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Is the Ambu® aScope™ equivalent for laparoscopic common bile duct exploration as a re-usable choledochoscope?

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ABSTRACT

Introduction: We have previously reported our institution's early experience on the use of the Ambu® aScope™ in LCBDE2. We demonstrated that the disposable scope was safe to use in LCBDE along with the benefits on cost reduction compared to reusable choledocoscopes.

Materials and Methods: A retrospective cohort study was performed where cases between groups from June 2011 to June 2015 (for a re-usable choledochoscope (Group A)) and from July 2015 to January 2018 (for the Ambu® aScope™ (Group B)) were collected and matched retrospectively. A survey was conducted among eight surgeons who had used the Ambu® aScope™ on their views regarding its use and in comparison to a re-usable choledochoscope.

Results: A total of 80 patients underwent an emergency LCBDE (40 in the re-usable choledochoscope group and 40 patients in the Ambu® aScope™ Group). The patients presented with acute cholecystitis, cholangitis, biliary colic, and pancreatitis, and there was no significant difference between the two groups.

One of the 40 cases in the Ambu® aScope™ group and three of the 40 cases in the reusable scope group was converted to an open procedure. The success of CBD clearance, rate of post-operative bile leak, and conversion to an open procedure was equivalent in both groups.

The majority of respondents (7/8) felt that the dexterity of the Ambu® aScope™ was inferior to the re-usable choledochoscope, and the same number (7/8) thought that the irrigation system using Ambu® aScope™ was inferior to the re-usable choledochoscope. Six of the eight surgeons reported more difficulties in using instrumentation with the Ambu® aScope™ in comparison to the re-usable choledochoscope.

Conclusion: We have shown that a disposable scope may be used safely in LCBDE. However, we feel that the Ambu® aScope™ is not ideal for this task. We would open the call to the industry to support the development of a disposable choledocoscope specific for this purpose.

Keywords: AmbuScope; common bile duct; laparoscopic.

Introduction

Common bile duct stones can associated with more than 15 % of gallstone diseases.[1,2] Laparoscopic common bile duct exploration has been proved to be safe and feasible procedure in many studies.[3,4] Laparoscopic common bile duct exploration (LCBDE) is an appealing technique for

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the management of common bile duct stones. This is notably the case in relation to a single stage procedure for removal of bile duct stones and synchronous cholecystectomy. This has cost saving implications and reduces the need for endoscopic retrograde cholangiopancreatogtraphy (ERCP).[5] This is beneficial in reducing patient exposure to procedural risks and also in reducing institutional pressure on endoscopic services.

We have previously reported our institutions early experience in the use of the Ambu® aScope™ in LCBDE.[6] We showed that the Ambu® aScope™ was safe to use in LCBDE along with the concurrent benefits of cost reduction compared to reusable choledocoscopes. These results have been replicated in other institutions experience in the recent past.[7,8]

In this study we report out longer-term outcomes over a 3-year period and compare them to our results using a conventional reusable instrument. We also report our surgeons' feedback on the use of the Ambu® aScope™ after a 3-year period of utilisation.

Materials and Methods

A retrospective cohort study was performed. Cases were collected retrospectively from a prospective database in the Northumbria NHS Trust, UK. Owing to the introduction in our practice of using the Ambu® aScope™ in 2015, we matched a group from June 2011 to June 2015 (for the re-usable choledochoscope group (Group A)) and from July 2015 to January 2018 (for the Ambu® aScope™ group (Group B)).

Our criteria for inclusion of a LCBDE were: cases assessed in the emergency or elective setting, evidence of CBD stones on preoperative investigations and a CBD diameter of 10 mm or more. Patient position and port placement were as per standard for laparoscopic cholecystectomy (LC). Most of the patients had LC and LCBDE at the same time except for a few who had solely LCBDE due to previous LC. We adapted both trans-cystic and choledochotomy approaches depending on the diameter of cystic duct. When the trans-cystic approach failed, we converted to a choledochotomy if the anatomy was favourable. Exploration of the CBD was performed using a re-usable choledochoscope (3 mm in trans-cystic and 5 mm in choledochotomy) or disposable bronchoscope (Ambu® aScope™) (3.8 mm in trans-cystic and 5 mm in choledochotomy). We used normal saline to irrigate and distend the CBD. A Dormia® basket was used to retrieve any CBD stones. After trans-cystic exploration we clipped the cystic duct with Titanium or absorbable locking clips. We closed the choledochotomy incision using either PDS® or Vicryl® suture (depending on surgeons preference). LC was performed at the completion of the procedure; we always used two drains in the choldechotomy group (one sub-hepatic and other sub-phrenic) and one sub-hepatic drain in trans-cystic group.

A survey was run among eight surgeons who had used the Ambu® aScope™ investigating their views on the use of the Ambu® aScope™ in comparison to a re-usable choledochoscope. Statistical analysis was performed using statistical software running the Chi-Square and T test.

