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G. Galizia · E. Lieto · P. Castellano · L. Pelosio
V. Imperatore · F. Canfora · C. Pignatelli

Comparison between the biofragmentable anastomosis ring and stapled anastomoses in the extraperitoneal rectum: a prospective, randomized study

Abstract Serious complications can be carried by intestinal anastomoses, particularly in the distal and proximal part of the gastrointestinal tract. The biofragmentable anastomosis ring (BAR) has been shown to be a safe anastomotic technique, but its clinical applicability in the extraperitoneal rectum has not yet been completely established. This study compared BAR anastomoses and stapled anastomoses in the middle rectum. Thirty-six consecutive patients initially suitable for elective colorectal anastomosis in the middle rectum were enrolled into this study. All patients had intraperitoneal rectum carcinoma, and 31 underwent a colorectal anastomosis in the middle extraperitoneal rectum. They were randomly allocated to a stapled technique or BAR anastomosis. Intraoperative findings and technical drawbacks, tumor behavior, and postoperative course were recorded. All patients were followed up, and late stenosis rate was investigated by endoscopy. The procedure was carried out in each of the 15 patients randomized to receiving a BAR anastomosis. No major difficulties were encountered, and the time needed was even less than that required for a stapled anastomosis. One patient in the stapled group had an early bleeding that required a further laparotomy. No significant differences in postoperative complications were noted between the two groups, although one patient with stapled anastomosis experienced a clinical leakage that needed loop colostomy. Biofragmentability was regular; buttons were eliminated in 3 weeks without any bowel disturbance. BAR ring insertion in the deep pelvis did not produce a shorter colonic resection. The late stenosis rate was similar between the groups. This study shows that in extraperitoneal middle rectum BAR anastomosis is as feasible and safe as the stapled method. The latter is more expensive, and manual suture is more difficult. Therefore the BAR is now the method of choice for this anastomosis in the authors' unit.

G. Galizia (✉) · E. Lieto · P. Castellano · L. Pelosio
V. Imperatore · F. Canfora · C. Pignatelli
Second University of Naples School of Medicine,
II Policlinico Ed. 17, Via S. Pansini, 5, I-80131 Naples, Italy,
e-mail: galizia@unina.it,
Tel.: +39-081-5666613, Fax +39-081-5666617

Introduction

Intestinal anastomoses may be followed by disappointing clinical course due to bleeding, leakage, or late stenosis [1]. To date three types of intestinal anastomosis have been available for abdominal and thoracic surgery: manual suture, stapled technique, and sutureless compression anastomosis by means of a button [2]. Especially in the proximal and distal parts of the gastrointestinal tract, classical hand-sewn sutures are sometimes very difficult to perform and are usually followed by high postoperative complication rates [3]. Stapled methods have certainly allowed some technical difficulties to be overcome, but they are quite expensive and not complication-free [4]. Sutureless compression anastomoses can be performed with either the AKA 2 or the Rosati ring [5]; however, these devices entail some disadvantages, and they have not been extensively used [6].

Wide international interest and application has been found by the biofragmentable anastomosis ring (BAR), described by Hardy et al. in 1985 [7] and distributed under the trademark Valtrac (Sherwood-Davis and Geck, St. Louis, Mo., USA). Since the first clinical experience in humans the BAR has shown its effectiveness and safety in performing sutureless anastomoses [8, 9]. Several reports and multicenter trials have compared the BAR with manual and stapled techniques in colorectal surgery [10, 11] as well as in the upper gastrointestinal tract [12]; these conclude that the BAR can be an alternative method to other anastomotic techniques [6]. However, in some anatomical regions such as the pelvic scavum, the BAR has a number of drawbacks due to its difficult handling and poor motility of the anastomotic stumps [13]. To date only few reports have assessed the feasibility and safety of the BAR in the extraperitoneal rectum anastomosis under the sacral promontory, where stapling techniques have already shown their best advantages [14].

The present randomized trial therefore compared the clinical feasibility, complication rate, and late results with the BAR and with stapling devices in extraperitoneal middle rectum anastomoses.

Patients and methods

Patients

From the 95 patients undergoing colorectal surgery at our unit from January 1997 to June 1998, 39 were prospectively chosen initially for anterior rectum resection with colorectal anastomosis in the middle rectum. All of the patients had intraperitoneal rectum carcinoma. Three emergency patients were subsequently excluded, and the remaining 36 underwent elective surgery with orthograde bowel cleansing. Each received preoperative radiotherapy (anteroposterior external beam, 40 cGy over 4 weeks). Informed consent was obtained from all patients before surgery and the study was approved by the ethics committee of the Department of Surgical Sciences of the Second University of Naples. Preoperative diagnostic methods included laboratory tests, barium enema, colonoscopy, echography, and computed tomography; diagnosis was always confirmed by histopathological examination of a biopsy specimen. Five patients (13.8%) were later excluded because at laparotomy cancer diffusion did not allow colorectal resection; thus 31 patients entered this randomized trial.

