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A COMPETITIVE STUDY OF STAPLER BOWEL ANASTOMOSIS AND CONVENTIONAL HAND SEWN BOWEL ANASTOMOSIS IN REGARD TO OUTCOME AND COMPLICATIONS IN A TERTIARY CARE HOSPITAL OF UPPER ASSAM

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ABSTRACT

Introduction: Intestinal anastomosis is a commonly performed surgical procedure done worldwide both in emergency and elective settings. Single or double layered hand sewn bowel anastomosis is standard method. Among the newer methods mechanical stapler devices have achieved preference among surgeon. Despite popularity it is not devoid of post-operative complications. Hence the study was aimed to find out credibility of stapler in comparison to conventional hand sewn method in our hospital.

Objective: The objective of our study is to determine the safety and effectiveness of stapler anastomosis in terms of morbidity in comparison to conventional hand-sewn anastomosis.

Methodology: Patients underwent elective gastrointestinal anastomosis surgeries in the Department of Surgery of Assam Medical College and Hospital for 1 year duration were included in the study. Emergency surgery, pediatrics population and pregnant mothers were excluded from study. Patients were divided into two groups depending on–

1. Patients underwent hand sewn bowel anastomosis
2. Patients underwent intestinal anastomosis with stapler devices.

Both the groups were compared in respect to duration of surgery, hospital stay and comorbidities.

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Results and Observations: Each group consisted of 30 patients. In hand sewn group mean duration of surgery was 192 minutes while in stapler group it was 124.87 minutes(p-value <0.0001; statistically significant). In regard to the return of bowel sound, resumption of oral feeding duration of hospital stay and development of complications both hand sewn and stapler groups were statistically similar respectively.

Conclusion: Stapler was found to be equally safe and even more advantageous than hand sewn method as it reduces duration of surgery and easier to apply in narrow places e.g. deep into the pelvis. Only disadvantage is the high price of the stapler devices.

Keywords: Intestinal Anastomosis, Hand sewn Anastomosis, Intestinal Stapler Anastomosis, Anastomotic leak.

INTRODUCTION

Intestinal anastomosis is common procedure practiced both in planned as well as emergency settings at various medical setups around the globe despite of its significant complications and morbidities. Methods of intestinal anastomosis are various e.g. traditional handstitched using sutures, mechanical staplers or biological glues and underwent modifications and innovations through ages but still not devoid of limitations and complications.[1] Whatever the method is prerequisites for successful gut anastomosis are proper apposition, correct alignment, adequate blood supply and equally spaced stitches without tension.[2]

Surgeries on intestine started long back in ancient India in hands of Sushruta who repaired intestinal perforation and operated for intestinal obstruction within 600BC to 1000BC.[3] After Hippocrates and Celsus, School of Salerene on 11th century used stents for gut anastomosis.[4] In 19th century Larry first attempted two layer bowel anastomosis marking the modern era of bowel anastomosis. Antoine Lembert in 1826 showed the importance of serosa apposition in intestinal anastomosis.[5] Along with this maintenance of asepsis proved by Lord Joseph Lister in the year 1867 were important advancements in anastomosis.[6]

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Intestinal tumours, inflammatory bowel diseases are indications for elective bowel resection and anastomosis while intestinal obstruction, perforated bowel following abdominal trauma are the common indications in emergency settings. Anastomotic leak is one of the most dreaded complications of intestinal anastomosis, defined as “Defect at the Anastomotic site leading to a communication between intraluminal and extraluminal compartments” that can be confirmed Radiologically, Endoscopically or intraoperatively.[7] Anaemia, hypoalbuminemia, previous radiation or chemotherapy, malnutrition, vitamin deficiencies, steroid use, diabetes mellitus, alcohol abuse, hypothermia, Crohn's disease and sepsis are all linked to poor anastomotic healing culminating to anastomotic leak.[2]

Hand sewn intestinal anastomosis is done with sutures acting as foreign bodies in bowel anastomotic sites to induce an inflammatory reaction. The ideal sutures material should cause minimal inflammatory tissue reaction at the cost of maximum anastomotic strength. The inner layer of a double-layered anastomosis is stitched continuously or intermittently using absorbable sutures, while the outer layer is stitched intermittently using non-absorbable sutures.[8] Among monofilament(Glycolide & e-caprolactone)is commonly used suture material while polyglactin is commonly used braided suture material in bowel anastomosis.

