Extracorporeal shock wave lithotripsy is a safe and effective treatment for pancreatic stones coexisting with pancreatic pseudocysts CME

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Background and Aims: We aimed to investigate outcomes of pancreatic extracorporeal shock wave lithotripsy (P-ESWL) for the removal of large pancreatic stones coexisting with pancreatic pseudocysts (PPCs) in chronic pancreatitis (CP).

Methods: This is a prospective study performed in CP patients with at least 1 stone (≥5 mm). Patients were divided into the PPC group (stones coexisting with PPCs) or the control group (stones alone). Patients were initially subjected to successive P-ESWL treatments, followed by ERCP. Primary outcomes were P-ESWL adverse events, and secondary outcomes were stone clearance, long-term pain relief, improved quality-of-life scores, and PPC regression.

Results: A total of 849 patients (59 in the PPC group and 790 in the control group) was subjected to P-ESWL between March 2011 and October 2013. Occurrences of P-ESWL adverse events were similar between the PPC group and the control group (11.86% vs 12.41%, $P = .940$). After the treatment of initial P-ESWL combined with ERCP, the complete, partial, and nonclearance of stones occurred in 67.24%, 20.69%, and 12.07%, respectively, of patients in PPC group, with no significant difference from the control group (complete, partial, and nonclearance: 83.17%, 10.40%, and 11.39%, respectively; $P = .106$). Fifty-five of 59 patients (93.22%) with PPCs were followed for a median period of 21.9 months (range, 12.0-45.1). PPCs disappeared in 56.36% (31/55) and 76.36% (42/55) of patients after 3 months and 1 year of follow-up visits, respectively. Moreover, complete and partial pain relief were achieved in 63.64% (35/55) and 25.45% (14/55) of patients, respectively. The scores for quality of life ($P < .001$), physical health ($P < .001$), and weight loss ($P < .001$) improved.

Conclusions: In our multispecialty tertiary center, initial P-ESWL followed by ERCP was safe in patients with coexisting pancreatic stones and PPCs and effective for stone clearance, main pancreatic duct drainage, and pain relief. (Gastrointest Endosc 2016;84:69-78.)

Abbreviations: CP, chronic pancreatitis; SF-36, 36-Item Short-Form; MPD, main pancreatic duct; P-ESWL, pancreatic extracorporeal shock wave lithotripsy; PPC, pancreatic pseudocyst.

DISCLOSURE: *The following authors received research support for this study from the National Natural Science Foundation of China: Z. Liao (grant no. 81270541) and L.-H. Hu (grant nos. 81100316 and 81470883); from the Shanghai ChenGuang Program: L.-H. Hu (grant no. 12CG40); and from the Shanghai Rising Star Program: Z. Liao (grant no. 13QA1404600). All other authors disclosed no financial relationships relevant to this publication.*

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0016-5107
http://dx.doi.org/10.1016/j.gie.2015.10.026

Received May 21, 2015. Accepted October 13, 2015.

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Approximately 50% of patients with chronic pancreatitis (CP) have developed pancreatic stones,[1] and about 20% to 40% of patients with CP have developed pancreatic pseudocysts (PPCs)[2] during the course of disease. The coexistence of PPCs and large stones, a condition mainly associated with increased pressure in the pancreatic duct caused by stones and/or stricture, is commonly observed. This complicated condition is possibly closely related to chronic pain and recurrent attacks of acute abdominal pain and poses clinical challenges, especially because treatment options have not been included in any guideline and consensus on CP.[3-7]

Drainage of the main pancreatic duct (MPD) with ERCP alone is often unsuccessful; thus, pancreatic extracorporeal shock wave lithotripsy (P-ESWL), an effective and safe microinvasive method used to fragment large pancreatic stones before ERCP, is needed to facilitate stone clearance and improve the success rate of MPD drainage via ERCP.[2,8-11] However, the safety of initial P-ESWL followed by ERCP in patients with PPCs remains to be confirmed considering the risks of adverse events directly or indirectly related to PPC.

