

COLONIC ANASTOMOSIS WITH SUTURELESS BIOFRAGMENTABLE RINGS

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ABSTRACT

Purpose of Study – To evaluate the safety and applicability of a biofragmentable anastomotic ring (VALTRAC BAR) in an Asian population and report on its performance as an alternative to sutures and stapling devices.

Selection of Study Subjects – A consecutive series of 20 patients undergoing colonic surgery over a 7-month period from October 1992 to April 1993.

Observational Methods and Main Findings – A protocol was drawn up for prospective record of data from 11 male and 9 female patients (age 34 years to 83 years). Information was collected regarding length of operation (average 3 hours), actual anastomotic time (average 13.5 minutes) and problems or complications associated with the Valtrac device during surgery (none). Postoperatively, the cases were carefully documented for intestinal obstruction from faecal impaction due to Valtrac fragments (none), the timing of bowel movements (majority 4th day, range 1-7 days), and awareness of passing fragments (none). There were no mortality and no anastomotic leakage though two patients developed wound infection.

Principal Conclusions – This preliminary study confirms that the biofragmentable anastomotic ring is a simple, rapid and efficacious method of bowel anastomosis comparable to existing procedures. It has the distinct advantage of being uniformly reproducible.

Keywords: surgical staples, Valtrac, colorectal cancer, colon surgery, anastomosis.

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INTRODUCTION

At the turn of the century, the mortality rate for colonic resection was 37% and it was only after the introduction of pre-operative antibiotics in the 1950s that sigmoid colectomy without diversionary colostomy managed to gain acceptance⁽¹⁾. Even today, anastomotic failure continues to plague the surgeons despite advances in peri-operative care, surgical nutrition and suture materials. Although there is much on-going discussion regarding inverting or everting anastomosis, continuous or interrupted suturing and single-layer or double-layer techniques, all surgeons are agreed that blood supply and avoidance of anastomotic tension are singularly important⁽²⁾.

Clinical leak rate in large series ranges from 0% to 12%, but studies which incorporate rigorous radiological investigations report leak rates as high as 60% to 70%, though most of these are not clinically significant⁽²⁻⁵⁾. In general, intra-peritoneal colonic anastomotic breakdown tends to be lower whereas leakage rate could be three times higher following anterior resection⁽³⁾. It is particularly telling, however, that there is a six-fold variation in the leakage rate among individual surgeons^(1,3).

Contemporary stapling devices were introduced as a rapid and uniform method of performing bowel anastomosis and closure. It has gained such popularity in the United States that many residents have more exposure to stapling instruments than to the traditional hand-suturing techniques⁽¹⁾.

In 1985, a biofragmentable anastomotic ring (Valtrac BAR) comprising two segments containing polyglycolic acid and barium

sulphate was introduced as yet another attractive alternative⁽⁶⁾ to reduce problems associated with variations in individual suturing techniques, especially imperfect ones. It is expelled as biofragmentable pieces in two weeks so that the anastomotic site is totally devoid of any foreign materials⁽²⁾, unlike non-absorbable suture materials or the stapling instruments. In fact, staples are known to cause a 'star-burst effect'⁽²⁾ which interferes with postoperative CT scan or MRI studies.

Several experimental and clinical studies have since confirmed its safety and ease of use. To date, there has been no report of similar studies outside the Western centres. This is a report of preliminary experience with the biofragmentable device in an Asian population.

