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ESWL Experience in the Therapy of Difficult Bile Duct Stones

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In recent years, alternatives to surgery for difficult bile duct stones have been developed. Routine endoscopy fails in about 10% of patients. To verify the role of extracorporeal shock wave lithotripsy in residual CBD stones, we treated 32 patients by HM4 or MPL 9000 Dornier lithotripters. Ten (34.4%) patients needed two extracorporeal shock wave lithotripsy sessions, and 3 (10.3%) patients three. Complete clearance was achieved in 29 patients (90.6%) after one or more sessions either by endoscopic (20 pts) or percutaneous (9 pts) extraction of the debris; of the remaining 3 patients, in 2 a bilioduodenal stent was placed and in 1 electrohydraulic lithotripsy was performed. Eighteen and seven-tenths percent transient mild hemobilia, 12.5% microhematuria, and no mortality were observed. It is possible to state that in site- or size-related difficult biliary stones, extracorporeal shock wave lithotripsy is a rapid, safe, and highly effective treatment as an additional nonoperative option to resolve the failure of routine endoscopic measures.

KEY WORDS: cholelithiasis; bile duct stones; ESWL; sphincterotomy; digestive system.

In recent years, a number of alternatives to surgery for gallstones have been developed. In the case of choledocholithiasis, surgical exploration is an accepted treatment albeit burdered with considerable mortality rate, which may be as high as 8% in the elderly or in high-risk patients (1, 2). Among these patients and, especially, in patients already cholecystectomized, the treatment of choice is endoscopic sphincterotomy (ES) and extraction. Although interventional endoscopic techniques have revolutionized the management of bile duct stones, routine measures fail in about 10% of patients (3). Advanced endoscopic procedures have been developed such as mechanical, laser, and electrohydraulic lithotripsy or dissolution by solvents (4, 5). Since these applications, to be successful, require a skilled endoscopist and a close and effective physical contact with the stone, they are technically difficult and sometime ineffective. Shock waves can be used to disintegrate stones (6) and can be generated with by methods: electrohydraulic, piezoelectric, and electromagnetic. Since 1986 ESWL has been applied to treat gallbladder stones (7, 8) and the first report of common bile duct stones lithotripsy appeared in 1989 (9). We report our 5-year experience with this treatment to assess the indications and results.

METHODS

Patients. Between 1990 and October 1995, 444 patients with bile duct lithiasis, all cholecystectomized except for 5 patients not operated due to poor general status or alithiasic gallbladder, were referred to our center: of these, 412 (92.7%) were successfully treated by an endoscopic (325 patients) or percutaneous (87 patients) approach. The remaining 32 patients (20 females, 12 males; mean age, 67 ± 20 years; range, 34–89) were managed with the ESWL procedure. According to Sauerbruch *et al.* (9), we have

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TABLE 1. ESWL THERAPY

Position	Prone 20 (62.5%) Supine 12 (37.5%)
Shock waves	1513 ± 521 (260–2226)
Duration (min)	68.8 ± 25.4 (28–104)
Voltage (kV)	22 ± 2.5 (18–25)
Total No. of sessions	48

included in this study patients with bile duct stones in the absence of coagulation disorders and no lung tissue, cysts, gas-filled bowel, vascular aneurysms, or calcified vessels during shock-wave path or in the focal zone. Previously all patients underwent sphincterotomy of the papilla of Vater: endoscopic in 28 cases (87.5%) and surgical transduodenal sphincterotomy in 4 (12.5%). Thirteen patients (41%) had a single stone, and 19 (59%) multiple stones; the size ranged between 10 and 25 mm (mean, 18 mm). Hepatic stones were multiple in all cases and ranged from 10 to 12 and from 10 to 14 mm, respectively, for right hepatic duct and left hepatic duct. In all these cases bile ducts were dilated. In one case of left hepatic duct stones there was a stricture.

As for the general clinical condition, 14 patients were ASA 1, 10 ASA 2, 4 ASA 3, and 4 ASA 4 (10). All patients received an antibiotic prophylaxis with intravenous cephalosporine. ESWL was performed without general anesthesia; four patients (12.5%) required intravenous opiate analgesia (fentanyl, 0.8–1.5 μg/kg). Of these, two patients had hepatic stones (one left hepatic duct and one right hepatic duct). In the remaining cases a preemptive analgesia with ketorolac (0.5 mg/Kg) was administered.

