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# A Retrospective Analysis of 3 Year's Experience of an Interdisciplinary Approach to Gallstone Disease Including Shock-waves

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1206 patients with gallstone disease were treated between January 1985 and December 1987, using an interdisciplinary concept that included surgery, endoscopic sphincterotomy, and extracorporeal shock-wave lithotripsy (ESWL). Twenty-five per cent of the patients who were admitted for gallbladder stones were treated by ESWL, whereas 75% underwent surgery. Mortality of elective treatment for gallbladder stones amounted to 0.25% (0.4% in surgery, 0% in ESWL). Postoperative complication rate was low (4.2% in surgery, 7.0% in ESWL). After ESWL treatment, 80% of the patients were free of stones after a follow-up period of 1 year. Recurrence rate in these patients amounted up to 10%: in seven of 70 patients, mean follow-up period was 6 months after complete disappearance of stones. Twenty-seven per cent of all patients who were admitted for bile duct stones underwent surgery, whereas in the other 73%, calculi were removed via endoscopy. ESWL treatment was used additionally, if necessary. Fragments were left behind in three of 75 patients (4.0%) after surgical treatment, and in 7 of 200 patients (3.5%) after endoscopic and ESWL treatment, respectively. In the latter group, three patients (1.5%) required an additional operation. There were no deaths in either of the groups. The use of ESWL for treatment of gallbladder stones needs to be evaluated in long-term follow-up studies. Thus far, surgery remains the dominating method. Endoscopic procedures, eventually combined with ESWL, represent the preferred treatment for patients with bile duct stones.

**A**T THE UNIVERSITY MEDICAL CENTER Grosshadern in Munich, extracorporeal shockwave lithotripsy (ESWL) was developed by Brendel and colleagues.<sup>1,2</sup> Subsequently, this new therapeutic principle led to an interdisciplinary approach to gallstone disease, changing the role of surgery in the treat-

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ment of gallbladder as well as of bile duct stones. Paumgartner and colleagues introduced ESWL into clinical practice.<sup>3-5</sup> The data presented here reflect our experience in the treatment of gallstone disease during the past 3 years with regard to various procedures including ESWL.

## Patients and Methods

From January 1985 to December 1987, 1206 patients were treated for gallstone disease at the University Center Grosshadern, Munich. Surgery was still the treatment applied most frequently for the management of gallbladder stones (Fig. 1). ESWL was performed in 250 patients. This figure corresponds to 25% of all patients admitted to our hospital and treated for gallbladder stones. The patients in whom ESWL was used had to meet the following criteria in having: a history of biliary pain, one to three radiolucent gallbladder stones with a diameter less than 30 mm, and a functioning gallbladder, as documented by visualization on oral cholecystography (Table 1).<sup>5</sup> For patients with more than three stones, very large or calcified stones, a nonfunctioning gallbladder, and complications from gallstone disease, however, surgery was still the treatment of choice.

With ESWL, the shock-waves are generated by high-current underwater spark discharge. The patient is placed in a prone position. Until recently, the patient had to be partially immersed in a water bath. With the second generation of lithotriptors, however, the application of shock-waves requires only a water bag to trans-

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Presented at the 108th Annual Meeting of the American Surgical Association, San Francisco, California, May 2-4, 1988.

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Submitted for publication: May 24, 1988.

mit the shock-waves into the body. The gallstones are visualized by ultrasonography, which also guides the positioning of the stones and which monitors fragmentation. In our series, all patients received an adjuvant litholytic therapy of bile acids to dissolve remaining stone fragments. Litholysis included the administration of ursodeoxycholic acid and chenodeoxycholic acid, 7–8 mg/kg body weight, each.<sup>6</sup> Drug therapy commenced at least 1 week before shock-wave treatment and was continued up to 3 months after complete disappearance of stone fragments.

The treatment regimen of common duct stones involved endoscopic sphincterotomy, ESWL, or surgery (Fig. 1). Today, the preferred treatment for most patients with bile duct stones is endoscopic sphincterotomy.<sup>6–9</sup> In our series, endoscopic sphincterotomy was used as solitary therapy in 149 patients, and was combined with ESWL in 51 patients. Seventy-five patients underwent surgery. The latter were patients who presented with simultaneous gallbladder and bile duct stones.

