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Original Contributions

Comparison of the Valtrac Biofragmentable Anastomosis Ring with Conventional Suture and Stapled Anastomosis in Colon Surgery

Results of a Prospective, Randomized Clinical Trial

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In a randomized, prospective study of 438 patients, the safety and efficacy of the Valtrac biofragmentable anastomotic ring (BAR) was compared with stapling and with conventional suture techniques. There was no significant difference in the morbidity, mortality, and clinical course of the patients. The BAR can effect reestablishment of intestinal continuity somewhat more rapidly, but its major advantage is its uniform applicability to all areas of the intestinal tract, except the low rectum. [Key words: Anastomosis; Valtrac; Suture; Stapler; Colon, Complications]

IN 1985, HARDY and colleagues described a biofragmentable ring for sutureless intestinal anastomosis.[1] Since the original publication of the results of the procedure as performed on animals, a number of patients have been submitted to the operation.[2] With the success of these initial efforts, a prospective, randomized, clinical study involving 30 institutions was developed to evaluate the safety and efficacy of the Valtrac Biofragmentable Anastomosis Ring (BAR, Davis and Geck, Medical Device Division, 1 Casper Street, Danbury, CT 06810) in bowel anastomoses and to compare it with the anastomotic methods of suturing and stapling.

§Only those investigators who contributed patients at the time of the analysis are included in this report. Please note that some investigators enrolled patients at more than one institution.

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The technique for effecting anastomosis with the device has been described elsewhere.[1-3] The ring is composed of two segments containing polyglycolic acid (Dexon) and 12 percent barium sulfate. The bowel ends are attached to the ring using purse-string sutures. The ring is then snapped shut with an audible and/or tactile click, and an inverted serosa-to-serosa anastomosis is created. Fragmentation usually takes place between 12 and 22 days. At this time the material is soft and is usually not apparent to the patient when it is passed.

Clinical Material

Four hundred thirty-eight (438) patients were entered into this study on a randomized basis at 30 institutions throughout the United States, Canada, Europe, and Australia from March 1986 to June 1987. Written informed consent was obtained from each patient, and Institutional Review Board approval of the study protocol was secured from each center. Patients who were terminally ill, who had evidence of infection, inflammation, coexistent disease, or concomitant therapy that might compromise wound healing, were excluded by protocol, although some were included in the trial.

Method of Statistical Analysis: During this trial data were collected on selected variables considered important in determining the safety and efficacy of the BAR. For purposes of this analysis the stapler and suture cases were amalgamated into a single control group. The type of analysis used to assess any significant difference in selected variables between the BAR and control treatments was determined by whether the dependent variable was discrete or continuous. Where the variable was discrete (*e.g.*, sex, diagnosis, coexistent disease), chi-square analysis with Yates correction was used, or Fisher's exact test was employed if appropriate. Where the variable was continuous (*e.g.*, age, time for return of bowel function) one-way analysis of variance was employed. In all calculations, a 5 percent level determined the significance of the statistical test.

Follow-up: Patients were followed for a minimum of six weeks after discharge from the hospital. Two patients in the BAR group were lost to follow-up. One failed to return despite numerous attempts to contact the patient, and one was disabled from metastatic carcinoma.

TABLE 1. *Procedures*

	Valtrac	Suture	Staple
Right hemicolectomy	49	46	20
Transverse colectomy	12	7	1
Left hemicolectomy	24	18	4
Sigmoid colectomy	59	42	9
Anterior resection	24	19	8
Subtotal colectomy	14	12	2
Colostomy closure	37	17	7
Ileostomy closure	3	1	3
TOTAL	222	162	54

Results

Demographics: Four hundred thirty-eight patients were randomized into three treatment groups: 162 (37 percent) to a sutured anastomosis, 54 (12 percent) to a stapling technique, and 222 (51 percent) to the biofragmentable ring (BAR). The reason for the failure to allocate sutured and stapled anastomoses in equal numbers is that surgeons were not compelled to apply a different conventional (suture or staple) technique than was their custom. More procedures coincidentally were, therefore, undertaken with the former approach. The mean ages of patients for suture, staple, and Valtrac anastomoses were 61 years (range, 18 to 88), 57 years (range, 22 to 83), and 62 years (range, 17 to 89), respectively. There was no significant difference between treatment groups.

There were 227 men and 211 women in the study. There was no significant difference in the distribution of patients between the treatment groups according to sex.

Diagnoses: Colon carcinoma was the most frequently reported diagnosis: 60 percent for suture (97 of 162), 43 percent for stapled (23 of 54), and 49 percent (109 of 222) for Valtrac. Diverticular disease was the next most frequent indication for surgery: 19 percent sutured, 15 percent stapled, and 22 percent Valtrac.

