Research Paper

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Comparison Between Stapler and Hand Sewn Anastomosis in Elective Gastrointestinal Surgeries Conducted at Government Tertiary Hospital, Western India: A Prospective Study

Medical Science

KEYWORDS : Comparative randomized study, Stapler, Hand sewn, Anastomosis

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ABSTRACT

Background and objectives: Intestinal obstruction, peritonitis from a perforated bowel, abdominal trauma, malignancy of the gastrointestinal tract and other bowel diseases are common surgical problems throughout the world which must be treated operatively. Hence, it is frequently necessary to join two sections of bowel together. This anastomosis is carried out either manually or by using staplers. Many studies have different opinions about these two techniques. So this study is carried out with objectives to compare these two methods of anastomosis in terms of its complications mainly anastomotic dehiscence.
Methods: Patients who underwent gastrointestinal anastomosis between June 2009 and November 2011 at SSG hospital were considered in the study after taking written informed consent. All these patients were thoroughly investigated pre- operatively. Patients were randomized alternatively either to the stapler group or the hand sewn group. Complications observed in both the groups were noted and managed.
Results: The study comprised of 50 patients undergoing 60 gastrointestinal anastomosis. Majority of patients were in the age group of 30-50 years. There was 13.3% anastomotic leak rate in hand sewn group and 3.3% stapler group. Other complications like burst abdomen, electrolyte imbalance, pulmonary complications, cardio-vascular complications, wound infection etc were also noted in few patients. The complications rate was significantly high in hand sewn group which is statistically significant. Death rate was high in hand sewn group but this difference was not significant.
Conclusions: There was significant reduction in the incidence of anastomotic complications with use of staplers but death rate showed no difference.

Introduction
Intestinal obstruction, peritonitis from a perforated bowel, abdominal trauma, gastric outlet obstruction, malignancy of the gastrointestinal tract and other diseases of the bowel are common surgical problems throughout the world. These problems must be treated operatively; hence, it is frequently necessary to join two sections of bowel together. Unlike joining two areas of skin, where there is a powerful evolutionary incentive to achieve rapid healing, joining two segments of bowel so as to restore intestinal function without leakage of intestinal contents is not easy. Accurate approximation of the bowel without tension and good blood supply both are necessary for anastomosis (1).

Failure of an anastomosis with leakage of intestinal contents is a common surgical experience even today. A leaking anastomosis greatly increases the morbidity and mortality associated with the operation: it can double the length of the hospital stay and increase the mortality as much as 10-fold. Dehiscence, when it occurs, has been associated with one fifth to one third of all postoperative deaths in patients who underwent an intestinal anastomosis (1).

Unfortunately, anastomotic dehiscence can occur even in ideal circumstances. This unwelcome fact has stimulated a great deal of debate regarding the reliability of various methods and approaches.

Although abdominal surgery has been practiced for centuries, it is only during the last 200 years that intestinal suturing has been performed with any degree of regularity. Although improved surgical techniques, anesthetic care, diagnostic accuracy, and antibiotic prophylaxis all have contributed to improved results, the increasing confidence of surgeons in their ability to obtain intestinal wound healing owes much to the recognition of the essential prerequisites for anastomotic security.(2) The factors that influence this, relate both to the systemic characteristics of the individual patient together with local and technical factors, such as the importance of an adequate blood supply, freedom from tension at the anastomosis, and the absence of active disease or distal obstruction. The need for good edge-to-edge apposition and adequate luminal patency are self- evident. (3)

It is unfortunate that despite the wealth of circumstantial evidence to suggest that manual suturing and surgical stapling are essentially equivalent in terms of their safety, there has been very little scientific activity to critically examine the comparative features of each technique. (4-9)

Hence the current study is carried out to compare the complications between surgical stapling and manual suturing technique in case of various elective gastrointestinal anastomoses.

Objective
To compare complication rates in stapler and hand sewn anastomosis group.

Materials and Methods
The randomized comparative prospective study of stapler versus hand sewn anastomosis in elective gastrointestinal surgeries was carried out in the department of surgery at Shree Sayaji General Hospital (SSGH), Baroda, between June 2009 and November 2011. SSGH is the third largest government hospital in Gujarat, western India.

All patients who were admitted in the hospital during the above mentioned time frame with symptoms and signs suggestive of gastric outlet obstruction, small bowel obstruction, obstructive jaundice, large bowel obstruction due to malignancy etc and all other patients in whom gastrointestinal anastomosis was planned were considered in the study.

Patients were randomized either to the stapler group or the hand sewn group. Each case taken for intestinal anastomosis was alternatively allotted to the hand sewn group and the stapler group. The procedures and their outcomes were well explained to all the patients. Patients were enrolled in the study after taking informed written consent. All were elective operations. Emergency procedures were excluded from this study.

