International Surgery Journal
Vasaiya MK et al. Int Surg J. 2020 Nov;7(11):3657-3660
http://www.ijsurgery.com
pISSN 2349-3305 | eISSN 2349-2902

DOI: https://dx.doi.org/10.18203/2349-2902.isj20204667

Original Research Article

A prospective study of 50 cases of laparoscopic intestinal anastomosis by Endo GIA universal loading stapler (green/blue) versus Endo GIA articulating reload with tri staple technology (purple)

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Received: 23 May 2020
Revised: 05 October 2020
Accepted: 06 October 2020

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ABSTRACT

Background: Intestinal anastomosis is a commonly performed procedure in surgery. Various evolvements have occurred in the field of intestinal anastomosis and recent advancement is the use of stapler in laparoscopic surgeries as a device for Gastrointestinal (GI) anastomosis. Few previous studies evaluating the clinical safety of the 2 laparoscopic linear stapling devices are available.
Methods: A prospective comparative study of 50 cases which met the inclusion and exclusion criteria were included in this hospital-based study. They were randomly allocated to two groups, Group A which underwent laparoscopic intestinal anastomosis by Endo GIA tri-staple (purple) stapler and Group B which underwent Endo GIA universal loading unit (blue/green) stapler. Primary outcome was assessed in terms of intra-operative staple line bleeding, operative time and post-operative anastomotic leak.
Results: Patients with laparoscopic intestinal anastomosis by Endo GIA tri-staple stapler (purple) have required less operation time as compared to Endo GIA universal loading unit. In Endo GIA universal loading unit (blue/green) 04% patients developed anastomotic leak and 40% patients had intra-operative staple line bleed while with Endo GIA tri-staple no postoperative anastomotic leak was found and 02% patients developed intra-operative staple line bleeding.
Conclusions: The result of our study has shown that the Endo GIA reload tri- staple (purple) is superior in terms of having no anastomosis leak, negligent staple line bleeding and less operation time as compared with Endo GIA universal loading unit (blue/green). Thus, laparoscopic intestinal anastomosis by Endo GIA reload tri-staple stapler (purple) technology is more effective and overall more efficient.

Keywords: Anastomotic leak, Endo GIA, Staple line, Laparoscopic intestinal anastomosis, Linear stapler, Stapler angulation

INTRODUCTION

In the era of minimal invasive approach, laparoscopic surgeries and specifically stapled devices provide great advantage because of its reach, flexibility and gripping in comparison with Endo suturing. With the advent of the modern stapling device, mechanical stapling is now widely used in various types of gastrointestinal surgery.[1,2] The effect of minimizing operative trauma has been the main attribute to the use of staplers. The Endo GIA universal loading unit (blue/green) is comprised of stapler unit which works by applying constant pressure and two stapler height 45 mm-4.8 mm and 60 mm-3.5 mm with cutting of the tissue at the same time. The tri-staple reload (purple) is a recently developed technology and is characterized by its incorporation of the stepped cartridge face and three different staple heights 2.5 mm, 3.5 mm and 4.8 mm. This technology is designed to improve staple security across a wide range of tissue thickness while preserving the blood supply of the intestinal

stump.[3,4] There are limited numbers of previous study evaluating the clinical safety of these two laparoscopic linear stapling devices. Our study compared these staplers using laparoscopic intestinal anastomosis. The Endo GIA reload with tri-staple technology combined with Endo GIA universal stapler is a novel endoscopic linear stapler with outstanding performance across a broader range of tissues and applications.[4] Delta-shaped anastomosis using the tri staple (purple) device in comparison with B shaped stapled line anastomosis by Endo GIA universal loading stapler (blue/green) provides better anastomosis which is one of the comparison criteria of this study. In present study the Endo GIA reload with tri-staple (purple) technique has articulating joint in device so it can be easy to use, it has three stapled line in comparison to standard stapling devices.[4,5]

METHODS

The aim of the study was to compare intraoperative and postoperative outcomes of laparoscopic intestinal anastomosis done by Endo GIA universal loading unit (green/blue) versus Endo GIA articulating reload tri staple technology (purple). This study was carried out at Department of General Surgery, Sir T Hospital and Government Medical College, Bhavnagar, Gujarat, India between August 2017 and August 2019.

In this prospective comparative study of 50 cases (patients) laparoscopic intestinal anastomosis was done. Ethical approval of local institutional review board was acquired and informed and written consent was obtained from all the patients of the study.

The cases were randomized into two groups Group A and Group B, who required laparoscopic stapled intestinal anastomosis irrespective of the diagnosis and pathology with random number table. One group (Group A) (25 patients) underwent laparoscopic intestinal anastomosis using Endo GIA articulating tri-staple reload staplers (purple) and another group (Group B) (25 patients) underwent laparoscopic intestinal anastomosis using Endo GIA universal loading stapler (blue/green). All the cases were observed for one month after operation and the data related to recovery was recorded.

The following characteristics were compared between the two groups: intra operative staple line bleeding, the ease of use, total operative time, post-operative anastomotic leak and hospital stay.

Randomized selection of sample size was done in this study.

