SINGLE LAYER VS DOUBLE LAYER SMALL GUT ANASTOMOSIS

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Abstract

This is a single-centre prospective, double-blind, randomized controlled comparative study **Methods**

Prior written informed consent will be obtained from all the study subjects after explaining them the study protocol. Randomization for each patient will be predetermined by a random number generator and performed using random permuted blocks of size 10. Participants will be randomly assigned to undergo either single layered extra-mucosal intestinal anastomosis (Group-A) or double layered intestinal anastomosis (Group-B) by opening a sealed opaque envelope indicating the technique to be used. These envelopes will be placed in the operating room and will be drawn sequentially just before surgery. At this point, each patient will be considered randomized. The study participants and the care providers who follow up the patients in the postoperative ward will be unaware of the type of anastomosis.

Results

In this study two patients who had developed anastomotic leak in group

B (double layer), among them 2(8%) patient responded well to conservative management and recovered. One more patient (4%) who had anastomotic leak in group B (double layer) died due to septicaemia and rest 22 patients (88%) were asymptomatic. In group A (single layer) two patient (8%) developed anastomotic leak and recovered with conservative management. p value if found out to be 0.14 and is not significant.

Conclusion

Duration required to perform a single layer intestinal anastomosis is significantly lesser when compared to double layer.

There is no significant difference in anastomotic leak between two groups.

There is no significant difference in duration of hospital stay in single vs double layered bowel anastomosis.

Aim and Objectives: Comparison of the efficacy of single layer vs double layer small gut anastomosis.

- To study postoperative complications like anastomotic leak in single and double layered intestinal anastomosis.
- To compare duration required to perform single and double layered intestinal anastomosis.
- To compare the duration of hospital stay in single vs double layered bowel anastomosis.

Introduction: Intestinal anastomosis is a routine surgical procedure used either in elective or emergency surgeries. For the practicing medical professionals it is important that they should be able to perform the anastomotic surgery perfectly and safely. The procedure of anastomosis depends on the location of the anastomosis, the condition of bowel along with the etiology of the disease present and the overall situation of the patient.1 Any type of surgery requires the skin and the perfection which can play a decisive role in the success of the surgery. Over the time period many such techniques are developed but use of sutures manually is such a skill which has been a prominent feature of intestinal anastomosis due to the availability and the affordability of the suture material, the cost effectiveness and the know how of the process. In the past, two layer anastomosis was the most common method used for surgical situation. It is cumbersome, lengthy

process and also there is high chances of anastomotic stricture development as a complication. In the recent time there has been an alternative developed, single layer suturing which involves continuous anastomosis. Monofilament type of suture is used by many practicing surgeons due to cost effectiveness of this type of suture. It is also less time consuming and there is less chances of leakage from the anastomotic site compared to double layer anastomosis method.2There are various complications which can occur after the intestinal anastomoses such as anastomotic leak. This can lead to peritonitis, abscess, fistula, necrosis and stricture. Various other factors can also lead to anastomosis related complications which includes, suturing techniques, suture material, presence of sepsis at the site, vascular defect, etc. Leaking from the anastomotic site is one of the most common complication of alimentary tract and it amounts to total 1.3 to 7.7% of the total complications. This can lead to increased morbidity and increased hospital stay. The present study aims to compare the outcomes of single layer anastomosis versus double layer anastomosis in the small bowel with respect to duration of the surgery, post operative complications, duration of the hospital stay of each group and prognosis.

Materials and Methods:

STUDY DESIGN: Single- centre prospective, double-blind, randomized controlled comparative study

SOURCE OF DATA: Patients admitted to surgery department in Krishna Hospital requiring resection and anastomosis in the period of DECEMBER 2020 To JUNE 2022 will be taken for study, considering the inclusion and exclusion criteria.

INCLUSION CRITERIA AND EXCLUSION CRITERIA

INCLUSION CRITERIA

1. Age limit: 18 to 65

2. Only haemodynamically stable patients with a haemoglobin level of > 8 gm/dl EXCLUSION CRITERIA

1. Patients <18 years

2. Patients with terminal illness.

3. Pregnant patients

RESULTS:

Disease group and patients:

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Disease group	Frequency	%	
Meckel diverticulum	9	18%	
Enterocutaneous fistula	13	26%	
Jejunal stricture	12	24%	
Multiple ileal perforation	8	16%	
Terminal ileal stricture	6	12%	
Strangulated bowel	2	4%	

Type and number of procedures performed:

Procedure	Frequency	%
Resection of ileum with ileo- ileal anastomosis	27	54%
Resection of jejunum with jejuno-jejunal anastomosis	17	34%
Resection of jejunum and ileum with jejuno-ileal anastomosis	6	12%

The table shows the procedure performed during the single or double layered anastomosis among the study population

Duration of minutes)	anastomosis	(in	Single layer		Double laye	er
10-15			3 (12%)			
16-20			19 (76%)			
21-25			3 (12%)		1 (4%)	
26-30					20 (80%)	
31-35					4 (16%)	
Total			25		25	
Groups	Range	Μ	ean±SD	Mean difference	t value	P value
Single layer	12-25	18	3.85±1.55	9.05	17.71	0.001
Double layer	26-35	27	2.9±2.01			

Duration of anastomosis:

