ERCP for bile duct stones across a national service, demonstrating a high requirement for repeat procedures

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ABSTRACT

Background and study aims Bile duct stones (BDS) represent approximately 50% of the requirement for endoscopic retrograde cholangiopancreatography (ERCP) within most services. Significant variation in outcome rates for BDS clearance at ERCP has been reported, and endoscopy societies have set standards for expected clearance rates. The aim of this study was to analyze procedure outcomes across a national service.

Patients and methods Using verified hospital episode statistics (HES) data for the National Health Service (NHS) in England, we analyzed all patients having first ERCPs for BDS from 2015 to 2017, and followed these patients for at least 2 years.

Results In total 37,468 patients underwent a first ERCP for BDS, with 69.8% undergoing only one procedure. This figure of less than 70% of BDS cleared at first ERCP is below the Key Performance Indicators as set by the British Society of Gastroenterology (>75%) and the European Society of Gastrointestinal Endoscopy (>90%). Of 55,556 ERCPs done for BDS, 52.9% were repeat procedures, with 11,322 patients needing multiple procedures. For hospitals performing significant numbers of ERCPs (more than 600 for BDS during the study period) patients undergoing repeat ERCPs for BDS ranged from 9% to 50%.

Conclusions In this nationwide study, the performance at clearing BDS at first ERCP was suboptimal, with high numbers of repeat procedures required. This may have a negative impact on both patient outcomes and experience, and increase pressure on endoscopy services. Apparent variation of outcome between acute hospital care providers requires further analysis.

Introduction

Bile duct stones (BDSs) are a common problem. The European Society of Gastrointestinal Endoscopy (ESGE) estimates that 10% to 15% of adults have gallbladder stones and up to 18% of them will have BDS [1]. Complications from BDS may include obstructive jaundice, biliary colic, infection (cholangitis or hepatic abscesses) or acute pancreatitis. Considering that more than 25% of patients with BDS will develop symptoms over time, BDS clearance is recommended by ESGE, irrespective of symptoms [1–4]. The management of BDS has two steps: clearance of stones from the biliary tree and cholecystectomy (if not

▶ **Table 1** ICD-10 codes for patients at first diagnosis and the mean number of ERCP procedures performed.

ICD-10 code	Description	Count of patients	% patients	Mean count of ERCP procedures
K803	Calculus of bile duct with cholangitis	6,210	16.57	2.156231186
K804	Calculus of bile duct with cholecystitis	4,085	10.90	2.044383436
K805	Calculus of bile duct without cholangitis or cholecystitis	23,130	61.73	2.100905197
K851	Biliary acute pancreatitis	4,043	10.79	1.983352601

ERCP, endoscopic retrograde cholangiopancreatography.

previously performed) to remove the pool of residual stones. The most common method of clearing BDS is endoscopic retrograde cholangiopancreatography (ERCP). BDS is the clinical indication for approximately 50 % of the ERCPs performed in the UK [5, 6].

Reported success of stone clearance at ERCP shows wide variation, ranging from 62.3 % to > 96 %[5, 7,8]. Factors explaining these differences may include study design (e. g., inclusion of patients who had previous ERCPs), prospective/retrospective data, specialist/non-specialist center enrollment, and self-reported results. A 2007 UK wide prospective audit reported overall success rates for ERCP at 70.4 % and a BDS complete clearance rate of 62.3 % [5]. Procedural success at first ERCP was 71.9 %, but this did not specifically report BDS clearance at first ERCP. A prospective Dutch registry study captured approximately 50 % of all ERCPs done nationally over a 1-year period, with 4,388 (51.2 %) of the 8,575 procedures performed for BDS. The success rate for these reported procedures was 85.2%, but included both first and repeat procedures. Of note, the success rate fell to 76 % among those cases not submitted for analysis [8]. Using a self-reporting tool, Cotton et al. reported on more than 18,000 ERCPs performed by 63 endoscopists in the United States. Stone clearance rates were extremely high (99 % for stones < 10 mm, 96 % for stones > 10 mm) [7]. However, the data were not based on intention to treat, and failure to adequately identify the ampulla was an exclusion criterion.

