Technoleg Iechyd Cymru
Health Technology Wales

HEALTH TECHNOLOGY WALES (HTW) GUIDANCE 015 (January 2020)

Single-operator per-oral cholangioscopy for the evaluation and treatment of hepato-biliary-pancreatic disorders

HTW Guidance:

Single-operator per-oral cholangioscopy (SOPOC) shows promise for the evaluation and treatment of hepato-biliary-pancreatic disorders, but the evidence is insufficient to support routine adoption. SOPOC should instead be considered for the following populations:

1. For the diagnosis of indeterminate strictures, where conventional ERCP is inconclusive or inappropriate.
2. For the therapeutic removal of difficult bile duct stones, where conventional ERCP methods are unsuccessful or inappropriate.

SOPOC improves the accuracy of visualisation and diagnosis of indeterminate biliary strictures. HTW economic analyses show that use of SOPOC for diagnosis of indeterminate biliary strictures has the potential to be cost effective following inconclusive conventional ERCP or where ERCP is inappropriate. SOPOC is also effective at clearing difficult bile duct stones and HTW economic analyses show that it has the potential to be cost saving where conventional ERCP methods are unsuccessful.

Why did Health Technology Wales (HTW) appraise this topic?

Biliary tract disorders, such as bile duct stones, biliary tumours or lesions, can be challenging to access for diagnosis or therapy. This is normally achieved through endoscopic retrograde cholangio-pancreatography (ERCP) modalities, such as cytology brushing or balloon dilation but sometime these methods are unsuccessful or inappropriate.

Unlike conventional ERCP methods, single-operator per-oral cholangioscopy (SOPOC) is able to directly visualise the biliary system, collect biopsies for diagnosis and deploy laser-based stone removal.

This topic was suggested through the Welsh Health Specialised Services Committee (WHSSC). Current access to SOPOC for eligible Welsh patients is through individual patient funding requests and referral to NHS England.

The status of HTW guidance is that NHS Wales should adopt this guidance or justify why it has not been followed. HTW will evaluate the impact of its guidance.

Evidence Summary

We identified four systematic reviews: three evaluated SOPOC for diagnostic accuracy and one evaluated SOPOC for stone removal. Additional primary evidence was also identified that was published subsequent to these reviews.

We also found economic evidence that evaluated SOPOC in three studies. These were reviewed and, where appropriate, adapted to help inform HTW de novo economic analyses.

Diagnosis (indeterminate biliary strictures)

The three systematic review reported pooled diagnostic outcomes for SOPOC for various populations: diagnosis of all indeterminate strictures, diagnosis of cholangiocarcinoma, diagnosis of indeterminate strictures in people with primary sclerosing cholangiatis and diagnosis of cholangiocarcinoma in people with primary sclerosing cholangiatis. Pooled sensitivity was 60.1%-71.9% and specificity was 97.0%-99.1%. One review also included accuracy of SOPOC following inconclusive conventional ERCP, for diagnosis of all indeterminate strictures or cholangiocarcinoma; pooled sensitivity and specificity was 67.3%-74.7% and 93.3%, respectively.

HTW carried out a cost-utility analysis comparing SOPOC-guided biopsy against conventional ERCP-guided brushing or exploratory surgery. The analysis showed that, in patients with indeterminate biliary strictures, SOPOC guided biopsy was more costly and more effective than ERCP guided brushing with an estimated ICER of £29,810 per QALY. Since this value is above the commonly applied NICE threshold of £20,000 per QALY, SOPOC would not be considered cost-effective in this setting.

In patients with indeterminate strictures after ERPC, the analysis differed depending on what was used as the comparator. In comparison to repeat ERCP guided brushing, SOPOC guided biopsy resulted in an ICER of £6,317 per QALY, indicating that SOPOC guided biopsy would be cost-effective. In comparison to exploration surgery, SOPOC guided biopsy was found to be less costly and less effective. The resulting ICER of £38,665 per QALY indicates that SOPOC saves £38,665 for each QALY that is lost and as such would be deemed cost-effective using a threshold of £20,000 per QALY.

Therapy (difficult bile duct stone removal)

One systematic review was identified, which reported a pooled stone clearance rate of 94.3%. Comparative primary evidence was extracted from this review and showed that stone clearance with SOPOC was more effective than or at least as effective as other methods.

HTW carried out a cost analysis estimating the cost of SOPOC in comparison to conventional therapy for the removal of difficult bile duct stones. The analysis showed that the initial treatment cost is higher with SOPOC but that this cost increase is offset, at least partially, by cost savings accrued through a reduction in subsequent procedures (as a result of the superior stone clearance rate with SOPOC). Overall, in comparison to conventional therapy, first-line use of SOPOC was shown to result in a net cost increase of £380 to £570 per patient. When SOPOC was used after unsuccessful ERCP, it was shown to result in a cost increase of £79 or cost saving of £102 (depending upon assumptions around therapy used after unsuccessful stone clearance).

