CHAPTER 1

GENERAL INTRODUCTION AND OUTLINE OF THIS THESIS

Peter van den Boezem
BACKGROUND

The introduction of laparoscopic techniques in the early 1990s revolutionized the field of surgery. Many traditionally open procedures were replaced by minimally invasive techniques. Laparoscopic surgery provides benefits to patients with regard to recovery, hospital stay, postoperative morbidity, return to normal activities and cosmetic results. Currently, the laparoscopic approach has become the standard of care for most abdominal procedures, including the treatment for gallstones and benign and malignant colonic diseases.

INTRODUCTION OF NOTES AND SINGLE-PORT SURGERY

In recent years, rapidly emerging technologies and improved techniques have blurred the boundaries between gastrointestinal (GI) surgery and therapeutic GI endoscopy and brought minimally invasive endoscopic surgery closer to a once-elusive goal: incisionless surgery. NOTES (Natural Orifice Transluminal Endoscopic Surgery) comprises a number of techniques, in which a natural orifice is used to gain access to the peritoneal cavity instead of initiating an operation with an incision through the skin. Natural orifices that can be used for a NOTES procedure are the vagina, the urine bladder, the stomach, or the rectum. NOTES challenges the basic paradigm of surgery; the idea that it should be avoided to enter the lumen of an organ to gain access into the patient’s abdominal cavity. Surgeons have always avoided to cross these borders unless they were operating on that specific organ.

Advantages

In theory NOTES can have enormous advantages for the patient. The most obvious, but perhaps least important benefit for patients is the absence of visible scars, resulting in an optimal cosmetic result. The absence of abdominal scars also means no wound infections and no long-term wound related complications such as hernias.

Other advantages of NOTES procedures when compared to conventional laparoscopy could be related to the reduced invasiveness and the amount of surgical trauma caused by the access route. The reduced amount of trauma could result in a faster postoperative recovery, reduced postoperative pain and therefore a lower requirement of anaesthetic drugs and possibly a shorter hospital stay. However, it will be difficult to prove that NOTES is less painful than current minor laparoscopic procedures such as an appendectomy. Larger and more complex procedures such as colorectal surgery are possibly better indicated to compare the postoperative pain profiles. However, reports describing colorectal NOTES are still scarce and it could therefore take a while before comparative studies will be carried out. Nonetheless, Marks et al. reported in 2007 a PEG rescue procedure and entered the peritoneal cavity under conscious sedation in a monitored care setting without the use of general anaesthesia.

Current Challenges

By performing transgastric peritoneoscopies in porcine models, Kalloo et al. were regarded as the first to describe a NOTES procedure in 2004 and attracted tremendous interest from
surgeons and gastroenterologists around the world. NOTES could be the logical next step in performing laparoscopic surgery. The challenges posed by NOTES surgery were thoroughly addressed in a “white paper” published in 2006 (Table 1). A working group called NOSCAR (Natural Orifice Surgery Consortium for Assessment and Research) wrote this paper. Although research and publications have shown an exponential growth since 2005, most of these challenges remain a threshold to the widespread introduction of NOTES in 2012.

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<th>Table 1. Potential barriers to clinical practice</th>
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<td>Access to peritoneal cavity</td>
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<td>Gastric (intestinal) closure</td>
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<td>Prevention of infection</td>
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<td>Development of suturing device</td>
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<td>Development of a multitasking platform</td>
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The peritoneal cavity can be accessed through mouth, vagina, rectum and urinebladder. Safe access and safe closure of these entry points is crucial for implementation in day-to-day clinical practice such as cholecystectomy or appendectomy. Current laparoscopy is safe and access related morbidity is very low, thus even a leakage rate of 1 or 2% after a NOTES procedure is not acceptable. Yet the stomach and the rectum, may be prone to complications from infections, should an incision fail to close properly. This is the main challenge for all NOTES procedures and in particular those who use the oral route.

The vaginal route is probably the easiest incision to close, as it can be done under direct vision, without the use of any special instruments. Moreover, transvaginal access is routine for gynaecologic surgeons and they have developed great experience with hydrolaparoscopy. Nonetheless, many GI surgeons question the safety of the transvaginal route. Several publications have emphasized the possible impact on fertility and change in sexual function. Younger nulliparous women express the greatest concern with any change in sexual functioning. On the other hand these patients are most concerned with cosmesis and are therefore ideally suited for NOTES. To our knowledge, there is no evidence in literature that supports a negative impact on fertility at this moment.