Expected standards for BDS clearance at ERCP have been set. The British Society of Gastroenterology (BSG) "ERCP – a way forward" position statement in 2014 [9] set a minimum standard of 75 % BDS clearance rate at first ERCP within an individual's, as well as a service's, practice. An aspirational target of 80 % for BDS clearance was also set. Because these are intention to treat, they incorporate all procedural challenges (e. g., failed esophageal intubation, selective biliary cannulation). The American Society of Gastrointestinal Endoscopy (ASGE) and ESGE have higher minimum expected levels of BDS clearance. Both the ASGE and ESGE state that for stones less than 1 cm, more than 90 % should be cleared at first ERCP. The ESGE state that this only includes those who have had successful biliary cannulation [1, 10].

ERCP carries risk, whether at index or subsequent procedure. Bodger et al showed a 30 day post-ERCP all-cause mortality rate of 5.3 %, of which specific procedural complication codes were identified in 1.2 % of deaths, representing 0.06 % of ERCPs [6]. Other studies have shown all-cause mortality post-ERCP ranging from 2 % to 5.9 % [5, 6, 11–14], with deaths directly related to the procedure ranging from 0.2 % to 0.5 % [15–17]. Definitive stone clearance at index ERCP is the optimal patient outcome. Long-term biliary stenting without stone clearance carries significant risk of adverse outcome [18, 19], including a 40 % rate of cholangitis, and up to 15 % biliary-related mortality [14].

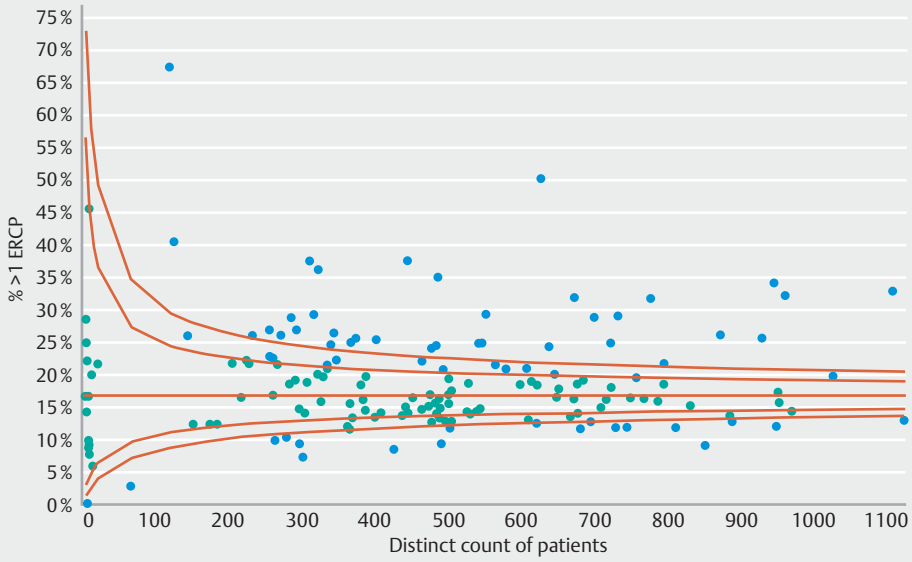
Most studies of ERCP for management of BDS have focused on outcomes for index or single procedures. The objective of this study was to assess the burden of ERCPs for BDS disease across a national service, as well as to investigate the technical success of first ERCPs for BDS, and the consequent need for, and success of, additional procedures.

Patients and methods

A retrospective analysis was performed of data from National Health Services (NHS) hospitals in England, including patients aged 18 years or over who were admitted between April 1, 2015 and March 31, 2019. Data were obtained from the Hospital Episode Statistics (HES) admitted patient care data set. This is an administrative data set that contains data on diagnoses and procedures as well as organizational characteristics and patient demographics for all NHS activity in England. An accredited clinical coder was recruited to support the identification of appropriate International Classification of Diseases 10th Revision (ICD-10) codes that classified a diagnosis of BDSs (▶ **Table 1**) as well as OPCS Classification of Interventions and Procedures (OPCS-4) to classify procedural codes to identiy the performance of ERCP for BDS.

Patients were included for analysis if an appropriate diagnosis (ICD-10 code) (▶ **Table 1**) and procedure (OPCS-4 code) (**Supplementary Table 1**) were included within HES, irrespective of diagnostic position. To identify the patient cohort, the pseudonymized patient identifiers attached to these episodes were selected.

