J Minim Invasive Surg Sci. 2014 May; 3(2): e11968.

Published online 2014 March 30. **Review Article**

Intra-Operative Endoscopic Sphincterotomy: State of the Art

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Received: May 5, 2013; **Accepted:** August 13, 2013

Context: Different approaches are routinely applied in the treatment of concomitant cholecystocholedocholithiasis. Most patients are treated by preoperative endoscopic sphincterotomy followed by laparoscopic cholecystectomy in a two-stage approach. However one-stage approach carrying out intraoperative endoscopic sphincterotomy (IOES) is emerging as a minimally invasive alternative option. Our review evaluates the outcomes and potential advantages of IOES compared to the other therapeutic options.
Evidence Acquisition: An accurate enquiry for papers relating to IOES and the different available options was performed on different medical databases. Endpoints considered were: successful clearance of common bile duct stones, overall complication rate, procedure related morbidity, conversion rate, duration of hospital stay and costs.
Results: Data were collected from 21 scientific papers including: 5 prospective randomized clinical trial, 4 Meta-analysis and 12 case series. Similar rates of successful clearance of common bile duct stones were reported between Intra Operative Endoscopic Sphincterotomy (IOES) and Pre Operative Endoscopic Sphincterotomy (POES) (96.9% versus 96.3). Overall morbidity showed no statistical significant differences between the two approaches (16.1% in two stage approach versus 19.9% in one stage approach). IOES resulted superior to two-stage approach regarding duration of hospital stay with a mean difference of 2.83 days. The shorter hospital stay ensued in a reduction of cost in most studies. No differences in conversion rate were observed between POES and IOES (3.8% versus 3.7%).
Conclusions: Intraoperative endoscopic retrograde cholangiography is a safe, effective and feasible treatment for patients with concomitant gallbladder stones and choledocholithiasis. This review highlighted the advantages of IOES as a minimally invasive, one-stage approach. However in order to guarantee the success of such approach a profound collaboration between surgeon and endoscopist is mandatory and an efficient logistic organization of the operating theatre is needed.

Keywords: Cholangiopancreatography, Endoscopic Retrograde; Cholecystectomy, Laparoscopic; Gallstones

1. Context

About 5%-25% of the adult Western population have gallstone. Some 2%-4% become symptomatic each year (1, 2). Laparoscopic cholecystectomy (LC) is the method of choice for managing symptomatic gallbladder stones. However the incidence of concomitant choledocholithiasis has been reported to range between 10% and 20% (3) and when such an association exists, the ideal management remains controversial. Several approaches are routinely applied in the treatment of such cases including: open or laparoscopic cholecystectomy coupled with bile duct exploration or endoscopic sphincterotomy (ES) pre, post or intraoperatively during surgical cholecystectomy.

LC with bile duct exploration shows good results compared to pre or post-operative ES (4), however the majority of surgeons prefer ES for management of mostly cases. Very probably due to a longer procedure time and lack of required equipment and skills for laparoscopic Common Bile Duct (CBD) exploration. ES can be performed with a two-stage approach, before or after LC, or intraoperatively (IOES) in a one stage approach. Currently the most frequent practice is to perform preoperative ES (POES) followed by LC, the main reason to apply this approach is to allow subsequent open or laparoscopic exploration of CBD if ES fails (5). However POES approach has shown different drawbacks such as: need of two anesthesia and sometimes two hospital admissions, an higher conversion rate due to increased difficulties of LC (6, 7), after ES and up to 10% of unnecessary ES even after strict patient selection (8) with concomitant higher cost.

Therefore, in the era of minimally invasive surgery in order to overcome the superintended shortcomings, an intraoperatively approach (IOES) has been proposed. Deslandres et al. (9) in 1993 described for the first time this combined approach for the treatment of three patients. Since then IOES has slowly acquired success with an increasingly number of authors, demonstrating its advantages in comparison with the previous approaches and describing different techniques. Currently the most

Implication for health policy/practice/research/medical education:
Intra-Operative Endoscopic Sphincterotomy is a valid solution, with same morbidity compared to the double approach, to treat in one stage concomitant gallbladder stones and choledocolithiasis reducing costs at the price of a close collaboration by endoscopist and surgeon.

popular IOES technique is the so called Laparo Endoscopic "rendezvous" (RV) which uses a guidewire reaching the duodenum through the cystic duct to facilitate the cannulation of the papilla (10, 11). With the help of the guidewire RV techniques results easy to use, with a shorter learning curve and minor technical requirements in comparison with laparoscopic management or standard endoscopic approach. Limitations of RV technique are related to impacted stones, which block the descent of the guidewire and the supine position, that is not the usual position for ERC and may challenge some endoscopist. Therefore others techniques have been proposed (12). This review has the goal to assess the role of IOES evaluating the different techniques adopted, their results and the opinions of the authors. Furthermore in this article the efficacy of IOES will be compared with the other two main treatment options.

