National Institute for Health and Care Excellence

IP1781 Electrohydraulic lithotripsy for difficult-to-treat bile duct stones

IPAC date: 11 February 2021

Com. no.	Consultee name and organisation	Sec. no.	Comments	Response Please respond to all comments
1	Consultee 1 NHS professional British Society of Gastroenterology	**1.1 and 1.4**	Thank you for asking me to comment on this IPG. I'm unsure if I am allowed to comment, as I was the expert assessor. I've agreed a response with [redacted] [consultee 2] and we've both commented. 1. We agree that the use of cholangioscopy-EHL with special arrangements would be an appropriate category of use, limited to specialist centres.	Thank you for your comment.
2	Consultee 1 NHS professional British Society of Gastroenterology	**3.1**	2. We also both feel that the use of many of the historical publications using PTC and mother and baby scope directed EHL is inappropriate in the assessment of this procedure. I did make this point at the meeting I had at NICE. A good example is a recently published study showing an increased stone clearance rate (McCarty et al Safety of Per-Oral Cholangioscopy with Intraductal Lithotripsy for Difficult Biliary Stones: A Systematic Review and Meta-Analysis. Endoscopy. 2020 Jun 16)	Thank you for your comment. The selection of studies met the inclusion criteria detailed in the overview (table 1, intervention: electrohydraulic lithotripsy) and was in line with the interventional procedures programme manual (section 9.2). Sections 3.5 and 3.7 specifically cover the evolving technique and the need for using the percutaneous approach. McCarty et al. (2020) has been added to the main extraction table.
3	Consultee 1 NHS professional	**3.1**	3. In particular the length of stay quoted in the historical literature is inconsistent with modern practice with length of stays currently at one-night post EHL.	Thank you for your comment.

© NICE 2021. All rights reserved. Subject to **Notice of rights**.

	British Society of Gastroenterology			The committee was aware of the length of stays in current practice and carefully considered both the practical information and the published evidence when making the recommendations.
4	Consultee 1 NHS professional British Society of Gastroenterology	**General**	4. We also both feel that it should be stated that the time taken for ERCP- cholangioscopy-EHL is longer than a standard ERCP.	Thank you for your comment. Relevant wording has been added to section 2.5, stating '*this procedure takes longer than a standard ERCP…*'
5	Consultee 2 NHS professional British Society of Gastroenterology	**3.1**	I have considerable experience of electrohydraulic lithotripsy for difficult to treat stones and am keen to comment and contribute to the excellent report by NICE. I perform electrohydraulic lithotripsy for difficult to treat bile duct stones using cholangioscopy approximately 100 times a year and have done so for the last 10 years. I agree with the draft recommendations but would wish to raise a number of points. The clinical and safety data reported generally refers to historical techniques which are now rarely used. Single operator cholangioscopy is now the most widely used technique in the UK and Europe for delivering electrohydraulic lithotripsy (EHL). This difference in technique and approach unavoidably results in a different balance of safety and adverse events. For example, a percutaneous procedure is understandably associated with a very low pancreatitis rate and increased risks of bleeding and leaks, compared with the data on single operator cholangioscopy (e.g. Brewer-Gutierrez 2018 data. The paper by Arya et al (2004) refers to mother-baby cholangioscopy techniques which are now not used in the UK. Other studies including Cannavale (2015) and Wen (2020) refer to percutaneous transhepatic techniques, which are both much less frequently performed and carry a	Thank you for your comment. The selection of studies met the inclusion criteria detailed in the overview (table 1) and was in line with the interventional procedures programme manual (section 9.2). Additional wording has been added to section 3.5 to reflect different techniques resulting in different outcomes: 'The committee was informed that the technique is evolving *and different techniques may have different efficacy and safety profiles*.'

© NICE 2021. All rights reserved. Subject to **Notice of rights**.

