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ORIGINAL ARTICLE

Purse-string approximation vs. primary closure with a drain for stoma reversal surgery: results of a randomized clinical trial

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Abstract

Purpose Stoma reversal carries a risk of surgical site infection (SSI). Purse-string approximation (PSA) has been reported as an attractive alternative to conventional primary wound closure for stoma reversal, but its efficacy is still under debate.

Methods Patients undergoing elective stoma reversal were randomized to undergo PSA or primary closure with a drain (PCD). All patients received preoperative bowel cleansing and antimicrobial prophylaxis. The primary endpoint was the incidence of wound healing at the stoma site 30 days after surgery. The secondary endpoint was the 30-day SSI rate after surgery.

Results A total of 159 patients (PCD group, $n=79$; PSA group, $n=80$) were eligible for this study. The incidence of wound healing at the stoma site was 92.4% in the PCD group and 62.5% in the PSA group [difference (95% confidence interval −29.9% (−42.9 to −16.9%)]. The 30-day SSI rate at the stoma site, as the secondary endpoint, was 8.9% in the PCD group and 5.0% in the PSA group ($P=0.35$).

Conclusions These results suggest that PCD may remain the standard procedure for stoma reversal surgery.

Keywords Stoma closure · Wound infection · Wound healing · Purse-string approximation · Randomized clinical trial

Introduction

A temporary stoma is commonly used in colorectal surgery, to decrease the risk of anastomotic leakage and reoperation rate [1, 2]. Stoma reversal surgery is usually performed when the patient's medical condition has improved sufficiently. Primary wound closure following stoma reversal is associated with a high incidence of surgical site infection (SSI) at the stoma site, ranging from 2 to 41% [3–5], because some degree of wound contamination of the stoma site is unavoidable. SSI after stoma reversal is associated with an increased risk of wound dehiscence and incisional hernia formation [6]. To prevent SSI following stoma reversal surgery, several alternative techniques to conventional primary closure (PC) have been attempted, including subcutaneous gentamycin sponge use, wound irrigation with iodine, PC with placement of a drain (PCD), secondary closure, delayed PC, and purse-string closure [7–11]. However, the optimal method of skin closure to reduce the risk of SSI following stoma reversal is still under debate.

In 1997, Banerjee [12] described the method of purse-string approximation (PSA) of the skin for stoma reversal, and its cosmetic benefit at the ileostomy closure site. In 2002, Sutton et al. [13] reported a 0% incidence of SSI in a series of 52 patients who underwent skin closure using the PSA technique. We were performing PCD for stoma reversal as a conventional method prior to the introduction of PSA in our institution. PCD may be a better procedure than PC for reducing the rate of SSI, based on our experience and recent reports [14, 15]. After PSA was reported as a superior treatment for stoma reversal in terms of low SSI and its cosmetic benefit, whether PSA or PCD is selected for stoma closure depends on the surgeons' preference in our institution. The potential risk of SSI following PSA is nearly zero, but meticulous wound care is necessary until complete

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epithelialization when this technique is used, which may compromise patient satisfaction. From this perspective, the choice of the skin closure technique may depend on the balance between the risk of SSI and the time to healing.

In 2007, until which time there had been no reports of prospective randomized trials evaluating the efficacy of PSA for stoma reversal surgery, we initiated a prospective randomized controlled trial to compare the merits of PSA with those of PCD for stoma reversal, focusing on wound healing and the incidence of SSI at the stoma site. We report the results of this prospective randomized controlled study, with a review of the recently published literature on this subject.

Materials and methods

The trial was designed to test the non-inferiority of PSA to PCD in terms of the incidence of wound healing 30 days after stoma reversal surgery. This study was conducted with the approval of the ethics committee of Saitama Medical Center, Saitama Medical University (no. 101), and is registered with the University Hospital Medical Information Network (UMIN, no. 000030772). Written informed consent for participation in the clinical trial was obtained from each participating patient.

