



ORIGINAL ARTICLE

Pure natural orifice transluminal endoscopic surgery for rectal cancer: Ta-TME and CME without abdominal assistance



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KEYWORDS

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Summary *Aim:* To report our institution's experiences with pure transanal total mesorectal excision (TME) of rectal cancer using single-port equipment and to discuss the feasibility and safety of the technique.

Methods: Between February and December 2017, 12 patients who were selected underwent NOTES TME in our institution. The preoperative assessment included blood analyses with carcinoembryonic antigen serum concentration, full colonoscopy, pelvic magnetic resonance imaging (MRI), and computed tomography (CT) of the abdomen and chest.

Results: Ten patients (male:female, 6:4) treated with transanal TME with colorectal anastomosis in our institution were reviewed. Pure TME was performed without laparoscopic assistance in 6 of 10 patients. The mean operative time was 303.5 min. The median distal margin was 2.1 (0.2–4.2) cm. The median number of harvested lymph nodes is 17.5. Except one patient with anastomotic leak, most patients started dietary intake on postoperative day (POD) 3 and were discharged on POD 7. Anastomotic leak was the only postoperative complication.

Conclusion: This study showed that pure natural orifice transluminal endoscopic surgery (NOTES) TME with coloanal anastomosis for rectal cancer is safe and feasible in selected cases. © 2018 Asian Surgical Association and Taiwan Robotic Surgery Association. Publishing services by Elsevier B.V. This is an open access article under the CC BY-NC-ND license (<http://creativecommons.org/licenses/by-nc-nd/4.0/>).

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1. Core tip

TME has become the gold standard for surgical treatment of colorectal cancer. Laparoscopic TME and open TME exhibit similar oncologic outcomes. Hybrid transanal TME using a laparoscopic approach was attempted in several centers. In addition, some reports describing the feasibility and efficiency of this approach have been published. This study showed that pure natural orifice transluminal endoscopic surgery (NOTES) TME with coloanal anastomosis for rectal cancer is safe and feasible in selected cases.

Won Jun Jeong, Byung Jo Choi, Sang Chul Lee. Pure natural orifice transluminal endoscopic surgery for rectal cancer: "The future has already come"

2. Introduction

Over the past decades, several advances in the treatment of rectal cancer have improved survival for patients with this disease. Heald et al documented their early experience with total mesorectal excision (TME); they reported that they ensured a specimen with an intact mesorectum with negative tumor margins in the majority of resectable rectal cancer.¹ Heald's series of 122 curative anterior resections showed a cumulative risk of local recurrence at 5 years of 2.7%. These excellent results made TME the gold standard for treatment of colorectal cancer. Moreover, preoperative chemoradiotherapy (CRT) in combination with TME resulted in tumor downstaging, leading to significant reduction in the size of the primary tumor, reduction in the penetration depth, and possible sterilization of the lymph nodes.²

In several studies, the oncologic outcomes were similar in both laparoscopic TME and open TME.^{3–6} In these studies, the laparoscopic group showed reduced blood loss, earlier return of bowel movement, and shorter hospital stay than the open surgery group. Laparoscopic colorectal surgery may enable better visualization for vessel dissection and facilitate better nerve preservation. No significant difference was observed in terms of postoperative morbidity and mortality.

Transanal TME is not a new concept. Transanal TME was developed as a result of experiences in transabdominal–transanal (TATA) operation. TATA operation has several advantages including measurement of the distal margin and linear stapler application. Both Transanal TME and TATA operation have the same advantages.

Transanal TME was introduced using different transanal platforms. In 2010, Sylla et al first reported transanal mesorectal dissection using TEM instruments assisted by laparoscopy abdominally.⁷ They demonstrated the feasibility of a down-to-up mesorectal excision. In the same year, Atallah et al reported an approach that was a hybrid between TEM and single-port laparoscopic surgery (SPLS) for the local excision of a rectal tumor, naming the procedure as transanal minimally invasive surgery (TAMIS).⁸ Transanal TME using a single-port device and laparoscopic instruments was first reported in 2011 by Tuech et al.⁹

These convenient approaches were welcomed by surgeons who were experienced in laparoscopic surgery;

subsequently, several reports have been published describing the feasibility and efficiency of these approaches.^{10–15} Charlotte et al compared transanal TME and laparoscopic TME as the surgical treatment of mid and low rectal carcinoma in the Colorectal Cancer Laparoscopic or Open Resection (COLOR) III trial.¹⁶ Although few case reports are available using pure transanal natural orifice transluminal endoscopic surgery (NOTES) approaches, more reports have been published on hybrid technique using transanal NOTES approach with laparoscopic assistance.

