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Technical note

Management of difficult bile duct stones and indeterminate bile duct structures: Reduced ERCP radiation exposure with adjunct use of digital single-operator cholangioscopy

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ABSTRACT

Introduction: Endoscopic Retrograde Cholangio-Pancreatography (ERCP) is an well-established endoscopic procedure for the management of biliary diseases. The use of fluoroscopy during ERCP has often raised concerns regarding potential risks from radiation exposure, particularly in complex cases. We investigated whether a new digital single-operator cholangioscopy (D-SOC) system, used adjunctively to ERCP, actually reduces patient radiation exposure.

Materials and methods: We retrospectively analyzed a prospective database (April 2016 to October 2018) including consecutive patients who underwent successful management of difficult-to-treat biliary stones or indeterminate biliary strictures by using either conventional ERCP (ERCP cohort) or ERCP in conjunction with D-SOC (ERCP/D-SOC cohort). The overall patient radiation exposure outcomes were compared in terms of Kerma Area Product (KAP), Fluoroscopy time (T) and the total number of films (F).

Results: Overall, 47 patients (mean 71.8 years, 59.6% males) were included (ERCP cohort = 29, ERCP/D-SOC cohort = 18), referred either for difficult bile duct stones (n = 36) or indeterminate biliary strictures (n = 11). The median KAP, T and F in the ERCP/D-SOC cohort were 12.3 $Gycm^2$, 3.7 min and 4 films respectively, compared with 52.1 $Gycm^2$, 8.4 min, and 5 films respectively in the ERCP cohort. Statistically significant differences (P = 0.0001) were found for KAP and T.

Conclusions: Adjunct use of a digital cholangioscopy platform appears to significantly reduce radiation exposure in patients undergoing ERCP for the management of difficult bile stones or indeterminate biliary strictures.

1. Introduction

Endoscopic Retrograde Cholangio-Pancreatography (ERCP) is the gold standard technique for evaluating and treating pancreaticobiliary diseases, including bile duct stones and cancerous or benign tumors of the biliary tract and pancreas [1]. However, ERCP applies fluoroscopic guidance to diagnose and treat these disorders, thus it inevitably poses patients and staff at some degree of exposure to ionizing radiation. Therefore, strict monitoring of the ERCP radiation dose is recommended, according to the standards set by the New European Radiation Protection Directive [2] and the International Basic Safety Standards [3]. Furthermore, the European Society of Gastrointestinal Endoscopy (ESGE) acknowledged the importance of radiation protection and radiation dose monitoring in its latest guidelines [4].

In recent years, a number of studies have reported on the radiation dose delivered to patients during ERCP [5–13] and values have largely ranged. As ERCP is a complex procedure, radiation dose levels are influenced by several factors [13–17] including the type of X-ray machine used [14], the experience of the endoscopist [15,16] or even the distance between the endoscopy and fluoroscopy screens in the ERCP suite [18]. Moreover, demanding clinical cases such as indeterminate bile duct strictures and difficult bile duct stones are expected to be associated with increasing odds of patient radiation exposure, as they often require prolonged and/or multiple ERCP procedures. Briefly, bile strictures are characterized as “indeterminate” when their nature remains uncertain following a basic laboratory work-up, abdominal imaging [e.g.; computed tomography (CT) and endoscopic ultrasound] and ERCP [19]. Difficult bile duct stones form another demanding situation, defined as biliary stones difficult to remove due to challenging access to the bile duct (e.g.; periampullary diverticulum, Billroth II

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anatomy, etc.), large (> 15 mm) bile stones, intrahepatic stones or impacted stones in the bile duct or cystic duct [20]).

Since 2015, a new digital single-operator cholangioscopy (D-SOC) system (SpyGlass Digital System, Boston Scientific) has been introduced in clinical practice, showing a dramatic improvement over the prior generation of fiberoptic cholangioscopy [21,22]. The system provides digital 120° field of view of the biliary tract, allowing diagnosis by direct visualization and the performance of visually-targeted biopsies and various therapeutic procedures (eg; difficult stone lithotripsy) in a radiation-free manner. However, even though a few recent studies reported on its clinical benefits [23–26], the radiation-sparing contribution of D-SOC has not been formally assessed. Herein, we aimed to investigate whether the novel D-SOC platform used adjunctively to ERCP actually reduces patient radiation exposure. For this purpose, a prospectively-stored database was analyzed including consecutive patients with indeterminate strictures or difficult choledocholithiasis successfully managed by ERCP with or without adjunct D-SOC. The diagnostic and therapeutic value of D-SOC has been reported elsewhere [21–26] and is outside of the scope of this study.

