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SHORT COMMUNICATION

Prospective trial evaluating new circular and linear stapler devices for gastrointestinal anastomosis: preliminary data

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Abstract Several commercial models of stapler devices are available. This study evaluated the ease of use, effectiveness and safety of new commercial stapling devices for gastrointestinal anastomosis. A total of 11 patients (5 men) requiring surgical therapy for benign or malignant disease of the digestive tract were recruited between July and October 2006. Eleven patients were treated with KYGW circular stapler or KYFB linear stapler (Changzhou Kangdi Medical Stapler). In these patients, 14 staplers were used and 21 stapled sutures (16 linear, 5 circular) were performed. Number of anastomoses successfully completed, postoperative anastomotic fistula or dehiscence, days to take fluid and normal diet, length of hospital stay and anastomotic stenosis were recorded. A 10-point questionnaire enquiring about the instrument and anastomotic features was administered to surgeons immediately after the operation in the study group and in 10 control patients treated with standard CDH circular and SDH linear staples (Ethicon Endo-Surgery). Mean scores on the questionnaire for the experimental and control groups were good (>7.5) and did not significantly differ for handling, closing ease, bleeding, and overall satisfaction. No case of intra-abdominal sepsis, leakage or intestinal obstruction was recorded in the study group. In the 5 patients with colorectal anastomosis, the anastomotic lumen at 15 days was wide open and at 3 months there were no strictures. These new instruments are valuable for performing gastrointestinal anastomosis and are in conformity with clinical requirements; their use is simple and seems to be safe.

Key words Stapling devices · Anastomosis · Gastrointestinal surgery

Introduction

Stapling technology was pioneered in the early part of the 1900s by Russian initiative; the original instruments were subsequently modified and further progress resulted in instruments that are widely available, reliable and totally disposable [1]. Although randomized controlled trials comparing stapled with hand-sewn colorectal anastomosis have not shown either technique to be superior, a stapling instrument may facilitate and expedite surgical procedures [2].

Stapling devices have become routinely used today and have a major impact on the practice of gastrointestinal surgery. The range of staplers consists of circular, linear, linear cutting, ligating and skin staplers [3]. Within each category, several commercial models are available, with their own unique features. Recently, a new brand of stapling devices has been introduced in the European market. We undertook this pilot study to assess the ease of use, effectiveness, reliability and safety of these commercial devices for gastrointestinal anastomosis.

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Materials and methods

We evaluated the KYGW circular stapler and the KYFB linear stapler (Changzhou Kangdi Medical stapler, People's Republic of China). Both models are available in different sizes to accommodate different visceral diameters and tissue length. The KYGW circular stapler consists of an anastomosis and cutting cartridge, a staple anvil and a drive section. Staples are loaded in the anastomosis and cutting cartridge in advance. In order to prevent triggering outside the preset area, the product has a safety locking mechanism that can only be released when the indicator is adjusted to the green zone. The mechanism is locked beyond this zone to prevent triggering, to ensure safety of the surgical operation. Diameters of 21.5, 25.5, 28.5, 31.5 and 33.5 mm are available. The KYFB linear stapler consists of a staples and device control assembly, composed of a cartridge, a staple anvil and a drive section. Staples are loaded in the cartridge in advance. Thirty, 45, 60, 90 cm models are available. Both staplers strike two rows of interleaved staples in the tissue requiring the suture. Formed staple height is adjusted from 1.0 to 2.5 mm, depending on the tissue thickness.

The new staplers were compared for intraoperative performance to a standard staples, the circular (CDH) and linear (SDH) (Ethicon Endo-Surgery, Cincinnati, USA).

Patients

A total of 11 patients (5 men) requiring surgical therapy for benign or malignant disease of the digestive tract were prospectively included in the study between July and October 2006. Two patients had rectal cancer, 4 had colon cancer, 3 had diverticulosis and 2 had gastric cancer.

Six patients underwent laparoscopic and 5 had laparotomic operations, which included 2 subtotal gastrectomies, 3 right colectomies, 3 left colectomies, 2 anterior rectal resections, 1 transverse colon resection plus 1 ileal resection in the same patient. In these patients, 14 stapler devices were used and a total of 16 stapled sutures and 5 anastomoses were performed (Table 1). In the control group, 4 left and 2 right colectomies, 1 total and 2 sub-total gastrectomies, and 1 rectal and 1 ileal resection were performed; 11 stapler devices were used for 6 anastomoses and 9 linear sutures.

The following items were evaluated in the experimental group: number of anastomoses successfully completed, ease of intraoperative use, intra- or postoperative bleeding, postoperative anastomotic fistula or dehiscence, days to take fluid and normal diet, length of hospital stay, and anastomotic stenosis. In case of colorectal anastomosis, during surgery, a pneumatic test was performed to evaluate possible anastomotic defects.

Immediately after surgery, the main surgeon completed a 10-point questionnaire regarding the instrument and anastomotic features. Questions focused on ease of handling and closing the device, overall satisfaction (0, worst; 10, optimum) and bleeding at the suture line (0, hemorrhage; 10, no bleeding).

On day 15, the shape and size of the rectal anastomoses were evaluated by digital exploration. After 3 months, these anastomosis were evaluated with sigmoidoscopy to assess shape and possible strictures.