ESWL Treatment. All patients were treated by ESWL using Dornier lithotripters: HM4 with fluoroscopic control was employed in 20 patients (62.5%) and MPL 9000 with an ultrasonographic guide in 12 (37.5%). Shock waves (SW) were generated by an underwater spark discharge and focused by an ellipsoidal metal reflector. In the HM4 the focal zone is 104 mm long and 18 mm wide and in the MPL 9000 the focal zone is 50 × 10 mm. HM4 Dornier lithotripter was used only in case of failure of US-guided system in detection of stones.

Twenty patients (62.5%) were treated in the prone position and 12 (37.5%) in the supine position.

On average, 1513 ± 521 SW (range, 260–2226) during a period of 68.8 ± 25.4 min (range, 28–104 min) were delivered, utilizing 22 ± 2.5 kV (range, 18–25 kV), triggered by an electrocardiogram. No more than 2500 discharges per session were delivered to patients with extrahepatic stones. Fifteen hundred SW were delivered to patients with intrahepatic stones to prevent any hepatic trauma due to shock waves (Table 1). The ESWL session was repeated in the case of failure or partial fragmentation (fragment size, ≥10 mm). The stones and the biliary system were visualized by a 3.0-MHz in-line transducer in all patients treated with MPL 9000 (Figure 1) and in patients treated with HM4 by contrast injected into the bile ducts using an endoscopically placed nasobiliary tube (10 pts), a postsurgical drain (4 pts: 2 T-tube, 1 transcystic, and 1 cholecystostomy), or a percutaneously transhepatic catheter (6 pts) (Table 2).

In all patients during lithotripsy we performed a bile aspiration (through a nasobiliary tube in patients treated with MPL 9000) to verify a possible hemobilia.

All patients underwent ERCP after ESWL, to extract fragmented stones and to control the bile duct clearance. In patients with an external biliary drainage catheter a cholangiographic control was performed before discharge: the drainage was disconnected but left *in situ* closed. Four weeks later a subsequent cholangiographic control was performed and the drainage was removed.

As for the personnel, ESWL treatment required a physician, an anesthesist, and a nurse: extraction of the stones required a radiologist or an endoscopist.

Patients were followed up with clinical examination, laboratory tests, and abdominal ultrasonography at 3, 6, and 12 months and then every 12 months.

All data concerning treatment and patients have been recorded in a database program.

RESULTS

Thirty-two patients underwent ESWL. Symptoms and signs on admission were jaundice (12 pts), recurrent cholangitis (9 pts), and biliary pain (19 pts). Twenty-four patients (75%) had elevated serum bilirubin (≥3-fold) and abdominal ultrasonography re-

TABLE 2. PROCEDURE AND RESULTS*

Site	*No. pts.*	*ES/TS*	*MPL/HM4 lithotripter*	*Session No.*			*Stone clearance*
				I	*II*	*III*	
CBD	22†	20/2	10/12	17	2	3	19 (86.4%)
CHD	3‡	3/0	1/2	2	1	—	3
HB	2‡	2/0	0/2	—	2	—	2
RHD	3	2/1	1/2	—	3	—	3
LHD	2	1/1	0/2	—	2	—	2
Total	32	28/4	12/20	19	10	3	29 (90.6%)

* ES, endoscopic sphincterotomy; TS, tranduodenal sphincterotomy; CBD, common bile duct; CHD, common hepatic duct; HB, hepatic bifurcation; RHD, right hepatic duct; LHD, left hepatic duct.

† One patient with alithiasic gallbladder *in situ*.

‡ Massive bile duct lithiasis.

