

Evaluating the initial result of transanal and transvaginal NOTES for colorectal cancer

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Abstract:

Objective: Natural Orifice Transluminal Endoscopic Surgery (NOTES) is an important evolution in minimally invasive surgery (MIS) nowadays. This paper presents the techniques and early results of the pure transanal and transvaginal laparoscopies (NOTES) used for the treatment of colorectal cancer. **Material and method:** Prospective studies were conducted at Hue Central Hospital, Vietnam. **Patients:** From December 2013 to September 2015, 22 colorectal cancer patients (18 rectum, 3 sigmoid tumors and 1 descending colon), adenocarcinoma, $T \leq T_3N_1M_0$. **Methods:** The patients were placed in lithotomy and Trendelenburg positions, and the lone-star retractor was placed in the anus (rectum cancer) or vagina (sigmoid cancer). The surgical cavity was then inflated with CO₂ and set at 12 mm/Hg. Dissection was continued until inside of the abdominal cavity (transanal technique). After that, the rectum was pushed into the abdominal cavity. The IMA and IMV were divided (TME included) in both techniques. After finishing dissection, the specimens were pulled out through the anus or vagina to prepare anastomosis. Coloanal and colorectal anastomosis were either hand-sewn (6 cases) or sealed with EEA staplers (16 cases). **Results:** 2 patients needed one more 5 mm umbilical port in RLQ, 2 patients needed two 5 mm trocars (post radiation hemorrhage, and urethral perforation). One patient converted to open and 1 patient converted to the HYBRID-NOTES procedure. The operation time was 258±40 (190-300) minutes. All patients required minimal analgesia. Bowel movement returned on the first day to 16 patients (average: two days, maximum: three days). The hospital stay was 7±2.8 (4-14) days. Kirwan classification (sphincter function) was very good (stage I: 18). **Conclusions:** Pure transanal and transvaginal laparoscopies for the treatment of colorectal cancer are feasible and safe. We believe that this is the first pure transvaginal laparoscopy (NOTES) for human in the world. A multicentric study in a large numbers of patients and a long follow-up is necessary.

Keywords: colorectal cancer, Hue Central Hospital, Natural Orifice Transluminal Endoscopic Surgery.

Classification number: 3.2

Introduction

From the first transgastric liver biopsy of Kallo, appendectomy of Rao in 2004, and first transvaginal cholecystectomy of Jacques Marescaux in 2007, Natural Orifice Transluminal Endoscopic Surgery (NOTES) is seen as the newest technique in minimally invasive surgery methods [1]. At many centers around the world, laparoscopic surgery conducted through natural orifices NOTES was tested on bodies from body snatchers, bodies of animals, and after that, it was applied on people to positive results. However, the report of NOTES use for patients with colorectal cancer is very limited [2]. In Vietnam, there are only a few cases of colorectal cut by Hybrid NOTES or a few cases of transvaginal cholecystectomy were reported, and no reports of NOTES for patients with colorectal cancer.

Objective: To introduce our first experiences in research and application of NOTES for colorectal cancer.

Materials and methods

We prospectively studied 22 patients who suffered from descending colons, sigmoid, or rectal cancers from 12/2013 to 9/2015. Patient's consents were obtained. All patients underwent elective surgery using the technique: Transanal or transvaginal endoscopic surgery.

Patient selection criteria included ASA 1-3, Body Mass Index (BMI) < 30 kg/m², tumor size < 5 cm and tumor stage (Dukes classification) ≤ T3. Patients were not in situations of

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Fig. 1. Operation team.

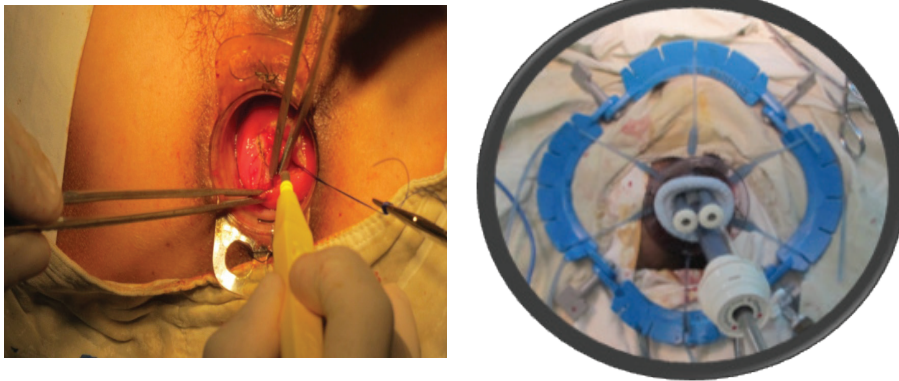


Fig. 2. Mucosal dissection and SILS port placement in anus.

