ORIGINAL ARTICLE

Primary versus secondary closure of stoma reversal skin wound: Randomized controlled trial

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Abstract

Objective: To compare the efficacy of primary versus secondary closure of stoma reversal skin wound in terms of wound infection.

Method: The study was conducted at Surgical B Unit of Ayub Teaching Hospital, Abbottabad, Pakistan, from January 1 to December 31, 2020, and comprised adult patients of either gender undergoing stoma reversal. The patients were randomised into primary closure group A and secondary closure group B. Surgical procedure was similar in both the groups except the skin closure technique. In group A, skin was closed with interrupted polypropylene sutures, while in group B, wound was dressed with saline-soaked gauze daily using aseptic technique and was allowed to heal by secondary intention or delayed primary closure later on. Postoperatively, the wound was assessed for infection till 30th postoperative day or complete wound healing. Data was analysed using SPSS 16.

Results: Of the 50 patients, 35(70%) were males and 15(30%) were females. The overall mean age was 28±1.65years. There were 25(50%) patients in each of the two groups. There were 19(76%) males and 6(24%) females in group A with a mean age of 32±2.8years. There were 16(64%) males and 9(36%) females in group B with a mean age of 23±3.5years. Overall, 10(20%) patients had wound-site infections; 9(36%) in group A versus 1(4%) in group B (p=0.005). Frequency of wound infection with respect to gender, type of stoma and length of hospital stay was not significant (p>0.05).

Conclusion: Secondary skin closure was found to be associated with significantly reduced wound infection rate after stoma reversal.

Clinical Trial Number: NCT04785404.

Link: https://clinicaltrials.gov/ct2/show/NCT04785404

Keywords: Stoma reversal, Primary closure, Secondary closure, Wound infection, Ileostomy, Colostomy.

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Introduction

Intestinal stoma is either a temporary or permanent surgically-created opening of bowel onto the body surface for the diversion of bowel contents when primary anastomosis is not suitable.[1,2] The primary goals for stoma-formation are maintaining effective decompression of gastrointestinal tract (GIT) or securing distal bowel anastomosis, in the management of diverticulitis, inflammatory bowel disease, colorectal carcinoma, perforations secondary to trauma, faecal diversion for an open perineal wound or in palliative situations. These temporary stomas are used to alleviate septic complications from anastomotic leaks and to avoid the need for reoperation.[1-4] Stoma itself carries complications, like bleeding, dehydration leading to acute kidney injury, necrosis, retraction, prolapse, stenosis, parastomal hernia and peristomal skin complications.[1,2] Stoma reversal is usually done after 6-12 weeks to allow inflammation from the first surgery to settle, stomal orifice to mature, and adhesions to soften.[5]

Various complications of stoma reversal have been reported,[2] with overall morbidity of 17.3% and mortality rate of 0.4%.[5] The postoperative complications include small bowel obstruction, anastomotic leaks, enterocutaneous fistula, stoma-site hernia further laprotomy and non-surgical complications (pneumonia, deep venous thrombosis [DVT], urinary tract infections [UTIs])[5,6] with infection of wound being the commonest complication.[2,5,7] Literature review shows wound infection incidence of 2-41%.[8,9] Surgical site infections (SSIs) increase the burden of disease, length of hospital stay (LOS), morbidity (wound dehiscence, seroma formation, sepsis, incisional hernia), discomfort and the total cost of treatment.[6,7,10]

Liang et al. proposed four risk factors of wound infection in stoma reversal; history of fascial dehiscence, thicker subcutaneous fat, colostomy, and white race.[6] Other risk factors include raised body mass index (BMI) and smoking, with protective effect (48%) of subcutaneous

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drain placement.[4] As stoma reversal is a clean-contaminated procedure due to peristomal skin housing enteric bacteria, traditionally it should be allowed to heal by secondary intention.[11]

Various techniques have been utilised to close stoma wounds, such as primary linear closure of wound, delayed skin closure, secondary closure, purse-string wound closure, and sub-dermal closure. There is a wide variation in wound infection rates among different techniques in literature.[3,7] Some studies show increased wound infection rates with primary closure,[10,12,13] others reveal increased rates with secondary closure,[8,11] while a few show no significant difference of infection rates between primary and secondary closures. A few studies favoured purse string closure with reduced infection rates.[14] Hence, there is lack of agreement regarding the best approach for closure of the wound after reversal of stoma. Almost all the relevant studies are retrospective in nature. The current randomised controlled trial (RCT) was planned to compare the efficacy of primary versus secondary closure of stoma reversal skin wound in terms of wound infection.