In our institution, SPLS was first performed at the end of 2008.

This study aimed to report the safety and feasibility of transanal specimen extraction for colorectal cancer.¹⁷ Transanal specimen extraction in SPLS has benefits in terms of reducing wound-related complications. We also reported ideal seamless operation, which can be designed by combining different procedures: creation of an incision in the anus, dissection through the anus, extraction specimen via the anus, and colo-anal anastomosis.¹⁸

Therefore, the concept of transanal TME may not be completely new, which is another type of minimally invasive procedure that basically merges different concepts of transanal surgery.

To achieve a minimally invasive rectal resection, we have tried to perform a pure transanal NOTES TME without transabdominal laparoscopic assistance for rectal cancer. We aimed to report our experiences with pure transanal total mesorectal excision of rectal cancer using single-port equipment and to discuss the feasibility and safety of the technique.

3. Methods

3.1. Patients and methods

Between February and December 2017, 12 patients who were selected underwent NOTES TME in our institution. Eligibility criteria included patients with middle and low rectal adenocarcinoma and an Eastern Cooperative Oncology Group (ECOG) score no greater than 2. The preoperative assessment included blood analyses with carcinoembryonic antigen serum concentration, full colonoscopy, pelvic magnetic resonance imaging (MRI), and computed tomography (CT) of the abdomen and chest. The patients with T4 tumor and patients with synchronous colon cancer or other malignancy were excluded from the study. The cases of total proctocolectomy and no anastomosis after transanal proctectomy alone were excluded.

Informed consent was obtained from each patient. They were informed about transanal NOTES, laparoscopic, and open surgeries and were free to choose or exclude any of the methods available.

The study was approved by the local institutional review board for NOTES clinical trials. The data were collected prospectively. The patients' demographics and characteristics and oncologic, perioperative, and follow-up data were analyzed and recorded.

3.2. Surgical technique

3.2.1. Surgical devices

All procedures were performed by an experienced laparoscopic colorectal surgeon (SC LEE).

Between 2014 and 2015, the single-incision laparoscopic surgery (SILS)[™] port (Covidien, Mansfield, MA, USA) or the Octo-Port (Dalim SurgNet, Seoul, Korea) was used. However, in 2017, the Glove port (Nelis, Bucheon, Korea) was used in all cases (Fig. 1). A 10-mm 30° scope, standard laparoscopic instruments, and LigaSure (Covidien, Medtronic, Dublin, Ireland, and Fridley, MN, USA) were used.

3.3. Transanal dissection of the mesorectum

The patients were placed in the Lloyd–Davies position under general anesthesia. Antibiotic prophylaxis was given intravenously. The Lone Star retractor (Lone Star Medical Products Inc., Houston, TX, USA) was used to expose the anal canal. The distal rectum was closed with a purse-string suture to prevent cancer cell dissemination in the surgical field and air passage into the proximal bowel. The anal canal was then irrigated with a diluted Betadine solution.

After setting up the single-port system in the anal canal, a low-pressure pneumorectum was established at a pressure of 8–12 mmHg CO₂. A 10-mm 30° scope was used with conventional instrument.

Proximal dissection along the plane of the perirectal fat was performed. Dissection started anteriorly, then posteriorly, and finally laterally. The order of dissection is not essential, and post dissection would be performed first. Initially, Denonvilliers' fascia was identified and dissected (Fig. 2). The exposure was achieved by gently pushing down the distal rectum and mesorectum proximally. On the lateral dissection, particular care must be taken to avoid

