Stapled Mesh reinforcement technique for cases with parastomal hernias: A controlled prospective pilot study

Original Article

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ABSTRACT

Background: Parastomal hernia is a common complication for fecal diversion that is well correlated with duration due to the progressive widening of the stoma aperture and peristomal muscle weakness. The study aimed to re-explore the Stapled Mesh-assisted Reinforcement Technique (SMART) of parastomal hernias for implementation on a wider scale.

Patients and Methods: Twenty (20) patients with permanent end stomas and symptomatic parastomal hernias, were recruited for the modified SMART repair of their hernias, and the perioperative outcomes were compared with the last 20 correlated patients in our Database undergoing direct hernia repair with onlay mesh using the key-hole technique, as regard operative time, logistic feasibility, the time needed for stoma functioning, local wound complications, stoma complications (necrosis, retraction, and prolapse) and hernia recurrence over a postoperative period of 1 month.

Results: Apart from the shorter operative time (about 20 min) in favor of the study group, there was no statistically significant difference as regard local wound and stoma complications between both groups during the early postoperative period.

Conclusion: SMART is feasible and promising in cases of symptomatic parastomal hernias.

Key Words: End colostomy, mesh reinforcement, parastomal hernias.

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INTRODUCTION

Despite being a common complication after fecal diversion, reaching up to 50% in some studies[1] or declared as 'practically unavoidable' by others[2,3], many controversies still exist around parastomal hernias (PSH). Authors define parastomal hernia as a visceral swelling within a peritoneal sac protruding beside a stoma on straining[4]. However, much debate exists about nearly anything else, starting from the 'most appropriate' mean of diagnosis; whether by only clinical examination[5–7], or adopting computed tomography (CT) scan routinely[8], up to the level of not having a 'gold standard' mean of diagnosis.[5] Consequently, the classification basis of PSH is more diverse.[5,9] Various risk factors were proposed by many authors for the occurrence and recurrence of PSH[10] raising more debate about the problem. Many surgeons around the world, adopt the strategy of watchful waiting because of the high incidence of recurrence based on personal experience mainly, with no solid evidence from literature to support such an approach[9]. While not forgetting the bad consequences 'such a decision' may have on the already disturbed quality of life for patients with fecal diversion[11,12], different techniques were introduced to manage PSH; broadly divided into mesh and nonmesh techniques[9,13]. Advocators of mesh repair of PSH, based their recommendation upon the markedly lower incidence of recurrence (22% vs. 45% radiological recurrence and 13% vs. 80% clinical recurrence)[2]. The American Society of colorectal surgeons (ASCRS), in their recent guidelines stated that mesh reinforcement of PSH repair is highly recommended (evidence 1c) with no consensus about, whether or not, to relocate the stoma[14]. Onlay, sublay, and inlay sites for mesh fixation, were reported[2]. With the introduction of surgical staplers, authors advocated their use in PSH repair either without[15], or with[16], mesh reinforcement in the sublay position. We present the application of stapled mesh-assisted stoma reinforcement technique (SMART) with mesh positioned in the onlay position.

PATIENTS AND METHODS:

Having obtained the approval of the 'ethical committee' board of our institution about the research protocol, 20 patients with end stomas (colostomies or ileostomies) were recruited as our study group starting from December 2023. All of the recruited patients had 'clinically significant' PSH i.e., affecting the patient's quality of life to the extent of requiring surgical intervention for their PSH. Informed

