

Pancreatotomy-Directed Electrohydraulic Lithotripsy for Pancreatic Ductal Stones in Painful Chronic Pancreatitis Using SpyGlass™

Short title: EHL for Pancreatic Ductal Stones

Noor LH Bekkali¹, MD, PhD; Sam Murray¹, MD; Gavin J Johnson¹, MD; Steven Bandula², MD; Zahir Amin², MD; Michael H Chapman¹, MD, PhD; Stephen P Pereira¹, MD, PhD; George JM Webster¹, MD.

1. Pancreatobiliary Medicine Unit, University College London Hospitals, London, UK
2. Radiology department, University College London Hospitals, London, UK

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Corresponding author:

Dr. George Webster

University College London Hospitals

250 Euston Road

NW1 2PG London

United Kingdom

george.webster@uclh.nhs.uk

Tel: 0203 447 9229

Fax: 0203 447 9218

Objectives

Painful chronic pancreatitis (CP) is often associated with main duct obstruction due to stones. Approaches to management are challenging, including surgery, extracorporeal shock wave lithotripsy, or endoscopic approaches. Here we report our experience of pancreatoscopy + electrohydraulic lithotripsy (EHL) for pancreatic duct (PD) stones using SpyGlass.

Methods

We retrospectively audited the use of SpyGlass (Legacy & DS™) + EHL. Indication, procedural details, and clinical outcome were assessed.

Results

118 SpyGlass + EHL procedures for stones were performed, of which 8 (7%) for pancreatic stones, in 6 patients (3 female, mean age 45 years \pm 7 years). All patients had painful CP, with radiological evidence of a dilated PD, and main duct stone disease. Surgical options had been considered in all cases. Stone fragmentation and PD decompression was achieved in 83% (n=5) without complications. Two patients required two EHL procedures to achieve clearance. One patient failed clearance, pancreatoscopy revealed a stone in the adjacent parenchyme and not in PD. All patients with successful EHL had pain relief/marked improvement at clinical review (mean follow-up 2.7 \pm 1.1 years).

Conclusion

Pancreatoscopy + EHL may have a valuable role in treating obstructing pancreatic ductal stones, possibly avoiding the need for surgery in some patients.

Keywords:

Chronic pancreatitis, calcific pancreatitis, pain, EHL, ERCP, pancreatoscopy.

Introduction

Pain in chronic pancreatitis is often multifactorial. ¹ A large multicenter study of 1000 patients with chronic pancreatitis revealed obstruction of the main pancreatic duct (MPD) in 50%, due to strictures and stones in 32%, and stones alone in 18%. ² As painful chronic pancreatitis may be associated with MPD obstruction due to stones, pancreatic duct therapy is usually considered as a means to improve pain control. However, approaches to manage MPD stones, including extracorporeal shock wave lithotripsy (ESWL), ERCP with stone clearance/ductal stenting, or surgery (e.g. pancreaticojejunostomy) are challenging. Surgery has been shown to be more effective than endoscopic approaches. ³ However, pain relief with surgery is rarely achieved if pain control has not been gained with endoscopic duct decompression, and many patients prefer an attempt at non-surgical approaches before embarking on surgery. As traditional methods have their limitations, newer techniques, such as electrohydraulic lithotripsy (EHL) with directed visualization using pancreatoscopy, are considered. Cholangioscopy using the SpyGlass (Boston Scientific, Mass., Legacy & DS™) system is increasingly used for treating difficult bile duct stones, with stone clearance in 90-100% and pain relief in >90%. ^{4,5}

In a recent overview by the ESGE in 2015, peroral cholangioscopy was included in the treatment options for bile duct stones, ⁶ but the ESGE guidelines from 2012 for pancreatic duct stones did not specify a role for EHL in the treatment for pancreatic stones in CP. ¹ In 2015 a new single operator cholangiopancreatocopy system was introduced, SpyGlass DS™ which included improved operating characteristics, compared with the previous system (SpyGlass legacy), including a x4 greater image resolution (240000 pixels)

Here we report our 3-year single center experience of SpyGlass (Legacy and DS™) pancreatoscopy and EHL for pancreatic duct (PD) stones.

Materials and Methods

Study period

We retrospectively audited our unit's use of SpyGlass (Legacy & DS™) EHL in the period February 2013- April 2016, with a focus on those patients undergoing pancreatic EHL.

Study population

Patients fulfilled the M-ANNHEIM criteria for the diagnosis of chronic pancreatitis.⁷ All patients who were referred to our tertiary center for pain management related to chronic pancreatitis from 2013-2016 were included in the study. All patients failed medical therapy and had previously undergone pancreatic duct stenting without longstanding pain relief. They were all discussed in benign multidisciplinary hepatopancreatobiliary meeting attended by specialist pancreatico-biliary surgeons, radiologists and gastroenterologists, with an agreed decision to discuss with the patient the option of performing endoscopic treatment using EHL as the next step, or the option of surgery.

Pancreatic endoscopic therapy

Dependent on the patient's previous tolerance of intravenous sedation for ERCP, either conscious sedation or deep propofol sedation was chosen to sedate the patients. All patients underwent ERCP combined with either SpyGlass legacy or SpyGlass DS (the latter available since June 2015), allowing direct PD visualization and the application of EHL to stones by one trained operator (GJW). EHL was administered through a 1mm probe passed down the working channel of the SpyGlass scope, with shocks applied at 80-100J, 10-20 shocks per pulse, from a commercially available generator (Northgate Autolith® Intracorporeal Electrohydraulic Lithotripsy iEHL Generator (9-201-00) (Elgin, IL, USA)).