Statistical analysis was carried out using the Statistical Package for the Social Sciences 11.0 (SPSS, Chicago, USA). Continuous variables were compared

Table 1 Surgical procedures performed in 11 patients using the new linear (*L*) and circular (*C*) staplers

Patient	Procedure	Approach	Stapler	Procedure
1	Sub-total gastrectomy	LPT	L 45	Closure of gastric stump and duodenal stump (2 staples)
2	Sub-total gastrectomy	LPT	L 60	Closure of gastric stump
			L 45	Closure of duodenal stump and jejunal stump (2 staples)
3	Right colectomy	LPT	L 60	Closure of colonic stump (2 staples)
4	Right colectomy	LPS	L 60	Closure of colonic stump (2 staples)
5	Right colectomy	LPS	L 60	Closure of colonic stump (2 staples)
6	Left colectomy	LPT	L 60	Closure of rectal stump
			C 28.5	Colorectal anastomosis
7	Left colectomy	LPS	C 28.5	Colorectal anastomosis
8	Left colectomy	LPS	C 31.5	Colorectal anastomosis
9	Anterior rectal resection	LPS	C 28.5	Colorectal anastomosis
10	Anterior rectal resection	LPS	C 31.5	Colorectal anastomosis
11	Transverse colon resection and ileal resection	LPT	L 60	Closure of colonic stump (2 staples)
			L 45	Closure of ileal stump (2 staples)

LPT, laparotomic; *LPS*, laparoscopic

Table 2 Surgeon's subjective evaluation of stapling devices at the end of the operation, by treatment. Values are mean (SD) on a 10-point scale

	New stapling devices, experimental group	Usual stapling devices, control group	p[a]
Handling	8.3 (0.8)	7.9 (1.2)	0.26
Closing ease	7.9 (0.7)	7.6 (0.8)	0.17
Bleeding	8.1 (1.4)	7.8 (0.9)	0.91
Overall satisfaction	8.0 (0.7)	7.8 (0.6)	0.78

[a] Wilcoxon's signed ranks test

using Wilcoxon's signed rank test. A p value <0.05 (two-sided) was considered statistically significant.

Results

Eleven patients (5 men) of mean age 66 years (range, 56–84) were treated using the new staplers while 10 patients (6 men) of mean age 67 years (range, 57–79) were treated with standard staplers. In the experimental group, no intraoperative failure during anastomosis performance was observed and all the planned anastomoses were successfully carried out. Intraoperative pneumatic test was negative in all the patients in whom a colorectal anastomosis was performed, in the experimental and control groups.

The results of the questionnaire completed by the main surgeon for the new staplers and the standard instruments are reported in Table 2. Mean scores were good (>7.5 on a 10-point scale) and no significant differences were observed for the evaluated items between the groups.

Postoperatively, no sign of intra-abdominal sepsis, leakage, bleeding or intestinal obstruction was recorded in the experimental group. Time to oral fluid and normal diet varied according to type of operation: 4–5 days and 5–6 days, respectively, for gastric surgery; 2–5 days and 3–5 days, respectively, for colorectal surgery. Patients were discharged 6–17 days after surgery (mean, 8.5). The rectal anastomotic lumen at 15 days was wide open and at the 3-month follow-up there was no sign of stricture.

Discussion

Since their introduction, stapling instruments have gained remarkable interest, becoming today routinely employed in colorectal surgery. At present there are 2 major manufactures, Ethicon Endo-Surgery and Tyco Healthcare (now Covidien) that produce a wide range of surgical stapler devices. Our study evaluated new commercial instruments for gastrointestinal suturing and stapling. Features of the new devices are similar to the previous ones: they are disposable, can accommodate different tissue lengths and thicknesses, several cartridge sizes are available, and a fast adjustment can be made, allowing the time of surgical operation to be shortened. Since the product design and the firing modality are similar to those of other products already on the market, the appraisal did not comprise a learning curve.

The first purpose was to assess how the instruments performed intraoperatively. This assessment was subjectively determined by the surgeon at the time of operation. Intraoperative evaluation showed that the anastomosis and suturing performance of the new products are in conformity with clinical requirements [4] since no intraoperative mechanical failure was noted nor was a defective instrument found. No unsatisfactory rating or specific complaint was given by the surgeons who performed the operations, about handling and closing ease of the new devices; these features were comparable with the standard stapler. Moreover, overall satisfaction was expressed by surgeons about the new devices that, ranging widely in measures and models, allowed tailoring the choice of the device to the single patient.

Secondly, safety and reliability were considered by examining postoperative complications, particularly bleeding and anastomotic dehiscence, and long-term results on anastomotic strictures. Satisfactory hemostasis was ensured in the sutures and anastomosis, since no case of intraoperative or postoperative bleeding was observed. Moreover, adequate blood supply was secured, which prevented tissue necrosis and dehiscence [5].

In the small group of patients who had colorectal anastomosis, the anastomotic seams were well distributed and wide open when examined after 15 days and 3 months, and no anastomotic stenosis was noted. Indeed, like other anastomotic devices, the annular blade inside the circular stapler can remove excess tissues, resulting in a smoother anastomosis and thus preventing strictures [6].

The number of patients in this preliminary study is small and a larger controlled trial should be undertaken to confirm the clinical results. However, this preliminary study showed that the new instruments could be valuable in performing gastrointestinal anastomosis; their use seems to be reliable, since no complications related to the instruments were noted, and simple, as confirmed by the surgeons' feedback from the questionnaire.

Since it seems that the new stapler devices perform as well as the comparative ones, in view of the increasing concerns about exploding costs in medical care, the decision to adopt new instruments should also be based on cost-benefit analyses. A detailed evaluation of costs is beyond the purpose of this study. However it should be noted that the cost of the new devices is approximately 10%–20% less than that of the other products.

Conflict of interest statement Authors do not have any financial relationship with Bio Ruma s.n.c.

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