Surgery

All the operations were performed under general anesthesia with patients in gynecological position. According to the usual surgical technique in reported in others' [15] and our own units, the inferior mesenteric vein, distal to the left colic vein, was preventively ligated before any large bowel dissection. The descending colon was divided using a proximal purse-string clamp and a distal surgical clamp. The sigmoid colon and upper half of the rectum were then dissected with their meso from up to down. A purse-string clamp was applied on the rectum distal to the tumor; a surgical specimen was removed and intestinal ends arranged for the anastomosis. A sealed envelope, opened at this moment of the operation, randomized 15 patients to receive a BAR anastomosis (group 1) and the remaining 16 a stapled anastomosis (group 2).

The BAR consists of polyglycolic acid (87.5%) and barium sulfate (12.5%); it is biodegradable and radiologically detectable. It is available in four different outer diameters and three anastomotic gaps; depending on the intestinal size and wall thickness, the 31-mm ring with a 2.0-mm anastomotic gap was applied in the present series. A monofilament absorbable thread with straight needles (2/0 PDSII, Ethicon, Norderstedt, Germany) was used to perform both purse-string sutures. The BAR anastomosis was an end-to-end anastomosis with the BAR inserted first in the proximal stump and then in the distal one. After closure of the BAR the anastomosis was carefully checked; additional supporting stitches were placed in the presence of serosal splits. Technical modalities for end-to-end colorectal anastomosis following insertion of the stapler through the anus are well-known. In brief, purse-string sutures were applied using the same technique as for the BAR anastomosis; depending on the size of the anastomotic stumps, a Premium Plus CEEA 31-mm (USSC, Norwalk, Conn., USA) was preferred. After firing, both anastomosis and stapler were carefully evaluated; anastomotic tears were treated by oversuturing the lesions. Loop colostomy was performed in only a single patient (see below). Operating time, time to create the anastomosis, blood loss, presence of adhesions, and distance between distal margin of the tumor and anastomosis were recorded. BAR feasibility and any technical difficulty were reported as well.

Postoperative parameters

Postoperative management was carried out according to the usual routine in the authors' surgical unit. Return of bowel function and dietary regimen were registered. Any complications related (such as bleeding, obstruction, or leakage) or unrelated to the anastomosis were recorded. Due to the strict rules applied, all patients underwent a water-soluble contrast enema before discharge (approximately at day 8 or earlier if indicated by clinical course).

Follow-up

The BAR outcome was assessed by radiological control 8, 14, and 21 days after surgery. None of the patients was lost to follow-up, which was complete by 30 June 1999. Patients were followed at regular intervals by surgeons and oncologists. Patients in Dukes' stage B or C underwent adjuvant chemotherapy. When tumor recurrence was suspected, it was investigated by diagnostic methods and always confirmed by histopathological examination. Unless otherwise indicated, an endoscopic control was performed 6 and 12 months after the operation.

Statistics

Statistical analysis was performed using the Mann-Whitney U test for unpaired data; as appropriate, the χ^2 test was applied. The significance level was set at $P<0.05$. All data are expressed as mean ±standard deviation.

Results

Clinical assessment

There were no differences between groups 1 and 2 in preoperative parameters. In particular, factors known to have adverse effects on the anastomotic healing, such as malnourishment and steroid therapy, were absent; in each group two patients had diabetes. The presence of adhesions by previous laparotomy and tumor findings did not differ significantly between the two groups. Anterior rectum resection is known to be more difficult in men and in fat patients [16, 17]; however, the two groups were matched well for sex and body surface/mass (Table 1).

Surgery and postoperative course

In the 15 patients allocated to receive a BAR anastomosis, no major technical difficulty was encountered and the ring could be inserted in each case. New auxiliary tools (e.g., dilation devices, grasping forceps, and purse-string suture clamp) facilitated BAR insertion and allowed drawbacks to be overcome that were due to pelvic narrowness and rectum fixity. The time required to create a BAR anastomosis was slightly shorter than that needed for a stapled anastomosis, although not a statistically significant difference; the operating time and blood loss were the same. In group 1 three overrunning sutures were necessary to treat small anastomotic tears; this occurred twice in group 2.

