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原　　著

Clinical Study of Extracorporeal Shock Wave Lithotripsy (ESWL) for Biliary Stones

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Introduction

Lithotripsy by extracorporeal shock wave, abbreviated as ESWL, was initiated by CHAUSSY[1] in 1980 to disintegrate renal calculus and it has now become well established in the urological area. Recently in Western countries, ESWL has expanded its clinical applications to the treatment of cholelithiasis, and is recognized as one of the most important therapies for gallstones. It will soon be the same in this country, because the health insurance for ESWL treatment of gallstones became effective in April, 1992.

Reports on the disintegration of gallbladder stones by ESWL are increasing and its effectiveness has been recently recognized[2-5]. ESWL has also been applied to common bile duct stones (CBDS) [6-12]. However, the performance of ESWL varies among institutions and depends upon ESWL apparatus. We performed ESWL on a total of 127 consecutive biliary tract stone cases for a period of 31 months between June 1988, and December 1990. This clinical study discusses safety and effectiveness of ESWL for cholelithiasis and furthermore establishes criteria of ESWL usage for gallbladder stones and CBDS.

Objects and Methods

The 127 cases of cholelithiasis consisted of 117 cases of gallbladder stones, 23 cases of CBDS, and 13 cases of both. The 117 cases of gallbladder stones consisted of 55 males and 62 females with an age distribution of 28 to 86 years-old (average; 55.0 years-old). Ultrasonography showed a thickening of the gallbladder wall, complicating cholecystitis in 7 cases (6.0%). 60 cases (51%) had a single stone and 57 cases (49%) had multiple stones (Table. 1). The diameter of the largest stone varied from 5 mm to 40 mm with an average of 16.7±7.6 mm (Table. 2).

In 9 out of 23 CBDS cases, CBDS had been incarcerated and jaundiced (average serum bilirubin value; 8.27 mg/dl (5.7~11.3 mg/dl)). 2 cases were complicated by obstructive

Key words: Cholelithiasis, Cholecystlithiasis, Choledocholithiasis, Extracorporeal shock wave lithotripsy (ESWL), indication
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Table. 1 Characteristics of Cholecystlithiasis
Cases of Cholecystlithiasis: total of 117

1) Age and Sex	Year-Old (y.o.)
Male	55
Female	62
Age	28～86
mean	55.0
2) Cases with symptoms	71 (61%)
3) Cases with CBDS	13 (11%)
4) Number of gallstones	cases
Single stone	60 (50%)
Multiple stone	57 (49%)
2	25
3	8
4	2
5～9	9
10～	13
5) Technique employed to visualize gallstone	
	cases
DIC	87
fluoroscopy only	15
PTCD	11
ERCP (including ENBD)	2
PTGBD	1
oral cholecystgram	1

Table. 2 Diameter of Gallstone

Diameter	cases
≦10 mm	25
10 mm<, ≦20 mm	49
20 mm<, ≦30 mm	33
30 mm<	10
Total	117

Table. 3 Characteristics of Choledocholithiasis (cases)
Cases of Choledocholithiasis: total of 23 cases

1) Age and Sex	Year-Old (y.o.)
Male	12
Female	11
Age	39～86
average	66.4
3) Jaundiced case	9
(including 2 cases of obstructive cholangitis)	
4) Post-cholecystectomy case	4
5) Number of stone	cases
Single stone	12 (52%)
Multiple stones	11 (48%)
2	5
3	1
4	1
5～10	4
6) Diameter of CBDS	
Diameter	cases
≦10 mm	8
10 mm<, ≦20 mm	9
20 mm<, ≦30 mm	4
30 mm<	2
7) Technique employed to visualize CBDS	
ERCP	6
ENBD	7
PTCD	5
PTGBD	2
DIC	1
C-tube	1
gallbladder drainage	1

Table. 4 Number of ESWL for CBDS (cases)
Number of ESWL 1～8 (average: 2.8)

1	5
2	9
3	3
4	2
5	1
6 or more	3

1 ESWL session: 1500～5000 shots
average; 2870 shots

cholangitis. Age distribution was 39 to 86 years-old (average; 66.4 years-old). There were 12 cases (52%) of single CBDS and 11 cases (48%) of multiple CBDS. The diameters of the stones were between 7 mm and 40 mm (average; 17.1±11.7 mm). Stone diameters over 20 mm were observed in 6 cases (Table. 3).

Methods and System

The ESWL system used was Lithostar® (Siemmens, Germany) which generates shock waves electromagnetically. This is the second generation dry type, which requires focusing shock waves under roentgen photoscopy. In all cases, ESWL was performed with an electro-cardiogram monitor and respiratory gating without anesthesia. The body was placed in the prone position for cholecystlithiasis cases, and in the supine position for choledocholithiasis cases.

Effects on Clinical Analysis

53 of the gallbladder cases with normal values from clinical analysis prior to ESWL, and who received no additional treatments like endoscopic retrograde cholangio-pancreatography (ERCP), percutaneous transhepatic cholangio-drainage (PTCD), endoscopic sphincterotomy (EST), and percutaneous transhepatic gallbladder drainage (PTGBD), which were expected to affect the clinical analysis values, were examined before and after the first ESWL session ("session" refers to one single therapy using ESWL). The examination included GOT, GPT, γ-GTP, Al-P, LDH, CPK, blood serum, and urinal amylase, urinal protein, and occult blood.

Gallbladder Stones

The techniques employed to visualize stones were as follows; drip infusion cholangiography (DIC) in 87 cases (74.4%), just fluoroscope alone (onlycalcified stone) in 15 cases (12.8%), PTCD in 11 cases (9.4%), PTGBD, ERCP, endoscopic naso-biliary drainage (ENBD) and oral cholecystrgam (Table. 1).

The number of ESWL sessions given were 1 to 12 (average; 2.7 sessioons). One session emitted between 1500 to 6000 shots (average; 2834 shots). After ESWL, 300 mg/day of ursodeoxycholic acid (UDCA) and 300 mg/day of chenodeoxycholic acid (CDCA) were administered in all cases.