Hultl first introduced surgical stapler devices in 1908 but due to heavy weight, high cost it did not gained popularity. But with the evolvement of disposable, dependable staplers for the last 30 years stapler devices have gained popularity specially in narrow anatomical spaces such as in anterior resection surgery deep in pelvis where hand-sewn method is much difficult.[9] Nowadays with most recent technological advancement with combined new functions stapler devices has produced improved quality and productivity with time saving as compared to conventional hand stitching although not always devoid of development of complications and mortalities.[10] Nowadays three types of stapler devices are used widely and they are, 1) Transverse Anastomotic Staplers, 2) Linear staplers and, 3) Circular stapler.

As there is no definite consensus regarding the choice of method as of now, we have planned this study to find out if any one of the procedures is superior to other in our practice.

AIM

To compare the outcome and complications of stapled anastomosis and conventional hand-sewn anastomosis in bowel surgery.

OBJECTIVE

To determine the safety and effectiveness of stapler anastomosis in terms of morbidity in comparison to conventional hand-sewn anastomosis.

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REVIEW OF THE LITRETURE

Although practice of bowel anastomosis and repair of perforation have been obtained since Sushruta's time until in 19th century, Lembert proposed his findings on intestinal anastomosis which made the cornerstone of the modern-day handsewn bowel anastomosis. Lembert in the year 1826 mentioned intestinal anastomosis by apposition of seromuscular layers taking sutures 3-5 mm apart at the open ends of bowel.[11] Kocher proposed a double layer bowel anastomosis method in 1880 where continuous mucosa and submucosa were apposed as the first layer using catgut and seromuscular as the second layer using silk.[12] Afterwards several surgeons like Halsted(1887) Connel(1892) came up with their proposal for safe and effective anastomosis methods and there are more than 150 methods of handsewn bowel anastomosis but whatever the method is "the key to a successful anastomosis is the accurate union of two viable bowel ends with complete avoidance of tension."[13]

Staplers are mechanical devices that act by implanting multiple rows of pins to join two portions of bowel i.e. anastomosis. Murphy Button described the first popular stapling device in 1892.[2] Following this Hungerian surgeon Humer Hültl in 1908 developed a stapler prototype which got several modifications to the modern-day bowel anastomosis staplers. Nowadays 3 types of staplers are routinely used in bowel anastomosis surgery and they are

1. Transverse Anastomosis (TA) Staplers
2. Linear Cutter/Gastrointestinal Anastomosis (GIA) Staplers
3. Circular Stapler.

Common principles of stapler mediated bowel anastomosis are 1) keeping adequate bowel lumen, 2) Preserving adequate perfusion, 3) Prevention of adapting tissue tension, 4) Prevention of anastomotic leakage and fistula, 5) Providing better homeostasis.

Few similar studies in regard to important findings relevant to our study are as follows-

Uvaish Parmar et al performed a similar study in 2022 titled "A Comparative Study of Staplers Versus Hand Sewn Anastomosis In Intestinal Surgeries" and found complications were relatively more in hand-sewn group 20% compared to stapled bowel anastomosis group which was 12%. They concluded that stapled anastomosis is safe and equally effective in bowel anastomosis and in view of anastomosis time and post-operative recovery it is superior but it is much more costlier than conventional hand-sewn method.[14]