PATIENTS AND METHODS

Twenty patient had ileocolic or colo-colic anastomosis performed with the Valtrac BAR device (Fig 1 – Davis & Geck, American Cyanamid Company, Danbury, CT 06810). At the site where the bowel was to be resected, the Valtrac purse-string device (Davis & Geck, American Cyanamid Company) was used as it was easy to apply and provided uniformity in procedure (Fig 2). Maxon 3-0 suture on a straight needle was used. The bowel was then divided and triangulated with polypropylene stay-sutures to facilitate the introduction of EEA™ sizers into the bowel lumen (Fig 3). The smaller of the 2 bowel circumference determined the size of the Valtrac device. The inserter with Valtrac BAR was advanced into the intestinal lumen (Fig 4), after which the purse-string suture was tightened snugly (Fig 5). It is important not to tie too tightly to avoid excessive necrosis at site of suture and the central portion of the Valtrac BAR⁽⁵⁾. The plastic inserter was next disengaged (Fig 6) and the other bowel end was tied around the second identical Valtrac BAR ring segment (Fig 7). Care was exercised to ensure that this purse-string suture did not tie on top of the previous one. The Valtrac BAR device was easily snapped shut by even pressure between the thumb, index and middle fingers of both hands applied first, in the horizontal axis and then in the vertical axis, to form a serosa-to-serosa inverted anastomosis (Fig 8).