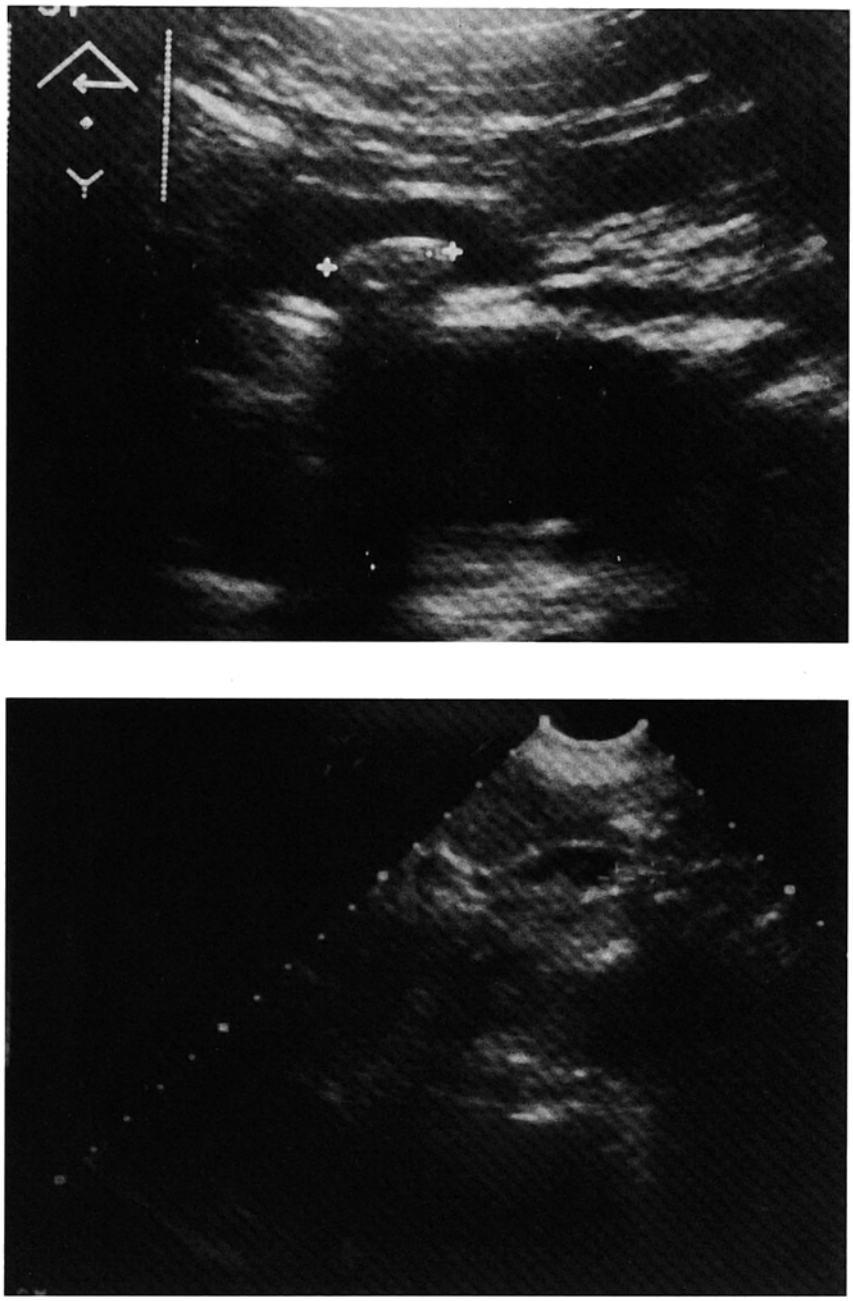

Fig 1. Top: Ultrasonographic scan of the stone (2.2 cm) located in the middle portion of the common bile duct. Pre-ESWL using the Dornier MPL 9000. Bottom: Ultrasonographic image after lithotripsy shows the remaining fragments in the common bile duct.

vealed a dilated bile duct (≥6 mm). In all patients endoscopic (Olympus JF1T 10 with Dormia basket 4–5 Fr or balloon catheter) or radiologic routine procedures (Cholangioscope Olympus URFP2 with an operative channel of 3 mm) had previously failed; in eight patients mechanical (5 pts) or alexandrite-laser (3 pts) lithotripsy had also failed. Causes of failure of mechanical lithotripsy (mechanical lithotripter of Soehendra, Wilson-Cook Inc.) were stones in the S-shaped biliary tree in four patients and entrapped giant stones in one patient. All three cases of failure of alexandrite-laser (performed in two cases under cholangioscopic guidance and in one case by ERCP introducing the laser probe in a balloon catheter inflated under the stone), lithotripsy were due to lack of fragmentation of the stones.