The 117 cases were classified into 2 groups according to the degree of effect. The "effective cases" included patients with remaining gallstones of diameter below 2 mm[13] or showing a complete disappearance (Group-A), and the "non-effective cases" included those with remaining gallstones with diameters over 2 mm or those showing no change (Group-B).

Common Bile Duct Stones (CBCS)

The techniques employed to visualize stones were as follows; ERCP in 6 cases (26%), ENBD in 7 cases (31%), PTCD in 5 cases (22%), PTGBD in 2 cases (9%), DIC, C-tube (bile drainage tube placed in the common bile duct via the cystic duct), and gallbladder drainage, each in 1 cases (4%) (Table. 3).

The number of ESWL sessions given were 1 to 8 (average; 2.8 session). One session emitted between 1500 to 5000 shots (average; 2870 shots) (Table. 4). As in the gallbladder stone cases, 300 mg/day of UDCA and 300 mg/day of CDCA were administered after ESWL in all cases.

The disintegration effect of ESWL expressed as "reduction rate" was calculated from the maximum diameter of the fragmented stone after ESWL divided by the maximum diameter of the stone before ESWL.

The non-paired t test was used to test significance[14]. A result below 5% was considered significant.

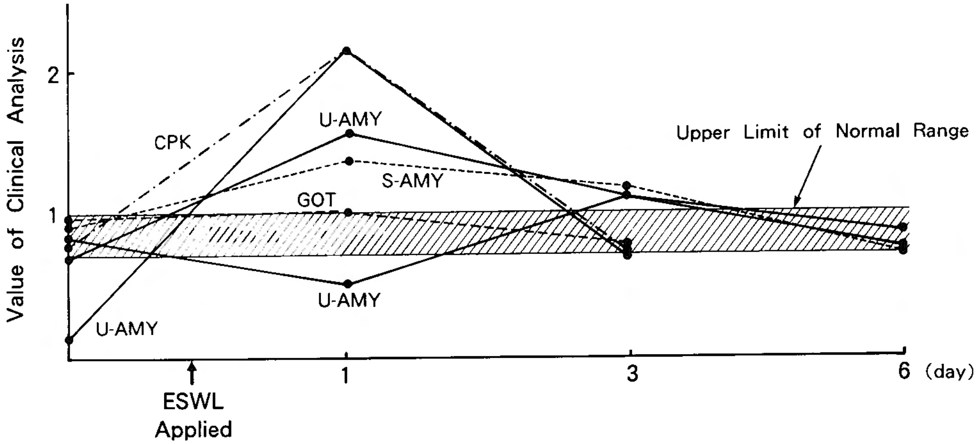

Fig. 1 Fluctuation of Values of Clinical Analysis Before and After ESWL
The graph represents each value. Upper limit of normal range is 1.
The shaded area represents the range of normal Clinical Analysis Values.

Results

Side Effects and Complications

Abnormalities in the laboratory data were observed in 6 out of 53 cases (11.3%) after 53 session of ESWL (3000 shots per session). These abnormalities consisted of 3 cases (5.7%) of urinal amylase, and 1 cases each (1.9%) of GOT, CPK, and serum amylase (Fig. 1). They were all slight and normalized within one week of ESWL. The urinalysis showed 2 cases (3.8%) of urinal occult blood positive and 1 cases (1.9%) of urinal protein positive. These values normalized within 3 days of ESWL.

A total of 380 ESWL sessions were applied to 127 cases. Cutaneous petichiae developed at the entry site of the shock wave in 86 cases (68%). Arrhythmia was observed in 4 cases (3.1%) although it disappeared when gated to ECG. 13 cases (10%) complained of pain, but no analgesics were needed. The pain was reduced by lowering the voltage of the electromagnetic shock wave generating system slightly and no ESWL sessions were discontinued. 4 cases (3.1%) felt nausea during ESWL sessions. No intense anemia or dyspnea were observed.

Disintegration Effect

Gallbladder Stones

79 gallstone cases (68%) showed disintegration by ESWL, but 38 cases (32%) showed no effect. In the 79 cases above, fragmented pieces below 2 mm remained (Group-A) in 25 cases (32%), and those over 2 mm in diameter remained (group-B) in 54 cases (68%). Gallstones disappeared completely in 14 out 25 cases (56%) during a period of a month after ESWL. It took 7 to 90 days (average; 41.2 days) before gallstones disappeared. The 2 groups were examined according to the diameter of largest stone, the number of gallstones, ultrasound classification, and the presence of calcification.

Average Diameter of Largest Gallstone and Disintegration Effects (Table. 5-A, B)

The average diameters of the largest stone in each patient in each group were 13.4±6.0 mm and

Table. 5-A Average Diameter of Largest Gallstone and Disintegration Effects

Disintegration Effect	Total (cases)	Average Diameter of Largest Stone (Mean ± SD) mm	
Group-A	25	13.4±6.0	*
Group-B	92	19.3±8.8	

* 5% statistical significan ce was achieved according to non-paired t test

Table. 5-B Disintegration Effects of Gallstone According to Echo pattern and Size

Echo pattern: type I

	Size of Gallstone mm		Total
	≦20	20<	
Group-A	12 (60)	6 (29)	18
Group-B	8 (40)	15 (71)	23
	20 (100)	21 (100)	41

Echo pattern: type II

	Size of Gallstone mm		Total
	≦20	20<	
Group-A	6 (35)	1 (5)	7
Group-B	11 (65)	21 (95)	32
	17 (100)	22 (100)	39

Numerical values in parenthesis represent %

Table. 6-A Number of Gallstone and Disintegration Effect

	Number of Gallstone (cases)						Total	Average Number of Gallstones ±SD
	1	2	3	4	5–10	10–		
Group-A	20 (80.0)	4 (16.0)	1 (4.0)	0 (0.0)	0 (0.0)	0 (0.0)	25 (100)	1.2±0.5 *
Group-B	40 (43.5)	21 (22.8)	7 (7.6)	2 (2.2)	9 (9.8)	13 (14.1)	92 (100)	4.0±4.8*
	60	25	8	2	9	13	117	

Numerical values in parenthesis represent %

* 5% statistical significance was achieved according to non-paired t test

Table. 6-B Disintegration Effects of Gallstone According to Echo pattern and Number