Abhilash N et al conducted a similar study in 2021 titled "A prospective study of outcome of resection anastomosis in elective GI surgeries" from Bangalore concluded that stapler anastomosis can be completed more quickly than hand-sewn anastomosis. In regard to other parameters the groups had no difference.[15]

Banurekha R et al conducted a retrospective comparative study in the year 2017 titled "Hand sewn versus stapler anastomosis in elective gastro intestinal surgeries" at the Surgery Department of G. D. MCH at Dharmapuri in Tamil Nadu, India. They concluded that the stapler technique has a shorter recovery period, lower mortality, and a much shorter surgical time. In

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circumstances where space is limited, such as low colorectal anastomosis, staplers are better alternative with quicker application.[16]

Narayan Prasad Belbase et al performed a similar study namely "A comparative prospective study of handsewn versus stapled anastomosis in lower gastrointestinal surgeries" at 'College of Medical Sciences' at Bharatpur in Nepal for one year(from 2014 to 2015). In the handsewn group, the average operational time was 147.12±20.91 minutes, while stapler took 132.52 ± 15.71 minutes ($p<0.05$). Post-operative hospital stay, the leak rate and surgical site infection rate was also similar between the two groups. Hence they concluded stapled bowel anastomosis is to be a preferable option to handsewn intestinal anastomosis for fast intestinal anastomosis.[17]

MATERIALS AND METHOD

PLACE OF STUDY : Department of Surgery, Assam Medical College and Hospital, Dibrugarh.

DURATION OF STUDY : One year (From 1st March, 2023 to 29th February, 2024)

TYPE OF STUDY : Hospital based observational, cross-sectional and comparative study

STUDY POPULATION : Patients admitted and underwent elective operations with gastrointestinal anastomosis in different wards of Department of Surgery.

SAMPLE SIZE : Considering the duration (days) of hospital admission after bowel anastomosis surgery by hand sewn and stapler anastomosis method to be 8.8+/-3.01 and 6.5+/-1.23 respectively sample size of this study was calculated followed by rounded off to 30 in each group with 95% confidence and 90% power.

INCLUSION CRITERIA

☑ Patients admitted at different wards of the Department of Surgery and underwent intestinal anastomosis surgeries for several benign and malignant diseases.

☑ Male and female patients of more than 12 years who underwent various gastrointestinal anastomosis surgeries.

EXCLUTION CRITERIA

☒ Paediatric patients i.e. age below 12 years.

☒ Emergency gastrointestinal anastomosis.

☒ All pregnant mothers.

☒ Presence of coagulopathy and patients on anti-coagulant therapy.

☒ Patients who did not give consent for study.

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ETHICAL CLEARANCE

Ethical clearance was obtained from the 'Institutional Ethics Committee (H) of Assam Medical College and Hospital', Dibrugarh prior to the initiation of the study. Written informed consent was also taken from all study participants.

METHODOLOGY

Patients who gave informed consent for including in our study, admitted in different wards of the Department of Surgery, AMCH within the study duration and underwent elective bowel anastomosis were enlisted followed by detailed history, physical examination, confirmation of diagnosis were done and subsequently planned for surgery. Comorbidities e.g. diabetes, hypertension, anemia, hypoalbuminemia etc were optimized.

Patients were selected for either a stapler or hand-sewn anastomosis based on the surgeon's decision. Conventional double layer anastomosis was done for the stomach and small intestine, while single layer bowel anastomosis was done for the colon. In stapler group mainly linear cutter and circular staplers were used. In few cases Transverse Anastomosis stapler was also used.

Various observations were done in both the groups, like

- Duration of the surgical procedure
- Time to return of peristaltic sounds after surgery
- Duration after surgery when oral feeding was reinstituted
- Hospital stay duration after surgery
- Development of post-operative complications e.g. bleeding, anastomotic site leak, wound infection and mortality in both groups were recorded in the following tables for analysis.

