Comparative prospective study of stapler versus hand sewn anastomosis in elective gastrointestinal surgeries conducted at tertiary level hospital, Vadodara

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ABSTRACT

BACKGROUND: 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 duration of anastomosis, duration of operation and duration of hospital stay. MATERIALS AND 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. Time taken for anastomosis was noted along with noting of total time of operation was done. RESULTS: The study comprised of 50 patients undergoing 60 gastrointestinal anastomosis. Majority of patients were in the age group of 30-50 years. Gastro jejunal anastomosis was the most common anastomosis in both the groups. The average time taken for stapler group was 4 minutes, while that of hand sewn group was 39 minutes which is found to be statistically significant. Whereas the average time taken for operation and the average hospital stay of the patients in both the groups was similar and was not found to be significantly different. CONCLUSION: The use of stapler is safe, easy and quicker as compared to the conventional methods like hand sewn. Of course cost is the negative factor for a country like India.

Keywords: Comparative randomized study, Stapler, Hand sewn, Anastomosis, Vadodara

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. 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. 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. 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. The appropriate place of stapling in clinical practice remains to be defined. Various claims have been made regarding the possible benefits that apply to stapled anastomosis, such as a reduction in tissue manipulation, trauma, bleeding, and edema, and with a more rapid return of gastrointestinal function and patient recovery. In contrast, stapling techniques have been criticized in view of their...
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apparent expense. Good clinical evidence on which to base the various claims and counter-claims remains hard to find. Several uncontrolled retrospective studies have reported conflicting results. Hence the current study is carried out to compare the two surgical techniques of anastomosis: stapling versus manual suturing in a prospective, randomized design.

Objectives:
1. To study the duration of anastomosis in stapler versus hand sewn anastomosis groups.
2. To study the duration of operation in stapler versus hand sewn anastomosis groups.
3. To compare duration of post operative hospital stay in both groups.

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 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 includes Hb, TC, DC, blood urea, S.creat, LFT, RBS, blood grouping. Urine routine and microscopic examination Chest X ray.ECG and USG were done. Other investigations like CT-scan were done as per case specification. Bowel preparation was done, Betadine scurb 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. Bowel anastomosis is done as per standard procedures in both hand sewn and stapler group. 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 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

Table 1: Anastomosis detail in both groups.

<table>
<thead>
<tr>
<th></th>
<th>Single anastomosis</th>
<th>Double anastomosis</th>
<th>Total number of patients</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stapler group</td>
<td>20 (80%)</td>
<td>5 (20%)</td>
<td>25 (50%)</td>
</tr>
<tr>
<td>Hand sewn group</td>
<td>20 (80%)</td>
<td>5 (20%)</td>
<td>25 (50%)</td>
</tr>
</tbody>
</table>

Table 2: Age and sex wise distribution of patients randomized in two groups

<table>
<thead>
<tr>
<th>Age range (yrs)</th>
<th>Stapler group</th>
<th>Hand sewn group</th>
</tr>
</thead>
<tbody>
<tr>
<td>20 - 71 yrs</td>
<td>16 (64%)</td>
<td>19 - 80 yrs</td>
</tr>
<tr>
<td>50 yrs</td>
<td>7 (28%)</td>
<td>40 yrs</td>
</tr>
</tbody>
</table>

Table 3: Type of gastro intestinal anastomosis performed in this study

<table>
<thead>
<tr>
<th>Type of Anastomosis</th>
<th>Stapler Group N (%)</th>
<th>Hand Sewn Group N (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gastro-Jejunal</td>
<td>12 (48)</td>
<td>14 (56)</td>
</tr>
<tr>
<td>Jejuno-Jejunal</td>
<td>5 (20)</td>
<td>5 (20)</td>
</tr>
<tr>
<td>Ileo-Ileal</td>
<td>1 (4)</td>
<td>2 (8)</td>
</tr>
<tr>
<td>Colo-Rectal</td>
<td>5 (20)</td>
<td>3 (12)</td>
</tr>
<tr>
<td>Ileostomy Closure</td>
<td>1 (4)</td>
<td>1 (4)</td>
</tr>
<tr>
<td>Colostomy Closure</td>
<td>1 (4)</td>
<td>1 (4)</td>
</tr>
<tr>
<td>Eso-Gastric</td>
<td>3 (12)</td>
<td>2 (8)</td>
</tr>
<tr>
<td>Ileo-Transverse</td>
<td>2 (8)</td>
<td>2 (8)</td>
</tr>
</tbody>
</table>

Table 4: Duration of gastro intestinal anastomosis, operation time and hospital stay among patients operated at SSGH

