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Validity of shape memory NiTi colon ring BioDynamix ColonRing™ (or NiTi CAR 27™) to prevent anastomotic colorectal strictures. Preliminary results

N. GRASSI, C. CIPOLLA, A. BOTTINO, G. GRACEFFA, L. MONTANA, C. PRIVITERA, R. GRASSI, M.A. LATTERI

SUMMARY: **Validity of shape memory NiTi colon ring BioDynamix ColonRing™ (or NiTi CAR 27™) to prevent anastomotic colorectal strictures. Preliminary results.**

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Purpose. *Anastomotic strictures occur in 3-30% of colorectal anastomosis and one of the main causes may be a reaction to the presence of the metal staples used for suturing. The aim of this study was to evaluate the efficacy of a compression anastomosis ring using the memory-shaped device in initial, i.e. nickel-titanium alloy (NiTi) for the prevention of colorectal anastomotic strictures.*

Patients and methods. *A compression anastomosis ring device (NiTi CAR 27™) was used to perform compression anastomosis in 20 patients underwent left hemicolectomy and anterior resection of the rectum for carcinoma. An endoscopic check of the anastomosis was carried out at one month and at six months after surgery.*

Results. *In 2 patients (10%) a dehiscence of the anastomosis occurred on the fifth and the eighth postoperative day. No anastomotic strictures were observed in any of the other 18 patients at six months follow-up after surgery.*

Conclusion. *Our preliminary results suggest that the use of a compression anastomosis ring might well be a valid method of preventing anastomotic strictures in colorectal surgery. Further studies involving a larger number of patients are needed in order to confirm these preliminary results.*

RIASSUNTO: **Efficacia dello *shape memory NiTi colon ring BioDynamix ColonRing™ (or NiTi CAR 27™)* nella prevenzione delle stenosi anastomotiche colo-rettali. Risultati preliminari.**

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Obiettivo. *Le stenosi di anastomosi colo-rettali hanno un'incidenza variabile tra il 3% ed il 30% dei casi. Una delle principali cause potrebbe essere la reazione infiammatoria da corpo estraneo dovuta alla persistenza dei punti metallici utilizzati per confezionare l'anastomosi. Lo scopo di questo studio è stato quello di valutare se confezionare l'anastomosi con una suturatrice meccanica "a compressione" potesse prevenire o ridurre l'insorgenza di stenosi anastomotiche.*

Pazienti e metodi. *Lo studio è stato condotto su 20 pazienti affetti da carcinoma colo-rettale sottoposti a emicolectomia sinistra o resezione anteriore del retto. L'anastomosi colo-rettale è stata confezionata utilizzando una suturatrice meccanica "a compresione" (NiTi CAR 27™). Un controllo endoscopico dell'anastomosi è stato eseguito a un mese ed a sei mesi dall'intervento chirurgico.*

Risultati. *In 2 pazienti (10%) si è verificata una deiscenza dell'anastomosi rispettivamente in quinta e in ottava giornata postoperatoria. Nessuna stenosi anastomotica è stata riscontrata nei rimanenti 18 patienti all'esame endoscopico condotto sei mesi dopo l'intervento.*

Conclusioni. *I nostri risultati, sia pure preliminari, suggeriscono che l'utilizzo di suturatrici meccaniche "a compressione" può essere una strategia utile nella prevenzione delle stenosi anastomotiche colo-rettali anche se ulteriori studi su un numero maggiore di casi sono indispensabili per confermarne la validità.*

KEY WORDS: Compression anastomosis ring - Nitinol - Anastomotic strictures - Colorectal surgery.
Suturatrici meccaniche a compressione - Nitinol - Stenosi anastomotiche - Chirurgia colorettale.

Introduction

Anastomotic strictures and leakage represent the most serious and important complications after colorectal resections. Anastomotic leaks occur 2,9% to 15,3% (1) and are more frequent after extraperitoneal anastomosis. This complication prolongs the length of hospital stay and is associated with an increase of postoperative mortality rate (2) and with a reduction of long-term survival (3-5).

University of Palermo, Italy
Department of Oncology
Division of General and Oncological Surgery

The incidence of anastomotic colorectal strictures ranges from 3 to 30% (6). Preoperative radiotherapy, anastomotic leaks, infections and the defunctionalization of the anastomosis brought about by protective ileostomy and/or colostomy may all be considered as possible conditions predisposing to the formation of anastomotic stenosis (7,8).

Another important factor which may lead to the formation of anastomotic stenosis is the inflammatory reaction to the foreign bodies represented both by sutures and by the metal staples inserted by the mechanical devices often used for bowel anastomosis. Several different "compression" devices have been designed in order to avoid the use of traditional sutures which cause such inflammatory reactions. Compression anastomosis involves the use of a device that traps the cut ends of the transected bowel, thus bringing them into apposition. This device will be left inside the abdomen until epithelization of the anastomotic interface is completed. At this point, the ischemic trapped segment of bowel will be expelled together with the device into the fecal stream. The absence of a large number of through-the-wall punctures avoids the risk of infection of the anastomosis; furthermore, no foreign bodies will remain in the healing zone since the clamping element will be expelled within a few days.