2. Material and methods

2.1. Study design and patients

This is a retrospective study of a prospective database conducted at a single tertiary-care referral center from April 2016 to October 2018. The study population consisted of 47 consecutive adults with indeterminate bile duct strictures or difficult biliary stones referred and successfully managed at the endoscopy unit of the Konstantopoulio General Hospital (Athens, Greece). Out of the 47 patients, 18 underwent ERCP with adjunct D-SOC (ERCP/D-SOC cohort) and 29 were managed exclusively by conventional fluoroscopy-based ERCP (ERCP cohort). No standardized clinical criteria were applied during the study period concerning the utilization of D-SOC. Considering that D-SOC requires special training and is associated with substantial costs, the institutional policy was to selectively use D-SOC in cases where conventional ERCP alone was deemed unlikely to be successful or considered inappropriate. Thus, the decision on whether to undertake D-SOC was at the discretion of the treating endoscopists, based on their personal experience and the review of Magnetic Resonance Cholangio-Pancreatography (MRCP) and/or CT findings. Data regarding demographics, procedure indication, the diagnostic and therapeutic maneuvers performed, radiation dose in terms of Kerma Area Product (KAP), fluoroscopy time (T) and the number of fluoroscopy images (I) obtained were all prospectively recorded. All patients provided written informed consent and the institutional review board approved the study protocol.

2.2. Equipment and procedures

All procedures were performed by two experienced endoscopists (K.P. and A.G.) under monitored anesthesia care. Standard duodenoscopes were used (TJF-Q180V; Olympus, Tokyo, Japan) along with the SpyGlass Direct Visualization System and accessories (Boston Scientific Corp, Natick, MA, USA). The configuration of the Spyglass Direct Visualization System is shown in Figs. 1a and 1b. Biliary sphincterotomy was usually carried out just before D-SOC. In certain clinical cases, a pre-existing sphincterotomy was extended or additional balloon dilation of the papilla was performed. The Spyglass was inserted either directly or passed over a guidewire into the proximal biliary tree. Using normal saline irrigation, the biliary tree was visually inspected. Targeted forceps biopsies were obtained in case of biliary strictures or abnormal lesions other than stones, using the disposable SpyBite (Boston Scientific Corp, Natick, MA, USA). For SpyGlass-guided electrohydraulic lithotripsy (EHL), a bipolar lithotripsy catheter probe was used (AUTOLITH, Northgate Technologies Inc, Elgin, IL). The EHL probe was introduced through the working channel of the cholangioscope and shockwaves were delivered in pulses until stone fragmentation under visual guidance [27]. Antibiotic prophylaxis was administered before the procedure according to institutional protocol. Detailed technical specifications and description of the standard D-SOC technique are provided elsewhere [21,28]. Patients in the conventional ERCP cohort underwent sphincterotomy or balloon sphincteroplasty or both in conjunction with balloon stone extraction and/or biliary stent placement and mechanical lithotripsy, as per standard practice. Brush cytology under fluoroscopic guidance was obtained in the subset of patients undergoing conventional ERCP for the evaluation of indeterminate biliary strictures.

The ERCP suite of the Konstantopoulio General Hospital is equipped with an overcouch Philips Essenta X-ray machine (Philips Medical Systems, Best, The Netherlands), installed in 2007, with a 30 cm diameter image intensifier and a high-frequency generator. Patient radiation dose is provided by the X-ray machine (reported on the X-ray console) in terms of KAP in microGym^2. The KAP meter is calibrated according to the method summarized in the 'National Protocol for patient dose measurements in Diagnostic Radiology' developed by the National Radiological Protection Board [29]. The X-ray equipment is controlled by a specially trained endoscopic radiographer who remains in the X-ray control room and performs fluoroscopy and/or radiography and further processing, if needed, according to the requirements of the endoscopist. The quality assurance program for ensuring optimal image quality of the X-ray machine with the lowest possible radiation dose is based on the national radiation protection regulations [30] and the Hellenic Accreditation System ELOT EN ISO 15189:2012 and ELOT EN ISO/IEC 170 accreditation requirements [31]. Quality control protocols are structured by the medical physics department based on the national protocols [30] and executed quarterly by a medical physics expert.

