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ORIGINAL ARTICLE

Instrumentation and surgical technique for an innovative safe sigmoid approach for NOTES

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Abstract
A set of new instruments was designed to establish an access to the abdominal cavity for NOTES via the rectosigmoid. It comprehends a metal overtube which is positioned using a modified TEM device. The entry point is targeted by transrectal ultrasound and secured by a purse-string suture. Closure is achieved by means of a linear stapler application. The applicability of the system could already be confirmed in animal survival studies.

Key words: *NOTES, transanal approach, transrectal access, ISSA, transanal endoscopic microsurgery, overtube*

Introduction

By definition, NOTES interventions are performed with a flexible endoscope through a natural orifice such as the mouth (stomach), vagina, uretra or the anus (1).

Still today, the creation of a suitable access to the peritoneal cavity remains a major obstacle to introduce NOTES into clinical practice (2), since each of the orifices presents specific disadvantages and drawbacks.

The transgastric approach has some disadvantages because of the long distance between the abdominal entry point and the natural orifice (mouth). Therefore, it is difficult for the surgeon to handle the long flexible endoscope and perform the surgical intervention. The secondary problem is that the entry point is situated in the anterior gastric wall, which makes it obligatory to manipulate in retroflexed direction for surgical interventions in the upper abdominal region.

A transvaginal or transcolonic approach would be by far more practical since the distance to the target region is much shorter and the abdominal cavity can be explored under conditions of optical correctness. The transvaginal access is a well-known access with a low contamination risk. Marescaux et al. performed the first human cholecystectomy through the vagina (3). However, this approach is only applicable to female patients and some concerns about side effects (dyspareunea) still prevail.

A transrectal/transcolonic access would have considerable advantages but it is refused by the majority of groups working on NOTES because the risk of bacterial contamination of the abdomen resulting in postoperative peritonitis is high and incisions to the colon are inclined to leak postoperatively. First experimental trials were disappointing (4).

We assumed that a sterile ''overtube'' could be helpful to avoid contamination when the endoscope is inserted or the instruments are changed. Furthermore, the surgical technique of transanal endoscopic microsurgery as developed by Buess (5) should provide a safe and secure closure of the entry point at the end of the procedure.

The aim of this study was to combine both elements and to design an adequate set of instruments to perform NOTES procedures via the anus. The usability should be evaluated under experimental conditions.

Material and methods

Design of the trocar

Commercially available laparoscopic trocars are inadequate for transrectal insertion since they are

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too short to reach the small pelvis and the space of Douglas. In addition, the tip would inevitably collide with the promontorium.

Therefore, a tube with a length of 310 mm and an outer diameter of 18 mm was chosen. The front end had to be curved to avoid collision with the promontorium. Using an anatomical model of the human pelvis, a radius of the curvature of 60° was determined as adequate. The inner diameter is 16 mm to permit the use even of large bore endoscopes.

Since NOTES is performed using a pneumoperitoneum, the trocar has to be gas-tight. Accordingly, a valve chamber (''trocar head'') was fixed to the rear end of the tube. The trocar head is connected by a bayonet coupling mechanism to the end of the trocar tube. Thus, it can be disassembled when the modified TEM device which is used to position the trocar is withdrawn (Figure 1).

To occlude the ski-like shaped endoscopic trocar for insertion, a semi-flexible obturator was constructed. The front end corresponding to the curved tip of the trocar is made of an elastic PVC-rod with an outer diameter of 12 mm.

Modification of the TEM device

The intra-abdominal part of the recto-sigmoid junction can be easily reached by using a commercially available instrument for transanal endoscopic microsurgery (TEM) (5). The TEM device consists of a rectoscope, an obturator and a stereoscopic telescope. The rectoscope has a diameter of about 40 mm and a length of 200 mm. The rear end is sealed with a gas-tight cap that has four entry points. Various instruments can be inserted into the three ports sealed by rubber caps. The telescope is inserted through an additional port.

