

A Randomized trial of Comparing single layer Continuous Versus Double layer Interrupted Intestinal Anastomosis Techniques in a group of Risk-Stratified Patients using APACHE-II Scoring System

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Abstract

Introduction: Bowel resection and anastomosis are very commonly performed gastrointestinal surgeries. Anastomosis integrity is a major determinant of mortality and morbidity among these patients, however there is no clear consensus on the technique used to create an anastomosis.

Aim: To compare and evaluate the clinical outcomes with reference to the rate of anastomotic leak, operating time and return of bowel activity between single layer continuous versus double layer interrupted intestinal anastomosis in risk-stratified patients using APACHE-II scoring system.

Material and Methods: All the patients were risk stratified using APACHE-II scoring system and those with a score of more than ten were excluded. Computer generated numbers were used for randomization. On half of the patients, the intestinal anastomoses were performed using a single layer continuous technique and on the rest, using a double layer

interrupted technique. The criteria for anastomotic leak are defined as complications of intra-abdominal abscess, radiographic demonstration of a fistula, visible disruption of suture line on re-exploration or leak of enteric contents from the wound. Secondary parameters including operating time, time of return of bowel activity and hospital stay were also calculated. Chi-square test was applied for categorical data (rate of anastomotic leak) and student -t test was applied for continuous data (time of anastomosis, return of bowel activity and hospital stay).

Results: A total of 60 patients undergoing intestinal anastomosis were included in the study. On 30 patients single layer (SL) anastomosis was performed and an equal number of patients underwent double layer (DL) anastomosis. The mean age for the SL group was 33.17 years and 32.37 for the DL group. The male to female ratio in the SL group and the DL group were 23:7 and 26:4 respectively. The rate of anastomotic leak in the SL group was 3.3% as compared to 6.6% in the DL group but the difference was statistically insignificant as the p-value was 0.550. The mean operating time for the SL group was 15min 34 sec and it was significantly better than the DL group with a mean of 24min 90 sec. The timing of return of bowel sounds was also statistically significant in the SL group (2.83 days) as compared to the DL group (3.87 days). The difference in the mean hospital stay was statistically insignificant in both the

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groups (SL group was 7.20 days & DL group was 8.43 days).

Conclusion: We did not find any statistical difference in the rate of anastomotic leak between the two groups but a bigger sample size or meta-analysis is required to establish superiority of one technique over the other in terms of safety. Single layer was significantly quicker to perform with an early return of bowel activity.

Keywords: Intestinal anastomosis; Single layer; Double layer; APACHE-II.

Introduction

Asepsis, haemostasis and gentleness to tissues are the bases of any surgeon's art. Nevertheless, recent decades have seen a shift in the emphasis from the attainment of technical skill to the search for new procedures. This attitude is a result from the extraordinary increase in the application of surgical methods to new fields. Historically, such a point of view led to an unremitting search for new procedures when results were unsatisfactory, although faulty technique rather than the procedure itself was the cause of failure in many instances. Now that all regions of the body have been explored, it is appropriate to stress the important relationship between the art of surgery and success in surgical therapy. The growing recognition of this relationship should reemphasize the value of precise technique.¹

Intestinal obstruction, perforation of the bowel frequently requires joining of the 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 but essential. Over time the basic principles crucial for obtaining successful results have been defined. Accurate approximations of the bowel without tension and with a good blood supply to both the ends being joined are obviously fundamental but good surgical technique is equally important.²

Anastomotic integrity is a major determinant of morbidity and mortality after operations on the gastrointestinal tract.³

Failure of anastomosis with leakage of intestinal contents is still a common surgical occurrence. A leaking anastomosis greatly increases the morbidity and mortality associated with the operation. It can increase the length of hospital stay manifold and increase the mortality rate by ten folds.⁴

Reported anastomotic failure ranges from 1.5-2.2%.^{5,6} It depends on what type of anastomosis was performed and whether the operation was an elective or an emergency procedure. Dehiscence, when it occurs, has been associated with one fifth to one third of all post-operative deaths in patients who underwent an intestinal anastomosis.⁷

Many different techniques are currently used to join segments of the intestinal tract following resection. These include anastomoses made with stapling devices, hand sewn single layer and double layer procedures in interrupted or continuous fashion using a variety of absorbable and nonabsorbable suture materials. No single method of anastomoses has proven to be clearly superior over others.⁸

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 to intestinal anastomosis. The ultimate test of suitability of a technique for intestinal anastomosis is its ability to heal without leakage and which can be performed in a reasonable time with average surgical skills.⁹

For a new technique to be acceptable, it needs to be demonstrated as safe and effective in multicenter trials and in a large number of patients. So the present study is designed to compare the outcomes of single layer continuous suturing technique with the traditional double layer interrupted suturing technique in the performance of intestinal anastomosis.