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consent was taken from all the candidates. For ethical purposes, all included patients were ASA I or II. Dealing with a relatively nonfamiliar technique, it was decided to include patients only with BMI, not more than 35 and the size of the hernia sac defect was not more than 5 cm by ultrasound. Patients with previous attempts of surgical repair for their PSH and those with concomitant midline incisional hernias, were excluded as well. In patients with peristomal dermatitis, preoperative admission and frequent dressing (twice daily) followed by zinc oxide application and daily change of the stoma appliance was done till complete resolution of dermatitis. We adopted the same technique (SMART) described by Williams *et al*.[15] and Manfredelli *et al*.[16] to address PSH, while keeping our dissection within the premuscular instead of retromuscular plane: the stoma was taken down via peristomal incision keeping the dissection plane close to the bowel loop, then the stoma was closed with a linear stapler 45 mm. A long prolene thread was tied to the loop end before allowing to retract in the abdomen to help later identification of the loop. The hernial sac was dissected from the abdominal wall and excised. The anterior abdominal wall was closed in mass, around the anvil of a 31 mm circular EEA stapler (29 mm in cases with ileostomies) placed at the proposed stoma site, using PDS loop size 0. The retromuscular plane was not dissected. A light-weight macroporous prolene mesh was applied on the onlay position and fixed to the abdominal wall using prolene sutures 2/0, passing the anvil across the mesh. The arm of the circular stapler was fitted to the anvil and fired, creating the new stoma site. The labelling prolene thread was detected and the closed stoma was exteriorized then reopened and matured to the skin after nippling, using 3/0 vicryl sutures. The patients were followed-up, recording the time needed for stoma functioning, stoma complications as regards site (retraction/prolapse) and viability (mucosal/full thickness gangrene), and any sign that may indicate bowel obstruction (unexplained persistent postoperative nausea and vomiting, distension, decreased stoma output, colics…….). After discharge, patients were scheduled for follow-up visits at the outpatient clinic, weekly for one month for detection of recurrence, surgical site infection (SSI) and delayed complications that may evolve (e.g., obstruction…….) at the short term. A scanning CT scan was planned during the last visit for detection of 'radiological' recurrence. The results of the study group were compared with those of the last twenty (20) correlated patients in our database, having their PSH directly 'repaired' with onlay mesh application technique without stoma relocation i.e., key-hole technique. Our standard technique for the control group was nearly similar to that applied for the study group, but with the following difference: a) the resultant abdominal wall defect after stoma take-down and hernia sac excision, was closed using PDS loop sutures leaving the assigned stoma site in the middle b) the key-hole defect in the mesh was done early to fit the size of the bowel loop before mesh fixation having the loop exteriorized early and held by a noncrushing clamp till finishing mesh fixation

Statistical analysis

Data were collected, revised, coded and entered into the Statistical Package for Social Science (IBM, north carolina, united states, SPSS) version 23. The quantitative data were presented as mean, standard deviations and ranges when parametric and median, inter-quartile range (IQR) when data found non-parametric. Also, qualitative variables were presented as numbers and percentages. The comparison between groups regarding qualitative data was done by using χ^2 test and/or Fisher exact test when the expected count in any cell found less than 5. The quantitative data and parametric distribution were done by using Independent t-test. The comparison between more than two groups regarding quantitative data and parametric distribution was done by using One Way ANOVA test. The confidence interval was set to 95% and the margin of error accepted was set to 5%. So, the *P value* was considered significant at the level of less than 0.05.

RESULTS:

Starting from December 2023 to May 2024, the study group included 12 males and 8 females. The results were compared with the last 20 correlated patients retrieved from the database. The demographic data of the recruited patients is shown in (Table 1). The medical records of the study population are shown in (Table 2, Fig. 1). The indications for diversion were various (Table 3, Fig. 2) and the indication for PSH repair was ill fitting stoma appliance and frequent peristomal dermatitis. The stomas of the study population were all of end form: 13 colostomies and 7 ileostomies, whether in the para-rectus or the trans-rectus location (Table 4, Fig. 3). The time interval following complete dissection of the hernial sac till complete closure of the abdominal wall defect, mesh fixation and loop exteriorization, just before stoma nippling and maturation, was about 19 min (40 min in the control group) (Table 5, Fig. 4). The time elapsed before the first bowl movement ranged from 1 to 3 days. One (1) case developed mucosal gangrene at the first postoperative day and was managed conservatively using hot fomentation twice daily and oral pentoxifylline (Table 6). Most of the patients were discharged by the third postoperative day (Table 7). Two important issues evolved during the study, leading to slight deviation from the assumed study methodology: firstly, being a pilot study meant that the indication for diversion, hence the suitability for diagnostic CT scan after one month, varied widely among patients. Secondly, a CT scan after one month is not a routine postoperative practice for PSH repair patients, which implied nonavailability of such findings in control patients. Therefore, it was decided to succumb to clinical examination of surgical site to detect early recurrence instead of a radiological examination. As recommended by the ethical committee, an interim analysis of the results in the study group was done after the first five cases regarding the safety of the procedure. The results were satisfactory, so the study project was completed.

Table 1: Demographic Data

	Study (*n*=20)	Control (*n*=20)	Test value	*P* value	Significance
Sex, *n* (%)					
Male	12 (60.0)	12 (60.0)	0.000*	1.000	NS
Female	8 (40.0)	8 (40.0)			
Age	49.05 (26–67)	48.55 (25–68)	–0.135≠	0.892	NS
BMI	30.5 (26–34)	30.3 (27–32)	–0.383≠	0.701	NS
Smoking, *n* (%)	13 (65.0)	12 (60.0)	0.107*	0.743	NS

P value greater than 0.05: Nonsignificant; *P value* less than 0.05: Significant; *P value* less than 0.01: Highly significant.
*: Chi-square test.
≠: Mann–Whitney test.