STATISTICAL ANALYSIS

Categorical data is represented as frequency (%), and continuous data is presented as mean $\pm$ standard deviation. The statistical significance between the two groups has been established using the t-test for continuous data and the Chisquare test/Fisher's exact test for categorical data. Statistical significance has been defined as a p-value of < 0.05.

RESULTS AND OBSERVATIONS

In our study total 60 patients were included who underwent intestinal anastomosis. They were divided into 2 equal groups having 30 patients in each-

1) Hand-sewn Intestinal anastomosis group
2) Stapler anastomosis group

Following information was obtained and tabulated.

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DISTRIBUTION OF AGE OF THE PATIENTS: -

TABLE-1: DISTRIBUTION OF AGE

Age Group *(in years)*	Hand-Sewn		Stapler		*p value**
	n	*%*	*N*	*%*	
12–20	1	3.33	0	0.00	0.898
21–30	2	6.67	3	10.00	
31–40	3	10.00	2	6.67	
41–50	11	36.67	13	43.33	
51–60	9	30.00	8	26.67	
>60	4	13.33	4	13.33	
TOTAL	30	100.00	30	100.00	
**'Fisher Exact Test; The p-value is not significant at 5% level of significance'*					
Mean ±S.D.	46.67±14.09		46.27±10.77		0.902

Handsewn group had average age of 46.67 years while that in stapler group was 46.27 years. Fifth decade was the most common age group to undergo surgery in both the groups- 11 (36.67%) subjects in hand-sewn group and 13 (43.33%) in stapler group.

DISTRIBUTION OF GENDER OF THE PATIENTS: -

TABLE-2: GENDER WISE DISTRIBUTION

Gender	Hand-Sewn		Stapler		*p value**
	n	*%*	*n*	*%*	
Male	16	53.33	15	50.00	0.848

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Female	14	46.67	15	50.00	
TOTAL	30	100.00	30	100.00	
Ratio (Male : Female)	1.14 :1		1 :1		
**'Chi-square Test; The p-value is not significant at 5% level of significance'*					

There were 16 (53.33%) males and 14 (46.67%) females in the handsewn subjects and 15 (50%) male and 15 (50%) female in the stapler group.

DISTRIBUTION OF TYPES OF ANASTOMOSIS SURGERIES PERFORMED: -

TABLE-3: DISTRIBUTION OF TYPES OF ANASTOMOSES

TYPES OF ANASTOMOSES	Hand-Sewn		Stapler		*p value**
	n = 30	%	*n* = 30	%	
Esophago-Gastrostomy	1	3.33	1	3.33	1.000
Gastro-Jejunostomy	9	30.00	8	26.67	0.775
Illeo-Ileal Anastomosis	4	13.33	3	10.00	0.688
Illeo-Collic Anastomosis	6	20.00	5	16.67	0.739
Colo-Colic Anastomosis	6	20.00	5	16.67	0.739
Colo-Rectal Anastomosis	4	13.33	8	26.67	0.197
**'Fisher Exact Test/Chisquare Test;The p-value is not significant at 5% level of significance'*					

Gastrojejunostomy was the most common type of bowel anastomosis performed, 9 cases (30%) in handsewn method and 8 cases (26.67%) using stapler. Colorectal anastomosis

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was the second most common bowel anastomosis procedure done in our study.

COMPARISON OF DURATION OF SURGERY: -

TABLE-4: COMPARISON OF DURATION OF SURGERY

Group	*Mean*	±*S.D.*	*Range*		*p value**
			Min	*Maz*	
Hand-Sewn	157.47	30.36	80	192	<0.001
Stapler	124.87	22.63	64	158	
**'Student t Test; The p-value is significant at 5% level of significance'*					

In the handsewn group, the average surgical time was determined to be 157.47 minutes, whereas in the stapler group, it was much less, only 124.87 minutes.