Review of Literature

The word anastomosis comes from the Greek words 'ανα', without, 'στομα', a mouth, i.e. when a tubular viscous (bowel) or vessel (mostly arteries) is joined after resection or bypass without exteriorization with a stoma, or having been tied off. Anastomoses in the bowel were not undertaken successfully until the nineteenth century. Before that, experience was limited to exteriorization or closure of simple lacerations.⁵ Lembert described his seromuscular technique for bowel anastomosis in 1826.¹⁰

The principles of intestinal anastomosis are in large part based on Halsted's late 19th century studies on the importance of sub mucosa as the layer providing strength to the suture line. Most of the early twentieth century procedures on the small intestine were related to the treatment of obstruction.¹¹

With good bowel preparation or an empty bowel, it is probably not necessary to apply clamps (even of the soft occlusion type), which are likely to cause some degree of damage. If there is any risk of intestinal spillage during anastomosis, when bowel is unprepared or obstructed for example, atraumatic intestinal clamp should be used. Clamps must not impinge on mesentery or its vasculature for the fear of necrosis. Ideally the bowel edges should be pink and bleeding prior to anastomosis. Excessive bleeding from the bowel wall may need oversewing if natural hemostasis is inadequate.¹⁰

Essentials for safe bowel anastomosis include local factors like, good blood supply, without tension, inverting anastomosis with an appropriate suture, accurate apposition and suture technique, avoidance of tissue damage by clamps and systemic factors like bowel preparation (and avoidance of spillage), antibiotic prophylaxis, maintenance of good perfusion and tissue oxygenation during anaesthesia (correction of shock), adequate nutritional attention, adequate resection margins (cancer or inflammatory bowel disease) and avoidance of chemotherapy/radiotherapy.¹⁰

This technique can be practiced on basic skills jigs. The bowel ends must be brought together without tension. Stay sutures, which avoid the need for tissue forceps, may help with the placement of the posterior, continuous, seromuscular layer. The all layers continuous inner suture can be undertaken with a double-ended suture to help to keep the anastomosis even, going from the middle posteriorly to the lateral edge on each side. At the corners, one or two Connell 'loop-on-the-mucosa' sutures help to invert the mucosa. The double-ended suture can then be tied in the middle (on the antimesenteric side of the bowel). Finally the anastomosis is inverted using a seromuscular, anterior, continuous Lembert suture. The apposition of bowel edges should, in each layer, be as accurate as possible. Bites should be approximately 4mm deep and 4mm apart. Suture materials should be of 2/0-3/0 sizes and made of an absorbable polymer, which can be braided (e.g. polyglactin), or a monofilament (e.g. polydioxanone), mounted on an atraumatic round bodied needle. Braided, coated sutures are the easiest to handle and knot.¹²

The process of intestinal anastomotic healing mimics that of wound healing elsewhere in the body that it can be arbitrarily divided into an acute inflammatory (lag) phase, a proliferative phase, and, finally, a remodeling or maturation phase. The strongest component of the bowel wall, the submucosa, owes most of its strength

to the collagenous connective tissue it contains. Collagen is thus the single most important molecule for determining intestinal strength, which makes its metabolism of particular interest for understanding anastomotic healing. Collagen is secreted from fibroblasts in a monomeric form called tropocollagen; this is a large, stiff molecule that can be visualized by electron microscopy. Collagen itself can be divided into subtypes on the basis of compositional differences i.e. different combinations of $\alpha 1$ & $\alpha 2$ chains. Type I collagen predominates in skin, bones, tendons and most organs; type II is found primarily in cartilage; and type III alongside type I is associated in remodeling of tissues such as the aorta, oesophagus, and the uterus. Synthesis of collagen is an intracellular process that occurs in polysomes. A critical stage in collagen formation is the hydroxylation of proline to produce hydroxyproline; this process is believed to be important for maintaining the three-dimensional triple helix conformation of mature collagen, which gives the molecule its structural strength. The amount of collagen found in a tissue is indirectly determined by measuring the amount of hydroxyproline, though no significant statistical correlation between hydroxyproline content and objective measurement of anastomotic strength has ever been demonstrated. Vitamin C deficiency results in impaired hydroxylation of proline and the accumulation of proline-rich, hydroxyproline-poor molecules in intracellular vacuoles.^{12,13}

