

Original Article

Transanal Minimally Invasive Surgery: A Community Hospital Experience

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Key Words

Transanal minimally invasive surgery;
Hybrid knife;
Community hospital

Purpose. Traditionally, the transanal colonic polypectomy or Parks procedure are used for rectal lesion surgery. The transanal endoscopic microsurgery was introduced in 1985, while the transanal minimally invasive surgery (TAMIS) with single incision laparoscopic surgery port (SILS port) was introduced in 2010 to improve rectal lesion surgery. Both techniques evolved and quickly replaced the Parks method. We report our experience with TAMIS.

Methods. We recruited patients who underwent transanal minimally invasive surgery at a single institution from July 2019 to May 2022. Patient characteristics, surgical data, and hospitalization data were retrospectively collected and analyzed.

Results. Twenty-seven patients (13 women and 14 men; median age, 56 years; mean body mass index, 25.6 kg/m²) were included comprising three cases of neuroendocrine tumor, one T1 adenocarcinoma, four carcinoma in situ, and one condyloma acuminatum. Thirteen patients had polyps, two had ulcer lesions (one confirmed foreign body reaction, while the other was an impressed fistula), and three underwent an incomplete resection of rectal lesion (one neuroendocrine tumor, one T1 adenocarcinoma, and one carcinoma in situ).

The average distance between the tumor and anal verge was 5.5 cm. In three cases, the tumor occupied more than half of the internal diameter of the rectum. One patient had three polyps, while one patient had a descending colon adenocarcinoma stage IIIA, and underwent concurrent laparoscopic anterior resection.

We used a GelPOINT® Path and 3D laparoscopic system. The energy device included 11 VIO®3 with HybridKnife®, one LigaSure™, and 15 monopolar. The wound was sutured in 20 cases and left open in seven. The average operative time was 75.5 minutes and average blood loss was 16.4 mL.

The average specimen length, width, and height were 3.2, 2.3, and 0.9 cm, respectively. The average tumor length, width, and height were 1.8, 1.4, and 0.7 cm, respectively. The average clear margin was 0.3 cm, and average clear margin to base was 0.2 cm.

Four patients had an indwelling Foley catheter postoperatively, mean antibiotic usage time was 1.9 days, and mean hospitalization period was 3.6 days. No surgical complications were observed, except constipation observed in one patient. No mortality or local recurrence was reported.

Conclusion. The TAMIS was clinically applicable in a community hospital, with general laparoscopic device, concurrent with GelPOINT® PATH or SILS™ port, and energy device.

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Over the past 30 years, minimal invasive surgery has facilitated organ-sparing surgery for rectal tumors. The recent updates in image systems, energy devices, and laparoscopic instruments have also facilitated further surgical evolution. In 1985, Buess et al.,¹ introduced TEM for the treatment of giant sessile polyps and early rectal cancer, which seemed to be an alternative to the conventional TAE. The TEM instrumentation has a better exposition, magnified 3D vision, and an operative field illumination that improves the clinical outcomes. However, the retraining learning curve and instrumentation costs hinder the popularity of this technique within the surgical community.

TAMIS was first reported by Atallah et al.,² and has progressively gained popularity for the treatment of mid and high rectal lesions, offering a feasible alternative to TAE, and TEM. This technique is performed using a disposable single-port device adapted to the transanal insertion, and subsequently performed through laparoscopy. Currently, there are two commercially available instruments; the SILS™ Port (Covidien Mansfield, Massachusetts, USA) and the GelPOINT® PATH (Applied Medical, Inc., Rancho Santa Margarita, California, USA).

TAMIS offers several technical advantages over TEM. The 3-cm-diameter and shape of the instrument improve the setup time and prevent anal sphincter muscle injury, when introduced into the anus. Compared with the TEM rigid conical mental working channel, the soft flexible material and shape of the operative channel of TAMIS allow for circumferential dissection. Its 360 degrees visibility is better than TEM's 220 degrees visibility within the rectal lumen.^{3,4} Because of its 30 degree and 3D flexible laparoscopic camera, the patient position does not need to be changed. More importantly, instruments already available in the modern operative room can be used. It makes the procedure universal, and surgeons trained to minimal invasive surgery can quickly master the surgical techniques during TAMIS.