Echo pattern: type I

	Number of Gallstone (case)			Total
	1	2	3～	
Group-A	15 (58)	2 (15)	1 (50)	18
Group-B	11 (42)	11 (85)	1 (50)	23
	26 (100)	13 (100)	2 (100)	41

Echo pattern: type II

	Number of Gallstone (case)			Total
	1	2	3～	
Group-A	5 (25)	2 (18)	(0)	7
Group-B	15 (75)	9 (82)	8 (100)	32
	20 (100)	11 (100)	8 (100)	39

Numrical values in parenthesis represent %

Table. 7 Ultrasound Classification of Gallstone and Disintegration Effect

Disintegration Effect	Ultrasound Classification of Gallstone				Total (cases)
	I	II	III	Others	
Group-A	18 (72.0)	7 (28.0)	0 (0.0)	0 (0.0)	25 (100)
Group-B	23 (25.0)	32 (34.8)	12 (13.0)	25 (27.2)	92 (100)

Numerical values in parenthesis represent %

Table. 8 CT attenuation value (HU) of Gallstone and Disintegration Effect

Disintegration Effect	Total (cases)	CT value (Mean±SD)HU	
Group-A	17	84.3± 96.0	] *
Group-B	28	295.4±291.0	

* 5% statistical significance was achieved according to non-paired t test

19.3±8.8 mm in Group A and Group B, respectively. 5% statistical significance was achieved between the 2 groups according to the non-paired t test. With regards to the echo-pattern and disintegration effect of gallstones, in echo pattern I stones of diameters of 2 cm or less and over 2 cm occurred in 12/20 cases (60%) and 6/21 cases (29%), respectively. While in echo pattern II, stones of diameters of 2 cm or less, and over 2 cm occurred in 6/17 cases (35%) and 1/22 cases (5%), respectively. ESWL had a lesser effect on gallstones lager than 2 cm.

Number of Gallstone and Disintegration Effect (Table. 6-A, B)

ESWL sessions had no effect on those cases with more than 4 stones. Group A was limited to the cases with less than 3 stones. The average number of stones in each group was 1.2±0.5 and 4.0±4.8 in Group A and Group B, respectively. 5% statistical significance was achieved between the 2 groups according to the non-paired t test. Regarding the echo-pattern of the gallstone, in echo pattern I, the disintegration effect in cases with 1 stone, 2 stones, and 3 or more stones. was 15/26 (58%), 2/13 (15%) and 1/2 (50%), respectively. While that of echo pattern II in cases with number 1, 2 and 3 or more stones was 5/20 (25%), 2/11 (18%) and 0/8 (0%), respectively.

Ultrasound Classification of Gallstone and Disintegration Effect (Fig. 2, Table. 7)

The disintegration effect was examined according to the echo pattern of the gallstone[15]. There were 18 cases (72.0%) of Type I and 7 cases (28.0%) of Type II in Group A, and 23 cases (25.0%) of Type I, 32 cases (34.8%) or Type II, and 12 cases (13.0%) or Type III in Group B (Table. 7).

CT Attenuation Value of Gallstone and Disintegration Effect (Table. 8)

The disintegration effect was examined using CT attenuation values acquired from the center of the gallstone in 45 cases prior to ESWL (Table. 8). CT attenuation value were 84.3±96.0 and 295.4±291.0 in Group-A and Group-B, respectively, which was found to be statistically significant.

Degree of Calcification and Fragmentation Effect

Cases of calcified stones and non calcified stones on the abdominal roentgenograms were 28 and 51 in the fragmented group, and 14 and 24 in non-fragmented group respectively. The presence of calcified gallstones showed no statistical significance between the 2 groups.

The Number of ESWL and Disintegration Effect

The relation between the disintegration effect and the average number of ESWL sessions was; 3.6±1.3 in Group A, and 2.5±2.4 in Group B.A 5% significant difference was observed between

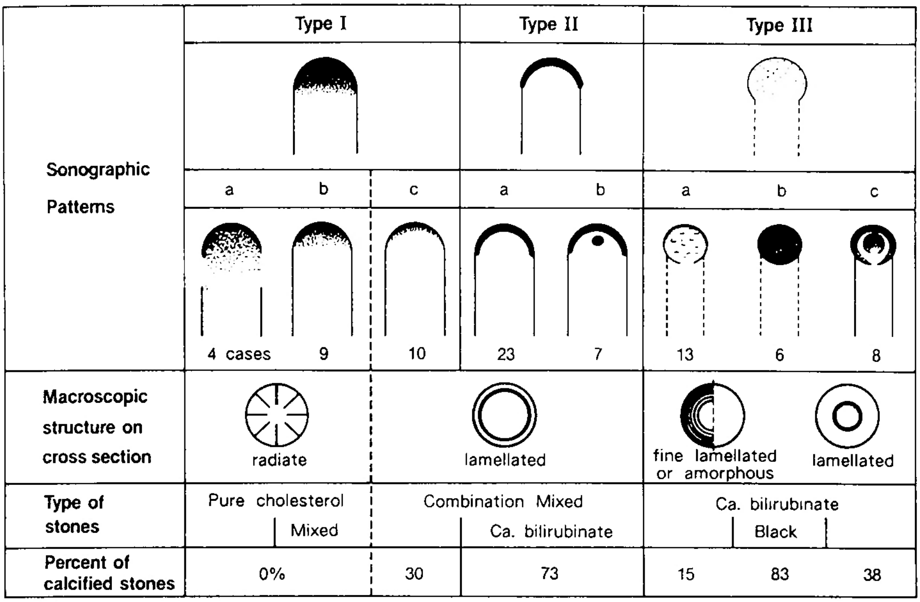

Fig. 2 Ultrasonographic Classification of Large Stones More Than 10 mm in Diameter[15]

Table. 9 Additional Treatment of ESWL for CBDS

Cases with disappearance of CBDS after ESWL	16
EST employed cases	11
(including 6 cases employing Basket)	
Not EST employed cases	5
Including the following	
Biliary lavage of glyceryl trinitrate	2
Balloon catheter via PTCD	1
Spontaneous passage	2

Table. 10 Disintegration Effect of CBDS (cases)

Fragmented cases	20 (87%)
Non-fragmented cases	3 (13%)
Reduction rate of CBDS	
75%≦	2 (10%)
50%≦, <75%	5 (25%)
25%≦, <50%	12 (660%)
<25%	1 (5%)

the 2 groups.