2. Evidence Acquisition

An accurate search updated to January 2013 was conducted on Medline databases, Cochrane Library, Embase, and Science Citation Index Expanded. The following medical subjects headings (MeSH) were used: "Intraoperative Cholangiography", "Intraoperative ERCP", "Intraoperative Sphincterotomy", "Laparoendoscopic Rendezvous", "Choledocolithiasis", "Cholecistolithiasis" and "Combined treatment for common bile duct stones". The search was restricted only to English language publications. All the resulting abstracts were reviewed and significant articles were obtained (5 prospective randomized clinical trial, 4 Meta-analysis and 12 case series). Particular attention was given to Randomized Controlled Trials, Meta-analysis comparing IOES and Two stage approach. Articles reporting interesting modifications of standard Rendezvous technique were considered as well.

References within the articles obtained were analyzed to identify additional valuable studies. The main endpoints considered in the articles analyzed in this review were: successful clearance of common bile duct stones, overall complications and procedure related morbidity, conversion rate, duration of hospital stay and procedures cost.

3. Results

Performing IOES several different techniques are described in literature. The main differences are principally connected to use a guidewire inserted through the cystic duct in order to help CBD cannulation, the so called Rendezvous technique, or to undergo an IOES aided only by visualization of the CBD by means of Intraoperative Cholangiography. Other differences are related to perform the IOES in the standard surgical supine position or to change patient position in a left lateral decubitus after LC completion (13). Lastly systematic use of transcystic cholangiography before ES varies greatly among different studies (14).

The most common one stage approach performed in the majority of the studies is undoubtedly the Rendezvous technique. It consists in the insertion of a long guidewire (4.5 meters) through the cystic duct, by the surgeon, reaching the duodenum. At this point, the endoscopist, positioned with the duodenoscope in front of the papilla captures the wire with a polipectomy loop or biopsy forceps, pulling it out of the working channel in order to be able to advance the sphincterotome over the wire. This allows an elective CBD cannulation without risk of inadvertent Wirsung duct cannulation (15). The meta-analysis comparing this one stage approach with a two stage approach showed similar percentage in successful clearance of CBD stones (16-18) (Table 1).

Gurusamy et al. conducting a systematic review with a total of 532 patients (263 IOES and 269 POES), reported no differences in rate of endoscopic stones clearance for the two groups (96.9 versus 96.3) (17). Wang et al. in their meta-analysis considering 631 patients (313 IOES and 318 POES) confirmed no statistical significant differences between the two groups; however a lower overall CBD clearance rate in IOES group was reported (92.4% vs. 97.1%) (18). The main factors reducing IOES technical success reported in the studies were: prepapillary impacted stones, from 1.5 up to 7% of cases (19) and periampullary diverticula (20).

Alexakis et al. reported in their systematic review of nine Randomized Controlled Trials with a study population of 933 patients (471 IOES and 462 POES) no overall morbidity differences between the two groups. In their review total patient morbidity considered as the presence after the procedure of one of the following: sepsis, clinical pancreatitis, cholangitis, bleeding, pneumonia, acute myocardial infarction, pulmonary embolus, reoperation, conversion to open surgery; was 76/471 (16.1%) in the two-stage group and 92/462 (19.9%) in the one stage group (21).