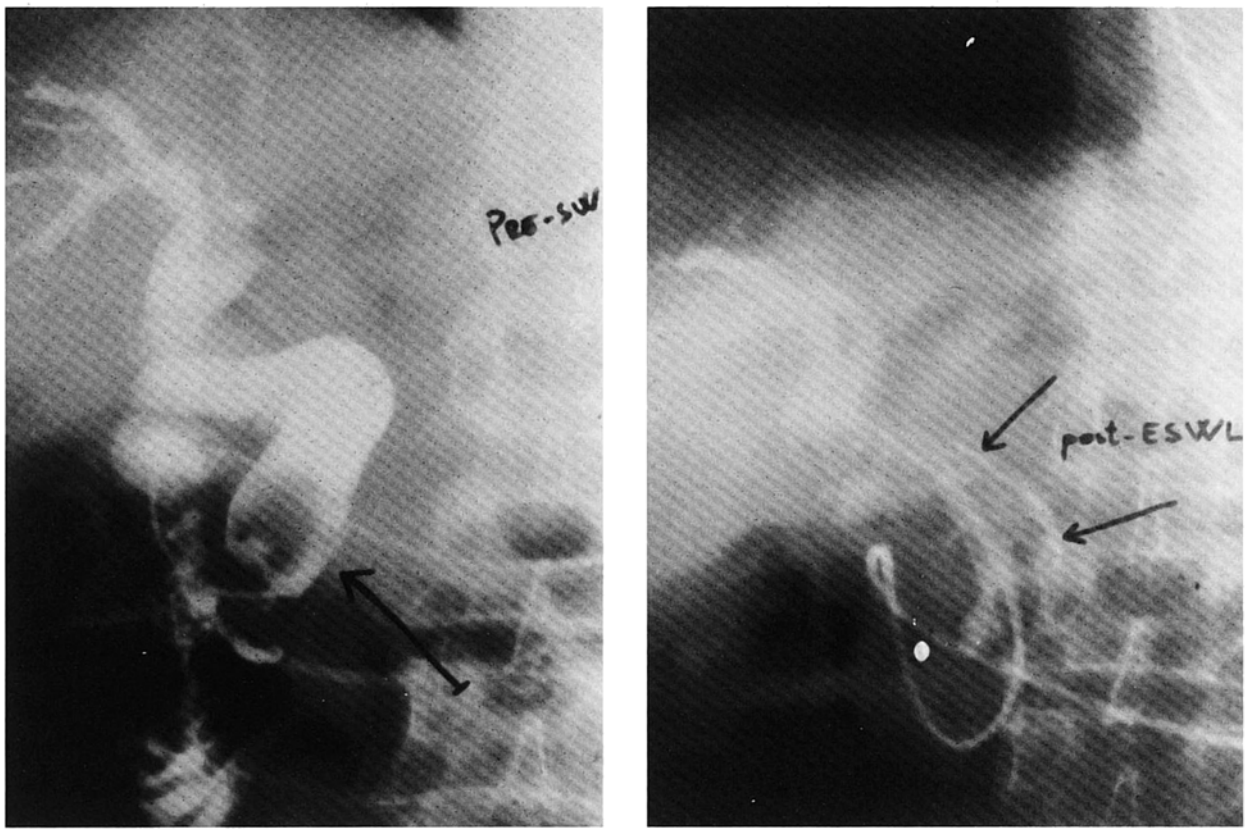

Fig 2. Left: Cholangiography through a nasobiliary tube. A large impacted stone is located in the prepapillary segment of the common bile duct. Right: Cholangiographic control after ESWL with the Dornier HM4.

The stones were localized in the CBD in 22 patients (68.7%) (Figure 2), in the right hepatic duct in 3 (9.4%), in the left hepatic duct in 2 (6.2%), at the hepatic bifurcation in 2 (6.2%), and at the common hepatic duct in 3 (9.4%). Two patients had a massive bile duct lithiasis. In a single patient the alithiasic gallbladder had not been removed (Table 2).

ESWL was repeated twice in 10 patients (31.2%) and three times in 3 patients (9.4%). Complete bile duct stone clearance with improvement of symptoms was achieved in 29 patients (90.6%) after one or more sessions either by endoscopic (20 pts) or percutaneous (9 pts) extraction of fragments (Table 2). Hepatic stones were extracted by an endoscopic approach in one case (right hepatic duct) and by percutaneous procedures in four (two right and two left hepatic duct) (Figures 3 and 4). Mean stone size after successful ESWL was less than 5 mm in 18 patients (62%) and 5–7 mm in 11 patients (38%). No reduction in stone size was observed in three patients (9.4%); in two of these an endoscopic bilioduodenal stent was placed and electrohydraulic intracorporeal lithotripsy was performed in the third. Hospital stay was 5 ± 2.5 days (range, 4–11 days), related to the number of ESWL sessions. No differences were observed in the results of fluoroscopic vs US-guided ESWL. The location and number of stones did not influence the success rate of the procedure.