The most recently-designed compression devices involve the use of a Memory-Shaped Alloy (MSA) in nickel-titanium (NiTi), a metal alloy with particular properties which make it possible for the device to change its shape according to the temperature. The MSA is a reversible, temperature-dependent, memory-shaped metal which goes into a martensite state and becomes supple when cooled to about 0°C when it is then applied to the bowel. After the application, the temperature of the device gradually rises and it returns to the austenite state, i.e. to its preprogrammed round shape (closed state), while compressing the intestinal edges and applying a uniform pressure which will induce controlled ischemia and necrosis. After approximately one week the device is discharged from the body [9].

At the present time, this type of device is available in the form of clip (Compression Anastomosis Clip or CAC) or as ring (Compression Anastomosis Ring or CAR); the latter version represents a particularly important development in the design of compression suturing devices.

The aim of our study was to evaluate the efficiency of the NiTi CAR 27 ™ (Bio Dynamix ColonRing™ NiTi™ Surgical Solution Ldt., Israel) device in the prevention of anastomotic strictures in transanal circular colon-rectal anastomoses.

Patients and methods

We used the NiTi CAR 27 ™ suturing device in 20 consecutive patients affected by carcinoma of the colon and of the rectum underwent left hemicolectomy or anterior resection of the rectum. Knight-Griffen's colorectal anastomosis was performed in all the patients.

Compression anastomosis ring device

The NiTi CAR 27™ is much like the end-to-end circular stapler (Fig. 1). It has a detachable anvil that is sewn into the proximal bowel with a purse-string suture and a handheld base that is inserted into the rectum. A pin is deployed through the stapled or sutured rectal stump by rotating a turnstile on the handle of the base, and the anvil and pin are subsequently joined and apposed as the turnstile in the handle is turned clockwise to close the gap. The NiTi CAR

Fig. 1 - NiTi CAR™ 27. Detail of the nickel-titanium ring.

27 ™ uses a ring made of a memory-shaped alloy of nickel and titanium (Nitinol) which is temperature-dependent. The ring is released from the base of the instrument to capture the tissue being joined together inside a plastic outer ring into which both cuffs (proximal and distal) are pulled as the turnstile is closed and cuts a central donut out of the ends of the bowel when the device is fired. The cut ends of bowel are held together within this ring of nickel-titanium as the plastic outer ring is released. Additionally, there are circumferentially placed and longitudinally oriented metal prongs that are deployed through the compressed tissue in the ring when the device is fired, fixing the tissue and adding further strength to the anastomosis and preventing axial movement of the tissue. The end result is a ring that exerts forces both in radial and longitudinal directions, creating a strong anastomosis. This ring is left behind undisturbed as the device is removed. The alloy ring has properties that create a constant pressure on the tissue being compressed. Within 7 to 10 days, the bowel held within the double ring undergoes necrosis and sloughs off, releasing the ring to be expelled from the body during a subsequent bowel movement.

The ends of the bowel fuse together before the detachment of the compression ring, resulting in a complete absence of retained foreign material in the patient.

Surgical procedure

In all patients bowel resection was performed after mobilization of the left colon flexure and after the ligature and division of the artery and of the lower mesenteric vein; in patients undergoing anterior resection of the rectum, the mesorectum was always removed *en bloc*. The head of the device was fixed to the proximal colon stump with a purse-string suture using non-absorbent 2/0 thread, while the rectal stump was closed with a linear stapler. The device was then inserted through the anus after bringing the temperature of the nickel-titanium ring down to about 4°C by immersing it in cold water.

After the anastomosis had been performed, its efficiency was tested by means of an injection through the anus of a mixture of water and methylene blue at room temperature, while keeping the bowel clamped together with two fingers at about 5 or 6 cm above the anastomotic zone in order to obtain a positive endoluminal pressure. A temporary colostomy was performed when the colorectal anastomosis was at less than 5 cm from the anal verge or in those cases in which an immediate leakage was found at the intraoperative anastomisis test. A drip-drainage was placed in the Douglas pouch. Patients were fed normally after confirmation of gas canalization and were sent home as soon as the nickel-titanium ring had been expelled.

Follow-up

All the patients underwent an endoscopic check at one month and at six months after surgery.

