Pulverisation of calcified and non-calcified gall bladder stones: extracorporeal shock wave lithotripsy used alone

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Abstract

Using a modified electromagnetic lithotripter (Siemens), extracorporeal shock wave lithotripsy (ESWL) was performed in 260 patients with gall bladder stones. Exclusion criteria for treatment were a non-functioning gall bladder, subcostal gall bladder location, and multiple stones occupying more than three quarters of the gall bladder volume. Stone pulverisation was the end point of ESWL. The number of shock wave discharges and sessions was not limited. Pulverisation was achieved in 250 patients (96.1%) after a median of three ESWL sessions (range 1-21). The number of sessions required depended upon stone composition and burden. More than three sessions were required in 60.2% of patients with calcified stones compared with 35.9% of patients with non-calcified stones ($p < 0.001$). 65.8% of patients with stones measuring more than 30 mm in total diameter required more than three sessions compared with 42.9% of patients with a stone burden less than 30 mm ($p < 0.01$). At 18-24 (8-12) months follow up, stone clearance was achieved in 94.3% (80.4%) of patients with non-calcified stones, compared with 89.5% (76.8%) in patients with calcified stones and in 75% (71.4%) of patients with a total stone diameter more than 30 mm compared with 95.7% (80.4%) for patients with a total stone diameter less than 30 mm ($p < 0.05$). ESWL related complications (gross haematuria) occurred in three patients. Thirty six (13.8%) patients experienced biliary colic; four had cholecystectomy, and five endoscopic papilotomy because of common bile duct obstruction. Stone recurrence was seen in 5.3% of patients over a follow up period of up to two years (median 16.6 months).

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lution treatment. As oral dissolution treatment was largely ineffective against non-cholesterol gall stones, ESWL was restricted to radiolucent stones. As a result, ESWL proved to be suitable for no more than 15-25% of patients with gall bladder stones.^{2,3} This was even further reduced to under 10% when computed tomography was used to select non-cholesterol stones.^{4,5}

Significant advances in ESWL technology since its introduction in 1985 made us question the validity of the treatment strategy. Both newer generation electromagnetic and piezoelectric machines have been shown to be significantly better tolerated.⁶⁻⁸ If current ESWL technology permits treatment without analgesia and severe side effects, an arbitrary limitation to the number of discharges applied and treatment sessions may not be necessary. This has not been investigated, however, in animal studies so far.

Experimental studies have shown that all gall stones can be fragmented by ESWL. The efficacy of fragmentation depended mainly upon the stone burden (size and number); larger and multiple stones required more shockwave discharges to achieve disintegration.⁹⁻¹² Thus, stones greater than 30 mm in diameter and multiple stones can be fragmented, provided an adequate number of discharges are applied. Further, clinical studies have shown that stone fragment size is the critical determinant of clearance rate.^{2,7,13} We hypothesised that if gall stones could be maximally disintegrated ('pulverised'), spontaneous clearance may be possible, obviating the need for adjuvant chemolysis. This would permit the inclusion of calcified stones, which would further increase the number of patients eligible for ESWL treatment.

Using a modified electromagnetic ESWL machine, we applied this strategy and report our results in the first 260 patients.

Methods

PATIENTS

Between January 1990 and December 1991, 558 patients with symptomatic gall stones were referred to our department of ESWL treatment. Of these, 88 (15.7%) were not eligible for ESWL treatment according to the exclusion criteria (Table I). To assess gall bladder function, gall bladder volume was measured by ultrasound before and after a fatty meal; a functional gall bladder was defined as a volume reduction of at least 30%.¹⁴ The exclusion of patients with stones occupying more than 75% of the gall bladder volume was based upon previous experience with combined ESWL and transpapillary contact

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The currently practised strategy for extracorporeal shock wave lithotripsy (ESWL) treatment of gall bladder stones evolved from the initial experience with the first generation lithotripter from Dornier.¹ Fragmentation of stones was established as the end point of ESWL to minimise the burden and risks of treatment. The procedure was cumbersome (performed in a water bath), and painful, requiring general anaesthesia or heavy sedation. ESWL was therefore limited to a maximum of two sessions or a maximum of 1600 discharges. Furthermore, stones numbering more than three or exceeding a total diameter of 30 mm were excluded. To achieve clearance of stone fragments, it was necessary to complement ESWL with oral disso-