Common Bile Duct Stone (CBDS)

20 out of 23 choledocholithiasis cases (87.0%) showed disintegration, and 3 cases (13.0%) showed no disintegration. 16 cases out of the 20 above (80%) became stone free. In those 16 cases, spontaneous passage was found in 2 cases, EST was used in 11 cases, biliary lavage of glyceryl trinitrate (GTN) was used in 2 cases, and balloon catheter via PTCD was used in 1 case (Table. 9). It took 7 to 52 days (average; 17.1 days) before CBDS disappeared. The reduction rate of CBDS was as follows, 75% or more, 2 cases (10%); between 50% and 75%, 5 cases (25%); between 25% and 50%, 12 cases (66%); under 25%, 1 case (5%) (Table. 10). The CBDS cases were separated into a "fragmented group" and a "non-fragmented group". Then the two groups were examined according to diameter of largest CBDS, the number of stones, the number of ESWL sessions applied, and the chemical composition of stones.

Average Diameter of Largest CBDS and Disintegration Effect (Table. 11)

The average diameter of the largest stone in each patient in the "fragmented" and "non-

Table. 11 Factors of CBDS and Disintegration Effect

Disintegration Effect	Total (cases)	Average Diameter of Largest CBDS (Mean±SD) mm	Number of CBDS (Mean±SD)	Number of ESWL (Mean±SD)
Fragmented Group	20	13.0±7.8 *	2.0±1.7 *	3.0±2.0
Non-fragmented Group	3	24.3±5.1	4.3±1.5	1.7±0.6

* 5% statistical significance was achieved according to non-paired t test)

Table. 12 Ultrasound Classification of Gallstones, Number of ESWL, and Disintegration Effect

Disintegration Effect	Ultrasound Classification of Gallstone		
	I	II	III
Group-A	2.0±1.0	3.8±2.9 *	——
Group-B	1.7±0.9	1.6±0.8	3.3±2.2

Values represent average number of sessions of ESWL given±standard deviation
* 5% statistical significance was achieved according to non-paired t test

fragmented" groups were 13.0±7.8 mm and 24.3±5.1 mm, respectively. There was a significant difference between the 2 groups. The average diameter of the largest CBDS is inversely proportional to the disintegration effect. In other words, the bigger the stone is, the smaller the disintegration effect becomes. From the data obtained in this study, the disappearance rate of the largest CBDS of 3 cm or less, and over 3 cm in diameter was 15/21 (71%) and 1/2 (50%), respectively.

Number of CBDS and Disintegration Effect (Table. 11)

The number of CBDS in the "fragmented" and "non-fragmented" groups were 2.0±1.7 and 4.3±1.5, respectively. There was a significant difference between the 2 groups (Table. 11). The number of CBDS is inversely proportional to the disintegration effect. The more stones there are, the smaller the disintegration effect becomes. The disappearance of 2 or fewer stones was observed in 14/17 cases (82%), 3 or more in 2/6 cases (33%).

Number of ESWL sessions and Disintegration Effect (Table. 11)

The number of ESWL sessions applied in the "fragmented" and "non-fragmented" groups was 3.0±2.0 and 1.7±0.6, respectively. There was no significant difference between the number of ESWL sessions applied.

Chemical Composition of CBDS and Disintegration Effect

The chemical composition was determined in 14 out of 23 cases by CT or cholangiography. 5 cases were cholesterol constituted stones, and 9 cases were bilirubin constituted stones. The reduction rate of CBDS was 0.54±0.28 in the cholesterol constituted stones and 0.69±0.15 in the bilirubin constituted stones. A significant difference was not observed. The cholesterol constituted stones were disintegrated in 80% of cases, and the bilirubin constituted stones were disintegrated in 78% of cases.

Discussion

Recently, the second generation "dry type" ESWL system was developed in replacement of the first generation "wet type" ESWL system in which shock waves were applied to the patient in a water tub. Since this "dry type" system requires no anesthesia, ESWL can be performed easily and repeatedly. There were 4 type of shock wave generators; a electrohydraulic type, a piezoelectric type, a electromagnetic type, and a microexplosion type[16,17]. We used the electromagnetic type system. According to COLEMAN[18], the barometric pressure of our ESWL system generating a shock wave in about 44 MPa (1MPa$=10^3$ atmosphere). The focusing methods of ESWL system are an ultrasound echo guided type and a X-ray guided type. We employed the X-ray guided type, the stone being visible on a roentgenogram. Using echo-guided ESWL apparatus CBDS could be visualised successfully in 70–80%[19] of cases, so this X-ray guided ESWL system is efficient for calcified gallstones and CBDS, but inconvenient for radiolucent gallbladder stones in that visualization of gallbladder stones by X-ray is difficult.

Side Effects and Complications

6 out of 53 cases (11.3%) yielded abnormal values from blood chemical analysis, but they were all slight and quickely returned to normal (Fig. 1). These values fluctuate more as the number of shock waves is raised[19]. It has been reported that fluctuation of these values in insignificant[21,22,23], fugitive and reversible[4,24,25], agreeing with our results. CHAUSSY et al[26]. mentioned that extrasystole is a common abonormality seen during ESWL. SACKMANN et al[4]. did not report such cases in their 175 patient series. We found non serious extrasystole in 4 cases (3.1%), and they were eliminated by electrocardiogram gating. SACKMANN et al[4]. who employed electrohydraulic type ESWL of the first generation type, reported cutaneous petechiae in 14%, and transient gross hematuria in 3% of the total 175 cases. Blood-chemistry tests showed no significant changes except leucocytosis, four hours after the procedure. This returned to normal after 24 hours. No other adverse effects relating to ESWL treatment were detected. MOSNIER[27], who employed the piezoelectric type ESWL to 57 patients, reportes 10 cases of moderate abdominal pain without abnormal liver function, and 1 case of biliary colic pain with a transient increase of Al-P. We have used the electromagnetic second generation type in 117 cases and recognized slight side effects without major complications. Taking our results from this study, together with those from the reports listed above[22,27–32] the clinical application of ESWL to gallbladder stones is considered to be quite safe.