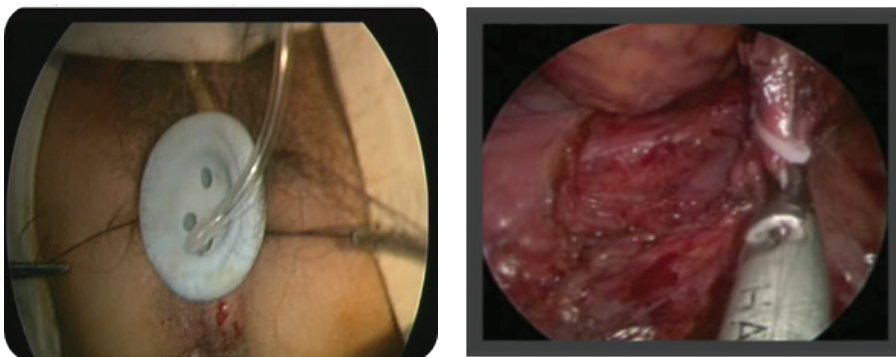


Fig. 3. Place SILS port in vagina and clip IMA by hemolock.

intestinal occlusion or sub-occlusion. Female patients with sigmoid cancer which could be operated by transvaginal endoscopic surgery had menopause and didn't have inflamed or infected vaginas. Exclusion criteria included pregnancy or distant metastasis.

Surgical technique: Pre-operative preparation for patients was similar to conventional laparoscopic colorectal resection. Under general anesthesia, patients were placed in the lithotomy position with a bladder catheter. The surgeon and first assistant stood between the patient's two legs. The laparoscopic

system was placed on the patient's left side. (Fig. 1). For instruments, we used a single access port (Covidien), Optic 30°, 5.5 mm, 50 cm and standard laparoscopic grasper with different lengths.

Transanal endoscopic surgery was used for rectal tumors and transvaginal for sigmoid and descending colon tumors.

In the transanal approach, lone-star retractors (for lower rectal cancer) or anal dilators from the Covidien hemorrhoidectomy set (for intermediate and high rectal tumors) were placed in the anus. Rectal lumen with purse-strings closed 1 cm below the inferior margin of the tumor by Prolene 2.0 and mucosal dissection started at 1 cm below the point of entry by the monopolar scalpel to go through the rectal wall (Fig. 2).

The dissection was from posterior and then around the rectum. When the space created enough for the SILS port of Covidien, it was placed (Fig. 3).

CO₂ inflation was done with a pressure of 12 mm/Hg. TME was continued around the rectum with either a harmonic scalpel or monopolar hook. A peritoneal fold was opened anteriorly and then around the rest of the way. The rectum then was pushed into the abdominal cavity. Mesocolon vessels were divided whether by hemolock or by endo GIA. Told fascia was then freed.

The length of the colon was checked to see if it was enough for a pull-through. The tumor and colon were then pulled out through the anus and resection was done 6 cm proximal to the tumor. Then, anastomose was performed via hand-sewn or EEA device.

For the transvaginal approach, posterior fornix was opened about 2.5 cm between two retraction sutures and SIL port device (covidien) was placed. After determination of tumor position, sigmoid was then divided under the tumor at 2 m through a mesentery window created next to sigmoid wall. The vessels were divided by hemolock or by endo-GIA. After the dissection finished, the tumor was pulled out through the vagina and the colon was resected 6 cm proximal to the tumor and prepare for anastomosis. Anastomosis was performed by EEA.

In difficult cases or intra-operative complication situations, we placed additional port 5 mm in order of priority: trans-umbilical, right lower quadrant and left lower quadrant.