The degree of fiber and fibril cross-linking relates to the maturity of the collagen and is probably important in determining the overall strength of the scar tissue. Of equal importance is the orientation of fibers and their weave. The bursting pressure of anastomoses has often been used to gauge the strength of the healing process. This pressure has been found to increase rapidly in the early post operative period, reaching 60% of the strength of the surrounding bowel by 3 to 4 days and 100% by 1 week.^{14,15}

Collagen synthesis is a dynamic process that depends on the balance between synthesis and collagenolysis. Degradation of mature collagen begins in the first 24 hours and predominates for the first four days. By one week, collagen synthesis is the dominant force, particularly proximal to the anastomosis. After 5 to 6 weeks, there is no significant increase in the amount of collagen in a healing wound or anastomosis, though turnover and thus synthesis are extensive. The strength of the scar continues to increase for many months after injury. Local infection increases collagenase activity and reduces the levels of collagenase inhibitors.^{16,17}

Collagen synthesis capacity is relatively uniform throughout the large bowel but less so in the small intestine. Overall collagen synthesis capacity is somewhat less in the small intestine although no significant difference has been found between the strength of ileal anastomoses and that of colonic anastomoses at 4 days.¹⁸

Various attempts have been made to improve the healing of intestinal anastomoses. A 2002 animal study concluded that the locally applied charged particles improved the healing of colonic anastomoses.¹⁹

Sewing bowel segments with various suture materials ranging from catgut to stainless steel wire, has been a standard technique for more than 150 years. Staplers, though first developed in the early 20th century, only began to have significant impact on GI surgery within past three decades. Staplers certainly appeal to the technically minded, and most studies suggest that they have small amount of operating time; however they remain relatively expensive, and it is still unclear whether the results are any better than can be achieved with suturing. Accordingly, it is worthwhile to examine the technical aspects of the two approaches to the bowel anastomosis and to compare their respective merits. There is no high quality evidence to indicate that hand sewing a gastrointestinal anastomosis is superior to stapling, or vice versa.²⁰

Sutures act as foreign bodies in the anastomosis and thus produce inflammatory reaction.²¹ Some studies that examined the amount of inflammation induced at the anastomosis by various types of sutures found that polypropylene (prolene), catgut, and polyglycolic acid (Dexon) were equivalent in this regard.^{22,23} Silk however produced a significantly greater cellular reaction at the anastomosis, and the reaction persisted for as long as 6 weeks.²³ A 1975 study reported on a series of 41 patients who underwent low anterior resection involving a primary side-to-end colorectal anastomosis with 5-0 stainless steel wire. The investigators of this study considered this material ideal because of its strength and relative inertness within the tissues, and they supported their claims with a relatively low leakage rate of 7.3%.²⁴ The ideal suture material is the one that causes minimal inflammation and tissue reaction while providing maximum strength during the lag phase of the wound healing is yet to be discovered.

Anastomotic leak has catastrophic consequences for the patient's health as well as the cost of care. Ischemia, tension on the anastomosis, and poor technique are clearly responsible for anastomotic

failure and all are under the direct control of the surgeon. It is not surprising, therefore, that both Fielding et. al.²⁵, and Tusan and Ever et. al.²⁶ found that leakage rates varied significantly between surgeons and tend to be lower with more experienced surgeons. Other traditional risk factors such as diabetes, steroids, surgical technique, blood loss, and nutritional factors have not clearly been predictive for anastomotic failure.¹⁹ Numerous studies in the literature comparing techniques (e.g. one-layer vs. two-layer, hand sewn vs. stapled, and end-to-end vs. end-to-side) have failed to demonstrate a clear superiority of one over the other.²⁶

Both continuous and interrupted sutures are commonly used in fashioning intestinal anastomoses. Double-layer anastomoses were described in the literature before single-layer ones. All such anastomoses are of essentially similar construction, consisting of an inner layer of continuous or interrupted absorbable or nonabsorbable sutures. Traditionally, double layer anastomoses have been considered more secure; however, for some time single layer anastomoses have been performed in difficult locations (e.g. low in the pelvis or high in the chest) with good results. Moreover, work from the 1980's suggests that the single layer technique has significant inherent advantages.²⁷⁻²⁹

