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A Randomized Controlled Clinical Trial Comparing the Outcomes of Circumferential Subcuticular Wound Approximation (CSWA) with Conventional Wound Closure After Stoma Reversal: An Interim Report

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The creation of a stoma is commonplace in colorectal surgery. Circumferential subcuticular wound approximation (CSWA) is a method of wound closure following stoma reversal proposed by Milanchi, et al. It has been reported to result in decreased wound infection rates and more desirable aesthetic outcomes. The authors aimed to determine the effectiveness of the CSWA method, in terms decreasing wound infection, and cosmesis by comparing the technique with the conventional method of wound closure.

Methods: All adult patients who presented for stoma reversal at the outpatient clinic of the Division of Colorectal Surgery at the University of the Philippines-Philippine General Hospital (UP-PGH) were randomized into two groups, CSWA and conventional, and their stomas cloud accordingly. Patients were followed up for one month, with photographic documentation of wound appearance and estimation of wound infections and complications. Patients were asked to complete a satisfaction survey at the end of the follow-up period.

Results: Sixty-two patients have been recruited since the start of the study, representing more than one-third of the computed sample size. Fifty-six patients were able to complete the one-month follow-up. No wound infection was documented for the CSWA arm, while 3 (11.11%) patients had a wound infection in the conventional arm (P=0.1055). Patients in the CSWA group had a higher overall satisfaction score (25.3 vs 23.6), but this did not carry statistical significance (P = 0.0749).

Conclusion: Performing the CSWA method resulted in a lower wound infection rate as compared to the conventional method of wound closure after stoma reversal. Patients who underwent CSWA were found to be more satisfied with the appearance of their wound. These initial results show that the CSWA method remains a viable option in wound closure after stoma reversal.

Key words: wound infection, ileostomy closure, colostomy closure, circumferential subcuticular wound approximation

The creation of a stoma is commonplace in colorectal surgery. Restoration of enteral continuity during stoma closure, however, may be fraught with complications. Apart from the possibility of anastomotic leaks, abscess formation and stricture development, wound infections after primary skin closure are common. Ileostomy closure is reported to have a 30 percent infection rate.[1] Closure of colostomies, on the other hand, portend greater wound infections due to the expectedly less sterile environment. Secondary closure may address the problem of wound infection but may compromise aesthetic results.

Milanchi, et al. proposed circumferential subcuticular wound approximation (CSWA) as a means of decreasing wound size leading to faster healing by secondary intent and a more aesthetic outcome.[2] A similar method was initially described by Banerjee in 1997.[3]

This study aimed to validate the use of the CSWA method after stoma closure by comparing infection and cosmesis-related outcomes to that of conventional closure.

The general objective of the study was to determine the effectiveness of the CSWA method for wound closure after stoma reversal in our setting. Specific objectives were to document time to complete epithelialization of wounds closed using the CSWA method, and document complications associated with the technique. Furthermore, the authors aimed to compare the wound infection rates and aesthetic results, as evaluated using a patient satisfaction scale, between

the CSWA and the conventional method of wound closure after stoma reversal. The study was approved by the IRB.

Methods

Inclusion and Exclusion Criteria

All adult patients (18 years and above) who sought consult for stoma reversal at the Outpatient Department (OPD) clinic of the Division of Colorectal Surgery were included in the study. All forms of stoma closure were included. Patients who did not provide consent were excluded from the study.

Sample Size

The computed sample size was 130 stoma closures, 65 of which were to undergo stoma closure using the CSWA method, and the other 65 using the conventional method (primary skin closure). This took into account a 10 percent dropout rate. This was computed using Fisher's exact test, with a level of significance of 0.05 and a 0.8 power of the test. The sample size was computed using the expected postoperative wound infection rate as the primary outcome. This was found to be 12.6 percent, at PGH, for the conventional method in 2009.[4] For the CSWA group, postoperative wound infection was set as 0 based on previous studies.[2] Dropouts were not replaced with new patients, and were documented accordingly. From February 1 to December 31, 2011, 56 patients had already completed the one-month follow-up period. This number is more than one-third of the required sample size.

