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MINIREVIEWS

Endoscopic ultrasound guided gastroenterostomy: Technical details updates, clinical outcomes, and adverse events

Jian Wang, Jin-Long Hu, Si-Yu Sun

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Abstract

Endoscopic ultrasound-guided gastroenterostomy (EUS-GE) has been transformed from an innovative technique, into a viable alternative to enteral stenting and surgical gastrointestinal anastomosis for patients with gastric outlet obstruction. Even EUS-GE guided ERCP and EUS-guided gastrointestinal anastomosis for the treatment of afferent loop syndrome have been performed, giving patients more less invasive options. However, EUS-GE is still a technically challenging procedure. In order to improve EUS-GE, several techniques have been reported to improve the technical details. With EUS-GE widely performed, more data about EUS-GE's clinical outcomes have been reported. The aim of the current review is to describe technical details updates, clinical outcomes, and adverse events of EUS-GE.

Key Words: Gastric outlet obstruction; Endoscopic ultrasound guided gastroenterostomy; Endoscopic ultrasound; Retrievable anchor; Duodenal stent; Surgical gastroenterostomy

Core Tip: Endoscopic ultrasound guided gastroenterostomy (EUS-GE) is still a technically challenging procedure. In order to improve EUS-GE, several techniques have been reported to improve the technical details. With EUS-GE widely performed, more data about EUS-GE's clinical outcomes have been reported. Knowledge of complications during performing EUS-GE is essential to perform it well. The aim of the current review is to describe technical details updates, clinical outcomes, and adverse events of EUS-GE.

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INTRODUCTION

Based on the development of accessory devices, such as lumen-apposing metal stents (LAMS)[1], more interventional endoscopic ultrasound (EUS) procedures could be performed[2-4], including EUS-guided gastroenterostomy (EUS-GE)[5, 6]. The first EUS-GE was reported in an animal study by Binmoeller *et al*[7] in 2012, demonstrating that EUS-GE was a technically feasible procedure. The indication of EUS-GE was initially for the treatment of malignant gastric outlet obstruction (GOO). With EUS-GE developing rapidly in the last five years, EUS-GE could be used to treat malignant GOO and benign GOO[8], as well as afferent loop syndrome[9-11]. Even EUS-GE assisted ERCP could be performed in patients with Roux-en-Y gastric bypass[12-15]. However, EUS-GE is a technically challenging procedure, because the intestinal cavity is small and small bowel is free. Adverse events, such as misplacement of metal stent, could occur during the procedure. In order to simply EUS-GE, several techniques have been reported[16-18].

The aim of the current review is to describe technical details updates, clinical outcomes, and adverse events of EUS-GE.

TECHNICAL DETAILS UPDATES OF EUS-GE

The direct EUS-GE is usually performed as follows: puncturing a small bowel loop adjacent to the stomach with a 22-gauge needle to dilate the target small bowel with saline. After puncture with a 19-gauge FNA needle, an enterogram is obtained and a wire is inserted through the needle into the small bowel. The tract is then dilated along the wire and the LAMS is placed. Based on direct EUS-GE, several techniques have been used to distend the jejunum, stabilize the target jejuna loop and simply the procedure.

It is of importance to know how to scan the suitable bowel to do EUS-GE. At first, when we scan the confluence of splenic vein and superior mesenteric vein, we can see the neck of pancreas, uncinate process and the second part of duodenum behind the uncinate process. We slightly rotate the endoscope, then we can see the bowel near to stomach and below the pancreas, which is a good place to perform EUS-GE (Figure 1).

To distend the jejunum, water-filling technique[19] and water-inflated balloon technique[20-22] have been used. For water-filling technique, before the performance of EUS-GE, a nasobiliary drain tube was usually inserted into jejunum over guidewire, through the stenosis, connected to a syringe. The saline with blue dye was injected into jejunum to distend intestinal lumen. The advantage of colored saline than only saline is that the pullback of blue saline by the needle can help confirm the successful puncture of jejunum, avoiding mispuncture of colon[23]. Instead of syringe, a waterjet system was used to constantly inject saline, which could be performed by the operator. For water-inflated balloon technique including single-balloon-occluded gastroenterostomy and double-balloon-occluded gastrojejunostomy bypass (EPASS), Itoi *et al*[24] first reported EPASS and it was widely used in clinical practice. In the EPASS technique, a guidewire and/or an overtube was used to facilitate passage of the double-balloon enteric tube into the jejunum beyond the ligament of Itoi *et al*[25] reported that a 0.89-inch large diameter guidewire was used to assist passage of the double-balloon enteric tube into the jejunum and a large diameter guidewire can avoid the looping of the balloon tube in the stomach fornix. The saline solution is only filled between two balloons over this area, making it easy to locate the distended jejunum under EUS guidance and allowing easy and safe access to the jejunum.

Because this device is not, however, available everywhere, an occlusive double-balloon device, using a widely available vascular balloon catheter, for EUS-GE has been reported[26].

To stabilize the target jejuna loop, the anchor wire[7] and retrievable anchor[27-29] was used to appose small bowel against the gastric wall. Small intestine is free in the abdominal cavity, which made EUS-GE difficult to perform. Any device to access small intestine might push small intestine away from the stomach, which made EUS-GE failed. Even with EPASS, two unsuccessful stent deployment cases occurred, due to guidewire pushing the distended jejunum to move away from the stomach[25]. So it is important to fix the small intestine. The distal end of the 0.035-inch wire has three triangular anchor components. The retrievable anchor is similar to T-tag anchor with a retrievable wire. When performing EUS-GE, the small bowel was punctured with a 19-G FNA needle, the anchor wire or retrievable anchor was inserted through a standard 19-G FNA needle to appose the small bowel against the gastric wall. Both the anchor wire and retrievable anchor could be retrieved after EUS-GE.

To simply the EUS-GE, electrocautery-enhanced LAMS[30,31] was used, even wireless EUS-GE[32-35] was performed. As mentioned above, any device to access small intestine might push small intestine away from the stomach. Electrocautery-enhanced LAMS can combine the tract dilation with stent insertion, which reduces tract dilation step of EUS-GE. For wireless EUS-GE, after confirmation of the target loop, the electrocautery-enhanced LAMS was inserted directly into the targeted jejunal loop without using a guidewire. In their opinion, if we can observe the distended small bowel and nasojejunal catheter adequately under EUS, confirmatory puncture by a 19-gauge needle and guidewire cannulation is an unnecessary step; it increases costs and procedure duration and may provide a false sense of security. During this procedure, the power should be set to enable LAMS entering small intestine quickly, otherwise LAMS might push the

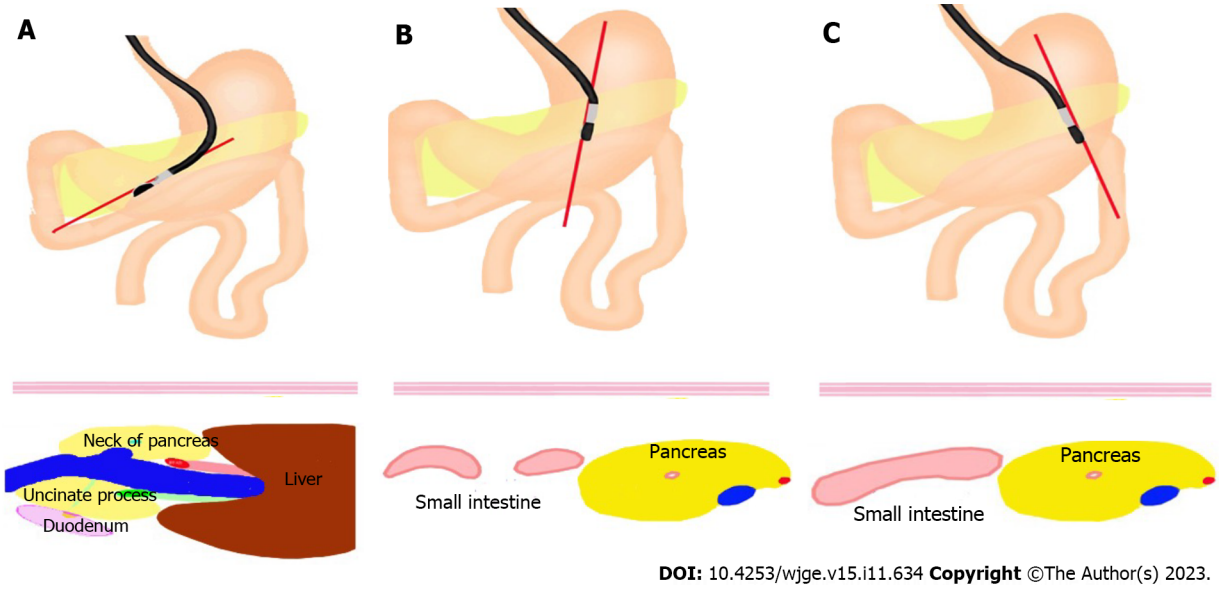

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Figure 1 Endoscopic ultrasound scans the suitable bowel to do endoscopic ultrasound- guided gastroenterostomy. A: We scan the confluence of splenic vein and superior mesenteric vein, we can see the neck of pancreas, uncinate process and the second part of duodenum behind the uncinate process; B: We slightly rotate the endoscope, then we can see the short-axis view of bowel near to stomach and below the pancreas; C: When we continue to rotate the endoscope, we can see the long-axis view of bowel.

small intestinal away.

CLINICAL OUTCOMES OF EUS-GE

With more articles about EUS-GE published in recent 5 years, systematic reviews and meta-analysis suggested that EUS-GE has good overall technical and clinical success, as well as acceptable complication rates, despite EUS-GE technique[36-38].

For success rate between different techniques of EUS-GE, only one study evaluated the direct and balloon-assisted techniques[39]. The two groups had similar technical success rate, clinical success rate, rate of complications, postoperative length of stay, need for re-intervention and survival, but the direct technique may be the preferred method, due to mean procedure time shorter with the direct technique ($P < 0.001$). All the medical centers included in this study were from United States and Europe and the single balloon-assisted EUS-GE was performed in this study. Further studies are expected to confirm the results.

The size of LAMS has been the subject of debate. The 15-mm LAMS has always been used to perform EUS-GE and it has been proven to be technically feasible, clinically effective, and safe. Madanat *et al*[40] first reported the use of the 20-mm LAMS for an EUS-GE. Theoretically, better clinical outcomes may be achieved with the 20 mm LAMS with a wider lumen. But it is concerned that 20-mm LAMS's wider luminal diameter and larger flange size may lead to difficulty in deploying. Sobani *et al*[41] reported EUS-GE with 20mm-LAMS is a technically feasible and safe option for patients with GOO allowing for tolerability of regular diet. A recent study compared 20-mm LAMS with 15-mm LAMS in performing EUS-GE. The type of diet tolerated at follow-up differed between the two groups, although clinical success was similar. A higher proportion of patients in the 20 mm LAMS group tolerated a soft/full diet compared to those in the 15 mm group ($P = 0.04$)[42]. The 20-mm LAMS is, thus, the preferred LAMS during EUS-GE.

Through maturation of the EUS-GE technique, EUS-GE was compared with surgical gastroenterostomy (SGE)[43-45] and enteral stenting for the treatment of GOO[46-48]. In several retrospective studies, EUS-GE has been proposed as an alternative to enteral stenting with similar safety and surgical range-efficacy. The most recent systematic review, including 625 patients, comparing EUS-GE with SGE showed that the pooled odds of technical success were lower for EUS-GE compared to SGE. Among the technically successful cases, EUS-GE was superior in terms of clinical success, lower overall AE and shorter procedure time. There was no significant difference about rates of severe AE and GOO recurrence between EUS-GE and SGE. The results suggested EUS-GE is a promising alternative to SGE because of its superior clinical success, overall safety, and efficiency[49].

Compared with enteral stent (ES), a recent systematic review including 659 patients demonstrated that EUS-GE and ES has a similar technical and clinical success rate, but the pooled re-intervention rate was significantly lower for EUS-GE than ES[50].

ADVERSE EVENTS OF EUS-GE

Knowledge of adverse events encountered with EUS-GE is essential to perform it well. The EUS-GE-related complications included LAMS misdeployment, abdominal pain, bleeding , infection , leakage at the site of the LAMS, gastric leak , stent ingrowth, stent failure, and LAMS mesh erosion[43,45,48,51,52].

LAMS displacement is the most typical adverse event evaluated in the largest multicenter cohort to date, and the different types of stent displacement were classified into four types[53]. Type I was defined as distal flange of stent displaced in the abdominal cavity without enterotomy. Type II was defined as distal flange of stent displaced in the abdominal cavity with concomitant enterotomy. Type III was defined as distal flange of stent into the small bowel and proximal flange of stent in the abdominal cavity. Type IV was defined as gastrocolonic anastomosis. Type I stent displacement was the most common among four types. For both type I and type II stent displacements, the majority of patients can be successfully managed by endoscopic methods or conservative treatment. Type I stent displacements were more frequently rated as mild than type II stent displacements. Depending on the type of stent displacement, it is important for endoscopists to have a better understanding of the implications and possible consequences of stent displacement. Depending on the subtype, the majority of stent displacement can be successfully managed by endoscopic salvage. Several rescue options have been previously reported for gastroenterostomy[54-59]. The rescue method was usually based on the status of guidewire. If the guidewire could not enter the target loop again, LAMS misdeployment can require natural orifice transluminal endoscopic surgery. For the most common situation, distal LAMS flange misplacement, we could enter peritoneal cavity through transgastric LAMS using a therapeutic gastroscope or double-channel gastroscope and put a second stent to form LAMS-in-LAMS salvage. If the guidewire kept in the target loop, a second stent can be deployed safely under peritonoscopy and fluoroscopy guidance[60].

Delayed intestinal perforation, caused by LAMS, were reported which was related with indwelling time[61,62]. Although the manufacturer recommends removal of the LAMS within 60 d of placement, this period is theoretical as no study has evaluated the optimal indwelling time. The stent indwelling time was different, depending on causes of GOO. For malignant GOO, palliative stents should be left in place for as long as possible. For diseases that may be reversible, such as GOO due to acute pancreatitis, where the pancreatitis may resolve after treatment, these stents should be removed as soon as the GOO resolves. For patients with nonreversible benign GOO, there is still no data to confirm the safety of long-term use and we should be cautious.

CONCLUSION

EUS-GE is an effective method to treat GOO, even for afferent loop syndrome and EUS-GE guided interventional procedure. An increasing data has demonstrated that EUS-GE may be a more effective alternative to enteral stenting and surgical gastroenterostomy. No standardized technique of EUS-GE has been confirmed and endoscopists perform it based on their habit. Randomized controlled studies are needed to confirm the standardized technique. Because EUS-GE is initially for the treatment of malignant GOO, most of studies focused on short outcomes. With EUS-GE performed for benign GOO, the ideal indwelling time of LAMS and long-term outcomes should be studied by large-volume prospective studies. Now almost all the EUS-GE procedures are performed in the tertiary medical centers. The training model should be studied to make EUS-GE more widely used.

FOOTNOTES

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ORIGINAL ARTICLE

Retrospective Cohort Study

Endoscopic retrograde cholangiopancreatography-related early perforations: A study of effects of procedure duration, complexity, and endoscopist experience

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Abstract

BACKGROUND

Perforations (Perf) during endoscopic retrograde cholangiopancreatography (ERCP) are rare (< 1%) but potentially fatal events (up to 20% mortality). Given its rarity, most data is through case series studies from centers or analysis of large databases. Although a meta-analysis has shown fewer adverse events as a composite (bleeding, pancreatitis, Perf) during ERCP performed at high-volume centers, there is very little real-world data on endoscopist and center procedural volumes, ERCP duration and complexity on the occurrence of Perf.

AIM

To study the profile of Perf related to ERCP by center and endoscopist procedure volume, ERCP time, and complexity from a national endoscopic repository.

METHODS

Patients from clinical outcomes research initiative-national endoscopic database (2000-2012) who underwent ERCP were stratified based on the endoscopist and center volume (quartiles), and total procedure duration and complexity grade of the ERCP based on procedure details. The effects of these variables on the Perf that occurred were studied. Continuous variables were compared between Perf and no perforations (NoPerf) using the Mann-Whitney U test as the data demonstrated significant skewness and kurtosis.

