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Role of Extracorporeal Shock Wave Lithotripsy in Hepato-Biliary-Pancreatic Surgery

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Since the early 1980s extracorporeal shock wave lithotripsy (ESWL) has partially replaced major operative procedures in various fields of surgery. In the interest of the patient, it is important to determine the exact role of ESWL in surgery. Comparing our own prospectively followed patients with other patient series, we have tried to assess this role. We treated 133 patients with cholecystolithiasis, 80 patients with choledocholithiasis, and 17 patients with pancreatic stones using a second-generation lithotriptor, the Siemens Lithostar (Siemens, Erlangen, Germany). The results suggest a limited role of ESWL for cholecystolithiasis, in which it is reserved for patients with high operative risk and patients who reject an operation. For choledocholithiasis ESWL seems to become an integral part of the treatment in the elderly patient in whom endoscopic stone removal proved impossible. Finally, ESWL could become a first option for the treatment of intractable pain in patients with chronic calcifying pancreatitis.

Shock waves, which can be used to disintegrate stones because of their physical characteristics, can be generated by three methods [1–3]. Since 1980 extracorporeal shock wave lithotripsy (ESWL) has been used in the case of urolithiasis and has replaced surgical treatment almost entirely [4, 5]. ESWL of gallbladder stones has been applied since 1985 [6, 7], and the first reports on ESWL of common bile duct stones and pancreatic stones appeared in 1989 [8, 9]. Despite the initial enthusiasm, restrictions for ESWL of gallbladder stones especially soon became evident. Rigid entry criteria, expensive adjuvant dissolution therapy, moderate results, and the possibility of stone recurrence after gallbladder-preserving therapies are major drawbacks [7, 10–17]. ESWL of common bile duct stones is useful in patients in whom endoscopic removal proves impossible [8, 18–21]. ESWL of pancreatic stones in chronic calcifying pancreatitis is still relatively unknown but seems effective [22]. The morbidity and mortality associated with ESWL are minimal [7, 8, 11–13, 18–22] and compare favorably to those with surgery. Therefore we have tried to assess the exact role of ESWL in this field with our own prospectively followed patients and other patient series.

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Patients and Methods

Using a so-called second-generation lithotriptor, the Siemens Lithostar (Siemens, Erlangen, Germany), which operates on a electromagnetic principle, we treated patients suffering from cholecystolithiasis (n = 133, group I), choledocholithiasis (n = 80, group II), and pancreatic stones (n = 17, group III). Characteristics of these patients are depicted in Table 1, and entry criteria for ESWL in the three groups are shown in Table 2.

Group I

All patients were treated on an outpatient basis. Directly after the first ESWL session, adjuvant oral bile acid (OBA) therapy (urso- and chenodeoxycholate) was started. Ten days after each session an ultrasound examination (US) was done to determine the fragmentation result. If fragments remained larger than 5 mm after repeated sessions, ESWL was considered a failure, and cholecystectomy was advised. US was performed at regular intervals (3 months, 6 months, 1 year, 1.5 years, and 2 years) after the first session. If US did not demonstrate stone material at two consecutive occasions, clearance of the gallbladder was assumed and the OBA therapy stopped.

Group II

All patients had one or more of the symptoms, depicted in Table 1. The stones were visualized by radiology and injection of contrast medium in the bile ducts via a biliary drain (Table 1). In 11 patients the biliary sphincter could not be reached at endoscopy. In those patients and in seven others, percutaneous drains and T tubes were used. Of the 47 patients without gallbladder, 12 had had a cholecystectomy recently and had also undergone a choledochotomy. In these patients, overlooked common bile duct stones were discovered on a postoperative T tube cholangiogram. The possibility of spontaneous clearance of the stones after endoscopic sphincterotomy was thought to be low because of the large size and impacted character of the stones.

All treatments were performed under antibiotic coverage and

Table 1. Patient characteristics before ESWL treatment.

