A Randomized Study Comparing Outcomes of Stapled and Hand-Sutured Anastomoses in Patients Undergoing Open Gastrointestinal Surgery

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Abstract Although stapling is an alternative to hand-suturing in gastrointestinal surgery, recent trials specifically designed to evaluate differences between the two in surgery time, anastomosis time, and return to bowel activity are lacking. This trial compared the outcomes of the two in subjects undergoing open gastrointestinal surgery. Adult subjects undergoing emergency or elective surgery requiring a single gastric, small, or large bowel anastomosis were enrolled into this open-label, prospective, randomized, interventional, parallel, multicenter, controlled trial. Randomization was assigned in a 1:1 ratio between the hand-sutured group ($n=138$) and the stapled group ($n=142$). Anastomosis time, surgery time, and time to bowel activity were collected and compared as primary endpoints. A total of 280 subjects were enrolled from April 2009 to September 2010. Only the

time of anastomosis was significantly different between the two arms: 17.6 ± 1.90 min (stapled) and 20.6 ± 1.90 min (hand-sutured). This difference was deemed not clinically or economically meaningful. Safety outcomes and other secondary endpoints were similar between the two arms. Mechanical stapling is faster than hand-suturing for the construction of gastrointestinal anastomoses. Apart from this, stapling and hand-suturing are similar with respect to the outcomes measured in this trial.

Keywords Gastrointestinal · Surgery · Stapled anastomosis · Hand-sutured anastomosis · Randomized

Introduction

Mechanical stapling is now an established and accepted alternative to conventional hand-suturing for the construction of anastomoses in gastrointestinal (GI) surgery. Individual trials comparing the safety and effectiveness of stapled with hand-sutured anastomoses have not shown either technique to be superior [1, 2]. Several trials have compared subject outcomes of hand-sutured with stapled anastomoses [1–10]. However, more recent trials *specifically* designed to compare the time of surgery, time of anastomoses, and return of peristaltic function in subjects undergoing GI surgery are lacking. This trial compares those parameters for hand-sutured versus stapled GI anastomoses. To our knowledge, this is the first prospective, randomized, controlled trial that has been adequately powered to *specifically* compare surgery times of hand-sutured with stapled GI anastomoses.

The work presented here compares the outcomes of hand-sutured versus stapled GI anastomoses carried out by three surgical teams at three separate facilities in India. The

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stapled anastomoses were constructed using the Advant™ 55 linear cutter/stapler which is indicated for applications in GI, gynecologic, thoracic, and pediatric surgery for transection, resection, and the creation of anastomoses during open procedures.

This trial confirms the findings of previous work [4, 5, 11–15] indicating that creation of hand-sutured GI anastomoses is relatively more time-consuming compared to stapled anastomoses with no significant difference in other subject outcomes.

Material and Methods

Trial Design

This was an open-label, prospective, randomized, interventional, parallel, multicenter, controlled trial to compare surgical and subject outcomes between stapled and hand-sutured groups in a government hospital setting in India. This trial was registered at <http://www.clinicaltrials.gov>, clinical trial number NCT00888849, and was sponsored by Ethicon Endo-Surgery (Cincinnati, OH, the United States) and Johnson and Johnson Medical India (Mumbai, India). Trial management, clinical monitoring, safety monitoring, data management, data analysis, biostatistics, and medical writing were provided by a contract research organization (Max Neeman International).

Subjects

Male or female subjects (between the ages of 18 and 75 years) undergoing emergency or elective surgery requiring a gastric, small, or large bowel anastomosis, who met predetermined criteria (listed below) and gave written consent after reviewing the informed consent document, were eligible for enrollment into the trial. Between April 2009 and September 2010, a total of 280 subjects were enrolled at three government hospitals in India (G. B. Pant Hospital in New Delhi, Government General Hospital in Chennai, and Indira Gandhi Government Medical College in Nagpur). Prior to any subject enrollment at their sites, each investigator received approval to conduct the trial from their hospital's ethics committee.