Refer to Evidence Appraisal Report 015 (EAR015) for a full report of the evidence supporting this Guidance.

Appraisal Panel considerations

- The Panel heard from the clinical experts that SOPOC provides easier, improved visualisation of the biliary system and confers several benefits over conventional ERCP, such as direct scopist evaluation, biopsy acquisition and more accurate stent placement.
- The Appraisal Panel were informed by clinical experts that the current use of SOPOC through NHS England is in cases where a conventional ERCP method has been used but has been unsuccessful in terms of providing a conclusive diagnosis or removing bile duct stones. One of the experts noted that for diagnosis of strictures, initial ERCP is not always possible and that ERCP findings may still be considered indeterminate where cytology brushings are negative (due to risk of false negatives). Therefore, experts suggested that SOPOC would also be beneficial in a first-line capacity for diagnosing indeterminate strictures.
- The Panel heard from clinical experts on the challenge faced by some people where initial ERCP for stone clearance is unsuccessful, who are not fit for surgery and therefore may go on to receive multiple further ERCP procedures. SOPOC would avoid repeating failed conventional ERCP methods for difficult bile duct stones.
- The expert also advised that using SOPOC for difficult bile duct stones would aid in reducing waiting list times and potentially relieve pressures on endoscopy services. The panel therefore considered that implementation of SOPOC may relieve some of the increasing pressures faced by endoscopy services, although limited by the proportion of patients within the indications.
- Overall, the Appraisal Panel concluded that there was sufficient clinical evidence for SOPOC for biliary disorders, and noted that the case was strongest for the evaluation of indeterminate strictures and removal of difficult bile duct stones. When taking the economic evidence into consideration, the panel noted that use of SOPOC was cost-effective or cost saving when used after conventional ERCP.
- The panel acknowledged that, while evidence exists where SOPOC is evaluated for other ERCP indications, the evidence was not sufficient to support routine adoption for all populations. However, the Panel noted that various studies are ongoing that may strengthen the evidence base for these indications and would welcome a review when this evidence becomes available.
- The panel noted that commission and provision of SOPOC should be carefully considered, taking into account potential volume, specialism and training requirements. The panel also noted the current difficulties in obtaining the number of people eligible for SOPOC following conventional ERCP, The panel would encourage the routine collection of audit data to address this.

Responsibilities for consideration of this Guidance

Health Technology Wales (HTW) was established by Ministerial recommendation[1,2] to support a strategic, national approach to the identification, appraisal and adoption of non-medicine health technologies into health and care settings. The HTW Appraisal Panel comprises senior representation from all Welsh boards with delegated authority to produce guidance 'from NHS Wales, for NHS Wales'. The status of HTW guidance is 'adopt or justify'. There is an expectation from Welsh Government that HTW guidance is implemented with adoption regularly audited by HTW.[3]

The guidance in this document is intended to assist Welsh care system decision makers to make evidence-informed decisions when determining the place of health technologies and thereby improve the quality of care services.

The content of this HTW guidance was based upon the evidence and factors available at the time of publication. An international evidence base was reviewed and external topic experts and HTW committee members consulted to contextualise available evidence to Wales. Readers are asked to consider the generalisability of the evidence reviewed to NHS Wales and that new trials and technologies may have emerged since first publication and the evidence presented may no longer be current. It is acknowledged that evidence constitutes only one of the sources needed for decision making and planning.

This guidance does not override the individual responsibility of health professionals to make decisions in the exercise of their clinical judgment in the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

No part of this guidance may be used without the whole of the guidance being quoted in full. This guidance represents the view of HTW at the date noted. HTW guidance is not routinely updated. It may, however, be considered for review if requested by stakeholders, based upon the availability of new published evidence which is likely to materially change the guidance given.

Standard operating procedures outlining HTWs evidence review methods and framework for producing its guidance are available from the HTW website.

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Declarations of interest were sought from all reviewers. All contributions from reviewers were considered by HTWs Assessment Group. However, reviewers had no role in authorship or editorial control and the views expressed are those of Health Technology Wales.

Chair, Health Technology Wales Appraisal Panel

1. National Assembly for Wales, Health and Social Care Committee. Access to medical technologies in Wales. December 2014.
2. Response to Recommendations from the Health & Social Care Committee: Inquiry into Access to Medical Technologies in Wales. February 2015.
3. Gething, V. Letter to all Health Board Chairs re Funding for Sacral Nerve Stimulation in Wales. VG_01655_17. September 2017.