COMPARISON OF RETURN OF BOWEL SOUNDS: -

TABLE-5: COMPARISON OF RETURN OF BOWEL SOUNDS

Variable	Hand-Sewn		Stapler		*p value**
	Mean	±*S.D.*	*Mean*	±*S.D.*	
Return of Bowel Sounds *(Days).*	2.62	0.36	2.53	0.39	0.397
**'Student t Test; The p-value is not significant at 5% level of significance'*					

The average time for the restoration of bowel activity was 2.62 days in hand sewn patients, whereas stapler group achieved the same on 2.53 days.

COMPARISON OF RESUMPTION OF ORAL FEEDS: -

TABLE-6: COMPARISON OF RESUMPTION OF ORAL FEEDS

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Variable	Hand-Sewn		Stapler		*p value**
	Mean	*±S.D.*	*Mean*	*±S.D.*	
Resumption of Oral Feeds *(Days)*	4.80	0.50	4.57	0.47	0.072
**'Student t Test; The p-value is not significant at 5% level of significance'*					

On average patients were put on oral feeds on day 4.8 in handsewn group while that in stapler group on 4.57 days. The groups were statistically indifferent in view of post-operative starting of feeding.

COMPARISON OF POSTOPERATIVE HOSPITAL STAY: -

TABLE-7: COMPARISON OF POSTOPERATIVE HOSPITAL STAY

Group	*Mean*	*±S.D.*	*Range*		*p value**
			Min	*Maz*	
Hand-Sewn	10.67	1.75	9	15	0.173
Stapler	10.07	1.62	8	15	
**'Student t Test; The p-value is not significant at 5% level of*					

Both the groups were statistically indifferent regarding hospital stay following surgery. For the hand sewn group, it was 10.67 days, while for the stapler group, it was 10.07 days on an average.

COMPARISON OF POST-OPERATIVE LOCAL COMPLICATIONS: -

TABLE-8: COMPARISON OF POST-OPERATIVE LOCAL COMPLICATIONS

Local Complications	Hand-Sewn		Stapler		*p value**
	n = 30	%	*n* = 30	%	

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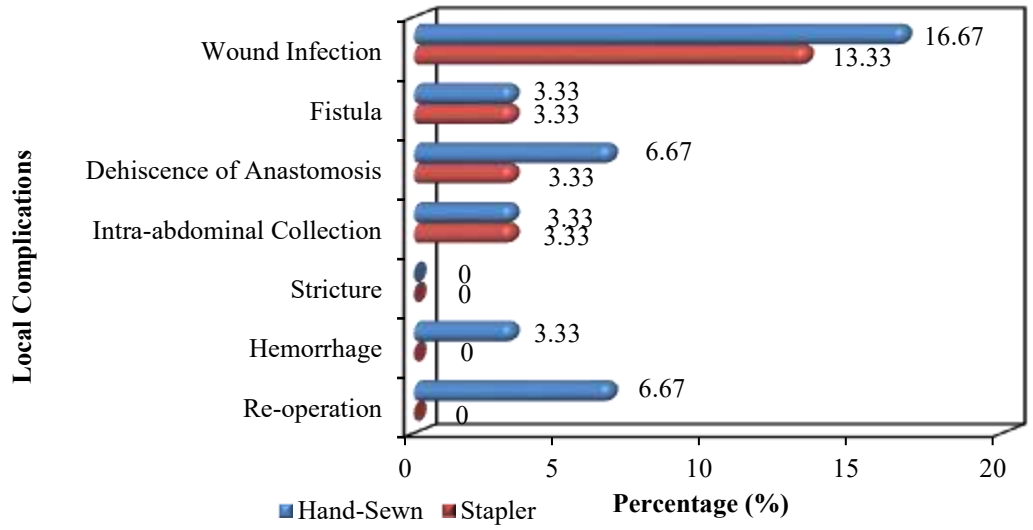
Wound Infection	5	16.67	4	13.33	0.447
Fistula	1	3.33	1	3.33	1.000
Dehiscence of Anastomosis	2	6.67	1	3.33	0.038*
Intra-abdominal Collection	1	3.33	1	3.33	0.553
Stricture	0	0.00	0	0.00	–
Haemorrhage	1	3.33	0	0.00	0.150
Re-operation	2	6.67	0	0.00	0.150
*'Fisher Exact Test; The p-value is significant at 5% level of significance'					