Randomization

One hundred thirty brown envelopes, half of which were pre-marked "CSWA" and the other 65 "conventional" were shuffled and dispensed in the sequence they were arranged after shuffling. All patient records were kept in the envelope.

Perioperative Care and Technique of Surgery

Patients for ileostomy closure were not required to undergo any form of bowel preparation, and were placed on NPO six hours prior to surgery. Patients undergoing colostomy closure, including reversal of Hartmann's, were given two (2) 45mL doses of Monophasic sodium phosphate/Diphasic sodium phosphate (Fleet phosphosoda®, Blooming Fields Phils., Inc.) in the morning and evening prior to surgery and underwent distal colonic irrigation. Prophylactic intravenous antibiotics were administered prior to incision. No further doses of antibiotics were given, unless gross spillage occurred.

Stoma closures were performed either by a Colorectal Surgery consultant, a Colorectal Surgery fellow, or a General Surgery resident. Skin closures for the CSWA group were performed either by a Colorectal Surgery consultant or fellow only. Diet progression was dictated by the primary surgeon as guided by an enhanced recovery pathway espoused by the Division.

The wounds of the patients were managed according to the CSWA method proposed by Milanchi, et al.[2] A circular incision was made along the mucocutaneous junction in paring the bowel away from the skin. Afterwards, the stoma was taken down, and end-to-end anastomosis was performed by handsewn (Gambee) technique, or side-to-side anastomosis using linear staplers. For reversal of Hartmann's end-to-end handsewn or a double-stapling anastomosis with a CEEA stapler was utilized. Fascial closure was performed with an absorbable braided suture using a continuous stitch. (Figure 1) Wound closure using the conventional method was performed using interrupted non-absorbable sutures. (Figure 2)

For patients in the CSWA group, the skin was partially closed using an absorbable monofilament suture placed circumferentially (similar to a purse-string suture) along the wound edges, and along the subcuticular plane. This left a circular void which was plugged by a piece of rolled gauze immersed in povidone iodine. The gauze was removed 48 hours postoperatively. The original paper recommended that the "wound (be) covered until healed and dry." In this study, the patients were advised to wash the wound with soap and water and apply

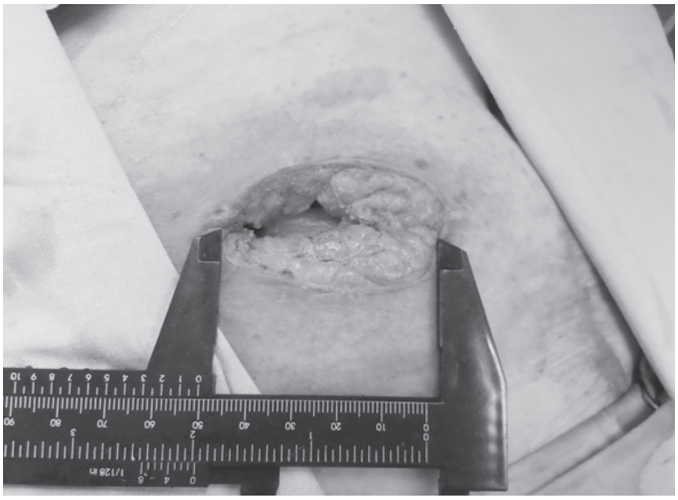

Figure 1. Wound after stoma takedown incision along mucocutaneous junction, anastomosis and fascial closure in a 68 year old female who underwent closure of ileostomy. UP-PGH, 2011.

Figure 2. Wound appearance after conventional closure (immediate postoperative period). UP-PGH, 2011.

povidone iodine to the site. The wound site was then covered with a light gauze dressing. In the original study by Milanchi, et al.[2] the recommended ideal diameter of the remaining defect was 0.5 cm.

