaneous passage of fragments (unmodified by oral agents as are gallstone ESWL fragments) is less likely.[18] Biliary drainage, most often by a nasobiliary catheter, is mandatory to decrease the likelihood of obstruction and allow access for subsequent radiographic studies and possible manipulation.

Patient 2. An eighty-seven-year-old woman with severe cardiac disease (coronary artery disease, atrial fibrillation, and aortic valve replacement) was transferred to our institution with cholangitis. She was afebrile after one week of intravenous antibiotics. Findings on physical examination were normal. Laboratory values included a bilirubin of 2.4 mg/dL, alkaline phosphatase (AP) 296 U/L, aspartate transaminase (AST) 32 U/L, and leukocyte count 23,500 cells/μL. Endoscopic retrograde cholangiopancreatography (ERCP) revealed a 2-cm common bile duct stone with dilatation of the biliary tree. Sphincterotomy was performed successfully, but the calculus could not be extracted. A nasobiliary catheter was placed. Under epidural anesthesia two days later, ESWL with a Dornier HM-3 lithotriptor successfully fragmented the stone using 1,350 discharges at 20 kV. Residual debris was endoscopically extracted the following day and the nasobiliary catheter was removed. Post-procedure laboratory values were improved, including an AP of 237 U/L, AST of 28 U/L, and leukocyte count of 17,700 cells/μL. The patient was discharged from the hospital three days later.

Patient 3. A seventy-nine-year-old man debilitated with congestive heart failure and coronary artery disease presented with jaundice, signs of overt cardiac failure, and right upper quadrant tenderness. He had undergone cholecystectomy fifteen years previously. Leukocyte count was 13,500 cells/μL, bilirubin 9.9 mg/dL, AP 450 U/L, and AST 32 U/L. Ascending cholangitis was diagnosed, and the patient was stabilized on intravenous antibiotics. At ERCP, eight to ten stones of 0.5–2.0 cm in diameter were identified but only a few could be removed with a Dormia basket and balloon catheter. A nasobiliary catheter was placed. Eight days later under epidural anesthesia, 2,000 discharges at 20 kV were delivered by a Dornier HM-3 lithotriptor. Multiple 5–10 mm fragments were extracted endoscopically and the nasobiliary catheter was removed. The patient was discharged to home five days later with normalizing laboratory values. A year and a half later there had been no stone recurrence.

ESWL is an effective adjuvant to the treatment of biliary calculi in most locations. Application to gallstones is most appropriate in patients with high surgical risk or those patients refusing open cholecystectomy. Bile duct calculi resistant to intracorporeal lithotripsy should be considered for ESWL. The adjuvant nature of ESWL with biliary calculi must be stressed. Oral dissolution therapy is necessary in patients with gallstones, and fragment extraction is often required for ductal calculi. ESWL for biliary applications remains experimental and requires an FDA Investigational Device Exemption. Trials should proceed in a scientific fashion with careful follow-up, as potential long-term complications remain unknown.

Laparoscopic cholecystectomy

The common disadvantage of all treatment options that leave the gallbladder in situ (except for successful and permanent gallbladder mucosal ablation) is stone recurrence. The estimated recurrence rate is approximately 50 per cent within five to ten years.[16] A new technique without this drawback is laparoscopic cholecystectomy. Reddick and Olsen[19] reported on 25 patients with symptomatic cholelithiasis. Exclusion criteria initially included common bile duct involvement, acute cholecystitis, or previous upper abdominal surgery, although these requirements have since been modified.[20] Laparoscopic instruments introduced through four abdominal incisions of 11 mm or less were used to completely remove the gallbladder. Average post-procedure hospitalization was 1.96 days, and the patients returned to work an average of 4.5 days later. There were no complications reported in this group, although the authors admit that laparoscopic dissection had been abandoned in 2 patients during preliminary development of the technique. There also have been reports from Europe,[10] and a multicenter international study has been convened to prospectively evaluate this new procedure.[21]

