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Stapled intestinal anastomoses with endoscopic staplers in premature infants☆

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ABSTRACT

Purpose: The safety and effectiveness of a stapled intestinal anastomosis in adults, children, and infants is well documented. However, in neonates it is not well validated. We hypothesized that premature infants who received a stapled bowel anastomosis utilizing endoscopic staplers had similar outcomes compared to patients with a handsewn anastomosis.

Methods: A retrospective study was performed reviewing premature infants who underwent an intestinal anastomosis over a 4-year period. Patients greater than 36 weeks gestational age at birth or a weight greater than 5 kg at surgery were excluded. Patient demographics, type of intestinal anastomosis, and anastomotic related complications within 3 months were collected and analyzed.

Results: Sixty-five patients underwent 71 operations involving an intestinal anastomosis: 33 cases were handsewn, and 38 cases were stapled. Groups were noted to have differences in age, weight, and diagnosis. Complications including leak and anastomotic stricture did not differ between groups. Reports of blood per rectum after surgery were more common in the stapled group (24% versus 6%, $p = 0.0522$), but this did not reach statistical significance.

Conclusion: There were no significant differences in anastomotic complications when comparing the handsewn and stapled intestinal anastomosis techniques in premature infants weighting less than 5 kg.

Type of study: Treatment Study.

Level of evidence: III.

The use of stapling devices for intestinal anastomoses has been reported with success in adults, children, and even infants [1–3]. The use of endoscopic staplers in smaller pre-term neonates has been reported; but many of these studies include only a small number of premature infants grouped with small children or full term infants. Our aim was to compare the outcomes between the stapled and handsewn techniques within the preterm infant population.

1. Methods

Approval for this study was obtained through our institution's IRB. A retrospective analysis was performed, reviewing all infants who received a bowel anastomosis at our institution over a 4-year period from June 2012 through April 2016. Patient demographics, type of intestinal anastomosis, and anastomotic related complications within 3 months were collected. Patients greater than 36 weeks gestational age at birth or with a weight greater than 5 kg at surgery were excluded. Patients that received both a handsewn and a stapled anastomosis at the same operation, or whose anastomosis was protected by an ostomy were excluded. All bowel anastomoses were performed by one of three pediatric surgeons. One of the surgeons prefers to exclusively handsew all anastomoses in neonates, while the other two surgeons will most commonly staple if the bowel will accommodate an endoscopic stapler. Handsewn anastomoses were performed using a single layer of interrupted 5–0 silk in an end-to-end fashion (Fig. 1). Stapled anastomoses were done using the 30 mm × 2.5 mm endoscopic staplers (Covidien, Mansfield, MA) in a side-to-side, functional end-to-end technique (Fig. 2). Anastomotic related complications were defined as; leak, stricture, and bleeding per rectum. Anastomotic leak was defined by bilious drainage from the surgical incision post-operatively or operative confirmation of a dehisced anastomosis. Anastomotic stricture was defined by clinically apparent obstruction at the anastomosis, proven radiologically, and requiring operative or endoscopic intervention.

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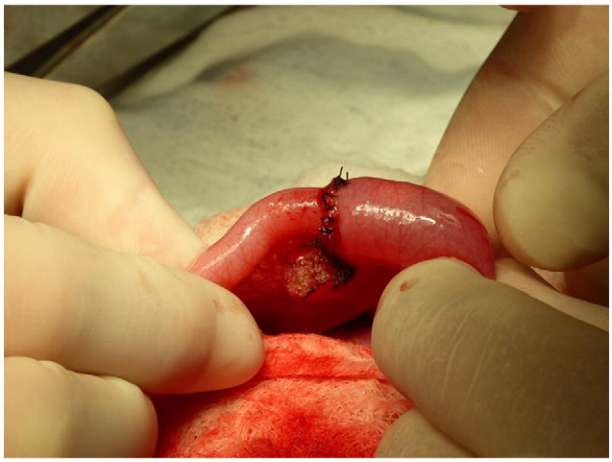

Fig. 1. Handsewn anastomosis: a completed 5–0 silk handsewn anastomosis being tested under pressure.