Follow-up

Digital photographs of the wound were taken during the immediate postoperative period (Figure 3), upon removal of the gauze on the 48th hour after surgery (Figure 4), prior to discharge or upon first follow-up (Figure 5), and at one month postoperatively. The size of the defect was measured using a caliper at the time the digital photographs were taken. Surgical and non-surgical complications were documented. Blinding was not possible since it was obvious to the assessor that the patient underwent closure using either the CSWA or the conventional method. On follow-up at one month after the procedure, patients were interviewed to assess their satisfaction in terms of wound healing.

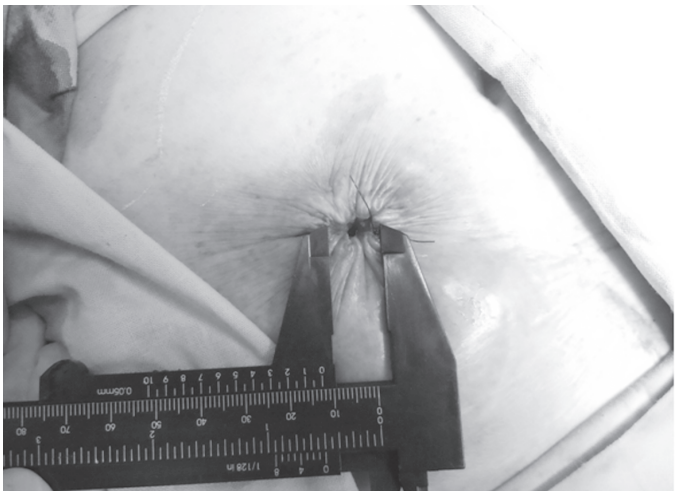

Figure 3. Wound appearance after circumferential subcuticular wound approximation (immediate postoperative period). Size of defect = 6 mm. UP-PGH, 2011.

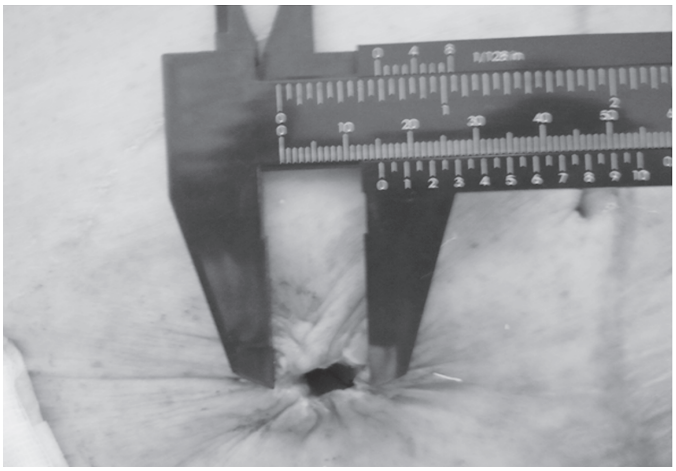

Figure 4. Wound appearance after circumferential subcuticular wound approximation (48 hours postoperatively). Size of defect = 8mm. UP-PGH, 2011.