We report our experience with the TAMIS technique and the results in a community hospital.

Materials and Methods

Patient selection

Patients who underwent TAMIS at our institution from July 2019 to May 2022 were enrolled in this retrospective case series. Those huge rectal lesions not suitable for TAE, or early malignance, were introduced to TAMIS. It means the irregular and sparing on pit pattern classification under colonoscopy narrow-band image (NBI),⁵ the larger size laterally spreading type (LST) polyp,⁶ the class 2B or 3 on the Japan NBI Expert Team (JNET) classification,^{7,8} risk consideration under Japanese Society for Cancer of the Colon and Rectum (JSCCR) guidelines⁷ or National Comprehensive Cancer Network® (NCCN) Guidelines®.⁹

We reviewed the patients' medical records and the details of the surgery were discussed during a preoperative meeting that included data on the patient, patient's family, and consulting physician. If early malignance was impressed, further discussion by the multidisciplinary team was initiated.

Demographic information including age, sex, body mass index (BMI), American Society of Anesthesiology class, tumor size, tumor location, surgical procedure, operative time, operative blood loss, pathologic report, postoperative hospitalization, antibiotic usage, and perioperative complications were collected prospectively.

Preparations prior to surgery

Depending on the clinical need, antegrade bowel preparation one day before surgery or cleansing enema in the morning of the operative day was arranged.

Prior to surgical incision, the patient was administered one gram of Flomoxef intravenously.

Surgical technique

The patient was placed in the lithotomy position, under general anesthesia, and sterilization was performed accordingly. Next, the anal dilatation was cautiously performed by the surgeon. The LoneStar® re-

tractor (Cooper Surgical, US) was used for obese patients, wherein the buttock and anus were not well exposed. A GelPOINT® Path (Applied Medical, Rancho Santa Margarita, CA, USA) was lubricated and gently introduced into the anal canna under steady manual pressure. TAMIS setup is challenging in obese patients with abundant adiposity in the gluteal region. To address this, we utilize sutures to secure the GelPOINT® PATH in the skin, effectively correcting the anal canal depression. Once seated in position, a gauze was inserted into the upper rectum for partial barricade of the pneumorectum. Three self-retained sleeve, two 5-mm and one 12-mm cannula, with access channels were introduced on GelSeal Cap and setup. Next, another insufflation-stabilized bag was connected and a 12- to 18-mmHg pneumorectum was established. A 3D laparoscopic (Endoeye Flex 3D; Olympus, Tokyo, Japan) access to the rectal vault was gained (Fig. 1A). A monopolar, or HybridKnife® was used to mark out a 5-mm tumor margin. The waterjet system of HybridKnife® (Erbe Elektromedizin GmbH) was used for injecting the fluid (normal saline mixed with indigo carmine) into the tissue and separating the surgical tissue plane (Fig. 1B). The monopolar or VIO® (Erbe Elektromedizin GmbH) was used for dissecting and coagulating the tissues (Fig. 1C). A laparoscopic grasp was used for assistance.

After the specimen was cut out, the wound was left open (Figs. 3C, 3D), or closed with sutures using

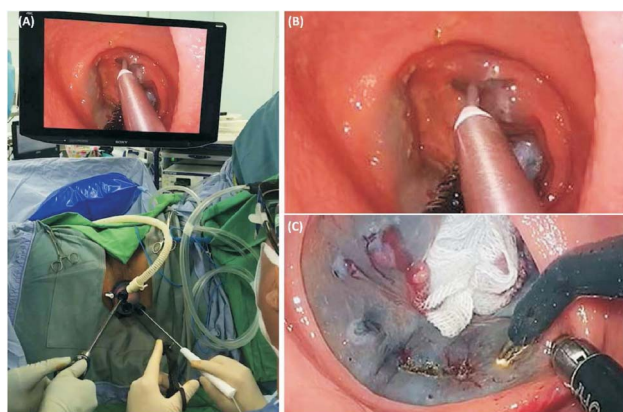


Fig. 1. (A) Setup of the GelPOINT® Path, 3D flexible laparoscopy, HybridKnife® and VIO®. (B) HybridKnife® submucosa injection. (C) VIO® dissecting and coagulation.

