

# Long-term Results of Extracorporeal Shockwave Lithotripsy and Endoscopic Therapy for Pancreatic Stones

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**Background & Aims:** The aim of this study was to evaluate the short- and long-term results of extracorporeal shockwave lithotripsy (ESWL) and endoscopic therapy for pancreatic stones. **Methods:** A total of 117 patients with pancreatic stones underwent ESWL and endoscopic treatment in our institute. Seventy patients who were followed-up for over 3 years after treatment were evaluated retrospectively. **Results:** Immediate pain relief was achieved in 97% and complete removal of stones was achieved in 56%. During the long-term follow-up evaluation, 49 of 70 patients continued to be asymptomatic. Pain recurred more frequently in patients with incomplete removal than in those with complete removal ( $P < .05$ ). Twenty-one patients who became symptomatic during the follow-up period underwent additional therapy, and pain relief was attained without surgery in all of them. Both endocrine and exocrine function deteriorated after the long-term follow-up period ( $P < .05$ ). **Conclusions:** ESWL and endoscopic treatment of pancreatic stones proved to be effective for long-term pain relief, especially in patients in whom stones were removed completely at initial therapy.

Chronic pancreatitis (CP) is characterized by a progressive loss of pancreatic parenchymal tissue, and after a subclinical phase of variable duration, recurrent attacks of abdominal pain occur, and exocrine and endocrine insufficiency becomes apparent.<sup>1</sup> In most patients with CP, pain is the predominant symptom<sup>2</sup> and ductal hypertension caused by stones and strictures is believed to be the major cause of pain in CP.<sup>1,3</sup> Thus, treatment of pain in CP has been directed toward pancreatic duct decompression. Surgical drainage is safer and preferable to preserve pancreatic function than resection of the pancreas.<sup>4</sup> However, surgical drainage is associated with a mortality rate of up to 5%, and long-term prognosis is not good because pain may recur in up to 50% of the patients within 5 years after the surgery.<sup>5</sup> In recent years, extracorporeal shockwave lithotripsy (ESWL) and endoscopic treatment were introduced to remove pancreatic stones,<sup>6-8</sup> and their effectiveness regarding stone removal and pain relief has been shown.<sup>9</sup> Because these

procedures are noninvasive, some investigators regarded ESWL and endoscopic treatment as the first-line treatment for pancreatic stones.<sup>3</sup> To our knowledge, most reports were based on short- and medium-term results, and there have been few reports on the usefulness of ESWL and endoscopic treatment after long-term follow-up evaluation. Therefore, we reviewed our long-term results of ESWL and endoscopic treatment for pancreatic ductal stones in addition to our short-term results.

## Materials and Methods

### Patients

From May 1991 to December 2003, 117 consecutive patients (85 men, 32 women; mean age, 47.8 y; range, 12-73 y) with pancreatic duct stones were treated in our hospital. The cause of CP was alcohol in 79 patients and other factors in 38. All the patients had abdominal or back pain associated with pancreatitis. The patients who had undergone pancreatic surgery and/or had been diagnosed with pancreatic cancer were excluded. Table 1 shows the characteristics of the patients. Written informed consent was obtained from all patients who underwent ESWL and endoscopic treatment.

### Definition

Before therapy, all patients underwent endoscopic retrograde pancreatography (ERP). Stone characteristics (number, maximum diameter, and location) and the presence of a main pancreatic duct (MPD) stricture were assessed. The MPD stricture was defined as a linear stricture ( $<1$  mm) on ERP without malignant findings (confirmed by brushing cytology or computed tomography). The maximum diameter of the MPD was measured at the body of the pancreas before and immediately after therapy with ultrasound. Fragmentation of stones was considered successful if each fragment was 3 mm or less in diameter judged by ultrasound and plain radiograph

*Abbreviations used in this paper:* BT-PABA, N-benzoyl-L-tyrosil-paraaminobenzoic acid; CP, chronic pancreatitis; ERP, endoscopic retrograde pancreatography; ESWL, extracorporeal shockwave lithotripsy; MPD, main pancreatic duct.

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**Table 1.** Clinical and Morphologic Characteristics of Patients With Pancreatic Stones

Sex	Male	85
	Female	32
Age (y)	Mean	48
	Range	12–73
Cause	Alcohol	79
	Others	38
Stones	Number	
	Single	37
Location	Multiple	80
	Head	100
Maximum diameter (mm)	Body/tail	17
	Mean	11.2
	Range	3–37
MPD stricture		57 (48.7%)

films. Complete removal of stones was defined as no filling defect in the MPD on ERP. Incomplete removal of stones was defined as the presence of remaining filling defect(s) in the MPD on ERP.