Double layer anastomoses were long believed to be essential for self-healing; however, subsequent pathologic analysis of these anastomoses revealed microscopic areas of necrosis and sloughing of the tissues incorporated in the inner layer as a result of strangulation.³⁹ Animal studies have confirmed that single-layer anastomoses cause less narrowing of the intestinal lumen³⁶⁻⁴¹, foster more rapid vascularization³⁹ and mucosal healing, and increase the strength of the anastomosis (as measured by the bowel sounds, passage of flatus and return to oral intake).^{30,31}

As ascertained by Doppler velocimetry, single layered sutured anastomoses had the least reduction in mucosal blood flow, at approximately 27%. Stapled anastomoses diminished blood flow by approximately 43% and a traditional double layer anastomosis, using silk and chromic, produced a nearly 60% reduction in blood flow.³²

Letwin and Williams (1967) showed that single layer inverting anastomosis in the small bowel of the dog resulted in less tissue destruction and anastomotic disruption by comparison with two-layer anastomoses.³³

Buchin and Van Geertrudyen (1960) concluded that the single layer inverting anastomosis was associated with lower incidence of anastomotic disruption and postoperative intestinal dysfunction by comparison with the standard double layer method on the basis of retrospective analysis of 437 anastomoses of which 133 were single layered. The histologic features of the healing of the two types of anastomosis showed that, with single layer anastomosis, there was less inflammatory reaction, less necrosis and no abscess formation in the layers of the bowel wall.³⁴

The theoretical advantages of a single layer over a double layer technique are essentially more rapid and reliable healing because of minimal interference with vascularity and more accurate apposition of the divided bowel.⁴⁹ Less oedema at the one layer suture line accounts for the ability to tolerate food and pass flatus one day earlier than with the double layer closures.³⁵

Gambee, etal (1956) found that anastomotic complications accounted for a mortality of only 3% in a study of 153 single layer anastomoses, and Beling(1957) observed no complication in his series of 60 cases treated by single layer anastomosis.^{36,37}

Some authors still favour double layer anastomoses when the tissues are very oedematous or friable or lie in highly vascular area. There are no data to indicate that this practice yields superior results.

APACHE-II (Acute physiology and chronic health evaluation) scoring system is an established method of assessing the general condition and predicting the outcome in patients with peritoneal sepsis.³⁸⁻⁴⁰

The APACHE-II scoring system is shown in appendix-I.

Aim and objective

To compare and evaluate the clinical outcomes with reference to the rate of anastomotic leak, operating time and return of bowel activity between single layer continuous versus double layer interrupted intestinal anastomosis in risk-stratified patients using APACHE-II scoring system.

Observation and Results

A total of 60 patients undergoing intestinal anastomosis were included in the study. On half of the patients, the intestinal anastomoses were

performed using a single layer continuous technique and on the rest, using a double layer interrupted technique. The mean age for the single layer continuous group was 33.17 years and the double layer-interrupted group was 32.37 years. The difference between the two groups was not statistically significant ($p=0.816$). Male to female ratio in the single layer continuous and the double layer interrupted groups were 23:7 and 26:4 respectively.

Rate of anastomotic leak

All the patients included in the study were observed in the post operative period and followed in the outpatient department after discharge for a minimum period of one month.

Anastomotic leak was defined as a radiographic demonstration of fistula, by the finding of a nonabsorbable material (charcoal) draining from the wound after oral administration, or visible disruption of the suture line during re-exploration. Complications of abscess without fistula were also included in the analysis because it is potentially related to the anastomosis.

One anastomotic leak (3.3%) occurred in the single layer continuous group out of 30 patients and two leaks (6.6%) occurred in the double layer interrupted group out of the 30 patients. Although the rate of anastomotic leak appeared to be more in the double layer interrupted group than single layer continuous group the difference between the two groups is statistically insignificant ($p=0.550$).

Operating time

The time recorded for construction of the anastomosis began with the placement of the first stitch and ended with cutting the excess material from the last stitch. The mean operating time for the single layer continuous group was 15.57 minutes and for the double layer interrupted group was 24.90 minutes. The difference between the two groups is statistically significant.

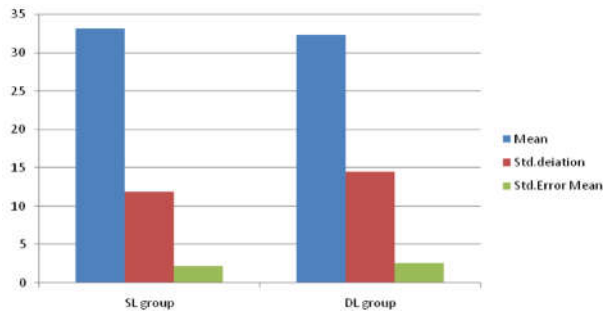
Timing of return of bowel sounds

Patients were examined for the return of bowel sounds daily following surgery. The mean time for return of the bowel sounds in single layer continuous group was 2.83 days and in the double layer interrupted group was 3.87 days. The difference between the two groups is statistically significant.

