

Original Research Article

Compare outcome in patients of ileostomy and colostomy closure with surgical stapler versus ileostomy and colostomy closure with hand sewn anastomosis: a prospective study

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ABSTRACT

Background: Diverting temporary stoma is created to protect the primary bowel pathology and distal anastomosis. Once that primary pathology has been overcome or distal anastomosis gets healed, closure of temporary stomas can be carried out. Invention of stapling devices for intestinal anastomosis provided another dimension than hand sewn method to the stoma closure techniques. In this study, we have compared two methods of loop stoma closure-hand sewn method versus stapler method.

Methods: This is prospective comparative study in which 50 cases of loop ileostomy/colostomy were taken. 25 patients underwent ileostomy/colostomy closure by hand sewn anastomosis (group A). Another 25 patients underwent ileostomy/colostomy closure by stapler anastomosis (group B). Time taken for operation, initiation of oral intake, anastomotic leak, post-operative wound infection and total hospital stay duration were compared between these two groups to conclude about which method is superior and in the best interest of patient and surgeon.

Results: Mean operation time 105.96 minutes (group A) and 72.84 minutes (group B). Mean time to start oral intake 5.36 days (group A), 3.6 days (group B). 16% patients (4/25) group A and 4% patients (1/25) group B developed anastomotic leak. 28% patients (7/25) group A and 8% patients (2/25) group B had post-operative wound infection. Mean hospital stay 10.4 days in group A and 7.84 days in group B.

Conclusions: Stapler method provides significant benefits in terms of less operative time, early oral intake and less hospital stay. Overall stapler method for stoma closure is more efficient and cost effective.

Keywords: Loop ileostomy, Ileostomy closure, Colostomy closure, Hand sewn anastomosis, Stapler anastomosis

INTRODUCTION

Stoma is a Greek word for mouth or opening.¹ Basic intention behind creating diverting temporary stomas is to protect the primary pathology at the stoma site and to protect bowel anastomosis distal to creation of stoma. Turnbull and Weakley were the first surgeons to describe the loop ileostomy in 1971.² Ileostomy/colostomy can be permanent or temporary depending on the basis of the primary pathology. Permanent stomas are irreversible as the name suggests. Temporary stomas require closure.

Once that primary pathology at the stoma site has been overcome or distal anastomotic site gets healed closure of temporary stomas can be carried out depending upon surgeon's choice.

Conventional hand sewn intestinal anastomosis for stoma closure was already an established technique since 19th century. Invention of stapling devices for intestinal anastomosis provided another dimension than hand sewn method to the stoma closure techniques. Stapling devices were first introduced by Hult in 1908.³ Widespread use of

stapling devices to reverse stoma began in later part of 1970s and earlier part of 1980s following successful trials comparing conventional hand sewn method with stapler anastomosis for intestinal anastomosis.

In this study, we have compared two well established methods of loop stoma closure-hand sewn anastomosis (HA) and stapler anastomosis (SA). It is always helpful to experiment and know about evolving surgical techniques and take help of innovations if it's proving to be superior to established techniques. There are various studies comparing hand sewn and stapled stoma closure and their conclusion varying widely suggestive of either no significant difference between the two methods in terms of anastomotic leak and post-operative complication or stapled anastomosis being significantly better for the same reasons. The aim was to compare hand sewn and stapled anastomosis for loop ileostomy/colostomy closure with objectives being operation time, initiation of oral intake, post-operative anastomotic leak and wound infection and total hospital stay.

METHODS

This study was carried out at Sir T. hospital and government medical college, Bhavnagar, Gujarat, India from August 2017 to August 2019. In this prospective comparative study, after obtaining clearance of local institutional review board, 50 cases that needed loop ileostomy/colostomy closure were selected. Participants were assigned groups following simple randomization to one of the two treatment groups. Stoma closure was done after 6-12 weeks of stoma creation. Informed and written consent was obtained from all the patients. Among them 25 were operated by hand sewn anastomosis (HA) method (group A-control group) and 25 were operated by stapler anastomosis (SA) method (group B-study group). The data

was collected prospectively. All the cases were observed for one month after operation and the data related to recovery was recorded. The following parameters were compared between the stapled and hand-sewn groups: operation time, initiation of oral intake, anastomotic leak, postoperative wound infection and total duration of hospital stay.