Prevention of infection is another issue that has to be addressed. It is difficult to create a sterile environment and access through another organ may increase the risk of intraperitoneal infection and contamination. However, during regular laparoscopic or open bowel surgery,
minor contamination is also common and well tolerated. In a study on female pigs, the intraperitoneal bacterial load and contamination during transgastric and transvaginal surgery was investigated\textsuperscript{21}. The transvaginal approach proved to be safer and produced less intra-abdominal contamination and sepsis, compared to the transgastric approach.

Besides a fear for an increase in complications caused by the access route, there is also a fear for an increase of complications due to an increased complexity. The reduced freedom of motion during NOTES procedures makes it more complex. The loss of spatial orientation is probably a bigger problem for surgeons than for gastroenterologists. Gastroenterologists are accustomed to working in-line with the camera because all instruments pass through working channels on the endoscope in contrast to laparoscopic surgeons, who work with different access sites (if not performing a Single-Port procedure). Loss of triangulation is also an issue that has to be encountered. If the principles learned in advanced laparoscopic surgery are applicable to NOTES, then orientation, as well as triangulation, will be fundamental requirements for any NOTES procedure\textsuperscript{24}. Development of multitasking platforms could be helpful to overcome these problems.

A considerable amount of work in this thesis is devoted to new techniques for cholecystectomies. A pivotal step during a laparoscopic cholecystectomy is the visualization of “critical view of safety” (CVS) according to the safety rules of Strasberg\textsuperscript{22,23}. Adherence to these rules minimises the risk of bile duct injuries. Loss of spatial orientation and triangulation makes it more difficult to reach CVS. NOTES can only be competitive with current surgical techniques if differences in speed and facility are minimal with (at least) equal safety of the procedures. As a result of loss of spatial orientation and triangulation progress during more complex procedures is slow. We regard a cholecystectomy already as a complex procedure because of the dissection in a small area and the subsequent need to obtain CVS. An increase in procedure related complications is not acceptable. Attempting to replace the most frequently performed and successful laparoscopic procedures is extremely difficult. Regular laparoscopic procedures as cholecystectomy and appendectomy are associated with a low risk of morbidity and a very low risk of mortality combined with a high level of patient satisfaction, so there is only little room left for improvement\textsuperscript{24}.

ACCESS ROUTE

All these challenges have divided research and development of NOTES. Gastroenterologists focus mostly on the transgastric and transesophageal route, endoscopic surgeons have explored the transvaginal route en more recently the transrectal route.

Independent of the route, safe introduction in the abdomen is essential. Pure NOTES procedures are therefore rare at this moment and most procedures are currently performed as a hybrid technique. During a hybrid NOTES procedure an extra 5 mm trocar is placed at the umbilicus to provide a safe entry through vagina or stomach. Currently, the transvaginal approach is the most popular. It provides a safe entry, a simple closure and the opportunity to utilize regular laparoscopic instruments\textsuperscript{21}. 
Transvaginal
The anatomical basis for the transvaginal approach is the wide posterior fundus of the vagina formed as a result of the anteversion position of the uterus. As it is not adherent to the anterior face of the rectum and has no interposed organ or anatomical structure, it allows direct entry to the peritoneum. The absence of pain nerves in the fornix posterior is a great benefit and makes it even possible to perform a hydrolaparoscopy under local anesthesia. Contra indications for transvaginal NOTES include radiotherapy and major surgery in the pelvis. As a result of an infection or a history of endometriosis, the Douglas pouch can shrink and thus making it difficult to insert a trocar without damaging a bowel. Most reported concerns with the transvaginal route focus on fear for dyspareunia, infertility and withdrawal of sexual intercourse for a number of weeks.

Transrectal
Dutch surgeons have a wide experience with transanal endoscopic microsurgery (TEM) for transanal surgery. TEM is used for the excision of both benign and malignant rectal tumours, but is relatively expensive and can be a challenging technique. Combination of Single-Port techniques and NOTES has increased the possibilities for TEM procedures and colorectal surgery in general. Transrectal specimen extraction after a laparoscopic sigmoid resection is an example of natural orifice specimen extraction. Currently, NOTES techniques are applied to rectal surgery. Visualization of the pelvic anatomy is excellent compared to open and laparoscopic rectal procedures.