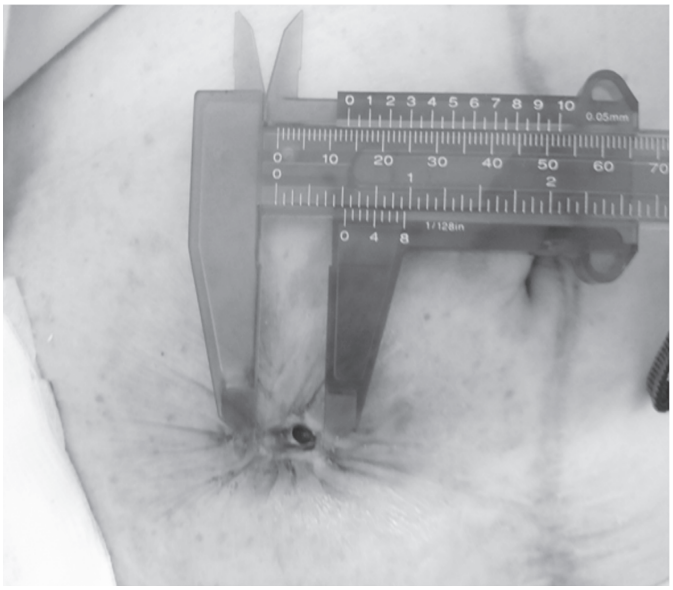

Figure 5. Wound appearance after circumferential subcuticular wound approximation (2 weeks postoperatively). Size of defect = 8mm. UP-PGH, 2011.

The following definitions of terms were used in reporting outcomes:

Epithelialized wound - the state of the previous stoma site wherein the initial circumferential gap has been covered by skin.

Complication/Morbidity - any untoward incident (surgical or medical event) that occurs during the patient's hospital stay (in-patient morbidity) or until 30 days after the surgery was performed.

Wound infection - evidenced by erythema, pain, swelling or presence of discharge around or at the previous stoma site or incision site (for those with a separate midline incision, or trocar insertion sites for those undergoing laparoscopic reversal of Hartmann's).

Patient satisfaction score - a value from 6 to 30 based on a satisfaction questionnaire that measures the following factors: scar appearance, expectations regarding the scar, level of postoperative pain, time to wound healing, ease or difficulty of wound care and limitation of activity caused by the healing wound. A higher score indicates better results.

Statistical Analysis

Pertinent demographic data were reported in terms of frequency and proportion, or by measures of central tendency (mean or median and range) as deemed applicable. Statistical analysis was performed using comparison of means (paired t-test), with a P-value of less than 0.05 considered statistically significant (95% confidence). Infection rates were compared using Fisher's exact test, with a P-value of less than 0.05 considered statistically significant.

Results

Sixty-two patients were enrolled from February 1 to December 31, 2011. Of these, 6 (9.68%) were unable to complete the one-month follow-up and were not included in the data analysis. Of the remaining 56 patients, 29 were in the CSWA arm and 27 were in the conventional arm. The baseline characteristics of the two groups are shown in Table 1.

Other reasons for bowel exteriorization in the CSWA arm were: small bowel obstruction from endometriosis, postoperative adhesions, penetrating trauma, gastrointestinal tuberculosis, sigmoid volvulus, stercoral perforation and appendiceal mucocoele. Other reasons for exteriorization in the conventional arm included: postoperative adhesions, penetrating trauma, blunt trauma, gastrointestinal tuberculosis, stercoral perforation, sigmoid and ileal volvulus, and neuroendocrine tumor. Possible risk factors are listed in Table I. In the CSWA arm, 15 patients (51.72%) had only 1 risk factor, 5 (17.24%) had 2 risk factors, 4 (13.79%) had 3 risk factors, and 5 (17.24%) had no risk factors. For the conventional arm, 6 patients (22.22%) had 1 risk factor, 8 (29.63%) had 2 risk factors, 2 (7.41%) had 3 risk factors, and 11 (40.74%) had no identifiable risk factors.

Three (11.11%) patients in the conventional arm developed superficial surgical site infection (SSSI). None of the patients in the CSWA arm developed wound infections.

Three patients had anastomotic leaks-one in the CSWA arm (3.45%), and 2 in the conventional arm (7.41%). The patient who had an anastomotic leak in the

CSWA arm underwent re-exploration and limited right hemicolectomy on his 6th postoperative day. The stoma closure site was still open 1 month postoperatively, but was free from infection. The wound was epithelialized at 2 months follow-up. The two patients in the conventional arm had anastomotic leaks that were converted to controlled fistulas. Both had spontaneous resolution by the first month after stoma reversal.

The patient satisfaction scores are shown in Table 2.