<table>
<thead>
<tr>
<th></th>
<th>Stapler</th>
<th>Hand sewn</th>
<th>Unpaired ‘t’ test</th>
<th>p Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Time taken for operation (average)</td>
<td>4.07 mins</td>
<td>39.12 mins</td>
<td>20.26</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Operative time (average)</td>
<td>148 mins</td>
<td>169 mins</td>
<td>1.53</td>
<td>0.133</td>
</tr>
<tr>
<td>Hospital stay (average)</td>
<td>14.7 days</td>
<td>15.1 days</td>
<td>0.004</td>
<td>1</td>
</tr>
</tbody>
</table>

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 a grand total of 60 gastrointestinal anastomosis were made in this study as shown in Table-1. Table-2 shows the age and sex wise distribution of patients in both the groups and it was not found to be statistically significant. The median age in stapler group was 50 years, while that of hand sewn group was 40 years.
Majority of patients in the stapler group were in the age range of 41-50 years while in the hand sewn group majority were in the age group of 31-40 years. The percentage of female patients in stapler group was 28% while that in hand sewn group was 36%. The net percentage of female patients was 32%. 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. Amongst all these patients majority of patients underwent gastrojejunal anastomosis for varied reasons. A total of 26 gastrojejunal anastomosis were done, while 3 ileo-ileal anastomosis were formed (which includes 2 ileostomy closures) which is shown in table-3. Stapler group in terms of duration of anastomosis had taken 4.07 mins which is very less time as compared to the hand sewn group which took 39.12 mins. The difference was of approximately 35 mins which is found to be statistically significant with t=20.26 and p=0.001. Whereas in terms of total duration of surgery/operation, the observed difference of 21 mins between both the groups is not found to be statistically significant with t=1.53 and p=0.133. Mean duration of hospital stay was nearly 15 days for all patients in both the groups. Certainly, there was no statistically significant difference between the total length of hospital stay with t=0.004 and p=1. Table 4 summarizes all these findings with exact value of student’s ‘t’ test and p value.

DISCUSSION

The use of stapler have gained popularity since they were introduced in the United States of America in the late 1960, when the conventional technique of bowel anastomosis was compared with the stapling technique this made no significant difference in mortality and morbidity. Nevertheless staple 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. We have avoided emergency cases, so as to get uniformity in our study. However patients who were presented subacute intestinal obstruction and were initially treated conservatively and then later on taken for surgical management are taken into the study. This is done because their general condition was improved during the initial conservative period. In this study, the median age was 50 years in stapler group and 40 years in hand sewn group, range being 19 years to 80 years. There were 16 female patients (32%). Similar pattern of age and sex wise distribution has been seen in studies conducted by Friend et.al, Brenan et al and Moreno et al. Majority of the patients in this study underwent gastro-jejunal anastomosis, it being 26 anastomosis coming to 43.33 %; while there were 5 ileo-ileal anastomosis. While, a study conducted by Docherty et al observed ileo-colic anastomosis as the most common. The study clearly indicates the advantage of staplers over hand sewn methods in terms of time for anastomosis and hence the total duration of surgery, which is much less in stapler group versus manual suturing. The average time for anastomosis in stapler group was 4 mins as compared to 39 mins of the hand sewn group. A study conducted by Weil et al also clearly showed that the time taken for stapler anastomosis (9 mins) was remarkable less as compared to conventional technique (17 mins)14. Similarly Hori et al study 2004 conducted in Japan also showed that the time taken by stapler anastomosis (14 mins) is relatively very less as compared to hand sewn method of anastomosis (25 mins)21. Due to decrease in time for anastomosis the net operative time also decreases. This in turn indirectly decreases certain complications like wound infection, bleeding, and other general anesthetic complications due to prolong anesthesia. Each step of the stapling procedure is fairly simple and anastomosis can be accomplished in few minutes. In certain situations, staplers offer the facility to achieve reconstruction that would be difficult to accomplish manually especially in the pelvis for example low rectal anastomosis22-23. The learning curve of stapler anastomosis seems to be less than that of conventional hand sewn anastomosis techniques. The post operative hospital stay in both the groups was not much different in our study. However in other studies there has been a difference in the length of hospital stay e.g. in a study conducted by Anwar et al of Hope Hospital UK in 2004 found that the average hospital stay in stapled group was 14.5 days as compared to hand sutured group which was 11.5 days24. CONCLUSION

Staplers are feasible, accessible and easy to use as compared to hand sewn methods, however cost is a major drawback in Government Hospital. Learning curve seems to be relatively less in staplers as compared to hand sewn methods. The duration for anastomosis using stapler is very much less than that taken by hand sewn anastomosis. No difference was found in post operative hospital stay in both the groups. Whenever feasible, accessible and available one should go for stapler anastomosis rather than hand sewn anastomosis; especially in critically ill patients in whom curtailment of operating and anesthesia time may be important and situations where manually reconstruction is tough, like pelvis (low rectal anastomosis). Although in government set up the cost of consumables per operation is increased when staplers are used. However we have
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economized the cost to a larger extent and ultimately this cost should be carefully weighed against the more efficient use of operative time.

REFERENCES