Patients and Methods

The RCT was registered at clinicaltrials.gov. Clinical trial number is NCT04785404.

The study was conducted at Surgical B Unit of Ayub Teaching Hospital, Abbottabad, Pakistan, from January 1 to December 31, 2020. After approval from the institutional ethics review committee, the sample was raised by enrolling all adult patients of either gender undergoing ileostomy or colostomy reversal. Patients with co-morbidities, like diabetes, chronic kidney disease (CKD) and chronic liver disease, those having stoma reversal through laparatomy, and those with post-operative anastomotic leak were excluded. Written informed consent was taken. The subjects enrolled were randomised into two equal groups of primary skin closure group A and secondary skin closure group B using blocked randomisation by creating permuted blocks of 6, like ABABAB.

Elective stoma reversal was performed a minimum of 6 weeks after the primary procedure. Closure of stoma was preceded by contrast radiographic examination (distal loopogram) to evaluate distal bowel integrity. Patients were admitted a day before surgery and kept on clear fluids and a solution of polyethylene glycol was utilised with distal stoma wash with 1 litre normal saline for bowel clearance. Injection ceftriaxone 1gm and injection metronidazole 500mg were given intravenously (IV) before the start of the procedure. The same surgical team performed stoma reversal in both groups using the same technique. Skin was disinfected with 10% povidone-iodine. Surgical technique included an elliptical incision around the stoma. Upon mobilisation of the bowel loops, anastomosis was done with suture using single-layer extra-mucosal interrupted repair. The sheath was closed with continuous polypropylene sutures. In group A, skin was closed with simple interrupted sutures, using polypropylene 2\0. In group B, skin was not closed; rather the wound was lightly packed with saline-soaked gauze daily using aseptic technique for healing by secondary intention or delayed primary closure later on. Until the discharge of patient, the wound was observed daily and after discharge weekly in both groups for 4 weeks. The wound was assessed for infection according to the criteria of the United States Centres for Disease Control and Prevention (CDC)15 till 30 days post-operatively or until complete healing of the site (Table-1).

Table-1: Centres for Disease Control and Prevention (CDC) guidelines for the diagnosis of superficial surgical site infection (SSI).

SrNo	Characteristics of superficial surgical site infection SSI
	(SSI occurs within 30 days of an operation and involves only the skin or subcutaneous tissue surrounding the incision and at least one of the abovementioned characteristics)
1	Purulent drainage, with or without laboratory confirmation, from the superficial incision.
2	Organisms isolated from an aseptically obtained culture of fluid or tissue from the superficial incision.
3	At least one of the following signs or symptoms of infection: Pain or tenderness, localized swelling, redness or heat and superficial incision deliberately opened by surgeon, unless the incision is culture negative.
4	Diagnosis of superficial incisional SSI by the surgeon or attending physician.

Data was collected using a predesigned proforma. The control of bias and confounders were done by strictly implementing the exclusion criteria. Data was analyzed using SPSS 16. Continuous data was represented as mean with standard deviation (SD) and categorical data as frequencies and percentages. Chi-square test was used to analyse categorical data. $P<0.05$ was considered to be statistically significant.

Table-2: Characteristics of patients of stoma reversal according to wound management strategy.

Sr No	Characteristics		Overall	Primary Closure Group	Secondary Closure Group
1	Age (Mean ± SD) in Years		28±1.65	32±2.8	23±3.5
2	Gender:	Male - n (%)	35(70%)	19(76%)	16(64%)
		Female - n (%)	15(30%)	6(24%)	9(36%)
3	Length of hospital Stay (Mean ± SD) in Days		6±1.9	6.4±2.2	5.7±1.5
4	Type of stoma Ileostomy		41(82%)	20(80%)	21(84%)
	Colostomy		9(18%)	5(20%)	4(16%)

SD: Standard deviation.