Inclusion criteria

All patients with loop ileostomy/colostomy of age between 18 to 80 years willing to participate in the study.

Exclusion criteria

All the patients of <18 and >80 years of age, patient unwilling to participate in the study, immunosuppressed patients, patients with intestinal tuberculosis, patients unfit for anaesthesia, permanent ileostomy/colostomy were excluded.

After doing thorough investigations and pre anaesthetic evaluation patients were posted for surgery on planned basis. Routine blood investigations with serum protein were checked in both groups and any deficiencies noticed were corrected before planning surgery. Loopogram to check distal stoma loop patency was done in all patients. Contrast-enhanced computed tomography (CECT) abdomen and colonoscopy were done if/when necessary. Operation for both the methods was performed under spinal anaesthesia using parastomal skin incision. For HA, loop stoma was closed with hand sewn technique with black braided silk 2.0 round bodied suture material in two layers in simple interrupted manner. For SA, GIA linear cutter of 60 mm and 80 mm size and TA linear stapler of 60 mm and 90 mm size were used depending upon the size of stoma and availability of stapling devices (Figure 1).

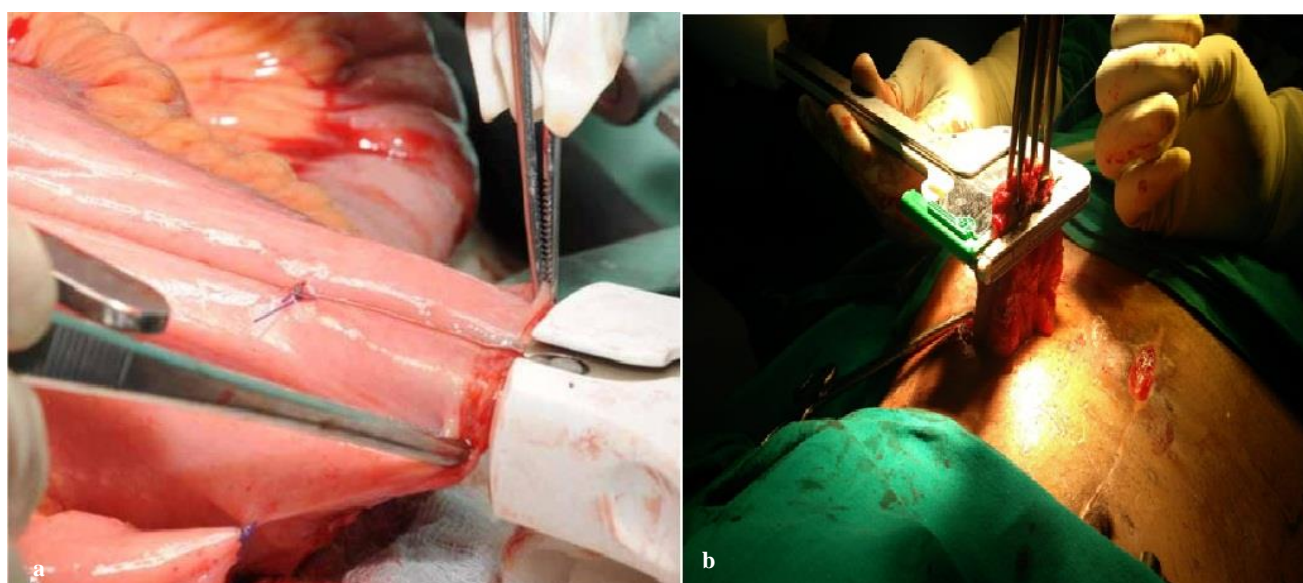


Figure 1: Application of (a) GIA linear cutter and (b) TA linear stapler.