All routine blood investigations were done. These include Hemoglobin, Total Count, Differential Count, blood urea, Serum creatinine, Liver Function Tests, RBS, blood grouping, Urine routine and microscopic examination, Chest X ray, ECG and USG. Other investigations like CT-scan were done as per case specification. Bowel preparation was done, Betadine scurb was given at night and in the morning before surgery. A single dose of intravenous cefotaxime 1 gm was administered 1 hour prior to surgery. All operations were done under general anesthesia and by standard surgical procedures.

All patients were observed till their complete post operative hospital stay. During the post operative time, initially patients were kept nil per oral and on intravenous fluids. Subsequently patients were switched over to sips orally followed by liquids and then on soft diet within a span of 3 to 5 days. All patients were monitored everyday and complications were noted if any. After about 10 to 15 days the patients were discharged, they were followed up in the OPD regularly at 2 weeks, 6 weeks and 3 monthly intervals. Those patients who did not come for follow up, were reminded through post or telephonic call.

Complications for the study were defined as below:

- Anastomotic dehiscence: it is defined as breakdown of anastomosis & release of intestinal contents into peritoneal cavity.
- Stricture: it is defined as development of narrowing at the site of anastomosis. It is a long term complication which occurs after anastomotic procedure.
- Wound infection: defined as redness & edema of sutured wound area developing in post operative period. Sometimes it also presents with abscess & responds well with incision & drainage & antibiotics.
- Burst abdomen: defined as breakdown of sutured rectus sheath & sutured skin in post operative period. Underlying bowel is exposed to surface.
- Septicemia: defined as presence of septic focus in blood which eventually leads to multi organ failure if not corrected promptly.
- Respiratory complications: defined as occurrence of pneumonia, pleural effusion in post operative period.
- CVS complications: defined as development of arrhythmias, myocardial infarction and congestive heart failure in post operative period.
- Electrolyte imbalance: defined as derangement in level of electrolyte occuring during post operative period.

All the above mentioned data was collected in specific predesigned proforma. Data was then checked for completeness and validated and then it was entered in Microsoft Excel 2007 and analyzed using Med Calc software version 6.7.1.

Results

A total of 50 patients were enrolled in the study, and were randomized as: 25 in the stapler group and 25 patients in the hand sewn group. Out of 25 patients in the stapler group, 5 patients underwent two anastomosis hence making a total of 20 + (5 x 2) =30 anastomosis. Similarly in hand sewn group out of 25 patients, 5 underwent two anastomosis, making a total of 20 + (5 x 2) = 30. So in all, 60 gastrointestinal anastomosis were included in this study.

Table 1 shows the age and sex wise distribution of patients in both the groups. The median age in stapler group was 50 years, while that of hand sewn group was 40 years. Majority of patients in both the stapler as well as hand sewn group were in the age range of 41-50 years. The percentage of female patients in stapler group was 28% while that in hand sewn group was 36%. There was no significant difference between both the groups in terms f their age and sex at the baseline. Further, there was no significant difference between the randomized groups with regards to preoperative variables, such as hemoglobin, white blood cell count, or basic anthropometric data.

As shown in Figure 1, gastrointestinal anastomosis was done most commonly in gastric outlet obstruction (42%) followed by ileal stricture (14%), carcinoma of colon (12%) and so on.

The rate of complications was 40% in stapler group and 72% in hand sewn group in our study. (Table 2) The difference was statistically significant. In our study amongst a total of 50 patients, there was leak (anastomotic dehiscence) found in 4 cases in the hand sewn group. In the stapler group there was one anastomotic leakage. Leakage was diagnosed on the basis of presence of fecal material or bile in drains or thro the wound. All these patients were managed conservatively without re-exploration. Apart from anastomotic dehiscence these patients also experienced other complications. Some of these complications were not directly related to gastrointestinal anastomosis. There were few patients with pulmonary complications (5 patients) mainly due to pre-existing pulmonary pathology or per se as a complication to prolonged operative time and its sequel. 5 patients also suffered from electrolyte imbalance, however none were life threatening. There were 3 patients with burst abdomen who were managed conservatively. Superficial wound infection was noted in 4 patients who had responded well to daily dressings and antibiotics. There was no evidence of any patient developing stricture in our study.

Of the 50 patients that underwent anastomosis, a total 6 patients died postoperatively making the mortality rate of 12.00% in our study. There were 4 mortalities in hand sewn group and 2 in stapler group. (Table 2) Septicemia and Pulmonary complications were the major causes of death. Out of 2 deaths in stapler group one was due to septicemia and the other due to pulmonary complication. While in hand sewn group two patients died in septicemia, two due to pulmonary complications.