Results

Ten of the 20 patients were male and 10 were female, with a mean age of 71.1±10.19, ranging from 44 to 86 years. In 14 cases (70%), the neoplasia involved descending or sigmoid colon and in 6 cases (30%) the rectum. Colorectal anastomosis was performed at an average of 10.89±10.44 cm from anal verge (range 2-20 cm); in 3 cases in which the colorectal anastomosis was at less than 5 cm from the anal verge a loop colostomy was performed. Table 1 shows the characteristics of patient and histological features of the tumors.

TABLE 1 - PATIENT FEATURES.

Mean age, yrs	71,10 ± 10,19 (range 44 – 86)
Sex (M/F)	10/10
Surgery, n (%)	
Left hemicolectomy	14 (70,0%)
Anterior resection of the rectum	6 (30,0%)
Histological features, n (%)	
NOS adenocarcinoma	17 (85,0%)
Mucinous adenocarcinoma	3 (15,0%)
pT stage, n (%)	
pT1	4 (20,0%)
pT2	5 (25,0 %)
pT3	11 (55,0%)

In all cases the anastomotic test performed during surgery gave a satisfactory result, with no leakage. Flatus occurred at a mean of 2.8±0.87 days after surgery (range 2-5 days), feces took place in 4.3±2.03 days (range 3-9 days). In 2 cases (10%) the anastomosis leakage occurred respectively on postoperative day 5 and day 8; in these two cases, flatus had occurred respectively on day 2 and day 3 and the patients had started to eat normally on postoperative day 3 and day 4.

The nickel-titanium ring was expelled at a mean of 12.1±2.18 days (range 8-16 days) after surgery. Spontaneous expulsion occurred in 17 patients, who were then sent home; in one case only, in one of the three patients who had undergone a protective colostomy, was it necessary to remove the ring manually on postoperative day 15. In one case, the patient was sent home on day 12 without expulsion of the ring, which was subsequently expelled spontaneously on day 16.

The postoperative endoscopy performed one month after surgery showed that only in 2 cases (10%) there was slight fibrosis of the anastomotic scar tissue, limited in both cases to about one third of circumference (Fig. 2), as confirmed by biopsy. The endoscopic follow-up at 6 months showed no further sign of fibrosis and the anastomosis appeared regular. In the other 16 cases, both the first and the subsequent endoscopic examinations performed at 6 months showed abundant, regular anastomosis (Fig. 3).

In the 3 patients undergoing a loop colostomy, this was closed after a colonoscopy performed six months after surgery confirming both the absence of stenosis and leakage. In all three cases, however, this time coincided with the end of adjuvant chemotherapy.

Discussion

Leakage and anastostomotic strictures represent the two most important complications in colorectal ana-

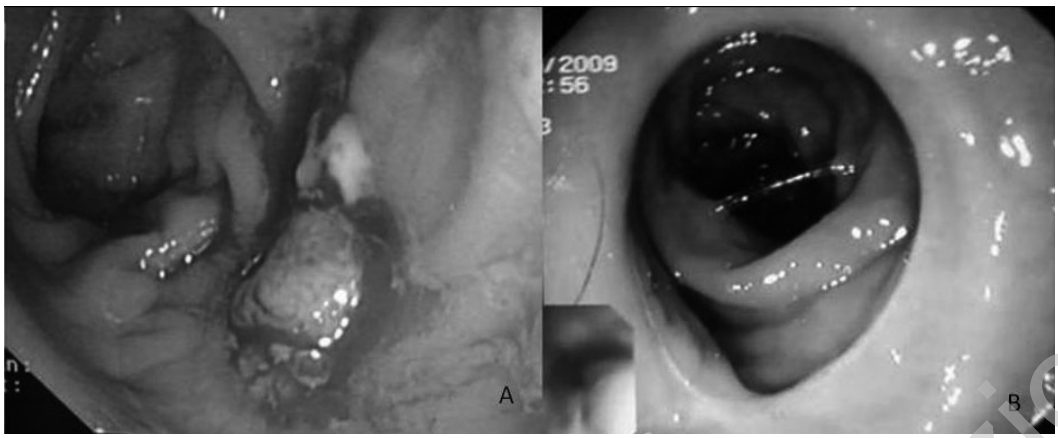

**Fig. 2 - a) Anastomotic scar-tissue fibrosis observed one month after surgery.
b) Regression of the fibrosis at 6 months endoscopic follow-up.**

stomosis. The main risk factor for leakage is the distance of the anastomosis from the anal verge; other parameters that independently predicted leakage were combined gynecological and urological procedures, advanced tumor stage and postoperative blood transfusions. The principal risk factors of anastomotic colorectal strictures are identified in preoperative radiotherapy, anastomotic leaks, infections, loop ileostomy and/or colostomy. Another important factor of anastomotic stenosis may be the inflammatory reaction to the foreign bodies represented both by sutures and by the metal staples inserted by the mechanical devices often used for bowel anastomosis. The advantage in eliminating foreign anastomotic materials can reduce the anastomotic complications in the form of the inflammatory process associated with suture materials such as leakage, bleeding, and strictures (10).