Table 1. Baseline characteristics of patients undergoing CSWA and conventional skin closure after stoma reversal. UP-PGH, February-December 2011.

Patient Age	CSWA (n = 29)	Conventional (n = 27)	P-value
Mean	51.28	46.07	0.2044
Range	20 to 72	21 to 79	
Gender			
Male	18 (62.07%)	17 (62.96%)	
Female	11 (37.93%)	10 (37.04%)	
Time from First Operation			
6 to 10 weeks	1 (3.45%)	0	
10 to 14 weeks	2 (6.90%)	1 (3.70%)	
14 to 22 weeks	1 (3.45%)	2 (7.41%)	
> 22 weeks	25 (86.20%)	24 (88.89%)	
Underlying Disease			
Colon cancer	6 (20.69%)	4 (14.81%)	
Rectal cancer	12 (41.38%)	6 (22.22%)	
Perforated non-specific enteritis/colitis	0	1 (3.70%)	
Perforated tuberculous ileitis	3 (10.84%)	1 (3.70%)	
Others	8 (27.59%)	15 (55.56%)	
Risk Factors for Infection			
None	6	11	
Malignancy	18	11	
Pelvic radiation	5	8	
Diabetes mellitus	3	0	
Cardiovascular disease	4	2	
Smoking	5	4	

Table 2. Patient satisfaction scores after CSWA and conventional wound closure after stoma reversal. UP-PGH, February-December 2011.

	CSWA (n = 29)	Conventional (n = 27)	P-value
Overall cosmesis	4.621	4.481	0.5095
Expectations regarding the scar	3.724	3.333	0.0943
Level of postoperative pain	4.483	4.037	0.1606
Rate of wound healing	3.724	3.444	0.3828
Ease or difficulty in wound care	4.517	4.481	0.8616
Effect on activities of daily living	4.207	3.852	0.1974
Total	25.276	23.630	0.0749

Discussion

A loop ileostomy or loop colostomy is commonly utilized as a means to temporarily defunctionalize a distal anastomosis and reduce possible anastomotic complications.[1,2,5] Temporary exteriorization after bowel resection is frequently seen in our setting particularly in undernourished patients where a primary anastomosis is not deemed safe. Reversal of stomas, is not without complications, the most common of which is wound infection. Previously reported data place the infection rate after ileostomy reversal at 2 to 41 percent, with a mean of 10 percent.[1,2] On the other hand, overall wound infection rate for colostomy closure was reported at 15 percent.[6] Colostomy reversal portends higher post-operative infection rates owing to their less sterile environment. The majority of wound infections are successfully treated conservatively with no further complications arising. Severe wound infections, however, result in increased morbidity and hospital expenses, prolonged hospital stay, and more frequent outpatient consults.[2] Severe wound infections are noted in 5 percent of ileostomy closures.

In an attempt to address wound complications after stoma closure, several quarters have espoused the use of delayed primary closure[7] or secondary skin closure.[1] Lower rates of wound infection have been documented

with these methods.[1] However, cosmetic outcomes are less than desirable.[2]

Lahat, et al. however, actually reported higher rates of wound infection when delayed primary closure is employed.[1] Secondary closure, on the other hand, has been widely-used historically as a means of preventing wound infection in contaminated and dirty wounds. Although the method has greatly decreased the occurrence of wound infections after stoma closure,[2,3,8] the downside to its utilization includes: patient discomfort, wound care-associated costs, increased wound healing time and less than desirable aesthetic outcomes.[2] The use of antibiotic implants has also been proposed as a means of decreasing postoperative infection,[9] but has not gained popularity.