TABLE I Number of patients excluded according to exclusion criteria

Exclusion criteria	No	%*
Stone(s) occupying more than 75% of gall bladder volume	58	10.4
Non-functional gall bladder	22	3.9
Subcostal location of gall bladder	8	1.4
Total	88	15.7

*Based on total number of referred patients (n=558).

chemolysis using methyl-*tert*-butyl-ether.¹⁵ Total stone diameter was measured by ultrasound in a fasting state. Preselection occurred due to preliminary screening by the referring physician; patients with a negative oral or intravenous cholecystogram, coagulation disorder, or pregnancy were not referred.

Of the 470 patients who were suitable for ESWL, 265 patients received ESWL treatment (the remaining patients are on the waiting list for treatment). Five patients stopped treatment before pulverisation could be achieved because of recurrent pain; all opted for laparoscopic cholecystectomy. These patients were excluded from the study, leaving 260 patients for study analysis. There were 163 women and 97 men with a median age of 54 years (range 18–87). All patients who were treated gave informed consent regarding the indication for and risks of treatment and were informed about alternative treatments including laparoscopic cholecystectomy.

STONE CHARACTERISTICS

Stones were characterised according to findings on ultrasonography, oral or intravenous cholecystography and computed tomography.

Calcification was additionally determined by computed tomography. Some 148 patients (56.9%) had non-calcified stones and 112 (43.1%) calcified stones. Of the group with non-calcified stones, 71 patients (27.3% of total number) had solitary stones. Solitary stones measured up to 20 mm in 49 patients, 21–30 mm in 19 patients, and greater than 30 mm in three patients. Twenty eight patients (10.8%) had 2–3 stones (10 with a total diameter of more than 30 mm), and 49 patients (18.8%) had more than three stones (16 with a total diameter of more than 30 mm).

Of the group with calcified stones, 52 patients (20%) of total number) had solitary stones. These measured up to 20 mm in 32 patients, 21–30 mm in 15 patients, and greater than 30 mm in five patients. Twenty one patients (8.1%) had two to three stones (4 with a total diameter of more than 30 mm) and 39 patients (15%) had more than three stones (seven with a total diameter of more than 30 mm). Stone diameter was determined by ultrasonography; for multiple stones the composite diameter was measured.

TREATMENT PROTOCOL

No adjuvant treatment was given. Patients were initially treated in hospital on a daily basis for a maximum duration of seven days and thereafter as outpatients on a weekly basis. Pulverisation was sonographically defined by the absence of any measurable stone fragment and any single echo shadow. After reaching pulverisation, follow up ultrasound examination was performed every one to three months using the Sonoline SL (Siemens AG, Erlangen, Germany) with an ultrasound scanner frequency of 3.5 or 5 MHz. ESWL was repeated if stone fragments were detected. ‘Stone free’ was defined as the absence of stone fragments or sludge. This was verified at a different date by an independent physician experienced in sonography. After that ultrasound examination was performed at intervals of three to six months. Examinations were carried out in the upright, supine, and left lateral decubitus positions.

Laboratory tests including white blood cell count, haemoglobin, creatinine, bilirubin, liver enzymes (alkaline phosphatase, γ -glutamyl-transferase, transaminases), and pancreatic enzymes (amylase and lipase) were obtained in patients who developed abdominal pain during the study. Patients suspected of having common bile duct obstruction or biliary pancreatitis had endoscopic retrograde cholangiopancreatography and, when indicated, papillotomy with stone extraction was performed.

EXTRACORPOREAL SHOCK WAVE LITHOTRIPSY

ESWL was performed with a prototype ‘Lithostar’ lithotripter (Siemens AG, Erlangen, Germany). The prototype device differed from the commercially available model in the control panel and table construction; this permitted easier targeting of stones. Shock waves were produced by electromagnetic generator and focused with an acoustical lens. Gall bladder stones were located by a 3.5 MHz in line ultrasound probe built into the shock wave overhead module, which permitted continuous real time monitoring of the procedure. Both the table and shock wave overhead module could be electronically steered in all directions to permit optimal targeting of the gall stone. The shock wave energy could be varied in stages from 1 to 9, which correlated with a pressure in the focal point of 23 to 70 MPa.¹⁶ The number of discharges applied/session was determined by patient tolerance and contractile state of the gall bladder. On average 4000 discharges/session were applied at a frequency of 2/second; dis-

Figure 1: Distribution of number of sessions to achieve pulverisation.