Characteristic	Group I	Group II	Group III
Patients (M/F)	133 (34/99)	80 (33/47)	17 (10/7)
Age, mean (range) (years)	49 (24–81)	73 (27–91)	42 (19–55)
Stones (no. patients)			
1	70 (53%)	34 (43%)	6 (35%)
2–5	55 (41%)	32 (40%)	7 (41%)
6–10	8 (6%)	14 (18%)	4 (24%)
Stone diameter mean (range) (mm)	17 (5–40)	25 (10–50)	21 (14–40)
Patients (no.) with			
ES		69 (86%)	17 (100%)
Biliary drain			
NBD		62 (78%)	
PTD		6 (8%)	
T-tube		12 (15%)	
Symptoms			
Biliary colic		39 (49%)	
Jaundice		36 (45%)	
Fever > 38.5°C		16 (20%)	
Cholecystectomy		47 (59%)	
Previous pancreatic surgery			3 (18%)
History of alcohol abuse			10 (59%)

ES: endoscopic sphincterotomy; NBD: nasobiliary drain; PTD: percutaneous transhepatic drain.

Table 2. Criteria for ESWL of gallbladder, common bile duct, or pancreatic stones.

Gallbladder stones
Symptoms: biliary colics
Opacification of gallbladder at oral cholecystography
No. of stones: 1–10; diameter of largest stone > 5 mm
Calcified rim of stone < 2 mm
No cholecystitis, cholangitis, pancreatitis, hepatitis, or concomitant choledocholithiasis at the time of ESWL
Common bile duct stones
Symptoms: obstruction of common bile duct (jaundice, abdominal pain, fever)
Endoscopic extraction impossible
Visualization of stones with contrast medium via a biliary drain
Pancreatic stones
Symptoms: recurrent abdominal pain
Endoscopic extraction impossible
Visualization of stones without contrast medium
No acute pancreatitis, acute cholecystitis, cholangitis, or concomitant choledocholithiasis at the time of ESWL
Gallbladder, common bile duct, and pancreatic stones
No lung tissue, cysts, or aneurysms in the shock wave path
No bleeding disorders
No pregnancy

continuous lavage of the bile ducts with 4 liters of sterile water per 24 hours. Shortly after ESWL the result was evaluated by cholangiography. In case of fragmentation (reduction of stone diameter, lines of contrast medium visible within the stone, or quick disappearance of the contrast medium from the biliary tree), cholangiography was repeated after 2 days of lavage. In the case of remaining fragments, a new endoscopic or percutaneous stone extraction was attempted. If it was not successful or in cases where stone fragmentation was never demonstrated, the patient underwent an elective bile duct exploration or had an endoprosthesis placed in the common bile duct.

Table 3. Characteristics of ESWL sessions in three groups of patients.

Characteristic	Group I (n = 133)	Group II (n = 80)	Group III (n = 17)
Sessions/patient (range)	2.2 (1–7)	1.9 (1–4)	1.9 (1–4)
SW/session (range)	2817 (75–4000)	4703 (1200–6000)	4660 (1000–8000)
Duration (min)/ session (range)	62 (35–210)	64 (30–150)	73 (20–105)
Patients (no.)			
GA	0	1	1
AS	133	71	15
No GA/AS	0	8	1

SW: shock waves; GA: general anesthesia; AS: analgo-sedation.

Group III

The diagnosis "chronic pancreatitis" was based on the patient's history (chronic upper abdominal pain or recurrent attacks of upper abdominal pain), the presence of calcifications in the pancreatic region on plain abdominal roentgenography, and the radiologic aspect of chronic pancreatitis on endoscopic retrograde cholangiopancreatography [23]. All patients were treated under antibiotic coverage. In 15 patients the stones could be visualized as calcifications by radiology alone. Shock waves were focused on these calcifications. In 2 patients additional injection of contrast medium via a nasopancreatic drain was necessary for visualization of the stones because of a low calcification grade. After the ESWL treatment a plain abdominal roentgenogram was obtained. If stone fragmentation was observed (clear change of contour of stone), another endoscopic stone extraction was attempted, after which a nasopancreatic drain was left in place for lavage (2 liters sterile water per 24 hours). If no stone material was observed, spontaneous clearance of the duct was assumed. If ESWL repeatedly failed in fragmenting the stones, an operation was contemplated.