Table 2: Comorbidities of study population

	Study (*N*=20) [*n* (%)]	Control (*N*=20) [*n* (%)]	Test value	*P* value	Significance
Medically free	5 (25.0)	5 (25.0)	0.000*	1.000	NS
DM	7 (35.0)	8 (40.0)	0.107*	0.743	NS
HTN	3 (15.0)	5 (25.0)	0.625*	0.429	NS
IHD	5 (25.0)	3 (15.0)	0.625*	0.429	NS
Others	2 (10.0)	1 (5.0)	0.360*	0.548	NS

P value greater than 0.05: Non-significant; *P value* less than 0.05: Significant; *P value* less than 0.01: highly significant.
*: Chi-square test.

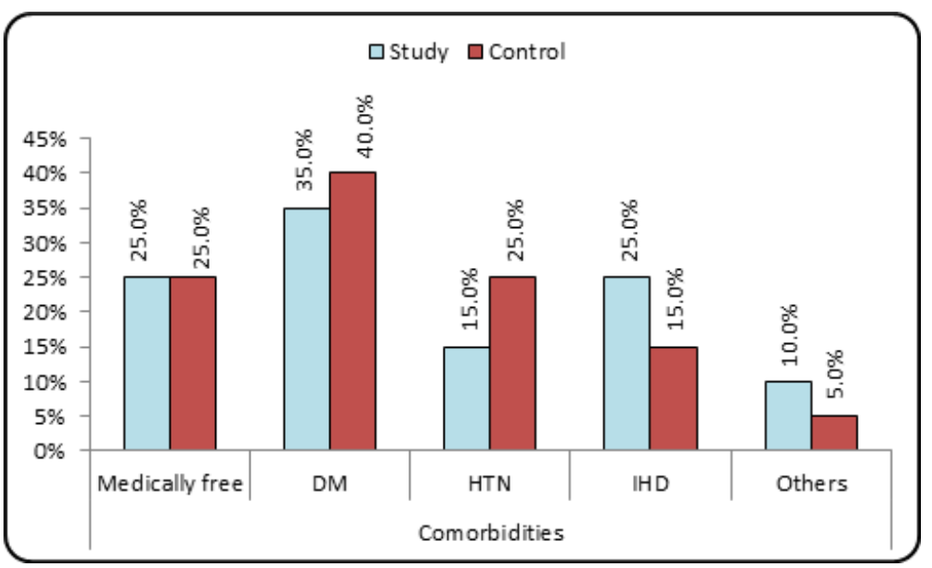

Fig. 1: Comorbidities.

Table 3: Indications for diversion

	Number of patients (study/control), *n* (%)
Anorectal cancer	8 (40.0)
DD	3 (15.0)
FAP	3 (15.0)
Perineal wound diversion	2 (10.0)
Persistent Hemorrhage	1 (5.0)
UC	3 (15.0)

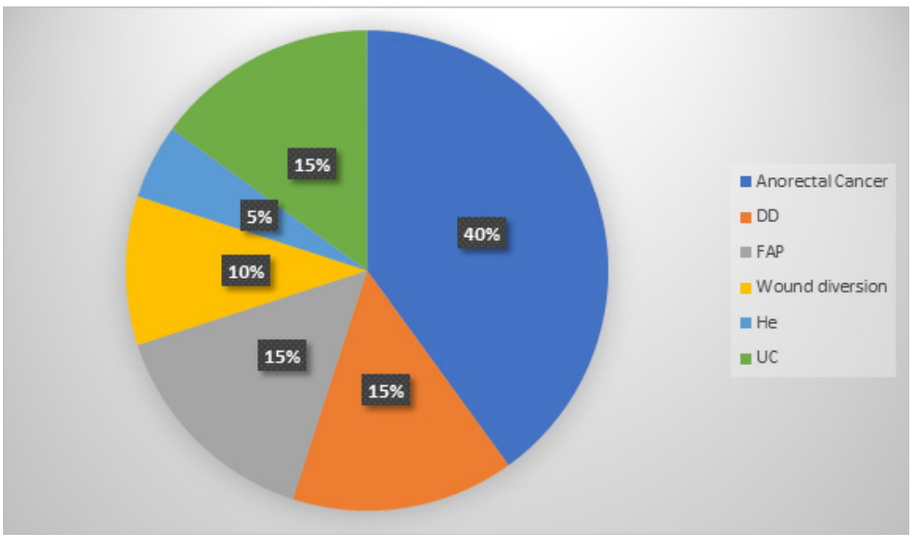

Fig. 2: Indications of diversion.