As for the application of ESWL to CBDS, we have performed 65 sessions of ESWL in 23 CBDS cases without any severe side effects or complications. In only one case after ESWL was jaundice with high fever observed, and was considered to be due to edema in the papillar caused by EST applied immediately before ESWL. The symptom was reduced by additional EST, and ESWL could be continued without complications. However, according to the reports of multicenter trials in Europe and America, there was a rather incidence of side effects and complications. SAUERBRUCH et al[33]. out of a total of 113 cases, reported 33 cases (29%) of slight complications such as petechiae, 13 cases; hematuria, 12 cases; pain, 10 cases and 9 cases (8%) of rather severe complications such as high fever, 6 cases; pain, 3 cases and one case of hematocrit decrease. MOODY[34] et al. reported 8% hemobilia, 6% hematuria and 4% cholangitis out of 56 cases. BLAND et al[35]. reported 10.5% pain, 7% hemobilia, 3.5% hematuria and 5% cholangitis out of 42 cases. BURHENNE et al[36]. reported 2 cases of transient hemobilia, 2 cases of slight hematuria, and 3 cases of short-term fever in a total of 9 cases. It should be taken into consideration that these reports on ESWL complications have been done using the first generation ESWL system, mainly under general anesthesia in a water tub. Concerning reports using the second generation ESWL system, STARITZ[37] reported neither complications nor drastic changes in blood tests in his 30 case study. Interestingly R. DEN TOOM et al[24] used first and second generation ESWL apparatus at a single institution. Transient hematuria in 11 out of 13 patients treated using the first generation ESWL apparatus were observed, compared with none in the 49 patients treated using the second generation ESWL. CHOUDHURI G. et al[38]. using a second generation lithotriptor, as used here, and applying a very high number of shock waves (18,267 shots per patient) in 6 patients, showed no appreciable complications. Taking the findings of these reports together with ours, it can be concluded that ESWL applied to CBDS is safe, especially using second generation systems.

Two cases of death during ESWL applied to CBDS were reported in the paper by SAUERBRUCH [33], using the first generation ESWL apparatus on 113 CBDS patients. 1 case was a 70 year-old male in a multimorbid state. Chronic atrial fibrillation induced a femoral artery embolism, and he died from multiorgan failure 27 days after ESWL. The other case was 83 years-old female with prolonged coagulation who died 70 days after ESWL. 23 days before ESWL, this patient received the implantation of a hip endoprosthesis, cholecystectomy, and a common bile duct revision due to gallbladder empyema. She suffered from septic shock with pancreatitis immediately after the ESWL, requiring a 2400 cc blood transfusion. Two months later, an abdominal mass was observed. Hematoma was confirmed by sonographically guided needle puncture. A direct relationship between the cause of death and ESWL was not proven in either or these two cases. We could not find any other reports of death directly related to ESWL in the literature. Thus generally, severe complications due to ESWL applied to CBDS seldom occurs. Even though side effects and complications are observed, they are slight and reversible, so that the clinical application of ESWL to CBDS is safe.

Disintegration Effect

Gallbladder Stone

SACKMANN et al[4]., employing the electrohydraulic type ESWL for 175 patients, limited its use to radiolucent solitary stones, in functioning gallbladders. The disintegration and disappearance rates were 99% and 91%, respectively. RAMBOW et al[28]., employing the electromagnetic type, reported a 97.5% (78 of 80 cases) disintegration rate. The disappearance rate was only 50% (40 of 80 cases). They selected patients with symptomatic cholecystlithiasis, contractile gallbladder, and the absence of pigment stones. Our disintegration rate was 68% (79 of 117 cases) and the disappearance rate was 12% within a 30 month (1–30 months; mean=12 months) follow up period. The results was not excellent when compared to the data reported in the papers by ALBERT et al[5]. and DARZI et al[39]. The main reason was that we applied ESWL to all gallbladder stones, in a fixed period, without restriction to certain criteria for its application. The difference in the results between reported data listed above and our data clearly demonstrate that it is important to determine certain criteria for the application of ESWL to gallbladder stones. However, it is possible that the type of shock wave generating equipment affects the results[18,40]. The effect using different systems needs to be discussed in the future.

Average Diameter of Largest Gallstone and Disintegration Effects

From our data the average diameter of the largest stone in each patient in Group B (19.3 ± 8.8 mm) was larger than that of Group A (13.4 ± 6.0 mm). From the disintegration effects of gallstones according to echo pattern and size, in both stones of echo pattern I and diameter of 2 cm or less, fragmentation was much better than that for stones over 2 cm; echo pattern I: $\leqq 2$ cm, 60%; >2 cm, 29%, echo pattern II: $\leqq 2$ cm, 35%; >2 cm, 5%. We conclude, therefore, that gallstones with diameters of 2 cm or less have a good chance of successful treatment by ESWL, in agreement with several other reports[28,42]. Sackmann et al[23]., who had performed ESWL on 711 patients in 3 ways (group-1: a water-tank lithotriptor, group-2: a water cushion lithotriptor at low energy levels, group-

3: a water cushion lithotriptor at high energy levels), showed that the rate of fragment clearance in cases with single stones of 2 cm or less in diameter was 76% for group-1, 60% for group-2, and 83% for group-3. in cases with single stones of 2.1 to 3 cm in diameter the results were 63% for group-1, 32% for group-2, and 58% for group-3. It is obvious that the bigger the stone is, the smaller the disintegration effect. Taking the finding of these reports together with ours, one can conclude that to achieve the best disintegration effect, the diameter of stone should be limited to 2 cm or less.