RESULTS

A total of 14153 ERCPs were performed by 258 endoscopists, with 20 reported Perf (0.14%) among 16 endoscopists. Mean patient age in years 61.6 ± 14.8 *vs* 58.1 ± 18.8 (Perf *vs*. NoPerf, P = NS). The cannulation rate was 100% and 91.5% for Perf and NoPerf groups, respectively. 13/20 (65%) of endoscopists were high-volume performers in the 4th quartile, and 11/20 (55%) of Perf occurred in centers with the highest volumes (4th quartile). Total procedure duration in minutes was 60.1 ± 29.9 *vs* 40.33 ± 23.5 (Perf *vs* NoPerf, P < 0.001). Fluoroscopy duration in minutes was 3.3 ± 2.3 *vs* 3.3 ± 2.6 (Perf *vs* NoPerf P = NS). 50% of the procedures were complex and greater than grade 1 difficulty. 3/20 (15%) patients had prior biliary surgery. 13/20 (65%) had sphincterotomies performed with stent insertion. Peritonitis occurred in only 1/20 (0.5%).

CONCLUSION

Overall adverse events as a composite during ERCP are known to occur at a lower rate with higher volume endoscopists and centers. However, Perf studied from the national database show prolonged and more complex procedures performed by high-volume endoscopists at high-volume centers contribute to Perf.

Key Words: Endoscopic retrograde cholangiopancreatography; Endoscopy complications; Perforations

Core Tip: We analyzed the profile of perforations (Perf) related to endoscopic retrograde cholangiopancreatography (ERCP) from the clinical outcomes research initiative-national endoscopic database over 12 years. The retrospective analysis of 14153 ERCPs done by 258 endoscopists reported a Perf rate of 0.14% (20 Perf) among 16 endoscopists. The cannulation rate was 100% for Perf and 91.5% for no Perf groups. 65% of endoscopists were high-volume performers, and 55% of Perf occurred in centers with the highest volumes (4th quartile). Higher volume endoscopists and centres are known to have less ERCP-related adverse events. However, this national database study on Perf has shown prolonged and complex procedures performed by high-volume endoscopists at high-volume centers contributed to Perf.

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INTRODUCTION

The indications for therapeutic endoscopic retrograde cholangiopancreatography (ERCP) have increased exponentially over the last decade[1]. Consequently, the complexity of procedures has also increased along with the training required to achieve competencies to perform such high-risk procedures. As a result, the completion success and complication rates vary widely and appear related to the endoscopist volume[2,3].

Although perforation (Perf) during ERCP is uncommon (1%), it can be fatal with up to 20% mortality[4,5]. Most data about ERCP-related Perfs is from case series or analysis of large databases. While a meta-analysis revealed lesser adverse overall events (bleeding, Perf, pancreatitis) during ERCP performed at high-volume centres[6], there is a lack of real-world data regarding endoscopist and centre procedural volumes, ERCP duration, and complexity on the occurrence of early Perf[5,7,8].

We analyzed a national endoscopic repository national institute of health (NIH)-clinical outcomes research initiative-national endoscopic database (CORI-NED) to study the profile of Perf related to ERCP by center and endoscopist procedure volume, ERCP time, and complexity.

MATERIALS AND METHODS

Database

CORI-NED is a large prospectively accrued population-based database maintained by NIH. CORI was established in 1995 to study the use and outcomes of endoscopy in diverse gastroenterology practice settings in the United States[9]. Participating physicians are provided with an electronic health record completed at the endoscopy time and generate procedure reports. Once submitted, the report cannot be altered. Users are required to document at least 95% of the procedures in CORI. A limited dataset from every report is sent to NIH, where it is quality tested and compiled into CORI-NED. Anonymized data is collected and stored per strict health insurance portability and accountability act standards, and users must obtain data user agreements and Institutional Review Board (IRB) approval. This study was IRB-approved. As CORI-NED contains information generated at the time of ERCP, we examined early Perf discovered before the procedure report was generated, signed off, and submitted to the repository.

Study cohort, design and statistical analysis

Our study is a retrospective population-based analysis of early Perf related to ERCP. Patients over 18 years of age who underwent ERCP from 2000-2012 were studied. Data collected included age, sex, center volume, endoscopist volume, ERCP and fluoroscopy duration, indication, ERCP difficulty, prior biliary surgery dilation of strictures, sphincterotomy, sphincterotomy device used, stent placement, peritonitis. Patients were stratified based on the endoscopist's and center's volume (quartiles), total procedure duration, and complexity grade of the ERCP based on procedure details. We aim to identify age factor, ERCP fluoroscopy time, and total procedure time between patients who suffered Perf *vs* those who did not in the immediate post-procedural period (before the procedure note is uploaded as per CORI-NED).

The effects of these variables on the Perf that occurred were studied. In addition, continuous variables were compared between Perf and no Perfs (NoPerf) using the Mann-Whitney U test, as the data demonstrated significant skewness and kurtosis. All analysis was performed using SPSS (v28.0). The statistical review of the study was performed by a biomedical statistician. The grades of ERCP difficulty were defined by the grading system (Supplementary Table 1) proposed by Raju[10], Schutz and Abbott[11] and were widely used during data collection.

RESULTS

14153 ERCPs performed by 258 endoscopists at 48 facilities were analyzed. 20 Perf (0.14%) were reported among 16 endoscopists. The mean patient age was 61.6 ± 14.8 *vs* 58.1 ± 18.8 years (Perf *vs* NoPerf, P = NS, Figure 1A). The cannulation rate for Perf *vs* no Perf was 100% and 91.5%, respectively. 11/20 (55%) of Perf happened in the centres with the greatest volumes (4th quartile), while 13/20 (65%) of endoscopists were high-volume achievers.

Total procedure duration was 60.1 ± 29.9 *vs* 40.33 ± 23.5 min (Perf*vs* NoPerf, P < 0.001, Figure 1B). Fluoroscopy duration was 3.3 ± 2.3 *vs* 3.3 ± 2.6 min (Perf *vs* NoPerf P = NS, Figure 1C). To evaluate the differences between patients who perforated *vs* those who did not Mann-Whitney U test was utilized. The test revealed a significant difference in total procedural time between those who suffered Perf *vs* those who did not (Median 51 *vs* 32 min, n = 20 *vs*. n = 14133), U = 8467 *vs* 5816, Z = 3.536, P < 0.001, r = 118 (large effect size). Hence H0 was rejected. However, age and fluoroscopy time did not differ between the groups.

Half of the procedures were complex and more than grade 1 difficulty (Table 1). 3 out of 20 (15%) patients had prior biliary surgery. 13 out of 20 cases (65%) had sphincterotomies with stent insertion. 1 case (0.5%) had peritonitis (Table 1).

We also performed a multivariate regression analysis of age category, endoscopist ERCP volume quartile, fluoroscopy time, and total procedure time (Table 2). The regression analysis results demonstrate that only prolonged total procedural time among the parameters studied is associated with Perf (hazard ratios 1.022, 95% confidence interval 1.001-1.043, P < 0.036).

DISCUSSION

Our nationwide population-based study about ERCP identified several factors related to procedure complexity, center, and endoscopist performance as significant risk factors for ERCP-related Perf. The risk factors for ERCP-related Perf were a higher grade of complexity requiring a longer duration of the procedure, a high-volume center, and a high-volume endoscopist.

Overall, greater volume endoscopists and centres are reported to have a reduced rate of adverse events during ERCP [6]. Currently, there is a lack of consensus on the minimum required volume to maintain ERCP competency. The minimum standards and mandatory curriculum required for an endoscopist and center to maintain ERCP skills have been recently defined in a multicenter clinical trial but have not been widely adopted[12]. Short-term ERCP complications occur in about 10% of patients, including cholangitis, pancreatitis, bleeding, and Perf[13]. It has also been suggested that ERCP-related complications, especially Perf, tend to occur more frequently in lower-volume centers by and with lower endoscopist volume by quartiles[5,6]. An analysis of the Swedish National Register for Gallstone Surgery and ERCP[14] has also shown that higher endoscopist and center case volumes are associated with safer ERCP, similar to our results. However, this study analyzed only ERCP for stones and malignancy as an indication of ERCP. They found that higher case and center volume correlated with lower complication rates and shorter procedure time in ERCP for Cannabidiol

Table 1 Details of the endoscopic retrograde cholangiopancreatographys associated with perforation for clinical outcomes research initiative-national endoscopic database

Physician	Physician volume quartile	Center volume quartile	Indication	ERCP difficulty grade	Dilation of strictures	Sphincterotomy performed	Stent placement	Sphincterotomy device	Peritonitis	Prior biliary surgery
1	4	4	LHD tumor biopsy	3	No	No	No	NA	No	No
2	4	4	Pancreatic tumor	3	No	Yes	Yes	[1]	No	Yes
2	4	4	CBD stone	3	Yes	Yes	Yes	Cotton cannulotome	No	No
2	4	4	CBD stricture	3	Yes	Yes	Yes	Cotton cannulotome	No	No
3	3	3	RHD tumor biopsy	3	No	Yes	Yes	Cotton cannulotome	No	No
4	3	2	CBD stone	1	No	Yes	Yes	Cotton cannulotome	No	No
5	4	4	CBD stone	1	No	Yes	Yes	Papillotome	Yes	No
6	4	3	Stent placement	1	No	Yes	Yes	Autotome	No	No
7	4	3	CBD stone	1	No	No	No	[1]	No	No
8	3	4	CBD stone	1	No	No	No	[1]	No	No
9	4	3	Pancreatic tumor	3	No	Yes	Yes	Cotton cannulotome	No	No
10	3	3	Sphincter of oddi dysfunction	3	No	Yes	Yes	[1]	No	No
11	4	4	CBD stone	2	No	Yes	Yes	Cannulating sphincterotome	No	Yes
11	4	4	Stent replacement	1	No	No	No	NA	No	No
11	4	4	Pancreatic pseudocyst drainage	4	No	Yes	Yes	Needle knife precut	No	Yes
12	4	4	CBD stone	1	No	Yes	Yes	[1]	No	No
13	4	4	CBD stone	1	No	No	No	NA	No	No
14	3	3	Stent placement	1	No	Yes	Yes	Cotton cannulotome	No	No
15	3	3	CBD stone	1	No	No	No	NA	No	No
16	3	3	CBD stone	3	No	No	No	NA	No	Yes

[1]Unavailable. LHD: Left hepatic duct; CBD: Common bile duct; ERCP: Endoscopic retrograde cholangiopancreatography.

stones. Conversely, factors associated with Perf in our study were the prolonged duration of the procedure, as shown previously by other studies [5,15,16]. A large review of 142847 ERCPs found a 0.39% Perf rate, where sphincterotomy was responsible for 41% of Perf[17]. Interestingly, in our study, ERCP with Perf had a 100% cannulation rate compared to 91.5% in ERCP with no Perf. Also, 50% of the Perf occurred in complex ERCPs (> grade 1 as per the classification proposed by Schultz and Abbott[11] and colleagues)[18]. The success rate of approximately ≥ 90% cannulation of the desired duct is a parameter to measure competency in performing ERCP[19].

The Perf rate following ERCP in our study was lower (0.14%) than in the three previous, where the rates were 0.45%, 0.72%, and 0.39%, respectively[4,5,17]. Participating physicians in CORI-NED database are provided with an electronic health record completed at the endoscopy time and generate procedure reports. Once submitted, the report cannot be altered. Hence only the Perf detected during the peri-operative period are reported in the database. Thus, only early Perf following ERCP are reported and studied. This may explain the low Perf rate reported in our study. However, research on Perf from the CORI-NED has revealed that extended, more complicated procedures carried out in high-volume centres by high-volume endoscopists are a factor in Perf. This is likely due to high-risk procedures with complex pathology been

Table 2 Details of the endoscopic retrograde cholangiopancreatographys associated with perforation for clinical outcomes research initiative-national endoscopic database

Parameter studied	B	SE	Wald	df	*P* value	HR	95%CI
Age category in yr (< 40, 40-60, 60-75, > 75). Endoscopist ERCP volume (*n*) quartiles (< 50, 50-100, 100-150, > 150) fluoroscopy time (minutes). Total duration of the procedure (minutes)	0.086	0.271	0.101	1	0.75	1.09	0.64
							1.856
	-0.094	0.241	0.152	1	0.697	0.91	0.568
							1.46
	-0.104	0.133	0.611	1	0.435	0.901	0.694
							1.17
	0.022	0.01	4.403	1	0.036	1.022	1.001
							1.043

ERCP: Endoscopic retrograde cholangiopancreatography; HR: Hazard ratios; CI: Confidence interval.

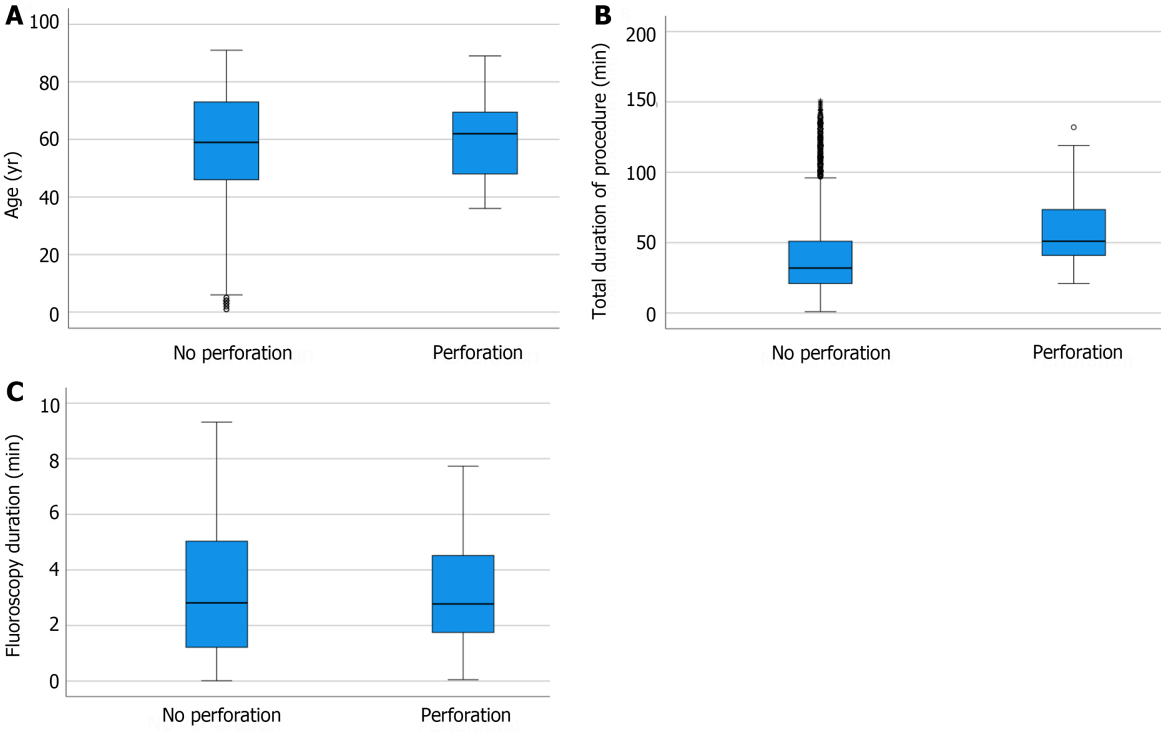

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Figure 1 Comparison of age and time between perforation and no perforationgroup. A: Mean patient age was 61.6 ± 14.8 *vs* 58.1 ± 18.8 years [Perforation (Perf) *vs* no Perfs (NoPerf), *P* = NS]; B: Total procedure duration was 60.1 ± 29.9 *vs* 40.33 ± 23.5 min (Perf *vs* NoPerf, *P* < 0.001); C: Fluoroscopy duration was 3.3 ± 2.3 *vs* 3.3 ± 2.6 min (Perf *vs* NoPerf *P* = NS).

undertaken at tertiary and quaternary centers.