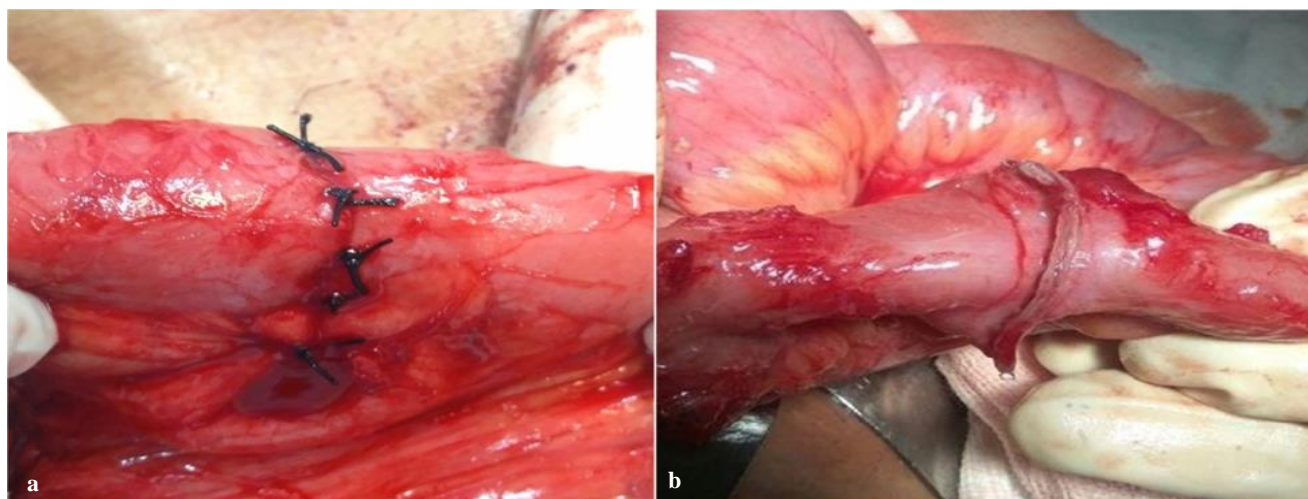


Figure 2: (a) Suture line and (b) stapled line of anastomosis.

After stoma closure in both the groups, intra-abdominal drain was kept and incision site was closed layer wise. Patients were assessed in ward in both groups according to predetermined criteria e.g. operation time, initiation of oral intake, anastomotic leakage, postoperative wound infection and total duration of hospital stay. Operation time was counted as minutes taken for operation from incision kept on parastomal skin to stoma closure and the last skin suture. Initiation of oral intake was counted as on which post-operative days patients allowed to take liquid per oral. Patients were allowed to start oral intake with clear fluid after appearance of bowel sounds on auscultation and passing flatus in both groups. Complications were observed and conservative approach was taken to manage majority of the complications. Post-operative bilious/faecal drain output or post-operative bilious/faecal wound discharge was considered as anastomotic leak. For anastomotic leak which is the most dreadful complication of stoma reversal conservative management was tried initially. If fistula remained uncontrolled or drain output remained consistently high, revision surgery was attempted by hand sewn method. Any wound with serous, seropurulent, purulent, bilious or faecal discharge was considered as having wound infection which was treated by taking swab for culture and sensitivity and by starting antibiotics according to sensitivity. Patients were discharged only after they had passed stool and started taking soft diet in both groups. Hospital stay was recorded as total number of days. Records of aforementioned details were kept on 1st, 3rd, 10th post-operative days and after 1 month interval of surgery.

Statistical analysis

Data was collected and analyzed as mean±standard deviation (SD) and percentage. Least significant difference for measuring intergroup variance of metric data was done by student's t-test, whereas non metric data was analyzed by Fisher's exact test. P value of less than 0.05 was considered as significant.

RESULTS

In group A: HA out of 25, maximum patients were found to be in age 21-40 and 41-60 years group (10 patients each) with mean age 41.48 ± 16.591 years. In group B: SA out of 25, maximum 15 patients were in 21-40 years age group with mean age 38.2 ± 18.012 years. In this study out of 50 patients mean age of patient having loop ileostomy/colostomy was 39.84 years. Among total 50 patients having loop ileostomy/colostomy in this study, 37 (74%) males and 13 (26%) females were there. In HA group out of 25 patients, there were 16 males and 9 females. While in SA group out of 25 patients, there were 21 males and 4 females.