Statistics were performed using the test for comparing proportions with binominal distributions and the Wilcoxon test for matched pairs.

Results

Table 3 summarizes the characteristics of the ESWL sessions for all three groups of patients. Table 4 depicts the fragmentation and clearance rates for all three groups. For group I the median follow-up (range) is 14 months (1–45 months), in group II 23 months (1–50 months), and group III 20 months (3–41 months).

Group I

Stone fragmentation (decrease of diameter of the largest stone > 25%) could be achieved in most patients (89%); but after

Table 4. Results of ESWL of the gallbladder, common bile duct, and pancreatic stones.

Group	No fragmentation	Fragmentation	→	Stone clearance
I (n = 133)	15 (11%) 8 Expectant 7 Operated	118 (89%) 52 Still OBA 23 Operated	→	43 (32%) 6 Recurrence 4 Expectant 1 Operated 1 OBA
II (n = 80)	14 (18%) All operated electively	66 (83%) 6 Endoprosth 6 Operated electively 2 Operated emergently	→	52 (65%) 14 Lavage 34 Endoscopic extraction 4 Percutaneous extraction
III (n = 17)	4 (24%) 1 Expectant 3 Operated	13 (76%) 4 Pain relief 2 Operated	→	7 (41%) All pain relief

OBA: oral bile acid therapy; endoprosth: endoprosthesis.

adjuvant OBA therapy stone clearance could be achieved in only 32% of the patients to date. In the remainder of the patients, OBA therapy continues or a cholecystectomy has been undertaken because of persistent biliary complaints or insufficient stone fragmentation. Patients with a solitary stone had a significantly better chance to become stone-free than patients with multiple stones: 26 of 52 (51%) versus 5 of 60 (13%), respectively, after 1 year of follow-up ($p < 0.001$: two sample proportion test).

Fourteen percent of patients with stone clearance (6/43) had stone recurrence: four of the six were not symptomatic, one underwent a cholecystectomy, and in one OBA therapy was restarted.

A total of 57 patients (43%) had biliary colic shortly after the ESWL treatment. Other complications were obstruction of the common bile duct in nine patients (7%), five of whom became jaundiced and in four of whom pancreatitis developed. Two patients (1.5%) had transient hematuria, one had acute cholecystitis after ESWL. OBA therapy resulted in diarhea in 15 patients (11%), which resolved in all cases after lowering the dose of OBA for 2 weeks. No mortality was observed.

Group II

Stone clearance was achieved in 52 patients (65%); in 14 cases biliary lavage was sufficient to clear the bile ducts; in 34 cases the remaining fragments were extracted endoscopically and in 4 cases percutaneously. In case of failure of the additional endoscopic or percutaneous attempts (n = 14, 18%), the final treatment—taking into account the patient's physical status—consisted in placing an endoprosthesis past the fragmented stones (n = 6) or undertaking an elective bile duct exploration (n = 6). In two cases emergency surgery was necessary after complications of an endoscopic procedure (one perforation of the common bile duct with a Dormia basket, one arterial bleeding after extension of a sphincterotomy). These two patients had an uneventful recovery.

Two patients (3%), one with and one without a gallbladder, had stone recurrence at 27 and 30 months after ESWL, respectively. The first patient could be treated with a renewed endoscopic extraction, and the other had a successful repeated ESWL treatment.

One patient had a subcapsular hematoma of the right kidney, as demonstrated on US. The hematoma resolved without clinical consequences. Notwithstanding antibiotic prophylaxis, one patient developed sepsis with a positive blood culture *(Escherichia coli)*. This patient received adequate medical treatment. There was no mortality after ESWL and adjuvant treatments.