Number of Gallstones and Disintegration Effect

All cases with 4 stones or more belonged to Group B. Group A cases were limited to 3 stones or less. In the case of a single stone, 20 out of 60 (33%); 2 stones, 4 out of 25 (16%), and 3 stones, 1 out of 8 (13%) resulted in Group-A. DARZI et al[39]. reported that results worsened as the number of gallstones increased. RAMBOW et al[28]., did not limit the number of stones, and acieved a 53% disappearance rate overall (80 cases), but only 33% in the multiple stone group. SACKMANN et al[23]., who had performed ESWL in 3 ways (mentioned above), showed that the rate of fragment clearance in cases with two or three stones was 38% for group-1, 16% for group-2, and 46% for group-3. Compared with his study of single stone cases, one can conclude that the more stones there are, the smaller the disintegration effect. Therefore, to achieve the best disintegration effect, the number of stones should be limited to one or two.

Ultrasound Classification of Stone and Disintegration Effects

The disintegration effect according to the ultrasound classification[15] of Group-A was Type I, 72%; Type II, 28%; and Type III 0%. From the above, stones of Type I were best suited for ESWL. MURATA et al[43]. reported Type Ia (subtype of Type I) to be the best suited group for ESWL. TSUCHIYA et al[44]. reported Type I to be the best. On the other hand, DYRSZKA et al[45]. classified gallstones into two echo types: type I —crescent to disc shape with gradual attenuation of echoes, and type II— rim-shape with abrupt shadowing. They reported that rate of stone clearance, 1 year after ESWL had been greater for type I stones (27 of 48 cases (56%)) than for type II (3 of 25 cases (12%)).

CT Attenuation Values and disintegration effects

As shown in Table. 8, the CT attenuation value of Group A (effective group) was very low (84.3 ± 96.0 HU). A CT attenuation value below 50 HU was considered appropriate for best results. ELL et al[46]. classified gallstones by their CT attenuation values, and found that a significantly higher degree stone disintegration was achieved with stones of group I ($\leqq 50$ HU) than with those in group II (<50 HU and $\leqq 90$ HU) and group III (>90 HU). No difference was observed between group II and III. In general, lower CT attenuation values show a better disintegration effect. Therefore, to achieve the best disintegration effect, the CT attenuation value of a stone should be limited to 50 HU. BARON et al[47]. showed that the inverse correlation between CT attenuation values and cholesterol levels was stronger than the correlation between CT attenuation values and calcium levels. They also showed that the difference in the CT findings on gallstones appeared to relate more to cholesterol content than to calcium composition. From the CT attenuation values, it was clearly demonstrated that cholesterol rich stones were easily disintegrated by ESWL.

Degree of Calcification and Fragmentation Effects

It was interesting that there was no significant correlation between the presence of calcium in the stone and the fragmentation effect. There were 14 calcified stone cases (18%) in the fragmented group, and 8 cases (21%) in non-fragmented group. That is calcified stones could be disintegrated by ESWL. However, of ESWL had been limited to non-calcified[4,48] stones. It can be seen from recent papers[5,39,49] that slightly calcified stones fragment and disappear.

Numbers of ESWL shots and Disintegration Effect

The relation between the disintegration effect and the number of ESWL sessions was as follows; 3.6 ± 1.3 sessions in Group A, 2.5 ± 2.4 sessions in Group B. Between the 2 Groups, 5% statistical significance was observed in the non-paired t test. As the number of ESWL sessions increases, stones showing echo patterns of Type II tend to be disintegrated (Table. 12). However, the number of ESWL sessions should be limited due to the cost. For example, the electro-magnetic generator we used for ESWL does not last long. After approximately 100,000 shots, the generator becomes useless and has to be replaced. The price of generator is 1,800,000 yen at present. Since one ESWL session requires 3,000 shots, the cost would be at least 54,000 yen per session. The number of health insurance points allowed to treat gallstone by ESWL is 20,000, which is equivalent to 200,000 yen. Considering the possiblity of recurrence[50,51,52], 2 sessions at most (108,000 yen) would be affordable. However, as shown in Table. 12. Only cholesterol stones (echo pattern Type I) can be completely disintegrated in 2 sessions of ESWL.

Significance of Litholytic Agents

Since litholytic agents were administered orally in all the cases of this study, we are unable to discuss its significance. No side effects were observed. MAHER et al[53]. reported that in the combined use of ESWL and litholytic agents, that UDCA seemed to shorten the disintegration period of ESWL. SACKMANN et al[23]. also found, in a study of 711 cases, that the clearance rate in patients who were compliant with bile acid therapy was higher than in those who were non-compliant. The efffect of litholytic agents with ESWL has been reported[23,53] and varies according to how fragmented stones disappear. There are two expected ways for fragmented stones to disappear. First, the fragmented stones simply dissolve. Second the fragmented stones pass through the cystic and common bile ducts and are excreted into the duodenum. In both cases the use of litholytic agents will be beneficial to stone clearance. Furthermore, when the surface area of a disintegrated stone affected by litholytic agents increases, it would be excreted faster. The administration of litholytic agents in either case would be reasonable. Almost all institutions prescribe litholytic agents. We administered 300 mg/day of UDCA and 300 mg/day of CDCA in all cases, in accordance with the recommendation of STIEHL[54].

Prospect of Stone Clearance

The follow up period of our cases was from 1 month to 30 months (mean = 18 months). Probably, a longer follow up period gives a better disappearance rate. SACKMAN et al[12]. said 84.4 ± 4% cases of complete stone fragmentation (fragment of 3 mm or less) disappeared within 2 years. So stones in 21 cases in our Group-A (25 cases) sould disappear. Furthermore, SACKMAN et al[12]. reported that 62.6 ± 6% of incompletely fragmented (fragment of more than 3 mm) stones disappeared, so stones in 33 of our 54 cases should disappear.

Recurrence of Stones

No cases of recurrence are found in our cases at present. Referring to the papers[55,56] the recurrence rate is about 9%. This recurrence rate is almost the same as that found by treatment with litholytic agents alone. As regards recurrence rate and cost-performance, laparoscopic cholecystectomy (LC) is more cost-effective than ESWL, and shows no recurrence. But LC is a more invasive therapy and has complications.