Operative Procedure: Operative procedures included right and left hemicolectomy, transverse colectomy, sigmoid colectomy, anterior resection, subtotal colectomy, and closure of ileostomy and colostomy (Table 1). A total of 157 anastomoses were performed between ileum and colon or rectum: 60 (37 percent) of sutured, 26 (48 percent) of stapled, and 71 (32 percent) of Valtrac. Two hundred eighty-one colocolonic or colorectal anastomoses were performed: 102 (63 percent) of sutured, 28 (52 percent) of stapled, and 151 (68 percent) of Valtrac. Because those patients who underwent an anastomosis below the upper third of the rectum were excluded from the study, rectal anastomosis was considered together with that of the colon.

Coexistent Diseases and Concomitant Medications: Forty-nine percent (214 of 438) of patients had coexistent diseases, most commonly hypertension (14 percent) and diabetes mellitus (6 percent). Thirty-four percent (147 of 438) were taking concomitant medications, most frequently cardiovascular preparations and antidiabetic agents.

No significant difference was found between treatment groups with respect to primary diagnosis, coexistent disease, concomitant therapy, and type of operation.

Bowel Preparation: There was no significant difference between treatment groups with respect to type of bowel

TABLE 2. *Operative "Complications" of Valtrac (Alternative Anastomotic Option)*

Bowel lumen too small	4
Mucosal or serosal tear	6
Anastomosis too low	1
Device visible	1
Error in diagnosis	1
TOTAL	13 (6%)

preparation (mechanical, dietary, and antibiotic) and the adequacy of colon cleansing.

Mortality: During the clinical trial, four patients in the sutured group, two in the stapled group, and five who underwent the BAR anastomosis died two days to six weeks following surgery. The overall death rate was 2.5 percent. There was no statistically significant difference between the groups. No death was related to the anastomotic technique.

Complications

Intraoperative: In 13 patients (6 percent) who were randomized to the BAR, a problem or complication developed during placement of the device which resulted in its removal. As a consequence, an alternative anastomotic option was selected (Table 2). In four of these instances the bowel lumen was too small to permit insertion of the narrowest diameter BAR. In six patients, a mucosal or serosal tear developed either during placement of the device or when attempting to secure the purse-string. In one patient the anastomosis was believed to be too low. The fact that the device could be visualized through the bowel wall caused the surgeon to abandon this approach on one occasion. Finally, an error in preoperative diagnosis resulted in the selection of an alternative option in one instance.

In nine patients (4 percent), problems occurred with insertion of the BAR which could be addressed without selecting another anastomotic technique (Table 3). Seven of these were due to a serosal or mucosal tear. Five were managed by means of reinforcing sutures or the reapplication of the purse-string. The other two patients underwent insertion of a smaller BAR.

One patient had a failed purse-string. A second BAR was inserted after the first had been removed and the purse-string reapplied. The presence of a "visible" device caused one surgeon to reinsert a smaller one.

Postoperative: A total of 159 postoperative complications occurred in 108 patients (25 percent). Of these, 26 (16 percent) were wound complications (*e.g.*, bleeding, infection, dehiscence), and 52 (33 percent) were related to the anastomosis (*e.g.*, fistula, ileus, obstruction, leakage, and hemorrhage [Table 4]).

TABLE 3. *Operative "Complications" of Valtrac (Solved)*

Tear reinforced with suture	5
Tear necessitated smaller Valtrac	2
Failed pursestring	1
"Visible" device	1
TOTAL	9 (4%)

Wound abscess of infection occurred with seven sutured, two stapled, and eleven Valtrac patients. The incidence of wound dehiscence as well as infection and abscess was not significantly different between the groups.

Local bleeding at the anastomotic site, either intraperitoneal or intracolonic, was noted on ten occasions: four sutured and six with the BAR. There was no such occurrence in the stapled group.

An anastomotic leak or fistula was noted in 11 patients: 4 sutured, 1 stapled, and 6 BAR. There was no significant difference in the number or type of complication for either the total population or for the protocol populations.

The incidence of postoperative intestinal obstruction was not significantly different. Three of the patients required reoperation. Another individual was unable to pass an intact BAR six days after having been discharged from the hospital. Endoscopic fragmentation of the device was successfully undertaken in the emergency room, and an uneventful recovery ensued.

One patient developed an anastomotic perforation three months after undergoing the procedure with the BAR. Resection was carried out. There was no adequate explanation for this complication.

Diet and Bowel Function: Use of the BAR did not alter the postoperative course with respect to the patients' diet or the return of bowel function. A clear liquid diet was commenced at a mean of 4.4 days in the suture group, 5.4 days in the stapled group, and 4.9 days with the BAR. A regular diet was tolerated at a mean of 9.4, 13.2, and 11.1 days, respectively.

