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Comparison Of Primary Versus Delayed Primary Closure Of Stoma: A Prospective Study In A Tertiary Care Hospital

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Abstract
Background: *Stoma closure is a fairly common procedure performed in the general surgery department. Wound infection in a stoma closure wound is also very common. In this study we compare between two different methods of stoma closure*
Methods: *A prospective randomized control trial was carried out in the Department of General Surgery, Medical College Baroda amongst all patients posted for closure of ileostomy or colostomy between June 2019 to November 2020. Approval for study was obtained from the Scientific and Ethical Review Committee of Medical College and Sir Sayajirao General Hospital, Baroda, IECHR-PGR-30/19. Patients were divided into delayed primary group (DPC) and primary closure group (PC) by closed envelop method and compared with respect to wound infection, healing time, length of hospital stay.*
Results: *36 patients were included in the study (18 in each group). 4 patients in the PC group developed SSI compared to only 1 patient in the DPC group. All intra-operative cultures taken after fascial closure were negative in both groups. The average number of dressings required in PC group is 4.6 SD1.4 times while the average number of dressing required in DPC group is 7.7 SD1.3. The average number of days a patient is admitted for stoma closure in the PC group is 16.7 SD4.8 days and is 15.6 SD6.7 days in the DPC group.*
Conclusion: *Primary closure had more SSI's but is better than delayed primary closure in terms of less number of dressings required and shorter wound healing time. Hence primary closure is recommended for closing any stoma.*
Keywords: *Stoma closure, Surgical site infection, SSI*

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I. Introduction

Stoma closure is a very commonly performed surgery with a few complications. Commonest amongst them is surgical site infection (SSI), ranging from 2% to 40%, with an average of approximately 10% [1]. The most frequent cause of wound infection is bacterial contamination of the skin surrounding the ileostomy or colostomy due to prolonged contact with bowel contents or due to leakage of the stomal contents [2-6].

Morbidity following infection includes poor peristomal wound healing, wound dehiscence, and incisional hernia formation at the prior stoma site. SSI is associated with prolonged in-patient stay, increased outpatient visits, additional home health care utilization, and treatment of SSI-related complications such as seromas and incisional hernias [1].

Several closure techniques for stoma wound have been described in published literarure [7]:

- Primary closure
- Primary closure with drain
- Loose primary closure
- Delayed primary closure
- Subcuticular purse string closure
- Secondary closure

The present study was conducted to compare these two common closure techniques for stoma reversal, delayed primary closure (DPC) and primary closure (PC). DPC is commonly used to reduce the wound infection rate. It can be used when two contaminated or dirty wounds are created, allowing the soft tissues to drain (thus preventing accumulation of micro-organisms in a confined space) before closing the skin a few days later. PC is defined as fascial and skin closure with sutures or staples at the same time. DPC is defined as the closure of

fascia done first with the skin closed 48 -72 hours later with sutures. There is no consensus as to the optimal method of stomal closure [8].

II. Patients and Methods

A prospective randomized control trial was carried out in the Department of General Surgery, Medical College Baroda amongst all patients posted for closure of ileostomy or colostomy between June 2019 to November 2020. Patients who underwent concurrent separate abdominal surgery or developed anastomotic leak in the post-op period were excluded from the study.

Patients were divided into delayed primary group (cases) and primary closure group (control) by closed envelop method. Approval for study was obtained from the Scientific and Ethical Review Committee of Medical College and Sir Sayajirao General Hospital, Baroda, IECHR-PGR-30/19.

All ileostomy closure patients were given clear liquids the day before surgery. Ceftriaxone (1 gm for adults and 50 mg/kg/dose for paediatric) was given as pre-operative intravenous antibiotic 30 minutes before skin incision. A circumferential incision was made around the stoma, bowel loops were mobilized up to the level of the peritoneum and a stapled or hand sewn anastomosis was performed. Fascial closure was done by interrupted No. 1 PDS suture.

All colostomy closure patients were given clear liquids the day before surgery, along with one packet of polyethyleneglycol (peglec) reconstituted in one litre of water the evening before surgery over a period of 2 hours as a bowel preparation. Ceftriaxone (1 gm for adults and 50 mg/kg for paediatric age group) and metronidazole (500 mg for adults and 15 mg/kg in paediatric group) was given as pre-operative intravenous antibiotic 30 minutes before the skin incision. A circumferential incision was made around the stoma, and bowel loops were mobilized up to the level of the peritoneum followed by a stapled or hand sewn anastomosis. Fascial closure was done using interrupted No. 1 PDS suture.