Operation time

In HA group mean operation time was 105.96 ± 13.578 minutes. In SA group mean operation time was 72.84 ± 11.785 minutes ($p < 0.01$) (Figure 3).

Initiation of oral intake

In HA group mean time required to start oral intake was 5.36 ± 2.234 days. In SA group mean time required to start oral intake was 3.6 ± 0.9129 days ($p < 0.01$) (Figure 4).

Anastomotic leak

In HA group 3 patients out of 25 patients (12 %) developed anastomotic leak, while in SA group 1 patient out of 25 patients (4%) developed anastomotic leak ($p = 0.60$). Patients developing anastomotic leak were closely observed and were managed conservatively at first. If the drain output or output of enterocutaneous fistula remained consistently high, revision surgery with hand sewn anastomosis was done. In HA group 1 patient expired because of septic shock due to anastomotic leak and 2 patients (8%) out of 25 required revision surgeries. In SA group 1 patient developed anastomotic leak and was

managed conservatively. Enterocutaneous fistula healed without any surgical intervention with conservative management after 13 days. Difference between two groups in terms of requiring revision surgery is not significant ($p=0.48$) (Figure 5).

Post-operative wound infection

In HA group 7 out of 25 patients (28%) have developed post-operative wound infection, while in SA group 2 out of 25 patients (8%) have developed post-operative wound

infection. Number of patient developing post-operative wound infection are less in SA group but there is no significant difference between two methods ($p=0.13$) (Figure 6).

Hospital stay

In HA group mean hospital stay was 10.4 ± 3.731 days. In SA group mean hospital stay was 7.84 ± 1.908 ($p=0.003$) (Figure 7).

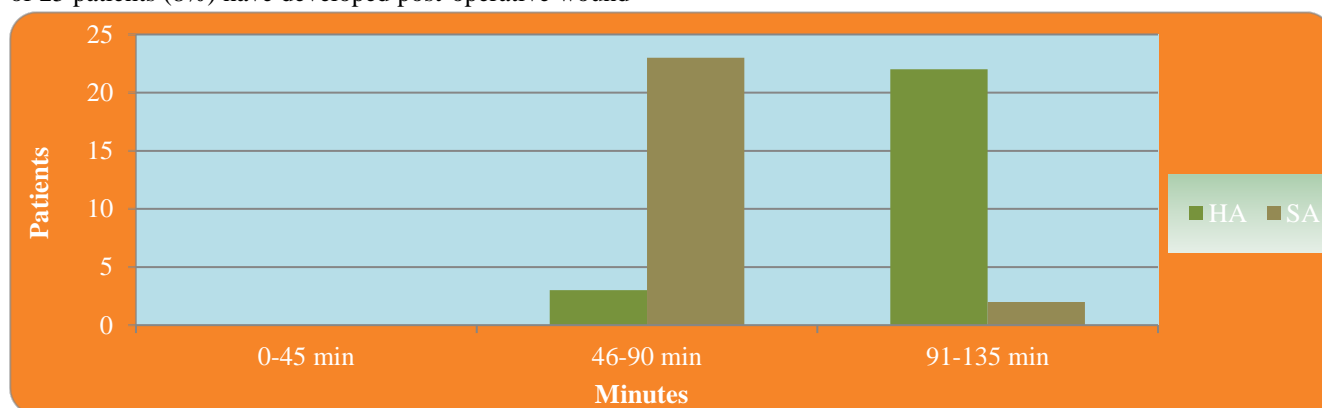


Figure 3: Time taken for operation (minutes), 25 patients each in HA and SA group.