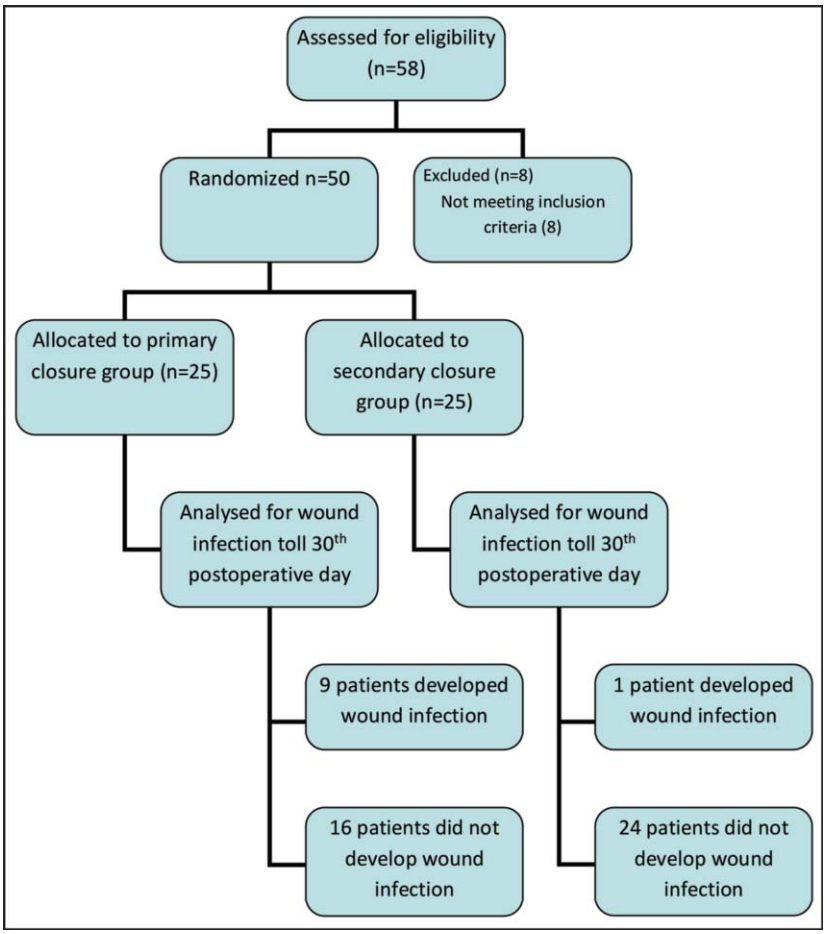

Figure-1: Study flow chart.

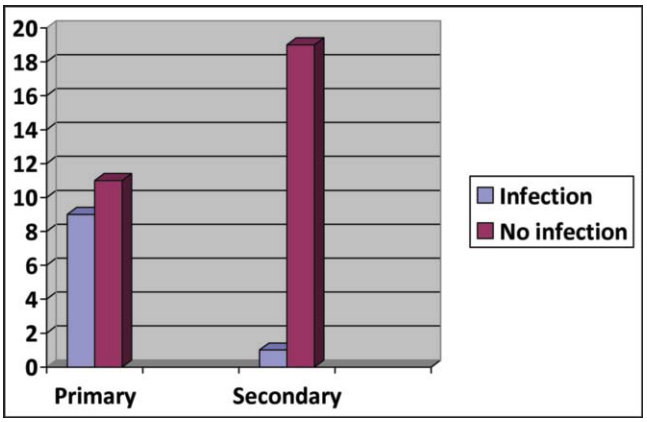

Figure-2: Outcome of stoma reversal patients according to wound management strategy.

Results

Of the 58 patients assessed, 50(86.2%) were enrolled (Figure-1); 35(70%) males and 15(30%) females with mean age 28±1.65years. Overall, 41(82%) patients had ileostomy reversal, while 9(18%) had colostomy reversal.

There were 25(50%) patients in each of the two groups. There were 19(76%) males and 6(24%) females in group A with a mean age of 32±2.8years. There were 16(64%) males and 9(36%) females in group B with a mean age of 23±3.5years (Table-2).