Figure–8: Comparison of Post-operative local complications



7 subjects (23.33%) in the handsewn while 6 patients (20%) in the stapler group had developed one or more local post-operative problems. Wound infection was the commonest local complication and anastomotic leak, the most significant one was observed in 4(13.33%) patients in hand-sewn and 3(10%) patients in stapler group.

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DISCUSSION

In our study each of these groups contained 30 subjects. We compared in between these two groups in regard to Age, Sex, type of anastomosis, duration of anastomosis, post-operative hospital stays and development of complications to find out advantages of particular method.

A) Age distribution:

Mean age of patients of stapler group was 46.27 years while that of hand sewn group was 46.67 years. Statistically the difference was not significant (p-value- 0.902). In both hand-sewn and stapler groups maximum patients belonged from the age group of 41-50 years. Similar findings were observed in other related studies done by Abhilash et al and Banurekha et al.[15,16]

B) Gender Distribution:

In our study out of 30 patients in hand-sewn anastomosis group 16(53.33%) were male and rest 14(46.67%) were female. In the Stapler anastomosis group the male and female each were 15 in number in each group. Similar finding was obtained by Nichkaode PB et al. in their study.[18]

C) TYPES OF BOWEL ANASTOMOSIS PERFORMED:

In our study Gastrojejunostomy(GJ) was most common type of anastomosis performed. GJ was done in total 17(28.33%) patients, 9(30%) with hand sewn and 8(26.67%) using stapler. Banurekha et al.[16] in their study also had 7(25%) and 8(28.57%) subjects underwent Gastrojejunostomy by handsewn and stapler method respectively, quite similar to our study.

Total 12(20%) patients underwent Colo-rectal anastomosis surgery with 4(13.33%) patients in hand-sewn method and 8(26.67%) using stapler. In comparison, Belbase et al. also had 24% patients underwent colocolic/colorectal anastomosis.[17]

D) COMPARISON OF DURATION OF SURGERY:

The mean operating time in hand-sewn intestinal anastomosis group was 157.47 minutes ranging from 80 minutes to 192 minutes. Whereas in using stapler it was only 124.87minutes with range from 64 minutes to 158 minutes making the difference statistically significant (p-value <0.001). Himabindu et al. also found similar finding with mean operating time of 150.12 and 128.32 minutes in hand sewn and stapler anastomosis group respectively which is quite comparable to present study. Belbase et al. and Nichkaode et al. also had similar findings in their studies.[17,18]

E) COMPARISON OF RETURN OF BOWEL SOUNDS:

Mean time taken in hand-sewn patients for return of intestinal motility was 2.62 days and that in stapler patients was 2.53 days which was statistically insignificant (p-value- 0.397).

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In the study done by Himabindu et al. mean duration for return of bowel sounds in hand sewn intestinal anastomosis group was 2.42 days, while that in stapler group was 2.3 days and the difference was statistically insignificant similar to the findings of our study.[19] Also similar results were obtained by Banurekha et al. in their study.[16]

F) COMPARISON OF RESUMPTION OF ORAL FEEDING:

In hand-sewn group mean time taken for resumption of feeding was 4.8 days and that in stapler group was 4.57 days. This is similar with the findings of study by Himabindu et al. (4.33 days for hand stitched and 4.28 days for stapler).[19] In both the settings the difference was statistically insignificant (p-value- 0.072). Similar result was obtained by Damesha et al, Banurekha et al in their studies.[20,16] In contrast to these findings few previous studies as by Arunkumar et al found to have early post operative initiation of oral feeding with stapler as compared to hand sewn.[21]

