Original Article

NOTES: 'pre-dilatation' as a remedy for technical issues during transgastric access

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Abstract

Objective: To identify and resolve procedural issues during transgastric access for the Natural Orifice Translumenal Endoscopic Surgery (NOTES), where feasibility and safety is established in animals and humans. However, several technical problems during viscerotomy result in considerable delay or procedure failure.

Methods: Gastrotomy was performed under general anaesthesia in survival canine models. Single channel (adult) colonoscope was used. Anterior gastric wall was punctured in mid corpus region with needle knife method and percutaneous endoscopic gastrotomy (PEG) technique in separate dogs. Post-operatively, animal was observed for 2 weeks but it was immediately sacrifised if the creation of viscerotomy had failed. Postmortem examination of these animals focused on the cause of failure and detection of visceral injury. On account of frequent complications, needle knife method was replaced with percutaneous endoscopic gastrotomy technique. Visceral aperture was successfully accomplished with over-the-wire (OTW) balloon dilators after 'pre-dilatation' of the primary puncture with over-the-wire plastic bougies.

Results: Gastrotomy was performed in dogs (23) using two methods: needle knife (4) and PEG (19). Initially, there were 5 failures: needle knife (3); PEG (2). The failures resulted from organ damage (2) and inability to insert over-the-wire balloon dilator into gastric puncture (3). The needle knife method was abandoned due to major complications in 4 animals: gastric bleeding (2); liver rupture (1); penetrating injury to anterior abdominal wall (1). Viscerotomy was achieved in (17) consecutive cases by 'pre-dilating' the site of initial puncture. There was no mortality.

Conclusion: 'Pre-dilatation' with over-the-wire plastic dilators is recommended for the creation of gastrotomy.

Keywords: NOTES, Pre-dilatation, Gastrotomy, OTW dilators (JPMA 62: 111; 2012).

Introduction

The concept of translumenal surgery dates back to 1949 when Bueno et al. performed incidental appendectomy during transvaginal hysterectomy.[1] Reiner et al. later reported a similar operation in 100 patients.[2] Tsin carried out the first transvaginal cholecystectomy and labeled it as 'Culdolaparoscopy.'[3] However, NOTES earned nomenclature and recognition following transgastric (TG) biopsy of the porcine liver. Until today, several NOTES experiments have been performed in animals: appendectomy,[4] splenectomy,[5] cholecystectomy,[6] anastamosis,[7] thoracoscopy[8] and the placement of diaphragm pacing system.[9] NOTES procedures in humans include peritoneoscopy[10,11] and appendectomy.[12] There is no consensus on the best route for peritoneal access, but TG procedures are generally popular. With growing realisation of a 'straight shaft' approach, trans-vaginal, trans-urethral and trans-colonic routes are practised for NOTES surgery in the upper abdomen.[13,14] The operator confronts several subtle and largely unexplored technical issues, that have a significant impact on the outcome of the NOTES procedure. Visceral anatomy, methodology of access and angle of entry into the peritoneal cavity are to name only a few in this regard. 'Pre-dilatation' of the primary puncture is an effective remedy which resolves most of these problems and ensures a smooth creation of visceral aperture.

Methodology

The present study was conducted at the animal centre of the Peoples' Liberation Army General Hospital (PLA-GH), Beijing, China, in August-November, 2009. Prior approval of the institutional review board was obtained.

NOTES experiments were performed on female Mongrel dogs (15-20kg). The animals were kept on liquid diet a day before the procedure and nil per oral overnight. Endo-tracheal anaesthesia was administered in supine position. Animals' teeth were covered with cotton pads. The anterior abdominal wall was shaved and cleansed with antiseptic solution. Flexible colonoscope (CF-H260AI, outer diameter 13mm: Olympus Beijing) with single accessory channel (3.7mm) was advanced into the stomach, which was thoroughly irrigated with normal saline. After adequate gastric distension, the site of entry was selected by thumb indentation in the epigastrium.

While using the needle knife methods, a 3-lumen needle knife (Microvasive: Boston Scientific Corporation, USA) was introduced in the accessory channel of colonoscope to make contact with the site of the penetration on the anterior gastric wall. Blended current (25W cut; 25W coagulation; 1 second pulse) applied with electrocautery unit (SICC 350 Lanmark; Zhuhai Weierkang Biotechnology Co. Ltd) resulted in primary trans-gastric puncture. After passing guide wire (5658, outer diameter 0.035 inch: Boston Scientific Corporation, USA) into the peritoneal cavity, the needle knife was replaced with OTW constant radial expansion (CRE) balloon dilators (5839, outer diameter 0.6-0.8cm; 5842, outer diameter 1.2-1.5cm: Boston Scientific Corporation, USA) for gastrotomy.