Gurusumay et al. considering the different complications separately, found both a lower (0.8% versus 4.3 %) incidence of post-ercp pancreatitis and a lower post-ES hyperamylasemia (1.5% versus 8.8%) in the IOES group however such deviations did not reached statistical significance (16) (Table 2). IOES resulted superior to two-stage approach regarding duration of hospital stay in all studies evaluated. Obviously IOES allowing to perform the combined treatment in a single step eliminates the days of hospitalization that have to occur between the two procedures of the sequential approach. Mean hospital stays varied in different studies (22, 23), from 1.3 days to 5.3 days for IOES group and from 3 days to 8 days for the POES group. Systematic analysis of these results produced a mean difference in hospital stay of 2.83 days for the IOES group (16). The shorter hospital stay observed in many studies ensued in most cases even a substantial reduction in cost. No differences were observed between the two groups in the conversion rate in an open cholecystectomy (3.8% POES versus 3.7% IOES) (16). The main reasons for open surgery were adhesions around Calot's triangle during dissection and failure to cannulate the cystic duct during laparoscopy preventing to perform intraoperative cholangiography (IOC) and to pass through the guidewire.

Table 1. Summary of Information Provided by Included Prospective Randomized Controlled Trials [a]

Study year	Design	Inclusion criteria	Number of patients		POES technique	IOES technique	Successful CBD stone clearance, %	
			IOES	POES			POES	IOES
Lella 2006 (3)	Prospective single-center randomi zed	Cholelithiasis and suspected CBD stones	60	59	Laparoscopic cholecystec-tomy within 24-48 h after ERCP	Laparoscopic endoscopic rendezvous technique	96.5	98.6
Morino 2006 (11)	Prospective single center randomized	Cholelithiasis and suspected CBD stones	45	46	Laparoscopic cholecystec-tomy within 24-72 h after ERCP	Endolaparo-scopic rendez-vous technique	80	95.6
Rabago 2006 (23)	Prospective single center randomized	Cholelithiasis and suspected CBD stones	64	59	Laparoscopic cholecystec-tomy within 8 weeks after ERCP	Modified rendezvous technique	96.6	90.2
Elgedie 2011 (22)	Prospective single center randomized	Cholelithiasis and suspected CBD stones	100	98	Laparoscopic cholecystec-tomy within 24-72 h after ERCP	Endolaparo-scopic rendez-vous technique partially	95.3	97.8
Tzovaras 2012 (15)	Prospective single center randomized	Cholelithiasis and suspected CBD stones	**49**	50	Laparoscopic cholecystec-tomy within 48 h after ERCP	Endol-aparoscopic rendezvous technique	94	90

[a] Abbreviations: CBD, common bile duct; IOES: Intra Operative Endoscopic Sphincterotomy; POES: Per Operative Endoscopic Sphincterotomy

Table 2. Summary of Information Provided by Included Reviews Article [a]

Study year	Study design	Number of patients		Successful CBD clearance		Morbidity		Mortality	
		POES	IOES	POES	IOES	POES	IOES	POES	IOES
Alexakis 2012 (21)	Systematic Review	462	471	72.6	74.4	16.1	19.9	0.8	0.6
Gurusamy 2011 (17)	Systematic Review	269	263	96.3	96.9	11.2	5.3	-	-
Wang 2012 (18)	Systematic Review	318	313	92.4	97.1	8.5	3.2	-	-
La Greca 2010 (16)	Review of IOES technique	795	-	92.3	-	5.1	-	0.37	-

[a] Abbreviation: CBD, common bile duct.

Table 3. Results From IOES Treatment for Cholecysto Choledocolithiasis [a]

Study Year	Number of Patients	Successful CBD Clearance	Mean Hospital Stay, d	Morbidity, %	Mortality, %
Cavina 1998 (10)	16	100%	3.9	12.5	6.2
Basso 1999 (30)	52	82.7%	3.3	5.6	1.9
Cemachovic 2000 (13)	49	93.9%	5.3	8.1	0
Kalimi 2000 (34)	21	95%	3.4	19	0
Iodice 2001 (19)	52	94%	3.1	0	0
Meyer 2002 (20)	60	91.6	4.6	3	0
Tricarico 2002 (36)	43	86%	3	2.3	0
Enochsson 2004 (35)	31	93.5%	2.6	0	0
Saccomani 2005 (24)	28	96.4%	4.8	6	0
Hong 2006 (25)	93	91.4%	4.2	8.6	0
Donatelli 2011 (12)	36	94.4%	4.8	16	0
Noel 2012 (33)	307	88.3%	2.5	4	0

[a] Abbreviation: CBD, common bile duct.