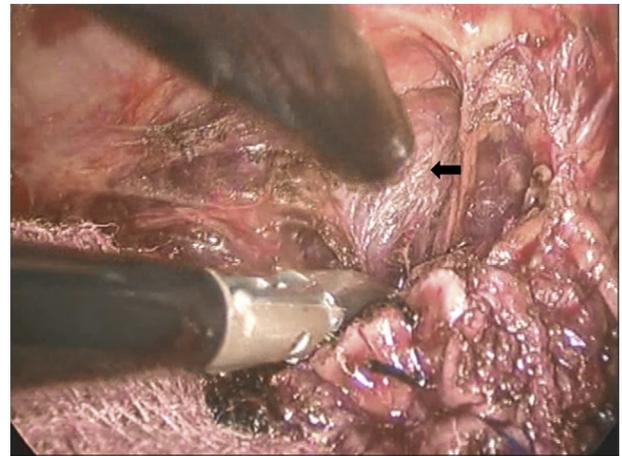


Figure 2 Anterior dissection plane of pure NOTES TME. Black arrow indicates the Denonvilliers' fascia.

injuries to the neurovascular bundles, such as the inferior rectal plexus and inferior hypogastric nerve. The peritoneal reflection was identified anteriorly and opened to enter into the peritoneal cavity within the pouch of Douglas (Fig. 3).

To prevent soiling or spillage from the specimen, the rectum was placed in a LapBag (Sejong Medical Co., Paju, Korea) and turned over the intraperitoneal space for further proximal dissection.

3.4. Transanal intra-abdominal dissection of the mesocolon

After turning over the bagged specimen, dissection was extended along the avascular plane (Fig. 4). The lateral attachment of the sigmoid colon was divided cephalad as

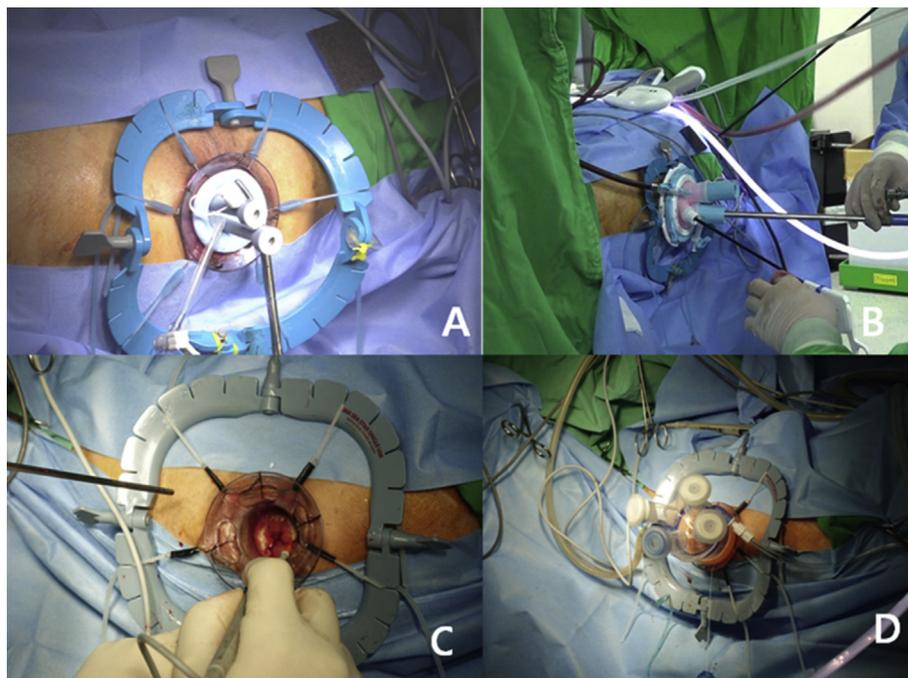


Figure 1 Port device. A: SILS port. B: Octo-Port. C: Circular anal dilator. D: Glove port.



Figure 3 Black arrow indicates the opened peritoneum, and hollow arrow indicates the seminal vesicle.



Figure 4 Transanal intra-abdominal dissection of the mesocolon. Black arrow indicates the bagged specimen.

high as possible. The medial attachment of the sigmoid mesocolon was mobilized extending the TME plane until the root of the inferior mesenteric artery (IMA) (Fig. 5). Inferior mesenteric vessels were divided using Hem-o-lok clips (Weck Closure Systems, Research Triangle Park, NC, USA) or LigaSure (Covidien, Medtronic, Dublin, Ireland, and Fridley, MN, USA). Then, mesenteric dissection and trimming along the pericolic arch were performed intracorporeally.