TABLE II Stone free rates of uncalcified stones according to size and number of stones

	0-2 months* n/n (t) (%)	2-4 months n/n (t) (%)	4-8 months n/n (t) (%)	8-12 months n/n (t) (%)	12-18 months n/n (t) (%)	18-24 months n/n (t) (%)
Solitary 1-20 mm	27/49 (55.1)	35/44 (79.5)	32/37 (86.5)	28/31 (90.3)	21/21 (100)	13/13 (100)
Solitary 21-30 mm	10/19 (52.6)	12/18 (66.7)	14/16 (87.5)	14/15 (93.3)	11/11 (100)	7/7 (100)
Multiple 2-3, <30 mm	8/18 (44.4)	9/16 (56.3)	8/15 (53.3)	8/11 (72.7)	9/10 (90)	2/2 (100)
Subtotal	45/86 (52.3)	56/78 (71.8)	54/68 (79.4)	50/57 (87.7)	41/42 (97.6)	22/22 (100)
Multiple 2-3, >30 mm	1/10 (10)	3/10 (30.0)	2/6 (33.3)	3/6 (50)	3/6 (50)	2/4 (50)
Solitary >30 mm	1/3 (33.3)	1/3 (33.3)	1/3 (33.3)	0/2 (0)	0/2 (0)	0/0
Multiple more than 3	18/49 (36.7)	22/48 (45.8)	31/45 (68.9)	25/32 (78.1)	19/22 (86.4)	9/9 (100)
Total	65/148 (43.9)	82/139 (59.0)	88/122 (72.1)	78/97 (80.4)	63/72 (87.5)	33/35 (94.3)

n=number of patients stone-free; n (t)=total number of patients during the respective follow up period; *0-2 months indicates an interval up to two months.

TABLE III Stone free rates of calcified stones according to size and number of stones

	0-2 months* n/n (t) (%)	2-4 months n/n (t) (%)	4-8 months n/n (t) (%)	8-12 months n/n (t) (%)	12-18 months n/n (t) (%)	18-24 months n/n (t) (%)
Solitary 1-20 mm	16/32 (50)	16/30 (53.3)	21/29 (72.4)	18/21 (85.7)	12/15 (80)	6/7 (85.7)
Solitary 21-30 mm	7/15 (46.7)	11/14 (78.6)	11/12 (91.7)	9/9 (100)	7/7 (100)	2/2 (100)
Solitary >30 mm	0/5 (0)	2/5 (40)	2/4 (50)	1/2 (50)	0/1 (0)	0/0
Multiple 2-3	7/21 (33.3)	9/16 (56.3)	9/14 (64.3)	7/10 (70)	7/9 (77.8)	3/3 (100)
Multiple more than 3	17/39 (43.6)	18/37 (48.6)	23/35 (65.7)	18/27 (66.7)	15/20 (75.0)	6/7 (85.7)
Total	47/112 (42)	56/102 (54.9)	66/94 (70.2)	53/69 (76.8)	41/52 (78.8)	17/19 (89.5)

*0-2 months indicates an interval up to two months; abbreviations as in Table II.

charges were not triggered by heart frequency. There was no upper limit to the total number of discharges. The energy level of discharges was progressively increased during each session to the maximum level tolerated by the patient. The average power setting was level 7; 75% of patients tolerated the maximum level of energy (level 9) without pain. Patients were treated in the supine or left lateral decubitus position. All patients tolerated ESWL treatment well and none of the patients required analgesics.

STATISTICAL ANALYSIS

The statistical significance of differences was assessed with the χ^2 test. p Values less than 0.05 were regarded as significant. The number of ESWL sessions and shock waves was expressed as median values with ranges.