V-LOC™ or Vicryl®, depending on the surgical site and surgeon's choice (Figs. 2C, 4D).

Postoperative care

After the surgery, a prophylactic intravenous antibiotic (Flomoxef) was prescribed for 1 day. Patients were offered liquids soon after recovery from anesthesia. No diet restrictions were imposed once the patients could tolerate liquids. All patients were allowed early mobilization.

Postoperative acetaminophen (Scanol) was administered to alleviate pain. Meperidine was administered intramuscularly if the oral medications did not relieve the pain. If urinary catheter was left after surgery, it was usually removed on the first postoperative day.

Discharge criteria included tolerance of general meals at least one day after surgery, stool passage tolerance, and no signs of infection. The patient was subsequently followed up at the out-patient clinic.

Results

A total of 27 patients were included in the study (Table 1). There were 14 male and 13 female patients

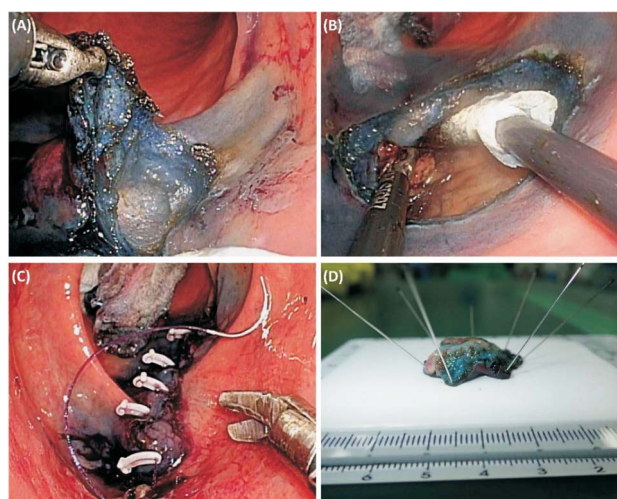


Fig. 2. A case of neuroendocrine tumor. (A, B) s/p full-thickness excision, mesorectum fat is visible. (C) Wound closure with Vicryl® and hemoclip. (D) Specimen.

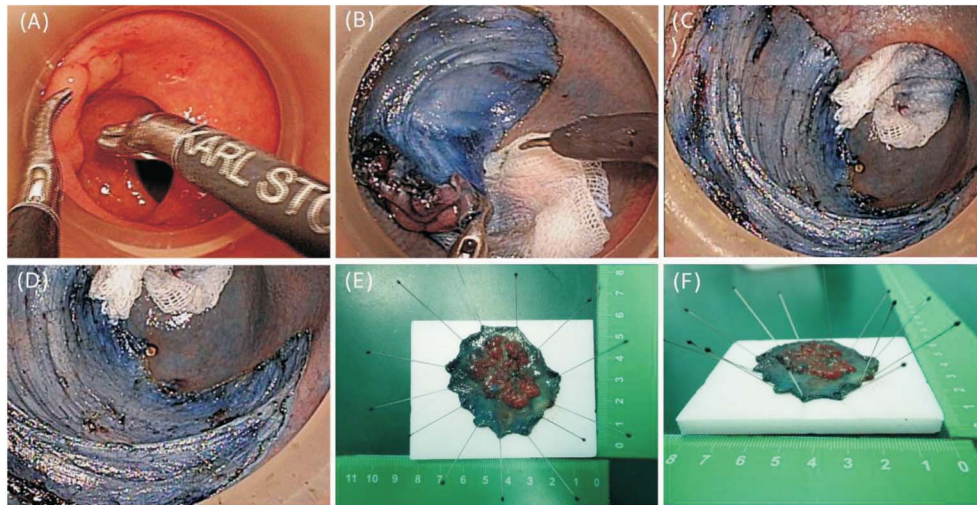


Fig. 3. A case of Tubulovillous adenoma with high grade dysplasia. (A, B, C, D) s/p complete submucosa dissection. (E, F) Specimen.

