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3 **Outcome of purse-string versus linear skin closure after ileostomy**
4 **stoma reversal in terms of stoma sites infection and cosmesis**

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11
12 **Abstract**

13 **Objective:** To evaluate the incidence of infection and patient satisfaction in
14 terms of cosmesis between purse-string closure and the usual linear closure of
15 stoma wound.

16 **Method:** The experimental randomised clinical trial was conducted December
17 2017 to December 2018 at the Surgical Unit 1, Lahore General Hospital,
18 Lahore, Pakistan, and comprised patients undergoing ileostomy stoma reversal.
19 The patients were randomised into 2 groups using computer-generated random
20 numbers. Group A underwent purse-string closure, while group B received
21 linear closure. Both groups were followed post-operatively at 1 and 3 months
22 for wound infection. Patient satisfaction was ascertained using standard tools.
23 Data was analysed using SPSS version 20.

24 **Results:** Of the 72 patients, there were 37(51.4%) in group A and 35(48.6%) in
25 group B. Overall, there were 50(69.4%) males and 22(30.5%) females. Infection
26 occurred in 2(5.4%) group A patients and in 8(22.8%) group B patients
27 (p=0.023). Patients in group A were more satisfied at 3 months post-surgery
28 than patients in group B (p=0.001).

29 **Conclusion:** Purse-string closure was found to be associated with a lower
30 incidence of wound infection and higher patient satisfaction compared to linear
31 closure.

32 **Key Words:** Ileostomy, Stoma reversal, POSAS score, SSI, Purse string
33 closure.

34

35 **Introduction**

36 A stoma is commonly used in the management of colorectal cancer surgery,
37 infective bowel diseases, like typhoid, tuberculosis, and inflammatory bowel
38 disease, like ulcerative colitis. Stoma closure is considered a minimally invasive
39 surgery, but complications can occur after stoma closure, including obstruction,
40 infection, necrosis, leakage and iatrogenic incisional hernia [1]. According to a
41 study, temporary stoma reversal after colorectal surgery is associated with
42 complication rates as high as 5% (2).

43 Surgical site infection (SSI) in stoma is a frequent complication after ileostomy
44 closure, with a reported incidence varying from 0% to 41% (3). The most
45 frequent cause of wound infection is bacterial contamination of the skin
46 surrounding the ileostomy / colostomy due to prolonged contact with bowel
47 contents or due to leakage of the ileostomy contents (4). It is associated with
48 increased costs for healthcare services, hospital stays, medications and nursery
49 care, as well as with increased morbidity and reduced quality of life (QOL).
50 Primary linear closure is linked with high rates of SSI, and, therefore, some
51 prefer leaving the wound open. Another modification is the circumferential
52 purse-string (PS) approximation technique, which has been associated with less
53 wound infection and scar formation, as well as with better cosmetic effect and
54 patient satisfaction [5]. The PS technique combines the concept of leaving the
55 wound open to provide drainage and minimise SSIs while still providing some
56 degree of wound apposition to reduce healing time [6]. A study [7] advanced
57 this technique and reported on a short series of successful infection-free

58 ileostomy reversals. The first large meta-analysis investigating PS
59 approximation in comparison to primary skin closure [8] found significantly
60 reduced SSIs for PS closure (PSC).

61 Studies have also concluded that primary closure technique is related to lower
62 wound infection [9, 10], and there was no associated increase in the risk of
63 wound infection [11]. Another study showed that PS circumferential
64 approximation of wound after ileostomy reversal closure significantly reduced
65 SSIs compared to linear closure (LC) without any effect on cosmetics and
66 patient satisfaction [12]. No data in this regard is available for South-Asia
67 population, especially Pakistan.

68 The current study was planned to compare SSI incidence and patient satisfaction
69 in terms of cosmesis in patients undergoing stoma reversal surgery either by
70 circumferential PSC or conventional LC of the wound.