Patients

Patients undergoing elective stoma (ileostomy or colostomy) reversal between November, 2007 and September, 2016 were screened for exclusion criteria, and if found to be eligible for the study, were asked if they would provide written informed consent for participation in the trial. The inclusion criteria were elective stoma reversal, an age of 18 years or older, and the capability to provide voluntary informed consent for participation. Patients who simultaneously underwent resection for colorectal liver metastasis were also included. The exclusion criteria were parastomal hernia requiring intensive repair, double stomas (a stoma for passage of stools and a mucous fistula) located close to each other, and refusal to provide consent for participation in the trial, regardless of the reason.

The randomization of patients

Patients were randomized at a 1:1 ratio to undergo either PCD or PSA of the skin for stoma reversal. Randomization was done using sealed envelopes containing randomized sheets. The patient allocation was revealed to the operator just before the surgery.

Techniques of stoma reversal and perioperative care

While all the surgeons had experience of performing PCD, only some had experience of performing the PSA technique. Surgeons without experience of the PSA technique were assisted by experienced consulting colorectal surgeons in their first cases.

PCD

In the PCD group, a transverse elliptical incision was made, with a 2- to 3-mm margin around the mucocutaneous junction of the stoma. The stoma was mobilized from the abdominal wall through dissection, and the opening was immediately closed with interrupted sutures. Fascia closure was achieved with interrupted 2-0 absorbable sutures. Following fascial closure, irrigation was performed with copious amounts of physiological saline (approximately 2000 mL) and the wound edges were approximated in a linear fashion with interrupted 3-0 non-absorbable sutures without subcutaneous approximation. A 5-mm silicone Penrose drain was placed under the wound, through its edge or through a separate incision. After the surgery was completed, a simple sterile dressing was applied. The drain was removed on postoperative day (POD) 2. In almost all patients with a stoma-site SSI, the wound was opened, and the defect was filled with saline-soaked gauze.

PSA

In the PSA group, a circular incision was made around the stoma, leaving a margin of 2–3 mm around the mucocutaneous junction. The methods for bowel mobilization, closure of the stoma opening, bowel anastomosis, fascial closure, as well as irrigation of the wound were the same as those used in the PCD group. A subcuticular absorbable 2-0 purse-string suture was applied, forming a skin defect 10–20 mm in diameter, depending on the tension of the surrounding skin and the original stoma size, while avoiding formation of marked radial skin creases around the defect. The defect was filled with saline-soaked gauze, providing a moist environment for wound healing, which is generally used for open wounds [16]. The gauze was removed on POD 2 and the patients were instructed to wash the wound once every day with running water and apply a saline-soaked gauze dressing over its base and cover it with an adhesive bandage until the serous effusion disappeared.

Bowel preparation and antimicrobial prophylaxis

Preoperative measures, such as bowel preparation (mechanical cleansing and antimicrobial prophylaxis) and intravenous antimicrobial prophylaxis, were the same in the two groups. They were in accordance with the CDC guidelines [17] and the same as those for patients undergoing elective colorectal cancer surgery during the same period [18, 19]. All patients were given kanamycin (3 g/day) and erythromycin (2.4 g/day) orally as three divided doses after mechanical bowel cleansing, within 24 h prior to surgery. The mechanical bowel preparation consisted of bowel lavage with 2L of polyethylene glycol or 34 g of magnesium citrate. For Hartmann's reversal, an enema with 100–200 mL of physiological saline was added according to the protocol of the surgeon. One gram of Cefmetazole, a second-generation cephalosporin, was administered intravenously just prior to the skin incision, and then again 3 h later. A single additional dose was given 1 h after completion of the surgery.