To ensure that patients in the cohort were analyzed from their first BDS diagnosis, pseudonymized patient identifiers were also identified if they were recorded in HES data as having an ICD-10 code consistent with BDS for the period from April 1, 2013 to March 31, 2015. These patient identifiers were then excluded from the study cohort, providing a 2-year exclusion window prior to the start of the study period. Patients were also re-



▶ **Fig. 1** Individual acute hospital care provider data demonstrating the number of patients in 2015 to 2019 undergoing ERCP for bile duct stones against the percentage of patients requiring more than one ERCP. Source: HES APC 2015/16–2018/2019. The straight line is the mean with two and three standard deviations from the mean displayed.

moved from the cohort if their first BDS diagnosis was recorded after April 1, 2017. This ensured that all patients in the study cohort had a minimum of 2 years of follow up from their initial diagnosis.

With the finalized list of patient identifiers for the cohort, all episodes of care for these patients between April 1, 2015 and March 31, 2019 were then identified. Procedures were identified using the relevant OPCS-4 codes.

Distinct patients and spells were counted according to various criteria as above. To provide comparison between acute hospital care providers (NHS Trusts), control limits to indicate variation from the national mean were calculated. These limits were calculated at the two-standard-deviation (95%) and three-standard-deviation (99.8) levels.

Statistical methods

To enable comparison between hospital endoscopy services (acute hospital care providers in England) in the proportion of patients undergoing more than one ERCP, a funnel plot to illustrate variation from the national mean was used [20]. We calculated control limits at two standard deviations and three standard deviations from the mean. These control limits were then plotted (▶ **Fig. 1**) with a count of patients for each acute hospital care provider on the X axis (denominator for this indicator) and the proportion of those patients who underwent more than one ERCP on the Y axis.

Results

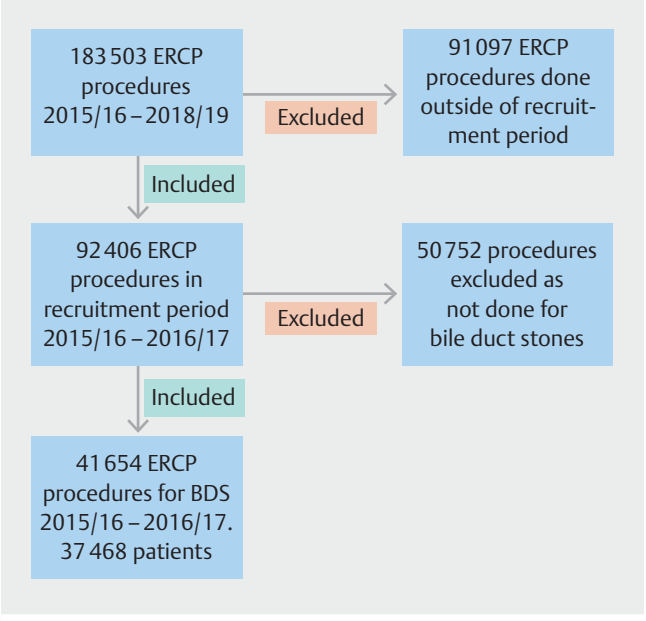
Coded data from 154 acute hospital care providers in England were assessed and all possible codes for an ERCP performed for BDS was identified. In the years 2015/2016 to 2018/2019, 183,503 ERCPs were performed. The number of ERCPs undertaken each year remained stable (▶ **Table 2**). In total 86,602 (47.2%) of the ERCPs in this 4-year period were undertaken for BDS. This figure includes all ERCPs performed for BDS over this period, including those excluded from the final study cohort who had an ERCP prior to the 2015–2016 fiscal year, and those who had a first ERCP for BDS after the 2016–2017 fiscal year (who were not then available for 2 years of follow up within the study period). During the study recruitment period (2015/2016 to 2016/2017), 37,468 patients had an initial presentation with BDS and underwent at least one ERCP. During this study recruitment period, 92,406 ERCPs were performed nationally and 41,654 (45.1%) of them were carried out for BDS. ▶ **Fig. 2** shows a flowchart of patient inception.