In patients who received only one ESWL session the mean number of stones was 1.7, vs 3.5 in patients who required two or three sessions. The mean diameter of the largest stone was 16.4 mm in patients who needed one session and 17.5 mm in patients who had several sessions. All patients with stones located in the right or left hepatic duct required more than one session to achieve complete clearance.

Analyzing the costs of the procedure, we observed that the first ESWL session cost $1300–1500 per patient, while the following sessions cost about $700–900 per patient. The total costs of ESWL-associated endoscopic or radiological procedures were, respectively, $700 and $800 per patient.

As for side effects and complications we have observed 18.7% (6 pts) mild and transient hemobilia without a drop in Hb during treatment, detected by bile aspiration performed in 22 patients through a

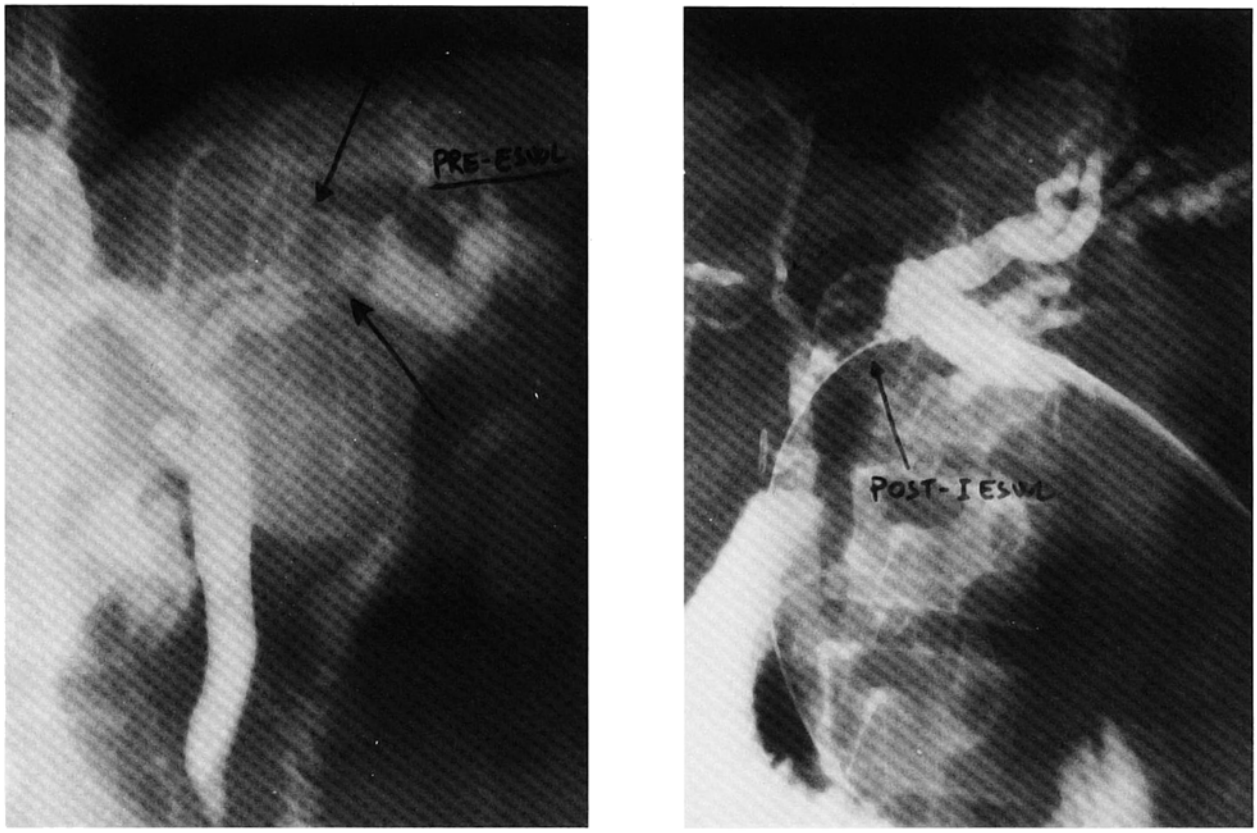

Fig 3. Left: Percutaneous cholangiography shows a large stone and other multiple small stones in the left hepatic duct. A stricture of the left hepatic duct was demonstrated. Right: Stone fragmented after two lithotripsy sessions using the Dornier HM4 device.