Group III

Thirteen patients had stone fragmentation (76%), of whom 11 (65%) had immediate pain relief after ESWL. The other two patients, with fragmentation but without clearance of stones, had recurrent pain attacks and consequently underwent a side-to-side pancreatojejunostomy 12 and 24 months after ESWL, respectively (Table 4). Seven patients (41%) had complete stone clearance (in three the pancreatic duct cleared spontaneously after ESWL, and in four the duct was cleared after 2 days of lavage with sterilized water). To date, none has had recurrent abdominal pain except one patient who had a pain attack after a large alcohol intake. The median follow-up of these seven patients was 22 months (6–41 months). Of the four patients without stone fragmentation, three had a side-to-side pancreaticojejunostomy. However, all three of them still report abdominal pain 38, 31, and 14 months after the operation, respectively. One has developed insulin-dependent diabetes mellitus.

The only complication directly after ESWL was an exacerbation of pancreatitis in one patient that could be treated medically. Again, there was no mortality after ESWL.

Discussion

The role of ESWL in surgery is becoming clarified. With the results achieved in our patients and in other patient series, more reasoned statements can be made now. Instead of optimistic or pessimistic views, patients benefit most from a well established treatment scheme in which the different modalities have their own, though sometimes limited, role.

Gallbladder Stones

(Laparoscopic) cholecystectomy remains the gold standard as the treatment for symptomatic cholecystolithiasis [24, 25]. Cholecystectomy carries morbidity and mortality rates of about 10% to 30% and 0.1% to 0.3%, respectively, and these rates increase with age [25]. With laparoscopic cholecystectomy these figures may be lower, but the higher incidence of bile duct injuries gives reason for concern [26]. There is no reported mortality associated with ESWL of gallbladder stones, and the rate of major complications is low [7, 11]. In our series, nine patients (7%) had common bile duct obstruction, and one patient had an acute cholecystitis after ESWL.

After optimistic initial reports in which finally more than 90% of the selected patients became stone-free [7], less favorable results gave rise to pessimistic comments [27]. However, most patient series have reported overall stone-free rates at 12

months of 30% to 84%, depending largely on stone characteristics [10–14, 28–31]. This point is in accordance with our own findings—that ESWL therapy is found to be more effective for solitary than multiple stones, for radiolucent than slightly calcified stones, and for smaller than for larger stones. In view of the above, we think that only patients with a high operative risk (ASA classification III–IV [32]) or patients who reject an operation should undergo ESWL, provided they comply with strict criteria to achieve the highest possible stone clearance rate. We estimate this rate to be about 50% after 1 year.

Common Bile Duct Stones

In the case of choledocholithiasis, surgical common bile duct exploration is an accepted therapy but carries a considerable mortality rate, which may be as high as 8% in the elderly or in high-risk patients [33–35]. Among this population, the treatment of choice is endoscopic sphincterotomy (ES) [36–38]. However, in about 10% of the cases it proves impossible to clear the bile ducts with endoscopy alone [8, 36, 39]. The natural history of common bile duct stones, with or without ES, still is not well known [37]. However, all our patients were symptomatic and needed therapy for the short term. In these patients ESWL is an attractive alternative to surgery: Stone clearance was achieved in 65% of our patients and in up to 88% in other studies [8, 18–21, 40, 41].

The failure rate can be due to the possibility of false positivity during radiologic targeting via a biliary drain. The morbidity rate of ESWL of common bile duct stones is low: Macrohematuria (in 2–11% of the patients) and hemobilia (2–8%) are reported to resolve within a few days [8, 18, 20]. Septic fever in 3% to 6% of the cases is often regarded as an exacerbation of already existing cholangitis [8, 18, 19]. There has not been any ESWL-related mortality, but mortality associated with the adjuvant endoscopic or percutaneous procedures, which is about 1% [36, 39], must be borne in mind. At least in the patient with an increased operative risk, ESWL should be considered before surgery after failure of endoscopic measures.

Pancreatic Stones

Although it remains uncertain whether pancreatic stones are the main cause of the pain in chronic calcifying pancreatitis (CCP), 11 of 13 patients with stone fragmentation were free of abdominal pain directly after the ESWL treatment (Table 4). Whether fragmentation without stone clearance can lead to long-lasting pain relief is doubtful. In our series two of six patients with stone fragmentation but no stone clearance had recurrent abdominal pain and an operation after ESWL. The other four patients have reported pain relief only at limited follow-up (median 7 months, range 5–10 months). ESWL resulted in clearance of stone material in 41% of our patients, and all of them have pain relief to date.