All patients after fascial closure were randomised into two groups. Group 1 contained patients in whom the skin was closed primarily, and group 2 contained patients in whom skin wound was kept open for DPC.

A. Primary Closure:

Intra operative swab cultures were taken after closing the fascia and sent for culture sensitivity. Povidone iodine 5% solution wash was given after closing the fascia. Skin was closed with Nylon 2-0 sutures. If the wound became infected (redness, fever and discharge from wound present), discharge was sent for culture sensitivity, and sutures were opened to drain the collection and antibiotics were changed according to culture sensitivity report. Re-suturing was performed according to requirement.

B. Delayed Primary Closure:

Intra-operative swabs were taken after closing the fascia and sent for culture and sensitivity. Povidone iodine 5% solution wash was given after closing the fascia and skin was kept open. Normal saline dressing was done daily. DPC was performed under local anaesthesia for adults and under general anaesthesia for pediatric patients. In case the wound had purulent discharge or slough the frequency of dressing was increased and the closure delayed. Swab for culture and sensitivity from such wounds was sent daily till closure.

Statistical analysis was carried out using Medcalc application and Microsoft Excel software. To examine the statistical significance of differences between two sets of qualitative data, the chi-square test was used, whereas for quantitative data, the unpaired t-test was utilized. A p-value <0.05 was considered significant. Continuous variables were expressed as mean (standard deviation [SD]).

III. Results

This prospective randomized case control study was carried out in Department of General Surgery, Medical College Baroda between June 2019 and November 2020. The expected sample size was 48 but due to the COVID-19 pandemic only 36 patients were enrolled, 18 each in PC and DPC groups.

Mean age of patients in the PC group was 26.3 years while it was 29.4 years for the DPC group. The demographic distribution of our study population has been illustrated in Table-1. The PC group had 62.5% men compared to 78% in the DPC group. One patient in the PC group had diabetes melitus and one had hypertension. All other patients did not have any co-morbidities. 33.33% of the stomas were made for congenital reasons, like anorectal malformations, in the PC group while in the DPC group it was 16.7%. The acquired reasons for stoma creation were majorly perforations or ischemic bowel for which resection anastomosis was done. The PC group had 9 each of ileostomies and colostomies while the DPC group had 11 ileostomies and 7 colostomies. There were 12 hand sewn anastomosis in the PC group compared to 6 in the DPC group, while there were 6 stapler anastomosis in the PC group compared to 12 in the DPC group.

In the PC group, 4 patients developed SSI compared to only 1 patient in the DPC group. Amongst the 4 patients in the PC group who developed SSI, 1 was after ileostomy closure and 3 after colostomy closure as

shown in Table-2. In the DPC group only one patient developed SSI in ileostomy closure. Wound culture of the PC group patients with SSI's grew, E. coli, Klebsiella and Acinetobacter in 3, 2 and 1 patients respectively as shown in Table-3. In the DPC group, the culture showed Acinetobacter in a single patient with SSI after fascial closure. All intra-operative cultures taken after fascial closure were negative in both groups. The average number of dressings required in PC group is 4.6 SD1.4 times while the average number of dressing required in DPC group is 7.7 SD1.3 as shown in Table-2. The average number of dressings required in the PC group patients with SSI is 5.3 SD1.9. The average number of days required for complete wound healing in PC group patients is 14.2 SD4.9 days while it is 17.2 SD3.3 days in the DPC group (Table-2).

The average number of days a patient is admitted for stoma closure in the PC group is 16.7 SD4.8 days and is 15.6 SD6.7 days in the DPC group. The average number of days a patient is admitted for stoma closure in the PC group with SSI is 20.6 SD6.7 days. No patient required re-admission in the follow-up period in both groups. Only one patient in PC group developed wound dehiscence, which was managed conservatively with daily dressing and secondary suturing was done.

IV. Discussion

Temporary stomas are commonly used for diverting bowel content in order to help the distal anastomosis to heal. Wound sepsis following skin closure during the closure of a stoma would appear almost inevitable because the wound is contaminated. Contaminated wounds as a principle are left to heal by secondary intention. Several prospective studies comparing DPC to PC of dirty wounds have shown controversial results. Still, DPC is a common technique performed for dirty wounds, assuming that it lowers rates of infection. The complications and the financial impact of wound infection are significant. Wound infection is a significant contributor for dehiscence [1-3]. It is also the cause for increased costs, associated with a longer hospital stay. The issue of wound infection following closure of a stoma has been evaluated in a few retrospective studies reporting high rates of infection [1,2,6,9,10]. DPC is an acceptable and widely used method for the contaminated stoma wound.