For our application, the commercially available TEM set had to be modified. Two ports are used for instruments, another one for the trocar and one for the telescope. Both instrument ports were repositioned and the diameter was reduced to 6 mm to permit the augmentation of the trocar port. The position of the telescope port was not changed. Only the length of the guiding tube was slightly changed to a length of 93 mm so that the endoscopic trocar with a ski-like shape can be inserted. The trocar port was set up to 19 mm and placed centrally because the diameter of the endoscopic trocar is 18 mm. If the trocar port is not in use, it can provide access for other laparoscopic instruments (ultrasound probe, retrieval bag, stapler, etc.) (Figure 2). To improve the exposition of the anterior wall of the rectum the oblique tip of the original TEM device was turned by 180° (Figure 3).

Results

Surgical procedure

The ISSA (innovative safe and sterile sigmoid access) was tested in animal experiments. The surgical procedure consists of four consecutive steps:

- First, taurolidin solution – a decontaminating fluid widely used in general surgery to prevent and treat peritonitis - is instillated via a Veress needle into the abdominal cavity. The rectosigmoid is entered using the TEM device with the inserted obturator. Then the obturator is removed and the cap is put on the TEM device.
- Second, through the modified TEM device the ventral aspect of the rectosigmoid junction is

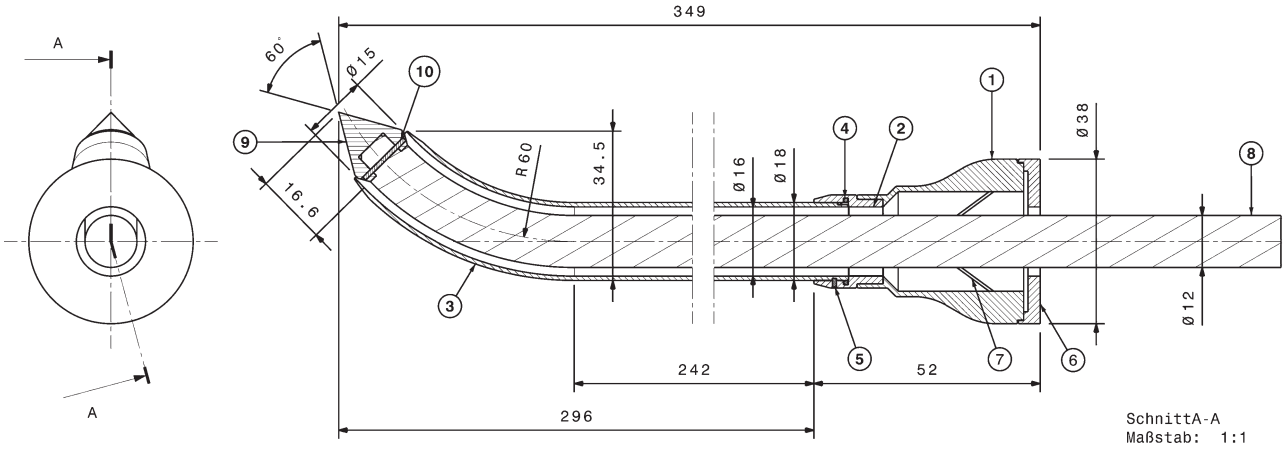

Figure 1. Cross-section of the ISSA trocar with inserted part flexible obturator; (1) trocar head, (2) trocar adapter, (3) trocar tube, (4) O-ring seal, (5) bayonet mechanism, (6) front cap, (7) trocar valve, (8) part flexible obturator, (9) conic front end, and (10) pin.