Shock-wave lithotripsy in patients with bile duct stones is performed in a kidney lithotripter, with the patient being in a supine position. A nasobiliary catheter is inserted to inject contrast medium into the common bile duct for visualization of the duct and of the stones. Monitoring is done via a two-dimensional x-ray system.<sup>10</sup>

### Results

The results of our concept in the treatment of gallbladder stones are shown in Table 2. Operative mortality in elective cases was 0.4%, in nonelective cases, 1.4%. Elective treatment was performed in all patients who underwent ESWL and in 73% of the patients who underwent surgery. None of the 250 patients treated by ESWL died. Two patients had to undergo surgery because the stones did not fragment. The total mortality of both groups was 0.25%. After ESWL and medical dissolution therapy, 80% of the treated patients were free of stones after 1 year and 90% after two years.

The complications that followed elective surgery were primarily of cardiac and pulmonary origin (Table 3). Wound infection, bleeding, and sepsis were rare. After ESWL, transient biliary pain was observed in 35% (Table 3). Complications included cystic duct obstruction in about 5% and mild pancreatitis in 2% of the cases. In one patient who was treated by ESWL, pancreatitis was cured by sphincterotomy and removal of two fragments from the common bile duct. Four patients recovered spontaneously.

For the treatment of bile duct stones, surgery was successful in 72 of 75 patients; in two cases stones were removed endoscopically, and in another patient a con-

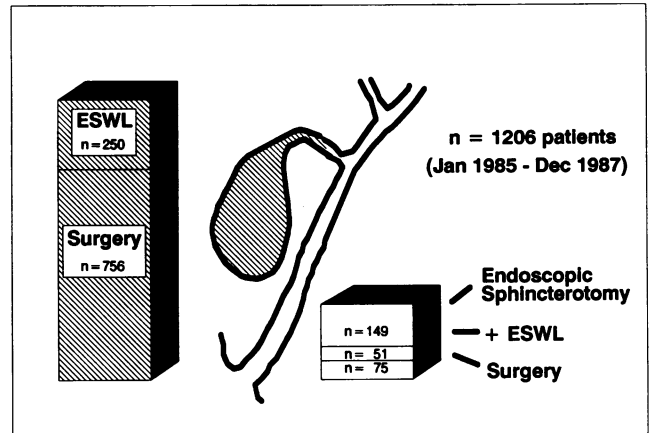


FIG. 1. Surgery, endoscopic procedures, and ESWL in the interdisciplinary treatment of gallstone disease. Patients (n = 1206) treated in the Department of Surgery and the Department of Internal Medicine II, Klinikum Grosshadern, Ludwig-Maximilian-University, Munich, West Germany.

TABLE 1. Selection Criteria for ESWL Treatment in Gallbladder Stones

History of biliary pain
1–3 radiolucent stones, <30 mm
Functioning gallbladder (oral cholecystography)

TABLE 2. Results of Surgery and ESWL Treatment for Gallbladder Stones

	Surgery (n = 681)	ESWL (n = 250)
Mortality		
Elective	0.4%	0%*
Nonelective	1.4%	—
All elective cases (Surgery and ESWL)		0.25%
Free of stones		
After 1 year		80%†
After 2 years	100%	90%†

\* Two patients operated electively.

† estimated by Kaplan-Meier.

TABLE 3. Symptoms and Complications After Elective Surgery and ESWL Treatment in Patients with Gallbladder Stones

Surgery (n = 544)	
Cardiac	1.1%
Pulmonary	1.0%
Wound infection	0.8%
Bleeding	0.5%
Bile fistula	0.4%
Sepsis	0.2%
Retained stones	0.2%
ESWL (n = 250)	
Transient biliary pain	35%
Cystic duct obstruction	5%
Mild pancreatitis	2%
Sphincterotomy (1)	
Spontaneous recovery (4)	

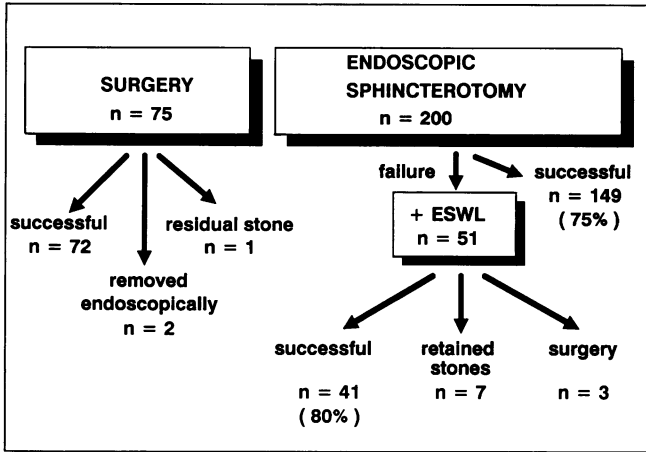


FIG. 2. Treatment of bile duct stones. Results of surgery (n = 75 patients), endoscopic sphincterotomy (n = 200 patients), and ESWL (n = 51 patients).