Primary and secondary endpoints

Because we initially expected that the SSI rate of PCD might be similar to that of PSA, based on the accumulated outcomes of stoma reversal in our institution, the primary endpoint was the incidence of wound healing 30 days after surgery. Wound healing of the stoma site was defined as complete epithelialization of the wound with complete coverage of the initial circumferential defect by skin in the PSA group [20], and as complete linear adaptation of the wound without any exudate in the PCD group. The secondary endpoint was the incidence of SSI at the stoma site 30 days after surgery. Wound infection was diagnosed by the presence of erythema, pain, swelling or discharge at or around the stoma site. The attending surgeons checked for these endpoints prospectively at the time of admission to hospital and/or at the time of periodic follow-up visits (at 7–14-day intervals) to the outpatient department and recorded them in the medical charts. The data were then analyzed retrospectively.

Sample size calculation

This trial was designed as a non-inferiority test in a prospective randomized fashion to detect a 15% difference in the incidence of wound healing at the stoma site 30 days after stoma reversal between the two groups. In other words, the expected incidence of wound healing in the PSA group was set at 90% with a margin (Δ) of non-inferiority of 15% vs. that in the PCD group, with a two-sided 95% confidence interval (CI) ($\alpha = 0.05$) and a statistical power of 80% ($\beta = 0.2$). We assumed that the incidence of wound healing in the two groups would be 90%, based on a review of the medical charts of the patients undergoing either of the stoma closure procedures between January, 2004 and December, 2007 (unpublished data). Based on the above considerations and an allocation rate of 1:1, the required sample size was calculated as 126 (63 for each group) [21]. The required number of patients for each group was set at 76, assuming a potential dropout rate of 10%.

Statistical analysis

Data are expressed as medians and ranges or 95% CIs. The primary endpoint in the PSA group would not be considered inferior to that in the PCD group, if the lower limit of the one-sided 95% CI for the difference in the primary endpoints (namely, the incidence of wound healing at 30 days after stoma reversal) was above − 15%. The *P* value for the non-inferiority assessment was calculated by the method described by Dunnet and Gent [22]. The secondary endpoint, being the 30-day incidence of SSI at the stoma site after stoma reversal, was compared between the groups by the Fisher exact probability test. Some clinicopathological factors, where appropriate, were also compared between the groups by the Fisher exact probability test or the Mann–Whitney *U* test. The Statflex ver. 3.0 for Windows (Artec, Inc, Osaka, Japan) software was used for the statistical analyses. *P* values of < 0.05 were considered significant.

Results

A total of 190 patients underwent elective stoma reversal during the study period (Fig. 1). Thirty patients were excluded from the analysis for the following reasons: refusal to provide consent for participation in the study ($n = 12$), information about the study was not shared by the consultant surgeons or residents ($n = 12$), associated severe

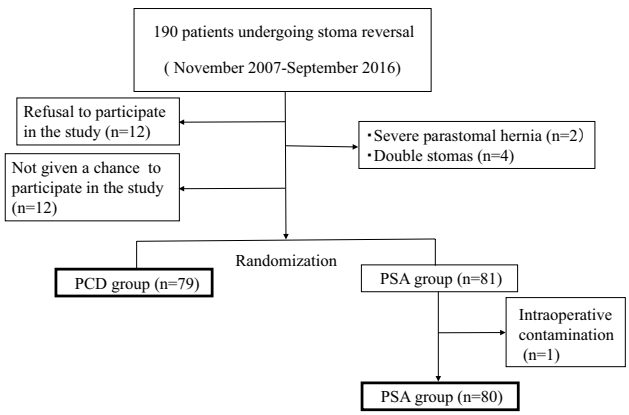

Fig. 1 Schematic representation of the study design. PCD: primary closure with a drain. PSA: purse-string approximation

parastomal hernia ($n=2$), and double stomas (functioning stoma and mucous fistula) located close to each other ($n=4$). The remaining 160 patients were randomized to one of the two surgical groups (PCD group, $n=79$; PSA group, $n=81$). Massive contamination during Hartman's reversal occurred because of severe intra-abdominal adhesions in one PSA group patient, who was excluded from the analysis. Finally, the data of 79 patients in the PCD group and 80 patients in the PSA group were analyzed for this study (Fig. 1).