			significantly higher (and different) complication rate to the more standard retrograde ERCP approach using cholangioscopy. In our unit, having performed more than 400 electrohydraulic lithotripsy procedures via ERCP we have not seen a significantly higher complication rate compared with conventional ERCP without EHL for difficult bile duct stones.	
6	Consultee 2 NHS professional British Society of Gastroenterology	**3.1**	The data on length of hospital stays also refers entirely to percutaneous procedures. In the vast majority of cases in the UK electrohydraulic lithotripsy, administered via single operator cholangioscopy, would be a day case or a single overnight stay procedure.	Thank you for your comment. The 'efficacy summary' section covered 2 studies (Adamek 1995; 1996) which used peroral cholangioscopy-guided electrohydraulic lithotripsy rather than the percutaneous approach. The committee was aware of the length of stays in current practice and carefully considered both the practical information and the published evidence when making the recommendations.
7	Consultee 2 NHS professional British Society of Gastroenterology	**General**	An important consideration that has not been presented in the draft is the alternatives to electrohydraulic lithotripsy for difficult to manage bile duct stones. By definition in these patients a conventional ERCP has been unsuccessful. We know that from NHS HES data the burden on patients and health services of failed stone clearance using a conventional ERCP is very significant, with 52% of all ERCPs for stones being repeat procedures. From this national data we have seen that patients may have multiple repeat ERCPs, often without success, without the	Thank you for your comment. Interventional procedures guidance is not comparative. This guidance is for 'electrohydraulic lithotripsy for difficult-to-treat bile duct stones' but not for the alternatives.

© NICE 2021. All rights reserved. Subject to **Notice of rights**.

			availability or use of electrohydraulic lithotripsy (Martin H et al Gastrointest Endosc 2020:91;AB376). Surgery for difficult bile duct stones is complex and carries a significant risk. The published data and personal experience suggest that bile duct surgery for difficult stones is very rarely necessary if electrohydraulic lithotripsy with cholangioscopy is available.	
8	Consultee 2 NHS professional British Society of Gastroenterology	**1.2**	I completely agree that decisions with regards to patient selection for electrohydraulic lithotripsy should be decided through a specialist multidisciplinary team, with experience of the procedure and the alternatives. Audit of outcomes following ERCP, including those involving electrohydraulic lithotripsy should be required of all units involved in these procedures.	Thank you for your comment. Section 1.2 covers the need for auditing this guidance – 'electrohydraulic lithotripsy for difficult-to-treat bile duct stones'.
9	Consultee 2 NHS professional British Society of Gastroenterology	**3.4**	The report mentioned that patient feedback was sought but not received. If the committee wished to pursue patient feedback on their experience of electrohydraulic lithotripsy for difficult to treat bile duct stones, we would be delighted to help with this.	Thank you for your comment. NICE followed its standard process to seek information about the impact of both the condition and the procedure on patients or their carers before the Committee meeting. Unfortunately, no feedback was received. According to the IP manual, 'To maintain timeliness, NICE does not delay guidance development if patient questionnaires are not available for a procedure.' We note the offer from the specialist society to assist in seeking patient feedback and will approach the society about this for future relevant procedures, and when the current procedure is reviewed.
10	Consultee 3 company Boston Scientific	**1.1**	We would like to as the committee to reconsider its decision to place this procedure in special arrangements. We believe its evidence base and position in the current patient pathway warrant a decision of standard arrangements.	Thank you for your comment. The committee has considered this comment but decide not to change the guidance.

© NICE 2021. All rights reserved. Subject to **Notice of rights**.

			It is an intervention that is now well established as standard of care in the NHS within specialist centres, in difficult to treat bile duct stones. It is used to treat a cohort of patients that have limited treatment alternatives and one concern is that a special arrangements ruling may be used by payers/decision makers to limit access and reimbursement of this technology. Boston Scientific supplies the single-operator per-oral cholangioscopy technology (SOPOC); that allows the user to access the biliary system and directly visualise the ductal stones whilst EHL therapy is administered. The EHL catheter is passed through the working channel of the SOPOC. We believe the following helps demonstrate the established position of this technology in the patient pathway. • SOPOC is provided to approximately 35 centres in the UK (confidential) • SOPOC has been a recognised category on the High Cost Tariff Excluded Device list for approximately 10 years • SOPOC was subject of a NICE MIB in 2015 (Ref 1) • Health Technology Wales assessed SOPOC via a HTA process in 2020 and endorsed it as a second line therapy after failed ERCP in both a diagnostic and therapeutic capacity (Ref 2) • Haute Autorité de Santé assessed Spyglass DS (Brand name for SOPOC) in Oct 2020 and endorsed its use as second line therapy after failed ERCP in both a diagnostic and therapeutic capacity (Ref 3) • ESGE recommends the use of cholangioscopy-assisted intraluminal lithotripsy (electrohydraulic or laser) as an effective and safe treatment of difficult bile duct stones (Ref 4)	Ref 1: There was 1 study (Maydeo et al. 2011) which was relevant to this procedure and was included in Veld (2018) in the main extraction table. Ref 2 has been added to the overview (existing assessments of this procedure). Ref 3 - non-English-language article - did not meet the inclusion criteria. Ref 4 and 5: The BSG and ESGE guidelines were included in the overview (existing assessments of this procedure).