Randomization and Surgery

Subjects were randomized in a 1:1 ratio to either open hand-suturing (conducted according to the investigator's standard practice) or open stapling using the Advant 55. This linear cutter/stapler has since been renamed the ValuTrus™ reusable linear cutter/stapler and disposable reloads. Randomization was stratified by anastomosis type (gastric, small

bowel, or large bowel) to achieve balance in the distribution of treatment across the two arms.

Endpoints

The primary endpoints were time of surgery (minutes), time of anastomosis (minutes), and time to return to bowel activity (days). Time of surgery was defined as the total time from the first incision (skin open) to the last suture (skin close). Time of anastomosis was defined as the total time from placement of stay suture to final anastomotic staple or final anastomotic suture. Time to return to bowel activity was defined as the number of days postsurgery to the appearance of peristaltic movement as determined by abdominal auscultation.

The secondary endpoints collected in this trial included the number of days to be fit for resuming normal life, total anesthesia time, frequency of postsurgical leaks, admission to intensive care unit (ICU) due to postsurgical complications related to the anastomotic procedure, length of stay in the ICU, intra-operative resource utilization (operating room staff, anesthesia, medications, and medical supplies), ICU resource utilization (staff, medications, medical interventions, diagnostic tests, and medical supplies), postoperative ward stay resource utilization (staff, medications, medical interventions, diagnostic tests, and medical supplies), and days to discharge.

Safety was assessed through a comparison of the incidence of intra-operative and postoperative adverse events (AEs) between treatment groups.

Sample Size

The trial enrolled a total of 280 subjects as it was predetermined that a sample size of 140 subjects per group would provide at least 80 % power to detect a meaningful difference between groups for time of surgery.

Statistical Methods

Between-treatment comparison for each of the three primary endpoints was conducted using separate mixed effects analysis of variance (ANOVA) models with the treatment group and the anastomosis type as fixed effects and trial site as a random effect. The Bonferroni-Holm step-down adjustment was applied to control the overall level of significance at 0.05 across the three comparisons.

Fisher's exact test was used to compare the occurrence of anastomotic leaks between treatment groups. For the remaining endpoints, no inferential comparisons between treatment groups were performed and only descriptive statistics were generated. Adverse events were coded using the Medical Dictionary for Regulatory Activities (MedDRA),

and the number and percentage of subjects experiencing AEs were summarized by MedDRA preferred terms for each treatment group.

Results

Between April 2009 and September 2010, a total of 280 subjects were enrolled at the three sites. Only enrolled subjects were entered into the database, and information on subjects that did not meet inclusion/exclusion criteria was not collected. As shown in Fig. 1, 280 subjects were randomized into either the hand-sutured group ($n=138$) or the stapled group ($n=142$). The primary analysis population was the intent-to-treat (ITT) population defined as all subjects who received the surgical procedure to which they were randomized. All 280 subjects were the part of the ITT and safety populations. A total of 266 subjects completed the trial, with 14 not completing the trial (11 deaths and 3 lost to follow-up). As can be seen in Table 1, baseline demographics were balanced between the two treatment groups.

Primary efficacy information is summarized in Table 2 and presented as the least square (LS) mean $\pm$ standard error (SE). Time of anastomosis of 20.6 ± 1.90 min for the hand-sutured group was significantly longer than 17.6 ± 1.90 min for the stapled group ($P=0.0008$). No significant differences were observed between the groups for time of surgery ($P=0.7774$) or return to bowel activity ($P=0.7774$).

There was no significant difference in the occurrence of postoperative anastomotic leaks ($P=1.000$) between the hand-sutured group (three subjects, 2.2 %) and the stapled group (three subjects, 2.1 %). For the remaining secondary efficacy information, there were no observable differences between the hand-sutured and Stapled groups.