Results

There were 80 patients had emergency LCBDE (40 in the re-usable choledochoscope group and 40 patients in the Ambu® aScope™ Group). Patients presented with acute cholecystitis, cholangitis, biliary colic and pancreatitis in both group and there was no significant difference between the two groups (Table 1). A number of cases were undertaken due to a failed preoperative ERCP (9/40 cases in group A and 2/40 in group B). There were 28 female and 12 male in group B while in group A there were 25 female and 15 male (p=0.21). Mean age were 54.5 and 60 years in both groups A and B respectively (p=0.50).

There were more trans-cystic (T) explorations than choledochotomy (C) in Group A (T/C= 12/28) in comparison to group B (T/C= 6/34), however there was no statistical significant difference (p=0.1) (Table 2). Operative time was slightly longer in group B (133 minutes) in comparison to group A (122 minutes) with no significant difference (p=0.3). There is a notable difference in hospital stay between the groups. However, this is not to statistical significance. Here were no specific factors to influence this difference.

1/40 cases in the Ambu® aScope™ were converted to an open procedure and 3/40 in the reusable scope (no statistical difference). The success of CBD clearance was equivalent in the two groups. Duct clearance and post procedure bile leak was marginally higher in group B (duct clearance 34/40 and bile leak 8/40) than group A (duct clearance 33/40 and bile leak 6/40) but not to statistical significance. Thirty days re-admission and mortality was equivalent in both group A and group B (1/40 and 3/40 group A and 2/40 and 0/40 group B p=0.24).

In terms of survey results, there were eight surgeons included in the survey and all of them have responded

Table 1. Demographic data and preoperative investigation

Parameters	Ambu® aScope™ (Group B)	Re-usable choledochoscope (Group A)	p
Gender, F/M	28/12	25/15	0.21
Age (mean), years	60	54.5	0.50
Overall hospital stay, days	5.3	8.5	0.014
Time to surgery, days	1.03	3.11	0.002
Diagnosis			
Biliary colic	9/40	14/40	0.2
Acute cholecystits	9/40	8/40	0.07
Cholangitis	14/40	7/40	0.07
Pancreatitis	8/40	11/40	0.2
MRCP/CT	38/40	30/40	0.01
CBD diameter (mean), mm	10.65	10.1	0.28
Pre CBD exploration ERCP	9/40	2/40	0.006

Table 2. Shows the summary of results comparing re-usable choledochoscope to disposable choledochoscope

Parameters	Ambu® aScope™ (Group B)	Re-usable choledochoscope (Group A)	p
Trans-cystic	6/40	12/40	0.1
Choledochotomy	34/40	28/40	0.11
Suture type			
PDS	5	4	0.7
Vicryl	29	24	
Continuous	26	8	0.004
Interrupted	8	20	
Intra-operative cholaingogram (IOC)	10/40	19/40	0.034
Conversion to open	1/40 1 impacted stones	3/40 1 impacted stones 2 adhesions	0.3
Operative time (mean), minutes	133	122	0.3
Post-operative bile leak	8/40	6/40	0.55
Post CBD exploration ERCP	3/40	6/40	0.20
CBD clearance	34/40	33/40	0.76
Re-admission rate (30 days)	2/40	1/40	0.34
Mortality	0/40	3/40	0.24

to all questions (Table 3). Four surgeons had performed 20-40 LCBDE with the Ambu® aScope™, two less than 10 and two more than 20 procedures. The majority of responders (7/8) felt the dexterity of the Ambu® aScope™ was worse than the re-usable choledochoscope and the same number (7/8) thought that the irrigation system using Ambu® aScope™ was not as good as for the re-usable choledochoscope. Six of eight surgeons felt there were more difficulties using instrumentation with the Ambu® aScope™ in comparison to the re-usable choledochoscope. Half of the responders felt the image quality was better with the Ambu® aScope™, two felt the same and two felt it was worse in comparison to the re-usable choledochoscope.

Table 3. Survey results of surgeons using AmbuScope

Questions					
How many times have you used the Ambu® aScope™ in CBD exploration?	**Less than 10** 2	**10-20** 4	**More than 20** 2		
How did you feel about the movement and dexterity of the Ambu® aScope™ overall compared to the re-usable scope?	**Better** 0	**Worse** 7	**Same** 1		
How did you find the use instrumentation (passing basket) with the Ambu® aScope™ compared to the reusable scope?	0	6	2		
How did you find the use of irrigation with the Ambu® aScope™ compared to the reusable scope?	1	7	0		
How did you find the image quality with the Ambu® aScope™ compared to the reusable scope?	4	2	2		
How did you find the ability to keep a luminal view with the Ambu® aScope™ compared to the reusable scope?	1	0	7		
Do you feel you were forced to abandon a trans-cystic exploration using the Ambu® aScope™ in comparison to the reusable scope?	**Yes** 4	**No** 4			
Do you feel that you made a decision to convert to an open procedure due to the use of the Ambu® aScope™ compared to the reusable scope?	**Yes** 0	**No** 8			
Do you feel uncomfortable using the Ambo scope for CBD exploration when it has not been purposefully made for the procedure or certified for the procedure?	**Strongly agree** 2	**Agree** 1	**Neither agree or disagree** 3	**Disagree disagree** 1	**Strongly** 1
Do you feel more likely that you would grasp the Ambo scope with a laparoscopic instrument compared to the reusable scope (due to less concerns over damage)?	3	2	3	-	-