Anastomotic bleeding was presumed when visible blood per rectum (BPR) was reported after surgery, in the absence of a demonstrable anal fissure. Chi-square tests, Fisher's exact tests, or the Wilcoxon-Mann–Whitney tests were performed as appropriate to examine the univariate association between anastomotic techniques or between anastomotic technique and diagnosis or complication. Multivariate logistic regression was performed to examine the association between type of anastomosis and complications by controlling for age and weight at surgery. Separate models were performed and areas under the curve were calculated for leak (0.79), stricture (0.72) and bleeding (0.75).

2. Results

After excluding nine patients by criteria, 65 were deemed eligible for the study. Seventy-one operations were performed on these patients; 33 in the handsewn group and 38 in the stapled group. To analyze age distribution, patients were placed into age groups: <60 days, 60–120 days, and >120 days of age. Gender and gestational age at birth had a similar distribution between the stapled and handsewn groups (Table 1). On univariate analysis patients that received a handsewn anastomosis tended to be smaller (2.15 kg versus 2.52 kg, $p = 0.0359$) and younger ($p = 0.0001$) at surgery. The most common diagnoses within the handsewn group were intestinal atresia (51%), and ostomy reversal for necrotizing enterocolitis (NEC) (36%). The most common diagnoses in the stapled group were ostomy reversal for NEC (55%), resection of NEC stricture (13%), and intestinal atresia (10%) (See Table 2). Only one patient underwent primary resection for NEC; this patient was in the stapled group. Anastomoses included were duodenal, jejunal, ileal, and colonic. Nine patients received more than one anastomosis, 6 in the handsewn group and four in the stapled group (18% versus 10%, $p = 0.49$). No statistically significant differences in the rates of anastomotic complications were noted between the stapled or handsewn groups (Tables 3 and 4). Three of the four leaks were in patients whose operations included more than one anastomosis. Blood per rectum was reported after surgery in 15% of cases. The time to bleeding after surgery ranged from 1 day to 2 months post-operatively. Only two patients had reports of BPR immediately post-op while the majority of reports were greater than one week after surgery. One case in the handsewn group and three in the stapled group had bleeding between 1 and 2 months post-operatively. One case in the handsewn group versus two in the stapled group had an associated transfusion with their bleeding event. One case from each group had recurrent bleeding episodes over several days, but bleeding in all cases resolved spontaneously with conservative management. None of the patients with BPR were ultimately diagnosed with NEC, but most were empirically treated for several days. When comparing the incidence of BPR between the two groups the stapled group had a higher incidence, but this did not reach statistical significance (Tables 3 and 4).

Table 1
Assessment of demographics table by anastomotic technique.

	Handsewn (n = 33)	Stapled (n = 38)	p
Gender			
Male	20 (41.67%)	28 (58.33%)	0.2402
Female	13 (56.52%)	10 (43.48%)	
Age at Surgery			
0–60 days	20 (80.00%)	5 (20.00%)	*0.0001
61–120 days	8 (25.81%)	23 (74.19%)	
Greater than 120 days	5 (33.33%)	10 (66.67%)	
	Median (Range)		
Weight at surgery (kg)	2.15 (1.53–4.89)	2.52 (1.42–4.90)	*0.0359
Gestational age at birth (weeks)	33.00 (23.29–36.14)	27.21 (22.71–36.57)	0.0666

chi-Square, Fisher's Exact, and Wilcoxon-Mann–Whitney tests were used to compute p-values as appropriate.
* Indicates a significant association.

3. Discussion

Traditionally, intestinal anastomoses in children have been performed using a handsewn technique, with good results [1–3]. The technique typically consists of a single layer of interrupted sutures in an end-to-end fashion. With reports of excellent outcomes using linear stapling devices for bowel anastomoses in adults [4,5], the use of linear staplers has become accepted for application in the pediatric population. Dr.

