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A Single Institution Review of Initial Application of a 5-mm Stapler

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Abstract

Background: Operating in small spaces presents physical constraints that can be even more challenging in minimally invasive operations. Recently, a 5-mm stapler was approved for use in general surgery and pediatric surgery. Here, we present our initial experience using the 5-mm stapler in pediatric general surgery.
Materials and Methods: A retrospective chart review was conducted to identify cases using the 5-mm stapler at our institution. Demographic data included age (in months) and weight (in kilograms). Operative data included indication for use, number of loads used, complications related to 5-mm stapler use, and interventions to address complications. A second review focused on patients undergoing the same operations, but using a 10-mm stapler.
Results: A total of 60 staple loads were deployed in 32 procedures. There were four adverse outcomes, all recognized intraoperatively. One bleed resulted from application on irradiated tissue and another bleed from application to a small noninflamed mesoappendix. A bronchial staple line leak resulted from improper stapler loading, and a bowel anastomosis leak was oversewn with a single stitch. When compared with 32 matched cases using a 10-mm stapler, there was no difference in age (5-mm = 39.11 months, 10-mm = 50.21 months, $P = .49$) or weight (5-mm = 16.34 kg, 10-mm = 19.93 kg, $P = .51$). A total of 60 staple applications were used, with one bleed noted. There was no significant difference in overall complication rate (5-mm rate = 4/60, 10-mm rate = 1/60; $P = .36$).
Conclusion: Our initial experience suggests that although there were more complications with the 5-mm stapler, there is no statistically significant difference in complication rates when compared with the 10-mm stapler. Furthermore, the 5-mm stapler complications can be corrected with device training and proper patient selection. In appropriately selected pediatric surgery cases with size limitations, the 5-mm stapler can be used to minimize the invasiveness of the operation.

Introduction

Pediatric surgery requires the ability to operate in small spaces. This task can become even more challenging in laparoscopic or thoracoscopic cases, with a goal of minimizing the impact that the surgical intervention has on the patient. To this end, 3- and 5-mm ports and instruments are often used to perform dissections. However, ports are often upsized to allow introduction of devices used to isolate specimens (i.e., staplers, harmonic scalpels, and energy sealing devices).

The United States Food and Drug Administration has recently approved a 5-mm stapler (JustRight 5-mm stapler; JustRight Surgical, Boulder, CO) for use in pediatric surgery and general surgery. There has been a review of use of a 5-mm stapler in the adult population,[1] but to our knowledge, no current literature reports experience with the device in the pediatric population. We have been using the 5-mm stapler in select cases since its approval. We sought to review our experience with the device and compare its safety and efficacy to more commonly used 10-mm endostaplers. We hypothesize that the 5-mm stapler can be used as safely and efficaciously as a 10-mm stapler in appropriately selected patients and surgical situations.

Materials and Methods

All study activities were conducted at the American Family Children's Hospital at the University of Wisconsin following IRB approval (IRB # 00028310). A retrospective

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chart review was conducted to identify cases in which the 5-mm stapler was employed. Demographic data included patient age (in months) and weight (in kilograms); clinical data included diagnosis, indication for stapler use, number of loads used, complications related to stapler use, and the intervention used to address any complication from stapler use.

We then conducted a second chart review to select age- and weight-matched cases that employed a 10-mm stapler for the same purpose. The same data were recorded as the 5-mm stapler cases. We then compared the complications seen with the 5-mm stapler with the complications seen with the 10-mm stapler. Fisher's exact test and Student's *t*-tests were used to determine significance, which was set at $P < .05$. All statistical analyses were performed using SPSS™ v.23 (IBM©, Armonk, New York).

Results

Patient demographics

We identified a total of 32 cases that made use of the 5-mm stapler. The median age for these patients was 6 months (average–39.11 months; range 0–204 months), and the median weight was 8.44 kg (average: 16.34 kg; range: 1.94–79.83 kg). In our age- and weight-matched cases that made use of the 10-mm stapler, the median patient age was 20 months (average: 50.21 months; range: 0–204 months) and the median patient weight was 11.2 kg (average: 19.93 kg; range: 2.55–73.66 kg). There was no significant difference between groups in either average age (39.11 months versus 50.21 months, $P = .49$) or average weight (16.34 kg versus 19.93 kg, $P = .51$).