Early diagnosis is most important to reduce associated significant morbidity and mortality rates; thus, prompt management should be initiated as soon as possible. The late recognition of ERCP-related Perf, failure to adequately treat a Perf, and delayed surgery following failed non-operative management worsen outcomes[4,19-22].

The strength of the study is that the CORI-NED was utilized as the primary data source. CORI has strict quality-control measures for all its data. The data repository is checked for anomalies on a daily basis, and unusual activity prompts contact by CORI staff[9]. Moreover, the data is derived from a variety of gastroenterology practice settings, with the majority of sites covered being community-based, followed by veterans' administration and academic hospitals. This provides an evaluation of real-world representation of the practice of endoscopy.

Limits of the study

Our study results should be considered in light of its limitations, most of which are inherent to large database studies. First, this study is prone to site-selection bias. The sites unwilling to share data with CORI-NED may differ in their clinical practice from the participating sites. Generally, smaller practices with higher administrative burdens do not participate in additional data sharing on databases. These practices also refer complex procedures to high-volume centers and endoscopists. It is also likely that less experienced practitioners rarely publish their data[16,23]. Second, CORI-NED database does not give the specific type of Perf encountered during the ERCP procedure. Thus we could not differentiate into duodenal Perf, peri-ampullary or bile duct Perf. Third, the endoscopic report was the source of data in this study. The CORI-NED database only records the clinical information and events during and immediately after the ERCP in the endoscopic report. Additionally, follow-up data analysis in CORI is limited. Hence delayed Perf would not have been picked up in the study. However, a review of 18 retrospective studies showed that most (73%) Perf are identified during the periprocedural period[17].

CONCLUSION

Our study shows that the increase in procedure complexity raises the requisite expertise to deal with complex pathology successfully. ERCP will continue its exponential growth to deal with more complex hepatobiliary pathologies. In order to raise the expertise of future endoscopists, higher volume centers with adequate training procedure numbers for aspiring endoscopists are the need of the hour.

ARTICLE HIGHLIGHTS

Research background

Endoscopic retrograde cholangiopancreatography (ERCP) is a widely performed procedure in gastroenterology. ERCP perforations (Perf) are rare complication however they lead to severe morbidity and can be fatal.

Research motivation

Clinical outcomes research initiative-national endoscopic database (CORI-NED) is a large prospectively accrued population-based database maintained by national institute of health (NIH). NIH established CORI in 1995 to study the use and outcomes of endoscopy in diverse gastroenterology practice settings in the United States. Our motivation was to study this large database and look into the complications associated with ERCP.

Research objectives

ERCP were stratified based on the endoscopist and center volume (quartiles), complexity of the ERCP and total procedure duration based on procedure details. The effects of these variables on the Perf were studied.

Research methods

ERCP related data from CORI NED database from 2000-2012 was analyzed. Continuous variables were compared between Perf and no Perf (NoPerf) groups using Mann-Whitney U test as the data demonstrated significant skewness and Kurtosis.

Research results

14153 ERCPs performed by 258 endoscopists at 48 facilities were analyzed. 20 Perfs (0.14%) were reported among 16 endoscopists. The cannulation rate for Perfs *vs* no Perfs was 100% and 91.5%, respectively. 11/20 (55%) of Perfs happened in the centres with the greatest volumes (4th quartile), while 13/20 (65%) of endoscopists were high-volume achievers. Total procedure duration in minutes was 60.1 ± 29.9 *vs*. 40.33 ± 23.5 (Perf *vs*. NoPerf, $P < 0.001$). Half of the procedures were complex and more than grade 1 difficulty (Table 1). 3 out of 20 (15%) patients had prior biliary surgery. 13 out of 20 cases (65%) had sphincterotomies with stent insertion. 1 case (0.5%) had peritonitis.

Research conclusions

Overall adverse events as a composite during ERCP are known to occur at a lower rate with higher volume endoscopists and centers.

Research perspectives

We analyzed the profile of Perfs related to ERCP from the CORI-NED database over 12 years. The retrospective analysis of 14153 ERCPs performed by 258 endoscopists reported 20 Perfs (0.14%) among 16 endoscopists. The cannulation rate was 100% for Perf and 91.5% for no Perf groups. 65% of endoscopists were high-volume performers, and 55% of Perfs occurred in centers with the highest volumes (4th quartile). Higher volume endoscopists and centres are known to have less ERCP-related adverse events. However, this national database study on Perfs has shown prolonged and complex procedures performed by high-volume endoscopists at high-volume centers contributed to Perfs.

FOOTNOTES

Author contributions: Aloysius M and Goyal H designed the study, performed the statistical analysis, generated the figures, and edited the manuscript; Nikumbh T performed the literature review and drafted the initial version of the manuscript and revised manuscript; Shah NJ, Hammoud GM, Mutha P, and Joseph-Talreja M edited the manuscript; John S, Aswath G, Wadhwa V and Thosani N critically reviewed manuscript.

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ORIGINAL ARTICLE

Retrospective Cohort Study

Nomogram to predict gas-related complications during transoral endoscopic resection of upper gastrointestinal submucosal lesions

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Abstract

BACKGROUND

Gas-related complications present a potential risk during transoral endoscopic resection of upper gastrointestinal submucosal lesions. Therefore, the identification of risk factors associated with these complications is essential.

AIM

To develop a nomogram to predict risk of gas-related complications following transoral endoscopic resection of the upper gastrointestinal submucosal lesions.

METHODS

We collected patient data from the First Affiliated Hospital of the Army Medical University. Patients were randomly allocated to training and validation cohorts. Risk factors for gas-related complications were identified in the training cohort using univariate and multivariate analyses. We then constructed a nomogram and evaluated its predictive performance based on the area under the curve, decision curve analysis, and Hosmer-Lemeshow tests.

RESULTS

Gas-related complications developed in 39 of 353 patients who underwent transoral endoscopy at our institution. Diabetes, lesion origin, surgical resection method, and surgical duration were incorporated into the final nomogram. The predictive capability of the nomogram was excellent, with area under the curve values of 0.841 and 0.906 for the training and validation cohorts, respectively.

CONCLUSION

The ability of our four-variable nomogram to efficiently predict gas-related complications during transoral endoscopic resection enhanced postoperative assessments and surgical outcomes.

Key Words: Complications; Endoscopy; Upper gastrointestinal tract; Nomogram; Forecasting

Core Tip: This is a retrospective study to create a nomogram that efficiently evaluates the risk of gas-related complications in patients undergoing transoral endoscopic resection of upper gastrointestinal submucosal lessions. Our study excluded upper gastrointestinal malignancies and explored risk factors for gas-related complications during transoral endoscopic resection. Predictive models were developed based on diabetes status, lesion origin layer, operative resection technique, and duration of the operation.

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INTRODUCTION

Submucosal gastrointestinal lesions, often referred to as subepithelial gastrointestinal lesions (SELs)[1], encompass a range of submucosal stromal tumors, leiomyomas, lipomas, and schwannomas. They also include non-neoplastic lesions such as heterotopic pancreas and cysts[2]. The incidence of SEL in the general population ranges between 0.76%-1.7%[3, 4]. Although most lesions are benign[5] and frequently identified during health screens due to abdominal discomfort, vomiting, acid reflux, or anemia, some carry risks of bleeding, obstruction, and potential malignant transformation over time[6]. Hence, treatment approaches must be individualized.

The application of minimally invasive endoscopic techniques has recently increased along with enhanced operative skills among endoscopists. This has resulted in an uptick in the number of gastrointestinal submucosal lesions that are treated endoscopically[7,8]. The repertoire of endoscopic interventions includes high-frequency electrocoagulation resection, endoscopic mucosal resection (EMR), endoscopic submucosal excavation (ESE), endoscopic submucosal dissection (ESD), submucosal tunnelling endoscopic resection (STER), and endoscopic full-thickness resection (EFTR).

Despite many advantages, all endoscopic procedures run the risk of potential complications. A significant proportion of these complications involve the unintended escape of gas outside the digestive tract wall, resulting in gas-related complications such as subcutaneous emphysema, pneumothorax, pneumomediastinum, and pneumoperitoneum. Studies have designated such complications as critical issues in endoscopic surgery because they lead to extended hospital stays and increased socioeconomic burdens on patients[9]. Consequently, we aimed to identify risk factors associated with gas-related complications during transoral endoscopic resection and to develop and validate a clinically useful nomogram.

MATERIALS AND METHODS

Patients

The First Affiliated Hospital Ethics Committee of the Army Medical University approved the study [Approval ID: (B) KY2023006], and all patients provided written informed consent.

This study included 353 patients [male, 163 (46.2%); female, 190 (53.8%); mean age, 48.12 ± 0.55 year; range, 17-76 year] who underwent transoral endoscopic resection of upper gastrointestinal submucosal lesions at the First Affiliated Hospital of the Army Medical University between July 2012 and June 2022. We randomized the patients into training (n = 247) and validation (n = 106) cohorts in a 7:3 ratio using R software version 4.1.2 (Foundation for Statistical Computing, Vienna, Austria).

The inclusion criteria comprised histologically confirmed diagnosis of upper gastrointestinal submucosal lesions, preoperative endoscopic ultrasonography (EUS) findings indicating the lesion origin layer, and having undergone transoral endoscopic resection at our institution. The exclusion criteria comprised intolerance to general anesthesia, intraoperative emergencies that halted the procedure, or undergoing concurrent endoscopic procedures. The patients were endotracheally intubated after general anesthesia and were grouped according to the presence or absence of gas-related complications.

Diagnostic criteria

We characterized subcutaneous emphysema as the finding of gas in subcutaneous tissues. Pneumothorax results from ruptures in the visceral or parietal pleura, leading to air entering the pleural space. Pneumomediastinum arises due to air

leaking into the mediastinal space. Pneumoperitoneum can arise from gut perforation or gas entering the peritoneum *via* the diaphragmatic foramina. Our diagnosis of gas-related complications relied on clinical findings, and computed tomography or postoperative radiographic images acquired within 24 h. We treated subcutaneous emphysema and pneumomediastinum conservatively[10]. Thoracic drainage, laparotomy, perforation repair, or surgical treatment were considered to alleviate pronounced symptoms.

Data collection

Clinical data comprised age, gender, body mass index, underlying conditions (diabetes, hypertension), disease duration, medical history, and EUS findings. Surgical data comprised the histological category of the lesion, lesion size, surgical duration, and resection method. We categorized the surgical duration as < 1, 1-2, or > 2 h and lesion size based on the largest lesion diameter as ≤ 2.0 or > 2.0 cm. The categories of histological lesions were leiomyomas, stromal tumors, schwannomas, heterotopic pancreas, cysts, and lipomas. The muscle layers where lesions originated were classified as non-intrinsic or intrinsic.

Instruments and equipment

Procedures involved the use of an Olympus Q260-J gastroscope (Olympus Optical Co. Ltd., Tokyo, Japan), a high-frequency electrogenic generator (Erbe Elektromedizin GmbH, Tübingen, Germany) a range of specialized knives, titanium clamps, biopsy forceps, loopers, ligatures, and disposable endoscopic syringes. Patients undergoing transoral endoscopic resection were insufflated with CO_2 at pressure of 1 MPa.

Statistical methods

All data were statistically analyzed using R (version 4.1.2) and SPSS version 26.0 (IBM Corp., Armonk, NY, United States) software. Continuous data are presented as means ± SD and were compared between cohorts using ANOVA or *t* test. Categorical data are presented as frequencies and ratios (%) with a comparative approach using Fisher exact, and χ^2 tests. We considered that values with $P < 0.05$ were statistically significant. Variables with a univariate analysis $P < 0.05$ were also included in the training cohort. We screened variables and identified factors influencing gas-related complications in transoral endoscopic resection using least absolute shrinkage and selection operator (LASSO) regression. These factors served as predictor variables to calculate risk scores and construct a nomogram. We plotted the receiver operating characteristic curves for the nomogram in the training and validation cohorts and calculated the area under the curve (AUC). We evaluated the predictive power of our model using calibration curves, decision curve analysis, and the Hosmer-Lemeshow test.

RESULTS

Patient characteristics

Gas-related complications arose in 39 (11.05%) of 353 patients, comprising 22 (6.20%) with subcutaneous emphysema and pneumomediastinum, 20 (5.67%) with pneumoperitoneum, and 4 (1.13%) with pneumothorax. Supplementary Table 1 shows the baseline demographics and characteristics of the patients. Symptoms that were mild in 29 patients with gas-related complications independently resolved within 3-5 d. Ten patients underwent thoracic drainage and perforation repair. Among these complications, 163 and 190 originated from the non-intrinsic and intrinsic muscular layers, respectively.

Univariate and multifactorial findings

Univariate analysis revealed that histological type, lesion layer of origin, diabetes, lesion size, surgical duration, and resection method significantly influenced the development of gas-related complications (Table 1). The LASSO regression analysis selected the resection method, surgical duration, diabetes, and lesion layer of origin as independent risk factors for gas-related complications during surgery in the training cohort (Figure 1). We then constructed a model based on these variables (Figure 2). The risk scores of patients were calculated by summing the scores of each item. The sum total scores predicted the likelihood of gas-related complications.

Nomogram validation

The training and validation cohorts yielded AUCs of 0.841 [95% confidence interval (CI): 0.774-0.908; Figure 3A] and 0.906 (95%CI: 0.845-0.966; Figure 3B), respectively. The discriminatory power of the model was excellent with a C-index of > 0.800 for both cohorts. Hosmer-Lemeshow tests demonstrated a good model fit, with $P = 0.36$ and 0.31 for the training and validation cohorts, respectively. The clinical decision curves derived from the model had a wide range of relative thresholds (5%-100%) and robust clinical applicability (Supplementary Figures 1 and 2), indicating that the model holds strong predictive validity.

Table 1 Univariate and multivariate analyses of factors influencing gas-related complications

Variables	Univariate		Multivariate	
	OR (95%CI)	*P* value	OR (95%CI)	*P* value
Sex	1.087 (0.512-2.310)	0.827		
Age	1.009 (0.975-1.045)	0.598		
Hypertension	0.267 (0.035-2.045)	0.203		
Diabetes	8.306 (1.135-60.774)	0.037	11.043 (0.921-132.452)	0.058
Medical history	1.032 (0.476-2.236)	0.936		
Histological type		0.019		
Largest lesion diameter	3.120 (1.483-6.565)	0.003		
Lesion origin layer	5.011 (1.855-13.534)	0.001	1.774 (0.583-5.394)	0.028
Resection method		< 0.001		< 0.001
Electrocoagulation	11.326 (3.025-42.403)		10.296 (2.714-39.059)	
Full-thickness	24.615 (6.802-89.074)		23.167 (6.367-84.295)	
Surgical duration	2.828 (1.823-4.387)	< 0.001	2.085 (1.290-3.370)	0.029

OR: Odds ratio; CI: Confidence interval; NI: Not included in multivariate analysis.

DISCUSSION

Gastrointestinal tract submucosal lesions

The rise of gastroscopy has led to increased rates of detecting submucosal lesions in the gastrointestinal tract during health examinations. Symptoms of these lesions are linked to their size and location. While most lesions are benign, they still carry risk of malignancy[11]. The American Society for Gastrointestinal Endoscopy and the National Comprehensive Cancer Network guidelines suggest endoscopic monitoring for asymptomatic lesions < 2 cm in diameter[12]. However, larger lesions, or those causing significant symptoms, require immediate intervention.

Transoral endoscopic resection techniques

The techniques of transoral endoscopic resection include high-frequency electrocoagulation, ESE, EMR, ESD, STER, and EFTR. High-frequency electrocoagulation resection is routinely applied in clinical practice due to its safety and simplicity. Although technically challenging[13], ESD is preferred for lesions originating from the superficial intrinsic muscular layer. It can also boost overall resection rates and decrease local recurrence rates compared with EMR[14]. A significantly higher incidence of perforation after ESD compared with EMR has been identified (3.6% *vs* 1.2%)[15]. STER is an extension of peroral endoscopic myotomy[16] that is typically used to resect lesions derived from the lamina propria of the esophagus or the cardia, or located in the body of the distal stomach[17]. Compared with ESD, STER helps to preserve the normal mucosal epithelium overlying the lesion surface that reduces the likelihood of gastrointestinal perforation to some extent[18]. One retrospective cohort study found overall STER and ESE resection rates of 70.2% and 67.5% respectively[19].