A total of 51 AEs were reported for 37 (26.8 %) subjects in the hand-sutured group and 71 AEs were reported for 45

(31.7 %) subjects in the stapled group. Table 3 presents MedDRA preferred terms occurring in ≥ 1 % of subjects in either group. As can be seen in Table 3, no meaningful differences between treatment groups are apparent regarding the type or frequency of AEs experienced. Additionally, no meaningful differences in the incidence of AEs between treatment groups were observed for the following: onset time period (operating room, ICU, or ward), event resolution status, maximum severity, action taken, AE relationship to trial procedures, and by trial device relationship. No product complaints were reported.

A total of 17 (6.1 %) subjects (hand-sutured 8 [5.8 %] and stapled 9 [6.3 %]) had at least one serious adverse event (SAE). A total of 25 SAEs (11 hand-sutured and 14 stapled) were reported in the trial. The most common SAE was cardiac arrest (1 [0.7 %] hand sutured and 3 [2.1 %] stapled). No other preferred term occurred in more than one subject in either group. No SAEs were considered related to the trial device, and one SAE in the hand-sutured group (failure to anastomose) was considered definitely related to the trial procedure. A total of 11 subjects (7 hand-sutured and 4 stapled) died during the trial. None of the deaths were considered related to the trial procedure or trial device.

Discussion

This trial has compared surgery time, anastomosis time, and time to return of bowl activity for subjects with hand-sutured versus stapled GI anastomoses. To our knowledge, this is the first prospective, randomized, controlled trial that has been adequately powered to *specifically* compare surgery times of hand-sutured with stapled GI anastomoses.

Prolonged surgery times can adversely influence subject and/or surgical outcomes. Hence, surgery time is an important variable to evaluate for open GI procedures that use stapled or hand-sutured techniques to form the anastomosis. In this trial

Fig. 1 Flow chart of trial subjects

Table 1 Subject demographics

	Hand-sutured (<i>n</i> =138)	Stapled (<i>n</i> =142)
Type of anastomosis		
Gastric	34 (24.6 %)	36 (25.4 %)
Large bowel	29 (21.0 %)	26 (18.3 %)
Small bowel	75 (54.3 %)	80 (56.3 %)
Site recruitment		
Site 201 (Dr. Agarwal)	41 (29.7 %)	39 (27.5 %)
Site 301 (Dr. Chandramohan)	50 (36.2 %)	50 (35.2 %)
Site 401 (Dr. Gajbhiye)	47 (34.1 %)	53 (37.3 %)
Males–Females	82:56	78:64
Mean age (years) ± SD	43.8±13.81	43.7±15.87
Race (Indian)	138 (100 %)	142 (100 %)
Mean height (cm) ± SD	163.0±6.97	162.6±8.48
Mean weight (kg) ± SD	51.9±8.10	52.1±8.71
Mean BMI ^a ± SD	19.53±2.917	19.77±3.515

^a BMI = weight (kg)/height (m²)

BMI = body mass index; SD = standard deviation

there was no significant difference between times of surgery (LS mean ± SE) for open hand-sutured (168.4±47.40 min) and stapled anastomoses (172.7±47.40 min). The surgery time reported here and the lack of a significant difference between the two groups is consistent with the findings of previously published trials [5, 11, 16]. However, a few trials have reported significantly shorter surgery times for procedures utilizing stapling of anastomoses. Laurent et al. [8] observed a significantly shorter duration of surgery for the stapled (261±40 min) versus hand-sutured (314±46 min) groups. The overall longer surgery times in Laurent et al. trial may be due to a different anastomosis type (colonic J-pouch-anal anastomosis) and the significant difference due to the lower location of the hand-sutured versus stapled anastomoses (19±9 mm versus 27±8 mm, respectively, from the anal verge). Others have also reported significantly shorter surgery times for stapled versus hand-sutured anastomoses [10, 17], but direct comparisons are complicated by differences in the types of anastomoses and concomitant procedures evaluated.