Table 4: Stoma form of the study/control group

	Pararectus	Transrectus	Test value	*P* value	Significance
Ileostomy	5 (25.0)	2 (10.0)	1.558*	0.211	NS
Colostomy	6 (30.0)	7 (35.0)	0.114*	0.735	NS

P value greater than 0.05: Nonsignificant; *P value* less than 0.05: Significant; *P value* less than 0.01: highly significant.
*: Chi-square test.

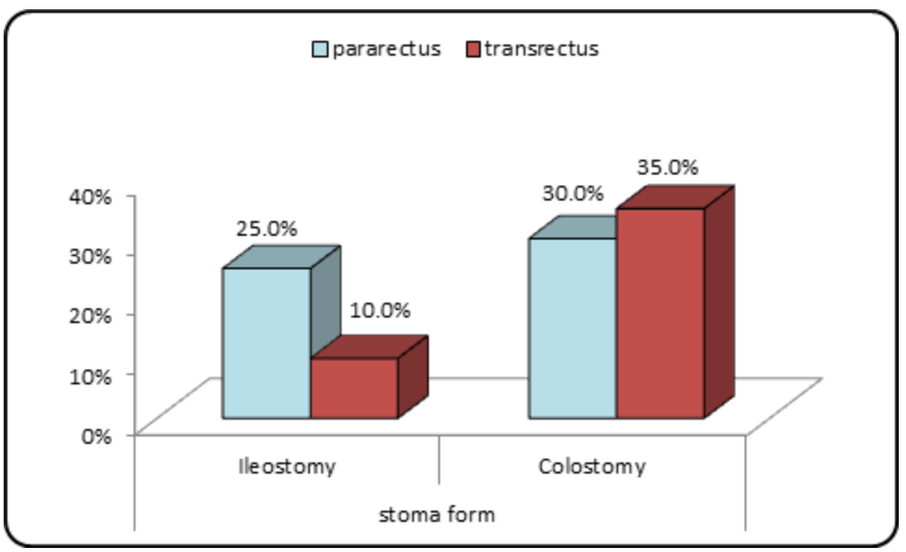

Fig. 3: Stoma form.

Table 5: Operative time (min)

	Study group	Control group			
	Median (IQR)	Median (IQR)	Test value	*P* value	Significance
Time for complete closure (min)	19 (17.5–20.5)	40 (38.5–42.5)	-5.421≠	<0.001	HS

P value greater than 0.05: Nonsignificant; *P value* less than 0.05: Significant; *P value* less than 0.01: highly significant.
≠: Mann–Whitney test.

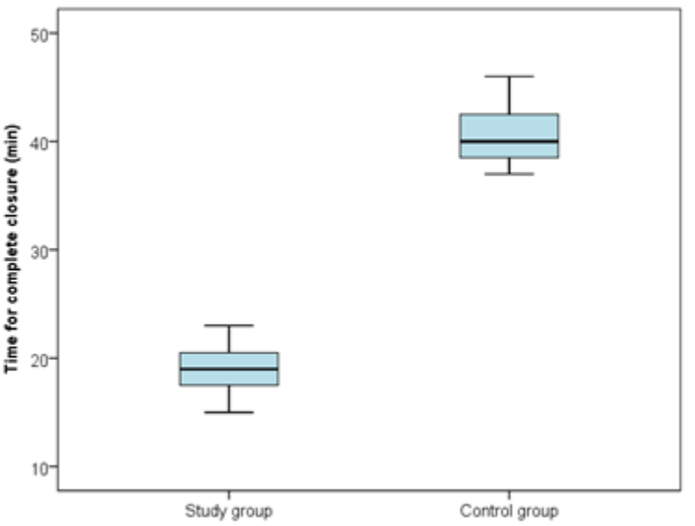

Fig. 4: Time for complete closure (min).