G) COMPARISON OF POSTOPERATIVE HOSPITAL STAY:

In present study the mean post-operative hospital stay was 10.67 days for hand stitched patients and that in stappled group was 10.07 days. The difference was not clinically significant (p-value- 0.078). Himabindu et al. estimated duration for post-operative hospital stay of 9.92 days in handsewn group and 9.75 days in stapler group in their study which is comparable to the present study.[19] In contrary Prabhat N. Nichkaode et al showed to have reduced post operative hospital admission with stapler as compared to hand sewn.[18]

H) COMPARISON OF POST-OPERATIVE LOCAL COMPLICATIONS:

In hand sewn group total 7(23.33%) patients and in stapler group 6(20%) patients had developed single or multiple local complications. While wound infection was the commonest, anastomotic leak, the most critical complication was observed in 4(13.33%) patients. There was no statistical and clinical difference between the groups. Damesha et al and Rushin et al also in their studies observed both the groups to be similar in terms of development of local complications.[20,22]

SUMMARY

In hand sewn group mean age of the patients was 46.67 years while that in stapler group was 46.27 years. In both the groups 5th decade of life were most common age group for undergoing surgery. Male and females were evenly distributed in each of the groups.

In the present study total 6 types of bowel anastomosis have been observed and they are Esophagogastrostomy, Gastrojejunostomy, Illeoilleal, Illeocolic, Colocolic and colorectal anastomosis. Most frequent of these was gastrojejunostomy- 9(30%) in handsewn method and 8(26.67%) in stapler method. Colorectal anastomosis was the next most common bowel anastomosis surgery in which 4(13.33%) had hand-sewn and 8(26.67%) had stapler

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anastomosis.

The mean time for surgery in hand-sewn group was found to be 157.47 minutes while that in stapler group was found to be 124.87 minutes making the difference statistically and clinically significant.

There was no significant difference in return of peristaltic sounds between the two groups which were 2.62 and 2.53 days in handsewn and stapler group respectively.

On average patients were put on oral feeds on day 4.8 in handsewn group while that in stapler group on 4.57 days and the difference was not statistically significant.

In regard to the post-operative hospital stay both the groups were similar - 10.67 days in hand sewn group while in stapler group it was 10.07 days.

In hand sewn group 7(23.33%) patients and in stapler group 6(20%) patients developed single or multiple local post-operative complications. Wound infection was most common local complication in both groups- 5 in handsewn and 4 in stapler group. In hand sewn group anastomotic leak was observed in 4(13.33%) patients while in stapler group 3(10%) patients had anastomotic leak rendering no statistically significant difference. In the hand sewn group, two patients required re-exploration- 1 for fistula formation and the other because of anastomotic site bleeding.

CONCLUSION

Conventional hand-sewn anastomosis is the standard technique for bowel anastomosis with respect to which all the newer methods are evaluated in view of safety and efficacy. Stapler devices had been formulated and evolved to reduce operation time, post-operative complications and to use in narrow spaces.

In respect to operating time stapler showed prominent benefit over handsewn anastomosis. Hence stapler should be preferred in elderly subjects, patients with comorbidities etc who cannot withstand prolonged anaesthesia. But in regard to reestablishment of intestinal function, post-operative restarting of feeds and hospital stay both methods were similar. Stapler has another benefit over the handsewn method that it can be applied much easily in narrow working spaces e.g. deep in the pelvis while performing Colorectal anastomosis following Low Anterior Resection (LAR) surgery, upper abdomen or chest as in esophagogastrostomy procedures etc.

Despite of the benefits stapler devices are costly which is a gross disadvantage. All the stapler devices used in this study were supplied free of cost from government.

In our study we could follow up the patients for a period of maximum 3 months. These patients required to be followed up post-operatively for a longer period of time to detect development of any late complications e.g. anastomotic site stenosis etc, which was out of the

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scope of our study.

CONFLICT OF INTEREST

Nil.

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