crement had to be left (Fig. 2). 200 patients underwent endoscopic sphincterotomy for stone removal (Fig. 2). This was successful in 149 patients (75%). Sphincterotomy and stone removal failed in 51 patients, and therefore ESWL was used. This high failure rate (25%) is due to the fact that a predominant number of patients admitted to our hospital present with complicated bile duct stones. In 41 of 51 patients, ESWL treatment was successful (80%). In seven patients, fragments were left. Mortality was 0%. Three patients required surgery; in one 81-year-old man, a Dormia basket became stuck during the attempt to remove stones from the common bile duct. The basket and stones had to be removed by choledochotomy. A second patient had to be treated by drainage of the retroperitoneum after rupture of a juxta papillary diverticulum caused by endoscopic manipulations. In a third case, emergency cholecystectomy was necessary because of acute cholecystitis. For all three patients, the postoperative course was uneventful.

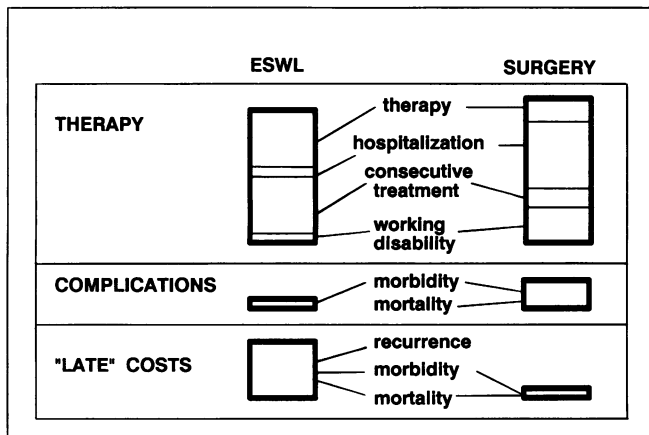


FIG. 3. Trends of cost-effectiveness of surgery and ESWL treatment for gallbladder stones.

### Discussion

For the therapy of gallbladder stones, conservative treatment with ESWL is limited primarily to elective cases that present with one to three radiolucent stones in a functioning gallbladder (Table 1). Applying these criteria, an optimistic estimation would be that up to 25% of symptomatic gallbladder stones could be treated with ESWL.<sup>5</sup> Surgery is still the primary therapy for patients with more than three stones, calcified stones, and/or huge stones, and especially in all nonelective cases.

For patients with common duct stones who simultaneously present with gallbladder stones, and especially for younger patients, surgery is preferred.<sup>6</sup> For older patients or those with high risk factors, therapeutic splitting seems to be indicated.<sup>9,11-14</sup> This includes endoscopic removal of duct stones, combined with ESWL, if necessary, and is followed by secondary cholecystectomy. In cholecystectomized patients or in high-risk patients, it would appear that surgery has almost lost its place, except for those patients in whom endoscopic therapy with or without shock-wave lithotripsy has failed.

More information has to be obtained concerning morbidity, mortality, recurrence rate, and cost effectiveness to establish the definite role of ESWL in the treatment of gallbladder stones.

After ESWL treatment, morbidity (5% cystic duct obstruction and 2% mild pancreatitis) seems to be higher, but less severe compared with surgery. There is no mortality after ESWL. Yet in contrast to surgery, depending on the rate of recurrence of stones, some late mortality may be expected.

The reported recurrence rate of stones after cholecystolithotomy is 81% within 15 years,<sup>15</sup> and after medical dissolution therapy, about 50% within 5 years.<sup>16-18</sup> At present, the recurrence rate after ESWL cannot be predicted exactly. Thus far, seven of 70 patients have again developed gallbladder stones after discontinuing adjuvant medical dissolution therapy. The mean follow-up period was 6 months. The treatment of recurrent stones consisted of ESWL and medical dissolution for three patients, and of exclusive medical dissolution for four patients. Because follow-up studies are still incomplete and are based on a short observation period only, no exact prognosis of recurrence can be deduced from these figures. But it seems that within 5 years, a recurrence rate of about 50% may be expected.