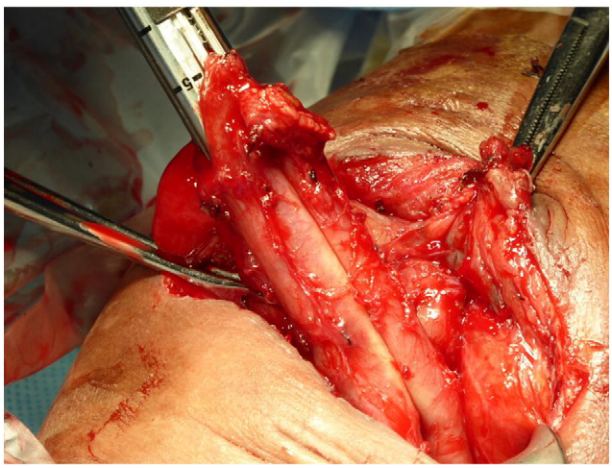

Fig. 2. Stapled anastomosis: a common enterotomy being created with an endoscopic stapler.

Table 2
Univariate analysis of diagnoses and anastomotic technique.

Diagnosis	Total	Handsewn	Stapled	*P*
NEC perforation or stricture	40(56.3%)	12(36.4%)	28(73.7%)	0.0016*
Small bowel atresia	21(29.6%)	17(51.5%)	4(10.5%)	0.0002*
Spontaneous perforation	2(2.8%)	1(3.03%)	1(2.63%)	1.0
Gastroschisis	3(4.2%)	1(3.03%)	2(5.26%)	1.0
Other†	5(7.0%)	2(6.06%)	3(7.89%)	1.0

chi-Square test and Fisher's Exact test used to compute p-values.
† Volvulus, bowel ischemia after colostomy, intussusception, perforated SBO, anastomotic stricture.
* Indicates a significant association.

Table 3
Univariate analysis of anastomotic technique and complications.

Anastomosis	Total (n = 71)	Leak (n = 4)	Stricture (n = 5)	Bleeding (n = 11)
Handsewn	33 (51.7%)	2 (50.0%)	4 (80.0%)	2 (18.2%)
Stapled	38 (48.3%)	2 (50.0%)	1 (20.0%)	9 (81.8%)
		p = 1.0000	p = 0.1762	p = 0.0522

Fisher's Exact test used to compute p-value.

Ravitch first reported the use of a linear stapler for a bowel anastomosis in children in the early 1970s, utilizing the stapler to perform a modified version of the Duhamel colorectal anastomosis [6].

The linear stapler works by initially laying down two parallel staple lines. Each staple line is made up of three rows of staples. After securing the staples, a blade divides the tissue between the two staple lines. When using a linear stapler to create an anastomosis, two ends of bowel are placed side-by-side and a common opening is created between them with a single fire of the stapler. The open end of the anastomosis is then closed using a second staple load. Linear staplers were used in larger children but due to size limitations they could not be used in infants. With the rise of laparoscopic surgery over the past two decades, a demand was created for smaller staplers that could fit through a 10-12 mm laparoscopic port. These endoscopic staplers were found to be small enough to fit into the lumen of neonatal bowel. An early report of the use of these staplers for an intestinal anastomosis by Powell et al. [7] reported no anastomotic leaks or patient deaths in seven infants ranging from 1 day to 6 months of age. Sato et al., reported good outcomes in 47 children and infants without a single anastomotic complication [8]. An early retrospective review from our institution reported by Simmons et al., showed good results in 18 neonates [9].

Most early reports of stapled anastomoses in infants and children have displayed few complications if operative technique is maintained. In a large series of 64 small children and infants that received a stapled anastomosis, Mitchell et al., reported one anastomotic stricture [10]. They attributed the stricture to a failure of their stapler device to create a common enterotomy before sealing the end of their anastomosis. This was treated with operative division of the septum, creating a patent anastomosis. Another case report detailed two delayed complications from stapled anastomoses in children. Jackson et al. reported intestinal obstruction in two patients, an infant and a child who had previously received stapled side-to-side anastomoses [11]. The child presented several years after operation, while the infant presented 2 months post-operatively. Both were found at laparotomy to have a dilated anastomosis, which had volvulized. While this complication has not been seen enough to deter surgeons from performing stapled anastomoses in children, it has lead them to be mindful of how large of a common enterotomy is created, and to not allow a large blind end to remain at the staple insertion side of the anastomosis.

