Can intraluminal devices prevent or reduce colorectal anastomotic leakage: A review

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Abstract

Colorectal anastomotic leakage is a serious complication of colorectal surgery, leading to high morbidity and mortality rates. In recent decades, many strategies aimed at lowering the incidence of anastomotic leakage have been examined. The focus of this review will be on mechanical aids protecting the colonic anastomosis against leakage. A literature search was performed using MEDLINE, EMBASE, and The Cochrane Collaborative library for all papers related to prevention of anastomotic leakage by placement of a device in the colon. Devices were categorised as decompression devices, intracolonic devices, and biodegradable devices. A decompression device functions by keeping the anal sphincter open, thereby lowering the intraluminal pressure and lowering the pressure on the anastomosis. Intracolonic devices do not prevent the formation of dehiscence. However, they prevent the faecal load from contacting the anastomotic site, thereby preventing leakage of faeces into the peritoneal cavity. Many attempts have been made to find a device that decreases the incidence of AL; however, to date, none of the devices have been widely accepted.

INTRODUCTION

Colorectal anastomotic leakage (AL) is a serious complication after colorectal surgery and may lead to high morbidity and mortality rates. The incidence of AL varies between 2.5% and 20% and the aetiology is multifactorial[1-5].

In recent decades, many strategies aimed at lowering the incidence of anastomotic leakage have been examined. A protective stoma reduces the consequence of anastomotic failure, thereby preventing the number of clinical leaks[6,7]. The Dutch TME trial demonstrated a lower rate of surgical re-intervention in patients with a diverting stoma ($P < 0.001$)[2]. However, a protective stoma can also result in stoma-related complications, and the obligatory operation to take down the stoma is associated with additional mortality, morbidity, and cost[8]. In addition, so-called temporary protective stomas tend to be left *in situ* for much longer than initially anticipated, sometimes even lifelong[9].

Many definitions are used to describe anastomotic leakage. The Surgical infection Study Group (1991) categorised AL into clinical and subclinical leakage[10]. In 2001, Bruce *et al*[11] recommended the subdivision of anastomotic leakage into three groups: radiological (no

clinical signs), clinical minor (no intervention needed), and clinical major (intervention required) leakage. This grading of AL resembles the grading of AL proposed by the International Study Group of Rectal Cancer (IS-REC)[12]. The ISREC defines AL as a communication between the intra- and extraluminal compartments due to a defect of the integrity of the intestinal wall at the anastomosis between the colon and rectum or the colon and anus. The extent or severity of AL should be graded according to the impact on clinical management. Grade A does not require active therapeutic intervention; grade B requires active therapeutic intervention, but is manageable without relaparotomy; and grade C requires relaparotomy.

In this review, we focus on the use and potential success of mechanical intraluminal devices that may protect a colonic anastomosis against leakage. Different strategies have been adopted to lower the incidence of AL. In this respect we will differentiate between transanal decompression, intracolonic, and biodegradable devices. In addition, devices encircling the bowel have been tested. The use of some of these devices showed promising results in lowering the incidence of AL (Table 1).

Considering the persisting associated morbidity and mortality of AL, and availability of intraluminal colonic devices today, a revival of the discussion of their effectiveness in lowering the incidence of AL is worthwhile.

LITERATURE SEARCH

This is a retrospective review describing the literature on devices protecting colonic anastomoses. In March 2010, an extensive literature search was performed using MEDLINE, EMBASE, and The Cochrane Collaborative Library for all papers related to prevention of anastomotic leakage by placement of an intraluminal device in the colon. Our search comprised the following: (tube OR tubes OR bypass* OR by-pass OR stent* OR device* OR coloshield) AND (anastomosis OR anastomo*) AND (leak* OR dehiscen*) AND (colon OR rectum OR colonic OR intracolonic OR colorectal) AND (prevent* OR protect*). Articles were marked as relevant if an intraluminal device was studied that protected a colonic anastomosis from leakage. Articles describing glues or fluids that protect the anastomosis are not included in this review, neither are studies on techniques of anastomosing the bowel. The reference list of each relevant article was checked for further relevant papers. All first authors of relevant papers were checked for other relevant publications. All articles were selected by one reviewer and in case of doubt, a second reviewer was consulted. The Internet was also searched using www.scholar.google.com. The search yielded 337 articles of which 44 were related to an intraluminal device intended to protect a colonic anastomosis. These 44 articles include experimental animal studies, as well as retrospective and prospective clinical studies.