Results

Gall stones could be pulverised in 250 of 260 patients (96.1%) after a median of three ESWL sessions (range 1-21). In the remaining 10 patients only fragmentation of stones could be achieved (seven patients had stones measuring more than 30 mm in total diameter, of which two were calcified); a median number of 10 ESWL sessions (range 3-24) were performed. Treatment was stopped because of poor response to shock wave treatment. For the entire patient collective, a median number of 4000 (range 1000-16 000) discharges were applied/session. The median number of shockwaves applied/patient was 14 000 (range 4000-26 000). The time required for a single treatment session of 4000 discharges was 60 minutes. All patients who had biliary symptoms during the treatment period reported resolution or a considerable reduction of symptoms that temporally correlated with pulverisation of stones. Figure 1 shows the distribution of number of sessions required to achieve pulverisation in 250 patients with calcified and non-calcified stones. Calcified stones

required significantly more sessions to achieve pulverisation compared with non-calcified stones. More than three treatment sessions were required in 65 of 108 patients (60.2%) and 51 of 142 patients (35.9%) of patients with calcified and non-calcified stones, respectively ($p<0.001$).

Twelve of 24 patients (50%) with non-calcified stones measuring greater than 30 mm in total diameter required more than three treatment sessions to achieve pulverisation compared with 39 of 118 patients (33.1%) with a total stone diameter less than 30 mm (not significant, $p>0.05$). Thirteen of 14 patients (92.9%) with calcified stones measuring greater than 30 mm in total diameter required more than three treatment sessions compared with 52 of 94 patients (55.3%) with a total stone diameter less than 30 mm ($p<0.01$). In total 65.8% (25/38) of patients with a total stone diameter of more than 30 mm required more than three sessions compared with 42.9% (91/212) of patients with a total stone diameter of less than 30 mm ($p<0.01$). Table II shows clearance rates according to stone characteristics and period of follow up after the first ESWL session. The observation intervals and stone characteristics were adapted from the Munich study² for the purpose of comparison.

Figure 2: Stone free rates of patients with uncalcified and calcified stones.

TABLE IV Stone free rates of gall stones with a total diameter greater than 30 mm

	0-2 months* n/n (t) (%)	2-4 months n/n (t) (%)	4-8 months n/n (t) (%)	8-12 months n/n (t) (%)	12-18 months n/n (t) (%)	18-24 months n/n (t) (%)
>30 mm, uncalcified	6/29 (20.7)	12/29 (41.4)	15/24 (62.5)	13/19 (68.4)	10/15 (66.7)	4/6 (66.7)
>30 mm, calcified	3/16 (18.8)	5/12 (41.7)	7/11 (63.6)	7/9 (77.8)	6/7 (85.7)	2/2 (100)
Total	9/45 (20)	17/41 (41.5)	22/35 (62.9)	20/28 (71.4)	16/22 (72.7)	6/8 (75)

*0-2 months indicates an interval up to two months; abbreviations as in Table II.

TABLE V Stone free rates of gall stones with a total diameter less than 30 mm

	0-2 months* n/n (t) (%)	2-4 months n/n (t) (%)	4-8 months n/n (t) (%)	8-12 months n/n (t) (%)	12-18 months n/n (t) (%)	18-24 months n/n (t) (%)
<30 mm, uncalcified	59/119 (49.6)	70/110 (63.6)	73/98 (74.5)	65/78 (83.3)	53/57 (93)	29/29 (100)
<30 mm, calcified	44/96 (45.8)	51/90 (56.7)	59/83 (71.1)	46/60 (76.7)	35/45 (77.8)	15/17 (88.2)
Total	103/215 (47.9)	121/200 (60.5)	132/181 (72.9)	111/138 (80.4)	88/102 (86.3)	44/46 (95.7)

*0-2 months indicates an interval up to two months; abbreviations as in Table II.

Tables II, III, IV, and V give the results for calcified stones, stones larger than 30 mm in total diameter, and multiple stones (more than three), which were not included in the Munich study. The data include patients in whom pulverisation was not achieved. Figure 2 shows Kaplan/Meier graph representation of stone free rates of patients with uncalcified and calcified stones. The numbers of stone free patients at 6, 12, 18, and 24 months were 157, 181, 186, and 188, respectively. The numbers of stone free patients seen for <6, 6-12, 12-18, and 18-24 months were 88, 64, 75, and 23, respectively (median 9.4 months).