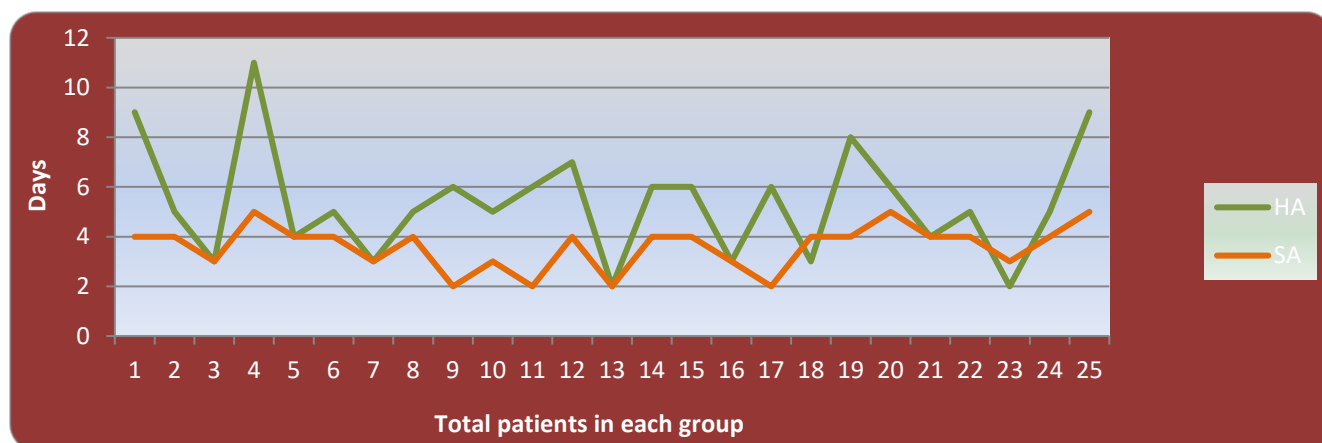


Figure 4: Time taken to start oral intake (days), 25 patients each in HA and SA group.

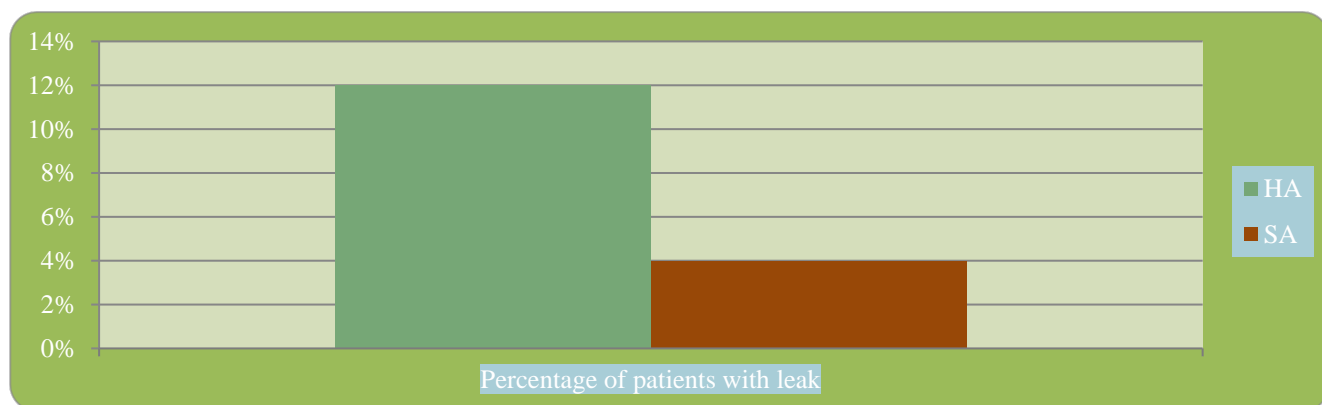


Figure 5: Anastomotic leak rate, (3/25 in HA group and 1/25 in SA group).