Data collected consisted of age, gender, BMI, tumor position, intraoperative complications, conversion rate to conventional laparoscopy, additional ports, post-operative complications, post-operative pain, specimen length, Quirk's assessment for TME, postoperative TNM staging, sphincter function (Kirwan) and follow-up time and actions.

Chemo-radiation: Adjuvant and neoadjuvant followed Hue Oncology Center protocol.

Results

From 12/2013 to 9/2015, 22 colorectal resections were performed by NOTES, in which there were 18 Transanal and four transvaginal. Male/female: 11/11. Mean age: 51,6±12,1 (30-96) years old. BMI 21,2±2,5 (17,3-27,3).

Lesions (Table 1, 2)

Table 1. Tumor location (18 rectum, three sigmoid, one descending colon).

Distance from anal margin	<5 cm	5-10 cm	>10-15 cm	>15 cm
N	6	6	6	4

Table 2. Classification.

I	II	III	
T2N0M0	T3N0M0	T2N1M0*	T3N1M0*
12	4	2	4

*: 1≤N1≤3 nodes (+).

Techniques (Table 3)

Table 3. Techniques of resection.

Anterior resection	Low-anterior resection	Pull-through	Transvaginal
6	6	6	4

Method to perform anastomosis:

Hand-sew: 6 coloanal,

EEA stapler: 16 coloanal

Operative duration: 258±40 (190-300) minutes.

Complications/Conversions to conventional laparoscopy (Table 4, 5)

The mean length of each specimen was 29.6±4.5 cm. No residual tumor cells at proximal resection margins were found in any patients. Quirk's assessment for TME was good in 18 cases of rectal cancer.

Evaluation of sphincter function following Kirwan was Kirwan I in all

Table 4. Causes of additional trocars (4 patients).

Reasons	NOTES	Number of trocar	N
Post-radiation/Hemorrhage	Anus	2	1
Limited working space/instruments	Anus	1	1
Disorientation/Loss of control	Anus	1	1
Fat/BMI: 27.3	Vaginal	2	1

Table 5. Causes of conversion techniques.

Reasons	Location of tumor	Convert technique	N
Hemorrhage due to injury of iliac artery	Low rectal cancer	Laparotomy	1
Location of tumor was lower posterior fornix, so surgeon didn't dissect transvaginal	Sigmoid tumor	Hybrid-NOTES	1

Mean bowel movement return was 2±0.5 days. Mean hospital stay was 7±2.8 (4-14) days. Mean VAS on the first post-operative day was 3.4±0.5 points.

There was one patient with post-operative complication recorded, and experienced leakage anastomosis coloanal on the 4th day, which showed redo-anastomosis and ileostomy.

patients at three months. No mortality and local recurrence at the end of this study was recognized with a median follow-up time of 12 months.

Discussions

Laparoscopic surgery has become increasingly popular in surgical practice and in the treatment of colorectal cancer. Although conventional laparoscopic

surgery has already significantly reduced the invasiveness of the procedure, many researchers [3, 4] are currently investigating the matter to maximize the advantages of minimal invasiveness by reducing the number of working ports (single port surgery), the size of instruments (mini-laparoscopy), and performing surgery via natural orifices (hybrid NOTES, or pure NOTES) [5-8].

At Hue Central Hospital, we have been performing laparoscopic natural orifice specimen extraction for ultra-low rectal cancers since 2007 with results presented at several domestic and international conferences [9, 10]. It could be considered an intermediate step toward NOTES for colorectal cancer at our hospitals. On the other hand, we also have had experiences with the transanal Soave procedure in pediatric patients with Hirschsprung's disease [11], considered as NOTES for benign disease. On these platforms, we decided to perform NOTES on patients suffered colorectal cancer.

Our study consists of 22 cases of operation by transanal and transvaginal NOTES, in which 16 cases were considered as pure NOTES. The results showed that NOTES was feasible and safe with a mean operative time of less than four hours and low complication rates.