Early postoperative recovery was uneventful in all patients but one; this patient suffered from bleeding of the

	BAR anastomosis	Stapled anastomosis	Pa
Sex: male/female	9/6	10/6	0.82b
Age (years)	66.5±5.3 (59–76)	68.9±5.5 (60–77)	0.22
Body weight (kg)	63.5±10.6 (50–82)	61.1±9.4 (44–78)	0.76
Body height (cm)	169.4±11.6 (150–187)	172±10.5 (154–189)	0.33
Previous laparotomy: no/yes	12/3	12/4	0.92b
Tumor distance from anal verge (cm)	11.3±1.4 (10–14)	11.4±1.5 (10–15)	0.85
Tumor length (cm)	4.8±1.3 (3–8)	5±1.4 (2.5–7)	0.78
Tumor clearance (cm)	3.1±0.3 (2.7–3.7)	3.0±0.4 (2.4–3.8)	0.39
Dukes' stage: A/B/C	5/6/4	5/7/4	0.97b

aMann-Whitney U test
bχ^2 test

	BAR anastomosis	Stapled anastomosis	Pa
Operating time (min)	175±29 (129–233)	180±33 (126–247)	0.55
Anastomotic time (min)	26±6 (15–39)	29±7 (16–44)	0.20
Blood loss (ml)	435±292 (60–850)	415±247 (100–900)	0.87
First flatus (days)	2.9±0.5 (2–4)	3.8±0.4 (3–5)	0.0002
First bowel movement (days)	4.8±0.6 (4–6)	5.9±0.6 (5–7)	0.0005
Liquid diet (days)	3.9±0.3 (3–4)	3.9±0.3 (3–4)	0.73
Solid diet (days)	5.9±0.4 (5–6)	5.8±0.3 (5–7)	0.64
Anastomotic distance from anal verge (cm)b	7.8±0.77 (7–9)	8.06±0.57 (7–9)	0.29
Discharge (days)	11.7±3.6 (8–20)	12.1±4.4 (8–23)	0.87

aMann-Whitney U test
bAssessed by clinical examination and endoscopy

stapled anastomotic site that required an immediate relaparotomy with a new stapled anastomosis and a protective colostomy. Overall, the BAR insertion was generally considered by the surgical team to be feasible and not more difficult than a stapled anastomosis.

Bowel functions returned sooner in patients with BAR anastomosis; renewal of regular diet and length of hospitalization were similar in the two groups. Neither length of tumor-free colon (e.g., tumor clearance) nor anastomotic distance from anal verge differed between the groups; therefore use of the BAR did not produce a shorter colonic resection (Table 2).

Complications and follow-up

No in-hospital deaths were recorded. Seventeen patients (eight in group 1 and nine in group 2) did not experience any postoperative complications. Four patients in group 1 and three in group 2 had complications not related to the anastomosis; following medical treatment, these patients could be discharged. Complications related to the anastomosis were observed in seven patients. Postoperative bleeding from a stapled anastomosis required immediate relaparotomy (see above). The overall leakage rate determined by radiology was 12.9% (two patients in each group). A patient with a stapled anastomosis developed a clinically relevant anastomotic leakage which was successfully treated by relaparotomy, drainage, and a diverting stoma (Table 3).

No patient in the BAR group experienced ileus due to obstruction or tilting of the BAR. All BARs were radiologically checked both to verify the position and to follow the process of fragmentation and elimination. On the 14th postoperative day the BAR was still in its anatomical site with some fragmented aspect. Between the 14th

Table 3 Postoperative complications: mean±SD (range)

	BAR anastomosis	Stapled anastomosis	P[a]
Anastomosis			
Bleeding	0	1[b]	0.97
Obstruction	0	0	
Leakage			
Total	2	2	0.64
Radiological	2	2	0.64
Clinical	0	1[b]	0.97
Late stenosis	1	1	0.49
Wound infection	2	1	0.95
Pulmonary infection	1	0	0.97
Cardiovascular	1	1	0.49
Neurological	0	1	0.97
None	8	9	0.84

[a] χ^2 test
[b] Relaparotomies

and 21st postoperative days the BAR was eliminated; on the third radiological control it had completely disappeared. Early detachment or opening was not observed. Ejection of the fragmented button produced no disturbance in bowel functions; only three patients were aware of the passage of BAR fragments.

The mean follow-up time was 20.1±5.1 months (range 12–28). At the end of the study all patients were alive; three in group 1 and four in group 2 were shown to have distant metastases. No local recurrence was seen in this small series. The two loop colostomies were successfully closed after 6 months. One patient in group 1 and one in group 2, who had had no anastomotic dehiscence, experienced problems with bowel functions (after 7 and 9 postoperative months, respectively). In both, colonoscopy showed a narrowed anastomosis that was being treated with progressive dilatations. In the remaining patients colonoscopy 6 and 12 months postoperatively showed a soft and wide anastomotic site; four patients in the stapled group had a slight anastomotic edema with metal material retention. Overall, no major differences were found in postoperative complications between BAR and stapled anastomoses (Table 3).