2.3. Outcomes and statistical analyses

Data were described as means (standard deviation [SD]) or medians (range) for continuous variables and percentages for categorical variables. The present study was aimed to assess the impact of D-SOC utilization on radiation exposure in patients who underwent ERCP for the management of difficult bile stones and indeterminate biliary strictures. For this purpose, the following variables were compared between the ERCP/D-SOC and ERCP cohorts: KAP in microGy.cm^2, fluoroscopy time (T) in min and total number of images (I). Because the KAP, T and I values showed non-normal distribution, the Mann-Whitney *U* test was applied for non-parametric intergroup comparisons, testing the null hypothesis that the medians of the two groups are equal. Analyses were two-sided and P values of < 0.05 were considered statistically significant. The statistical analyses were performed using the SPSS version 23 software (IBM Corp., Armonk, New York, USA).

3. Results

A total of 693 patients underwent ERCP during the study period, of whom 39 were referred for difficult bile duct stones and 15 for indeterminate bile duct strictures. Complete bile duct clearance was achieved in 36/39 patients with difficult choledocolithiasis, whereas a final diagnosis concerning the nature of indeterminate strictures was reached in 11/15 patients (malignant in 7 and benign in 4 cases). Thus, a total of 47 patients who underwent successful management of difficult bile duct stones (n = 36) or indeterminate biliary strictures (n = 11) finally comprised the study population. There were 18 patients in the ERCP/D-SOC cohort, compared to 29 patients in the ERCP cohort. Overall, the mean (SD) age of the patients was 71.8 (14.4) years and 28 (59.6%) were males. The baseline and procedural characteristics between the two cohorts are summarized in Table 1. Overall, ERCP with or without adjunct use of D-SOC appeared to be clinically useful, allowing the performance of a wide variety of diagnostic (brush

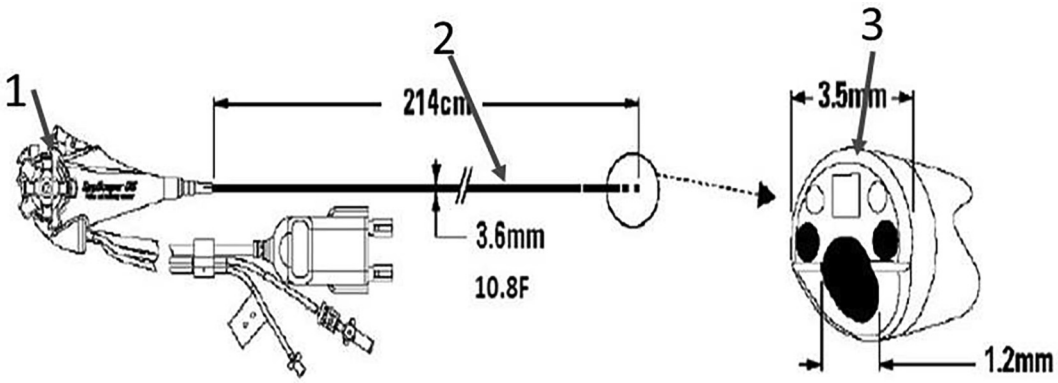

Fig. 1a. Configuration of the Spyglass™ direct visualization system is shown below; 1) delivery system, 2) catheter and 3) detail of the catheter end.