Role of EUS in diagnosing lesions

EUS is instrumental for diagnosing and localizing lesions; it uses a high-frequency probe and is frequently used to detect submucosal lesions in the gastrointestinal tract[20,21]. The layered structure of the upper gastrointestinal tract wall can be robustly visualized on EUS images[22], which helps to identifying the origins of lesions[23]. Distinct types of lesions with different ultrasonographic features can be discriminated by EUS[24-26]. Hence, EUS plays a pivotal role in directing the choice of endoscopic treatment.

Postoperative complications

Complications after transoral endoscopic resection are common, and those that are gas-related are the most frequent[27]. These specific issues arise due to the accumulation of gases in tunnels. During surgery, gas can leak continuously into the mediastinum, subcutaneous space, and thoracic or abdominal cavity due to the integrity of the digestive tract wall being disrupted. Being absorbed 150-fold faster than air in the digestive tract, CO_2 can be eliminated through the pulmonary circulation, significantly reducing the occurrence of gas-related complications, air embolism, and other complications[28-30]. Insufflation with CO_2 effectively diminishes patient discomfort and pain[31-33]. However, rapid CO_2 absorption by the gastrointestinal tract, excessive surgical durations and injections of gas that exceed mucosal absorption capacity can still lead to gas-related complications. This was corroborated by our previous findings[34].

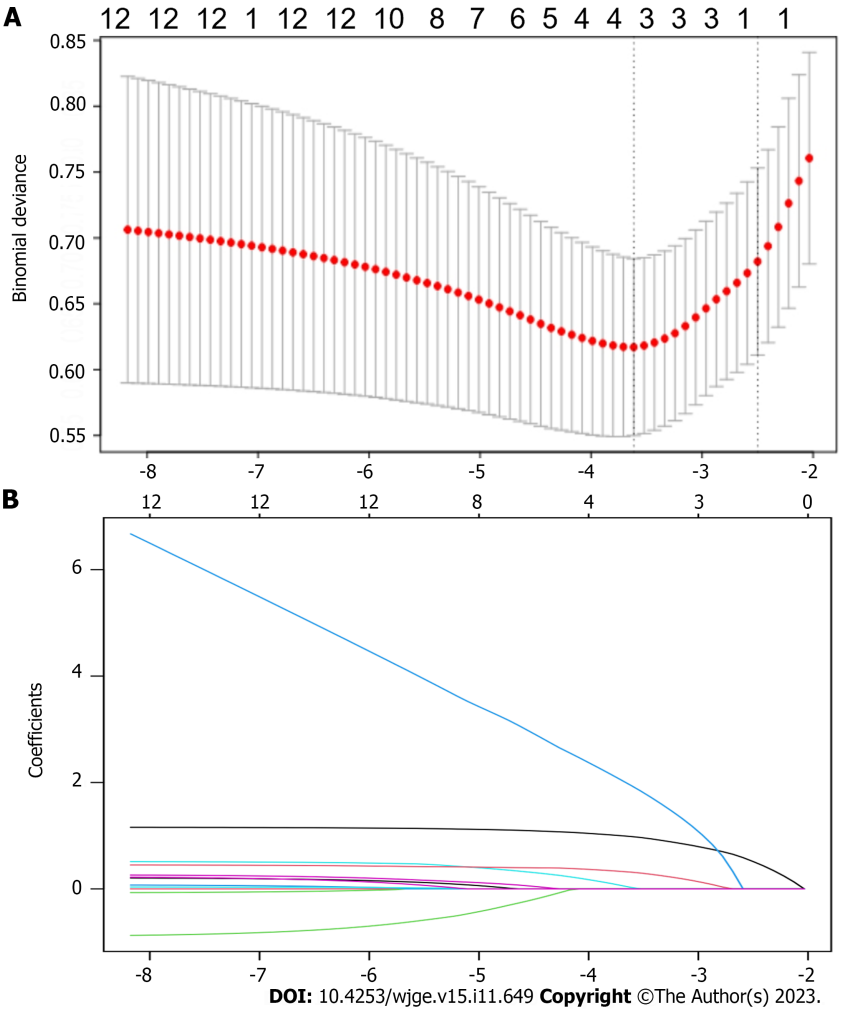

Figure 1 Variable selection using least absolute shrinkage and selection operator binary logistic regression model. A: The selection of the optimum value of the parameter λ in the Lasso regression model *via* the cross-validation method; B: The variation characteristics of the variable coefficients.

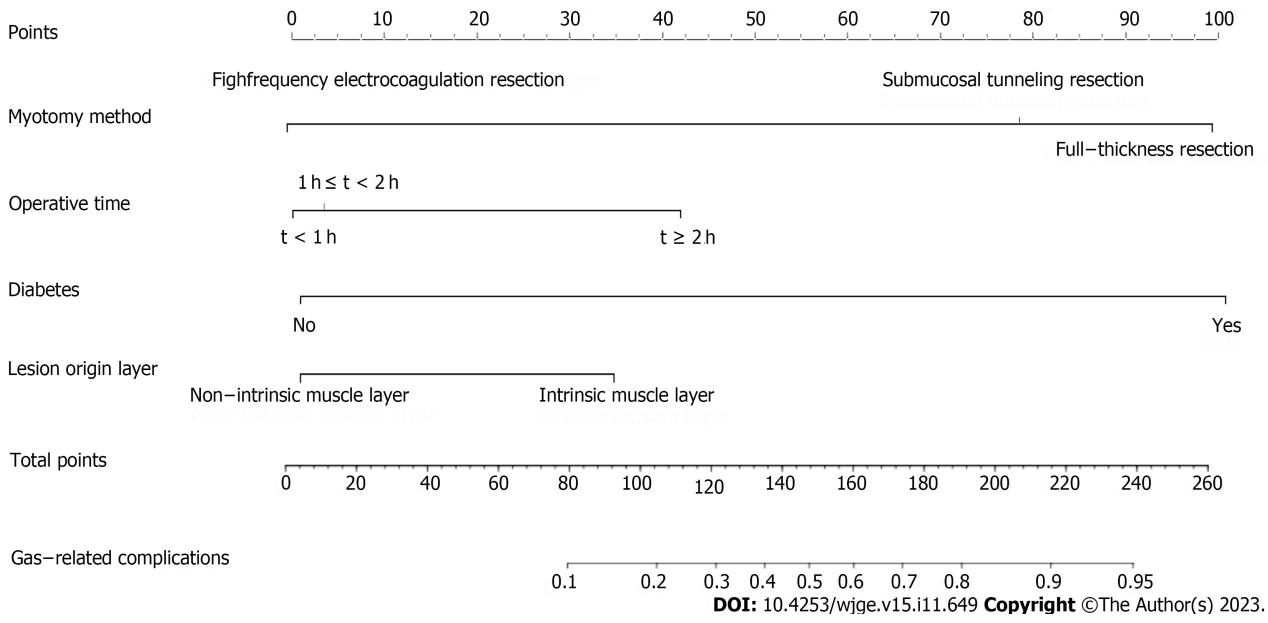

Figure 2 Nomogram of predicted likelihood of gas-related complications.

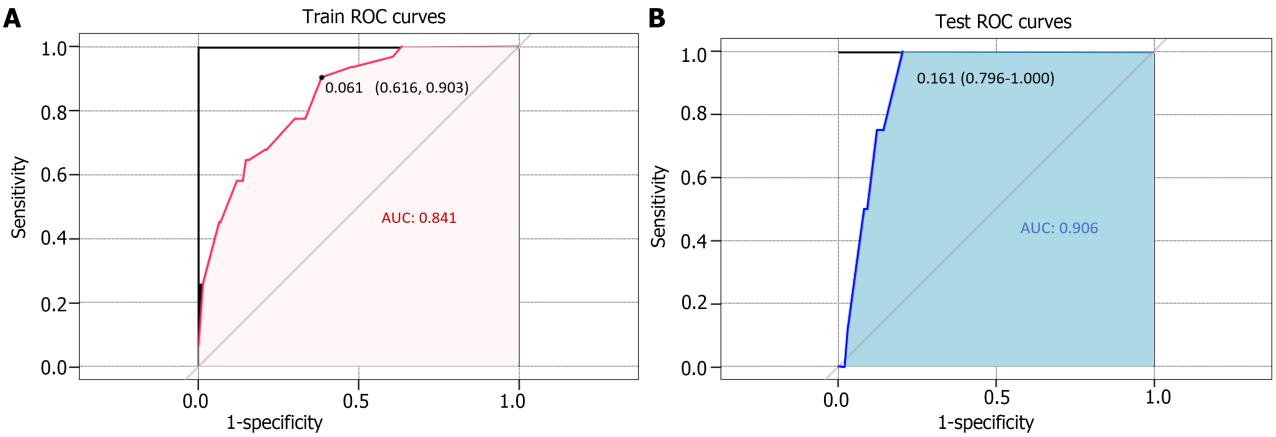

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Figure 3 Receiver operating characteristic curves and respective areas of prediction model. A: Training group; B: Validation group. AUC: Area under the curve.

The probability of gas-related complications during transoral endoscopic resection significantly varies based on the surgical method of resection. Full-thickness resection inherently risks gastrointestinal tract perforation. Gas-related complications can arise if the gastrointestinal wall is not repaired during the procedure. Submucosal tunnelling resection that removes the mass by creating a tunnel between the mucosa and the submucosa is less likely to have gas-related complications compared with full-thickness resections. However, submucosal tunnelling is susceptible to gas-related complications when the plasma layer is damaged. Leaving the mucosal epithelium on the perforated surface intact and maintaining a distance from the tunnel opening can prevent gas-related complications if the tunnel opening is closed promptly. The present study did not find any gas-related complications due to high-frequency electrocoagulation resection.

Patients with diabetes mellitus (DM) often have compromised immunity. Prolonged hyperglycemia can harm the nervous system and slow peristalsis in the gastrointestinal tract. Prolonged hyperglycemia can also cause microangiopathy, that significantly slows blood flow to the gastric mucosa and weakens its defense mechanism. Anxiety and prolonged tension in some patients can result in sympathetic excitation and vasoconstriction of the gastrointestinal tract, further diminishing mucosal circulation. This can decrease the defensive function of the gastrointestinal mucosa and increase the incidence of gas-related complications during surgery[35].

Therefore, our nomogram can help to screen patients at elevated risk of gas-related complications. Controlling blood glucose levels, reducing surgical durations, and selecting the most appropriate method of surgical resection might positively affect the prognosis of high-risk patients.

However, our study has some limitations. We primarily relied on retrospective data that might not account for all factors such as infection with *Helicobacter pylori* that might be associated with gas-related complications. Furthermore, the data were sourced from a single center with a limited patient cohort. Prospective studies with larger patient cohorts at several institutions are crucial to enhance the predictive capacity of our model. External validation or future prospective trials might help to determine the applicability and generalizability of our model and guide the preoperative management of high-risk patients.

CONCLUSION

Our nomogram incorporating surgical duration, method of surgical resection, DM, and the lesion layer of origin had excellent predictive efficacy. Its practical application in clinical settings can serve as a valuable guide for endoscopists.

ARTICLE HIGHLIGHTS

Research background

With the popularity of endoscopy, more and more digestive tract lesions have been discovered. Some of these lesions affect the quality of life of patients, and are potentially fatal. Oral endoscopic resection is becoming the main treatment.

Research motivation

Gas-related complications are inevitable in endoscopic resection. The occurrence of gas-related complications during surgery may increase a patient's burden and prolong their hospital stay.

Research objectives
The risk factors of gas-related complications were analyzed, and a corresponding prediction model was established.

Research methods
The variables were screened by univariate and multivariate analysis.

Research results
Univariate analysis showed statistically significant differences in histological type, lesion layer of origin, diabetes, lesion size, surgical duration, and resection method. Diabetes, lesion origin, surgical resection method, and surgical duration were incorporated into the final nomogram.

Research conclusions
Our nomogram had excellent predictive efficacy.

Research perspectives
We hope to conduct a multi-center study with a larger sample size for verification in the future.

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FOOTNOTES

Author contributions: Chen L conceived and designed this study; Yang J and Chen ZG collected and analyzed patient data; Yang J and Yi XL drafted and completed the manuscript; Yang J, Chen ZG, and Chen J prepared the tables and figures; and all authors are accountable for interpreting the data and revising the manuscript.

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ORIGINAL ARTICLE

Basic Study

Animal experimental study on magnetic anchor technique-assisted endoscopic submucosal dissection of early gastric cancer

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Abstract

BACKGROUND

Gastric cancer (GC) has high morbidity and mortality. Moreover, because GC has no typical symptoms in the early stages, most cases are already in the advanced stages by the time the symptoms appear, thus resulting in poor prognosis and a low survival rate. Endoscopic submucosal dissection (ESD) can realize the early detection and diagnosis of GC and become the main surgical method for early GC. However, ESD has a steep learning curve and high technical skill requirements for endoscopists, which is not conducive to its widespread implementation and advancement. Therefore, a series of auxiliary techniques have been derived.

AIM

To evaluate the safety and efficacy of magnetic anchor technique (MAT)-assisted ESD in early GC.

METHODS

This was an *ex vivo* animal experiment. The experimental models were the isolated stomachs of pigs, which were divided into two groups, namely the study group (n = 6) with MAT-assisted ESD and the control group (n = 6) with traditional ESD. Comparing the total surgical time, incidence of surgical complic-

ations, complete mucosal resection rate, specimen size, and the scores of endoscopist's satisfaction with the procedure reflected their feelings about convenience during the surgical procedure between the two groups. The magnetic anchor device for auxiliary ESD in the study group comprised three parts, an anchor magnet (AM), a target magnet (TM), and a soft tissue clip. Under gastroscopic guidance, the soft tissue clip and the TM were delivered to the pre-marked mucosal lesion through the gastroscopic operating hole. The soft tissue clip and the TM were connected by a thin wire through the TM tail structure. The soft tissue clip was released by manipulating the operating handle of the soft tissue clip in a way that the soft tissue clip and the TM were fixed to the lesion mucosa. *In vitro*, ESD is aided by maneuvering the AM such that the mucosal dissection surface is exposed.

RESULTS

The total surgical time was shorter in the study group than in the control group (26.57 ± 0.19 *vs* 29.97 ± 0.28, $P < 0.001$), and the scores of endoscopist's satisfaction with the procedure were higher in the study group than in the control group (9.53 ± 0.10 *vs* 8.00 ± 0.22, $P < 0.001$). During the operation in the study group, there was no detachment of the soft tissue clip and TM and no mucosal tearing. The magnetic force between the AM and TM provided good mucosal exposure and sufficient tissue tension for ESD. The mucosal lesion was completely peeled off, and the operation was successful. There were no significant differences in the incidence of surgical complications (100% *vs* 83.3%), complete mucosal resection rate (100% *vs* 66.7%, $P = 0.439$), and specimen size (2.44 ± 0.04 cm *vs* 2.49 ± 0.02, $P = 0.328$) between the two groups.

CONCLUSION

MAT-ESD is safe and effective for early GC. It provides a preliminary basis for subsequent internal animal experiments and clinical research.

Key Words: Endoscopic submucosal dissection; Gastric cancer; Digestive disease; Magnetic anchor technique; Magnetic surgery; Magnetic anchor device

Core Tip: Endoscopic submucosal dissection (ESD) is helpful in the early detection and treatment of gastric cancer but has a long learning curve. Magnetic anchor technique (MAT) was used to shorten the total surgical time and improve the endoscopist's satisfaction with the surgical procedure by providing good mucosal exposure and sufficient tissue tension for ESD. MAT shows advantages over other assistive technologies, such as the flexibility to change the magnitude and direction of traction. This method shows great auxiliary potential in ESD and has good prospects for clinical application.