Stone clearance in 59% of 123 patients with CCP, treated with ESWL and subsequent endoscopic drainage, has been reported [22]. The authors emphasized the importance of deep endoscopic drainage in the pancreatic duct after ESWL.

The ESWL technique compares favorably with an operation for pain relief in CCP: It is noninvasive, there is no need for general anesthesia, no mortality has been reported, and the number of complications is low (in our series one exacerbation of pancreatitis). It is unlikely that pancreatic insufficiency will be induced by ESWL. Furthermore, the hospitalization time is short (about 3 days per ESWL session). Pancreatic surgery is accompanied by considerable morbidity and mortality (rates of 20–40% and 2–5%, respectively) [42, 43]. In large surgical series, long-lasting pain relief cannot be achieved in 20% to 40% of the cases [42–46]. In view of the above, a randomized trial comparing ESWL with surgery or the natural history of this disease is warranted.

In conclusion, if a decision must be made about whether to operate on a patient with CCP or treat him or her with ESWL followed by endoscopic drainage, we think that ESWL is the better alternative. It seems important to achieve stone clearance and not mere stone fragmentation. Of course abuse of alcohol must be treated as a condition that may interfere with the success of this therapy of CCP.

Résumé

Pendant ces 12 dernières années, la lithotritie extracorporelle (LE) a été proposée pour remplacer certaines techniques chirurgicales. Dans l'intérêt du patient, il était important de déterminer le rôle précis de la LE en chirurgie. Nous avons suivi prospectivement 133 patients ayant une lithiase vésiculaire, 80, une lithiase de la voie biliaire principale et 17, des calcificatins pancréatiques, tous traités par un lithotriteur de deuxième génération le Siemens Lithostar (Siemens, Erlangen, RFA). Les résultats suggérent que la LE a un rôle limité dans la lithiase vésiculaire, réservée uniquement aux les patients à très haut risque chirurgical et à ceux qui refusent l'intervention. Chez les patients ayant une lithiase de la voie biliaire principale, son rôle se borne au traitement des patients âgés, inopérables chez lequels la sphinctérotomie est un échec. Enfin, la LE pourrait être le traitement de choix chez les patients ayant des douleurs résistantes au traitement médical dans la pancréatite calcifiante chronique.

Resumen

A partir de 1980 la litroticia extracorpórea por ondas de shock (LEOS) ha sido eficazmente utilizada en la urolitiasis y ha venido a suplantar casi totalmente al tratamiento quirúrgico. La LEOS de cálculos de la vesícula biliar está en uso desde 1985, y los primeros informes sobre LEOS de cálculos del colédoco y del páncreas aparecieron en 1989. A pesar del entusiasmo inicial, bien pronto se hicieron evidentes las restricciones sobre su aplicación, especialmente en el caso de cálculos de la vesícula biliar. En el interés del paciente, aparece importante definir el papel de la LEOS en la cirugía. Hemos tratado de hacerlo comparando nuestros pacientes, seguidos en forma prospectiva, con los de otras series. Nuestro grupo ha tratado 133 casos de colelitiasis, 80 de coledocolitiasis y 17 de cálculos pancreáticos con un litotritor de segunda generación, el Lithostar de Siemens (Siemens, Erlangen, Alemania). Los resultados sugieren un papel limitado de la LEOS en colelitiasis, entidad para la cual se usa sólo en pacientes de muy alto riesgo operatorio o en aquellos que rehusan la operación. En la coledocolitiasis la LEOS aparece como parte integral del tratamiento en pacientes de edad avanzada, en quienes resulte

imposible la remoción endoscópica de los cálculos. Finalmente, la LEOS puede representar la primera opción en el manejo del dolor intratable en pacientes con pancreatitis crónica calcificada.

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