There were balanced opinions about being forced to convert from trans-cystic to choledochotomy exploration due to using the Ambu® aScope™. None of the surgeons felt that they had been forced to convert to open procedure from laparoscopic because of using the Ambu® aScope™ than the re-usable choledochoscope.

Discussion

We have reported our institutions 15-year experience of laparoscopic common bile duct explorations (LCBDE) in the literature.[9] We have shown comparable results to other institutions experinence.[1] Our institution has a specialist practice in benign biliary disease with an established

practice in LCBDE. LCBDE is an appealing technique for the management of common bile duct stones. This notably the case in relation to a single stage procedure for removal of bile duct stones and synchronous cholecystectomy. This also reduces the need for ERCP. This is beneficial in reducing patient exposure to procedural risks and also in reducing institutional pressure on endoscopic services.

Here we report our further experience with the Ambu® aScope™ instrument in LCBDE over a 3-year period. We have shown equivalent results between the Ambu® aScope™ and reusable choledocoscope for LCBDE. There was no significant variation in procedure time or in complications. As such, we have shown the Ambu® aScope™ to be safe and acceptable in LCBDE. This safety is upheld from our results published previously for the safety of the Ambu® aScope™.[5] However, despite this equivalence, the feedback from our team of surgeons has shown that the technical performance of the Ambu® aScope™ is inferior to the reusable choledocoscope. As a result, we have taken an institutional decision to use reusable choledocoscopes as our instrument of choice in this procedure and to discontinue the use of the Ambu® aScope™.

As illustrated in our results, the inferior performance of the Ambu® aScope™ principally relates to an inferior manoeurevability of the instrument. Our team have felt that the Ambu® aScope™ does not handle as well as a reusable choledocoscope and is not as manoeuvrable for insertion into the bile duct. A principal concern also relates to the poor application of irrigation during choledocoscopy with the Ambu® aScope™. We have found that there is a persistent leak of irrigation liquid from the attachment port on the scope. This is unsatisfactory during a procedure. There is also a concern around instrumentation with guide wires when using the Ambu® aScope™. This relates to wires not entering the channel inside the scope mechanism and being difficult to manipulate down the channel for stone removal. The majority of these issues principally relate to the fact that this instrument has not been purposefully designed for choledocoscopy. The instrument is purpose built as a disposable bronchoscope.

We have also found a limitation with the Ambu® aScope™ in performing a trans-cystic LCBDE. This has been due to the fact that the smaller diameter scope is too wide to enter the cystic duct. Our surgeons have felt that a reusable scope would have been possible in this setting. This is not ideal, as it concurs a risk of a higher rate of choledocotomy if a trans-cystic approach fails.

In looking at the wider issue of disposable instruments versus reusable in LCBDE, there is no question that a disposable scope offers several advantages. This principally relates to reduced costs and ease of access to equipment. A major limitation in surgical practice is that many institutions in the UK have not been able to afford the upfront costs of establishing a LCBDE service. A single reusable scope may cost upwards of £10000. Disposable scopes obviate the high upfront costs of buying reusable scopes and maintenance. A single unit Ambu® aScope™ costs around £150. There are other costs of consumables associated but the financial benefits are clear.

Limitations

This study is a retrospective control study showing the results of the introduction of a new instrument. Our historical control group is for the resusable choledocoscope. There is a limitation in that we are comparing results to a historical group. However, we feel that there are negligible factors over time to have altered our outcomes apart from the introduction of the new instrument we are investigating.

The study is also limited by a small study size. However, we have are reporting a longer term follow up of results for a novel instrument. As such, we feel the results are still of scientific merit.

Conclusions

We have shown that a disposable scope may be used safely in LCBDE. However, we feel that the Ambu® aScope™ is not ideal for this task. We would open the call to industry to support the development of a purpose disposable choledocoscope. This could revolutionise access to this technique and concur significant benefit to patients for access to this procedure. This would give access to a desirable single stage procedure for selected patients.

Disclosures

Ethichs Committee Approval: Ethical committee approval is done by Northumbria Healthcare NHS Foundation Trust via Caldecott approval 2018.

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L.H.; Literature search – Y.M.A., D.L.; Writing – Y.M.A., D.L.; Critical review – L.H., D.L., Y.M.A.

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