Finally, estimates of costs for the therapeutic procedure itself seem to reveal slightly higher costs for cholecystectomy than for lithotripsy, particularly in cases in which postoperative complications occur (Fig. 3). On the other hand, for ESWL, recurrence of stones may become the major factor of late costs and would therefore be the primary determinant of the total amount of money needed for ESWL in the treatment of gallstone

disease. When considering kidney stone disease, it has to be said that the therapy of kidney stones, which is provided almost entirely by ESWL, increased costs considerably in West Germany in 1986, as recently published.<sup>19</sup>

In conclusion, the interdisciplinary concept for treatment of gallstone disease seems to be beneficial to the patients. But it has to be taken into account that the late consequences of ESWL, especially the recurrence rate of stones, remain to be evaluated in long-term follow-up studies. For the next decade, it is safe to predict that within interdisciplinary therapeutic concepts for the treatment of gallstone disease, surgery will maintain its major role.

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### DISCUSSION

DR. FRANK G. MOODY (Houston, Texas): Professor Heberer and his colleagues at Munich are to be congratulated on bringing us a step further in the treatment of gallstones, especially in the high-risk patient.

This application of technology is to be commended. What they have done is to fragment stones with shock waves and provide a larger surface area for the bile salts to dissolve them over time, and this I believe is a very intriguing application.

One multihospital trial utilizing this technology is being conducted in this country for the FDA. I believe that this trial in the United States will show as it has in Germany, that stones will disappear as a function of time. We likely will have the same problem of recurrence.

I am a monitor of a multihospital trial for common duct stones, which are difficult to remove. Very early in the trial using the Dornier machine and technology, the stones yield to fragmentation by shock waves and then can be extracted by the endoscope.

The problem that I see is the type of application of this technology in our environment. Where should the treatments be done, and who should perform them? This will provide us with a challenge because this is something we want to bring to the high-risk and older patient.

I would like to ask Dr. Heberer to comment on how he sees this being resolved in Europe where they have more control over the flow of patients and the application of this type of approach. Secondly, who should be on the team? What is the surgeon's role? What is the entry point for the patients, because if you look at this carefully, you see that this is a highly selected population of patients in whom if you performed a cholecystectomy, the mortality rate would likely be zero. I am delighted to hear from Dr. Heberer that indeed surgery is here to stay, but we have to watch this new technology carefully because the surgeons could be put out of the loop quickly.

DR. ROBERT E. HERMANN (Cleveland, Ohio): I remember my first exposure to extracorporeal shock wave lithotripsy (ESWL) on a visit

to Munich about 6 or 8 years ago, and the concern I had when I realized that they were not only working on shock wave therapy for kidney stones, but also were beginning to investigate the destruction of gallstones as well. It disturbed me very much at that time.

It appeared to me that they were taking a simple surgical problem and creating a potentially more complicated one, but I believe we now know from their carefully documented studies and reports that ESWL not only works, but its morbidity is low and its mortality is less in selected patients than that of surgery.

I would like to ask Professor Heberer several questions to amplify his report. Do you still exclude patients with calcified stones? In our trial in the United States, I believe we will include patients with calcified stones.

Do you pay any attention to the anatomy of the distal bile duct and the ampullary regions so that you could do an endoscopic sphincterotomy if stone fragments were caught in the common bile duct? How often was endoscopic sphincterotomy necessary in your experience?

Could you expand on the cost of this procedure in Deutsche marks or in U.S. dollars, and what is the average hospitalization time of the patients who have had this procedure?

DR. JAMES C. THOMPSON (Galveston, Texas): President Bahnson: I have had the privilege of knowing Professor Heberer for more than a decade, and of visiting his clinic on several occasions.

First, the technique of lithotripsy does work, and we all need to know that. I am very impressed with the results shown here, and I would like to ask Professor Heberer just a few questions because this is a treatment in evolution. Will you tell us about the current management of discomfort during treatment? I know that once you take the patient out of the water bath you eliminate the need for anesthesia, but how discomforting are one of these sessions? We hear about the application of 2000 or 3000 shock waves. That must get a little tiring, and I wonder about the management of anesthesia.

We are told that there is a certain failure rate in patients with multiple stones, and therefore, you usually limit the procedure to patients