In the present study patients were observed pre-operatively for factors affecting wound healing like age, co-morbidities like hypertension, diabetes mellitus, steroid usage, indication for stoma construction, chemotherapy, radiotherapy. Post-operatively the rate of SSI was observed in both groups and compared in terms of number of dressing required, healing time, and hospital stay.

In the present study almost $1/3^{rd}$ cases had a congenital indication for stoma creation while the rest had acquired indications. This ratio is almost reverse in the study done by Massenga et al [11]. Our institute is a tertiary care centre which caters to patients of peritonitis from various district health centres. And our paediatric surgery department is not very well established which leads to a greater number of adult referral patients than neonates. This could also be the probable reason for disparity of data of indication for stoma creations in both studies.

Amongst the acquired indications for stoma formation, the present study observed enteric fever to be commonest causative entity similar to study done by Ahmad et al [12]. As per global typhoid fever study done by Marchello et al, South Africa has comparatively lower incidence than India [13]. This may be the reason of less percentage of ileostomy cases, as observed in the study done in Tanzania by Massenga et al [11] when compared to our study and the Indian study done by Ahmad et al [12].

Out of 18 patients in the PC group 4 were infected in the post-operative period. Amongst them, 3 patients were managed conservatively by changing antibiotics according to sensitivity and drainage of collections. In the DPC group, only one patient developed SSI in the post-operative period after skin closure, and was managed conservatively. Even though incidence of SSI was less in the PC group than DPC it could not reach statistical significance due to limited sample size.

Unlike the current study, SSI in the DPC group was significantly less than PC group in study done by Phang et al [9] and Li et al [14] (Table-4). This may be due to the reason that both studies were done on larger sample size. Similar to present study Lahat et al [1] had smaller sample size may be this could be the reason why significant results difference in SSI rate was not observed.

Overall 2 patients developed SSI after ileostomy reversal one from each group and total 3 patients developed SSI after colostomy closure, all were from the PC group. There was no significant difference in patients according to type of stoma closure performed in both groups ($p=0.718$, $p>0.05$).

In present study the rate of SSI after colostomy closure was higher than ileostomy closure though it was not significant. This difference may be due to the fact that anaerobic bacterial counts from ileostomy fluid have been found to be lower by a factor of 10^5 compared with normal feces whereas the bacteriology of colostomy effluent is very similar. Similar results of more SSI in colostomy cases than ileostomy cases were observed in studies done by Bell et al [15] and Vermulst et al [10].

According to the existing literature, it is expected that colostomy closure is more likely to be associated with infected wounds than ileostomy closure. Unlike study done by Lahat et al [1] ileostomy closure with

primary closure of the skin at the stoma site resulted in significantly more wound infections compared to delayed closure of the skin. This difference was not found in case of colostomy closure. Although not proven, this phenomenon could probably be the result of microleakage of small bowel contents in the wound before skin closure, as small bowel contents are thought to leak more easily compared to the more thickened large bowel contents.

Amongst the handsewn anastomosis patients, four developed SSI, out of which 3 were in PC group and 1 was in DPC group. Amongst the stapled anastomosis patients, only one developed SSI whose skin was primary closed. Similar to the present study Hasegawa et al [16] and García-Botello et al [17] found no difference in SSI in two different method of anastomosis performed in stoma reversal surgery.

In our study, the average number of dressings required in the PC group is 4.6 times (4.6 SD0.6 for 95% CI) with lowest number of 3 and highest of 12 in one infected primary closure patient. Average number of dressings required in DPC group is 7.7 (7.7 SD0.6 for 95% CI) times with highest number of 10 and lowest of 5, which is statistically significant ($p=<0.0001$). Considering these values PC group require significantly lower number of dressing than DPC group. Average number of dressings required in PC with SSI group is 7.7 times, so there is no statistically significant difference in PC with SSI versus DPC in terms of number of dressing required. Study done by Ussiri et al [18] observed more number of dressings in both the groups compared to our study (11 vs 4.6, 16 vs 7.7). This may be due to the fact that Ussiri et al [18] kept the wound open for 5 days for DPC compared to our study where it was kept open for 48-72 hours. Moreover they did the study on laparotomy wounds, where the incision is much longer than our study's stoma closure wound.