Inclusion criteria

Age 15 years to 70 years; patient fit for general anesthesia; patient without inflammatory intestinal pathology.

Exclusion criteria

Age Below 15 years and above 70 years; intestinal tuberculosis; patients with co-morbidity like Diabetes Mellites, chronic pulmonary disorders.

Operation for both the methods was performed under general anesthesia. Patients underwent laparoscopic intestinal anastomosis using articulating tri-staple reload (purple) stapler in Group A and universal loading unit (blue/green) in Group B.

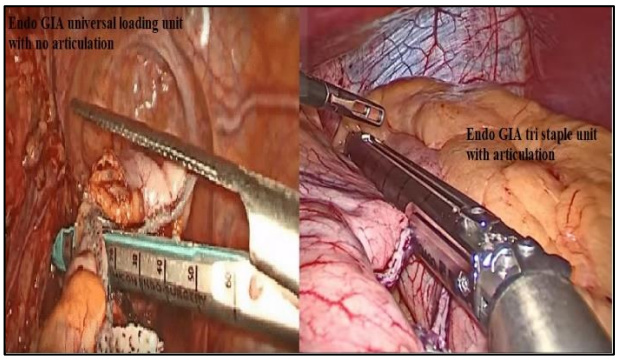

Figure 1: Laparoscopic stapling device having no articulation (green) versus having articulation (purple).

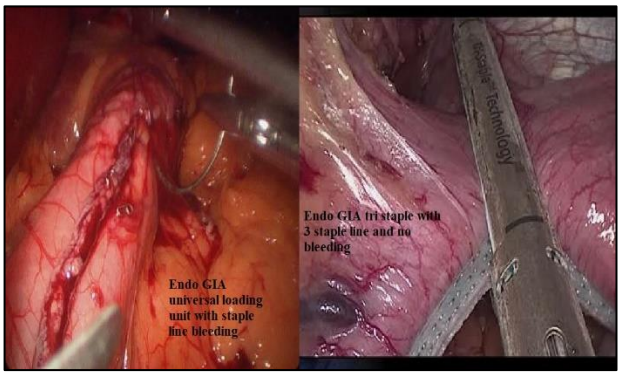

Figure 2: Staple line bleeding (blue) versus no staple line bleeding (purple).

Statistical analysis

Comparisons between the two groups was done using the unpaired t-test (quantitative data) or fisher's exact test (categorical data). For all the tests, $p<0.05$ was considered statistically significant.

RESULTS

In this study 25 patients, Group A of tri staple unit (purple) had 12 patients in 15-30 years age group with mean age 40±1.73 years and Group B of universal loading unit (blue/green) had 17 patients in 15-30 age group with mean age 30±1.60 years. In Group A of tri staple unit (purple) out of 25 patients, there are 10 males

and 15 females. While in Group B of universal loading unit (blue/green) out of 25 patients, there are 09 males and 16 females.

In this study, in Group A of tri staple unit (purple) among total 25 patients mean operation time required is 2.94±1.327 hours. In Group B of universal loading unit (blue/green) among total 25 patients mean operation time required is 3.024±1.504 hours. Patients operated for intestinal anastomosis by Endo GIA tri-staple method required relatively less time than those operated by Endo GIA universal loading unit stapler (p=0.535) that was not statistically significant. In Suda et al study operation time was shorter in tri-staple group as compared to blue/green universal stapler (p=0.025) which was found to be statistically significant.[5]

Table 1: Comparison of operating time between group A and group B.

Operation time (hours)	Group A (mean = 2.94 ±1.327 hours)	Group B (mean = 3.024 ±1.504 hours)
<3 hours	14	19
3-5 hours	10	04
>5 hours	01	02

In this study, in Group A of tri staple unit (purple) 2% patients developed intra-operative staple line bleeding, while in Group B of universal loading unit (blue/green) 40% patients developed intra-operative staple line bleeding. In comparison, Endo GIA anastomosis had lesser percentage of stapler line bleeding than Endo GIA universal loading unit. (p=0.0046) which is statistically significant. In Suda et al study intraoperative bleeding from the staple line was significantly less in the tri-staple group (p=0.02).[5]

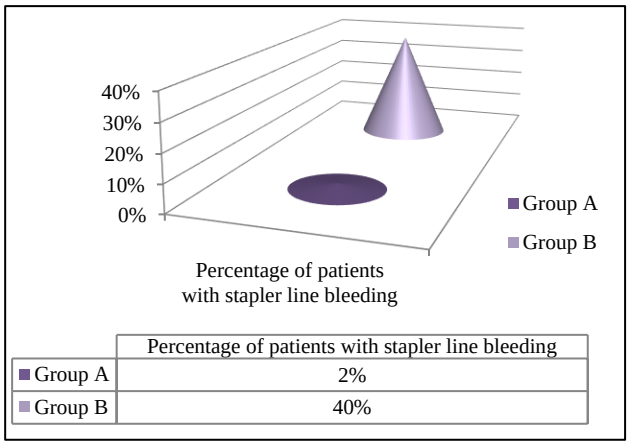

Figure 3: Percentage of patients with staple line bleeding.