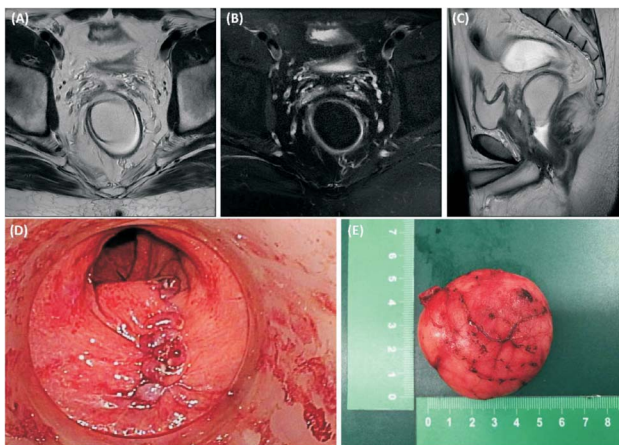


Fig. 4. A case of rectal lipoma. (A) Magnetic resonance imaging (MRI) T2-weighted image sagittal view. (B) MRI fat-sparing mode, sagittal view. (C) T2 coronal view. (D) Wound closure with V-LOC™. (E) Specimen.

with a median age of 56 years and mean BMI of 25.6 kg/m².

Eight patients underwent oral antegrade bowel preparation using two packs of Bowklean® powder 1 day before surgery, seven were administered enema (Fleet®) before surgery, and 12 did not undergo preoperative bowel preparation.

The indications for TAMIS are listed in Table 2. The enrolled patient cases comprised three endocrine tumors, 18 huge polyps (pathology report one T1, four carcinoma in situ, 13 adenoma), one condyloma acuminatum, two ulcer lesions (pathology report one for-

Table 1. Patient characteristics

Patient characteristics	
Age (years)	56.0 (±17.1)
Sex	
Women	13 (48.1%)
Men	14 (51.9%)
Body height (cm)	163.1 (±11.3)
Body weight (kg)	68.2 (±12.8)
BMI	25.6 (±3.7)
ASA	
1	2 (7.4%)
2	18 (66.7%)
3	7 (25.9%)

Values are presented as the mean ± standard deviation unless otherwise indicated.

BMI, body mass index; ASA, American Society of Anesthesiology.

eign body inflammation, one fistula inflammation), and three post colonoscopic polypectomy with unclear margins (one neuroendocrine tumor, one adenoma, one carcinoma in situ).

Despite the colonoscopy, the preoperative image survey included seven MRIs and four CTs.

The average distance between the tumor and anal verge was 5.5 cm. There were three cases where the tumor occupied more than half of the internal diameter of the rectum; we could not obtain the data on lesion location for four patients. One patient had three polyps, while a 39 year-old patient presented with pT1 and refused further surgery, radiation, chemo-

therapy or other treatment. She had no local recurrence after 23.8 months of follow-up. One patient with a descending colon adenocarcinoma stage IIIA underwent concurrent laparoscopic anterior resection. Detailed characteristics of the lesions are summarized in Table 2.

The pathology results of the patients are summarized in Table 2. There were 21 patients accepted partial-thickness resection, and six patients accepted submucosal layer resection. The average tumor length, width, and height were 1.8, 1.4, and 0.7 cm, respectively. The average specimen length, width, and height

were 3.2, 2.3, and 0.9 cm, respectively. The average border of clear margin and base of clear margin were 0.3 cm and 0.2 cm, respectively.

We used GelPOINT® Path and 3D laparoscopic system. The average operative time was 75.5 minutes, and average blood loss was 16.4 mL. The energy device we used included 11 VIO®3 with HybridKnife®, one LigaSure™, and 15 monopolar (Table 3).

After resecting the tumor, the wound was sutured in 20 cases but left open in seven (Table 3). Four patients had an indwelling Foley catheter postoperatively, which was removed after an average of 1.9 days. All patients tolerated oral intake after recovery from anesthesia. The mean antibiotic usage time was 1.9 days, and the mean hospitalization period was 3.6 days (Table 4).

There was no mortality or conversion. A patient had constipation, which was not resolved even after 8 months of follow-up. There were no other complications. After an average follow-up of 9 months, there was no local recurrence. The pT1 adenocarcinoma patient refused further surgery or radiation (Table 4).