Table 6: Postoperative outcome

	Study group (*N*=20) [*n* (%)]	Control group (*N*=20) [*n* (%)]	Test value	*P* value	Significance
First bowel movement (days)	1.7 (1–3)	1.65 (1–3)	-0.270≠	0.787	NS
Mucosal gangrene	1 (5.0)	2 (10.0)	0.360*	0.548	NS
Full thickness gangrene	0	0	–	–	–
Stoma retraction	0	0	–	–	–
Bowel obstruction	0	0	–	–	–
Recurrence after one month	0	0	–	–	–

P value greater than 0.05: Non-significant; *P value* less than 0.05: Significant; *P value* less than 0.01: Highly significant.
*: Chi-square test.
≠: Mann-Whitney test.

Table 7: Postoperative hospital stay

	Study group (*N*=20) [*n* (%)]	Control group (*N*=20) [*n* (%)]	Test value	*P* value	Significance
1 day	–	–			
2 days	5 (25.0)	4 (20.0)			
3 days	14 (70.0)	13 (65.0)	1.148*	0.766	NS
More than 3 days	1 (5.0)	3 (15.0)			

P value greater than 0.05: nonsignificant; *P value* less than 0.05: significant; *P value* less than 0.01: highly significant.
*: Chi-square test.

DISCUSSION

Having an 'abnormal' aperture within the muscles, implies the inevitable disturbance of the 'geometry', and consequently the 'stability' of the anterior abdominal wall.[17] It was estimated that there is a progressive increase in the diameter of the stomal aperture in the abdominal wall at a rate of 22 mm/month[18]. This may explain the high incidence of PSH among patients with permanent faecal diversion. The idea of mesh application during management of such hernias aimed to prevent such an increase by reinforcement of the defect edges or even, 'diversion' of the applied forces at the site of bowel exit[19] acting as a mechanical buttress[20]. The most common techniques for such 'mesh-reinforcement' are the sugarbaker and keyhole techniques. Some authors advocate the 'Sugarbaker' technique assuming lower recurrence rate[21]. However, bowel obstruction due to dense adhesions at the mesh-bowel contact points and the sharp 'bowel angulation' limited the spread of that technique[19]. The 'Keyhole' technique is faster and easier to perform and thus, more common to be applied in many centres, including our institute. Multiple issues were raised,

concerning the application of synthetic mesh near bowel loop exteriorized for faecal diversion. Mesh infection and mesh erosion into the bowel loop could be very devastating for the patient. Mesh contraction over time can lead to decreasing the effectiveness of mesh reinforcement, and increasing the trephine size in the mesh can lead to inevitable recurrence in a more dangerous form as the defect edges are the widened sharp edges of the mesh i.e., 'buttonhole' hernia[19,22,23]. Those doubts were nullified by many authors assuring the safety of prosthetic mesh application in PSH cases[20,24–26]. In their recent guidelines, the American Society of Colon and Rectal Surgeons and the European Hernia Society, considered mesh application in cases of PSH, the standard of care[9,14]. In our technique, we avoided stoma relocation. This goes with the most recent recommendations condemning this act denoting it as an 'unnecessary' morbidity added to the patient 'increasing' the risk of incisional hernia at the original site while 'keeping the same' risk to have PSH at the new site[19,26]. Our study population was 12 males and eight females in either groups (study and control) nearly correlated as regards age, BMI and smoking habits. According to many authors, these factors were independent risk factors for PSH[27–30]. BMI of 35 kg/m^2 was decided in our inclusion criteria based on the personal assumption of the authors to have adequate thickness of anterior abdominal wall muscles traversed by staples to avoid misfiring of the staplers while having a reasonable thickness of subcutaneous fat to cover the mesh. Many authors found the thickness of abdominal wall muscles to be about 1 and 1.5 cm at the rectus and lateral abdominal wall muscles (external, internal obliques, and transversus abdominis), respectively, with subcutaneous fat about 2 cm thick[31–33]. In our pilot study, we tried to include patients with various indications for end stomas (colostomy or ileostomy) and their stomas at the pararectus or transrectus site keeping in mind the still ongoing debate about the necessity of passing the stoma across the rectus abdominis muscle as a protective factor against herniation[1,9,28,33]. We included patients having type I parastomal hernia, according to the classification of the European hernia society[34]. Those patients were deemed to have their hernias suitable to investigate our proposed technique without having other factors affecting abdominal wall 'geometry', represented by concomitant incisional hernia and significantly weakened abdominal wall by a large hernia defect, to assess incidence of short-term recurrence. Following complete dissection of the hernial sac, the advantage of our proposed technique was obvious as regards feasibility and operative time needed. The abdominal wall muscles were closed in mass using PDS loop while passing the anvil of the circular stapler at the proposed stoma site. We did not have to 'dissect the preperitoneal space'[15,16] nor leaving an average defect for the stoma 'after direct repair of the hernial defect'[35] which are the techniques frequently done in our institution (having the latter adopted in the control group before mesh application). Such a modification saved us much time (about half an hour) and resources, while being an easy step to adopt. The initial motivation for the proposed technique was the attempt to avoid some of the complications 'traditionally' related to prolene mesh application near stoma site, namely mesh migration, widening of the stoma aperture at the mesh, and loop herniation below the mesh in a 'buttonhole' pattern[19,22,23]. We decided to apply circular staplers for both the aperture creation across the abdominal wall and mesh fixation to get a uniform aperture with 'evenly' reinforced edges. The diameter of the aperture did not exceed the optimum diameter (2.5–3.5 cm) proposed by many authors[36–39]. After a short term follow-up (1 month), it was clear there is no significant difference between the study and control group as regards the postoperative outcome; namely stoma viability and peristomal 'occurrence' (prolapse, retraction, infection, and early recurrence). In the original SMART technique proposed by Williams *et al*.[15] and Manfredelli *et al*.[16], the preperitoneal space has to be dissected; a step that is both time consuming and technically demanding having to work in a 'nonvirgin' plane. Having the mesh placed in the onlay plane is both time saving and technically feasible with an additional advantage: Having the mesh in such a plane facilitates its extraction in cases of mesh infection or stoma compromise while preserving the preperitoneal space as a 'back-up' for subsequent stages. The ongoing debate about the optimal site for mesh placement is worth to mention. Despite being easy to perform, the onlay position has an inherently higher rate of SSI either from an external source (leaking faecal material to the dissected subcutaneous plane and peristomal infections) or due to seroma formation after elevation of skin flaps for mesh fixation[40]. In their meta-analysis, Timmermanns *et al*., on the other side, did not find statistically significant difference between the two groups as regards the rate of infection[41]. A recent systemic review by Köckerling found no significant difference between the two techniques i.e., onlay and preperitoneal mesh fixation as regards recurrence rates and postoperative complications (other than risk of postoperative infection). He concluded that onlay mesh application is still the preferred technique in certain situations and suggested certain precautions to 'get the full benefit' of it[42]. A recent systemic review by Pereira and colleagues however, did not find that difference in infection rate. It is worth to state that they attributed that finding to the great heterogeneity of the included studies[43]. During our short term follow-up, we did not encounter any case of SSI. This can be attributed to the prophylactic antibiotic protocol in our institute (3rd generation cephalosporin and metronidazole) and our routine intraoperative wound lavage using