A multistep strategy that involves EUS-guided PPC drainage and stent implantation/removal is usually needed before P-ESWL and ERCP to drain PPCs and remove stones. However, this multistep strategy renders high cumulative risks and low success rates.[6,12-14] Surgery is occasionally performed as the primary choice or as a complementary method, although these procedures are highly invasive.[4,15-17] Initial P-ESWL combined with ERCP, a simplified microinvasive method that requires a short duration of hospitalization, is a potential strategy. However, the safety and efficacy of this approach is yet to be confirmed.

Only a few studies on P-ESWL involve patients with PPC; thus, insufficient information is available about the possibility of PPC-related adverse events,[9,18] such as pseudoaneurysm,[19] rupture, and bleeding. The few studies that include PPC cases presented no specific safety evaluation of these patients.[19-21] In addition, P-ESWL in patients with PPCs has not been indicated in any guideline and consensus on CP.[3-7] Theoretically, P-ESWL should be safely used for stone pulverization in patients with PPCs because shock wave transmission through a PPC consumes a low amount of energy. This article presents the results of initial P-ESWL followed by ERCP in CP patients with coexisting large pancreatic stones and PPCs to evaluate the safety and effectiveness of this strategy in such patients.

METHODS

This research was conducted to evaluate the prospective outcome of P-ESWL in patients with PPCs within the specified period. Written informed consent was obtained from each patient, and this study was approved by the Ethics Committee of Changhai Hospital.

Patients

CP was diagnosed mainly through CT, magnetic resonance imaging (MRI), or EUS in accordance with the Asia-Pacific consensus.[3] P-ESWL was recommended in patients with painful CP and at least 1 pancreatic stone with a diameter $\geq$ 5 mm. Patients suspected with or diagnosed with malignancy, pancreatic ascites, and pregnancy were disqualified for P-ESWL. Consecutive CP patients who were subjected to P-ESWL from March 2011 to October 2013 were included. A PPC is a collection of fluid in the pancreatic or peripancreatic area with a well-defined wall containing no visible solid debris or recognizable parenchymal necrosis.[2] All patients included in this study were routinely evaluated by contrast-enhanced CT scan before P-ESWL; in addition, 3-dimensional imaging stone reconstruction and curved planar reformatted imaging of the MPD were conducted[22] (Fig. 1).

Treatment strategy

In this study patients were initially treated with P-ESWL followed by ERCP. P-ESWL was performed by 2 gastroenterologists (L.H.H. and B.Y.) using an electromagnetic lithotripter (Compact Delta II; Dornier Medical Technology, Wessling, Germany) with a bidimensional fluoroscopic targeting facility. In each patient a P-ESWL session was repeated on consecutive days until the stones were fragmented down to a diameter $\leq$ 3 mm. Intravenous sedation (a combination of flurbiprofen and remifentanil) was administered to induce analgesia during the procedure. Meanwhile, shock waves per session were limited to a maximum of 5000 shocks. During the procedure an intensity ranging from 1 to 6 was used with a frequency of 60 to 120 shocks per minutes. Each session lasted for 60 to 90 minutes. After the last P-ESWL session was completed, ERCP was performed to remove stone fragments and to treat pancreatic duct stenosis. Pancreatic stents (5F-10F) were inserted into patients with dominant MPD strictures and/or pseudocysts that required a stent for drainage.[2] The inserted stent was removed or replaced with a larger stent after a year.[2]

For patients with PPC, a pancreatic surgery team stood by while the study was ongoing. Transcutaneous drainage was performed before P-ESWL in patients with palpable masses of PPCs. In addition, shock wave intensity was fixed at level 6, and post-ESWL ERCP was performed 48 hours after the last P-ESWL session was completed.

Baseline data collection

The demographic data and disease course of CP, including onset, manifestations, diagnosis, previous treatments, and assessment of quality of life, were recorded in detail. A brief assessment of quality of life was based on a scale of 1 to 10, wherein 1 represents the lowest quality of life and 10 represents the best quality of life.[8] Additionally, quality-of-life scale scores, as a more objective

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