In this study, in Group A of tri staple unit (purple) no patients have developed anastomotic site leakage, while in Group B of universal loading unit (blue/green) only 04% patients (1/25 patients) have developed anastomotic site leakage (p=1.000 which is not significant). In Suda et al study there was no difference between two groups in postoperative anastomotic leak.[5]

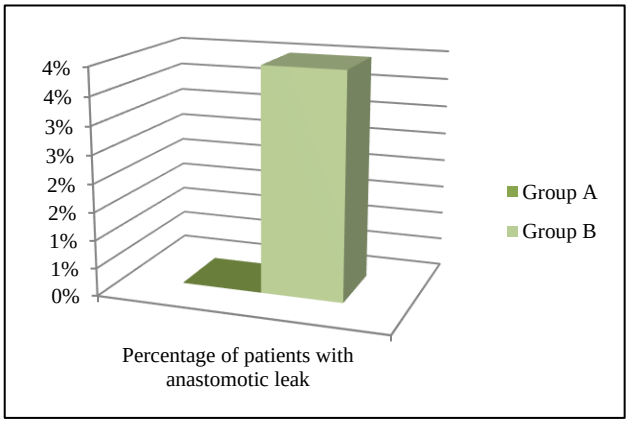

Figure 4: Percentage of patients with anastomotic leak.

In this study, in Group A of tri staple unit (purple) all 25 patients stayed in hospital for 0-7 days, with mean hospital stay with mean stay 5.64±0.995 days. In Group B of universal loading unit (blue/green) total 24 patients stayed in hospital for 0-7 days, 01 patients stayed for 08-15 days with mean stay 5.76±1.128 days (p=0.691, not significant).

DISCUSSION

The present study demonstrated the feasibility and safety as well as the potential advantages and intraoperative and postoperative out comes of performing anastomosis using Tri-Staple and Endo GIA universal loading stapler. In this study 25 patients, Group A of tri staple unit (purple) had 12 patients in 15-30 years age group with mean age 40±1.73 years and Group B of universal loading unit (blue/green) had 17 patients in 15-30 age group with mean age 30±1.60 years. In Group A of tri staple unit (purple) out of 25 patients, there are 10 males and 15 females. While in Group B of universal loading unit (blue/green) out of 25 patients, there are 09 males and 16 females.

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The study yielded four major findings.

First, there was no difference in anastomosis-related local complications between the Endo GIA universal loading and Tri-Staple groups. Second, intraoperative bleeding from the staple line was significantly reduced in the Tri-Staple group. This can certainly be attributed to the advantages of the Tri-Staple such as the Tri-Staple technology and use of a fresh knife at each stapling.

Third, regarding the postoperative courses, anastomotic leak and hospital stay, postoperative pain, there was no difference between two groups, but operating time was reduced in Tri-staple technology stapler as compared to Endo GIA universal loading stapler.

Totally laparoscopic Billroth-I distal gastrectomy using Tri-Staple was feasible and safe with favorable short-term surgical outcomes. There were no differences between the groups in anastomosis-related local complications, morbidity, non-anastomosis-related local complications, total systemic complications, and short-term outcomes with the exception of significantly reduced blood loss in the Tri-Staple group [ETS versus Tri-Staple: 37 (10-306) versus 15 (5-210) ml, p=0.02]. Intraoperative bleeding from the staple line was significantly reduced in the Tri-Staple group. The postoperative drain indwelling period [ETS vrsus Tri-Staple, 6 (4-10) versus 4 (2-43) days, p=0.032], fasting period [5 (3-7) versus 3 (3-24) days, p=0.022), and hospital stay [14 (10-47) versus 11 (6-58) days, p=0.025] were significantly shorter in the Tri-Staple group. There was no mortality in this series. Acceleration assessed as indices of blurring of stapler tip might have a significant adverse influence on staple-line bleeding at stapling sites.[7,8]

The present study has certain limitations. First, this study was prospective and randomized. Second, selection bias is possible. Third, the anastomosis technique may have varied according to each surgeon's experience. Finally, our results may be affected by a lack of power due to the relatively small sample size.

CONCLUSION

Laparoscopic intestinal anastomosis with Endo GIA tri staple technique was done with ease, without any bleeding from stapled line. Due to its articulating technique it is very easy to place along the axis of bowel and to fire accordingly. Three stapled line in articulating tri staple unit provided extra layer hence no chances of anastomosis leak. In Group B universal loading (blue/green) stapler was used with some difficulty. Due to its non-articulating technique it requires more time to adjust axis of bowel before firing the stapler. Overall Endo GIA tri staple articulating technique is more suited for laparoscopic intestinal anastomosis with effective and comparatively easy application as well as better fulfillment of desired objectives in terms of perfect anastomosis.

Funding: No funding sources
Conflict of interest: None declared
Ethical approval: The study was approved by the Institutional Ethics Committee

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Cite this article as: Vasaiya MK, Shah SM, Gohil VB, Vaghasia MS. A prospective study of 50 cases of laparoscopic intestinal anastomosis by Endo GIA universal loading stapler (green/blue) versus Endo GIA articulating reload with tri staple technology (purple). Int Surg J 2020;7:3657-60.