Transgastric
Endoscopic gastroenterologists have developed significant experience with transgastric drainage of pancreatic pseudocysts and pancreatic necrosis, most of which are found in a retrogastric position. It was only a small step to relocate the gastrostomy to the anterior gastric wall and advance the endoscope into the peritoneal cavity. Several devices have been developed and tested in animal models and are currently tested in trials with humans. The safety of performing a transgastric staging peritoneoscopy prior to a pancreaticoduodenectomy has also been extensively demonstrated. Transesophageal access using a submucosal tunnel is another well-studied NOTES approach. Lymph node biopsy following mediastinoscopy has been carried out in animal experiments and could be helpful in lung cancer staging in the future. Promising results have been reported for the peroral endoscopic myotomy procedure (POEM) in the treatment of achalasia. The gallbladder is one of the major targets of NOTES researchers. It can be challenged whether the transgastric access is ideal for approaching the gallbladder. From a geometric point of view the transvaginal, or theoretical transcolonic, access provides a straight route to the upper abdomen diminishing the need for complicated and expensive flexible devices. The transgastric route is not subject to discussion of this thesis and the techniques are therefore not discussed in detail.
SINGLE-PORT SURGERY

During the development of NOTES, the single-incision laparoscopy trocar was introduced as a new scarless approach and considered as a spin-off of all NOTES-related research. Due to the technical skills required for NOTES procedures and the slow development of NOTES devices, the field of medical practitioners who could easily adopt to NOTES did not appear to be very large. With the introduction of Single-Port trocars these problems were partially overcome. One of the most important advantages of single-incision laparoscopic surgery (SILS) over NOTES is the possibility to use conventional laparoscopic instruments. This has currently led to an overall greater acceptance of SILS than NOTES. The market for SILS is projected to encompass 25% of all laparoscopy procedures by 2014, with many more surgeons able to perform this approach than NOTES. Using SILS, multiport laparoscopic procedures can be performed through one small incision, often hidden in the umbilicus. A SILS port can also be used at a future ileo- or colostomy site or even transanally as discussed in this thesis.

![Diagram of single-port laparoscopy](image)

**Figure 1.** Contributions, interactions and possible future developments.
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However, many of the previously mentioned challenges during NOTES procedures are also applicable to the principle of SILS. But the challenges during SILS are probably easier to overcome and therefore SILS can be seen as an intermediate step in the development and implementation of NOTES. SILS results in a minor scar when used at the umbilicus, but potential complications like a wound infection or a postoperative hernia are still possible.

The SILS technique can be used for a wide range of laparoscopic procedures. Pioneers with the SILS technique all started to utilise this technique for cholecystectomies and to a lesser extent appendectomies and in urology. As discussed earlier, loss of triangulation and spatial orientation has to be overcome. If two straight instruments are used in a SILS port during a dissection in a small area, like a cholecystectomy, clashing of the instruments is unavoidable. By using roticulating instruments, a wider range of motion could be created at
the tip of the instruments. However, roticulating instruments also increase the complexity of the procedure (Fig 2).

**OUTLINE OF THIS THESIS**

The aim of this thesis is to study the introduction of new minimal invasive techniques such as NOTES and SILS, that can be used within the field of abdominal surgery and in particular laparoscopic surgery.

In **chapter 2** we evaluate our initial experiences with the SILS trocar for cholecystectomies. In a case-control setting, the SILS cholecystectomy is compared to the conventional four port laparoscopic cholecystectomy. As our experience increased with the SILS technique, we also started to perform single incision laparoscopic colectomies (SILC). It was first used for benign indications, but we rapidly expanded to malignant indications. In **chapter 3** we discuss the results of our first 50 consecutive cases. One of the most performed SILC procedures is a right colectomy. **Chapter 4** is a two centre, prospective case control study in which the short-term surgical outcomes after SILC and multiport laparoscopic right colectomy are evaluated.

Our research group is the first group in the Netherlands to perform a hybrid-transvaginal cholecystectomy on a regular basis. In **chapter 5** the feasibility of this procedure is investigated. **Chapter 6** evaluates the clinical outcomes of our first year performing transvaginal cholecystectomies. Patient related outcomes such as body image and cosmesis are also evaluated. In **chapter 7** we evaluate the clinical and cosmetic outcomes of a case control study comparing single incision, transvaginal and conventional laparoscopic techniques for cholecystectomy.

Transanal endoscopic microsurgery (TEM) is widely used for the excision of both benign and malignant rectal tumours. TEM is relatively expensive and can be a challenging technique. Even

![Figure 2. multiport laparoscopy (A) versus SILS (B-E) hand instruments and orientations. Reproduced, with permission 52.](image-url)
though not developed for transanal use, the SILS port could be ideal because of its shape and texture. **Chapter 8** is a feasibility study in which a SILS port is used for transanal resection of large polyps.

In patients with rectal cancer it can be difficult to dissect the rectum below the tumor. In **chapter 9** we discuss the results of a feasibility study in which we conduct a hybrid NOTES procedure to mobilise the rectum transrectally with the use of a single port in the rectum.

The general discussion (**chapter 10**) summarizes the main findings of this thesis and discusses future perspectives.
REFERENCES