normal saline before mesh application. Köckerling suggested that increased surgical experience to reduce unnecessary subcutaneous dissection, application of fibrin glue, abdominal binders and drains in the postoperative period can favor the onlay plane for mesh application via decreasing the postoperative seroma; the only significant disadvantage of this plane[42]. Those items should be studied in dedicated research.

Limitations

Our pilot study aimed to assure the feasibility and safety of the proposed technique. This poses certain limitations to our results. The study population was of small number. The study population was 'standardized' as much as possible using strict inclusion and exclusion criteria. We excluded cases of recurrent PSH, which are assumed to be the population most likely to benefit from our proposed technique. Certain logistics may pose obstacles to our technique e.g., the availability of the staplers and the familiarity of surgeons with their use. The cost-benefit ratio of our 'SMART' technique has to be evaluated on a wider community-based scale. Selection bias as regards the control group was inevitable; aiming to get 'correlated' patients from the database to compare our findings with. Despite the initial intent to record radiological recurrence of PSH using pelviabdominal CT, the absence of such data in the control group and the inability to expose all the study group to radiation forced us to succumb to clinical examination as a 'substitute'. The long-term outcome of our technique application can be the basis of further studies.

CONCLUSION

'SMART' is a safe and feasible technique for cases of PSH that is easy to adopt.

ABBREVIATIONS

ASA, American society of anaesthilogists; **ASCRS**, American society of colorectal surgeons; **BMI**, body mass index; **CT**, computed tomography; **DD**, diverticular disease; **DM**, diabetes mellitus; **FAP**, familial adenomatous polyposis; **HTN**, hypertension; **IHD**, ischemic heart disease; **IQR**, interquartile ratio; **PONV**, postoperative nausea and vomiting; **PSH**, parastomal hernia; **QOL**, quality of life; **SMART**, stapled mesh-assisted stoma reinforcement; **SSI**, surgical site infection; **UC**, ulcerative colitis.

CONFLICT OF INTEREST

There are no conflicts of interest.

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