



Topic Exploration Report

Topic explorations are designed to provide a high-level briefing on new topics submitted for consideration by Health Technology Wales. The main objectives of this report are to:

1. Determine the quantity and quality of evidence available for a technology of interest.
2. Identify any gaps in the evidence/ongoing evidence collection.
3. Inform decisions on topics that warrant fuller assessment by Health Technology Wales.

Topic:	SpyGlass for the management of hepatobiliary-pancreatic disorders
Topic exploration report number:	TER106

Introduction and aims

Health Technology Wales researchers searched for evidence on SpyGlass direct visualisation system for the management of hepatobiliary-pancreatic disorders. Spyglass is a single-operator visualisation and intervention system.

This topic aims to explore use of Spyglass during endoscopy of the biliary system, for disorders such as bile/pancreatic duct stones, pancreatitis and primary sclerosing cholangitis. It is intended to be used in secondary or tertiary settings, when standard techniques have failed or are inappropriate.

Summary of findings

Clinical evidence

A NICE Medtech Innovation Briefing (MIB21) was published in 2015, reporting small prospective single-arm cohort studies. NICE has confirmed that they do not have plans to develop guidance on this topic (personal communication, 2019).

A recent ECRI product brief was published on SpyGlass DS Direct Visualisation System for Evaluating and Treating Bile Duct Disorders (2018). This review included a total of eight studies, none of which had been referenced by the earlier NICE medtech innovation briefing. ECRI included one systematic review (Navaneethan), one RCT (Franzini), one non-randomised comparative study (Riditid), one diagnostic accuracy cohort study, and two abstracts. The ECRI authors excluded two systematic reviews - one (Sun 2015) because it contained the same primary sources as Navaneethan et al. (2015), and the other (Korrapati 2016) because it did not report outcomes for SpyGlass separately.

A new search of MEDLINE, based on the same search strategy used by NICE (but updated and filtered to include publications from 2014 onwards) identified three additional systematic reviews:

- Njei 2016 "Systematic review with meta-analysis: endoscopic retrograde cholangiopancreatography-based modalities for the diagnosis of cholangiocarcinoma in primary sclerosing cholangitis"
- Jin 2019 "Single-operator peroral cholangioscope in treating difficult biliary stones: A systematic review and meta-analysis"
- Kaura 2019 "Role of pancreatoscopy in management of pancreatic disease: A systematic review"

Another systematic review (with meta-analysis) protocol is registered on the PROSPERO database, and results are expected to be published this year.

Economic evidence

The update of the MIB search was filtered to identify three studies reporting economic findings:

- Njei 2017 "Cost utility of ERCP-based modalities for the diagnosis of cholangiocarcinoma in primary sclerosing cholangitis"
- Deprez 2018 "The economic impact of using single-operator cholangioscopy for the treatment of difficult bile duct stones and diagnosis of indeterminate bile duct strictures"
- Mellemgaard 2018 "Single-operator cholangioscopy is useful for visual assessment of bile duct pathology".

Areas of uncertainty

This report focused specifically on SpyGlass; a full appraisal of this topic may need to consider inclusion of generic "single operator" or "direct visualisation" procedures. Furthermore, both the NICE and ECRI reviews focused on biliary disorders; it is uncertain whether refining this topic to exclude hepatic and pancreatic problems would be more appropriate.

It is uncertain what the 'standard care' comparator would be when using SpyGlass in this setting, i.e. where standard techniques (such standard endoscopic retrograde cholangiopancreatography) have failed.

Conclusions

The likelihood of low numbers of eligible patients may mean that consideration of this procedure is not a high priority for Wales. Published evidence about SpyGlass focuses on procedural outcomes and diagnostic accuracy; longer-term patient-centred outcomes have not been reported. Identification of a suitable comparator may be challenging, and is likely to have a significant influence on any economic analyses.

Patients in Wales are currently only able to access treatment if an Individual Patient Funding Request (IPFR) is granted. This is not guaranteed, and can introduce a system delay (which may prove critical for patients with suspected malignancies). This geographical inequity, coupled with the availability of new evidence, suggests that a more detailed review may be warranted.