Regardless of the type of procedure, surgeons always have to ensure the surgical and oncologic safety of patients. Therefore, there are three important issues that need to be considered when performing NOTES: proper indication, technical competency, and good outcome (short-term as well as long-term). In our study, we chose patients with tumors \leq T3 and without ganglion invasion. Patients with obesity were also a contra-indication in our study. Related to the position of tumors, most published reports focus on rectal cancers in which Transanal NOTES

can be applied [12-16]. However, in our study, for rectal cancers, we performed Transanal NOTES for tumors in all three parts of the rectum using two different procedures (lower anterior and intersphincteric) which were feasible and safe. Our remarks correspond to the opinions of Isha Ann Emhoff [17] in a review of NOTES for colorectal cancer. For sigmoid cancer, we chose to perform transvaginal NOTES. In transvaginal NOTES, the position of posterior vaginal fornix corresponded to the recto-sigmoid junction, so we determined the tumor position that way. We first resected the sigmoid under the tumor, 2 cm through the mesenteric window, which was created next to sigmoid wall. The division of mesenteric vessels was then conducted. There was one study published that mentioned this technique, but used for benign diseases in human [18]. Therefore, we consider this to be the first publication in the world of pure transvaginal resection for sigmoid cancer.

There were four patients in our study needing additional ports (Table 4). The reasons were loss of control, limited working space, thick mesocolon, and hemorrhaging. Regarding disorientation, in the first cases, we intended to go far back, but when we needed to be familiar with the surgical field, the disorientation was managed. To solve the problem of limited working space, we used long optic 5 mm instruments with different lengths and a harmonic scalpel. In addition to that, we noted that in order to have a good working space, we needed to open the peritoneal folder when the rectum was totally freed. If not, the CO₂ would go into the abdominal cavity and resulting in reduced perirectal space. Concerning the thick mesocolon, we determined that it is best if the elected patients have a BMI under 25 kg/m². In review of Emhoff, most patients operated on using NOTES had a BMI under 25 kg/m² [17]. One intra-operative hemorrhage

occurred in our study. The patient had a T3 and ganglion invasion, and suffered a short-course of radiotherapy four weeks before the operation; this situation led to challenges with coagulation of the middle rectal artery; however, with two trocars from the abdomen, we controlled the bleeding.

Following Antonio [19] and new research to the present, the dissection from anal of TME (down-to-up) had many advantages in terms of oncology than the traditional dissection, the only difficulty that required experienced surgeons and TME dissection at the beginning of the surgery through the anus. One patient who was converted to open surgery is one of the first patients of the study group and the surgeon had "go too far" off TME.

In regard to anastomosis, in our study, the hand-sewn technique was performed in six low rectal cancers. In the other 16 patients anastomosis was performed using staplers. Both Leroy [15] and Zhang [16] performed coloanal anastomosis by hand-sewn interrupted sutures. We saw that in some situations, when the anastomose was high enough, performing the anastomosis by stapler was easier.

One problem encountered relating to NOTES, was intra-abdominal cavity infection due to a colon being pulled out through an "infection source" anus or vagina. However, some reports of NOSE or NOTES supported the safety of these techniques [5, 12-16, 20]. Our study did not recognized any intra-abdominal cavity infections.

Until now, most NOTES articles published have been case reports. Therefore, long-term oncologic results are not available. However, a study of 20 patients from S. Atallah, et al. [2] investigates 20 colorectal cancer patients treated with hybrid NOTES, as well as our study about NOSE

techniques used for the treatment of colo-rectal cancer showed no local recurrence after a 6-month follow-up [9, 10]. Similar results were found in our study with the follow-up duration of 12 months. In addition, Pathologic findings of our specimens showed good quality in TME following Quirk assessments and no residual cancer tissues in proximal resection margins in any patients. We believe that this indicates the effectiveness of this technique.

Rapid postoperative recovery and less pain in this study were advantages of this technique. Sphincter function in 18 patients was good (Kirwan I) after three months. So, we considered that long duration of retraction didn't affect anal sphincter.

Conclusions

Transanal and transvaginal NOTES for rectal cancer is feasible, safe and effective. Pure transvaginal NOTES for colon cancer at Hue Central Hospital could be considered as the first report conducted in the world. However, multi-centric studies with larger series and longer follow-up to evaluate the surgical as well as oncologic outcomes are necessary.

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