The use of purse-string skin closure in approximating the wound edges and decreasing the wound gap[3,8] addresses the issues of wound infection and cosmetic result. The method has been referred to by Milanchi, et al.[2] as CSWA. The technique involves creating a circular incision along the mucocutaneous junction instead of the usual elliptical incision. Closure of the stoma proceeds in the conventional manner with mobilization and excision of the stoma, anastomosis and fascial closure. The original technique used a running subcuticular 2-0 monocryl suture placed circumferentially around the wound, leaving a 5-mm circular gap.[2]

A method similar to the CSWA was initially described by Banerjee,[3] who used 2-0 polypropylene sutures to appose the skin defect in a purse-string fashion. The defect allowed for the drainage of residual hematoma and wound exudates. The non-absorbable sutures were removed 8 to 10 days after surgery. Excellent healing and cosmetic results were reported in "more than 20 patients." Ninety percent of the patients achieved complete healing at 8 weeks, the remaining had complete healing at 3 months.[3]

In a separate study by Reid, et al.[10], 61 patients undergoing ileostomy closure were randomized into conventional or purse-string closure, with the primary outcome being the incidence of surgical site infection. Purse-string closure was found to result in fewer surgical site infections as compared to conventional closure (6.7% of patients in the purse-string group versus 38.7% of patients in the conventional group, $P = 0.005$).[10]

All the previous studies using purse-string closure, only included patients undergoing ileostomy closure. We ventured to investigate if such results may be duplicated in patients with colostomies where the environment is expectedly less sterile, and the stoma trephine larger. There being no surgical site infection in this study thus far, there seems to be no difference in terms of infection in ileostomy vs colostomy patients. The less sterile milieu that the large bowel provides, in fact, makes the CSWA a more appropriate method of wound closure to allow for the drainage of potentially infective exudates. For the CSWA group, initial wound size ranged from 6 to 21 mm. Between ileostomy (mean initial size of 9.24 millimeters) and colostomy (11.17 millimeters) closures, there was no statistical difference in mean initial wound size ($P = 0.2381$). There were 8 patients (25.79%) who had wounds that did not reach complete epithelialization at one month. Four of these had colostomy closure and the other 4 had ileostomy closure. These patients were followed-up and epithelialization was noted in 6 to 8 weeks' time. Figures 8 and 9 show the wound appearance of one of these patients. It would then seem that the ideal wound size of 5mm after CSWA may be foregone especially if attempts to attain it would only lead to increased suture tension, and the possibility of skin necrosis and suture breakage. The authors also did not observe a difference in the initial size of wound defects after CSWA in patients who underwent emergency diversion due to obstruction, despite expectedly larger trephines due to the dilated and edematous bowels. It may, therefore, be safe to conclude at this point that the CSWA is applicable to all forms of stoma regardless of bowel segment involved, trephine size and indication for diversion.

For the 8 patients who still had non-epithelialized wounds at 1 month, mean satisfaction score (25.88/30) was comparable to the total mean satisfaction score for the entire CSWA arm (25.28/30).

Available data from the Division of Colorectal Surgery show that among the reversals performed in 2009, 12.6 percent of patients had a postoperative wound complication.[4] Studies have failed to elucidate the factors that account for the high infection rates

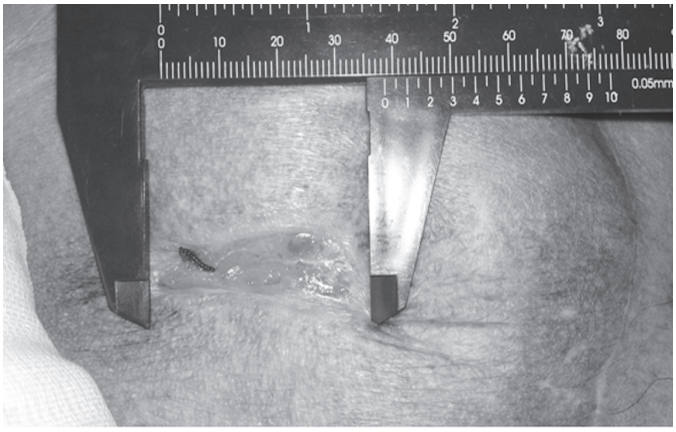

Figure 8. Wound appearance after circumferential subcuticular wound approximation (1 month postoperatively) in a 51 year old male patient who underwent colostomy closure. UP-PGH, 2011.