nasobiliary tube and in 10 through an external biliary drainage. In these cases lithotripsy was interrupted and repeated after 2–3 days when macroscopic hemobilia was stopped. Four patients (12.5%) had microhematuria and two patients (6.2%) had cholangitis, 24 hr after ESWL, treated with an aminoglycoside and biliary irrigation. Transient cutaneous petechiae were observed in four patients (12.5%). No mortality was reported. No significant alterations of laboratory tests were observed after ESWL, except for a slight increase in amylase in three patients (9.4%) after endoscopic extraction.

Long-Term Results

Mean follow-up was 14.5 months (range, 5–34 months). Twenty-eight patients (96.5%) were symptom- and stone-free, with normal laboratory tests. In one patient (submitted to endoscopic sphincterotomy) presenting mild postprandial abdominal pain with a slight increase in alkaline phosphatase and ALT, ultrasonography and HIDA-scintigraphy were performed: US was negative, while HIDA-scintigraphy demonstrated a slow passage of the bile into the duodenum. ERCP with a new endoscopic sphincterotomy was performed for stenosis of the papilla, with relief of symptoms and laboratory tests.

DISCUSSION

Endoscopic sphincterotomy in the treatment of CBD stones has a 90% success rate, 10% morbidity, and 0.5–1% mortality (3). Failure of endoscopic therapy can be related to the stone or to the specific anatomical morphology of the biliary tree. The stone may be too hard or too large or positioned in an inaccessible endoscopic area. Sometimes the bile ducts can be a problem for the endoscopist because of strictures or tortuosity. In some cases, surgery such as Roux-en-Y anastomosis or Billroth II gastric resection does not allow the endoscopic procedure. In these cases many nonoperative procedures to manage bile duct stones have been developed in recent years, with various indications and results. Among these, laser and intracorporeal electrohydraulic lithotripsy (5, 11) require a close contact of the probe with the stone for effective fragmentation. Furthermore, there