Complications: Anastomotic Leak

Complication	Single layer	Double layer
Anastomotic leak	2	3
No leak	23	22

Comparision of mean duration of hospital stay:

Group	Range	Mean ±SD (in days)	Mean difference	T value	P value
Single layer	5-12	7.48±1.88	0.53	0.84	0.40
Double layer	5-14	8.01±2.52			

Unpaired t test was used to analyse the statistical significance of hospital duration stay, the p value was found among the study population was 0.40. which was suggestive of there is no statistical significance difference between comparison of mean duration of the hospital stay. **Final outcome :**

Outcome	Single layer	Double layer
Death	0	1
Recovered	2	2
Asymptomatic	23	22

p = 0.14 ns (fisher's exact test)

In this study two patients who had developed anastomotic leak in group B (double layer), among them 2(8%) patient responded well to conservative management and recovered. One more patient (4%) who had anastomotic leak in group B (double layer) died due to septicaemia and rest 22 patients (88%) were asymptomatic. In group A (single layer) two patient (8%) developed anastomotic leak and recovered with conservative management. p value if found out to be 0.14 and is not significant.

Discussion:

The present study assessed the efficacy and safety of single layered anastomosis in comparison with double layer anastomosis after intestinal resection and anastomosis. The study included two groups single layer and double layer, each group had 25 cases altogether 50 cases. Cases were allotted to either group alternatively, requiring single layer anastomosis and double layer

anastomosis for various clinical conditions of small bowel. Anastomosis was done at different levels of intestine and depending up on the position of the viscera. The efficacy of both groups were compared in terms of duration required to perform single and double layered intestinal anastomosis, study postoperative complications like anastomotic leak in single and double layered intestinal anastomosis, the outcome associated with single and double layered anastomosis and the duration of hospital stay in either of them. In both the groups similarity was according to the age group. Out of 25 patients in each group, 24% were present in 20-30 years, 32% in 31-40 years, 20% in 41-50 years and 24% present in 51-60 years in the single layer anastomosis group. Whereas in double layer anastomosis group, 36% patients were in the 31-40 years, 28% in the 41-50 years, 20% in the 20-30 years and 16% of the total patients were in the double layer anastomosis. According to the gender distribution it was observed that the majority of the patients were male in both the groups. 72% of the single layer group were males and 64% of double layer group were males. Which was suggestive of predominance of male gender in our study. The current study is based on the small intestinal diseases in which either single layer or double layer anastomosis was performed. Various diagnoses were found in these surgeries such as necrotising enterocolitis, Meckel diverticulum, enterocutaneous fistula, inflammatory bowel disease, jejunal stricture, multiple ileal perforation and terminal ileal stricture and diagnoses were present in relatively less proportion. In the anastomosis of small intestine various types of procedures performed for the anastomosis. Majority of anastomosis performed were resection of jejunum with jejuno-jejunum anastomosis followed by resection of ileum with ileo-ileal anastomosis in 26% of the study population also resection of jejunum and ileum with jejunojejunal anastomosis in 26%. Anastomotic site used for the study population most commonly in both the groups were ileo-ileal followed by jejuno-jejunal and jejuno-ileal. All the anastomosis performed in the study group of end to end type in 100% of the study population. Duration of anastomosis was measured during the surgeries. It was found that more time was taken by double layer anastomosis. The time taken in single layer anastomosis ranged between 10-25 minutes whereas in the double layer anastomosis it ranged from 26-35 minutes. Mean time taken by the single layer anastomosis was found to be 18.85±1.55 whereas in the double layer it was measured to be 27.9±2.01. The results were compared using unpaired t test, the result was statistically significant with p value 0.001.Complications such as anastomotic leak was noted in both the groups. Two cases of single layer anastomosis showed anastomotic leak whereas three cases of double layer anastomosis showed anastomotic leak of 25 patients. The chi square test was applied to calculate the statistical significance. It was found that the p value was 0.6 which showed there is no statistical significance between the two groups related to complications. The final outcomes after the single layer and double layer were assessed. It was noted that there was one death in the double layer population whereas one patient from each group showed total recovery while rest of the patients were asymptomatic.

Fishers exact test was applied to analyse the statistical significance of the final outcome, the p value was found to be >0.05 which suggested that there is no statistical significance among the final outcome of both the surgeries.

Mean hospital duration of stay post surgery was also analysed, the mean time taken in single layer group was 7.48 ± 1.88 days whereas it was 8.01 ± 2.52 days in the double layer group. T test showed no statistically significant difference among the study population.

CONCLUSION:

This prospective comparative study included fifty cases of various clinical conditions of small bowel requiring resection and anastomosis. The study had two groups, single layer and double layer comprising twenty five cases in each group. Each group was evaluated and compared with respect to duration required, anastomotic leak in single and double layered intestinal anastomosis, outcome associated and the duration of hospital stay in single vs double layered bowel anastomosis. Though a large number of patients need be to studied to do a dogmatic conclusion, based on the results obtained in the present study following conclusions can be drawn: Duration required to perform a single layer intestinal anastomosis is significantly lesser when compared to double layer.

There is no significant difference in anastomotic leak between two groups.

There is no significant difference in duration of hospital stay in single vs double layered bowel anastomosis.

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