Stapler use

The most common indication for use in the 5-mm stapler group was appendectomy (11 cases), followed by nonappendix bowel resection (6 cases), and lung resection (5 cases). Table 1 shows indication for 5-mm stapler use in all 32 cases. These indications were matched in the 10-mm stapler group.

A total of 60 loads of the 5-mm stapler were used in the 32 cases. In these 60 deployments, 4 complications were noted and all were corrected intraoperatively. For the cases using the 10-mm stapler, there were also 60 deployments, with 1 complication noted and corrected intraoperatively. There was no significant difference in complication rate related to device deployment (4/60 versus 1/60, $P = .364$). All complications and the measures taken to correct the complications are displayed in Table 2.

Table 1. Indications for Use of 5-mm Stapler

Indication	*Number of cases*
Appendectomy	11
Bowel resection (not appendectomy)	6
Lung resection	5
Bronchus closure	4
Bowel anastomosis	4
Gastrostomy closure	1
Cystic duct division	1

Table 2. Interventions for Complications After 5-mm Stapler and 10-mm Stapler Load Deployments

Complication	*Intervention*
5-mm Stapler	
Air leak at bronchus	5-mm clip applier
Failed saline test at bowel anastomosis	Oversewn with single interrupted stitch
Bleeding at mesoappendix staple line	Endoloop applied
Failed hemostasis on lung parenchyma	10-mm staple load applied
10-mm Stapler	
Failed hemostasis at bowel resection	Second load applied

Discussion

Our initial experience suggests that the 5-mm stapler is safe to use for a number of different indications in pediatric surgery. Although there was an increase in the number of complications, this increase was not significant. Moreover, looking at the nature of the complications, it is reasonable to interpret that some of the complications relate to issues outside of the stapler itself. In the case where an air leak was seen after stapling across the bronchus, the staff surgeon in the case notes that he incorrectly loaded the stapler before firing. With appropriate training, this technical error would not likely recur. In the case where bleeding was noted from the lung parenchyma, the stapler was fired on irradiated tissue, which may not be an appropriate use for a smaller stapler. If these two complications are corrected, the rates of complication from the 5-mm stapler to the 10-mm stapler in our sample become even more indistinguishable (2/60 versus 1/60, $P = 1.000$).

We believe that there is a role for a 5-mm stapler in pediatric surgery, and that our preliminary experience supports that the device is as safe as current stapler options. In case reports involving minimally invasive approaches, there is a recurrent need to upsize port incisions to introduce staplers in both elective[2] and emergent operations.[3,4] The increase from a 3- or 5-mm incision to a 10- or 12-mm incision is not large in an absolute sense, but it likely increases the risk of subsequent development of incisional hernia.[5–8] There are other devices that may be used through smaller ports (i.e., energy devices,[9] electrocautery,[10] and endoloop[11,12]), but the availability of a stapling device that can be used without increasing the size of the port enhances the options available to the surgeon and may augment the number of cases that can be done successfully from a minimally invasive approach. Not only can it expand the variety of cases that can be completed without increasing port size, its smaller size may offer a superior view of the operative field.

Given these results, we recommend use of the 5-mm stapler in minimally invasive cases where the 10-mm stapler would normally be used. In appropriate selected cases, the 5-mm stapler may offer advantages over a 10-mm stapler without increasing the risk of complications. Physician discretion should be exercised, however, in the use of the 5-mm stapler on tissue at a high-risk for bleeding, such as an irradiated field. Surgical judgment should also prevail in situations where the 2.0-mm stapler leg height is inappropriate to achieve the

desired result. Overall, in many pediatric surgery cases, we believe that the 5-mm stapler is a safe option that may offer similar outcomes with a less invasive operation.

Disclosure Statement

P.F.N is a scientific advisor for MedAware Systems (Boulder, CO). His role has no interaction with the subject material of this article. For all other authors, no competing financial interests exist.

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