TABLE 4. *Wound, Intra-abdominal, and Anastomotic Complications*

	Valtrac (Percent)	Suture (Percent)	Staple (Percent)
Wound infection	11 (5)	7 (4.3)	2 (3.7)
Wound hematoma	1 (0.4)	1 (0.6)	0 (0)
Wound dehiscence	1 (0.4)	2 (1.2)	1 (1.9)
Hemorrhage	6 (2.7)	4 (2.5)	0 (0)
Abdominal or pelvic abscess	2 (0.9)	1 (0.6)	1 (1.9)
Anastomotic leak	6 (2.7)	4 (2.5)	1 (1.9)
Intestinal obstruction	9 (4.1)	3 (1.9)	2 (3.7)
Ileus	3 (1.4)	5 (3.1)	3 (5.6)
Other	2 (0.9)	-	-
TOTAL	41 (18.5)	27 (16.7)	10 (18.5)

The return of bowel function was 4.7 days for sutured anastomoses, 4.9 for stapled, and 5.1 for the BAR. There was no significant difference in the time to first flatus between treatment groups for either the total trial population or the protocol populations. This was also true for the time to the first bowel action and the ability to tolerate progressive diets.

Hospitalization Time: The hospital stay, as determined from the day of surgery to the day of discharge, ranged from 6 to 11 days for 72 percent of the patients in the trial (316 of 438). There was no significant difference for the total trial population, for cases (excluding deaths) that had a complicated postoperative course, and for patients who had an uneventful postoperative course.

Discussion

The complications attributed to attempts at coapting the ends of intestine have stimulated an enormous surgical literature.[4-18] Among the factors reported to be associated with anastomotic septic and fistulous complications are diseased bowel, poor blood supply, tension on the suture line, inaccurate placement of sutures, failure to obtain a water-tight seal, trauma, perforation, the use of drains, and construction of an anastomosis below the peritoneal reflection.[4,14-18] Patients of advanced age, those with diabetes, those on steroids, anemic, or with atherosclerotic disease are also at particular risk for development of complications.[4] In this study we have attempted to limit possible sources of complications by excluding those individuals who are known to present an increased risk. It is, therefore, virtually impossible to compare the results of this study with those of other reports, because such patients generally are not isolated. Furthermore, one of the major risk factors, that of the performance of low rectal anastomosis, was not possible according to the protocol. Despite this modest drawback it can be safely stated that in a population of similar patients one should be able to perform an intestinal anastomosis today, in elective circumstances, in the mid or upper rectum or higher, with a leak rate not in excess of 5 percent and a wound infection rate of no greater than 10 percent. The fact is that all three modes—suture, staple, and BAR—were associated with a lower incidence of complications than this, and there were no statistically significant differences between the BAR and control methods of anastomosis.

Experimental studies on dogs and pigs have shown that among the three techniques, the "burst" pressure was highest at day 0, and overall tissue necrosis was least with the BAR anastomosis.[1] Later clinical evaluation revealed that the use of the BAR expedites the operation, is technically easier to accomplish, and is associated with improved healing.[2] There was no doubt among the investigators that the BAR afforded a rapid and secure anastomosis, but the few moments saved represented only a small percentage of the time for the entire operation. It is self-evident that mobilization and resection of the intestine as well as opening and closing the abdomen contribute considerably to the length of the procedure. Therefore, saving time is probably not an important advantage, except in the situation where a number of anastomoses must be undertaken (*e.g.*, trauma, multiple small bowel resections).

Of greater potential value to the surgeon is the fact that the BAR permits a uniform technique throughout the colon, that is, an ileocolonic anastomosis can be accomplished by the same method as that of a colorectal anastomosis. Currently, the stapling techniques require different instruments as well as several modifications of instrument application, depending on the level of the anastomosis. Obviously this potential advantage is not different from that of conventional suturing.

It is possible, although by no means proved by this study, that the BAR may create a more "forgiving" anastomosis. As experience was gained and the surgeon overcame his or her fear of seeing the device occasionally transilluminated beneath the serosa, there often developed an attitude borne out by subsequent events that even without a perfect serosa-to-serosa apposition, the anastomosis was safe. Its potential benefit in the emergency situation, in the presence of obstruction, perforation, and sepsis, with radiation or inflammatory bowel disease, awaits further evaluation.

The primary drawback of the BAR as currently employed is its lack of applicability to the low rectal anastomosis. To date it cannot compete with the circular stapler for reestablishing intestinal continuity in this area. The possibility of the subsequent development of a transanal insertor would obviate some of the difficulty, but it is unlikely that the BAR would be of comparable value when a purse-string cannot be technically applied; one cannot gainsay the advantages of a double-stapling approach.

Conclusion

The Valtrac Biofragmentable Anastomotic Ring is a safe and effective instrument for performing an intestinal anastomosis. When it is available for commercial distribution it should be successfully incorporated into the surgical methodology.

Note Added in Proof

Thomas G. Hardy, Jr., M.D. died before publication of this paper. He was the inventor of the Biofragmentable Anastomosis Ring.

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