© NICE 2021. All rights reserved. Subject to **Notice of rights**.

			• BSG 2017 guidelines recommend that cholangioscopy-guided EHL or LL be considered when other endoscopic treatment options fail to achieve duct clearance (Ref 5) References 1. NICE MIB 2016: The SpyGlass direct visualisation system for diagnostic and therapeutic procedures during endoscopy of the biliary system: Retrieved from: https://www.nice.org.uk/advice/mib21/resources/the-spyglass-direct-visualisation-system-for-diagnostic-and-therapeutic-procedures-during-endoscopy-of-the-biliary-system-pdf-63499040090053 2. Heath Technology Wales 2020: Single-operator per-oral cholangioscopy for the evaluation and treatment of hepato-biliary-pancreatic disorders Retrieved from: https://www.healthtechnology.wales/wp-content/uploads/2019/11/EAR015-SOPOC.pdf 3. Haute Autorité de santé 2020: Retrieved from: https://www.has-sante.fr/jcms/p_3169456/fr/spyscope-ds 4. Endoscopic management of common bile duct stones: European Society of Gastrointestinal Endoscopy (ESGE) guideline – European Society of Gastrointestinal Endoscopy (ESGE). Retrieved from: https://www.esge.com/endoscopic-management-of-common-bile-duct-stones-esge-guideline/ 5. Williams E, Beckingham I, El Sayed G, Gurusamy K, Sturgess R, Webster G, Young T. Updated guideline on the management of common bile duct stones (CBDS). Gut. 2017 May 1;66(5):765-82."	
11	Consultee 3 company Boston Scientific	**overview**	Evidence review feedback We also encourage the committee to consider the following points regarding the evidence assessment.	Thank you for your comment. McCarty et al. (2020) has been added to the main extraction table.

© NICE 2021. All rights reserved. Subject to **Notice of rights**.

			• A recent meta-analysis published after the literature search was concluded by NICE, helps exemplify how the technology has evolved since its inception and shows some of the limitations of the older papers currently within the overview. McCarty T, Gulati R, Rustagi T. Efficacy and Safety of Per-Oral Cholangioscopy with Intraductal Lithotripsy for Difficult Biliary Stones: A Systematic Review and Meta-Analysis. Endoscopy. 2020 Jun 16 Within this analysis they assessed efficacy (via overall fragmentation and single session fragmentation) and adverse events of different per-oral cholangioscopy technologies. As stated earlier; EHL is delivered under direct visualisation. Originally this was achieved using a mother-daughter system, this was superseded by single operator cholagioscopy and more recently by a second generation of this technology called Spyglass DS which is now standard of care in the UK, for delivering EHL therapy. The improvement in pooled rates of both efficacy and safety are reported and highlighted below. It clearly demonstrates how efficacy and safety have improved as the technology has evolved. We urge the committee to consider this when assessing the evidence and encourage them to consider a more recent evidence base alongside the current publications being assessed within the overview. Mother – Daughter system Pooled rate (95% CI) Overall Fragmentation: 89.3% (81.5-94.1) Single session Fragmentation: 66.8% (54.0–77.5) Adverse events: 13.5% (8.5–20.7)	The BSG and ESGE guidelines were included in the overview (existing assessments of this procedure). Health Technology Wales (2020) has been added to the overview (existing assessments of this procedure).

© NICE 2021. All rights reserved. Subject to **Notice of rights**.

			First Generation direct visualisation single-operator cholangioscopy Overall Fragmentation: 90.1% (82.1-94.6) Single session Fragmentation: 80.6% (65.5-90.1) Adverse events: 9.8% (6.5-14.4) Second Generation direct visualisation single-operator cholangioscopy Overall Fragmentation: 95.0% (92.2-96.8) Single session Fragmentation: 82% (74.9-87.5) Adverse events: 4.6% (3.1-6.9) In addition, we would also like to highlight the following statements concerning safety reviews 1. Health Technology Wales concluded in section 7 of their evidence review document: Overall, the comparative studies showed similar or reduced adverse event rates with SOPOC compared to other modalities. 2. BSG guidelines stated: Cholangioscopy is safe but cholangitis has been reported to occur in up to 9% of patients, necessitating the use of prophylactic antibiotics. Otherwise complications are comparable to conventional ERCP. Cholangioscopy-guided lithotripsy is an important advance in the management of CBDS and is a useful strategy for patients in whom standard techniques fail. 3. ESGE: Cholangioscopy-assisted intraluminal lithotripsy (electrohydraulic or laser) as an effective and safe treatment of difficult bile duct stones"	
12	Consultee 3 company	**Overview**	We would also ask the committee to consider our concerns regarding some of the evidence base used within the	Thank you for your comments.