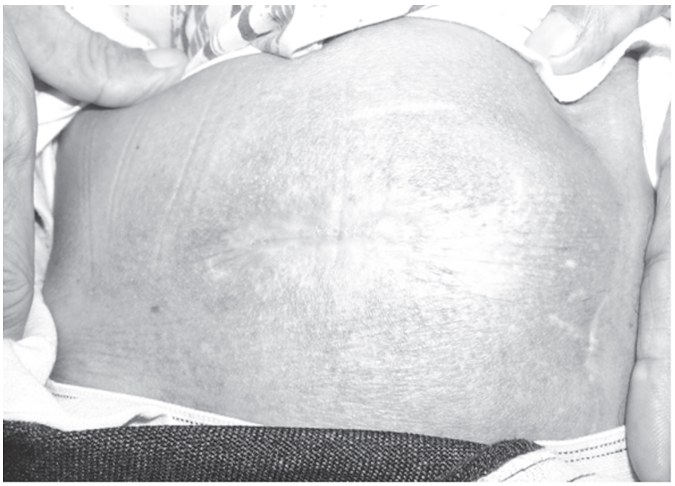

Figure 9. Wound appearance after circumferential subcuticular wound approximation (2 months postoperatively). UP-PGH, 2011.

accompanying stoma closure. Association with low body mass index (BMI), previous cancer surgery, steroid use, anemia or blood transfusion have failed to account for the high rates of wound infection after closure of ileostomy.[11] Bacterial contamination of the parastomal skin has been implicated to play a role in the high infection rates.[9] In this study, the authors have tried to identify possible risk factors for infection. They incurred an 11.11 percent wound infection rate (3 out of 27 patients) for patients who underwent conventional wound closure. They could not make a correlation between risk factors and wound infection rate because the 3 patients had varying risk factors, and different underlying diseases for which exteriorization was initially performed. The first patient was a smoker, the second had malignancy and smoking, and the third had malignancy and pelvic irradiation. The first patient underwent exteriorization for penetrating abdominal trauma, the second for colon cancer, and the third for rectal cancer.

The decrease in wound infection rates using the CSWA method may be attributable to the fact that it allows for drainage of potentially infective material. A slight decrease in wound infections using the conventional method compared to previous institutional data was observed. This may be explained by improved operative techniques, particularly closer regard for operative field sterility. A standardized protocol dictated by the study methodology, protection of wound from contamination, tissue handling, and mandatory subcutaneous washing may have contributed to a decrease in wound infections using the conventional method. Furthermore, closer supervision of the Colorectal Surgery consultants and fellows of the less experienced surgeons may have contributed in improved outcomes. This is an interesting aspect that the authors may have to delve in further as they complete the study, and perhaps, isolate the factor or factors that contributed to such an outcome in a separate study.

The authors observed an expected slight increase in wound size from the immediate postoperative period to 48 hours to a week postoperatively in patients in the CSWA group. This increase in size ranged from 1 to 4 mm (mean: 1.4 mm). The almost negligible increase in size is likely attributable to resolution of tissue edema accompanying the process of wound healing.

Satisfaction scores for both arms were tallied at the end of the one-month observation period (Table 2). Questions addressed were: overall wound cosmesis, expected scar appearance, pain control, rate of wound healing, ease or difficulty in caring for the wound, and how the wound affects activities of daily living. For all questions, CSWA scores were better as compared to those of the conventional method. However, the differences in scores were not found to be statistically significant.

Conclusion

Decreased wound infection rates and higher patient satisfaction scores were observed in patients who underwent CSWA compared with those who underwent conventional wound closure. Although these did not reach statistical significance, the early results of this trial show that CSWA remains a viable option for wound closure after stoma reversal.

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