3.5. Transanal specimen extraction and anastomosis

When adequate length was mobilized, the specimen was pulled out transanally. The specimen was transected (Fig. 6), and a coloanal anastomosis was performed using end-to-end (EEA) technique or manual Gambee suture technique. Typically a 25 mm anvil (DST EEA stapler, Covidien) is introduced into the proximal stump and gentle tugging allows the stump is delivered into anal canal. To position the EEA anvil centrally, tagging sutures are made. Then purse string suture is placed on distal stump and the EEA stapler is introduced through the anus. After the anastomosis is visually inspected a rectal tube is inserted

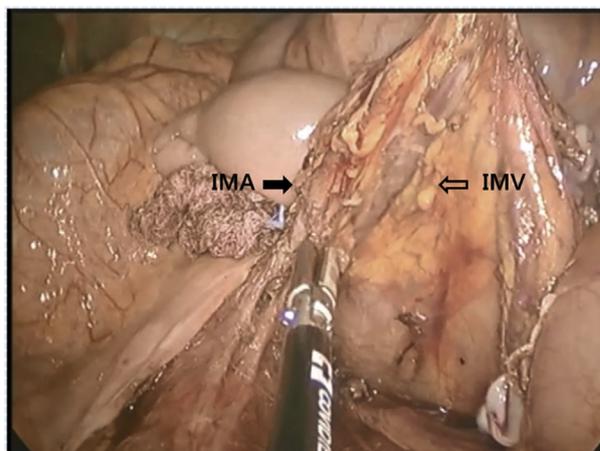


Figure 5 Intra-abdominal procedure: dissection of vessels. Black arrow indicates the inferior mesenteric artery, and hollow arrow indicates the inferior mesenteric vein.



Figure 6 Resected specimen.

transanally for decompression. To prevent small bowel injury patient is placed in the Lloyd–Davies position during EEA technique.

4. Results

Initially, we enrolled 12 patients but, 2 patients were dropped because of total colectomy due to synchronous colon cancer of one patient and the transanal proctocolectomy without anastomosis in the other. Between February and December 2017, 10 cases (male: female, 6:4) of TME with colorectal anastomosis were performed. The Demographic characteristics are summarized in Table 2. The mean operative time was 303.5 min. The median distal margin was 2.1 (0.2–4.2) cm. The median number of harvested lymph node is 17.5. Except one patient with anastomotic leak, most patients started dietary intake on postoperative day (POD) 3 and were discharged on POD 7 (range 6–11). Operative details and pathologic data are summarized in Table 3.

4.1. Conversions and intraoperative complications

Among the 10 cases, 4 cases switched from pure NOTES to hybrid NOTES using a single-port approach. One case was

Table 1 A series of 10 patients.

| Patient | Sex/Age (yrs) | BMI (kg/m ²) | Radiation (Y/N) | OP time (min) | Pure NOTES (Y/Hybrid) | Stapling (Y/N) | Proximal margin (cm) | Distal margin (cm) | Lymph nodes |
|---------|---------------|--------------------------|-----------------|---------------|-----------------------|----------------|----------------------|--------------------|-------------|
| A | M/82 | 23.2 | Y | 300 | Y | Y | 20 | 3 | 10 |
| B | M/42 | 23.1 | Y | 259 | Y | Y | 16 | 0.2 | 11 |
| C | M/72 | 18.9 | Y | 407 | Hybrid | Y | 11 | 2.2 | 16 |
| D | F/77 | 20.2 | Y | 345 | Hybrid | Y | 9.5 | 4.2 | 17 |
| E | M/74 | 21.5 | Y | 225 | Y | Y | 23.5 | 0.5 | 19 |
| F | M/85 | 20.0 | Y | 274 | Y | Y | 34 | 3.5 | 26 |
| G | M/73 | 22.9 | Y | 255 | Y | Y | 11 | 2 | 8 |
| H | F/77 | 26.4 | N | 330 | Y | N | 23 | 3 | 25 |
| I | F/75 | 30.4 | Y | 335 | Hybrid | N | 50 | 1 | 23 |
| J | F/70 | 27.1 | Y | 305 | Hybrid | Y | 16 | 1 | 18 |

Ileostomy: C, I, J.

Ureter injury: D.

Anastomotic leak: C.

converted due to intraoperative complication, and three conversions were made for difficult dissection.