Discussion

TAMIS represents a relatively new therapeutic

Table 2. Tumor characteristics

From anal verge (cm)	5.8 (±2.2)
Located direction in the rectal wall	
Unknown	4
Anterior more than half circumference	1 (3.7%)
Posterior more than half circumference	2 (7.4%)
Anterior	3 (11.1%)
Left anterior	3 (11.1%)
Left	4 (14.8%)
Left posterior	3 (11.1%)
Posterior	3 (11.1%)
Right posterior	3 (11.1%)
Right	3 (11.1%)
Resection depth	
Partial-thickness	21 (77.8%)
Submucosal layer	6 (22.2%)
Tumor size	
Length (cm)	1.8 (±1.0)
Width (cm)	1.4 (±0.9)
Height (cm)	0.7 (±0.3)
Specimen size	
Length (cm)	3.2 (±1.5)
Width (cm)	2.3 (±1.0)
High (cm)	0.9 (±0.7)
Clean margin	
Nearest (cm)	0.3 (±0.2)
From base (cm)	0.2 (±0.1)
Pathology	
Neuroendocrine tumor	3 (11.1%)
Adenoma, polyp	13 (48.2%)
Adenocarcinoma in situ (pTis)	4 (14.8%)
Adenocarcinoma pT1	1 (3.7%)
Condyloma acuminatum	1 (3.7%)
Ulcer, inflammation	2 (7.4%)
Erosion, incomplete colonoscopic polypectomy	3 (11.1%)

Values are presented as the mean ± standard deviation unless otherwise indicated.

Table 3. Operative outcomes

Pre-operative bowel prepare	
Antegrade laxatives	8
Enema	7
None	12
Operation time (minutes)	75.5 (±30.6)
Blood loss (cc), range (cc)	16.4 (1-150)
Surgical devices	
GelPOINT® Path	27
LoneStar®	14
Indocyanine green (ICG)	3 (11.1%)
Energy device	
HybridKnife®	11 (40.7%)
Monopolar	15 (45.6%)
LigaSure™	1 (3.7%)
Defect closure	
V-loc™	16 (60.8%)
Vicryl®	4 (14.8%)
Non-suture	7 (25.9%)

Values are presented as the mean ± standard deviation unless otherwise indicated.

^a *p* are calculated with Mann-Whitney U test.

Table 4. Postoperative outcomes

Postoperative outcomes	
Follow up (month), range (month)	9.0 (0-37)
Postoperative hospital stay (days)	3.6 (\pm 1.3)
Remove Foley immediate postoperation	13 (48.2%)
Keep Foley to wards	4 (14.8%)
Foley removed (days), range (days)	1.9 (0.5-4.5)
Additional pain control (patients)	
Long-acting Nalbuphine	1
Antibiotics (days), median (range)	3.5 (\pm 3.1)
None	1 (3.6%)
Prophylactic (< 1 days)	13 (48.2%)
Therapeutic (days)	6.5 (\pm 1.8)
Complication	
Constipation	1 (3.7%)
Morbidity	0

Values are presented as the mean \pm standard deviation unless otherwise indicated.

approach for removing pathological rectal lesions. TAMIS was introduced in 2010 along with rapid technological development of equipment for laparoscopic surgery.²

In our daily clinical practice, we have observed technical limitations associated with traditional TAE when dealing with the removal of large polypoid lesions or early malignancies located in the rectum. Prior to the introduction of TAMIS, those patients were traditionally treated through open or laparoscopic procedures, which were linked to a significantly elevated risk of morbidity and mortality. With the advent of TAMIS, surgeons now have an alternative option for managing these lesions. TAMIS shares similarities with single-port laparoscopic surgery and can be comfortably adopted by surgeons trained in minimally invasive procedures. The setup of TAMIS apparatus is swift and straightforward. The platform does not have to be attached to the operating table, enhancing its mobility. Utilizing a 30 degree or 3D flexible laparoscopic camera, there is no need to reposition the patient during the operation. This approach offers a comprehensive 360-degree field of visibility and facilitates circumferential dissection. Furthermore, all the necessary instruments can be seamlessly integrated into modern operating rooms.