For the 37,468 patients with an initial BDS presentation recruited during the 2-year period, a total of 55,556 ERCPs were performed from recruitment to the end of 2018/2019. In total

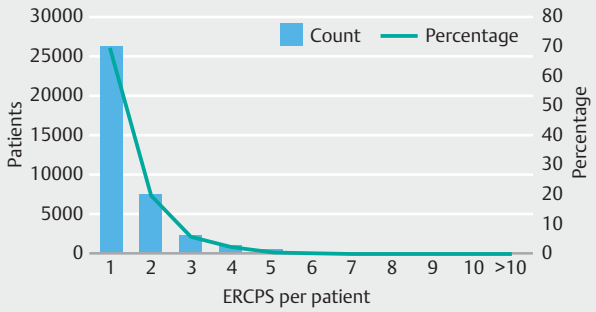
▶ **Table 2** ERCPs performed in England NHS by year, according to HES data and OPSC 4.6 procedural codes.

Fiscal year	No. ERCPs
2015/2016	45824
2016/2017	46241
2017/2018	45326
2018/2019	46112
Total	183503

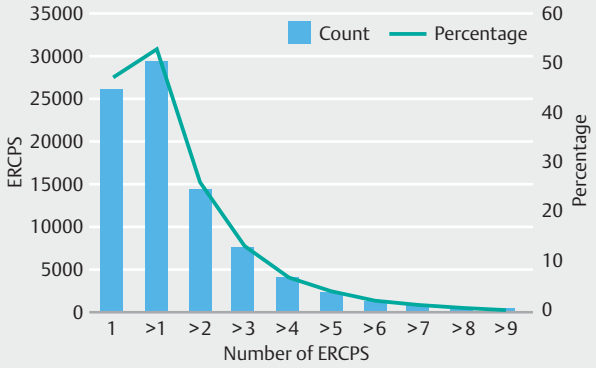
ERCP, endoscopic retrograde cholangiopancreatography; NHS, National Health Service; HES, hospital episode statistics.



▶ **Fig. 2** Flowchart of cohort inception.



▶ **Fig. 3** Number of patients undergoing specific number of ERCPs from 2015 to 2019, after first presentation with BDS in 2015 to 2017.



▶ **Fig. 4** Total number of initial and repeat ERCPs from 2015 to 2019, after first presentation with BDS from 2015 to 2017.

26,146 of the 37,468 patients recruited in this period had only one ERCP. This may suggest a BDS clearance rate at first ERCP of 69.8 %.

A total of 11,322 patients underwent more than one ERCP, with a total of 29,410 ERCPs performed in this group. Over the whole study period, 52.9 % of the ERCPs done for BDSs in those who presented with an initial BDS in 2015/2016 to 2016/2017 were done as a repeat procedure. The breakdown of these results is shown in ▶ **Fig. 3** and ▶ **Fig. 4**.

An assessment was made of the number of ERCPs performed per patient presenting with BDS according to acute hospital care providers in the NHS in England (▶ **Fig. 1**), applying BSG Key Performance Indicator (KPI) of a minimum stone clearance rate of 75 % at first ERCP for stones. ▶ **Fig. 1** shows that 32 of 154 providers (20.8 %) required more than 25 % of their patients to have more than one ERCP.

▶ **Fig. 1** shows data for individual acute hospital care providers (within the NHS in England) demonstrating the number of patients undergoing ERCP for BDS during the study period against the percentage of patients requiring more than one ERCP for BDS. Each data point represents an acute hospital care provider.

▶ **Table 1** shows the mean procedure count for each ICD-10 definition for BDS. Patients with a diagnosis of BDS and cholangitis needed the most ERCPs, with 2.156 procedures per patient. In contrast, those with acute biliary pancreatitis needed the least ERCPS with 1.983 procedure per patient.

Discussion

BDSs remain a common clinical problem and a major indication for ERCP. Failure to clear stones at a first ERCP exposes patients to risks of further procedures, as well as risks linked to retained stones. The aim of this national population study was to capture every ERCP performed for BDSs in England, and included 37,468 patients followed up for a minimum of 2 years. This provided an objective assessment of not only the success rate of clearing BDSs within a national population, but the chronology of procedural success following the index ERCP.

The study showed that approximately 45,000 ERCPs were performed annually in England, with just under half of these for BDSs. These data are similar to BSG (UK) audit data from 2006/2007 [6], and suggest that the electronically recorded HES accurately captures complete data.