ADVERSE EVENTS

During a follow up period of up to two years (mean 11.8 months, median 11.8 months, range 0.4-24.0) 36 patients (13.8%) experienced biliary colic. Four patients had cholecystectomy, two because of recurrent colic and two because of acute cholecystitis. Of the remaining 32 patients 12 had laboratory evidence of cholestasis, of whom two also had an increase in pancreatic enzymes. If five of these patients an endoscopic retrograde cholangiopancreatography and papillotomy was performed, whereby stone debris was extracted in three cases. Seven patients could be managed conservatively with full resolution of cholestatis within a few days. Gross haematuria was seen in three patients during our initial experience with ESWL and was not seen later. Based on clinical parameters, there was no other evidence of tissue damage. Of the 39 patients who had complications, 30 could be successfully treated conservatively. Cystic duct obstruction was not seen.

RECURRENCE

We defined a recurrence as detection of stones in a previous stone free patient on follow up ultrasound examination. Of 188 patients who became stone free, 10 (5.3%) were found to have gravel like stones on follow up ultrasound examination. No correlation with previous stone characteristics was seen. The median observation period was 16.6 months (range 11.8-24). Of these, the gall bladder could be cleared of stones in two patients after one and six further ESWL sessions, respectively.

Discussion

In our study we could achieve pulverisation of gall stones in 96.1% of patients regardless of size, number or composition of gall stones using a modified electromagnetic lithotripter. Sedation or analgesic treatment was not required in any of the patients.

After pulverisation, spontaneous clearance of stone debris occurred without adjuvant oral bile acid treatment. This confirms previous studies, which have shown that the clearance rates are proportionate to the size of fragments. Sackmann *et al*^{2,17} showed that for fragments less than 3 mm in size the clearance rate at one year was 70%, whereas for fragments larger than 5 mm the clearance rate was only 30% for the same time period. Ponchon *et al*¹³ found that patients with complete fragmentation had significantly higher clearance rates compared with patients with partial fragmentation (55 v 0% after six months; 80 v 29% after nine months; 90 v 33% after 12 months). Other authors have also suggested that smaller fragments clear more rapidly.^{7,18}

In our study, the rapidity with which pulverisation of gall stones was achieved depended upon the stone composition and burden. Calcified stones required significantly more sessions to achieve pulverisation compared with non-calcified stones. The composition of the stone, however, did not significantly affect clearance rates. Apparently, once pulverisation is achieved, there is no difference in the clearance rates between non-calcified and calcified stones. In contrast, other authors have found clearance rates to differ when fragmentation was the end point of ESWL treatment. Rawat and Burhenne¹⁹ have shown that calcified stones cleared more slowly from the gall bladder than non-calcified stones using an electromagnetic device. Ell *et al*,⁵ found that the rate of complete stone disappearance was higher for non-calcified stones than for calcified stones using a second generation piezoelectric lithotripter.

Several studies included partially calcified stones in the treatment protocol. Sackmann *et al*²⁰ recently reported the results of ESWL for gall bladder calculi with a radio-opaque rim comparing three different lithotripsy treatment modalities. Higher clearance rates were found for stones less than or equal to 3 mm in diameter compared with larger fragments. Other studies did not separately analyse clearance rates for

calcified stones.^{2,8,19} Albert *et al*²¹ reported clearance of a densely calcified stone within one week of a single session of ESWL. The stone was fragmented to particles of less than 1–2 mm, which presumably accounts for this rapid clearance.

In our study calcification was primarily detected on plain radiographs; only 15% of patients with calcified stones were diagnosed by computed tomography. A comparison of our data with those of other studies that have evaluated the efficacy of ESWL for stones of variable calcium content^{5,20} is difficult because the end point of ESWL treatment in these studies was fragmentation.

Patients with stones measuring more than 30 mm required significantly more sessions to pulverise stones compared with patients with stones less than 30 mm. It is also noteworthy that patients with stones larger than 30 mm in total diameter showed lower clearance rates compared with those with stones less than 30 mm (75 v 95.7% at 18–24 months; $p < 0.05$). Using a piezoelectric lithotripter, Darzi *et al*⁶ extended their selection criteria in a study of 124 patients to include larger and calcified stones and reported successful fragmentation in only four of eight patients with stones larger than 30 mm. None of the patients achieved complete gall bladder clearance. In this study 6000 shock waves were applied/session up to a maximum of six sessions, but the end point of ESWL was fragmentation less than 4 mm, compared with pulverisation in our study. Using an electromagnetic lithotripter (Siemens Lithostar Plus), Meiser *et al*²² extended their selection criteria to include patients with stones up to 38 mm in size and more than three stones. Seven of 27 patients with three or more stones became stone free over a follow up period of at least 12 months. Although other authors have included some patients with a total stone size greater than 30 mm, this variable has not been separately analysed.^{6,23}