TRANSANAL DECOMPRESSION DEVICES

A decompression device functions by keeping the anal sphincter open, thereby decreasing the intraluminal pressure, as well as the pressure on the anastomosis. In this way, the device serves as a protective vent. In addition, a number of authors have hypothesized that some tubes permit reinforcement and prevent angulation of the bowel and anastomosis. As early as in the 13th century, Lanfrank reported the placement of a reed pipe as an intraluminal stent in the colon[13]. More recently, Gurjar[14] assessed the current practice of rectal tubes in the United Kingdom and Ireland. A questionnaire was sent to all members of the Association of Coloproctology (ACP-GBI). The response rate was 58%, and 35% of those reported to use a rectal tube, in the majority of cases after ileo-anal or colonic pouch surgery. Sixteen percent used the tube after low anterior resection (LAR). Predominantly, a Foley catheter was positioned above the anastomosis (80%). The catheter was left *in situ* for a median of five days. Most respondents used the tube with the intention to decompress the rectum and/or pouch.

Animal studies

In 1988, Goldman *et al*[15] tested an intrarectal, conically shaped flexible silastic tube in a dog model of LAR. The tube was fixed to the submucosa 5 cm proximal to the anastomosis. Twenty-five dogs underwent an LAR; 15 with a tube and 10 controls. In some animals, the anastomosis was deliberately made incomplete, leaving gaps. Mortality occurred only in the control group. Morbidity in the control group was six times higher (three colocutaneous fistulae and three anastomotic abscesses). Only one dog with a tube and an incomplete anastomosis was diagnosed with a pelvic abscess. The tubal fixation sites showed oedema and minor inflammatory reaction on microscopic examination. The authors concluded that their procedure presented effective practical implications, such as omitting the need for a proximal protective colostomy.

Human studies

Indwelling rectal tubes: Stewart[16] used an indwelling rectal tube in 153 patients who underwent a left hemicolectomy or sigmoid resection. After completion of the anastomosis, a No. 32-34 French latex tube was introduced through the anal canal and directed through the anastomosis to a distance of approximately 15 centimeters above the anastomosis. The rectal tube was sutured to the perianal skin for fixation. Twice daily, the tube was irrigated with neomycin solution and after five or six days, the tube was removed. Suture-line complications occurred in seven patients (4.6%), with three patients being graded as C according to the ISREC classification. In the other four patients, the anastomotic complications were grade A/B (haematoma, stricture, and abscess noted only on sigmoidoscopy). Adverse effects of the tube (e.g., ulceration of the colon) were not observed.