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Fig 1 – Valtrac BAR Device

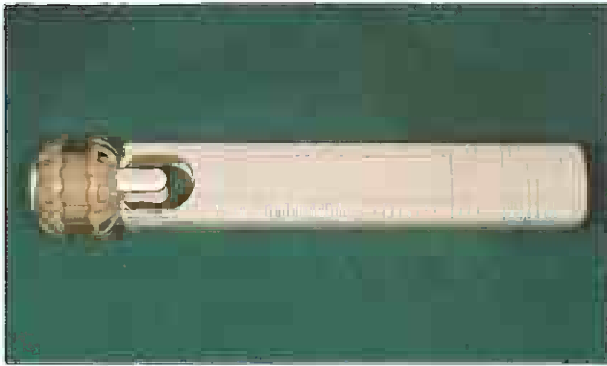


Fig 2 – Valtrac purse-string device in use

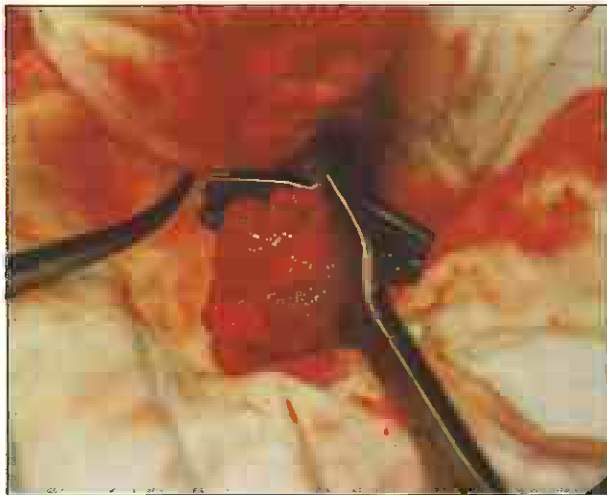


Fig 3 – EEA Sizer to determine Valtrac BAR diameter



Fig 4 – Stay-sutures to triangulate bowel opening

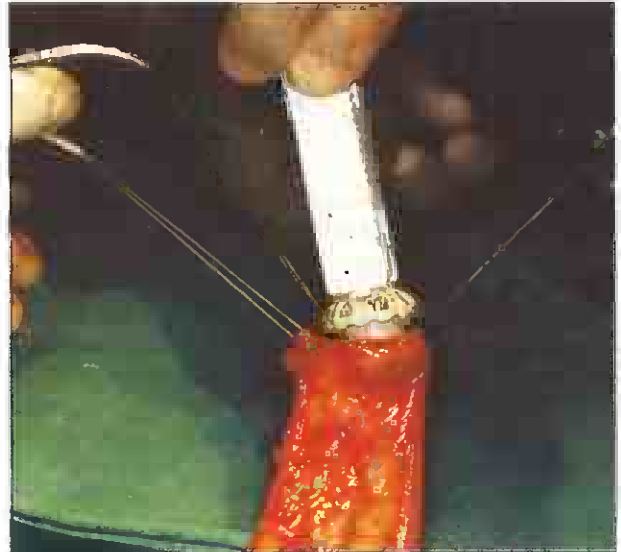


Fig 5 – Purse-string tied snugly but not too tightly around Valtrac ring

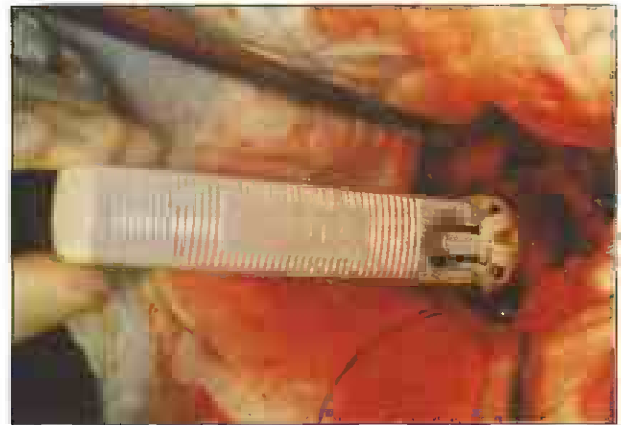


Fig 6 – Plastic inserter disengaged from Valtrac device

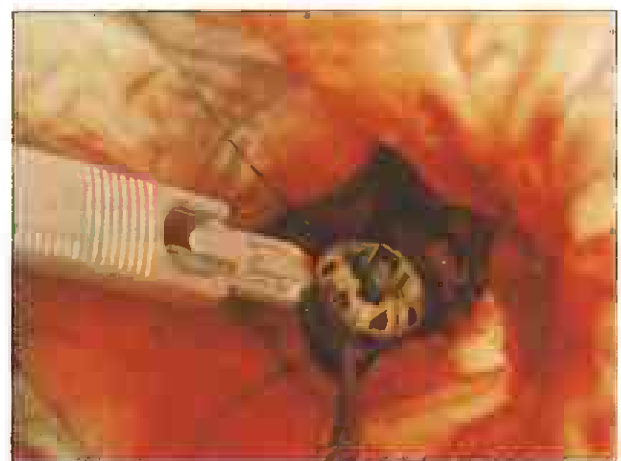


Fig 7 – Distal Valtrac ring segment inserted into other bowel

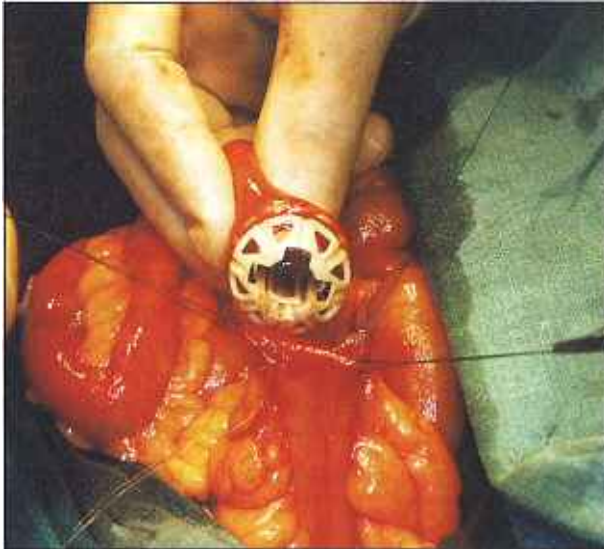


Fig 8 – Valtrac device snapped shut by even pressure between fingers at 180° apart



RESULTS

Eleven male and nine female patients of age ranging from 34 years to 83 years (mean 63 years) had Valtrac BAR anastomosis. All but three patients had malignant colonic lesions – the exceptions were patients with appendicular mass or diverticular disease for which limited Rt hemicolectomy were performed. Among the cancer patients, 7 had bowel resection for right-sided colonic tumours, 3 had splenic flexure tumours, one with descending colon cancer, 4 patients had sigmoid and rectosigmoid carcinoma and one had carcinoid tumour of the appendix encroaching into caecal wall. The remaining patient had closure of colostomy which was a staged procedure following left hemicolectomy for obstructing cancer of the descending colon. The time taken for Valtrac BAR anastomosis ranged from 8 minutes to 20 minutes (mean 13.5 minutes). Sixty percent of patients started to move their bowels by the fourth postoperative day (range 1-7 days) and there were no cases of stool impaction at the Valtrac BAR anastomotic site. None of the patients was aware of Valtrac

fragments in their stools. In this study, no attempt was made to demonstrate leakage by means of gastrograffin enema and clinical outcome was the sole criteria. There were no mortality in all 20 patients. The only complication was wound infection in two patients.