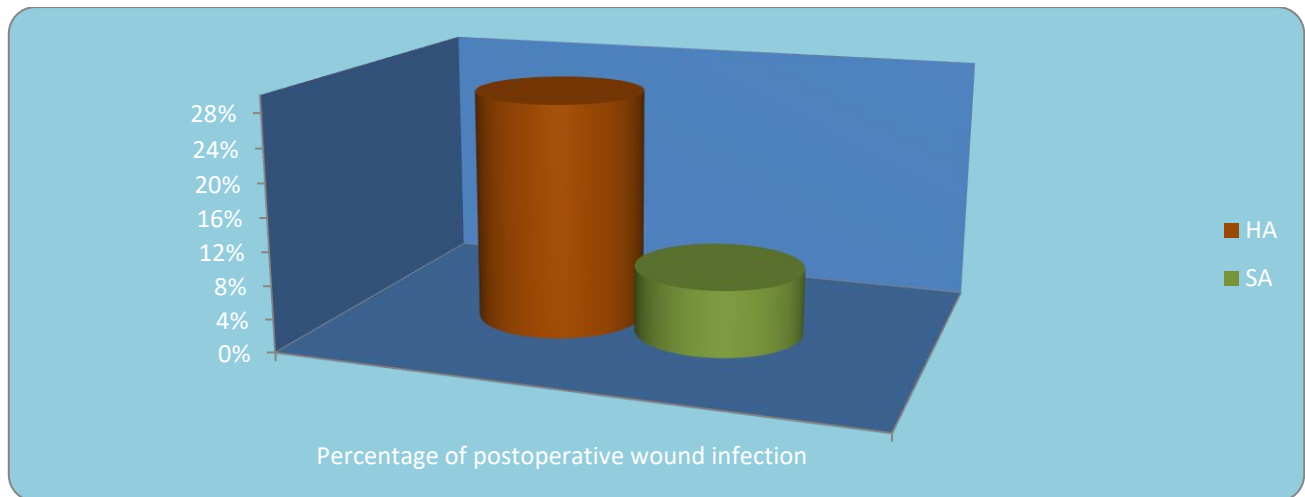


Figure 6: Wound infection rate, (7/25 in HA group and 2/25 in SA group).

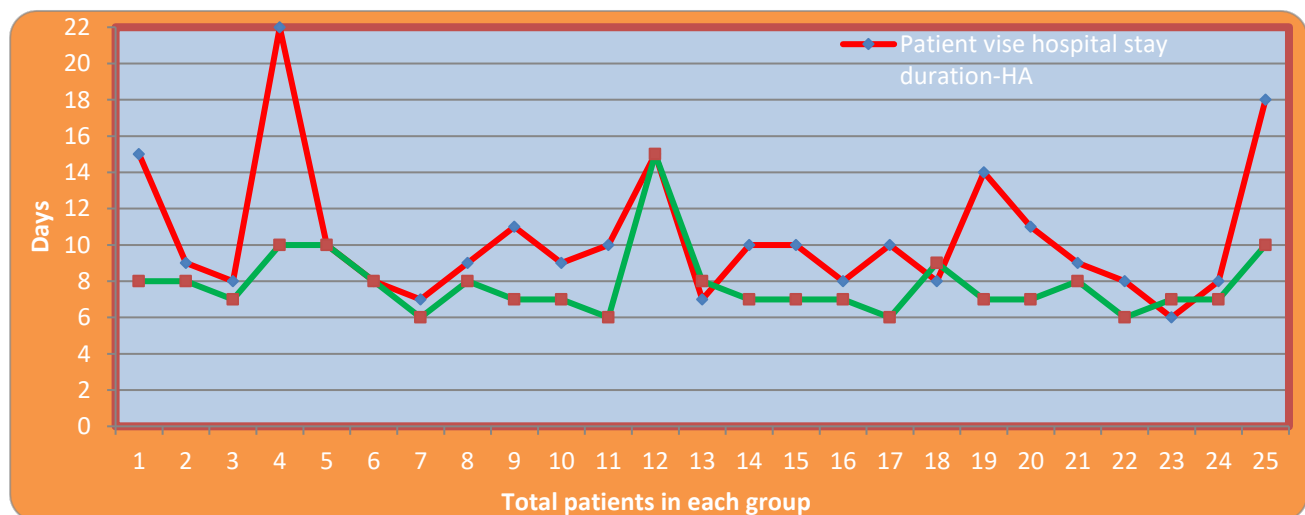


Figure 7: Total duration of hospital stay (days).