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INTRODUCTION

Cancer continues to be an immense threat to human health and exerts a huge medical and economic burden. In 2020, there were more than 1 million new cases of gastric cancer (GC) and an estimated 769000 deaths (equivalent to 1 in 13 deaths globally). GC has the fifth-highest incidence and the fourth-highest mortality of all cancers worldwide[1]. Due to its large population, China accounts for approximately 44% of GC cases worldwide, and in 2020, GC in China had an adjusted incidence rate of 20.6/100000 individuals[2]. GC is usually at an advanced stage by the time the symptoms appear, which leads to a poor prognosis. Although the 5-year survival rate for advanced GC is 10%, the 5-year survival rate for early GC can be as high as 85%[3]. Therefore, it is possible to carry out population-based screening in high-risk areas or high-risk groups to achieve early detection, diagnosis, and treatment of GC, thus reducing the burden of GC on public health. The use of endoscopy screening in high-risk groups can reportedly significantly reduce GC mortality[4,5]. At present, the 5-year survival rates of GC in Japan and South Korea are relatively high at 60.3% and 68.9%, respectively [6]. These rates are attributed to the effectiveness of large-scale endoscopic screening programs, which help identify a higher proportion of early GC cases at the time of screening[7,8].

The primary treatment option for early GC is endoscopic therapy, which includes endoscopic mucosal resection (EMR) and endoscopic submucosal dissection (ESD)[9,10]. ESD is developed on the basis of EMR and is used for dissecting large tumor lesions that are not suitable for EMR[11]. Compared with EMR, ESD has higher en bloc resection rates (90.2 *vs* 51.7%), higher histologic complete resection rates (82.1 *vs* 42.2%), and lower recurrence rates (0.65% *vs* 6.05%)[12]. However, ESD is not like traditional surgery, and as the surgeon's hand cannot enter the alimentary canal lumen, it is difficult to obtain sufficient tension and good field. These challenges result in a long operation time, high risk of adverse

events, and high incidence of postoperative complications (bleeding and perforation)[13]. Therefore, to circumvent these challenges and avoid these complications, many assistive technologies have been developed[13], such as the clip-with-line method[14], pulley method[15,16], sheath traction method[17,18], external forceps method[19,20], double scope method[21], the S–O clip[22,23], ring thread countertraction[24], multiloop technique[25], double clip and rubber band traction[26], clip band technique[27], pocket creation method with a traction device[28], and clip-flap method[29]. However, these auxiliary techniques have some disadvantages, such as inflexibility in changing the magnitude of the traction force, a single direction of the traction force, and inability to resect any lesion regardless of its location.

Magnetic anchor technique (MAT)-assisted ESD is a new type of assistive technology with some potential advantages, such as control over traction direction and traction size. It was first proposed by Kobayashi *et al*[30] in 2004. The magnetic anchor system includes internal and external magnetic components. The outer magnetic assembly is usually a permanent magnet, and the inner magnetic assembly includes an inner magnet and a tissue clip[31]. MAT-ESD has been successfully applied to various thoracoscopy and laparoscopy procedures, such as laparoscopic cholecystectomy[32] and thoracoscopic lobectomy[33]. The application of this technique reduces surgical trauma and interference between surgical instruments, thus improving the exposure of the surgical field and the operability of the surgery[31]. Therefore, in this study, we explored the safety and feasibility of MAT-ESD in early GC in an *in vitro* porcine model using the self-designed magnetic anchor device.

MATERIALS AND METHODS

Magnetic anchor device

The self-designed magnetic anchor device made by Shaanxi Jinshan Electric Co., Ltd. comprises three parts (Figure 1): The anchor magnet (AM), the target magnet (TM), and the soft tissue clip. The AM is a cylinder made of the Nd–Fe–B permanent magnet material, and the surface is protected by nickel plating. To avoid interference from other ferromagnetic objects during use, the AM cylinder is covered with a 5-mm U-shaped resin shell. The AM is located outside the body and is used to pull the TM. The AM is 140-mm high and has a base diameter of 50 mm and a surface field strength of 6000 GS. The TM is also made of the Nd–Fe–B permanent magnet material. The TM is divided into a cylindrical magnetic core and a permalloy shell. The surface is coated with nickel or titanium nitride. The TM is sent into the digestive tract through the gastroscopic biopsy hole. To adapt to the size of the digestive tract, the magnetic core is a cylinder with a height of 5.5 mm and a bottom diameter of 4 mm, and the surface field strength is 3000 GS. In addition, the permalloy tail has a circular hole structure with a diameter of 1 mm for connection with soft tissue clips. The soft tissue clip is processed by the Micro-Tech (Nanjing) Co., Ltd. It can be connected to the tail end structure of the TM through a thin wire, and the TM can be fixed to the lesion mucosa.

Animals

This *ex vivo* experiment involved two groups: The study group (MAT-ESD) and the control group (traditional ESD). The pigs were obtained from the Experimental Animal Center of Xi'an Jiaotong University. The animal protocol was designed to minimize pain or discomfort to the animals. The isolated pigs' stomachs were obtained from euthanized pigs; euthanasia was performed by an intravenous overdose of sodium pentobarbital (60 mg/kg) after the end of other experimental projects by our team. We used stomachs isolated from 12 Bama miniature pigs, with 6 pigs (3 males and 3 females) in the study group and the other 6 pigs (3 males and 3 females) in the control group. The sex of the animal was not a factor in data analyses. A total of 6 endoscopists completed the surgery for both groups. The experimental protocol was approved by the laboratory animal care committee of Xi'an Jiaotong University (approval NO. XJTULAC2019-1006) and was in accordance with the ethical standards for experimental animals of Xi'an Jiaotong University. All animal experiments complied with the ARRIVE guidelines and were carried out in accordance with the National Institutes of Health Guide for the Care and Use of Laboratory Animals (Eighth edition, 2011).

Surgical procedure in the study group

On the basis of the end of other animal experiments, the isolated pig stomachs were obtained, and about 5 cm of the esophagus and duodenal stump was retained. First, the duodenal stump was clamped with intestinal forceps, and then, a gastroscope was inserted from the esophageal stump to inflate and observe the airtightness of the stomach and the integrity of the mucosa (Figure 2A). Second, the mucosal lesion to be resected was marked by electrocautery under gastroscopic guidance (Figure 2B). Third, the TM was fixed to the mucosal lesion by a soft tissue clip. The soft tissue clip was inserted through the operation hole of the gastroscope, and the TM was connected to the soft tissue clip with a thin wire; however, the TM did not affect the opening and closing of the soft tissue clip (Figure 2C). Finally, the magnetic force between TM and AM was used to expose the mucosal dissection surface and maintain tissue tension. The AM was gradually brought close to the stomach *in vitro*, and the state of the TM was observed using the endoscope (Figure 2D). The TM was seen to be pulled toward the AM, and at the same time, the soft tissue clip was driven to lift the lesion mucosa. The position of the AM was adjusted according to the operation requirements, and the pulling direction and strength of the mucosal lesion were flexibly changed until the lesion was completely removed (Figure 2E and F).

Statistical analysis

The statistical methods of this study were reviewed by Xiao-Peng Yan from the first affiliated hospital of Xi'an Jiaotong University before the submission. The quantitative data that were consistent with the normal distribution were expressed

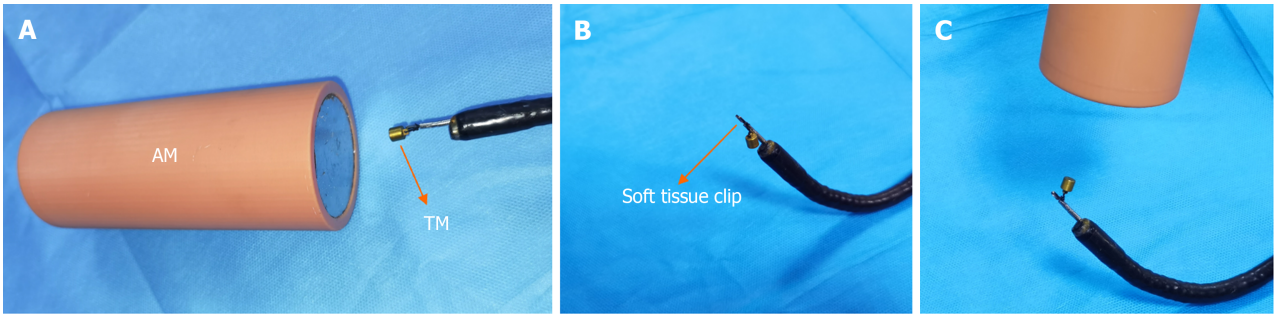

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Figure 1 Magnetic anchor device. A: The anchor magnet (AM) and target magnet (TM); B: The soft tissue clip; C: The connection between the TM and soft tissue clip, and the magnetic force between the AM and TM. AM: anchor magnetic; TM: target magnetic.

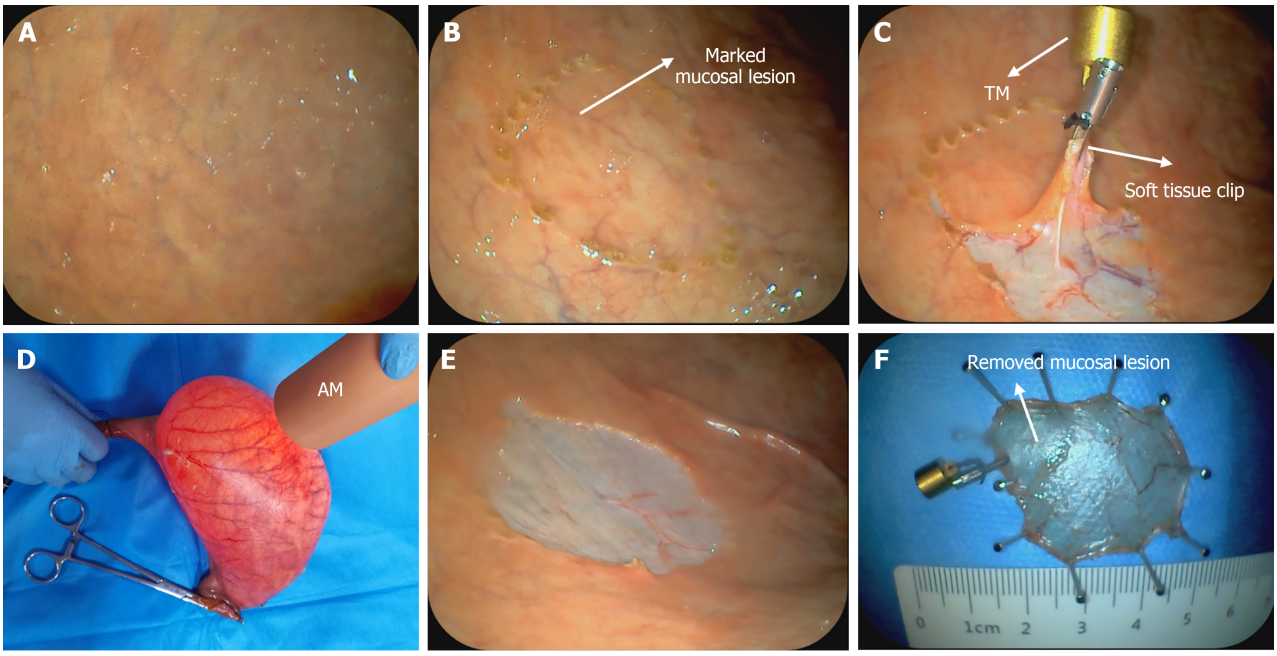

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Figure 2 Magnetic anchor technique-assisted endoscopic submucosal dissection operation process. A: The isolated stomach was examined using a gastroscope; B: The mucosal lesion to be resected was marked by electrocautery under gastroscopic guidance; C: The target magnet (TM) and the soft tissue clip were connected and placed in the gastric lumen and the soft tissue clips clamped the mucosa; D: Anchor magnet (AM) was placed outside the stomach. Under the attraction of the AM, the TM hangs in the stomach cavity and pulls the mucosa; E and F: The mucosal lesion has been stripped.

as mean ± SD. Two-group mean comparison was performed using the independent *t*-test. Non-normally distributed data were expressed as the median (interquartile interval). The nonparametric test was used for comparisons between the two groups. Qualitative data were expressed as the number of actual cases (proportion, %), and its comparisons were drawn using the χ^2 test. Statistical analysis was performed using IBM SPSS Statistics version 26.0 (IBM Corp., Armonk, NY), with $P < 0.05$ indicating statistical significance.

RESULTS

According to Table 1, the mean total surgical time was 26.57 min in the study group and 29.97 min in the control group. With the assistance of MAT, the total surgical time was greatly reduced and the endoscopist's surgical satisfaction scores were improved (9.53 *vs* 8.00, $P < 0.001$). By clamping the duodenal stump, the isolated stomach was made airtight, and the mucosa was intact. In the study group, after the mucosal lesion was successfully marked, the gastroscope, the TM, and the soft tissue clip were smoothly entered into the stomach through the digestive tract and advanced until the lesion was reached. During the entire operation, the soft tissue clip was tightly connected with the TM to avoid falling off or separation, and the TM did not affect the opening, closing, and release of the soft tissue clip. Furthermore, surgical instruments, except the AM and TM, were not disturbed by the magnetic force. By changing the position of the AM, the pulling direction and pulling force of the soft tissue clip could be easily changed, the mucosal dissection surface was well

Table 1 Comparison between the study group and control group

	Study group (*n* = 6)	Control group (*n* = 6)	*P* value
Total surgical time (min)	26.57 ± 0.19	29.97 ± 0.28	< 0.001
Incidence of surgical complications[1] (%)	100	83.3	-
Complete mucosal resection rate (%)	100	66.7	0.439
Specimen size (diameter, cm)	2.44 ± 0.04	2.49 ± 0.02	0.328
Endoscopist's satisfaction with the procedure[2] (score)	9.53 ± 0.10	8.00 ± 0.22	< 0.001

[1]Incidence of surgical complications include bleeding and perforation.
[2]Endoscopist's surgical satisfaction scores which ranged from 0 to 10 reflect their feelings about convenience with the surgical procedure. Higher scores indicate better satisfaction.

exposed, and sufficient tension was maintained. In addition, the soft tissue clip did not fall off and the mucosa was not torn. The marked mucosal lesions were completely stripped without any complications, but there was one case of perforation and two cases of incompletely stripped marked mucosal lesions in the control group. The diameters of specimen sizes did not significantly differ between the two groups (2.44 *vs* 2.49, $P > 0.05$; Table 1).

DISCUSSION

Our results emphasize the safety and efficacy MAT-ESD in early GC. Six operations were successfully completed, and in all of these operations, the mucosal lesion was completely peeled off without tearing of the mucosa or detachment of the TM and soft tissue clip.

The MAT belongs to the category of magnetic surgery. It is currently an auxiliary technique for ESD with great application prospects. The MAT primarily uses the magnetic force between the magnets, and this helps overcome the disadvantage of ESD being difficult to operate and also gives the endoscope operator a "third hand". The magnetic materials used in the magnetic anchor system are primarily electromagnets and permanent magnets[34]. For electromagnets, the intensity of the magnetic field can be controlled by changing the amount of electricity. However, they are large and bulky, making it challenging to use them in the narrow digestive tract. Conversely, high-performance permanent magnets are based on compounds with excellent intrinsic magnetic properties and optimized microstructure and alloy composition. At present, the most powerful permanent magnet materials are RE–TM intermetallic alloys, which derive their exceptional magnetic properties from the favorable combination of rare earth metals (RE = Nd, Pr, and Sm) with transition metals (TM = Fe and Co); specifically, magnets based on $(Nd, Pr)_2 Fe_{14}B$ and $Sm_2(Co, Cu, Fe, Zr)_{17}$ are particularly good permanent magnets[35]. In addition, considering the low corrosion resistance of neodymium magnets, which is of particular concern in the acidic environment of the stomach, and the possibility of interference of the magnetic field with other surgical instruments, the shielding material used must be inert to the human body and unobstructed to the magnetic field, such as titanium alloys, ring oxygen resin, or a copper-based alloy (with additional coating)[34].