In a complication case, single-port laparoscopic D-J catheter insertion and primary closure of the ureter were performed due to ureter injury (Table 1; patient D).

In one case, conversion to Cecil procedure was made due to severe adhesion of the prostate and fascia propria during transanal dissection of the mesorectum (Table 1; patient C). This patient had a mass on the anterior wall of the rectum, and tumor adhesion occurred on the seminal

vesicle after concurrent chemoradiotherapy (CCRT). The operative time of this case was 407 min. This patient had protective defunctioning ileostomy, but anastomotic leakage developed postoperatively. Single-port laparoscopic washing and transanal primary closure of anastomosis were performed.

In other 2 cases, conversions to Cecil procedure were performed due to difficult colon mobilization. Both patients were female and had a history of hysterectomy (Table 1; patient I, J).

Table 2 Demographic characteristics.

| Characteristics | Values | |
|---|----------------|---|
| Age (yrs, mean ± SD) | 72.7 ± 11.7 | |
| Sex (M:F) | 6:4 | |
| Body mass index (kg/m ² , mean ± SD) | 23.4 ± 3.6 | |
| Distance from AV (cm, mean ± SD) | 6.9 ± 3.5 | |
| | Upper (≤12 cm) | 3 |
| | Middle (≤8 cm) | 4 |
| | Low (≤4 cm) | 3 |
| Preoperative concurrent chemoradiotherapy history | 8/10 | |

Table 3 Operative and pathological data.

| Characteristic | Value | |
|---|-----------------------|------------------|
| Operative time (mean ± SD) (min) | 303.5 ± 53.2 | |
| Anastomosis | Hand-sewn Stapling | 2 8 |
| Estimated blood loss | <50 | |
| Ileostomy | 3 | |
| Proximal margin (median, range) (cm) | 18 (9.5–34) | |
| Distal margin (median, range) (cm) | 2.1 (0.2–4.2) | |
| Circumferential resection margin positive | 0 | |
| No. of harvested lymph nodes (median) | 17.5 (8–26) | |
| TNM stage | I II III IV | 2 4 4 0 |

5. Discussion

Low anterior resection is a difficult and challenging procedure, especially in obese male patients or patients with narrow pelvis. In such cases, transanal TME might be a convenient approach and welcomed by surgeons who were experienced in laparoscopic surgery. Several studies have reported the feasibility and efficiency of this procedure.^{10–15}

Since Sylla et al first reported transanal mesorectal dissection using TEM instruments, several authors have used an additional abdominal approach.

There are several groups reporting purely transanal approach.^{19–21} Except case reports, only Chouillard et al reported on their preliminary experiences in 18 patients. Of the 18 patients, 10 patients underwent NOTES TME with colo-anal anastomosis without any abdominal assistance.

In these purely transanal TME groups, several postoperative complications occurred (anastomotic leak, urinary infection, small bowel obstruction at the ileostomy site).²⁰ All complications were treated conservatively. Leroy et al reported hematoma collection, which was treated using CT-guided drainage. In our study, of the 10 patients, 6 patients underwent pure TME without laparoscopic assistance. Anastomotic leak was the only postoperative complication.

In a systematic review by Wolthuis et al, they described the advantages of transanal TME.²² Transanal TME can be determined by looking directly at the distal margin, which allows a sufficiently long distal margin to be determined at the beginning of surgery and a single stapled anastomosis at the stapled anastomosis to lower the anastomosis leak rate. We also found that splenic flexure dissection would maximize these advantages.

In this study, two patients underwent splenic flexure dissection, one through laparoscopic approach and the other one through transanal approach. The operation times including the splenic flexure dissection were 330 min and 335 min, respectively, which took about 30 min longer than the mean operation time. A long laparoscopic device was used to perform splenic flexure dissection, and a 44-cm Maryland LigaSure was used for dissection and ligation. The conventional scope was used since we did not have a long 10-mm scope. The long scope and long instrument should be provided for transanal splenic dissection without a transabdominal approach.

Regarding IMA ligation, there is no difficulty in transanal high ligation of IMA. In these cases, the Sacral promontory does not interfere with transanal vessel ligation, but it is difficult to assert that the sample size of this study was small and conducted in a limited race.