Construction of a good anastomosis calls for a mechanically “optimal” connection that prevents early leaks and promotes complete and natural healing to prevent late leaks and speed restoration of normal function. Thus, it is one of the most critical components of the overall procedure. This trial demonstrated a significantly shorter anastomosis time when utilizing stapling compared with the hand-suturing technique (17.6±1.90 min, 20.6±1.90 min, respectively; *P*=0.0008). Although statistically significant, the difference of approximately 3 min was not considered to be clinically or economically meaningful. This finding is uniformly consistent with previous trials [4, 5, 8, 10, 11, 17] which also reported significantly shorter times

Table 2 Primary efficacy parameters

Parameter statistics	Hand-sutured (<i>n</i> =138)	Stapled (<i>n</i> =142)
Time of anastomosis (minutes) ^a		
<i>n</i>	138	142
LS mean (SE)	20.6±1.90	17.6±1.90
95 % CI	13.2, 28.0	10.2, 25.1
Between group comparison ^{b, c}		
LS mean (SE)	2.9±0.80	
95 % CI	1.4, 4.5	
<i>P</i> value	0.0003	
Adjusted <i>P</i> value ^d	0.0008	
Time of surgery (minutes) ^e		
<i>n</i>	138	142
LS mean (SE)	168.4±47.40	172.7±47.40
95 % CI	−32.8, 369.7	−28.5, 373.9
Between group comparison ^{b, c}		
LS mean (SE)	−4.3±7.69	
95 % CI	−19.4, 10.9	
<i>P</i> value	0.5781	
Adjusted <i>P</i> value ^d	0.7774	
Return to bowel activity time (days) ^f		
<i>n</i>	132 ^g	142
LS mean (SE)	4.2±0.71	4.0±0.71
95 % CI	1.2, 7.1	1.0, 6.9
Between group comparison ^{b, c}		
LS mean (SE)	0.2±0.21	
95 % CI	−0.2, 0.6	
<i>P</i> value	0.3887	
Adjusted <i>P</i> value ^d	0.7774	

^a Time of anastomosis = total time (minutes) from placement of stay suture to final anastomotic staple (stapled) or final anastomotic suture (hand-sutured)

^b LS mean, SE, 95 % CI, and *P* value were obtained from ANOVA mixed model with treatment group and anastomosis type as fixed effects, and trial site as random effect

^c Between treatment comparison was calculated as hand-sutured minus stapled

^d Adjusted *P* value was obtained from the Bonferroni-Holm step-down adjustment to the raw *P* values obtained from the between group comparison for each of the three primary efficacy comparisons

^e Time of surgery = total time (minutes) from first incision (skin open) to last suture (skin close)

^f Bowel activity time = total time (days) postsurgery to appearance of peristaltic movement

^g Days to return to bowel activity were missing for 6 of the subjects who died

ANOVA = analysis of variance; CI = confidence interval; LS = least square; SD = standard deviation; SE = standard error

when constructing anastomoses using the stapling technique. Although this difference in anastomosis time is considered not

Table 3 Preferred terms of AEs where at least one of the groups had an incidence ≥ 1 %

Preferred term ^{a, b, c}	Hand-sutured ^d (n=138)	Stapled ^d (n=142)
Wound infection	11 (8.0 %)	19 (13.4 %)
Wound secretion	4 (2.9 %)	6 (4.2 %)
Pyrexia	6 (4.3 %)	3 (2.1 %)
Anemia	3 (2.2 %)	2 (1.4 %)
Wound sepsis	4 (2.9 %)	1 (0.7 %)
Cardiac arrest	1 (0.7 %)	3 (2.1 %)
Hypoproteinemia	2 (1.4 %)	2 (1.4 %)
Wound dehiscence	1 (0.7 %)	3 (2.1 %)
Diarrhea	0 (0.0 %)	3 (2.1 %)
Postprocedural bile leak	1 (0.7 %)	2 (1.4 %)
Dyspnea	0 (0.0 %)	2 (1.4 %)
Hemoglobin decreased	2 (1.4 %)	0 (0.0 %)
Metabolic acidosis	0 (0.0 %)	2 (1.4 %)

^a Subjects may have reported more than one event per preferred term

^b Subjects were only counted once for each preferred term

^c Adverse events were coded using MedDRA version 12.1

^d Percentage was calculated taking number of corresponding treatment group as denominator

MedDRA = Medical Dictionary for Regulatory Activities

clinically meaningful, given the critical nature of this task to the success of the entire procedure, the shorter time required for stapling likely places less stress on the surgeon relative to hand-suturing [5].