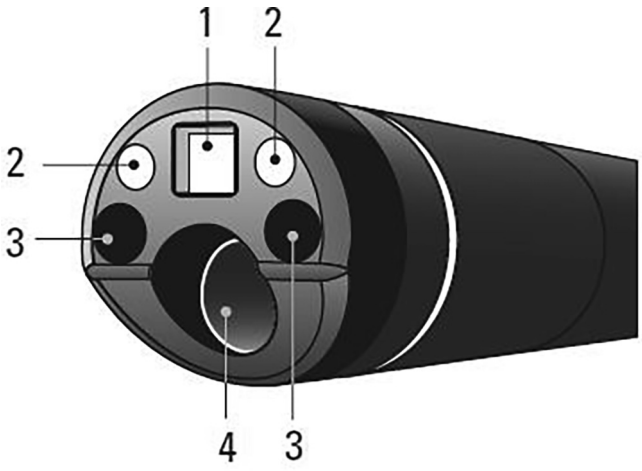

Fig. 1b. Details of the catheter are shown: 1) video imaging sensor, 2) illumination parts, 3) irrigation channels and 4) working channel for various accessories and irrigation.

Table 1
Baseline and procedural characteristics between conventional Endoscopic Retrograde Cholangio-Pancreatography (ERCP) and ERCP with digital single-operator cholangioscopy cohorts (ERCP/D-SOC).

	ERCP/D-SOC	ERCP
Number (N) of patients	18	29
Female/male, N	5/13	14/15
Mean age (SD) in years	69.8 (14.0)	72.9 (14.7)
Clinical indication		
• Difficult stones	11	25
• Indeterminate strictures	7	4
Diagnostic maneuvers, N		
• Brush cytology	–	3
• SpyBite biopsies	6	–
Therapeutic maneuvers, N		
• Biliary stent placement	12	9
• Biliary stent exchange	4	1
• Balloon extraction	5	24
• Electrohydraulic Lithotripsy (EHL)	4	–

cytology = 3, SpyBite biopsies = 6) and therapeutic procedures (stent placement = 21, stent exchange = 5, balloon extraction of stones = 29, EHL = 4).

The radiation parameters in terms of KAP, T and I both for the ERCP/D-SOC and the ERCP cohorts are shown in Table 2. The median fluoroscopy time was significantly reduced when D-SOC was used in conjunction with ERCP (P = 0.0001). Accordingly, the median

Table 2
Main dosimetric and technical parameters for ERCP and ERCP/D-SOC; Kerma Area Product (KAP), fluoroscopy time (T) and the number of fluoroscopy images (I).

	ERCP	ERCP/D-SOC	P-value
Median T (range), min	8.4 (4.0–26.4)	3.7 (1.5–9.6)	0.0001
Median I (range)	5.0 (1.0–7.0)	4.0 (3.0–12.0)	0.67
Median KAP (range), $Gycm^2$	52.1 (11.3–175.9)	12.3 (4.6–38.9)	0.0001

radiation dose was significantly reduced in the ERCP/D-SOC cohort compared to the ERCP cohort (P = 0.0001). Contrarily, no statistically significant difference was detected concerning the median number of images between the ERCP and the ERCP/D-SOC cohorts (P = 0.67).

4. Discussion

ERCP is an established procedure for the management of pancreaticobiliary diseases, including stone removal and strictures management [1]. Despite its undoubtful clinical advantages, ERCP is a fluoroscopy-based procedure; thus, it inevitably places patients and staff at some risk of radiation exposure. Recently, an improved, user-friendly version of digital cholangioscopy has been used in conjunction with ERCP, allowing for direct visualization of the biliary and pancreatic ducts [21,22]. A recently published study outlined the clinical utility of D-SOC, showing a trend towards higher technical success rate for diagnostic procedures compared with the previous generation of fiberoptic cholangioscopy (83% vs 58%, p = 0.07) [32]. Accordingly, utilization of D-SOC in this study allowed for a significant number of supplementary diagnostic (direct SpyBite biopsies, n = 6) and therapeutic (EHL, n = 4) maneuvers, not possible by conventional ERCP alone. To this end, use of D-SOC is steadily arising as a non-radiation adjunct modality, providing sufficient technical feasibility and diagnostic accuracy to reduce, or even completely eliminate, the need of fluoroscopy [33]. However, no comparative studies have been performed gauging the impact of a combined fluoroscopic/cholangioscopic approach over conventional ERCP on fluoroscopy time and radiation exposure. To the best of our knowledge, this is the first report highlighting the radiation-sparing effect of D-SOC. By analyzing a prospectively-stored database, we determined that adjunct use of D-SOC is associated with substantially shorter fluoroscopy times and thus imparts a much lower radiation dose to patients as compared with conventional fluoroscopy-based ERCP.