71

72 **Patients and Methods**

73 The prospective, randomised controlled trial (RCT) was conducted at the
74 Department of General Surgery, Lahore General Hospital, Lahore, Pakistan,
75 from December 2017 to December 2018. After approval from the institutional
76 ethics committee, the sample size was calculated at 5% level of significance,
77 80% power of test and an expected percentage of wound infection in PSC 16%
78 and LC 5.6% [13]. Those included were adult patients of either gender who
79 underwent temporary stoma formation secondary to typhoid perforation.
80 Patients aged <18 years, those who had a stoma formation for other pathologies,
81 who died or did not continue the follow-up, and who needed secondary surgery
82 at other centres were excluded. The RCT was registered with ChiCTR
83 (Registration No: ChiCTR1900025624).

84 After taking informed consent from the patients, they were divided into PSC
85 group A and LC group B using computer-generated sheets. Data regarding
86 demographics, including age and gender, co-morbidities, like diabetes mellitus

87 (DM), hypertension (HTN), chronic obstructive pulmonary disease (COPD),
88 ischemic heart disease (IHD) and liver dysfunction, alcohol or cigarette
89 consumption, and medications, including steroids usage, was recorded. All
90 surgeries were performed by consultant surgeons. All patients underwent an
91 ileostomy reversal with a hand-sewn ileo-ileal anastomosis, and rectus sheath
92 closed with interrupted full thickness Prolene-1 sutures. For skin, patients in
93 group B had a conventional skin closure in interrupted manner with Prolene-2/0,
94 and patients in group A had PSC with Vicryl-2/0. Both groups were compared
95 for incidence of SSIs, patient satisfaction in terms of cosmetic, intestinal
96 obstruction/leakage, and hospital stay using the guidelines of the Centres for
97 Disease Control and Prevention (CDC) for the diagnosis of superficial SSI [14]
98 and Patient and Observer Scar Assessment Scale (POSAS)[15]. The assessment
99 was done at 1 and 3 months. Data was analysed using SPSS version 20, and
100 frequencies and percentages were calculated for demographic variables. Chi
101 square test was used to compare qualitative variables, and t test was used to
102 compare quantitative variables. $P < 0.05$ was taken as significant.

103

104 **Results**

105 Of the 72 patients, there were 37(51.4%) in group A and 35(48.6%) in group B.
106 Overall, there were 50(69.4%) males and 22(30.5%) females (Table 1).
107 Infection occurred in 2(5.4%) group A patients and in 8(22.8%) group B
108 patients ($p=0.023$).

109 There was no significant difference in operative time and post-operative
110 complications between the groups ($p > 0.05$). Also the difference in terms of
111 mean hospital stay was also not significant ($p > 0.05$).

112 Patients in group A were more satisfied at 3 months post-surgery than patients
113 in group B ($p=0.001$) though there was no significant difference at 1 month
114 (Table 2; Figure).

115

116 **Discussion**

117 The RCT compared PSC and LC techniques for stoma closure. The
118 demographics of the patients were equally distributed in both the groups And
119 pre-existing co-morbidities and body mass index (BMI) were also similar at
120 baseline. Both the groups were similarly distributed for general characteristics
121 and aetiologies of the stoma formation.

122 The SSI rates were significantly low in the PSC group compared to the LC
123 group. These results are in agreement with recent systemic reviews favouring
124 the PSC technique over LC for stoma reversal in terms of lower SSI rates (16-
125 18). Two studies (6,8) showed significant reduced SSI rates (6.7% and 2.4%) in
126 PSC group compared to LC group (38.7% and 29.6%). In the current study, all
127 patients with SSIs were managed with simple opening of the incision site
128 without any need of re-operation.

129 The 2nd most crucial variable in the current study was cosmesis and patient
130 satisfaction, for which POSAS score was used. The score overall satisfaction at
131 1 month was entirely satisfactory for both the groups, but at 3 months, patients
132 were more satisfied in the PSC group than in the LC group. Like the current
133 study, Camacho-Mauries et al. [15] found higher patient satisfaction scores in
134 the PSC group (70% vs. 20%; $p=0.0001$), but Reid et al. [6] found no
135 differences between the groups. There was a significant difference between the
136 scar length in the two groups (PSC 35mm vs. LC 53mm; $p=0.046$).