Brief literature search results

Resource	Results
HTA organisations	
Healthcare Improvement Scotland:	No relevant records were identified.
Health Technology Assessment Group	No relevant records were identified.
Health Information and Quality Authority	No relevant records were identified.
UK guidelines and guidance	
SIGN	No relevant records were identified.
NICE	<ul style="list-style-type: none"> • MIB21 (February 2015) The SpyGlass direct visualisation system for diagnostic and therapeutic procedures during endoscopy of the biliary system (this is the basis of the current HTW review). • MIB69 (June 2016) Cellvizio confocal endomicroscopy system for characterising pancreatic cysts (possible comparator).
Secondary literature and economic evaluations	
ECRI	<ul style="list-style-type: none"> • Custom product brief (inc. rapid review), last updated October 2018: SpyGlass DS Direct Visualization System (Boston Scientific Corp.) for Evaluating and Treating Bile Duct Disorders
Cochrane library	<ul style="list-style-type: none"> • No results for SpyGlass were identified. Cochrane review of comparator “ERCP vs intraoperative cholangiography for diagnosis of common bile duct stones” (Feb 2015)
Medline	<ul style="list-style-type: none"> • Jin Z, Wei Y, Tang X, et al. (2019). Single-operator peroral cholangioscopy in treating difficult biliary stones: A systematic review and meta-analysis. Digestive Endoscopy. 31(3): 256-69. doi: https://dx.doi.org/10.1111/den.13307 • Kaura T, Willingham FF, Chawla S. (2019). Role of pancreatoscopy in management of pancreatic disease: A systematic review. World Journal of Gastrointestinal Endoscopy. 11(2): 155-67. doi: https://dx.doi.org/10.4253/wjge.v11.i2.155 • Navaneethan U, Hasan MK, Lourdasamy V, et al. (2015). Single-operator cholangioscopy and targeted biopsies in the diagnosis of indeterminate biliary strictures: a systematic review. Gastrointestinal endoscopy. 82(4): 608-14.e2. doi: https://dx.doi.org/10.1016/j.gie.2015.04.030 • Njei B, McCarty TR, Varadarajulu S, et al. (2016). Systematic review with meta-analysis: endoscopic retrograde cholangiopancreatography-based modalities for the diagnosis of cholangiocarcinoma in primary sclerosing cholangitis. Alimentary Pharmacology & Therapeutics. 44(11-12): 1139-51. doi: https://dx.doi.org/10.1111/apt.13817 • Sun X, Zhou Z, Tian J, et al. (2015). Is single-operator peroral cholangioscopy a useful tool for the diagnosis of indeterminate biliary lesion? A systematic review and meta-analysis. Gastrointestinal endoscopy. 82(1): 79-87. doi: https://dx.doi.org/10.1016/j.gie.2014.12.021
Primary studies	
Medline	<ul style="list-style-type: none"> • Adler DG, Cox K, Milliken M, et al. (2015). A large multicenter study analysis of adverse events associated with single operator cholangiopancreatography. Minerva Gastroenterologica e Dietologica. 61(4): 179-84.

- Arnelo U, von Seth E, Bergquist A. (2015). Prospective evaluation of the clinical utility of single-operator peroral cholangioscopy in patients with primary sclerosing cholangitis. *Endoscopy*. 47(8): 696-702. doi: <https://dx.doi.org/10.1055/s-0034-1391845>
- Kurihara T, Yasuda I, Isayama H, et al. (2016). Diagnostic and therapeutic single-operator cholangiopancreatography in biliopancreatic diseases: Prospective multicenter study in Japan. *World Journal of Gastroenterology*. 22(5): 1891-901. doi: <https://dx.doi.org/10.3748/wjg.v22.i5.1891>
- Lee YN, Moon JH, Choi HJ, et al. (2019). Tissue acquisition for diagnosis of biliary strictures using peroral cholangioscopy or endoscopic ultrasound-guided fine-needle aspiration. *Endoscopy*. 51(1): 50-9. doi: <https://dx.doi.org/10.1055/a-0645-1395>
- Majeed A, Castedal M, Arnelo U, et al. (2018). Optimizing the detection of biliary dysplasia in primary sclerosing cholangitis before liver transplantation. *Scandinavian Journal of Gastroenterology*. 53(1): 56-63. doi: <https://dx.doi.org/10.1080/00365521.2017.1385840>
- Navaneethan U, Hasan MK, Kommaraju K, et al. (2016). Digital, single-operator cholangiopancreatography in the diagnosis and management of pancreatobiliary disorders: a multicenter clinical experience (with video). *Gastrointestinal endoscopy*. 84(4): 649-55. doi: <https://dx.doi.org/10.1016/j.gie.2016.03.789>
- Parbhu SK, Siddiqui AA, Murphy M, et al. (2017). Efficacy, Safety, and Outcomes of Endoscopic Retrograde Cholangiopancreatography With Per-Oral Pancreatography: A Multicenter Experience. *Journal of Clinical Gastroenterology*. 51(10): e101-e5. doi: <https://dx.doi.org/10.1097/MCG.0000000000000796>
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- Thosani N, Zubarik RS, Kochar R, et al. (2016). Prospective evaluation of bacteremia rates and infectious complications among patients undergoing single-operator choledochoscopy during ERCP. *Endoscopy*. 48(5): 424-31. doi: <https://dx.doi.org/10.1055/s-0042-101407>
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- Deprez PH, Garcés Duran R, Moreels T, et al. (2018). The economic impact of using single-operator cholangioscopy for the treatment of difficult bile duct stones and diagnosis of indeterminate bile duct strictures. *Endoscopy*. 50(2): 109-18. doi: <https://dx.doi.org/10.1055/s-0043-121268>
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Ongoing secondary research

PROSPERO database <i>Check for recent systematic review protocols.</i>	One protocol identified - the study is due to report in 2019 but is not yet available: Pittayanon and Kulpatcharapong (2018). Role of cholangioscopy in biliary stricture: a systematic review and meta-analysis. CRD42018113081 Available from: http://www.crd.york.ac.uk/PROSPERO/display_record.php?ID=CRD42018113081
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Ongoing secondary research

Other	Email enquiry sent to NICE mibs@nice.org.uk - no plan to update MIB. Via ECRI, found a review on the Boston Scientific website, summarising other published studies: http://www.bostonscientific.com/en-US/products/direct-visualization-systems/spyglass-ds-direct-visualization-system/clinical-data.html The search identified a potential source of expert insight (a user of the SpyGlass system): https://www.hse.ie/eng/services/list/5/kerryhealthservices/uhk/professionals/consultants/dr-israr-un-nabi.pdf
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Date of search:	May 2019
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Concepts used:	spyglass/OR single operator cholangioscopy/OR direct visualisation cholangioscopy
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