Pancreatic Calculi

Chronic relapsing pancreatitis is characterized by recurrent bouts of abdominal pain and functional insufficiency of the pancreas. Obstructive intraductal pancreatic concrements producing abnormally high pressures in the pancreatic ducts have been implicated.[22] Ethanol, the most common cause of chronic pancreatitis, leads to a secretion of pancreatic juice containing increased amounts of protein, which may precipitate to form protein plugs.[23] Pancreatic calculi, the main component of which is calcium carbonate, contain substantial amounts of "pancreatic stone protein."[23]

Palliative surgical techniques aimed at improving the drainage of exocrine pancreatic secretions (pancreaticolithotomy, pancreaticoduodenostomy, pancreaticojejunostomy) or removing the pancreas (subtotal or total pancreatectomy) entail significant morbidity. Recent case reports document relief of the pain of chronic pancreatitis after removal of pancreatic calculi by minimally invasive techniques.

Endoscopy

Endoscopic sphincterotomy with subsequent Dormia basket or balloon catheter extraction of pancreatic calculi has resulted in cessation of pancreatic pain episodes.[22,24] One third of patients suffered transient pain immediately post-procedure, associated with a rise in pancreatic enzymes.[24] No significant complications were reported in the small series to date. Long-term follow-up is not available.

Intracorporeal lithotripsy

Ultrasonic lithotripsy through a rigid ureterorenoscope at the time of pancreaticojejunostomy has been used to remove an impacted pancreatic duct calculus.[25] Laser lithotripsy through a surgically placed percutaneous pancreatostomy drainage catheter also has been described.[26]

ESWL

In 1987, Sauerbruch *et al.*[27] from Munich reported the first application of ESWL to a pancreatic calculus. Four subsequent studies have evaluated the technique, using a variety of lithotriptors.[24,28-30] If fluoroscopy is used to locate minimally calcified stones, a nasopancreatic catheter must be placed for instillation of contrast material.

The most recent article from the Munich group[29] reports 8 chronic pancreatitis patients treated with 13 ESWL sessions. The mean number of discharges was 1,356, at 18 kV (spark gap generator) or 11–15 kV (electromagnetic generator). Fragments were extracted endoscopically after ESWL. In 4 patients total clearance was achieved, in 3 patients the large stones were disrupted but smaller peripheral calcifications persisted, and in 1 patient treatment failed completely. On average, amylase and leukocyte counts did not rise significantly after ESWL, although 2 patients experienced abdominal or flank pain post-procedure and 1 patient suffered a bout of frank pancreatitis. During a mean follow-up of eleven months, 3 patients had complete relief of pain, 1 patient had improvement in symptoms, and 4 patients experienced no relief. Resolution of symptoms did not correlate with the degree of stone fragmentation in this small patient group. In another study, improvement in pancreatic exocrine and endocrine dysfunction after ESWL of pancreatic calculi was reported.[30]

We present the first 2 cases of ESWL for pancreatic calculi described in North America.

Patient 4. A twenty-year-old woman with chronic familial pancreatitis had suffered six severe pain attacks in two years. Physical examination revealed epigastric tenderness. Laboratory values were normal. ERCP revealed three calculi in a side branch of the main pancreatic duct that were unretrievable with a basket. She underwent ESWL with a Dornier HM-3 lithotriptor, 1,000 discharges at 16–17 kV, under general anesthesia. Amylase the next day was 82 U/L, and she experienced no pain. She was discharged to home on the third post-procedure day. One week later the pancreatic ducts were swept with a balloon endoscopically, leaving only residual debris. Abdominal plain film seven months later revealed persistence of a smaller number of tiny fragments in the head of the pancreas. At one year's follow-up she had experienced only one episode of abdominal pain requiring hospitalization.