Gallbladder Function

There was no significant correlation between gallbladder contractility and stone disappearance rate in our cases. But, if the fragmented stone goes through the cystic and the common bile ducts to be excreted into the duodenum, then a contractile gallbladder is needed to push out gallstones. Even if a lytholytic agent causes stone fragments to disappear, a functioning gallbladder is necessary for the intake of a lytholytic agent into the gallbladder. The use of ESWL on gallstones has been widely applied based on the criteria set SACKMANN et al[4]. of a solitary radiolucent stone and a functioning gallbladder. Reports on successful disintegration of calcified and non-cholesterol stones are increasing[5,39,49] and the application has been expanded. Recently, laparoscopic cholecystectomy (LC) has become the standard method for the surgical treatment of gallbladder stone. LC is minimally invasive surgery and has great advantages compared to the conventional open cholecystectomy[57]. Therefore, there are many choices in the treatment of gallbladder stones. At present we choose the therapy for gallbladder stones with normal gallbladders as follows: gallbladder stones of echo pattern Ia are treated by oral litholytic agents or ESWL according to the patient's requests. Gallbladder stones of echo pattern Ib or Ic are treated by ESWL. Gallbladder stone of echo pattern II are recommended to be treated by LC because of the cost-benefit, even though they can be treated by ESWL if the patient requests. Gallbladder stones of echo pattern III or non-functioning or inflamed gallbladders are treated by LC.

Common Bile Duct Stones

Application and Results

In 1986, SAUERBRUCH et al[2]. performed ESWL in 5 cases that were untreatable by endoscopic extraction and succeeded in 4. In Japan, KATO et al[58]. reported a similar case in 1987. SAUERBRUCH[33], MOODY[34], BLAND[35] reported the result of a multicenter trial in 1989. In all cases, there was difficulty to remove stones by endoscopical techniques, and EST or other additional treatments prior to ESWL were given[33,34,35,59]. We applied ESWL to 23 CBDS cases that had not previously been treated. 20 cases (87%) showed fragmentation. CBDS had disappeared in 16 out of the 20 cases (80%) above. In 97 out of 113 cases (86%) by SAUERBRUCH et al[33]., 44 out of 56 cases (79%) by MOODY et al[34]., and 31 out of 42 cases (74%) by BLAND et al[35]., CBDS disappeared. Despite the fact that these results were all from multicenter trials, they were surprisingly good. As for single institution results high disappearance rates have also been reported; 100% (in 13 cases) in first generation ESWL and 73% (in 49 cases) in second generation ESWL by DEM TOOM et al[24]., 80% (in 45 cases) by MERRETT et al[50]., and 88% (in 16 cases) by FRIED et al[51]. 85% (in 27 cases) by HIRATA et al[52]. and 77% (in 13 cases) by AOYAGI et al[53]. have been reported in this country. Thus it is clear that ESWL on CBDS yields excellent results. It would be the first choice for the treatment of CBDS, especially for patients with a poor general condition or incarcerated stones in the common bile duct.

Diameter and Number of CBDS and Disintegration Effect

There was a significant difference in the average diameter of the largest CBDS and the number of stones between the "fragmented" and "non-fragmented" groups (Table. 11). The disintegration effect is inversely proportional to the average diameter of CBDS[33,34,64]. The bigger the stone is, the smaller the disintegration effect becomes. In vitro, the number and size of the stones, i.e. their total volume are the major determinants of fragmentation by ESWL[55]. In our experience, the diameter of the largest CBDS was the crucial factor in achieving clearance. Stones below 3 cm in diameter resulted in 86% (1821) disintegration. There were only two cases the largest stones had diameters of over 3 cm, so that the effect of ESWL to the larger CBDS should be re-estimated in future. It is clear, however, that ESWL is very effective in cases where tha largest diameter of CBDS is below 3 cm. As for the correlation between the size of CBDS and the effect of ESWL. NICHOLSON et al[66]. reported that the factor determining success of fragmentation was the size of the stones. In their study, CBDS of up to 33 mm in diameter showed some disintegration, but the resulting fragments were large. In a study by OKUSHIMA et al[67]., all cases with stones less than 10 mm were disintegrated and natural excretion was found in 90% of cases. In cases with stones over 10 mm, disintegration was achieved in 75% of cases, but the natural excretion rate was 11%. In these cases additional therapy including EST were needed.

Now we turn to the number of CBDS and their disappearance. One or two cases of CBDS occured in 14 out of 17 cases (82%), 3 or more in 2 out of 6 cases (33%). ESWL has a lesser effect on CBDS in which the number of stones is greater than 2. From this study, taking cost into account, the use of ESWL for the treatment of CBDS should only be made in cases where there are one or two CBDS with diameter below 3 cm. As for the number of CBDS and stone size, SAUERBRUCH and STERN[33] reported the mean stone size when a first ESWL session failed, to be 30 ± 13 mm versus 22 ± 7 mm in patients with successful treatment. He also said the number of stones had no significant influence on the success rate. MOODY et al[34]. also said the number of treatments required was related to the size of the largest stone rather than to the number of stones or their location. But BLAND et al[35]. state that the increase in stone number did not correlate with the necessity for a second treatment. In contrast, as stone burden increased, as defined by the sum of the diameters of the largest stones, the probability of a second treatment increased. AOYAGI et al[63]. applied 15 sessions of ESWL to 10 cases of single CBDS and achieved complete stone clearane in 90% of cases (9 cases). On the other hand, 8 sessions were applied to 3 multiple CBDS cases, and was successful only in 1 case (33%). 5 cases of CBDS with diameter below 1 cm received 1 ESWL session each and was successful in 4 cases (80%). 8 cases of CBDS with diameter above 1 cm received a total of 18 ESWL sessions and achieved complete stone clearance in 6 cases (75%). From the above we see that ESWL works best when there are one or two CBDS with diameters of 3 cm or less.

Type of CBDS and Disintegration Effect

Unlike gallbladder stones, there are no precise reports submitted regarding ESWL effectiveness on CBDS types, indicating effectiveness does not depend on CBDS type. According to the fragmentation experiment in vitro done by SCHACHLER[55], the type of CBDS does not affect the fragmentation result. SAUERBRUCH et al[33]. also reported that the chemical composition of stones is probably of minor importance. The study by UENO et al[68]. showed that fragmentation was achieved in 3 out of 3 cholesterol CBDS cases (100%) and 5 out of 7 bilirubin CBDS cases (72%). Our cases also showed that bilirubin constituted stones were disintegrated (7 out of 9; 78%) at a similar level to cholesterol constituted stones (4 out of 5; 80%) in the common bile duct.