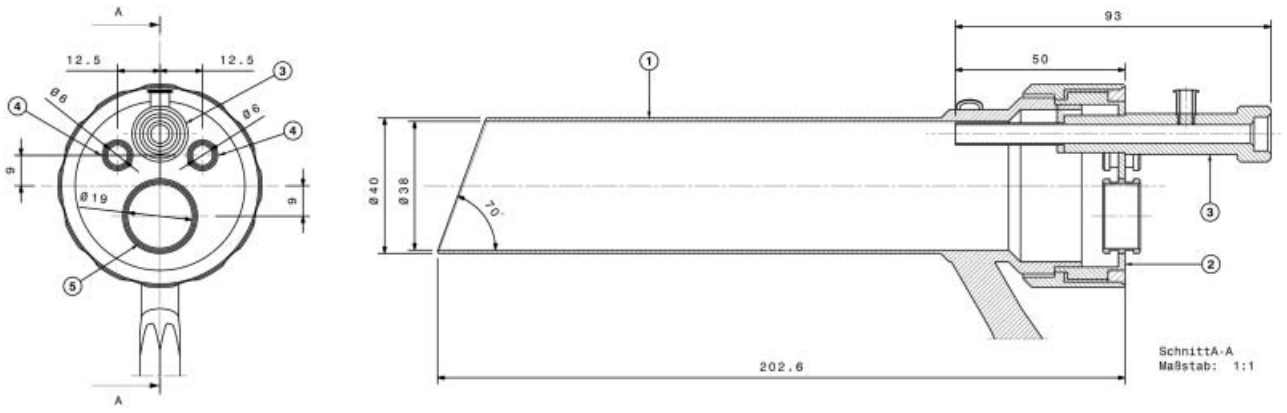

Figure 2. Cross-section of the modified TEM device; (1) rectoscope, (2) TEM cap, (3) shortened optic port, (4) instrument ports, and (5) trocar port.

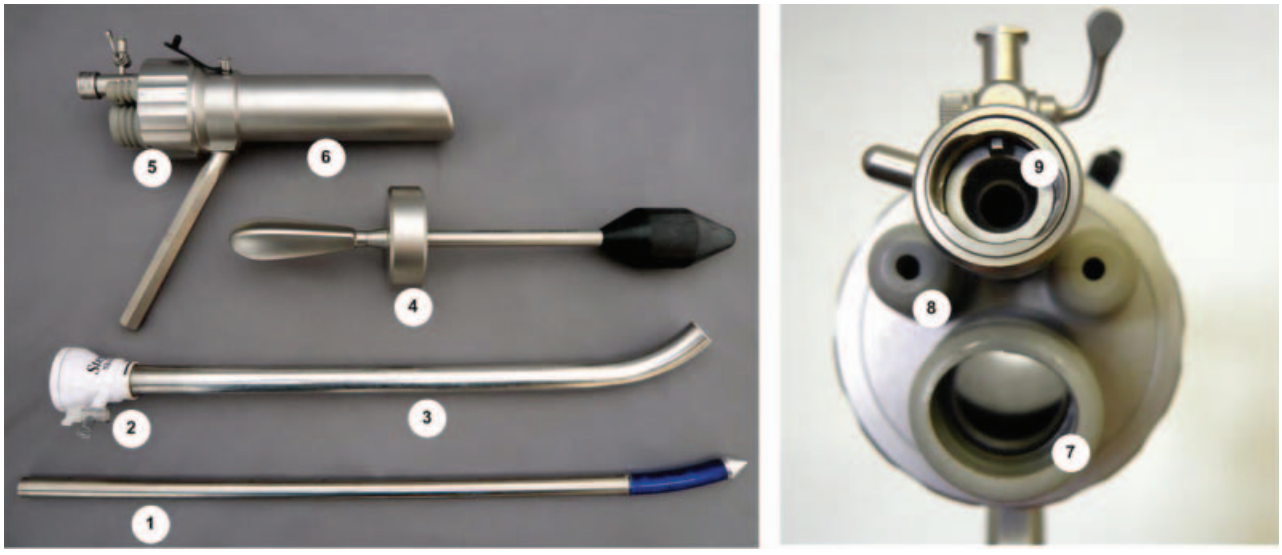

Figure 3. The new set of instruments (ISSA) designed to permit sterile sigmoid access for transcolonic surgery; (1) part flexible obturator, (2) trocar head, (3) trocar tube, (4) TEM obturator, (5) modified TEM cap, (6) modified rectoscope, (7) trocar port, (8) instrument ports, and (9) optical port.

identified and marked by a short diathermic application. With a rigid ultrasound probe inserted through the trocar port the anatomical situation beyond the intended entry point is examined. When the surgeon confirms that the entry point is covered by ascites and the small bowel loops are at a safe distance, a purse-string suture is applied.