Stone fragmentation was assessed directly using the SpyGlass, and via fluoroscopy. Fragmented stones were trawled using 8.5-12mm extraction balloons. Prophylactic pancreatic stents (5-7Fr, 5-7 cm) were placed when indicated.

Outcome

Patients' baseline characteristics, procedural details, stone size and density (Hounsfield Unit (HU) on CT imaging), clinical outcome and follow-up were assessed.

Main pancreatic duct stone clearance was defined as successful stone fragmentation and removal with an extraction balloon. Duct decompression was defined as decrease in MPD size on follow-up imaging.

Results

A total of 118 SpyGlass procedures combined with EHL were performed; 7% (n=8) for main pancreatic duct (MPD) stones in six patients (3 female, mean age 45 years \pm 7 years). All patients had radiological evidence of a dilated pancreatic duct, and main duct stone disease within 2 cm of the ampulla. Prior to EHL all patients had undergone endoscopic attempts at stone clearance, including pancreatic sphincterotomy and at least one previous pancreatic duct stenting trial. Six procedures (see table 1), were performed with SpyGlass legacy and two procedures using SpyGlass DS . The mean procedural time was 48 \pm 15 minutes. For the pancreatograms and pancreatoscopic views, see figure 1, and Supplemental Digital Content 1 for a video of the pancreatoscopic procedure.

Mean size of dominant intraductal stones was 10.6 \pm 3.9 mm, with stone density 1235 \pm 606 HU. Stone fragmentation, clearance, and duct decompression, were achieved in 83% (5/6) of patients. Two patients required two EHL procedures to achieve clearance. In the patient with failed clearance, pancreatoscopy revealed that the stone (with low stone density at 197 HU) was not in the main duct, but in the adjacent parenchyma/side branch, but with an associated stricture. There were no procedure-related complications.

All patients with successful EHL had pain relief/marked improvement at clinical review (mean follow up 2.7 \pm 1.1 years). On imaging, MRCP and/ or CT, all patients had decreased PD size. Two patients needed significantly less opiate analgesia compared to pre-procedure and the 3 others who were successfully treated didn't require any analgesia.

Discussion

In this study we have demonstrated that in selected patients with an obstructing stone in the main pancreatic duct, pancreatoscopy and visually directed electrohydraulic lithotripsy (EHL) may facilitate successful stone clearance and duct decompression, leading to pain relief and avoidance of surgery. European guidelines suggest ESWL as a first line treatment when conventional ERCP fails to remove a MPD stone.¹ In biliary stones ESWL, first reported in 1989, is successful in clearing 84-89% of

stones, with cholangitis as the main adverse effect.^{8,9} Recently, a prospective study including 214 chronic pancreatitis patients showed similar MPD clearance rates, with a 4% complication rate reported.¹⁰ This study also showed that more than 50% of patients needed at least two ESWL sessions and up to 11% needed more than 4 sessions prior to removal of stones with ERCP.

In the UK, access to ESWL is limited. Patients who undergo ESWL need admission after the procedure and an ERCP within 24-48 hours according to the local protocol), whereas pancreatoscopy combined with EHL is a day case requiring less than 4 hours in total. Another advantage of direct pancreatoscopy is that both, ERCP and lithotripsy are performed in the same session, allowing both stone fragmentation and removal. ERCP also allows the treatment of PD strictures, as outlined in a recent report by Shin et al, where a fully-covered metal stent was inserted to dilate the stricture following stone removal with EHL.¹¹

Lastly, although this study and other studies did not show any SpyGlass/EHL related complications, larger numbers are needed to further compare with ESWL data.^{11,12}

Successful pancreatic duct stone removal with EHL in this study was 83%, and only failed in one patient where the stones were found to be in the side-branch rather than the MPD. As ESWL has poor success rates in patients with very dense, hard, stones (attenuation value of >900 HU) and high BMI values¹³, pancreatoscopy and visually-directed EHL may have a particular role in MPD stones located in head of pancreas who fail treatment following conventional ERCP. To further emphasize the latter, this current study has shown that despite a mean Hounsfield score of over 1200HU, EHL was still effective in fragmenting stones. Supporting this, Ito and colleagues showed that EHL was effective where ESWL had failed.¹⁴ Nevertheless, in a recent clinical practice study from Japan to treat MPD stones, ESWL was recommended as an option, but not EHL.¹⁵

The limitations of this current study are, of course, its retrospective nature and small procedure numbers to date. However, it provides an overview of early experiences with EHL for pancreatic stones using pancreatoscopy. More numbers and studies are needed to further assess the advantages of EHL over ESWL.

Conclusion

ERCP using SpyGlass™ pancreatoscopy + EHL has a role to play in the management of difficult obstructing pancreatic stones in painful chronic pancreatitis, particularly in the setting of 'hard' stones (Hounsfield Unit > 1000), in whom other non-surgical approaches are unlikely to be successful.

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Figure 1. Main pancreatic duct stones, (A) pre- and (B) post EHL and (C) pancreatoscopic views.