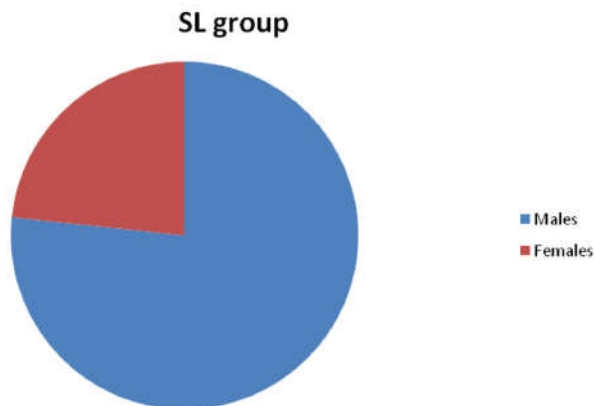
Number of days of stay in the hospital

The number of days of patient stay in the hospital

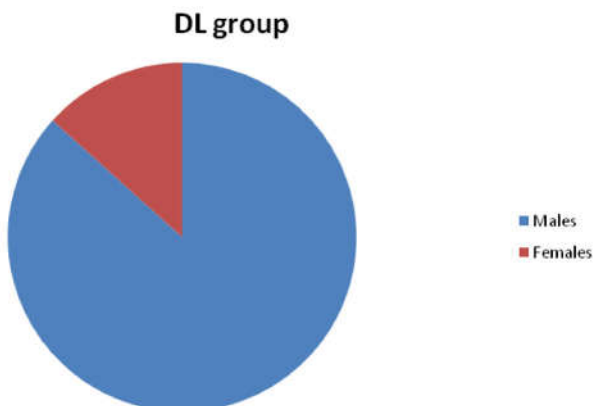
was calculated from the day of operation to the day of discharge from the hospital. The mean number of days of stay in the hospital in the single layer continuous group was 7.20 days and in the double layer interrupted group was 8.43 days. Although the mean length of stay in the hospital appears to be shorter in the single layer continuous group as compared to the double layer interrupted group but the difference is statistically insignificant.



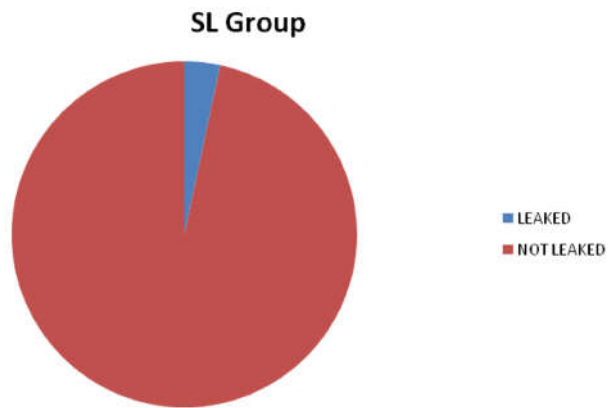
Graph 1: Age distribution (in years) of patients in the selected groups.



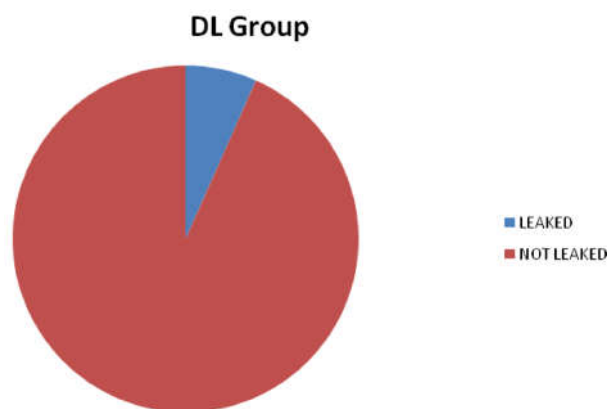
Graph 2a: Sex distribution in the single layer group.