© NICE 2021. All rights reserved. Subject to **Notice of rights**.

	Boston Scientific		overview which no longer reflects current standard of care in the UK. Specifically, 2 papers that are >20 years old; namely Adamek et al (1995) and Adamek et al (1996). Neither consider technologies that are reflective of current practice. These papers are also used to reference topics such as length of stay which is significantly higher (15.5 days) than current care pathways. In addition we would also highlight that several papers used in the assessment, utilise the mother + baby scope technique which is no longer routinely used in UK practice; namely Ayra et al (2004), Wen et al (2020), Cannavale et al (2015) and Adamek et al (1995 and 1996). Whilst we acknowledge these results can be considered within this review, we believe the age and relative disadvantages of these studies should be taken into account. We would also encourage greater consideration in the review for more recent papers that reflect current standard if care. To supplement or replace elements of the evidence base with would like to suggest the following papers for consideration. Papers not in current review Jin Z, Wei Y, Tang X, Shen S, Yang J, Jin H, Zhang X. Single-operator peroral cholangioscope in treating difficult biliary stones: A systematic review and meta-analysis. Digestive Endoscopy. 2019 May;31(3):256-69. Rationale: SLR and meta-analysis was not considered within the review. This analysis includes sub-group analysis	The selection of studies met the inclusion criteria detailed in the overview (table 1) and was in line with the interventional procedures programme manual (section 9.2). Additional wording has been added to section 3.5 to reflect different techniques resulting in different outcomes: 'The committee was informed that the technique is evolving *and different techniques may have different efficacy and safety profiles*.' Jin et al. (2019) and Mizrahi et al. (2018) have been added to the appendix. Turowski et al. (2018), Bokemeyer et al. (2019) and Maydeo et al. (2019) were included in the appendix.

© NICE 2021. All rights reserved. Subject to **Notice of rights**.

			of EHL delivered via SOPOC. It reported a pooled AE rate of 7.2% (95% CI 3.5-12.4%) Mizrahi M, Khoury T, Wang Y, Cohen J, Sheridan J, Chuttani R, Berzin TM, Sawhney MS, Pleskow DK. "Apple Far from the Tree": comparative effectiveness of fiberoptic single-operator cholangiopancreatoscopy (FSOCP) and digital SOCP (DSOCP). HPB. 2018 Mar 1;20(3):285-8. Rationale: Compares Spy 1st gen and Version 2 (current standard of care) in diagnostic and therapeutic applications. Cohort of 94 patients treated with EHL. Reports complication rate. Papers identified in the review but not considered in the final evidence assessment. Turowski F, Hügle U, Dormann A, Bechtler M, Jakobs R, Gottschalk U, Nötzel E, Hartmann D, Lorenz A, Kolligs F, Veltzke-Schlieker W. Diagnostic and therapeutic single-operator cholangiopancreatoscopy with SpyGlassDS™: results of a multicenter retrospective cohort study. Surgical endoscopy. 2018 Sep 1;32(9):3981-8. Rationale: Cohort of EHL patients, pooled complication rates. EHL delivered via SOPOC. Bokemeyer A, Gerges C, Lang D, Bettenworth D, Kabar I, Schmidt H, Neuhaus H, Ullerich H, Lenze F, Beyna T. Digital single-operator video cholangioscopy in treating refractory biliary stones: a multicentre observational study. Surgical Endoscopy. 2019 Jul 15:1-9. Rationale: EHL specific cohort with detail on AE's. EHL delivered via SOPOC	

© NICE 2021. All rights reserved. Subject to **Notice of rights**.

			Maydeo AP, Rerknimitr R, Lau JY, Aljebreen A, Niaz SK, Itoi T, Ang TL, Reichenberger J, Seo DW, Ramchandani MK, Devereaux BM. Correction: Cholangioscopy-guided lithotripsy for difficult bile duct stone clearance in a single session of ERCP: results from a large multinational registry demonstrate high success rates. Endoscopy. 2019 Oct;51(10):C4. Rationale: Cohort of EHL patients (n=39) and detail that reports on safety profile/AE's. EHL delivered via SOPOC"	

"Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees."

© NICE 2021. All rights reserved. Subject to **Notice of rights**.