The cause of primary stoma formation was gut perforation secondary to road traffic accident (RTA) 10(20%), firearm injury 8(16%), typhoid perforation 8(16%), colorectal carcinoma 5(10%), intestinal tuberculosis 5(10%), iatrogenic gut perforations in other surgeries 4(8%), strangulated inguinal hernia 3(6%), hirschsprung disease 2(4%), fall 2(4%), sigmoid volvulus 1(2%), gangrenous appendix 1(2%) and assault 1(2%),

Overall, 10(20%) patients had wound-site infections; 9(36%) in group A versus 1(4%) in group B (p=0.005) (Figure-2).

Swab for culture showed positive results in 5(10%) patients, showing growth of pseudomonas (P.) aeruginosa in 2(4%) and escherichia (E.) coli, enterococcus and staphylococcus (S.) aureus in 1(2%) each. In group B, 7(28%) wounds were not closed and left for secondary closure, while 18(72%) wounds were closed on the 4th post-operative day. Mean LOS was 6±1.9 days; 6.4±2.2 days in group A and 5.7±1.5 days in group B (p=0.249). In patients with wound infection, LOS was prolonged 8.6±1.3 days. Out of 41(82%) patients with ileostomy reversal, 7(17%) had wound infection, while out of 9(18%) with colostomy reversal, 3(33%) had wound infection (p>0.05). Moreover, frequency of wound infection with respect to gender and LOS was not significant (p=0.26).

Based on the results, the statistical power of the current study was 89%.

Discussion

Wound infection is the most common complication after stoma reversal.[2,5,7,16] The prolonged contact of bowel contents with bacterial contamination of stoma-site skin is the most common cause of wound infection.[14] In the current study, wound infection rate was 20% overall; 36% in the primary closure group and 4% in the secondary closure group, which was statistically significant. Studies using CDC guidelines had similar overall infection rate (22% and 18%).[10,17] A few studies had a wide range of

wound infection rate, from 2% to 41%.[8,9] Wound infection was more prevalent in primary than secondary skin closure group. This was observed in most previous studies.[10,12,13] Vermulst et al. found 36% versus 5% infection in primary versus secondary skin wound closure after stoma closure.[13] Secondary closure technique is used in treating wounds in contaminated conditions and has shown to reduce the frequency of infection, wound dehiscence, and hernia formation along with reduction in overall LOS.[18] But its drawbacks include more frequent follow-up visits and bigger scar.[19] Studies showing increased infection rates in the secondary closure group mostly did not use CDC guidelines for wound infection definition, used different surgical techniques and had inconsistent use of prophylactic antibiotics.[8,11] A few studies showed increased infection rate in the primary closure group.[8,11] The reasons for this can be different guidelines for wound infection definition, surgical techniques and incoherent use of antibiotics. Another drawback of these studies is their retrospective nature.[2,7] Recently purse-string approximation of skin after stoma reversal showed promising results in terms of wound infection. Klint et al. found that wound infection occurs more frequently in primary linear wound closure than purse-string approximation (17% vs. 5%).[20] Similar results have been reported by others as well.[21,22]

The current study found the most common cause of stoma formation to be intestinal perforation due to RTA (20%), followed by firearm injury and typhoid perforation (16% each). Similar results were found by local studies.[16] But others found colorectal neoplasms to be the most common cause for stoma formation.[17] Mean LOS duration in primary versus secondary closure (6±1.9 vs. 5.7±1.5) was comparable to other studies as well.[7]

Rate of wound infection after ileostomy versus colostomy reversal was not statistically significant, and the findings corroborated those of several other studies.[7,10,11] As both ileostomy and colostomy skin wounds harbour skin microbes at the time of surgery, both may be equally susceptible to infection.[10] The current study further stratified the frequency of wound infection in relation to gender and LOS and did not find statistically significant differences. Similar findings have been reported in other studies.[20-22]

The limitation of the current study is that it did not estimate the sample size owing to paucity of resources as well the low workload of the surgical unit. However, statistical power calculated on the basis of the results was 89%, which is appropriate.

Conclusion

There was significantly reduced wound infection rate with secondary closure than primary closure after stoma reversal. Skin at the stoma site should not be closed after reversal and left for secondary or delayed primary closure.

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Conflict of Interest: None.

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