The role of the bile acid ursodiol as adjuvant treatment after ESWL is still a subject of debate. Bile acids in conjunction with ESWL seem to be clearly superior to bile acid treatment alone.^{24,25} The American national biliary lithotripsy study, which included 600 patients with 1–3 radiolucent or slightly calcified (less than 3 mm nidus or rim calcification) gall stones 5–30 mm in diameter, showed that ESWL with ursodiol was more effective than ESWL alone.²⁶ In an initial study of similar design by Torres *et al*²⁷ no significant difference between the ursodiol and placebo groups was found; however, in a follow up study²⁸ the stone free rate at 12 months was noted to be significantly higher for patients with a single, non-calcified stone up to 20 mm in diameter in patients treated with adjuvant bile acids. Unsatisfactory results with bile acid treatment may be because most gall stones are not pure cholesterol stones. In a study that analysed the faeces of patients during the first three days after ESWL treatment for radiolucent stones, Greiner *et al*²⁹ found most stone fragments were from mixed stones. Stone fragments measured 0.5–8 mm in diameter. This study suggests that the clearance of gall stones after ESWL mainly depends upon a functioning gall bladder and sufficiently fine fragmentation.

The Vancouver group was the first to use ESWL as the sole treatment. With a higher number of shock wave discharges (up to 20 000), they could disintegrate stones to fragments measuring less than 3 mm.³⁰ The overall stone free rate at 12 months was 61%. The data included patients with calcified and multiple (more than three) stones. The authors concluded that, with an expanded protocol that includes patients with up to six stones and calcified stones, the results of monotherapy were comparable with that of combined ESWL and oral bile acid treatment reported in other centres. The clearance rate, however, for calcified stones in this study was poor (clearance in only two of 17 patients).

We could achieve clearance rates similar to the Munich group without adjuvant bile acid treatment both for non-calcified and calcified stones. For patients with non-calcified stones equal to or less than three in number and 30 mm in total mass, the Munich group reported stone free rates of 30% at 0–2 months, 48% at 2–4 months, 63% at 4–8 months, 78% at 8–12 months, 91% at 12–18 months, and 93% at 18–24 months.² Our results with ESWL as the sole treatment showed significantly more rapid clearance during the first four months and comparable clearance rates thereafter. This can be explained by the fact that pulverisation of stones was the end point of our treatment with ESWL compared with fragmentation by the Munich group. The lower initial stone clearance rate in the Munich study is presumably because of the delayed effect of bile acids on stone dissolution.

We believe that the most critical factor determining ESWL success is the precise targeting of stones or stone fragments. This has been previously shown in experimental studies by Zeman *et al*.³¹ Both the expertise of the physician performing ESWL and the lithotripter technology available contribute to precise targeting. The Lithostar lithotripter used in this study permitted fine adjustments in both patient and overhead module position to optimise targeting. We believe that this explains why sedation or analgesia was not required in our patients and complications directly attributable to shockwave therapy were so low (gross haematuria occurred in three cases during the initial phase of the study) despite high numbers of discharges up to 16 000 discharges/session using an electromagnetic lithotripter.

Acute cholecystitis, bile duct obstruction, and pancreatitis occurred with similar frequency to that reported in other studies.^{2,7,8,17,23} In our study, however, the incidence of biliary colic after ESWL was lower (14% v an average of 30% in other studies). This may be explained by the fact that the end point of ESWL in our study was pulverisation compared with fragmentation in other studies.

ESWL is still burdened by the problem of stone recurrence after clearance. Recurrence has been reported in 11% at 1.5 years without further increase up to three years.³² Our recurrence rate was 5.3% in a follow up period of up to two years (median 16.6 months). No correlation with previous stone characteristics was seen.

In conclusion, this study has shown that, when

the number of shockwave discharges and sessions are not restricted, ESWL can effectively pulverise gall stones in nearly all patients selected for treatment. A high rate of clearance was achieved without adjuvant bile acid treatment.

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