As for the PEG technique, a spinal (lumbar puncture) needle (18 guage) was pushed transcutaneously in the epigastric region to enter the stomach under direct vision. Proximal end of the guide wire (5658, outer diameter 0.035 inch: Boston Scientific Corporation, USA) was passed through the needle. In the gastric lumen, the guide wire was grasped with biopsy forceps and gradually pulled out of the accessory channel. Distal (soft) end of guide wire was redirected into the peritoneal cavity. CRE balloon dilator (5839, outer diameter 0.6-0.8cm; 5842, outer diameter 1.2-1.5cm: Boston Scientific Corporation, USA) was passed over guide wire for dilatation of the initial puncture.

'Pre-dilatation' technique was also used in which, after rerouting guide wire into the peritoneal cavity, (as was done in PEG procedure), an OTW plastic catheter (outer diameter 7F: Olympus Beijing) was passed down the accessory channel to reach the site of the primary puncture (Figure-1A). 'Pre-dilatation' was achieved by advancing colonoscope over the plastic bougie until catheter tip penetrated the gastric wall with a sensation of 'give' (Figure-1B). The manoeuvre was repeated with 10F OTW plastic bougie, which was then replaced with OTW balloon catheter (5839, outer diameter 0.6-0.8cm; 5842, outer diameter 1.2-1.5cm: Boston Scientific Corporation, USA) for further dilatation of the tract (Figure-1C).

Another approach was through entry into the peritoneal cavity. Here, viscerotomy was created by maximum distension of CRE balloon dilator with normal saline. After slight deflation, the balloon catheter was pushed in line with the endoscope to enter the peritoneal cavity. Guide wire and OTW balloon were removed together prior to NOTES experiment.

In terms of post-operative steps, the access was closed with hemoclips. Blood samples were sent (before and) after each procedure. The animals were allowed regular food and water soon after recovery from anaesthesia. They were regularly observed for any change in behaviour, appetite, bowels and abdominal girth.

Results

TG access was attempted in 23 dogs with needle knife method in 4 and PEG technique in 19. Initially, there

Table-1: Favourable impact of 'Pre-dilatation' (n = 23).

Technique	No. of procedures	Before "Pre dilatation"		After "Pre dilatation"	
		Success	Failure	Success	Failure
NK method	4	1	3	0	0
PEG technique	19	0	2	17	0

NK= Needle knife; PEG= Percutaneous endoscopic gastrotomy.

Table-2: Technical issues causing procedure delay (n = 23).

Major issues	No. of animals	Minor issues	No. of animals
Laxity of gastric mucosa	8	Varying convexity of anterior gastric wall	5
Insertion of inflated OTW balloon	6	Guide wire or endoscope slipping into stomach	5
Insertion of non-inflated OTW balloon	4	Spasm or recoil of gastric musculature	4
'Memory curve' of NK	3	Local bleeding and oedema with NK	4
Minor injuries with NK	3	Tangential approach of endoscope	4
Angle of guide wire	3	Spontaneous closure of access	3

OTW= Over-the-wire; NK= Needle knife.

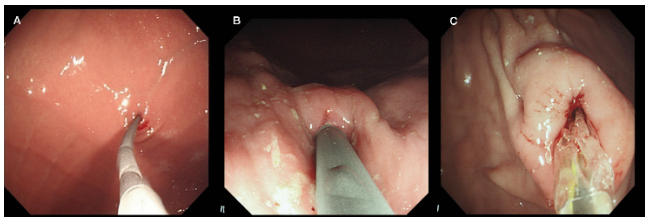

Figure-1: 'Pre-dilatation Technique' (A) Tip of OTW plastic catheter abutted against gastric mucosa. Gentle curve in catheter tip suggests oblique intramural course of guide wire (B) OTW plastic dilator pushed through gastric wall for 'pre-dilatation' of initial puncture (C) Free insertion of OTW balloon dilator possible after 'pre-dilatation' of primary tract.