In our study healing time is defined as total numbers of the days from the day of operation to complete suture removal with complete epithelization. In PC group, the average healing time is 14.2 days (14.2 SD2.3) and in DPC group it was 17.2 days (17.2 SD1.5). By using t-test both groups were compared which is statistically significant at 95% confidence interval with $p<0.05$. This shows that delayed PC group requires more healing time because skin was kept open for 48-72 hours before closure was performed. Even in PC with SSI, the average healing time required is 11.7 days (11.7 SD1.96), which is significantly less than the DPC group.

Average hospital stay for PC group is 16.7 days (16.7 SD2.22) and in DPC group it is 15.61 days (15.61 SD6.47) which is statistically insignificant ($p>0.05$, $p=0.57$) for PC with SSI average hospital stay is 15 days (15 SD2.12). In our study we used to keep patient admitted for pre-operative work up. Availability of OR is also a major factor because fixed days were allotted for planned surgery and that's why the difference is reflected in healing time of both groups and not in hospital stay. Most of our patients are from rural areas, and hence they prefer to stay at the hospital till complete wound healing occurs. Due to these reasons, the length of hospital stay in our study was more than Lahat et al [1].

V. Conclusion

Primary closure of stoma had a higher rate of SSI compared to delayed primary closure irrespective of age and type of stoma. Present study also concludes that primary closure is better than delayed primary closure in terms of less number of dressings required and shorter wound healing time. So, primary closure can be the preferred method of skin closure after stoma reversal.

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Tables:

Table 1: Demographics of patient population. PC-Primary closure group; DPC- Delayed primary closure group
Table 2: Outcome. PC-Primary closure group; DPC-Delayed primary closure group; No.-Number
Table 3: Bacterial culture from wound. PC-Primary closure group; DPC-Delayed primary closure group; SSI-Surgical site infection
Table 4: SSI rate in various studies. PC-Primary closure group; DPC- Delayed primary closure group

	PC (n=18)	**DPC (n=18)**	**p-value**
Age			0.16
Age >40 yrs	14 (77.8%)	10 (55.6%)	
Age <40 yrs	4 (22.2%)	8 (44.4%)	
Sex			0.72
Male	12 (62.5%)	13 (78%)	
Female	6 (37.5%)	5 (22%)	
Anastomosis type			1
Hand sewn	12 (66.7%)	12 (66.7%)	
Stapled	6 (33.3%)	6 (33.3%)	
Type of stoma			0.77
Ileostomy	9 (50.0%)	11 (61.1%)	
Transverse loop colostomy	7 (38.9%)	5 (27.8%)	
Sigmoidostomy	2 (11.1%)	2 (11.1%)	
Indications for stoma			0.25
Congenital	6 (33.3%)	3 (16.7%)	
Acquired	12 (66.7%)	15 (83.3%)	

Table 1: Demographics of patient population. PC-Primary closure group; DPC- Delayed primary closure group

	PC (n=18)	**DPC (n=18)**	**p-value**
Surgical site infections	4 (22.2%)	1 (5.6%)	0.15
Average no. of dressings required	4.6 ± 1.4	7.7 ± 1.3	<0.001
No. of days for wound healing	14.2 ± 4.9	17.2 ± 3.3	0.03
Hospital stay (days)	16.7 ± 4.8	15.6 ± 6.7	0.57

Table 2: Outcome. PC-Primary closure group; DPC-Delayed primary closure group; No.-Number

Bacteria	SSIs of PC (n=4)	From wound before DPC (n=5)	Infected DPC (n=1)
E. coli	3	4	0
Klebsiella spp.	2	1	0
Acinetobacter	1	1	1
Pseudomonas	0	1	0
No growth	14	13	-

Table 3: Bacterial culture from wound. PC-Primary closure group; DPC-Delayed primary closure group; SSI-Surgical site infection

Study	PC	DPC	P value	Sample size
Phang et al (1999)	14.9%	4%	Significant	366
Li et al (2014)	43%	15%	Significant	146
Lahat et al (2005)	10%	20%	Not significant	40
Present study	22.2%	5.6%	Not significant	36

Table 4: SSI rate in various studies. PC-Primary closure group; DPC- Delayed primary closure group