One patient excluded in the analysis had synchronous triple colorectal cancer, and total proctocolectomy with ileal pouch–anal anastomosis was performed. Splenic flexure dissection and right side colon dissection including hepatic flexure mobilization were also performed transanally without an abdominal approach.

Concerning the complications, Wolthusis et al reported that the major perioperative complication that is specific to transanal TME is urethral injury. Rouanet et al described two urethral injuries that were sutured transanally.¹²

As ureter injury occurred, the surgery was switched to single-port laparoscopic surgery. A D-J catheter was inserted intracorporeally, and the ureter was sutured, 8 points, with 4-0 Vicryl.

Buchs et al also reported that urinary retention and transient urinary dysfunction were the most common complications.²³ In the present study, the urinary catheter was removed on POD 3 without training, and there was no urinary retention.

Oncologically, the safety and feasibility of surgery could be defined as attainment of lymph nodes and surgical margins. Theoretically, surgeons with experienced in transanal TME could acquire a clear distal margin under direct vision. In their series, Chouillard et al reported that the mean number of harvested lymph nodes per specimen was 21 (range 11–81) and the mean length of distal margin was 3.6 (range 0–8) cm.

In the current study, the median length of distal margin was 2.1 (range 0.2–4.2) cm, and the mean number of harvested lymph nodes was 17.5 (8–26). To achieve the principle of oncologic resection, a minimum of 12 lymph nodes must be harvested.

As we encountered more surgical cases, we have been trying to change the instruments we use and refine our techniques. To perform purse-string suture and fix the Glove port, we used a circular anal dilator. A circular anal dilator with a diameter of 34 mm was introduced with an obturator device. After removing the obturator, we secured the circular anal dilator to perianal skin with sutures. A circular anal dilator ensures the operation field and serves as a holder for the glove port (Fig. 1C and D).

When dissecting the lateral side wall of the mesorectum, particular care must be taken not to injure the nerves, ureter, and vessels. At the end of transanal TME, capping of the distal stump with LapBag is performed. Bagging the distal stump before intra-abdominal dissection prevents spillage or soiling and helps with specimen retrieval. Turning over the bagged specimen into the intraperitoneal space exposes the avascular plane to help dissection by angular favor (Fig. 4). For vessel ligation, we usually used a vessel sealing device, LigaSure without using clip or Hem-o-lok. Prior to specimen retrieval, the patient was placed in reverse Trendelenburg position for a few minutes to remove the intraperitoneal fluid from the dissected field maximally through the anus. During the specimen retrieval, the string of the LapBag could be a good handle.

As abovementioned, transanal TME has several advantages. A transanal purse-string suture below the tumor provides and promises an adequate oncological distal margin, and transanal approach using laparoscopy could facilitate the dissection of the Denonvilliers' fascia with optimal vision minimizing injury to the prostate and seminal vesicle. However, cases of patients with hostile pelvis or abdomen, adhesions on seminal vesicle after chemoradiotherapy, or previous abdominal surgery make dissection more difficult to perform. In intraoperative complication cases, the problem can be easily solved using single-port laparoscopic approach. Splenic flexure dissection would be needed in some cases, and it could also be achieved transanally with the help of proper instruments.

The present study has several limitations. The series being too small and selection bias prevent us from concluding about the safety of the technique. In addition, the sphincter function was not evaluated. However, as the number of cases increases, we expect to overcome these limitations.

In conclusion, this study showed that pure NOTES TME with coloanal anastomosis is a safe and feasible treatment for rectal cancer. Considering the benefits of transanal TME, further clinical studies are necessary before wide application of this technique.

"The future has already come."

Author contributions

Prof. Lee designed the study and performed surgery.

Dr. Choi collected and analyzed data.

Dr. Jeong wrote the paper.

Supportive foundations

No financial support was received by any author for this research.

Institutional review board statement

The study was approved by the local institutional review board for NOTES clinical trials.

Informed consent statement

Informed consent was obtained from each patient.

Conflict-of-interest statement

Page any conflicting interests (including but not limited to commercial, personal, political, intellectual, or religious interests) that are related to the work submitted for consideration of publication.

Data sharing statement

STROBE statement: The manuscript was prepared and revised according to the STROBE Statement.

Appendix A. Supplementary data

Supplementary data to this article can be found online at <https://doi.org/10.1016/j.asjsur.2018.08.010>.

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