Another notable advantage of this technique lies in its waterjet application. The Waterjet Applicator

(HybridKnife®), which injects water under high pressure into the submucosa, separates and elevates the resection area by water cushion formation. The contrasting fluid also increases the conductivity and improves the cutting features of monopolar electrosurgical resection, especially in fat-rich tissue. We used Highcut and Swift coagulation for the dissection, and bipolar softCOAG® mode for hemostasis. They effectively decreased blood loss. Three patients had blood loss of 50, 100, and 150 mL, respectively without waterjet application. The average blood loss was 24.6 mL and 3.5 mL for the non-waterjet and waterjet application groups, respectively. However, there was no statistical significance between the two groups as per our data ($p = 0.061$).

Baral¹¹ used the waterjet knife application concurrently with indigo carmine, and stated that it may highlight the submucosal vessels for visibility, which helps the surgeon achieve hemostasis. This could prove advantageous when determining the appropriate depth for surgical excision. In instances where micro-dissection using a waterjet knife in combination with pneumorectum fails to effectively separate the submucosal layer, surgeons should consider the necessity of extending the excision margins sufficiently. Notably, eleven cases in our series underwent full-thickness excision.

Despite the use of a waterjet application, the closure of wounds can still be beneficial. Khan's research has indicated that sutures may contribute to reducing the occurrence of postoperative bleeding. An additional advantage of TAMIS over ESD is the ability to perform direct suturing. Nevertheless, no cases of post-operative hemorrhage were reported in our case series.

The indications for TAMIS for benign and early-stage malignant lesions are similar to those of conventional TAE and TEM lesions, and are briefly summarized as literature reviews.^{13,14}

For benign polypoid lesions, Sumrien et al.¹⁵ showed that the average positive resection margin is 5.7 cm. And the average overall positive resection margin was 8.6%.¹³ Although there is no corresponding randomized trial data, it is reported that TEM is better than colonoscopy ESD in terms of R0 resection

(88.5% vs. 74.6%), en-bloc resection rates (98.7% vs. 87.8%), and recurrence rates (2.6% vs. 5.2%).¹⁶

The possible explanation for this phenomenon could be attributed to the effective countertraction achieved using two or three instruments during both TAMIS and TEM. This countertraction aids in precise identification and dissection of the surgical plane. Additionally, the creation of pneumorectum may contribute to a pneumo-dissection effect. In clinical practice, it proves challenging to establish a stable pneumorectum environment with a pressure range of 12-18 mmHg during ESD. There were three cases where the rectal lesion occupied more than half of the internal diameter of the rectum. The hugest one is a 7.8 cm × 2.2 cm condyloma acuminatum with intermediate grade squamous dysplasia, which occupied two-thirds of the rectal lumen, from the left to posterior to the right. The better surgical view exposure of TAMIS advantage is necessary for those cases. All pathology margins were clear in this study.

For the early malignant lesions, the NCCN⁸ suggested the indications as (1) pT1 only, (2) movable and nonfixed rectal tumors, (3) small sized tumors less than 3 cm, (4) tumors invading less than one-third of the rectal wall circumference, (5) no lymphovascular invasion, (6) well to moderately differentiated, and (7) no lymphadenopathy metastasis. The JSCCR⁷ restricted the pT1 lesion to SM1, because there is a 15% risk of lymph node metastasis on sm2-3 cases.^{17,18}

The recurrence rate stands at 7.2%, but it's noteworthy that there were no recurrences in our specific case series. It's worth mentioning that there was one case classified as pT1; however, this patient opted against further curative surgery. It's also noteworthy that none of the four pTis patients and one pT1 patient experienced recurrence during the follow-up period.

The complication rate on an average was 18.4%, conversion rate was 5.1% with the peritoneal entry occurring in 6.0% cases.¹³ The main complications were bleeding, postoperative urinary retention, fever, and penetration into the peritoneal cavity. Surgical intervention was required to manage 9.9% of these complications. Sutures were suggested for the prevention of postoperative bleeding.¹² Anterior peritoneal entries are often difficult to repair with TAMIS; laparo-

scopic abdominal approach is often required, mostly in cases with more than 8 cm distance from the anal verge.^{12,17}

This issue pertains to surgical decision-making in cases involving rectal lesions. Generally, it is not advisable to utilize TAMIS for rectal lesions located 10 cm away from the anal verge. When the lesion is situated near the rectosigmoid junction, there is a risk of inadvertently entering the peritoneal cavity. Additionally, instrument manipulation becomes challenging due to the curvature of the rectum.