Usefulness of Gryceryl Trinitrate (GTN)

GTN is found to relax the Oddi sphincter[69,70]. GTN lavage was performed through the biliary tract using PTCD or PTGBD tubes and spontaneous passage of CBDS was achieved in 2 cases after successful ESWL. The same process was also applied to 2 other cases with remaining CBDS after surgery. Lavage in the biliary tract or intravenous administration of GTN had the advantage of causing stones to be excreted by relaxing papillar sphincter. Its clinical application will further be expanded in the future. ESWL treatment of CBDS requires no sophisticated techniques and therefore, should be performed widely. Excellent reports often involve EST and attention should be paid therefore to other additional treatments besides ESWL. In the USA and Europe, ESWL is limited to cases that are incapable of endoscopic treatment. SAUERBRUCH et al[33]., for example, applied EST prior to ESWL in all cases. Oral administration of litholytic agents is uncommon in CBDS cases, however, and addtional treatments are applied after ESWL instead. SAUERBRUCH et al[33]., applied endoscopic extraction of CBDS (71 cases) and injected litholytic agents (3 cases) out of 113 cases. MOODY et al[34]. used an adjunctive procedure in 30 cases (54%). Application of such additional treatments prior to ESWL raises a question of whether or not ESWL alone causes CBDS to disappear. Use of drainage from the biliary tract in the treatment of CBDS by ESWL is required in Europe. We applied ENBD and EST only in the cases with cholangitis induced from ESWL. 16 out of 23 CBDS cases (70%) were free of stones by ESWL, and 5 cases (31%) in the above were not treated with EST. We administered GTN into the biliary tract in 2 cases. FRIED et al[61]. applied ESWL to 16 cases of CBDS and spontaneous passage was observed in 5 cases through the intact sphincter. AOYAGI et al[63]. performed ESWL, omitting EST in all 13 cases and disappearance of the stone was achieved in 10 cases (77%). They did not restrict ESWL application to non-endoscopicable cases only. NORMAN R. W. et al[64]. mentioned also that EST was not necessary before ESWL. So ESWL is very much expected to be the first choice in the treatment of CBDS.

Conclusion

Side effects and complications related to treatment by ESWL in this study were all slight and reversible. Therefore, clinical application of ESWL can be regarded to be a quite safe therapy for the treatment of gallstones. However, its application should be limited under certain criteria, taking the cost-benefit into account. Those criteria for cholecystlithiasis are:

— one or two stones.
— the maximum diameter of stone is below 2 cm
— I type stone in ultrasound classification, or CT attenuation value of the center of the stone below 50 HU.
— Functioning gallbladder without inflammation.

In cases of calcified stone, it should be limited to slightly calcified stones or only those with only a calcified rim as observed by X-ray.

Criteria of ESWL for CBDS are as follows:

— one or two stones.
— the maximum diameter of stone is below 3 cm

Disintegration effects of CBDS by ESWL can be expected to be high irrespective of stone composition. As a therapy for CBDS, ESWL should be expanded in its clinical application and could be used without EST. Gryceryl trinitrate is useful to help excretion of fragmented CBDS after ESWL.

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和文抄録

胆石症に対する体外衝撃波結石破砕療法 (ESWL) の臨床的研究

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体外衝撃波結石破砕療法 (ESWL) を胆石症127例(胆嚢結石症117例，総胆管結石症23例，両者合併13例）に対して行い，ESWL の安全性を調べ，結石の破砕効果から ESWL の適応を検討した．

安全性について；ESWL を施行した胆嚢結石症例のなかで ESWL 前の検査値が正常範囲内にあり，付加的処置 (ERCP, PTCD, EST, PTGBD) を行っていない53例を対象として，GOT, GPT, γ-GTP, Al-P, LDH, CPK, 血清及び尿中アミラーゼを ESWL の施行翌日，3日目，6日目の値を施行前と比較した．その結果，のべ6例（11.3%)に異常を認めた．その内訳は尿アミラーゼの異常が3例（5.7%)，GOT, CPK 血清アミラーゼの異常が各1例（1.9%)であった．しかし，それらは軽微ですべて6日目には正常化した．また，127例に合計380回の ESWL 施行中，ECG で不整脈が4例（3.1%)に認められたが，これらはすべて照射を心電図に同期することにより消失した．疼痛を訴えた症例は13例（10%)あったがすべて鎮痛剤は使用せず，衝撃波を軽度弱めることにより治療を継続できた．

ESWL の結石破砕効果；胆嚢結石症117例中79例(68%)に破砕効果を認めた．破砕効果と結石の最大直径，結石の個数との関係は，それぞれ，小さいもの(2 cm 以下)，結石の少ないもの（2個以下）で有意差をもって破砕効果が認められた．また，ESWL は，照射回数の多い程有意に破砕効果が上がり，石灰化の有無は破砕効果に影響を及ぼさなかった．一方，結石の CT 値との関係は，CT 値が低いコレステロール結石に高い破砕効果が認められ，超音波分類との関係でも，I 型のコレステロール結石に高い破砕効果が認められた．

総胆管結石症23例中20例（87%)に結石の破砕効果があり，うち16例（70%)では結石の消失が得られた（5例は EST なしで自然消失)．結石の大きさ及び個数では，それぞれ結石のサイズ（3 cm 以下)，結石数（2個以下）で有意差をもって破砕効果があった．また，結石の性状からコレステロール系結石以外にビルルビン系結石にも本法が有効であることが明かとなった．

結論：胆石症に対する ESWL は，無侵襲かつ極めて安全な方法であり，適応症例を選べば非常に有効な治療法である．今回の ESWL の臨床応用から，本法の適応を以下に挙げた．

胆嚢結石症：1)超音波分類 I 型のコレステロール結石（結石の CT 値 50 HU 以下)，2)結石数2個以下，3)結石の最大直径 2 cm 以下，4)炎症を伴わない機能性胆嚢．

総胆管結石症；結石数2個以下，結石の最大直径 3 cm 以下の症例で高い破砕効果が得られる．また結石の性状に関係なく有効で，本症の治療法の一つとして有用である．