4. Discussion

The treatment options for gallbladder and suspected CBD stones are in continuous evolution. Presently the most used treatment is a sequential approach with the ES performed before or after LC. However this approach presents some intrinsic risks related to unnecessary preoperative ES due to a certain degree of uncertainty in diagnosis of CBD stones and the need of a second surgical intervention in case of failure of postoperative ES. IOES has been proposed and evaluated by an increasing number of authors as an innovative one-stage approach capable to overcome the superintended shortcomings (Table 3).

The review in literature showed that IOES is a safe, effective and feasible technique that allows intraoperative clearance of CBD stones. Several advantages of IOES compared with the two stage approach were outlined by different authors. IOES results in a reduction of anesthetic procedures, hospital stay and total costs (24, 25). Del Rio et al. noted that these factors improved patients compliance and eliminates possible patient drop out occurring when two stage approach requires two different hospital admissions (26). IOES eliminates the problem concerning the proper timing between ERCP and LC. Recurrent biliary complications are possible in patients who do not undergo LC after POES within a short interval (7). Moreover different studies have shown that LC is more difficult after POES, due to disruption of Oddi's Sphincter and bacterial colonization of biliary tract leading to inflammation and scarring of hepatoduodenal ligament hindering dissection of Calot's triangle (27). Finally it minimize the risks related to standard ERCP avoiding its principal critical phases consisting in retrograde inadvertent cannulation of pancreas and papillary manipulation thanks to rendez-vous technique (28, 29).

The review of literature outlined the importance of some modifications in surgical techniques to guarantee the safely success of IOES. The main concern when applying this one-stage approach is the overinsufflation of the stomach and small intestine that reduce the surgeon's vision. Mainly four tricks are proposed to overcome this inconvenience: i) Perform dissection of the Calot's Triangle, ligation of the cystic artery and dissection of the most part of the gallbladder from the liver before starting the endoscopic procedure (30); ii) Keep the endoscopic insufflation as low as possible (34); iii) Maintain pneumoperitoneum throughout the IOES (using CO_2 insuflattion) (15); iv) As proposed by Morino et al. (11), reducing small intestinal distension positioning a laparoscopic bowel clamp on the first jejunal loop.

These fundamental modifications may results in a little increase in operational time for LC. A second concern, that may results in difficult CBD cannulation for inexpert endoscopist, is the patient position. During LC, IOES is performed in supine position and it requires an extra-rotation by the endoscopist in order to achieve a correct alignment between the sphincterotome and the CBD axis. However supine position has the advantages of reducing operational time and results in a better visualization of the biliary anatomy particularly at the hilum allowing therefore a finer detection of small stones (31) and a better definition of anatomical variations that could confound the surgeon. Lastly is fundamental to stress the importance of the endoscopist being in the operating theatre during the IOC in order to improve the interpretation of challenging cholangiogram especially in cases of uncertain images of stones or delayed passage of contrast in duodenum (32).

The principal factor hindering the routinely application of IOES in clinical practice seems related mainly to logistical and organizational problems (33, 34). Two different (surgical and endoscopic) teams and equipment are needed to be present in the operating theatre at the same moment requiring an high level of collaboration.

Moreover, some authors (35, 36) reported as possible limitations to IOES with rendez-vous technique presence of prepapillary impacted stones, stenosant papillitis, Mirizzi's syndrome and preampullary diverticula. Donatelli et al. (12), proposed an interesting IOES technique called: ISEEG (intraoperative supine endoscopic sphincterotomy by endoscopist-controlled guide wire cannulation) capable to overcome the possible limitations of rendez-vous. It consists of the endoscopist performing a guidewire cannulation of the CBD manipulating himself the sphincterotome and guide wire using a RX® system, according by the cholangiogram obtained by means of IOC. This technique, although requiring an experienced biliary endoscopist, showed good efficacy, good stone clearance and low morbidity. We can conclude that IOES is a safe, effective and feasible minimally invasive surgical treatment for patients with concomitant gallbladder stones and choledocholithiasis. This single-stage, multidisciplinary approach seems to reduce ERCP related complications, length of hospital stay and costs. Acknowledging the increasing role of flexible endoscopy in the surgical management of patients, we recommend that modern operating theatres should have both these facilities and the proper nurse training in order to spread the clinical use of IOES.

Acknowledgements

There is no acknowledgment.

Authors' Contribution

Each author contributes to drafting and revision of manuscript.

Financial Disclosure

The authors declare no conflict of interests.

Funding/Support

No funding or support.

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