A regular follow up with all these patients was a very difficult task. Patients were followed up at 3 weeks, 6 weeks, and then 3 monthly. They were evaluated for gastro-intestinal complaints, wound related complaints etc. Out of a total of 50 patients, about 30 of them regularly visited OPDs for follow up. None amongst them had any significant complaints. The remaining 20 were irregular in follow up in spite of reminders through post. However it could be considered that these patients had no relevant complications post operatively.

Discussion

The use of stapler has gained popularity since they were introduced in the United States of America in the late 1960s, when the conventional technique of bowel anastomosis was compared with the stapling technique. This made no significant difference in mortality and morbidity. Nevertheless stapler technique has the advantage of enhancing the blood flow across the anastomosis, causes less tissue trauma, necrosis, causing less anastomotic edema and reduced operating time.

The main complication which is worrying a surgeon after gastro-intestinal anastomosis is its leakage, i.e. anastomotic dehiscence. Our study has shown that the anastomotic dehiscence was less in stapler group as compared to the hand sewn group. Other similar studies by Choy PYG et al, Demetria et al, Seiji et al and Kracht et al have also shown similar results. (10-13)

The complications which we have encountered in our study apart from anastomotic leak cannot be attributed to the technique of anastomosis stapler or hand sewn directly. They are part and parcel of any major surgery.

Our study found higher rate of mortality in the handsewn group, other similar studies have reported similar mortality rates in both the group. There were 6 deaths in our study. Two in stapler group (8.00%) and four in hand sewn group (16.00%). The total mortality rate of 12.00% was observed in our study. In Docherty et al 1994 study, 28 (4.3%) of the 652 randomized patients died within 30 days of surgery (13 sutured and 15 stapler). 8 deaths were related to anastomotic breakdown; the rest were the result of a variety of cardio respiratory causes.(14) In Suzana et al 2002, a randomized control trial study conducted in Sao Paulo, Brazil, which included 1233 patients of colorectal anastomosis showed equal mortality of about 13%.(15)

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Conclusion

Thus, in this study of ours, in a smaller number of patients, in a set up like ours, catering to poor and rural patients, this technique of stapler anastomosis, is as effective and much easier than the conventional method of hand sewn anastomosis with an important added advantage of less complication rates which is significant,. The decision on which technique to use must remain at the discretion of an appropriate judgment by the surgeon, i.e. based on his/her personal experience, circumstantial facts and resources available.

Although in our set up the cost of consumables per operation is increased when staplers are used. However we have economized the cost to a larger extent and ultimately this cost should be carefully weighed against the more efficient use of operative time with reduced anastomotic dehiscence.

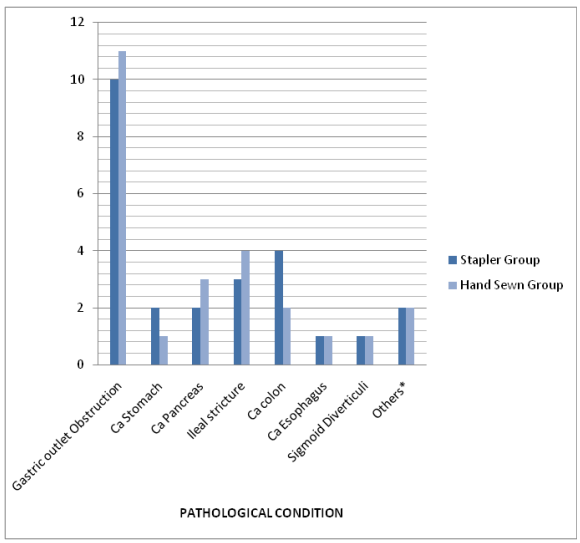
Table 1: Age and Sex wise distribution of patients randomized in two groups

	Stapler group	Hand sewn group
Age range Median Age (yrs)	20 - 71 yr 50 yrs	19 - 80 yrs 40 yrs
Age group: 31-40 41-50 51-60 61-70 71-80	 8 9 4 3 1	 4 11 4 3 2
Sex Male Female	 18 7	 16 9

Table 2: Post-operative complications & mortality in both groups

Complications	Stapler (n=25)	Hand sewn (n=25)
Anastomotic dehiscence	1	4
Wound infection	2	2
Burst abdomen	1	2
Septicemia	1	3
Pulmonary complication	2	3
Electrolyte imbalance	2	3
CVS complication	1	1
Total Complications	10 (40%)	18 (72%)
χ^2 (p value)	3.977 (0.046)	
Total deaths	2 (8%)	4 (16%)
χ^2 (p value)	0.189 (0.66)	

Figure 1: Pathological indications for anastomosis in study patients



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