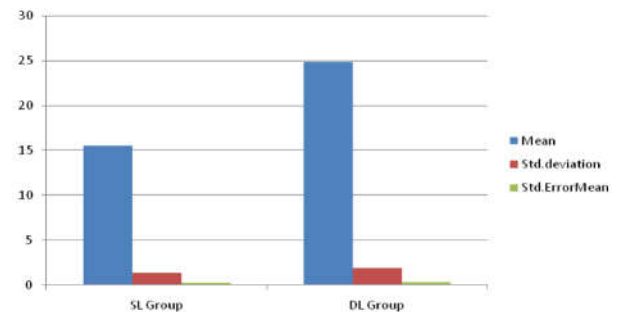
Graph 2b: Sex distribution in the double layer group.



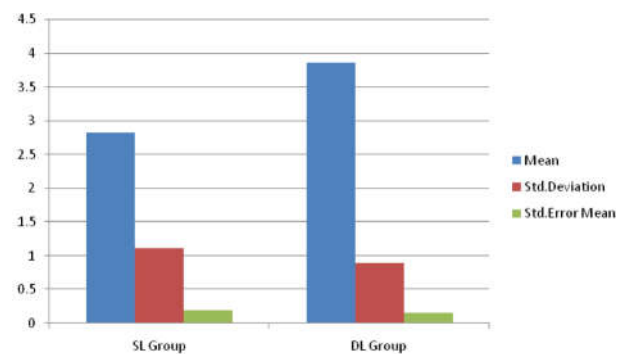
Graph 3a: Rate of anastomotic leak in the single layer group.



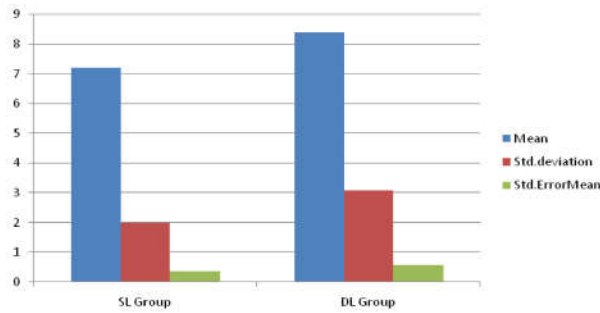
Graph 3b: Rate of Anastomotic leak in the double layer group.



Graph 4: Comparison between the two groups in terms of operating time.



Graph 5: Comparison between the two groups in terms of timing of return of bowel sounds.



Graph 6: Comparison between the two groups in terms of number of days of stay in the hospital.

Discussion

Intestinal obstruction, perforation and other diseases of bowel, benign or malignant are common surgical problems especially in the developing countries, frequently requires bowel resection and anastomosis. Many different techniques of bowel anastomosis are currently used; double layer-interrupted anastomosis being the traditional technique and is most popular. No single method of anastomosis has proven to be clearly superior over the other.

Anastomotic integrity remains a major concern for surgeons whenever anastomosis is constructed, as it is a major determinant of morbidity and mortality after operations on the gastrointestinal tract.

Various reports are available in recent literature regarding comparison in the net outcome of anastomoses on various parameters based on different techniques namely single layer continuous, single layer interrupted, double layer continuous, hand sewn and stapling techniques. The use of single layer interrupted sutures for anastomosis for the gastrointestinal tract is in use since 1887, Halsted. Numerous studies in the literature comparing various anastomosis techniques (e.g. one layer vs. two layers, hand sewn vs. stapled and end-to-end vs. end-to-side) have failed to demonstrate a clear superiority of one over the other.

A single layer continuous running suture is quick to perform generally and it allows good mucosa-to-mucosa apposition. It can offer evenly distributed minimal tension across the anastomosis with less risk of strangulating the intervening layer than in a two-layer anastomosis. In our study the mean operating time for single layer continuous group was significantly shorter. Faster anastomosis implies a shorter period of anaesthesia required for the patients and hence lesser anaesthetic complications.

Regarding the anastomotic leak which being a major parameter of concern, in our study, the difference between the two groups is statistically insignificant.

Single layer continuous anastomosis is not only faster but the return of bowel activity is also earlier as is depicted in our present study. The return of bowel activity heralds the early enteric feeding in already nutritionally compromised patients. Early feeding is associated with a better convalescence and lesser complications.

In this study we observed that in bowel anastomosis a single layer continuous running suture is quick to perform generally with an average skilled surgeon allowing a good mucosa-to-mucosa apposition. A good meta-analysis would be required to make a definitive statement regarding the net outcomes of various parameters such as anastomotic leak, length of hospital stay and may clearly define superiority of one technique over the another.

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