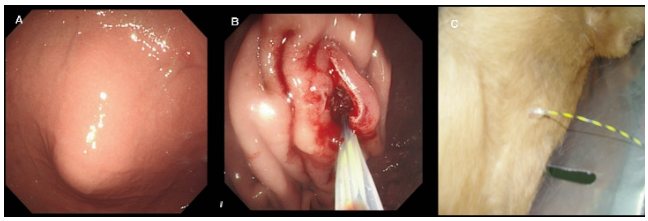

Figure-2: Initial Problems (A) Truly vertical puncture difficult as loose gastric mucosa is lifted by penetrating spinal needle during 'PEG' technique (B) Considerable mucosal trauma with needle knife (C) OTW balloon dilator exits from anterior abdominal wall following penetrating injury with needle knife.

were 5 failures (needle knife, 3 and PEG, 2) caused by organ rupture (2) and inability to push OTW balloon dilator into the primary puncture (3). The latter problem occurred during both methods: needle knife (1) and PEG (2). Non-inflated OTW balloon dilator could be inserted without 'pre-dilatation' in 1 case (Table-1). Needle knife method was replaced with PEG technique due to serious complications in 4 animals: gastric haemorrhage (2), liver rupture (1), and penetrating injury to the anterior abdominal wall (1). Laxity of gastric mucosa was the commonest cause of procedure delay in 8 animals. It accounted for failure to insert non-distended and distended OTW balloon catheters in 4 and 6 animals, respectively. 'Memory curve' in the needle knife had similar influence in 3 animals. Tangential approach of the endoscope caused procedure delay in 4 animals. Abrupt leakage of gastric air occurred in 5 animals. It affected angle of guide wire in 3 animals. The guide wire and/or colonoscope slipped back into the stomach in 5 animals. Needle knife caused electrical 'burns' on the abdominal parieties and gastric injury in 3 and 4 animals, respectively. Spontaneous closure of viscerotomy obstructed re-insertion of endoscope in 3 animals. Reflex spasm or recoil of gastric musculature accounted for same problem in 4 animals (Table-2). Most of these technical issues were successfully overcome in 17 consecutive animals by 'pre-dilatation' of the primary tract with 7F and 10F OTW plastic bougies. There was no mortality.

Discussion

NOTES has recently emerged as potential replacement of conventional and laparoscopic surgery. However, it has made slow progress in the past 5 years due to its dependence on technology 'borrowed' from flexible endoscopy. Majority of NOTES interventions are carried out with accessories which are primarily meant for intra-luminal use. They lack rigidity and triangulation so that high grade NOTES procedures are currently not feasible.[15] The basis for alarm revolves around paradoxical creation of a visceral perforation with needle knife or PEG techniques. These limitations have generated concerns about the safety and ethical justification of NOTES.[16,17] The study opted for transgastric access, which is usually considered a safe and effective method particularly for NOTES surgery in the

lower abdomen.[10,18] In spite of retroflexed view of viscera in the upper abdomen, the popularity of transgastric route is apparently related to lower risk of bacterial contamination by oral orifice than with anal, vaginal or urethral approaches. Contrary to general preference for pigs, the study conducted its experiments on dogs. The choice of canines was made on anatomical grounds. In our experience, there is a higher risk of injury to the overlying liver and spleen in pigs during penetration of the anterior gastric wall.

Damage to the endoscope was prevented by covering animals' teeth with cotton pads. We avoided the use of over tube to permit easy manoeuverability of endoscope. There was no septic complication in the animals although we did not use peri-operative antibiotics or antiseptic gastric lavage.[19] The preference for colonoscope was based on exploiting its structural toughness for the creation of gastric aperture.

We believe that there are several technical issues which determine the outcome of procedure for viscerotomy. Unusual laxity of the gastric mucosa seems to be one of the most important reasons in this regard. The gastric mucosal folds often tend to persist despite maximum distension of the stomach with air. It is due to regional anatomy, intermittent endoscopic suction and leakage of gastric air during the procedure. Loose mucosa is easily lifted by the penetrating needle so that the resulting tract is obliquely oriented (Figure-2A). This problem is encountered more often during PEG method when the needle approaches from without inwards during transcutaneous puncture of the stomach. The mechanism of organ injury with needle knife is different from the PEG method. With 'memory curve' in its lower end, the needle knife tends to pursue a curvilinear course within the gastric wall. It may insinuate between layers of the gastric musculature to cause intramural bleeding and haematoma formation. The complication rate with needle knife is reported to be 13.2%.[20] Local haemorrhage (Figure 2B) and penetrating injuries (Figure 2C) were serious problems which obliged us to replace needle knife method with the PEG technique.