Table 1 summarizes the demographic and clinicopathological characteristics of the patients. There were no significant differences between the groups in terms of age, sex, type of disease, type of stoma (ileostomy/colostomy, single barreled/double barreled), frequency of simultaneous hepatectomy for colorectal liver metastasis, American Society of Anesthesiologist physical status (ASA) score, operation time, or estimated blood loss.

The primary endpoint; namely, the incidence of wound healing 30 days after surgery, was 92.4% (95% CI 86.1–98.7%) in the PCD group and 62.5% (95% CI 52.1–72.9%) in the PSA group. The difference between the two groups was −29.9% (95% CI −42.9 to −16.9%). Furthermore, the *P* value calculated for the non-inferiority assessment was 0.998. Because the upper limit of the one-sided 95% CI was not above −15%, the outcome in terms of the incidence of wound healing in the PSA group could not be proven to be better than or equivalent to that in the PCA group (Table 2).

The secondary endpoint; namely, the 30-day incidence of SSI at the stoma site, was 8.9% (95% CI 2.2–15.3%) in the PCD group and 5.0% (0.5–19.4%) in the PSA group.

Table 1 Clinical characteristics of patients who underwent stomal closure using primary closure with a drain vs. those who underwent purse-string approximation

	PCD group ($n=79$)	PSA group ($n=80$)	*P* value
Age (years)[a]	64 (18–83)	62 (18–82)	0.63
Sex (male:female)	45:34	47:33	0.87
Type of diseases			0.14
Benign	28	38	
Malignant	51	42	
Type of stoma			0.12
Ileostomy, single barreled	4	4	
Ileostomy, double barreled	50	48	
Colostomy, single barreled	17	25	
Colostomy, double barreled	8	2	
Synchronous hepatectomy	4	2	0.41
ASA score			0.13
1	40	46	
2	36	25	
3	3	8	
4	0	1	
Body mass index (kg/mm^2)[a]	21.6 (14.8–33.7)	21.0 (15.5–32.2)	0.34
Operative time (min)[a]	85 (32–425)	86 (19–460)	0.47
Estimated blood loss (mL)[a]	20 (10–1900)	30 (10–1700)	0.2

ASA American Society of Anesthesiologist physical status, *PCD* primary closure with a drain, *PSA* purse-string approximation

[a]Median (range)

Table 2 Wound healing at the previous stoma site 30 days after stoma reversal

	PSA group ($n=80$)	PCD group ($n=79$)	Difference (95% CI)	*P* value
Wound healing (%)	50 (62.5%, 95% CI 52.1–72.9%)	73 (92.4%, 95% CI 86.1–98.7%)	−29.9% (−42.9 to −16.9%)	0.998

Table 3 Surgical site infection at the stoma site within 30 days of stoma reversal

	PSA group ($n=80$)	PCD group ($n=79$)	*P* value
Surgical site infection (%)	4 (5.0%, 95% CI 0.5–19.4%)	7 (8.9%, 95% CI 2.2–15.3%)	0.35

There was no significant difference in the 30-day incidence of SSI at the stoma site after the surgery between the groups ($P=0.35$) (Table 3). Although we included both ileostomy and colostomy in the PCD and PSA groups (Table 1), there were no differences in the incidence of SSI according to the type of stoma (Supplemental Table 1).

Discussion

To our knowledge, this is the seventh report of a prospective randomized controlled trial comparing PSA and PC for stoma reversal, although in our trial, a drain was used in the primary closure group (Table 4). In the previous six trials, published between 2010 and 2016, the 30-day incidence of SSI at the stoma site after stoma reversal was set as the primary endpoint, whereas in our trial, the incidence of wound healing 30 days after stoma closure was set as the primary endpoint. Generally, epithelialization of the PSA wound takes a long time and requires continuous wound care, although the SSI incidence tends to be low. However, it may be difficult for elderly patients to perform self-care management such as cleaning the wound. Moreover, if the incidence of SSI at the stoma site can be minimized according to the choice of PC or PCD, the choice of PSA itself seems to have little impact in clinical practice. We could not prove non-inferiority of PSA to PCD in terms of the incidence of wound healing (62.5% vs. 92.4%) at the stoma site 30 days after surgery. Moreover, we found that the 30-day incidence of SSI at the stoma site after PCD was 1.8 times higher (8.9% vs. 5.0%) than that after PSA, although the difference was not significant ($P=0.35$). Our results suggest that PSA need not be selected if PC (with or without a drain) is able to be performed with an acceptably low incidence of SSI at the stoma site. It is also noteworthy that our trial was undertaken based on sample size calculation before its initiation, whereas the previous six trials were potentially underpowered by a small sample size.