Radiation doses in the current study and those in some previous reports are summarized in Table 3. Notably, the radiation dose attributed to conventional fluoroscopy-based ERCP may appear somewhat higher in our setting. Nevertheless, comparisons should be interpreted cautiously, due to significant heterogeneity. First and foremost, our cohort comprises procedures with a high degree of technical difficulty.

Table 3
Radiation dose values in the current study as compared to those in the recent literature.

Study	Procedure	Median KAP ($Gycm^2$)	Range KAP ($Gycm^2$)
This study	ERCP/D-SOC	**12.3**	**4.6–38.9**
This study	ERCP	47.1	11.3–175.9
Tsapaki V 2017 [13]	ERCP	15.6	
Tsapaki V 2016 [5]	ERCP	8.0	0.4–130.2
Seo D 2016 [9]	ERCP	47.06 (mean value)	
Saukko E 2015 [8]	ERCP	8.0	0.08–57
Liao C 2015 [15]	ERCP	8.8–13.98	
ESGE guidelines 2012 [4]	ERCP	39	8–333

These clinical cases are usually associated with prolonged fluoroscopy times and increased patient radiation exposure. In one of our previous studies in 2016 [5] we suggested preliminary DRLs for ERCP based on data from different hospitals and a mixture of very different fluoroscopic modalities such as C-arm, angiography, under couch or over couch fluoroscopy machines. Our study in 2017 [13] included data from 1632 patients during 8 years of patient dose monitoring for both diagnostic and therapeutic procedures, showing a progressive reduction in radiation dose within the years. Saukko *et al.* reported lower median KAP values from 10 hospitals in Finland, including both diagnostic (lower radiation dose procedure) and therapeutic ERCPs. However, this difference is likely attributed to a lesser degree of procedure complexity, as this study was not specifically concerned with difficult bile duct stones or indeterminate strictures [8]. Liao *et al.* also included different levels of ERCP complexity; however, they reported median KAP values largely comparable to those reported by the present study [15]. Nevertheless, both endoscopists participating in the current study were high-volume ERCP endoscopists (> 200 ERCPs per year), whereas most ERCPs in the study by Liao were performed by low-volume endoscopists, likely associated with significantly higher radiation exposure.

This study is not free of limitations. Firstly, based on our data, the radiation-sparing effect of D-SOC is largely attributed to the possibility of direct visualization of the biliary tract, so that diagnostic and therapeutic maneuvers can be partly or entirely performed in a radiation-free manner. Although we did not undertake a specific analysis, a certain degree of correlation between KAP and T appears reasonable to postulate for both groups in this study. Nevertheless, previous data have shown that this correlation is minimal, indicating that fluoroscopy time is an imperfect surrogate of radiation exposure [34]. However, other major factors that may affect total exposure (e.g.; patient size, rate of delivery, site of skin exposure and fractionation of exposed dose) were not captured. Thus, the exact mechanisms behind the radiation-sparing effect of D-SOC warrant further robust assessment. Secondly, this is the first report exclusively focusing on radiation exposure during complex procedures, such as ERCP performed for difficult bile stones and indeterminate strictures. Therefore, our results may not be generalizable in settings with a lesser degree of procedural complexity and/or procedures performed by less experienced endoscopists. Thirdly, we did not use a valid ERCP complexity scale to grade technical difficulty. Thus, the radiation doses between the ERCP and ERCP/D-SOC cohorts may have been affected, to a certain extent, by differential technical difficulty. Fourthly, we could not detect any difference in terms of the number of fluoroscopy images obtained. However, this is not a plain measure of radiation exposure and may rather reflect archiving requirements. Last but not the least, our study may be criticized for the small sample. Nevertheless, statistically significant differences were detected with respect to T and KAP, thus we do not believe that a larger sample would have affected by any means the study findings.

5. Conclusion

In conclusion, we determined that a combined fluoroscopic/cholangioscopic approach with the use of D-SOC offers a radiation-sparing alternative to the management of difficult choledocolithiasis and indeterminate biliary strictures compared to conventional fluoroscopy-based ERCP alone. Future technological improvements in the field of D-SOC along with better standardization of cholangioscopic appearances may allow to further decrease or even outplace radiation exposure in patients with pancreaticobiliary disorders.

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