The success rate for BDS clearance at first ERCP (69.8 %) does not meet the KPIs set by the BSG (> 75 %) or ESGE (> 90 %). It is comparable to the overall success rate of first ERCP, for all indications, in England in 2004 (84 % cannulation rate, 74 % procedural success). Direct comparison for initial ERCP for BDS is not possible as this was not collected in the UK study [21]. In a more recent national Dutch study by Ekkelenkamp et al [8], 4388 of the total 8575 ERCPs were performed for BDSs (51 %), with an overall 85 % stone clearance rate. However, only 59 % of ERCPs were performed in patients with a native papilla (an indicator of first ERCP) and cannulation was achieved in 83 % in this group. Again, direct comparison between this study and the

Dutch study is not possible as the Dutch study did not collect the data on those who had first ERCP for BDS. The Dutch study did a data verification exercise. This involved randomly selecting eight of the 61 hospitals involved and verifying the data submitted to the study. For this group, they looked at 20 % of the submitted ERCPs, or 281 ERCPs, all but one of which were submitted accurately. Second, from the same hospitals, the ERCPs not submitted to the database were checked. Those 441 ERCPs were mainly procedures from participating endoscopists rather than endoscopists who did not participate in the study. The success rate of the ERCPs not submitted was significantly lower than those recorded in the study (76.0 % vs 85.8 %; $P<0.001$) [8]. It seems probable that the overall outcome for stone clearance for first ERCP in the Dutch population would be similar to that seen in this study. Moreover, in some studies, data on ERCP outcome, including cannulation, are only recorded once identification of the papilla is achieved rather than based on intention to treat. In self-reported studies, this risks significant data bias and may contribute to exceptionally high success rates of 97 % for even the most difficult stones [22].

The term unsuccessful or failed ERCP needs to be qualified. This definition, used in this study and in the previous UK audit by Williams et al [5], was applied when a repeat ERCP was required following an index procedure. However, this will include both patients who have failed cannulation (with an ongoing risk of worsening jaundice and cholangitis) and those in whom stone clearance was achieved, but in the setting of severe cholangitis and a profoundly septic patient, a stent was placed to ensure optimal drainage. The former case would clinically represent a poor outcome and the latter a good outcome. The data in this study do not allow this clinical distinction to be made reliably, and both scenarios necessitate the patient requiring a further procedure. However, ▶ **Table 1** shows that those patients with cholangitis did not undergo significantly more procedures than those without cholangitis. This suggests that a need to remove a biliary stent inserted as insurance in the setting of cholangitis was not an obvious factor in explaining an increase in overall repeat ERCPs. The reasons for failure to clear BDSs are unclear but may relate to a range of factors, including endoscopist experience, unit volume and referral practice [23]. Individual endoscopist procedural outcome cannot be concluded from this study, although the introduction of the National Endoscopy Database within the NHS will make the monitoring of individual endoscopist activity and outcomes simpler and more transparent. However, apparent significant variation was seen between acute hospital care providers (▶ **Fig. 1**). ▶ **Fig. 1** shows that a number of acute hospital care providers who performed a significant number of ERCPs in patients with BDSs (e. g., 600 to 700 patients during the study) required wide variation in need for repeat procedures (ranging from < 15 % to > 50 %). The reasons for this are unclear. An explanation might be referral differences, with one unit receiving a high proportion of perceived complex stone cases prior to index ERCP. Enhanced techniques for stone clearance, including endoscopic papillary large balloon dilatation (sphincteroplasty) [24] and cholangioscopy with visually directed lithotripsy [25], may significantly improve the clearance of difficult stones. The use and availability of these techniques may have impacted outcome and they are both recommended by ESGE [1]. It is possible, but not proven, that higher recall rates might also reflect an increased frequency of stent and return, with suboptimal attempts at definitive stone clearance at index ERCP. Whatever the explanation, the data suggest different patient outcomes depending on procedure location. Within the NHS, the GIRFT (Getting It Right First Time) program is aimed at systematically improving care by reducing unexplained variation and the need for repeat procedures. The data from this study suggest that renewed focus on the quality of ERCP for patients with BDSs may be relevant. Many patients requiring more than one ERCP underwent multiple procedures, such that 52.7 % of all ERCPs for BDSs in this study were repeat procedures. Given the fact that approximately 50 % of ERCPs within a service are for stones, the data from this study would suggest that as a conservative estimate, > 20 % of all ERCPs performed within the NHS in England are repeat ERCPs for stones not definitively treated during a previous procedure. With a mean cost of £2,519 (circa €3,020) per ERCP (as per 2017/2018 NHS national tariff) this would represent a cost of more than £22.5 million (circa €27 million). This potentially avoidable procedure burden also extends to endoscopy capacity and environmental costs related to consumables. The impact of repeat ERCP on patient experience, to our knowledge, has not been measured but must be assumed to be materially detrimental.