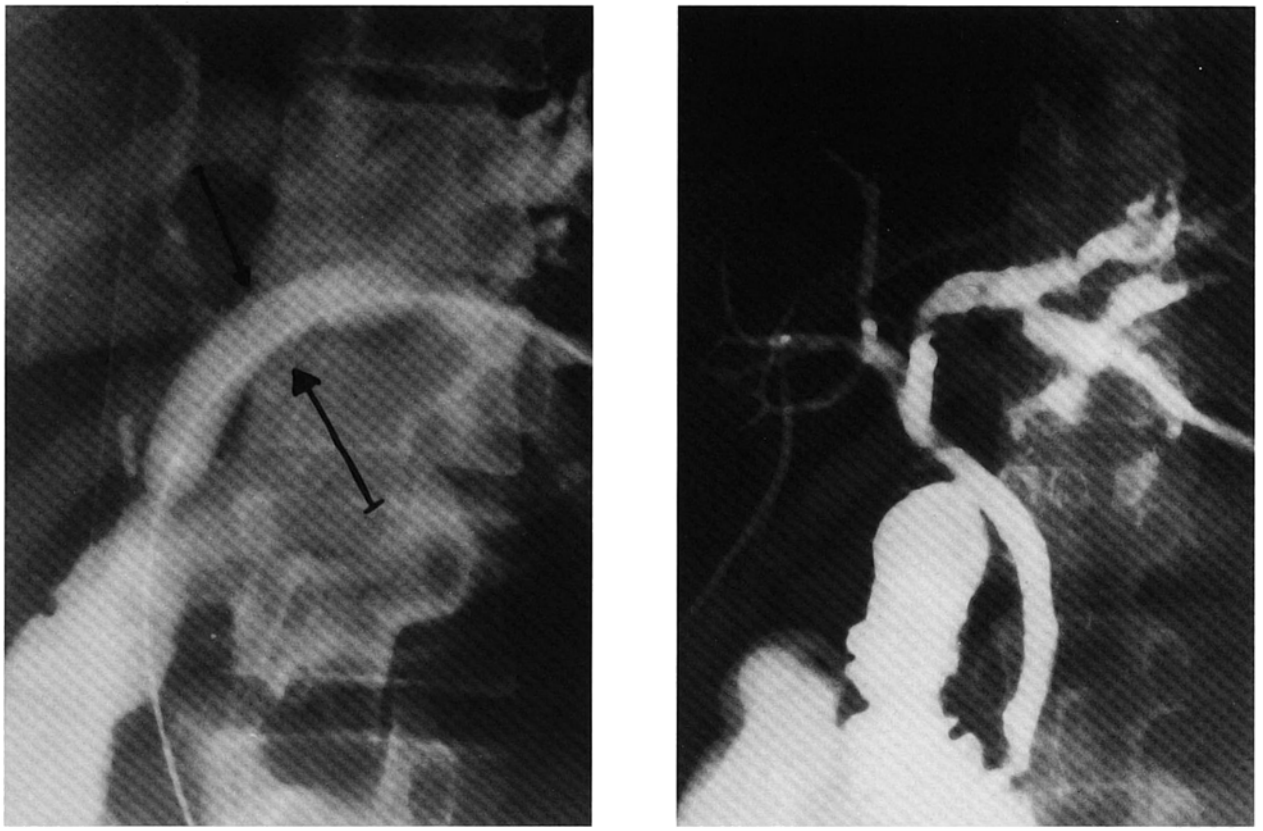

Fig 4. Left: In the same case as in Fig. 3, a balloon dilatation of the left hepatic duct was performed. Right: Cholangiographic control shows complete fragment clearance of the entire biliary tree.

is a risk of important complications related to the impact of the probe on the bile duct wall, which may result in perforation of the biliary tree and bleeding. Moreover, mechanical lithotripsy requires that the stone must be secured in the Dormia and it may fail if the stones are too large, impacted, or inaccessible as in the case of intrahepatic stones (11). Chemical dissolution treatments with monooctanoin or MTBE are not risk-free, require some weeks, and are ineffective in 50% of cases (4).

In these cases ESWL is an additional nonoperative treatment in biliary stone disease (12–14). ESWL is highly effective, with a 90.6% success rate in our report. Hepatic stones were multiple and usually smaller than common bile duct stones: results in these cases were particularly good (100% clearance rate) but they required, in all cases, two treatment sessions. Two of the four patients with hepatic stones requested intravenous opiate analgesia.

Our study was performed using two Dornier lithotripsy units: the HM4 (fluoroscopic-guided) Dornier lithotripter was used in the case of difficult detection and localization of the stones by the US-guided system MPL 9000 Dornier lithotripter. Results of the two systems did not show any significant difference.

Mean hospital stay is short, especially for patients requiring only one session of ESWL. In our series this has represented more than 55% of cases and contributed to limit the costs of the procedure, comparable to those of other approaches.

Moreover, in contrast to the more complex procedures previously described, ESWL does not require any direct contact with the stone, preventing the risk of injury of the biliary tree. The technique is quite easy, requiring routine endoscopic measures such as sphincterotomy and positioning of a nasobiliary tube and, in selected cases, radiologic positioning of a percutaneous transhepatic catheter.

In our experience morbidity was low: petechiae, hemobilia, and microhematuria had no clinical significance, although in the case of hemobilia lithotripsy was interrupted and repeated after several days when hemobilia was stopped, prolonging the hospital stay. The incidence of cholangitis, observed in two cases (6.2%) without biliary catheter drainage during treatment, was acceptable; the routine use of antibiotics,

in our opinion, may have contributed to the decreased septic complications.

While other studies report a significant number of cases with spontaneous passage of stones (15, 16), in our experience we have always adopted endoscopic or percutaneous extraction to ensure complete clearance and relief of symptoms before the discharge of patients.

In conclusion, ESWL is an effective technique in the treatment of biliary stones for patients in whom endoscopic removal has failed. In our opinion ESWL is a safe procedure with an acceptable complication rate. We believe it to be the procedure of choice after failure of routine endoscopic techniques for treatment of difficult biliary stones, a disease that requires a multidisciplinary approach involving surgeons, endoscopists, and radiologists.

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