Conversely, when the rectal lesion is less than 5 cm from the anal verge, the setup for the GelPOINT® PATH can be somewhat challenging. The GelPOINT® PATH has lengths of 3 cm and 4 cm. In our case series, the tumor location ranges from 3 cm to 10 cm away from the anal verge. Consequently, TAMIS presents fewer technical difficulties when dealing with rectal tumors located between 5 cm and 10 cm away from the anal verge.

There were no immediate surgical complications in our series; however, we noted one constipation case of the 73 year-old woman who needed frequent manual evacuation for defecation and did not recover until 8 months post-surgery.

The TAMIS technique has been extended to other fields as well. Few surgeons have applied it to treat anastomosis leakage, pelvic abscess, anastomosis stenosis resurgeries.²³ Borstlap et al. tried two with full TAMIS along, among the 17 reconstructive anastomosis. We have reported an interesting case of a 5.5 cm × 4.5 cm lipoma situated in the anterior mesorectum of a 42 year-old man (Fig. 4). After surgery, he had a smooth recovery and the rectal compression sensation was resolved.

Conclusion

The TAMIS procedure using laparoscopic instrumentation seems convenient and feasible in the modern operative room. It provides certain advantages, especially while treating benign rectal lesions and early rectal cancers along with being clinically applicable in community hospitals. Limited number of cases and

short-term follow-up data limit a wide application of our case series. Further prospective studies are needed in this regard.

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原 著

地區醫院使用經肛門微創內視鏡手術的短期經驗報告

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目的 在 1985 年出現的經肛門內視鏡顯微手術，以及 2010 年另外一種新型的經肛門微創手術出現後，逐漸取代傳統的 Parks 方式來處理直腸病灶。我們報告我們在地區醫院運用經肛門微創手術處理直腸各種疾病的短期成果。

方法 我們回溯收集從 2019 年 7 月至 2022 年 5 月，在敝院實行肛門微創手術患者，分析及報告病人的基本資料、手術狀況和術後恢復結果。

結果 共 27 位病人，含 13 位女性、14 位男性。平均年齡 56 歲。平均 BMI 25.6。有 3 位是神經內分泌腫瘤，1 位 T1 腺癌，4 位腺癌原位癌，13 位直腸息肉，1 位尖狀濕疣，1 位異物引起之潰瘍，1 位疑似瘻管癒合後之潰瘍，3 位大腸鏡病灶未切除乾淨之患者（神經內分泌腫瘤，T1 腺癌，原位癌各 1 位）。

距離肛門口平均為 5.5 公分。其中有 3 位腫瘤範圍超過一半直腸內徑，有 1 位患者有 3 顆息肉。1 位合併橫結腸腺癌第三期同時開低位切除術。

手術標本平均長、寬、高為 3.2 公分、2.3 公分、0.9 公分。腫瘤平均長、寬、高為 1.8 公分、1.4 公分、0.7 公分。腫瘤距離切割標本邊緣平均為 0.3 公分，距離切割底部邊緣平均為 0.2 公分。

手術器械皆使用 GelPOINT® Path 及 3D 腹腔鏡，能量器械方面則有 11 個患者使用 VIO® 及 HybridKnife®，1 個使用 LigaSure™，15 個使用單極電燒。20 個患者有縫合傷口，但 7 個沒有。平均手術時間是 75.5 分鐘。平均手術流血量是 16.4 毫升。

手術後只有 4 個患者帶尿管回病房。平均術後住院天數為 3.6 天。有 1 個患者在追蹤 8 個月後有便秘的併發症，無其他手術後併發症。無手術後死亡案例。無局部復發案例。

結論 使用 GelPOINT® 或 SILS，合併腹腔鏡及能量器械，是可以在地區醫院運用肛門微創內視鏡手術。

關鍵詞 經肛門微創內視鏡手術、海博刀、地區醫院。