A number of predictors of failure of BDS clearance at ERCP are known, including stones above strictures, unfavorable stone-to-distal-duct diameter, stone size > 10 mm, stone impaction, multiple stones, Mirrizzi syndrome, and intrahepatic stones [26–28]. Over the timeframe of this study 3854 patients had three or more ERCPs for stones. It may be that early referral of cases to a specialist pancreaticobiliary multidisciplinary team would have provided additional therapeutic options. Certainly, there is a significant body of evidence that access to cholangioscopy increases the success rate for removal of BDSs. A recent large, international, multicenter analysis showed a 97 % duct clearance rate using single-operator cholangioscopy (SOC), with this achieved in a single session in 77 % of patients [25]. In that paper, 86 % of patients undergoing SOC had a previous failed procedure. Notwithstanding the caveat of retrospective cohort data, this and other studies suggest that the availability of cholangioscopy within a managed geographical network for the management of complex stones would be expected to reduce the burden of repeat procedures.

A particular strength of this study is that it is a complete data set from a large national service over a 4-year period. The data were recorded by non-clinical coders not affiliated with a clinical team and there was no reliance on voluntary reporting. Therefore, there is likely to be minimal clinical or reporting bias in the outcome. Success in this study is measured objectively, as no more ERCPs needed. Reporting bias might be an explanation for the differences in reported success in ERCP in the patient groups included and not included in the Ekkelenkamp study, as outlined above. In previous large studies, including that by Williams et al of a nationwide service, there was the op-

tion of individual endoscopists opting out of participation, which is not possible in this study [5, 8].

The study has limitations. The data are dependent on coding recorded by non-medical personnel, based on clinician-derived medical reports, and so may be subject to coding error or poor documentation. However HES data have been found to be > 90 % accurate when used as a research tool [29]. Campbell et al showed that routinely collected data sets (including HES) were more accurate in coding for procedures, such as ERCP, than diagnosis, with a procedural accuracy rate of 97 % [30].

Data from HES including diagnoses have been found to be reliable, with accuracy consistently above 70 % for diagnosis and frequently over 90 % [30–32]. A systematic review found an overall accuracy rate for operations and procedures of 69.5% in England and Wales and 98 % in Scottish studies [30]. The same review showed a diagnostic coding accuracy rate of 91 % in England and Wales and 82 % in Scotland.

While in clinical practice a proportion of patients undergoing ERCP for suspected BDSs will have an alternative diagnosis, the ICD codes are generated after the patient episode, increasing the confidence that the recorded ERCPs were performed for BDSs. A limitation of our study is an assumption that for those having only one ERCP, this ERCP resulted in successful BDS clearance. Included in this may have been patients who were lost to follow up, refused/were advised against further procedures, or died. This might suggest that the true stone clearance rate after a single ERCP is lower than the 69.8 % reported in this study. Similarly, the exclusion of patients who had undergone an ERCP in the 2 years prior to the study may have failed to exclude some who had a first ERCP before 2013 (e. g., having previously been lost to follow up). Another limitation is that HES data do not capture ERCPs done in private, non-NHS facilities. They do capture private ERCPs done in NHS facilities. However no more than 1 % of all ERCPs in England are performed in the private sector, so it is unlikely they will influence the data.

Conclusions

This population-wide study of hospital data suggests that overall BDS at ERCP falls below expected national and international standards. Significant variation between providers exists in the proportion of patients requiring repeat ERCPs after an initial procedure, and nationally more than 50 % of all ERCPs for BDSs are repeat procedures. Approaches to reduce the need for repeat procedures, including stratification according to predicted case complexity, network-based delivery, and the availability of advanced techniques for difficult stones, including cholangioscopy, may improve patient experience and the burden on ERCP capacity and health costs.

Competing interests

Dr George Webster has received honoraria for teaching and participation on advisory boards for Boston Scientific, Pentax Medical, Olympus Medical and Cook Medical. Dr Richard Sturgess has received honoraria for teaching and participation on advisory boards for Boston Scientific.This study was supported in part by an unrestricted educational grant from Boston scientific inc.

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