- Third, the sterile trocar tube with the obturator is introduced through the trocar port. The entry point is perforated with the sharp tip to provide entry into the abdominal cavity.
- In the fourth step the obturator and TEM device can be removed. Then the trocar head is put on the trocar tube and the flexible endoscope can be inserted into the abdomen to verify the correct position of the trocar. Now the intervention can be performed (Figure 4).

As soon as the surgical procedure is finished and the flexible endoscope is withdrawn, the trocar head is removed and the modified TEM device is once again

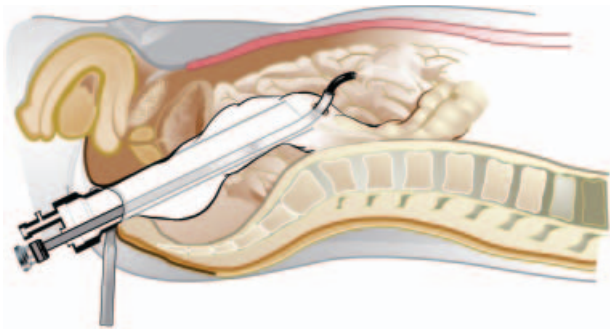

Figure 4. Surgical procedure: ISSA is inserted into the abdominal cavity by perforating the anterior rectal wall. A flexible endoscope can then be inserted into the abdominal cavity through this trocar.

Figure 5. Application of ISSA in a cadaveric study. ISSA was evaluated in five human cadavers to confirm the clinical applicability and the entrance into the peritoneal cavity.

inserted over the overtube. Under visual control the endoscopic trocar can now be removed and the purse-string suture can be closed. The small nipple - resulting from the purse string - is secured by using the linear stapler. Therefore, tight and reliable closure of the entry site is achieved.

Cadaver studies

The ISSA could also be successfully evaluated in cadaver studies (five human bodies with a body mass index of 18–33 kg/m^2). The instrumental set was introduced into the rectosigmoid as soon as the abdomen had been opened during necroscopy (Figure 5). In all cases, the trocar with the obturator entered the space of Douglas without any laceration of adjacent structures.

Discussion

Transanal endoscopic microsurgery (TEM) is a standard surgical procedure that involves dissection and suturing within the rectal lumen (6). This technique has several advantages for the patients (7) but also certain limits. In our case, the limited degrees of freedom and a working distance of only up to 15–20cm from the anal verge did not play a role. The TEM device could be adjusted successfully to the requirements of the procedure. The oblique tip of the original TEM was turned by 180°, the ports in the cap were repositioned and the diameters of the ports were adapted to the purpose.

The second key issue is a new endoscopic trocar (''overtube'') that allows inserting a flexible endoscope through the sigmoid into the abdominal cavity. The prototype was applied in experimental studies (8). In each case the target could be accessed and the surgical interventions could be finished successfully.

The experimental evaluation has proven that the use of an endoscopic trocar has many advantages. Compared to other natural-orifices the entry point can be targeted precisely and under visual control. Likewise, a safe and secure closure of the entry point is possible using well-established surgical techniques. The costs per operation are acceptable because all parts of our new set of instruments can be sterilized and used again. The diameter of the trocar is sufficient for all currently available flexible endoscopes.

A particular problem in NOTES is the difficult maneuvering of the flexible endoscope in the abdominal cavity. The ISSA trocar serves as a guide of the endoscope and makes it steerable from outside. Difficult manipulations of the endoscope are, thus, significantly facilitated.

In summary the ISSA device allows a sterile and standardized entrance into the peritoneal cavity. A wide spectrum of NOTES procedures, in particular in the upper and middle abdomen, should be easily feasible. However, today it is still a matter of debate whether NOTES may ever gain real clinical importance. What is for sure is that many things have to be optimized and improved before it becomes a clinical application. These development processes can be sped up when already established techniques and systems will join with new ideas. Our new set of instruments is a good example for this approach.

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