Patient 5. A thirty-year-old woman with a history of bimonthly attacks of pancreatitis over a twelve-year period demonstrated multiple 5–6 mm calcifications in the head of the pancreas by computerized tomography. ERCP revealed multiple calculi in the head of the pancreas, in the main pancreatic duct, and extending into the ducts of the uncinate process, as well as impaired ductal drainage. After a recurrent attack, the patient was admitted for ESWL. A Siemens Lithostar (Erlangen, FRG) was used to deliver, under intravenous sedation, 2,500 discharges at 15.1 kV to a 2 × 1-cm irregular calculus in the head of the pancreas. The following day her amylase was 40 U/L, compared with 34 U/L preprocedure, and she was discharged from the hospital. Subsequent endoscopic balloon sweeping and irrigation of the pancreatic ducts were successful in removing all but a few fragments. Five months later she reported infrequent pain attacks of markedly lessened severity.

Although the experiences with ESWL and endoscopic extraction of pancreatic calculi are limited, initial results are encouraging. The scientific basis for the relief of pancreatic pain following removal of calculi and decompression of ducts is sound and is supported by the aforementioned empirical data. Insufficient numbers of patients have been reported to reveal any infrequent but possible significant complications. A large prospective study is needed to clarify the roles of these two modalities, but initial impressions are that ESWL should be used on impacted or large pancreatic concrements resistant to endoscopic extraction in patients with chronic pancreatitis complicated by recurrent bouts of abdominal pain. The goal of therapy is relief of pain and possibly improvement in the exocrine and endocrine dysfunction of chronic pancreatitis (malabsorption and diabetes). Endoscopy is necessary to sweep the ducts clear of fragments post-ESWL.

Other Applications of Shock Waves

Several additional applications of extracorporeal shock waves (ESW) that may have clinical relevance have been reported. After a case report in 1986,[31] two studies examined the effects of ESW focused on the bone-cement interface in dog femora packed with cement and a steel rod. Microfracturing of the cement and disruption of the bone-cement interface were seen,[32,33] and mechanical loosening was demonstrated.[32] It was suggested that ESW might be helpful in the revision of hip prostheses.

ESW have been evaluated for their adjunctive application to healing bone. In a model using the fractured femora of rats, radiographic and histologic findings indicated enhanced healing after the delivery of ESW.[34] Clinical applications are unknown at this time.

Numerous articles and presentations have demonstrated toxic effects of ESW on in vitro and in vivo tumor cells. First described by Russo *et al.* in 1985,[35] investigators have subsequently shown inhibition of clonal expansion and variable effects on immediate cell viability in cell lines derived from prostate cancer,[36,37] bladder tumors,[38,39] renal carcinoma,[40] ovarian tumors,[41,42] melanoma,[37] and endometrial carcinoma.[41] ESW enhances the cytotoxic effects of vinblastine,[36] cisplatin,[38,41] Cytoxan,[41] and doxorubicin (Adriamycin).[41] Preferential injury to renal carcinoma cells as opposed to normal human embryonic kidney cells has been demonstrated in vitro.[40] The exact mechanism and nature of the ESW-induced injury is unknown. Data are insufficient to allow for clinical application to human malignancies at present.

Conclusion

The minimally invasive alternatives in the treatment of biliary and pancreatic calculi are just becoming established. As technology improves, open procedures are performed less frequently, more options are included in our decision-making—and, most importantly, the patient is better served. Endoscopic removal of retained common bile duct stones is an accepted modality. Other treatment options presented here are still under development; further studies are needed to define their appropriate roles.

The urologist can serve in a unique capacity in the evolution of these treatment methods. We are not and never should be primarily responsible for patients with biliary or pancreatic diseases. Our role is that of teacher and advisor regarding the utilization of endourology and ESWL, both in development (several urologists were investigators in the Dornier U.S. Bile Duct Lithotripsy Study)[17] and application.

The benefits of cooperation between urologists, general surgeons, radiologists, and gastroenterologists are many. Patient care will progress. Professional cooperation can only lead to the expansion of the knowledge base of all parties involved. Improved applications might be devised. Finally, the addition of biliary and pancreatic calculi to the list of entities potentially treated by ESWL may justify locating lithotriptors at smaller institutions. As intracorporeal and extracorporeal lithotripsy of biliary and pancreatic calculi move from investigational use, the urologist can offer consultation and technical assistance as part of a unified "stone team."

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