Table 4 Review of randomized clinical trials comparing purse-string approximation and primary closure/ primary closure with a drain in stoma reversal surgery

References	Country/year	Stoma type	Interventions	Randomly assigned participants eligible	Mechanical cleansing	Antimicrobial prophylaxis	Wound infection (%)	Wound healing
Reid et al. [23]	Australia/2010	Ileostomy	PC vs. PSA	31 vs. 30	ND	ND	39% vs. 7% ($P=0.005$)	24.6 days vs. 20.6 days (not significant)
Dusch et al. [24]	Germany/2013	Ileostomy	PC vs. PSA	41 vs. 43	ND	ND	24% vs. 0% ($P=0.0004$)	NA
Camacho-Mauries et al. [26]	Mexico/2013	Ileostomy/ colostomy	PC vs. PSA	30 vs. 31	ND	ND	36.7% vs. 0% ($P<0.0001$)	5.9 weeks vs. 3.8 weeks (mean, $P=0.0002$)
Lee et al. [25]	USA/2014	Ileostomy (86) /colostomy (27)	PC vs. PSA	55 vs. 58	ND	ND	15% vs. 2% ($P=0.01$)	24.1 days vs. 34.6 days (mean, $P=0.02$), 85% vs. 79% (Healing rate at 30 days, $P=0.54$)
Lopez et al. [20]	Philippine/2015	Ileostomy/ colostomy	PC vs. PSA	60 vs. 61	No (ileostomy), yes (colostomy)	No	10.0% vs. 1.6% ($P=0.06$)	NA
O'Leary et al. [27]	Ireland/2017	Ileostomy	PC vs. PSA	27 vs. 34	ND	ND	30% vs. 8% ($P=0.03$)	NA
Current study	Japan	Ileostomy/ colostomy	PCD vs. PSA	79 vs. 80	Yes	Yes	8.9% vs. 4.9% ($P=0.35$)	92.4% vs. 62.5% (healing rate at 30 days, non-inferiority not ascertained)

PC primary closure, *PCD* primary closure with a drain, *PSA* purse-string approximation, *ND* not described, *NA* not assessed

PSA leaves a small opening to allow continuous drainage of exudative and suppurative fluid from the grossly contaminated wound in the early postoperative period, preventing the development of symptomatic infection and allowing seamless granulation tissue formation and epithelialization of the opening over several weeks [23]. The 30-day incidence of SSI of 5% in our PSA group is consistent with the range of 0% − 8% in the previous six trials [20, 23–27]. Conversely, the 30-day incidence of SSI at the stoma site in the PC group (10–39%) was significantly higher than that in the PSA groups of the previous six trials.

The reason for the low incidence of wound infection (8.9%) in our PCD group is unclear, but probably not attributable to the placement of a Penrose drain for the first 2 PODs. We know of only one randomized trial comparing PCD and PC for stoma reversal surgery [9]. In that study, Berne et al. [9] prospectively compared PC ($n=38$), PCD ($n=29$), and delayed PC in patients undergoing colostomy reversal. The incidence of wound infection at the colostomy site was 2.6% in the PC group, 3.4% in the PCD group, and 7.8% in the delayed PC group. The results of our PCD group were similar to those reported by Berne et al., suggesting that placing a drain is unlikely to contribute to a reduction in the incidence of SSI at the stoma reversal site. It is notable that all patients underwent mechanical bowel preparation and antimicrobial prophylaxis with kanamycin and erythromycin in this study. We speculate that the low SSI incidence in the PCD group can be explained by the preoperative bowel preparation and oral antimicrobial prophylaxis, both of which could have influenced the outcome, since none of the previous six trials provided sufficient information about preoperative bowel preparation or antimicrobial prophylaxis.