Comparisons of stapled and handsewn techniques for ileocolic anastomoses in adults have shown that not only are stapled anastomoses equivalent, but in terms of leak rate are likely superior [4,5]. Due to small numbers of patients, complication rates between different anastomotic sites in children have not been compared. However, stapled and handsewn techniques for intestinal anastomoses have been compared in small children, infants, and neonates as a group. Wrighton et al. performed a retrospective analysis comparing 189 handsewn to 106 stapled cases [12]. No difference was found in rate of adhesive obstruction, stricture, or leak rate. Reduced operative times were seen in the stapled group. Patients that received a stapled anastomosis were however, older and larger. This is likely due to the natural limitation of the endoscopic stapler not being used in the smallest neonatal population.

By limiting the patients in our study to those who have a history of prematurity and weight under 5 kg we compared only the smallest group of patients that could receive a stapled anastomosis. In addition, with one of our surgeons exclusively performing handsewn anastomoses in neonates, an element of equivalence between groups was provided. Our results were similar to what has been previously reported in the literature for adults. Both the handsewn and stapled groups experienced an equal number of anastomotic leaks. The handsewn group experienced a higher number of strictures (4 versus 1, p = 0.17), but this was not statistically significant. This difference may be due to a greater portion of the handsewn anastomoses being performed on those infants with the smallest caliber bowel that would not accommodate the stapler. This would also explain our differences in groups, with handsewn being on average smaller and younger. All handsewn anastomoses in our study were performed with non-absorbable silk suture. While literature supports a higher stricture rate with the use of silk in the esophagus [13], our literature review did not identify any studies comparing silk to absorbable suture in neonatal intestine. Therefore, we are unable to conclude if the use of silk lead to the higher incidence of stricture in the hand-sewn group or if it was the preferential use of handsewn anastomoses being used on the smallest caliber bowel.

Anastomotic bleeding, while rare, typically resolves without any invasive intervention. We acknowledge that few neonates in our study had episodes of anastomotic bleeding associated with a blood transfusion, thereby meeting the traditional definition of clinically significant bleeding. In premature neonates however, BPR can lead to a considerable setback in the hospital course. This population is at high risk for necrotizing enterocolitis and BPR often triggers treatment of medical NEC. This leads to cessation of feeds, which can have significant implications in the premature. Golda et al. performed a large retrospective study looking at the incidence of lower gastrointestinal bleed after ileocolic anastomoses in adults [14]. They identified an increased risk of bleeding in patients that received an end-to-side stapled anastomosis. Handsewn end-to-end and stapled side-to-side anastomoses were not associated with an increased risk of bleeding. Most other studies however, involving stapled and handsewn comparisons do not report anastomotic bleeding [5]. Although the stapled anastomosis was ultimately shown to not have an inherent increased risk of anastomotic bleeding, we did report a higher incidence of bleeding in the stapled group. This could be explained by a significant portion of the stapled group being made up of patients with a history of NEC. This would suggest that the etiology of the bleeding might be due to the patients original pathology, as opposed to the type of anastomosis received. In patients with late bleeding (1–2 months) the etiology was presumed to be an anastomotic ulcer. However, this was never confirmed with endoscopy because bleeding always resolved with a short course of bowel rest.

Several limitations exist that are important in interpretation of this study. Similar to other pediatric surgical studies, this is an initial, single institution report that may have limited generalizability. Further, the retrospective nature leaves the study vulnerable to elements of selection and recording bias. Follow-up was limited to 3 months, allowing only conclusions regarding short-term anastomotic complications to

Table 4
The odds of complications by anastomotic technique.

	Leak	Stricture	Bleeding
Handsewn	2.69 (0.35, 25.40) p = 0.3222	4.48 (0.35, 57.84) p = 0.2501	Reference
Stapled	Reference	Reference	2.23 (0.39, 12.84) p = 0.3710

Model adjusted for age and weight at surgery

be made. Although controlled for with multivariate analysis, differences in baseline characteristics existed between treatment groups. Further work, ideally multicenter and prospective, is needed to confirm and extend these findings.

4. Conclusions

This is the largest study to date comparing stapled to handsewn anastomoses within the pre-term neonatal population. Our results are consistent with what is reported in the literature in adults and children in regards to significant anastomotic complications, which were equivalent between the stapled and handsewn techniques. The higher incidence of blood per rectum reported in our stapled group might be due to the higher rate of NEC seen within that group.

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