Following surgical intervention, normal motility of the GI tract is temporarily impaired. Resumption of bowel activity after surgery is an important quality of life determinant and is a critical measure of successful recovery. Postoperative colonic motility trials reveal a period of relative hypomotility associated with random and disorganized electrical activity [18, 19]. Postoperative hypomotility may affect the entire GI tract, but with differential recovery times for each part [20–23]. Small intestine function normalizes first, often within a few hours; normal gastric motility returns within 24–48 h, and colonic motility returns last within 48–72 h after surgery [18, 21, 22]. In this trial there was no significant difference between the LS mean times to return of bowel activity for procedures in which anastomoses were hand-sutured or stapled (4.2 ± 0.71 , 4.0 ± 0.71 days, respectively). Time to return of bowel activity reported here is similar to that noted by others (48–72 h) for procedures mostly utilizing stapled anastomosis [18, 21, 22]. The lack of difference between times to return of bowel activity for the hand-sutured versus stapled groups reported here is consistent with the findings of George et al. [6] and Hori et al. [5] who each found that sutured and stapled groups exhibited restored GI function by the fifth day postsurgery.

Postoperative anastomotic leaks are associated with increased mortality, morbidity, and risk of permanent stoma. In the present trial, a total of 6 (2.1 % of randomized) subjects experienced postoperative leak. These subjects were evenly distributed (3 in each group) between the two groups. This finding is consistent with several recent comprehensive meta-analyses and other trials [2, 9, 24–26], which conclude that current evidence regarding postoperative anastomotic leak is insufficient to demonstrate superiority of stapling over hand-suturing techniques. In contrast, Choy et al. [1] concluded that stapled anastomoses were associated with significantly fewer anastomotic leaks compared with hand-sutured anastomoses. It should be noted that direct comparison of meta-analyses is complicated, and the different results of the analysis by Choy et al. [1] may be due to inclusion of only ileocolic anastomoses.

A total of 11 subjects (7 hand-suturing and 4 stapled) died during the trial due to SAEs not related to the device or trial procedures. Secondary endpoints (including number of days to be fit for resuming normal life, total anesthesia time, frequency of post-surgical leaks, operating room/ICU/Ward utilization, and days to discharge) and AEs were collected during the trial. Descriptive statistics for these secondary endpoints and AEs (including time of onset and severity) suggest no apparent differences between the two groups. None of the reported AEs were related to the trial device or led to subject withdrawal.

There were several limitations of this trial. First, although both were eligible for inclusion in this trial, the elective or emergent status of the surgeries was not collected. Therefore, it was not possible to determine the differences in outcomes between subjects who underwent elective versus emergent surgery. Second, because the conditions requiring surgery were described only in generic terms (i.e., gastric, small, or large bowel pathologies), it was not possible to determine the impact of specific pathologies on outcomes. Third, the type of surgery performed was not limited to one procedure. Hence, the outcomes recorded are those from the typical mix of procedures seen at an Indian government hospital. Finally, concomitant procedures were performed in some surgeries and were documented as such but their duration was not collected. Hence, it was not possible to remove the duration of the concomitant procedure from the total surgery time for the primary procedure in some surgeries.

Conclusion

In subjects undergoing GI surgery, mechanical stapling is significantly quicker than hand-suturing, but this difference is not clinically meaningful. These two techniques are similar with respect to time of surgery, return of peristaltic function, and intra- and postoperative AEs. Stapling is a

safe and effective alternative to constructing anastomoses using the hand-suturing technique.

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