### Treatment

**Initial treatment.** After hospitalization, ESWL was performed as the first-line treatment and those in whom stones were not removed by ESWL were subjected to endoscopic treatment. The treatment goal was complete removal of stones. ESWL was performed with a piezoelectric lithotripter (LT-01, 02; EDAP International Inc., Paris, France, or Piezolith 2500; Richard Wolf, Inc., Knittlingen, Germany). Targeting of pancreatic stones was performed by radiograph or ultrasound. Patients were treated with ESWL twice a week until each fragment was 3 mm or less in diameter. When removal of pancreatic stones was insufficient, endoscopic pancreatic sphincterotomy and basket extraction were performed to remove the stones at post-ESWL ERP. Those who had an MPD stricture underwent balloon dilation of the stricture. In patients with impacted stones at the MPD, laser lithotripsy under peroral pancreatoscopy was performed. Patients in whom ERP after pancreatic stone treatment showed a poor excretion of contrast agents because of MPD stricture underwent pancreatic duct stenting. Patients who had MPD stricture but a good excretion of contrast agents did not undergo pancreatic duct stenting. We used 7F, 8.5F, and 10F plastic stents. The stents were changed every 3–6 months, but were not replaced if the strictures were found to have improved on ERP.

**Additional treatment.** The patients who felt pain after the initial therapy underwent additional treatment. All the patients underwent conservative therapy, and if they did not respond to conservative therapy, ESWL and endoscopic treatment was repeated.

### Evaluation of Clinical Symptoms

Clinical data were collected until June 2004. On their first visit to outpatient clinics, patients were interviewed by doctors regarding the presence of pain, the use of analgesics, and previous hospitalizations. These results were included in the clinical notes. When clinical testing for a patient (includ-

ing blood test, ultrasound, computed tomography, and endoscopy) showed that the cause of pain was unrelated to the pancreas, the patient was excluded from the group assessed for remaining pain. During the follow-up period, the patients were requested to visit the clinic every 6 months. Pain scores were determined in August 2004 based on those clinical records.

Pain was assessed retrospectively according to a 4-grade scale: none, mild (no use of analgesics, including discomfort), moderate (requiring analgesics), and severe (requiring hospitalization). Remaining pain was moderate or severe, and pain relief was defined as none or mild pain. Pain relapse was defined as moderate or severe pain that appeared after pain relief had been obtained.

N-benzoyl-L-tyrosyl-paraaminobenzoic acid (BT-PABA) test was used to evaluate pancreatic exocrine function. N-benzoyl-L-tyrosyl-paraaminobenzoic acid is administered in this test, and Chymotrypsin cleaves N-benzoyl-L-tyrosyl-paraaminobenzoic acid, yielding p-aminobenzoic acid, which is absorbed and can be measured in urine. Diabetes was evaluated according to the American Diabetes Association.<sup>10</sup> Post-ERCP and ESWL pancreatitis was defined according to consensus criteria.<sup>11</sup>

### Follow-up Evaluation

For short-term results, stone removal, pain relief, complete removal of stones as a prognostic factor, and complications were evaluated in all cases.

Long-term results were assessed in those patients who were followed-up for 3 years or more after the initial therapy. Pain relief, pain relapse as a prognostic factor, pancreatic function, and survival rate were evaluated. The effectiveness of pancreatic stenting also was evaluated in patients with an MPD stricture. Pain was assessed by interview at several time points: 1 year before treatment, and 1 year, 1–2, 2–3, 3–5, 5–7, and 7–10 years after treatment.

### Statistical Analysis

The results are presented as the mean value  $\pm$  SD. For the statistical analysis of quantitative parameters, the  $\chi^2$  test or the Fisher exact test was used. The Mann–Whitney *U* test was used to compare the difference between 2 groups. The Wilcoxon paired signed-rank test was used to compare the change in each group. To determine the risk factors for pain relapse, we used the Cox proportional hazards regression model. For the analysis of long-term results after successful or unsuccessful treatment and survival rates, we used Kaplan–Meier curves and the log-rank test. A *P* value of less than .05 was considered statistically significant.

## Results

### Short-term Results

Fragmentation of the stones was achieved in 113 patients (96.6%) and complete removal of stones was achieved in 65 patients (55.6%). Table 2 shows technical and clinical results. A total of 114 patients (97.4%) had

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