The TM used in previous studies is a simple magnetic ring[36-38], whereas our TM uses permanent magnets (Nd–Fe–B) and a permalloy shell to shield the impact of magnetic fields on surgical instruments and people, thus enhancing the attraction between the AM and TM. Finally, the size of the TM was optimized considering the size of the digestive tract and the physiological environment, and the tail suspension structure was designed for connection with the soft tissue clip considering both the characteristics of the digestive tract and magnetic requirements.

The main disadvantage of this experiment is that it was an external experiment, and the findings may differ in an internal animal experiment or a clinical study. However, we were unable to assess the risk of postoperative complications, such as bleeding, perforation, and strictures. Second, because the abdominal thickness in human beings differs from that in pigs, our findings cannot help predict the effect of abdominal wall thickness when this technique is applied to humans. Third, because the mucosal lesion is marked by the experimenter and is subjective, it was not possible to evaluate the influence of surgery on the size and location of the lesion.

However, MAT has shown great clinical potential when used as an auxiliary technique for ESD. The results of this study show that MAT-ESD is safe and effective. This study lays a solid foundation for the next animal experiment and clinical study and provides a preliminary foundation for the accuracy and optimization of the magnetic anchor device.

CONCLUSION

The safety and efficacy of MAT-ESD have been demonstrated in early GC, albeit only in external animal experiments. However, MAT shows advantages over other assistive technologies, such as flexibility to change the magnitude and direction of traction. This method shows great auxiliary potential in ESD and has good prospects for clinical application.

ARTICLE HIGHLIGHTS

Research background

Gastric cancer (GC) has high morbidity and mortality, which are already in the advanced stages when diagnosed, resulting in poor prognosis and a low survival rate. Endoscopic submucosal dissection (ESD) has become the main surgical method for early GC, improving the detection and therapy of GC. However, endoscopists are limited by some deficiencies of ESD, such as the steep learning curve and high technical skill requirements. Therefore, an assistant technique, the magnetic anchor technique (MAT), has been invented to improve the procedure of ESD.

Research motivation

ESD has become the standard therapy for early GC, but it still has the space for improvement. There are some assisted techniques, such as the clip-with-line method, pulley method, sheath traction method, and external forceps method, improving the endoscopists' feeling of operation. However, recent assisted techniques also have trouble controlling and maintaining tissue tension. Our own designed assisted technique, MAT, are objective to solve the mentioned problems above.

Research objectives

This study aims to evaluate the safety and efficacy of MAT-assisted ESD in early GC.

Research methods

This was an *ex vivo* animal experiment. The experimental models were the isolated stomachs of pigs, which were divided into two groups, namely the study group (n = 6) with MAT-assisted ESD and the control group (n = 6) with traditional ESD. The magnetic anchor device for assisting ESD in the study group comprised three parts, an anchor magnet (AM), a target magnet (TM), and a soft tissue clip. The soft tissue clip and the TM, which were connected by a thin wire through the TM tail structure, were delivered to the pre-marked mucosal lesion through the gastroscopic operating hole under gastroscopic guidance. Then, the soft tissue clip was released by manipulating the operating handle of the soft tissue clip in a way that the soft tissue clip and the TM were fixed to the lesion mucosa. *In vitro*, ESD is aided by maneuvering the AM such that the mucosal dissection surface is exposed. Finally, Comparing the total surgical time, incidence of surgical complications, complete mucosal resection rate, specimen size, and the scores of endoscopist's satisfaction with the procedure reflected their feelings about convenience during the surgical procedure between the two groups.

Research results

All operations were successfully completed. The total surgical time was shorter in the study group than in the control group (26.57 ± 0.19 *vs* 29.97 ± 0.28, P < 0.001), and during the operation in the study group, and there were no significant differences in the incidence of surgical complications (100% *vs* 83.3%), complete mucosal resection rate (100% *vs* 66.7%, P = 0.439), and specimen size (2.44 ± 0.04 cm *vs* 2.49 ± 0.02, P = 0.328) between the two groups. In the study group, there was no detachment of the soft tissue clip and TM and no mucosal tearing. The magnetic force between the AM and TM provided good mucosal exposure and sufficient tissue tension for ESD. Therefore, the scores of endoscopist's satisfaction with the procedure were higher in the study group than in the control group (9.53 ± 0.10 *vs* 8.00 ± 0.22, P < 0.001).

Research conclusions

MAT-ESD is safe and effective for early GC.

Research perspectives

This *ex vivo* experiment provides a rudimentary for subsequent internal animal experiments and clinical research. With the accumulation of operational experience, this technique has broad clinical prospects.

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FOOTNOTES

Author contributions: Lyu Y and Yan XP conceived and designed the study; Pan M and Zhang MM performed the research and acquired the data; Zhao L wrote the manuscript; Pan M and Zhang MM revised the manuscript; Lyu Y and Yan XP examined the final manuscript; All authors read and approved the final manuscript.

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Institutional animal care and use committee statement: All animal experiments conformed to the internationally accepted principles for the laboratory animal care committee of Xi'an Jiaotong University (approval NO. XJTULAC2019-1006) and was in accordance with the ethical standards for experimental animals of Xi'an Jiaotong University.

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CASE REPORT

Hybrid laparo-endoscopic access: New approach to surgical treatment for giant fibrovascular polyp of esophagus: A case report and review of literature

Seda Dzhantukhanova, Lyudmila Grigori Avetisyan, Amina Badakhova, Yury Starkov, Andrey Glotov

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Abstract

BACKGROUND

Fibrovascular polyps are rare type of esophageal submucosal neoplasms. They are highly vascularized and can cause difficulty swallowing and even fatal complications such as uncontrolled bleeding and death caused by asphyxiation in case of tumor migration to oropharynx. In the article we describe a novel hybrid technique to surgical treatment – an endoscopic submucosal dissection with laparoscopic removal of the tumor.

CASE SUMMARY

The patient with a giant fibrovascular esophageal polyp presented with cough, discomfort in the throat, difficulty swallowing, and an episode of tumor migration into oropharynx. The patient was investigated with several imaging studies and was diagnosed with a giant highly vascularized esophageal fibrovascular polyp. The follow-up period of eight months accompanied with no complications.

CONCLUSION

This method has been shown to have comparable rates of recurrence and a low risk of complications.

Key Words: Esophagus; Fibrovascular polyp; Benign esophageal tumor; Endoscopic

resection; Minimal invasive surgery; Case report

Core Tip: In our case the patient was investigated with several imaging studies and was diagnosed with a giant highly vascularized esophageal fibrovascular polyp. It is crucial to consider the size and vascularization of fibrovascular polyps when assume endoscopic removal as a treatment option and to carefully plan the surgical technique to avoid difficulties or discomfort during the procedure. However, there is an alternative approach to traditional surgical removal known as the endoscopic approach that can be both safe and effective for treating giant fibrovascular polyps in the esophagus. Therefore, the aim of our study is to demonstrate demonstrate a novel hybrid technique to surgical treatment – an endoscopic submucosal dissection with laparoscopic removal of the tumor.

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INTRODUCTION

Fibrovascular polyp (FVP) are rare (approximately 0.03% of esophageal tumors), benign, richly vascularized tumors of the esophagus or hypopharynx[1]. The etiology of this disease has yet to be well-known. Esophageal fibrovascular polyps arise from the submucosal layer of the esophagus and usually are covered with normal mucosa, mostly appearing from the esophagus's upper third. Also, the lesions can be attached to the inferior aspect of the cricopharyngeal muscle and often have a stalk. Histologically the polyp contains loose or dense fibrous tissue, adipose tissue, and vascular structures [2].

In the early stages, FVP are clinically asymptomatic. The clinical symptoms correlate with the size of the tumor. The most common complaints are dysphagia, chest discomfort, and foreign body sensation[2]. There can also present other symptoms, such as odynophagia, dyspnea, coughing, neck pain, respiratory distress, and gastrointestinal bleeding[3].The most common complications that can cause even fatal exits are fatal bleeding and airway obstruction due to the aspiration of a tumor.

Even though in the modern world of the 21st century there are a lot of technologies and facilitating methods of diagnosis and treatment, the difficulties are still relevant. Furthermore, depending on the size of the polyp, there can be either endoscopic or surgical resection[4].

CASE PRESENTATION

Chief complaints

A 70-year-old female presented to the endoscopic surgical department of the A. V. Vishnevsky National Medical Research Center of Surgery in October 2022.

On admission, the patient complained of cough, dysphagia, discomfort in the throat, and the presence of large soft mass in the esophagus with episodes of its migration into oropharynx. The patient was examined.

History of present illness

During the last 5 years, a tumor was discovered during the examination and an episode of tumor migration into oropharynx.

History of past illness

The patient has consistently maintained a state of general well-being throughout her life, without encountering notable medical complications. Nevertheless, the patient mentioned that she has experienced persistent elevation of blood pressure, for which she received a diagnosis of stage 1 arterial hypertension (measuring between 140-145 mm Hg). In an effort to regulate her blood pressure levels, perindopril and indapamide in combination (marketed as Noliprel) were prescribed for her.

No allergies, recent infections, or harmful habits (such as smoking, alcohol consumption, or drug use) were reported. There is no family or personal history of genetic hypertension/cardiovascular issues; the elevated pressure seems to be linked to lifestyle factors. Apart from the prescribed anti hypertensives, the patient did not mention the use of any concurrent medications or supplements.

Personal and family history

The patient is married and has two daughters. No significant family medical history of diseases or conditions pronounced.

Physical examination

The Patient observed without any signs of visible immediate discomfort. Upon admission, the vital signs were measured: blood pressure at 140/80 mmHg, heart rate at 72 bpm, temperature at 98.6°F (37°C), and oxygen saturation at 98%. A thorough examination of all organ systems was done, and no abnormalities were found.

During the palpation the abdomen was non-tender, without masses, and both the liver and spleen were non-palpable below the rib cage. No palpable lymph nodes were found in cervical, axillary, or inguinal areas. Patient reported no discomfort during palpation.

Laboratory examinations

The blood count and coagulation assessment results revealed that all measured parameters resided comfortably within established normative reference intervals. The concentration of Albumin manifested at 3.73 g/dL, alanine transaminase at 8 g/dL, and Aspartate transaminase at 26 g/dL, as shown in Table 1.

Imaging examinations

The upper gastrointestinal (GI) endoscopy showed a base of non-epithelial tumor right behind the upper esophageal sphincter (UES). Tumor continues distally throughout the esophagus, freely locating and occupying almost the entire space of esophageal lumen. The neoplasm was a 25 cm in length and 4-5 cm width in the distal part, covered by a normal mucosa of squamous esophageal epithelium. Also, there was significant dilation of the esophagus due to a large size of the tumor, maximum up to 6 cm in middle and lower thirds. The tumor had a complex configuration, the distal part of the tumor splits into two parts and it reaches the stomach cardia. On retroflexion the distal part of non-epithelial neoplasm is visible in the gastric lumen, size of the diaphragmatic crura is up to 5 cm with sliding of cardia and fungus above diaphragm during examination - signs of sliding hiatal cardiofundal hernia (Figure 1A and B).

For identification of tumor features, type of growth and localization related to layers of the esophageal walls, an endoscopic ultrasound (EUS) was done. An ultrasound scanning showed heterogeneous hypo-echoic neoplasm with a smooth, clear-contoured, irregular cylindrical shape. The base of the tumor is located right behind the UES and originates from the submucosal layer of the esophagus (3rd echo-layer), type 1 according to the classification of non-epithelial tumors of the gastrointestinal tract[5]. The doppler color mode showed a hypervascular zone at the base of the tumor with multiple large feeding vessels, up to 4-5 mm in diameter, extending along the wall of the esophagus for 8-10 cm. Paragastric lymphatic nodes are not enlarged (Figure 2A and B). EUS imaging, most likely, corresponded to a FVP of the esophagus.

Computed tomography (CT) with intravenous contrast enhancement revealed an expansion of the esophagus up to 5-6 cm in the distal part, a hypervascular neoplasm in the lumen of the esophagus extending throughout the entire length from UES to the gastric cardia with a maximum diameter of up to 6 cm (Figure 3A and B).

FINAL DIAGNOSIS

Fibrovascular polyp with foci of highly differentiated liposarcoma, tumor tissue at the sight of endoscopic dissection is not determined, R0, M 8850/3; Grade 1.

TREATMENT

Hybrid laparo-endoscopic access - endoscopic submucosal dissection with laparoscopic removal of the tumor.

The course of intervention

Before to start an endoscopic submucosal dissection (ESD) first step of the procedure was creating a lifting by injection of Gelofusine solution dyed with indigo carmine into submucosal layer. Thereafter, using an endoscopic knife, a dissection of the mucosa and submucosal layer was performed immediately behind UES in horizontal plane (Figure 4A). In order to achieve a stable position of the endoscope in the submucosal layer, a transparent dissection cap was installed on the distal end of the endoscope according to the standard ESD technique. Next, the steps of dissection in the submucosal layer were performed up to 11 cm distally until the tumor was completely cut off at the base. For the dissection of the submucosal layer an endoscopic knife was used. For the coagulation of large feeding vessels in the submucosal layer a coagrasper was used. Using high frequent electro generator, the larger vessels of the submucosal layer were coagulated using <Soft coagulation> mode and the smaller vessels using <Spray coagulation> mode (Figure 4B-D). On the control endoscopic view the area of ESD was 1.5 cm × 2.5 cm × 11 cm in size.

The expected challenges of surgical intervention for esophageal FVP are the technical difficulties of adequate endoscope positioning, instrumental manipulations, and exposure of the surgical field because of anatomically limited space of UES, which corresponds to area of tumor base. One more challenge is the transoral extraction of the tumor with a high risk of stuck of the tumor in a small space of UES and oropharynx due to the large size of the tumor especially in the

Table 1 The blood count and coagulation assessment results revealed that all measured parameters resided comfortably within established normative reference intervals

AST	26	0-40 U/L
ALT	8	0-41 U/L
Albumin	3.73	3.5-5.5 g/dL
Urea	25.2	16.6-48.5 mg/dL
Creatinine	0.42	< 1.2 mg/dL
Sodium	140	136-145 mmol/L
Potassium	4.61	3.5-5 mmol/L
Chloride	104	98-106 mmol/L
Calcium	7.9	7.6-11 mg/dL
Procalcitonin	0.26	< 0.5 ng/mL
Blood culture	Sterile	Sterile

ALT: Alanine transaminase; AST: Aspartate transaminase.

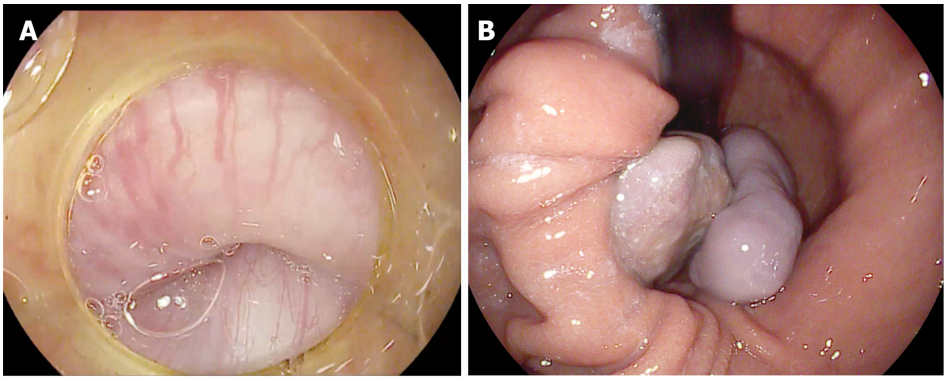

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Figure 1 Esophagogastroduodenoscopy. A: Right behind the upper esophageal sphincter is visualizing the base of a non-epithelial tumor, which continues distally throughout the esophagus, freely locating and occupying almost the entire space of the esophageal lumen; B: On retroflection, the distal part of the non-epithelial neoplasm splits into two parts, visible in the gastric lumen. Diastases of the diaphragmatic crura is up to 5-6 cm with sliding of cardia and fungus above the diaphragm during examination - signs of sliding hiatal cardiofundal hernia.