DISCUSSION

In this study of total 50 patients mean age of patient having loop ileostomy/colostomy was 39.84 years. It correlates with a study done by Krishnaswamy et al on 74 patients with mean age being 37.8 years.⁴ Among total 50 patients having loop ileostomy/colostomy in this study 37 (74%) males and 13 (26%) females were there. In a study done by Krishnaswamy et al on 74 patients, 73% were males and 27% were females.⁴

Mean operation time in HA group was 105.96 ± 13.578 minutes and in SA group was 72.84 ± 11.785 minutes. In a study done by Bulent et al over 68 patients, the mean operation time was 75.4 minutes in HA group and 46.7 minutes in SA group ($p < 0.01$).⁵ Thus it can be said that time for SA is very less than HA.

Mean time required to start oral intake in HA group was 5.36 ± 2.234 days and in SA group was 3.6 ± 0.9129 days. In a study done by Bulent et al over 68 patients, the mean

time required to take oral intake was 4.50 days in HA group and 3.26 days in SA group ($p = 0.02$) which is similar to our study.⁵ Based on this observation we can say that oral intake can be resumed earlier in patients operated for stoma closure by stapler method.

Anastomotic leak rate was 12% (3/25) in HA group and 4% (1/25) in SA group. A meta-analysis done by Madani et al shown that the anastomotic leak rate was 2.93% (55/1,877) in the HA group and 2.08% (25/1,202) in the SA group with $p = 0.52$.⁶ We can say that there is no superiority in terms of having less anastomotic leak between these two methods and further study with large group of patient is required to strengthen this analysis.

Wound infection rate was 28% (7/25) in HA group and 8% (2/25) in SA group. A study over 225 patients (129 HS, 96 SA) done by Balik et al shown that the wound infection rate was 3.11% (7/129) in the hand-sewn and 4% (9/96) in the stapled group ($p > 0.05$).⁷ Wound infection depends upon various factors other than surgical technique and it is

not significantly differentiated whether any surgical method is better in terms of having less wound infection or not.

Mean hospital stay in HA group was 10.4 ± 3.731 days and in SA group was 7.84 ± 1.908 days. A study over 225 patients (129 HS, 96 SA) done by Balik et al. shown that mean hospital stay was 8.581 days in the hand-sewn and 6.063 in the stapled group ($p=0.002$).⁷ Thus it can be said that patients operated for stoma closure by stapler method requires less hospital stay duration.

CONCLUSION

In this study, patients requiring loop ileostomy/colostomy closure operated by SA required less operation time than those operated by HA. Patients operated by SA have started taking oral intake earlier in comparison of those operated by HA. Patients operated by SA required less hospital stay. Patients operated by SA has developed post-operative wound discharge and anastomotic leak in less percentage of patients than those operated by HA but there is no significant statistical difference to show superiority of one method over the other. Percentage of patients requiring revision surgery because of anastomotic leak is lower in patients operated by SA. Patient treated with SA for loop ileostomy/colostomy closure is superior in terms of less operative time, early oral intake and shortened hospital stay duration as compared to HA. SA method has less post-operative wound infection and controlled anastomotic leak. HA technique overall increase economic burden on both patients and hospital due to its complications while after SA patients can easily and early resume their work which is economically beneficial to patient and hospital both. Over all our present study suggests that SA technique is better than HA technique for stoma closure. Although the cost of stapler devices is a major issue but on long period its effectiveness for stoma closure is quite good with less operating time, less complication and overall short hospital stay.

Limitations

Availability of staplers is major limitation of the study. Cost effectiveness and procurement, makes it difficult for

all centers to have staplers. Co-morbid conditions affect healing of anastomosis in both groups limiting desired outcomes of the study. Bleeding tendencies and inflammatory effects at stoma site causing bowel edema affects healing of anastomosis which acts as a limitation to the study.

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Conflict of interest: None declared

Ethical approval: The study was approved by the Human Ethics Committee, Government Medical College, Bhavnagar taken. IRB (HEC) No. 731/2017. Date: 27/07/2017

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