It is a common observation that flexible endoscope with straight tip has truly perpendicular (i.e. end-on) approach in two areas of the stomach: high up on the anterior wall and in the pre-pyloric area. Between these two regions, the access becomes increasingly tangential as the endoscope is advanced against the anterior gastric wall. The problem of creating an oblique or curvilinear initial puncture is thus augmented by the subtle angle, which forms between tangentially oriented tip of the endoscope and the anterior wall of the stomach. The gastric and serosal ends of the resulting tract are poorly approximated so that the transmural placement of non-distended OTW balloon for gastrotomy is rendered extremely difficult. It was this particular situation which actually prompted us to consider 'pre-dilatation' of the primary tract before balloon dilatation. We experienced frequent impaction of distended OTW balloon within the visceral aperture due to its oblique intramural course. The OTW balloon tended to 'kink' within gastrotomy, especially if the guide wire was too flexible. The problem was apparently accentuated by disparity in the axis of orientation of each layer in the gastric wall, starting from mucosa to the serosa. This axial incongruity is another important factor which leads to the formation of a curved transmural puncture. We believe that each gastric layer offers variable resistance to the penetrating accessory during the creation of gastrotomy by any method.

The angle of guide wire within and outside the gastric wall had an important influence on the transgatsric insertion of OTW balloon. We found that re-routing distal end of guide wire into the peritoneal cavity was an essential manoeuvre, which facilitated free advancement of the CRE balloon catheter. In one instance without placement of guide wire into the peritoneal cavity, the CRE balloon was accidentally pushed through the anterior abdominal wall (Figure-2C). The angle of guide wire within the gastric lumen is also important as it is increased by abrupt decompression of the stomach. The guide wire repeatedly dislodged when we attempted to straighten its intragastric angulation during the PEG method. Sugimoto et al. have described a 'rendezvous technique'[21] to reduce guide wire exchange. Here, CRE balloon catheter was introduced through transabdominal trocar and a needle grasper was passed through the same skin puncture to facilitate the removal of the gallbladder. They have described a 'hybrid' NOTES experiment with laparoscopic assistance. In our opinion, the laparoscopic guidance for transluminal intervention addresses many issues which handicap 'pure' NOTES surgery. Moreover, creation of a large defect in the skin practically negates the cosmetic advantage of NOTES. After transgressing the stomach wall with CRE balloons, we dilated separately the gastric and peritoneal ends of viscerotomy in order to straighten the intramural tract. Before pushing it into the peritoneal cavity, slight deflation of the CRE balloon helped overcome obstruction due to 'residual' kink in the transgastric aperture. Spontaneous closure of gastrotomy due to recoil of gastric musculature or reflex muscle spasm impeded re-insertion of endoscope if it was dislodged during the procedure. We have inferred from the present study that most of the aforementioned issues can be readily overcome by 'pre-dilatation' of the initial puncture with 7F & 10F OTW plastic dilators.

'Pre-dilatation' is an excellent remedy that shortens the procedure time and favourably impacts the outcome of NOTES intervention (Table-1). It can be conveniently

accomplished by virtue of the rigid texture and tapered tip of OTW plastic catheters. The risk of iatrogenic injury with the plastic bougie is minimal on account of its short and linear intra-mural course. Successive 'pre-dilatation' with 7F and 10F plastic catheters creates a straight tract which is wide enough to accommodate the CRE balloon catheter for further dilatation. OTW plastic dilators circumvent the need to repeat transabdominal PEG in case the viscerotomy is spontaneously closed. Under these circumstances, gastrotomy can be easily re-opened by using plastic catheters, followed by dilatation with OTW balloons. We found that the entire procedure for visceraotomy becomes smooth and rapid by incorporating the 'pre-dilatation' technique. The access closure is more secure after 'pre-dilatation' due to significant reduction in local trauma and more precise application of hemoclips.

Conclusion

'Pre-dilatation' with 7F and 10F OTW plastic bougies resolves several technical issues which adversely impact the creation of a visceral aperture. 'Pre-dilatation' is, therefore, recommended as an essential step during NOTES gastrotomy.

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