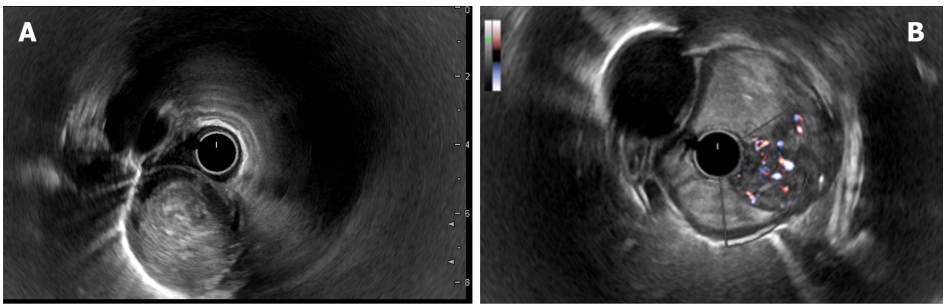

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Figure 2 Endosonography of the esophagus. A: A heterogeneous hypoechoic mass with a smooth and clear borders, cylindrically shaped, originating from submucosal layer (3rd echo layer); B: A doppler color mode shows a hypervascular zone at the base of the tumor with multiple large feeding vessels, up to 4-5 mm in diameter, extending along the wall of the esophagus.

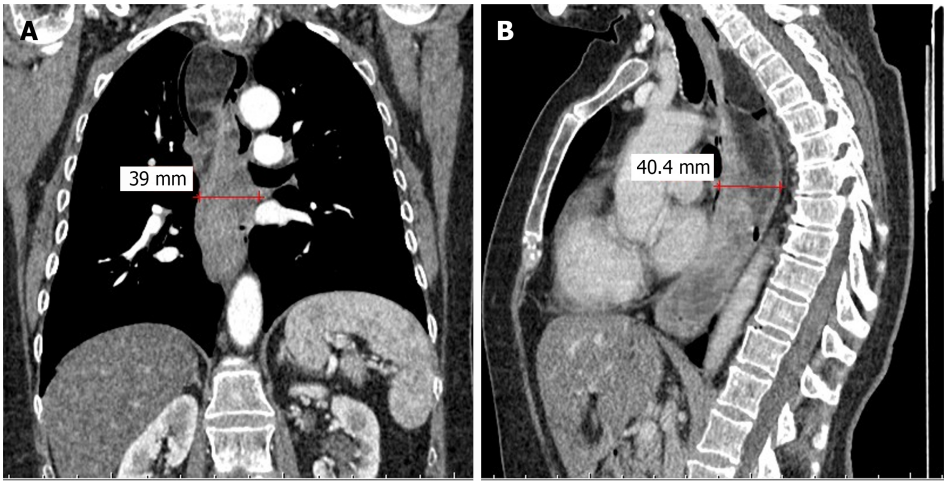

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Figure 3 Chest computed tomography scan. A: Coronal plane; B: Sagittal plane. Computed tomography with intravenous contrast enhancement revealed an expansion of the esophagus up to 5-6 cm in the distal part, a hypervascular neoplasm in the lumen of the esophagus extending throughout the entire esophageal length from upper esophageal sphincter to the gastric cardia with the maximum diameter of the tumor up to 6 cm.

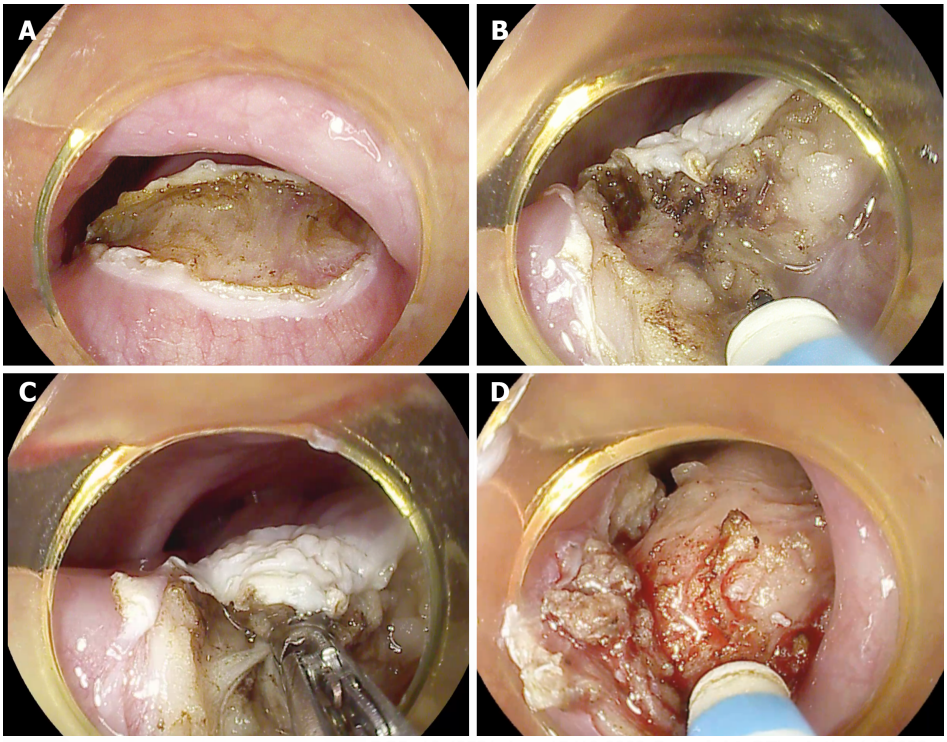

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Figure 4 Endoscopic steps of the surgery. A: Dissection of the mucosal and submucosal layers behind UES at the base of the tumor; B: Endoscopic submucosal dissection using endoscopic needle-knife; C: Coagulation of large feeding vessels in the submucosal layer using the coagrasper; D: The tumor is almost fully mobilized from the esophageal wall at its base.

distal part. That is why we decided to implement an innovative technique - a hybrid laparo-endoscopic approach. After complete excision of the tumor by ESD technique at the base, the neoplasm was brought down into the stomach and removed through a laparoscopic gastrotomy (Figure 5A and B). The detection of the neoplasm did not entail complications, since the patient was also diagnosed with a hernia of the esophageal opening of the diaphragm, characterized by a distance between its size of 5 cm (Figure 5C and D). Next, a standard technique for hiatal hernia repair was performed - diaphragm crurorraphy with Nissen fundoplication (pictures from the operation).

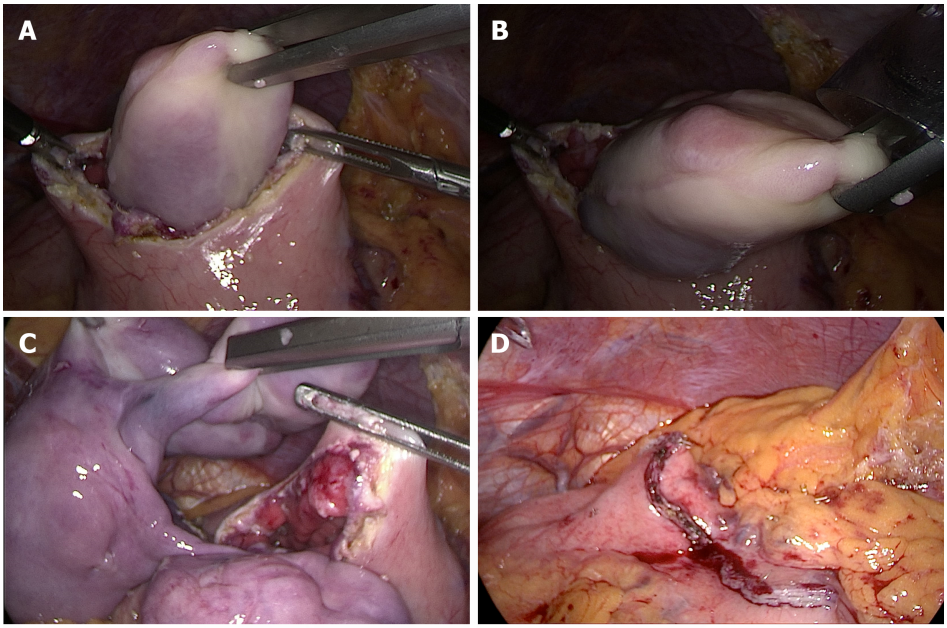

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Figure 5 Laparoscopic steps of the surgery. A: Using a laparoscopic grasper, the tumor is captured through a gastrotomy on the anterior wall of the gastric body; B: Removal of the tumor from the gastric body after it was completely brought down from the esophagus; C: The complete extraction of the tumor from the stomach into abdominal cavity; D: Gastrotomy closure with laparoscopic EndoGIA stapler suture.

OUTCOME AND FOLLOW-UP

The duration of the operation was 3 h and 50 min. There were no intraoperative and postoperative complications. At the follow-up X-Ray examination done on the 3rd day after surgery, swallowing was not disturbed when taking a contrast, the esophagus was free to pass a contrast agent, no exit of the contrast beyond the walls of the esophagus was registered; no signs of pneumothorax and hydrothorax were revealed. The patient was discharged on the 7th postoperative day. The removed specimen represents a tumor of an irregular elongated shape splitting into two parts at the distal end, 25 cm × 4 cm × 5 cm in size, with a smooth surface covered by intact mucosa (Figure 6). On section, the tumor is represented by vascularized adipose tissue with foci of fibrosis. Morphology study showed fragments of tumor represented by adipose tissue, separated by wide fields of sclerotic fibrous tissue with numerous vessels and cells of the inflammatory infiltrate. Among the fibrous tissue there are unilocular and different-sized adipocytes and hyperchromic cells with angular nuclei (Figure 7A and B). Morphology report: fibrovascular polyp with foci of highly differentiated liposarcoma, tumor tissue at the sight of endoscopic dissection is not determined, R0, M 8850/3; Grade 1 (Figure 7A and B).

The follow-up endoscopic examination 3 mo after surgery showed no residual fragments of the tumor, no narrowing and pathological changes of the mucosa at the area of endoscopic dissection (Figure 8A and B). The fundoplication cuff is well closed, located below the diaphragmatic crura, no gastroesophageal reflux was noted by the patient. The follow-up period up to date is 6 mo. At the moment, the patient has no complaints.

DISCUSSION

The giant FVP of the esophagus are benign non-epithelial tumors that originate from submucosal layer, covered with normal esophageal mucosa. Usually they appear from the esophagus's upper third at the level of upper esophageal sphincter. Previously the tumor was known as pedunculated lipoma, myxofibroma, and fibroma[6]. FVP are rare tumors, that are composed of around 0.03% esophageal tumors and less than 2% esophageal benign tumors[1,7,8].

There have been fewer than 100 reported cases so far, with most cases occurring in males aged between their late sixties and early nineties[9]. The risk of malignancy is extremely low.

The term 'fibrovascular polyp' is collecting the esophageal neoplasms, such as fibroma, fibrolipoma, lipoma, or fibromyxoma, according to World Health Organization classification[10]. Different terms for this type of tumor appeared because the polyps can be composed of various tissues, such blood vessels, muscles, fat, and fibrous tissue.

The etiology of giant fibrovascular polyps is debated. One theory suggests that the lack of muscular support at the pharyngoesophageal junction causes elongation of tissue due to peristalsis traction and swallowing[11]. Another theory, supported by a cytogenetic study, proposes that giant fibrovascular polyps is a neoplastic process with chromosomal changes indicating instability[12]. Retrospective analysis of cases previously labeled as giant fibrovascular polyp of the esophagus lipoma, or liposarcoma revealed murine double minute 2 amplification in all cases, suggesting that most large polypoid fat-containing masses in the esophagus are actually liposarcoma[13].

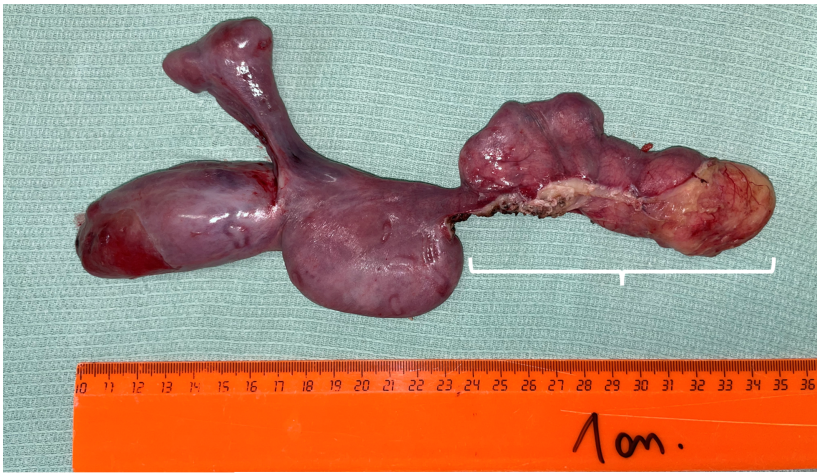

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Figure 6 Specimen. The removed specimen represents a tumor of an irregular elongated shape splitting into two parts at the distal end, 25 cm × 4 cm × 6 cm in size, with a smooth surface covered by intact mucosa. The area of endoscopic submucosal dissection at the tumor's base is 11 centimeters long (marked with square bracket).

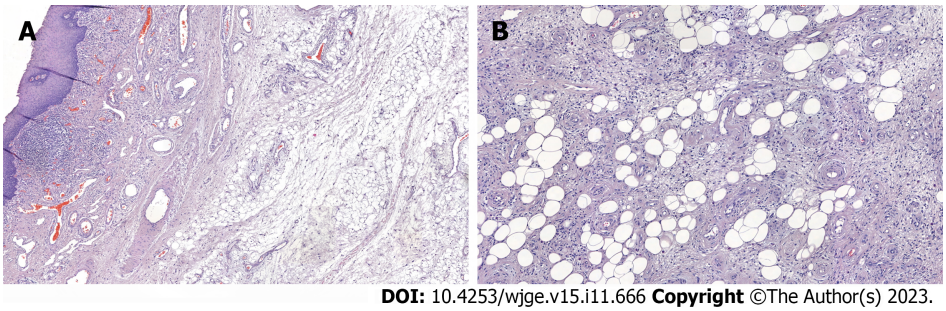

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Figure 7 Morphology. A and B: The tumor is represented by adipose tissue, separated by wide fields of sclerotic fibrous tissue with numerous vessels and cells of the inflammatory infiltrate. The adipocytes are uninuclear and different-sized. Among the fibrous tissue there are hyperchromic cells with angular nuclei. Morphology report: fibrovascular polyp with foci of highly differentiated liposarcoma, tumor tissue at the sight of endoscopic dissection is not determined, R0, M 8850/3; Grade 1.

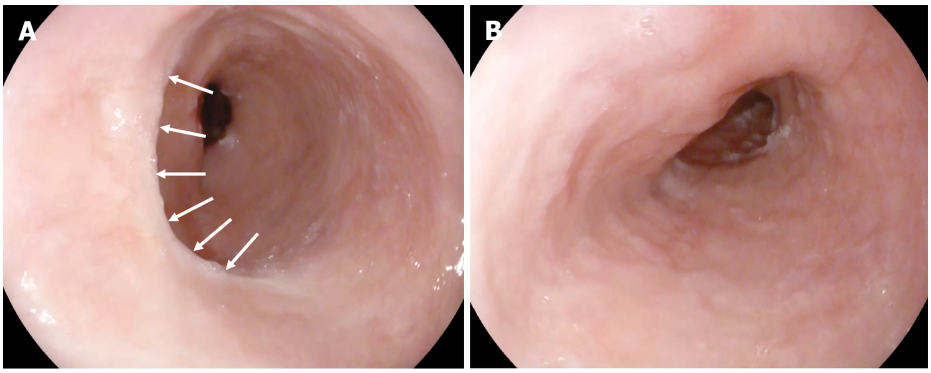

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Figure 8 Follow-up esophagoscopy three months after surgery. A: A white linear scar is observed in the submucosal layer behind the upper esophageal sphincter, where endoscopic dissection was previously performed (marked with white arrows). There are no residual tumor fragments and no signs of narrowing of the lumen at the sight of dissection; B: No alterations in the esophageal lumen along its entire length.