The concept of compression anastomosis was first introduced by Felix-Nicholas Denans in 1826, who performed termino-terminal bowel anastomosis on an animal model with the use of a metal ring made of silver or zinc (11,12). This idea was later developed by Bonnier in 1885 and by Murphy in 1892 (13-17). The devices concerned had little success, however, due to the high rate of anastomotic stenosis, occurring both immediately and some time after surgery, probably caused by their tightness. In 1984, Kanschin (18) developed the first compression device to be used clinically in colorectal surgery, the AKA-2, made up of two rings that were spontaneously detached from the anastomotic zone after 4 to 6 days and expelled through the alimentary canal. In 1985, Hardy et al. (19) introduced the Valtrac defragmentable ring (BAR), consisting of two identical rings that were automatically reabsorbed in 14 – 21 days.

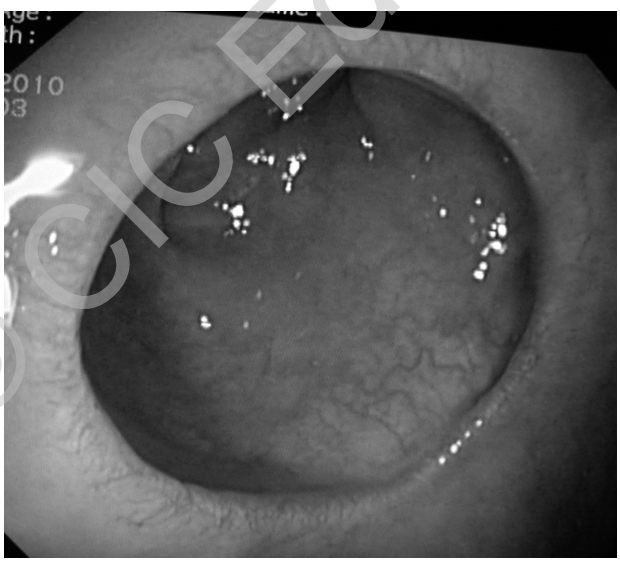

Fig. 3 - Colorectal anastomosis 6 months after surgery.

More recently, a new compression device based on the memory-shaped properties of the nickel-titanium alloy has been introduced. This is available either as a clip (Compression Anastomosis Clip or CAC) or as a ring (Compression Anastomosis Ring or CAR). The former has already been in use for bowel anastomosis and several experimental and clinical studies had demonstrated its feasibility and that it is a safe, reliable method (20-23). The CAR has so far been used only on animal models, which have confirmed its efficiency. Stewart et al. (24) have compared the use of the CAR 27™ mm with the 29 a 29 mm stapler in porcine models and found that compression anastomoses had higher mean failure pressures than stapled anastomoses at 0 time (103 vs 29.9 mm Hg) but at 2 weeks, there was no difference between failure pressures (256 vs 250 mm/Hg). Moreover, there were no clinical or radiographic leaks by barium enema at 2 weeks. There were dense adhesions in 7 out of 12 anastomoses (58.3%), whereas only one of 12 (8.3%) of the compression anastomoses had flimsy adhesions. Kopelman et al. (25) evaluated the feasibility and safety of the nickel–titanium compression anastomosis ring to create an end-to-end colorectal anastomosis in

a porcine model. The histopathological examination of the anastomotic site after 2 weeks revealed evidence of good and uniform healing processes with minimal inflammation. The anastomotic line was represented by a very thin transmural circular band of fibrosis and granulation tissue with moderate leukocyte infiltrate in the muscularis. Minimal focal fibrosis was present, with no evidence of inflammation two months after the procedure.

In our own experience, 18 of the 20 patients (90%) with NiTi CAR 27™ showed perfect synthesis of the colorectal anastomosis and at endoscopic follow-up at 3 and 6 months after surgery no stenosis was present. Two patients presented early anastomotic dehiscence, respectively on postoperative day 3 and day 8, probably due to a condition of hypoproteinemia observed in them both before and after surgery, which may have invalidated the process of anastomotic epithelization.

Conclusions

The results of our study are certainly preliminary, nevertheless, they indicate that this type of anastomotic device should be considered as a valid method for the prevention of stenosis following surgical colorectal anastomosis.

Further studies involving a larger number of patients are needed; with this aim in mind, the "Italian ColonRing Register" ("Registro Italiano ColonRing") has recently been created in order to collect and process the experience of Italian surgeons who perform biodynamic compression anastomosis of the colon-rectum with the use of this device. Furthermore, we ourselves intend to conduct a study on the results of the use of the NiTi CAR27™ compared with those of traditional staplers, not only with regard to the rate of anastomotic stenosis, but also of the other complications.

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