It may be argued that the initial scar formation with multiple radial skin creases after PSA is esthetically unappealing [28]; however, Tremolada et al. [29] reported that the final scar formation occurs along natural skin tension lines, which is cosmetically pleasing. Most of our patients who underwent PSA were left with only a pin-point scar, although some patients who were followed up for a long time had persistent radial scars. Further data need to be collected in this regard.

Reid et al. [23] pointed out that fascial closure can be occasionally difficult when the PSA procedure is performed in patients with a thick abdominal wall because of the limited access. Although the traditional incision can be extended at either end, the PSA approach may hamper access and adequate closure, and increase the risk of incisional hernia, but this can be avoided by horizontal extensions of the incision at the 3- and 9-o'clock positions. On the other hand, this can result in a larger 'open' defect.

The time required for wound healing is an important topic for discussion in relation to PSA. Williams et al. [30] reported concern about the longer wound healing period and the increased medical costs of PSA. For patients undergoing this procedure, it is imperative to keep the wound clean at home by washing it regularly with soap and water. Three randomized trials compared wound healing at the stoma site between patients undergoing PSA and those undergoing PC. Reid et al. [23] found no significant difference in the healing time between the two groups (mean, 20.6 days in the PSA group vs. 24.6 days in the PC group), whereas Lee et al. [25] reported that the complete healing time was significantly shorter in the PC group than in the PSA group (mean, 24 days vs. 35 days, $P=0.02$), although the incidence of delayed healing (> 30 days) did not differ significantly between the two groups (21% in the PSA group vs. 15% in the PC group; $P=0.54$). A prospective non-randomized trial by Yoon et al. [31] found that the time to complete healing was significantly shorter in the PC group than in the PSA group (mean, 18.6 days vs. 32.1 days, $P<0.001$). Our results regarding wound healing in the two groups agree with those reported by Yoon et al. [31], and also partly with those reported by Lee et al. [25].

How satisfied patients are with their surgical scars is important, but was out of the scope of this study, and not evaluated. The methods for evaluation of their level of satisfaction after stoma reversal seem to be difficult to standardize and few randomized or non-randomized studies have focused on this issue. A randomized trial by Camacho-Mauries et al. [26] revealed that 70% of patients who underwent PSA were very satisfied, according to a visual analog scale (VAS), vs. 20% of those who underwent PC ($P=0.0001$). O'Leary et al. [27] analyzed patient satisfaction 30 days and 6 months after surgery in their randomized trial and reported no significant difference between the two groups in terms of the mean quality of life score ($P=0.5$) or the mean cosmetic satisfaction score ($P=0.14$). Yoon et al. [31] reported from their non-randomized trial, that there were no significant differences in the patients' satisfaction with the appearance of the scar, severity of postoperative pain, difficulty with wound care, or limitation of activities between their PSA group and their PC group. Further studies using optimal standardized methods are needed to address issues such as patient satisfaction after stoma reversal by different stoma reversal procedures.

Conclusions

This prospective randomized trial could not prove non-inferiority of PSA to PCD in terms of the incidence of wound healing at the stoma site 30 days after stoma reversal. The 30-day incidence of SSI at the stoma site did not differ significantly between the PSA group and the PCD group. These results may be attributable, at least in part, to the use of standardized perioperative management procedures,

including mechanical bowel preparation and antimicrobial prophylaxis, but further research is needed to establish definitive conclusions. Our results suggest that PCD may remain as the standard procedure for stoma reversal surgery.

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Compliance with ethical standards

Conflict of interest We have no conflicts of interest to declare.

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