The size of the tumor can vary from a few centimeters up to large sizes (the widest reported size was 25 cm), which can cause serious complications such as asphyxia as a result of obstruction of the aero-digestive crossroads, dysphagia associated with the tumor's complete occupation of the lumen of the esophagus. Usually, symptoms are not presented in the early stages due to a small size of the tumor, and the risk of previous complications is mainly presented for tumors above 8 cm[14]. Other clinical symptoms that can alert to this disease are foreign body sensation, coughing, dyspnea, chest discomfort, neck pain, and odynophagia[3].

Diagnosis of fibrovascular polyps is not easy and often requires a combination of patient`s symptoms, history, invasive and non-invasive methods of diagnosis. Among non-invasive methods of diagnosis, barium swallow can show a dilated esophagus and long, smooth filling defects in the lumen of the upper esophagus[14]. However, the sensitivity of this method is not high. CT scans and magnetic resonance imaging are still regarded as the most reliable method to identify the characteristics and origin of a mass. A CT scan of the cervicothoracic region provides important information about a mass, including its characteristics, location in relation to surrounding organs and tissues, and blood supply. This information is crucial in deciding the best approach for clinical treatment[15]. In addition to regular CT scan, positron emission tomography (PET)-CT can also be used to identify, which can help to identify abnormal F-fluoroxy-d-glucose values in various parts of the polyp, which aided in distinguishing between benign and malignant lesions. As a result, PET-CT can be recommended for certain diagnostically challenging cases[15].

Sometimes esophageal polyps are not correctly identified during diagnosis. Around 25% of esophagoscopy may result in misdiagnosis due to the microscopic appear of the polyp[16].

GI endoscopy and EUS play a crucial role in identifying and differentiating between various forms of esophageal fibrovascular polyps. EUS enables real-time ultrasound scanning to gather information about the polyp's origin, echogenicity, and blood supply[17]. Some studies showed that fine Doppler can be unsuccessful in showing vascularization due to the mobile characteristic of fibrovascular polyp. In such cases EUS with contrast enhancement could be helpful. Using EUS with a contrast Sonovue®, tissue microcirculation was highlighted inside the entire head of the polyp, leading to better appreciate the risk of bleeding related to its resection. Sonovue®, as enhancement contrast agent, confirmed its efficacy in identifying microvascularization and improving characterization of a submucosal tumor of the upper digestive tract[6]. On endoscopy, fibrovascular polyps are usually seen as a large intraluminal mass that can be freely moved through the lumen of the esophagus and covered by regular mucosa. However, on occasion, these polyps may go unnoticed if they are covered by normal mucosa or they may be misidentified as cancerous tumors because their pedicles are not easily visible[18].

The accepted approach to address fibrovascular polyps is through surgical excision[19].

This method not only alleviates symptoms but also eliminates the possibility of choking. It can be performed through various approaches, including transoral, transthoracic, transcervical, and endoscopic resection[9,20-24]. Cockbain *et al*[25] presented a study on the open technique treatment of four patients with epidural field potentials, recommending it for polyps more prominent than 10 cm due to its advantages. However, there were difficulties with polyp removal, but there were no recurrences during long-term follow-up. Quijano *et al*[26] believe the open technique is best for treating recurrent polyps. The review analyzed 31 patients who underwent transluminal resection, with 15 cases undergoing transoral resection using instruments such as the Weerda laryngoscope and the Weerda diverticuloscope[19]. According to Iván *et al*[27], transoral resection is a safe approach for giant fibrovascular polyps if specific criteria are met. In one of the reported case series, a combined endoscopic/transoral approach was used to extract the polyp through the oral cavity gradually, and an endo-Gia stapler was used for the stalk section[19].

The neoplasms usually are pedunculated and does not contain deep muscular layers of esophagus which is one of the benefits for minimal invasive surgery[10]. The stag beetle knife can be beneficial in removing large polyps along with their stalks, as it can grab, evaluate, extract, and cauterize specific tissues[28].

Endoscopic resection is a minimally invasive option, but the procedure can be challenging, particularly for larger polyps with a broad pedicle measuring > 8 cm, which may have a higher risk of bleeding. New and more flexible endoscopic guides have made the approach more feasible[29]. The most commonly used technical device is the Endoloop, which is used to trap the polyp stalk and section it with an electrosurgical snare, after which the polyp can be removed by transoral or gastrotomic passway[19]. However, the difficulty of exposing the lesion and the risk of uncontrollable bleeding is higher with endoscopic resection, especially for larger polyps. In choosing the appropriate treatment method, surgeons must consider the size, location, and characteristics polyp's size, as well as the patient's overall health status. If a lesion has only one pedicle, it can be eliminated by endoscopic resection by ligating and electrocoagulating the pedicle [30].

However, endoscopic follow-up examination, typically once every three years, is strongly recommended, as the risk of recurrence is high (up to 50% reported in the literature)[25].

Overall, the treatment and management of fibrovascular polyps require a multidisciplinary approach involving a team of specialists, including gastroenterologists, thoracic surgeons, and endoscopists, to ensure optimal outcomes for the patient.

CONCLUSION

It is crucial to consider the size and vascularization of fibrovascular polyps when assume endoscopic removal as a treatment option and to carefully plan the surgical technique to avoid difficulties or discomfort during the procedure. However, there is an alternative approach to traditional surgical removal known as the new laparo-endoscopic approach that can be both safe and effective for treating giant fibrovascular polyps in the esophagus.

FOOTNOTES

Author contributions: Dzhantukhanova SV and Starkov YG contributed equally to this work; Dzhantukhanova SV, Starkov YG - concept and design of the study, editing, approval of the final version of the article; Badakhova AB, Avetisyan L - concept and design of the

study, writing text, editing; Glotov AV - contributed new reagents and analytic tools.

Informed consent statement: All study participants, or their legal guardian, provided informed written consent prior to study enrollment.

Conflict-of-interest statement: Author(s) certify that there is no conflict of interest related to the manuscript. If any potential conflict-of-interest exists, author(s) certify that it is fully disclosed.

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CASE REPORT

General anesthesia with endotracheal intubation ensures the quick removal of magnetic foreign bodies: A case report

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Abstract

BACKGROUND

The incidence of ingestion of magnetic foreign bodies in the gastrointestinal tract has been increasing year by year. Due to their strong magnetic attraction, if multiple gastrointestinal foreign bodies enter the small intestine, it can lead to serious complications such as intestinal perforation, necrosis, torsion, and bleeding. Severe cases require surgical intervention.

CASE SUMMARY

We report a 6-year-old child who accidentally swallowed multiple magnetic balls. Under timely and safe anesthesia, the magnetic balls were quickly removed through gastroscopy before entering the small intestine.

CONCLUSION

General anesthesia with endotracheal intubation can ensure full anesthesia under the condition of fasting for less than 6 h. In order to prevent magnetic foreign bodies from entering the small intestine, timely and effective measures must be taken to remove the foreign bodies.

Key Words: Magnetic foreign bodies; General anesthesia with endotracheal intubation; Magnetic balls; Endoscopy; Case report

Core Tip: We report the successful and timely removal of multiple magnetic balls in a 6-year-old child using endoscopic retrieval under general anesthesia with endotracheal intubation. The procedure was efficient, safe, and free of complications. Prompt intervention and a multidisciplinary approach involving anesthesiologists and endoscopists are crucial in managing pediatric patients with ingestion of gastrointestinal foreign bodies. This report highlights the importance of timely intervention to prevent potential complications associated with magnetic foreign bodies.

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INTRODUCTION

Foreign body ingestion is a common problem that mainly occurs in children[1]. Over more than 80% of ingested foreign objects may pass through the gastrointestinal tract uneventfully, while the rest require treatment[2]. Among them, magnetic foreign bodies pose a unique challenge due to their potential for complications. These objects, often small and attractive to children, can be accidentally ingested or inserted into the gastrointestinal tract. The ingestion of these magnetic balls can lead to intestinal perforation due to their ability to attract and cause pressure necrosis on tissues[2,3].

Endotracheal intubation under general anesthesia and timely endoscopic intervention can effectively prevent the passage of magnetic foreign bodies into the small intestine. This report describes the successful removal of multiple magnetic balls in a 6-year-old child.

CASE PRESENTATION

Chief complaints

A 6-year-old girl attended the clinic one hour after accidentally swallowing magnetic balls.

History of present illness

The girl presented to the hospital after accidentally swallowing multiple magnetic balls.

History of past illness

The child had been in good health.

Personal and family history

The child denied any family history.

Physical examination

The patient's vital signs were stable. Physical examination revealed a soft abdomen with no tenderness or rebound tenderness. Bowel sounds were normal.

Laboratory examinations

Routine blood tests showed no abnormalities.

Imaging examinations

The abdominal X-ray revealed that the balls had attracted together and formed a ring-like structure in the upper left abdomen (Figure 1A).

FINAL DIAGNOSIS

Multiple magnetic foreign bodies in the gastrointestinal tract.

TREATMENT

The child had consumed solid food approximately 2 h before coming to the hospital. In order to avoid the balls entering into the small intestine, our anesthesiologist promptly evaluated the child and performed the necessary airway

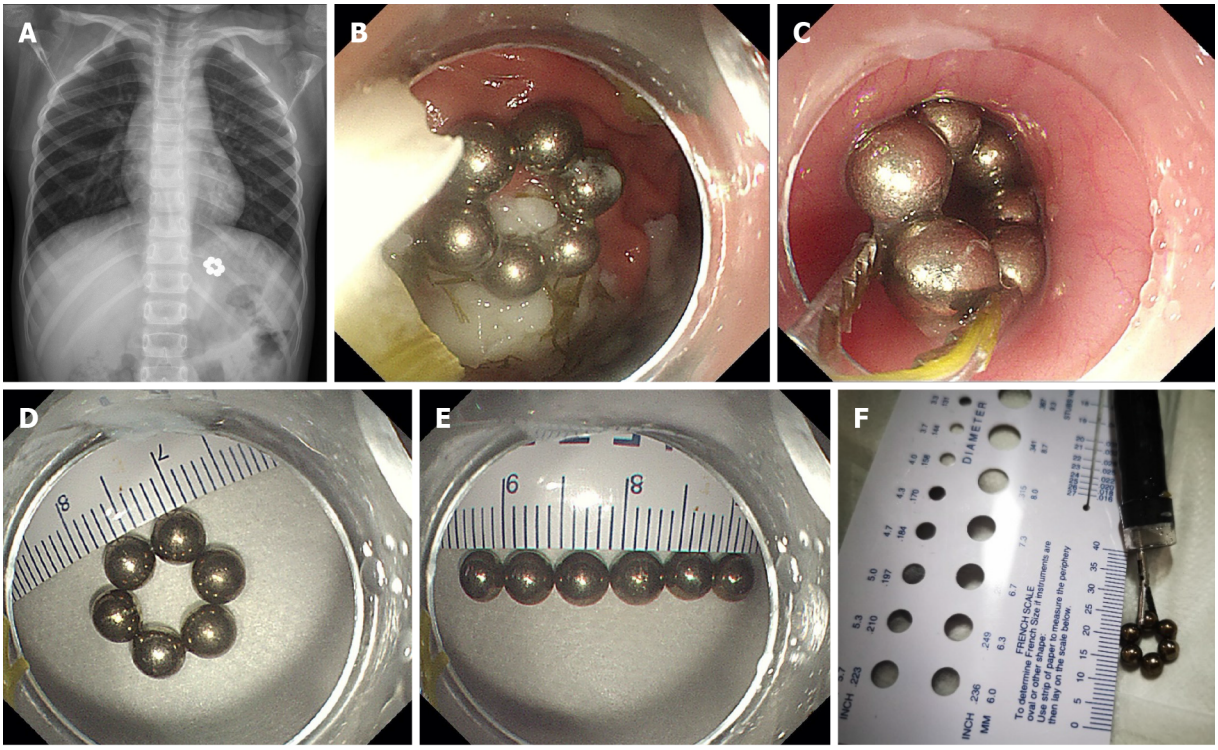

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Figure 1 Imaging and endoscopic examination of the magnetic balls. A: Abdominal X-ray shows that the 6 magnetic balls are located in the upper left abdomen; B: Endoscopic examination shows 6 magnetic balls attracting each other and forming a circular shape; C: Using foreign body forceps to clamp one of the magnetic balls, all 6 magnetic balls are removed through gastroscopy with the help of the mutual attraction between the magnetic balls; D-F: Measurements indicate that the diameter of the magnetic balls is approximately 0.5 cm, and the diameter after forming a circular shape is about 2.5 cm.

management. Then the child was provided general anesthesia with endotracheal intubation. The endoscopy was successfully performed only 38 min after admission. During the endoscopic examination, the magnetic balls were visualized inside the stomach, and arranged in a ring formation (Figure 1B). No mucosal damage was observed, but significant solid food residue was present (Figure 1B). Using grasping forceps, one of the magnetic balls was securely clamped, and with the help of their mutual attraction, all six balls with a diameter of approximately 2.5 cm were successfully removed (Figure 1C-F).

OUTCOME AND FOLLOW-UP

No mucosal or abrasion injuries were observed during the retrieval. After the procedure, the child's endotracheal tube was successfully removed, and she was transferred to the recovery room for observation. The patient reported no discomfort or complications postoperatively. The follow-up visit demonstrated a normal healthy child with no sequelae or complications.

DISCUSSION

Ingestion of foreign bodies is a common pediatric emergency, especially among young children[1]. Small objects can usually pass through the gastrointestinal tract naturally, but larger or sharp objects may become lodged or cause mucosal injury[2]. Magnetic objects pose a unique risk, as they can lead to pressure necrosis and perforation if not promptly removed.

The attractive force between the magnetic objects can cause them to adhere to each other across the intestinal wall, leading to pressure necrosis, perforation, or obstruction. The clinical presentation of patients with ingestion of magnetic foreign bodies can vary widely, ranging from asymptomatic to severe abdominal pain, vomiting, and gastrointestinal bleeding[4].

Diagnosis of magnetic foreign bodies is primarily based on a combination of clinical history, physical examination, and radiographic imaging. Abdominal X-rays, including both anteroposterior and lateral views, are commonly used to identify the presence, location, and number of magnetic objects within the gastrointestinal tract. In some cases, additional imaging modalities such as computed tomography or magnetic resonance imaging may be required for a more detailed evaluation[5].

Management of magnetic foreign bodies depends on several factors, including the location, number, size, and clinical symptoms of the patient. In asymptomatic patients with small, single magnetic object, conservative management with close observation and serial radiographic monitoring may be appropriate. However, in symptomatic patients or those with ingestion of multiple or large magnetic foreign bodies, endoscopic or surgical intervention may be necessary to remove the objects and prevent potential complications[6,7].

Children have a shorter gastric emptying time than adults, with a reported gastric emptying time after consuming solid food being less than 4 h for children[8]. For children, this means that foreign objects accidentally swallowed by the child may be expelled into the small intestine within a short period of time. Therefore, timely endoscopic intervention can prevent magnetic foreign bodies from entering the small intestine, thereby avoiding the occurrence of intestinal perforation, bleeding, ischemia, and necrosis. Current guidelines recommend that children undergo general anesthesia after fasting for more than 6 h[9]. However, after 6 h, as food is emptied from the stomach, foreign objects may also be expelled into the small intestine, thereby increasing the difficulty of their removal. General anesthesia with endotracheal intubation can prevent the occurrence of aspiration and choking after anesthesia, ensuring the safe implementation of endoscopic procedures under general anesthesia.

In this case, timely performing endoscopic removal under the protection of endotracheal intubation helped prevent the migration of the magnetic balls into the small intestine, reducing the difficulty of retrieval and the risk of bowel perforation.

CONCLUSION

Magnetic objects can pose a unique risk, as they can lead to pressure necrosis and perforation if not promptly removed. In this case, the timely and safe performance of endoscopic removal under the protection of endotracheal intubation helped prevent the migration of the magnetic balls into the small intestine, reducing the difficulty of retrieval and the risk of bowel perforation.

FOOTNOTES

Author contributions: Tian QF and Zhao AX contributed to manuscript writing and editing, and data collection; Du N, Wang ZJ and Ma LL contributed to data analysis; Men FL contributed to conceptualization and supervision; all authors have read and approved the final manuscript.

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