137 Studies have reported that the hospitalisation period after ileostomy reversal did
138 not differ according to the wound closure technique [6, 13, 18]. But in the
139 current study, there was reduced hospital stay in PSC group compared to the LC
140 group (4 vs. 6). However, the difference was statistically non-significant. Also,
141 no significant difference was found in mean operative time and other post-
142 operative complications, like anastomotic leak and hernia formation.

143 The limitation of the current study is that it was conducted at a single centre.
144 Besides, the study was underpowered due to a small sample. Finally, the follow-
145 up was limited to 90 days only.

146

147 **Conclusion**

148 After stoma closure, PSC was associated with a lower incidence of wound
149 infection and higher patient satisfaction compared to LC.

150

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152 **Conflict of interest:** None.

153 **Source of Funding:** None.

154

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157 low anterior resection for rectal cancer. *British Journal of Surgery:*
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224 **Table 1: Demographic details and co-morbidities.**

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Demographic Parameters	Purse-string Closure (n=37)	Linear Closure (n=35)	P value
Median age(years)	41.3	45.9	0.887
Male	25(68%)	25(71%)	0.365
Female	12(32%)	10(29%)	0.454

Diabetes	5	4	1
Hypertension	9	7	0.642
Asthma	1	0	1
BMI	23.81	23.76	0.767

226 BMI: Body mass index.

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230 **Table 2: Inter-group comparison.**

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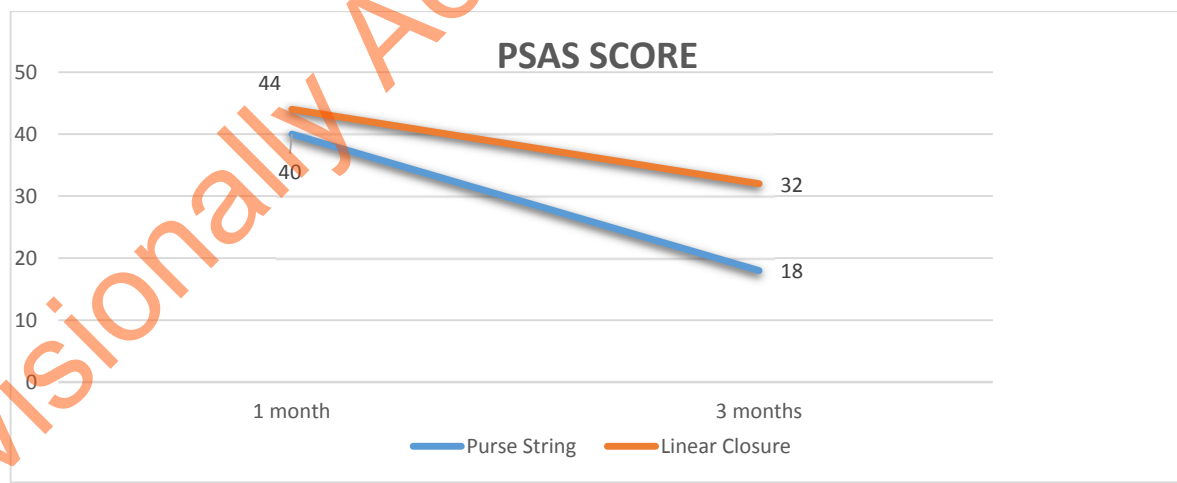
Perioperative Outcome	Purse String Closure (n=37)	Linear Closure (n=35)	P value
Mean duration of surgery(min)	142.3	150	0.889
Mean Hospital stay(days)	5	7	0.076
SSI	2	8	0.023
Anastomotic Leak	0	0	1
Hernia Formation	0	1	0.848
POSAS Score 1 Month	40	44	0.067
POSAS Score 3 months	18	32	0.001

232 SSI: Stoma site infection; POSAS: Patient and Observer Scar Assessment Scale.

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236

237 **Figure: Comparison of Patient Scar Assessment Scale (PSAS) score in both**

238 **groups.**

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