Discussion

Healing of the intestinal anastomosis is not a fully elucidated process; molecular and biochemical factors, along with technical details, have been postulated as affecting the healing process [1]. However, a recent meta-analysis has demonstrated that there are no significant differences between hand-sewn and stapled anastomoses in colorectal surgery [4]. Therefore the healing process does not seem to be related to anastomotic technique. Nevertheless, it is undeniable that manual sutures, in some anatomical sites and under particular circumstances, are

more time consuming and less safe than other methods [3, 18]. Therefore stapled techniques are widely preferred in the middle and lower rectum [19], even though they have not led to a significant decrease in complications while still having a high incidence of intraoperative mishaps [14].

The ideal anastomotic technique must be easy and fast to perform, feasible to be carried out at all times, easy both to learn and to teach, safe, and as inexpensive as possible [20]. It should approximate bowel layers to each other without any foreign materials [10]. The BAR offers many of these characteristics, is generally widely available, and provides a well performed anastomosis in a short time. Owing to new auxiliary tools, the BAR anastomosis is simpler and easier to perform; it also costs considerably less than stapling devices [3, 9, 21]. Experimental studies have demonstrated a higher bursting strength with the BAR than with hand-sewn or stapled anastomoses [2, 11]. The lack of any foreign materials in the BAR, which limits the inflammatory process, reduces anastomotic weakening [1] and may help explain, together with the absence of necrosis of the intestinal ends [22], the low postoperative leakage rate observed after BAR anastomosis [3, 6, 21]. Owing to its rigid structure, the BAR guarantees an intestinal lumen, which helps avoid early intestinal obstruction due to anastomotic swelling [6]. Some authors fear that the BAR would increase the risk of anastomotic stenosis [10, 20, 23]; however, many experimental studies have demonstrated that the early absence of foreign material and the consistent BAR biodegradability, which both reduce bacterial proliferation and allow a regular fibroblastic activity, are the best assurance against anastomotic stenosis [7, 11, 14, 24].

In this study, a BAR anastomosis was performed in all cases required by randomization; conversion to other anastomotic methods was never required. Although the surgical field was deep and the distal intestinal stump hardly movable, no substantial difficulty was encountered. The BAR anastomosis required a shorter intestinal margin freed from mesentery and fat than the stapled technique, which can represent a real advantage [12]. The T-shaped clamp allowed an easier and safer pursestring suture, while dilation devices and grasping forceps conveniently supported the BAR insertion [14]. After a short learning curve (9 patients), in these 15 cases we obtained a successful ring implantation, with only three serosal splits which were easily treated with an overrunning suture. The BAR anastomoses even took less time to perform than stapled anastomoses, and no early or late bleeding from the anastomotic site was seen. Of note, the use of the Valtrac ring did not compromise the general oncological rules for colonic cancers. There were no differences between the two groups in tumor clearance or anastomotic distance from the anal verge, thus demonstrating that the extension of the colorectal resection was similar. The return of bowel functions was uneventful. None of the patients experienced intestinal obstruction, and stool passage through the BAR anastomosis pro-

duced no early detachment of the ring [25]. All buttons were partially fragmented at 2 weeks and had disappeared by 3 weeks postoperatively.

Leakage is the most significant postoperative complication after intestinal anastomosis and its rate differs greatly depending on the anastomotic site, surgeons' experience, and technique used [1, 14]. In this series no patient in the BAR group complained of symptoms related to anastomotic dehiscence, although a radiological leakage was observed in two cases (13.3%). Of interest, this rate was similar both to that in group 2 and to that previously reported in BAR or stapled colorectal anastomoses [3, 6, 10, 21]. Only a late colonic stenosis was observed in a patient who had undergone BAR anastomosis. We are aware that a short follow-up may not be satisfactory for recording all the possible adverse effects [10]; however, anastomotic stenosis usually occurs within 6 months after surgery [14, 20], and no patient in the present study had a follow-up time less than 1 year, with two postoperative endoscopic controls.

In conclusion, the clinical applicability of the BAR in the middle rectum anastomosis seems to be good; feasibility is excellent, and no substantial difficulty is usually encountered. The BAR anastomosis is as safe as a stapled technique, and its early and late results may even be better. However, an important aspect in the choice of anastomotic technique is the cost, with manual sutures being less expensive than any other techniques available [10]. In Italy a Valtrac BAR and a Premium Plus CEEA cost 433 and 665 euro, respectively. Therefore the authors prefer BAR anastomosis in the extraperitoneal middle rectum, where stapled methods are more expensive, while hand-sewn sutures, although less costly, are both more difficult to carry out and accompanied by a greater complication rate.

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