DISCUSSION

In the 19th century, the idea of a sutureless anastomosis using metal intraluminal devices had already progressed from the conceptual stage to clinical practice by Denan (1826), Bonnier (1885) and Murphy (1892)^(7,8). However, the devices failed to gain acceptance because the Denan's apparatus (and the more famous Murphy's button) involved an approximation of two metal rings which prevented faecal flow until the trapped circular intestinal segments underwent ischaemic necrosis and released the ring devices as they sloughed off^(8,9).

The Valtrac BAR device is an improvement of the old concept by having an internal lumen 14mm less than its outer diameter and permitting faecal passage even before its actual fragmentation. Most are expelled in the faeces between 14–16 days^(8,10). Often the patients are unaware of passage of the devices, as with our cases. The Valtrac BAR devices are visible on radiographs because of the presence of 12.5% barium sulphate. It is suggested that the scalloped rims of the caps minimise compromise of the intra-mural blood supply at the bowel ends and hence avoid causing necrosis at the site of anastomosis⁽¹¹⁾. Experimental animal studies actually demonstrated that the immediate anastomotic strength measured by the 'burst' pressure was substantially higher than stapled or sutured anastomosis but became equal in all 3 anastomosis at the 7th and 16th day^(6,12).

The Valtrac BAR device is especially useful for ensuring a uniformly reproducible method of inverting bowel anastomosis by all grades of surgical staff. Nonetheless, the cardinal surgical principles of good blood supply at the bowel ends and avoidance of anastomotic tension⁽¹³⁾ must be strictly observed for it was reported in a recent European trial that one particular surgeon was responsible for 50% of the anastomotic failures⁽¹⁴⁾.

Intra-operative difficulties with BAR placements occur in 6-10% patients and are usually related to problems with using devices that are too large. Surgical problems include serosal splitting, purse-string inadequacy, incorrect size and inadvertent ejection⁽¹¹⁾. Most problems arise during the initial 'learning curve'^(10,14). We avoided problems by using EEA sizers to gauge the dimension of Valtrac BAR device needed for anastomosis. The Valtrac BAR is an easy device to use and requires very little time to be familiar⁽²⁾ – this was quite well attested by the results from a recent multi-centre prospective, randomised trial of 782 patients in which 50 surgeons from 34 centres in 9 countries participated. Despite prior inexperience with Valtrac BAR, the postoperative complications were not significantly more than the randomised control group which had either stapled or sutured anastomosis⁽²⁾.

Studies have shown that the mean anastomotic time is shorter with the Valtrac BAR device (22 minutes) compared with suturing (37 minutes) and stapling (33 minutes)⁽¹⁰⁾. However, some assert that faster anastomotic time is not of great advantage as it constitutes only a small proportion of the entire operation⁽¹³⁾. In our experience, since the operations average 3 hours and Valtrac procedures average 13.5 minutes, the actual anastomoses constitute 7.5% of operating time. We managed to decrease the actual anastomotic performance time with Valtrac BAR device because we use the Valtrac purse-string device which is very easy to use and which ensures uniform purse-string application. Most studies have reported manual purse-string suturing and this usually requires laborious stitching.

The major drawback with Valtrac BAR device is that it cannot be used for low anterior resection because there is no endoanal introducer⁽¹⁴⁾. We understand that the manufacturers are exploring technological improvements to enable such anastomosis to be carried out in future. On the other hand, a high anterior resection for rectosigmoid tumours is feasible and we have performed Valtrac BAR anastomosis for one such patient.

Our preliminary experience confirms the studies in Western surgical centres that the Valtrac BAR device is a safe and efficacious method of bowel anastomosis. Although it is much more expensive than hand-sewn anastomosis, the cost is comparable to using stapling devices.

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