Table 1 Studies on intracolonic devices aimed at preventing anastomotic leakage

Study[Ref.]	Yr	n	Site	Device	Anastomotic complications
Rack[17]	1966	32	Sigmoid or rectum resection	Rectal tube	0 AL
Stewart et al[16]	1968	153	Left colon or colorectal resection	Rectal tube	4 Grade A/B AL (3%)
					3 Grade C AL (2%)
Balz et al[18]	1978	392 (including 153 patients from study Stewart)	Left colon or colorectal resection	Rectal tube	3 Grade A/B AL (1%)
					6 Grade C AL (2%)
Castrini et al[33]	1984	19	Left colon or rectal resection	Intracolonic bypass	0 AL
Ravo et al[35]	1987	28	Sigmoid resection	Intracolonic bypass	0 AL
Cuilleret et al[53]	1991	14	Left colon resection	Intracolonic bypass	0 AL
Ravo et al[34]	1985	29	Left colon or rectal resection	Intracolinic bypass	0 AL
Ravo[29]	1988	Case report	Sigmoid resection	Intracolonic bypass	0 AL
Keane et al[37]	1988	6	Sigmoid or rectal resection	Intracolinic bypass	0 AL
Rosati et al[36]	1992	29	Left colon or rectal resection	Intracolinic bypass	2 AL (7%)
Egozi et al[38]	1993	Case report	Sigmoid	Intracolinic bypass	Colon necrosis at site of tube
Yoon et al[41]	1994	10	LAR	Condom	0 AL
Sterk et al[19]	2001	50	LAR	Transanal tube	3 Grade A AL (6%)
					2 Grade C AL (4%)
Amin[1] et al[20]	2003	76	LAR	41 transanal stent	Stent: 3 Grade C AL (7%)
				35 loop stoma	Stoma: 1 Grade A AL (3%)
					1 Grade C AL (3%)
Bülow[2] et al[21]	2006	194	LAR	98 Transanal stent	Stent: 17 AL (17%)
				96 controls	Control: 8 AL (8%)
Ye[3] et al[47]	2008	83	LAR	44 VIB	VIB: 2 Grade A AL (5%)
				39 Loop ileostomy	Stoma: 2 Grade A AL (5%)
Kolkert et al[48]	2010	15	Sigmoid or rectal resection	C-seal	0 AL

[1]Randomized trial; [2]Randomized trial, with/without stent and with/without ostomy; [3]Patient could choose between VIB and LI. AL:Anastomotic leakage, according to the ISREC classification[12]; LAR: Low anterior resection; VIB: Valtrac-secured intracolonic bypass; LI: Loop ileostomy; ISREC: International Study Group of Rectal Cancer.

Figure 1 Transanal stent.

In 1978, Balz *et al*[18] reviewed a series of 392 patients undergoing anterior resection with placement of an indwelling rectal tube. Anastomotic complications occurred in 3.8%. In addition to decompression, the rectal tube facilitated intraluminal antibiotic irrigation of the anastomosis.

Transanal rubber drain: In 2001, Sterk *et al*[19] used a transanal rubber drain to protect the anastomosis after low anterior resection in 50 patients. The maximal distance between the anastomosis and the anal skin was 7 cm. The transanal rubber drain had openings on the side, a length of 40 cm, and a diameter of 12-15 mm. The tip of the drain was positioned about 10 cm proximal to the anastomosis; the other end was fixed to the

perineal skin. Two patients (4%) developed a grade C AL and three patients (6%) a grade A AL. The authors concluded that the transanal drain was at least equivalent to a conventional colostomy to reduce symptomatic AL.

Human trials
Transanal stent: The transanal stent (TAS) is a radio-opaque soft silicone tube, 4 cm in length with funnel-shaped flanges. It is inserted into the anal canal at the end of the procedure, and is left *in situ* for 5-7 d (Figure 1). Amin *et al*[20] performed a randomised trial with the TAS in LAR for rectal cancer. Forty-two of 118 patients were not randomised because of high dose pre-operative radiotherapy, concern about the anastomosis, or obstructing tumours. Seventy-six patients were randomised to TAS or a proximal defunctioning loop stoma (LS). No significant difference in AL rate was demonstrated between the two groups (TAS: three AL's, all grade C; LS: two AL's grade A and C). Patients with a TAS had fewer general infectious complications (17% *vs* 35%) and a shorter hospital stay (13 *vs* 23 d; *P* < 0.001). This study is one of the few trials that actually tested an intracolonic device. Unfortunately, the randomisation strategy is not very clear and no control group with patients without an LS or TAS were described.

In 2006, Bülow *et al*[21] performed a prospective randomised trial to evaluate TAS in patients undergoing anterior resection for a mobile rectal tumour. The use of a protective ileostomy was left to the discretion of the operating surgeon. After completion of the opera-
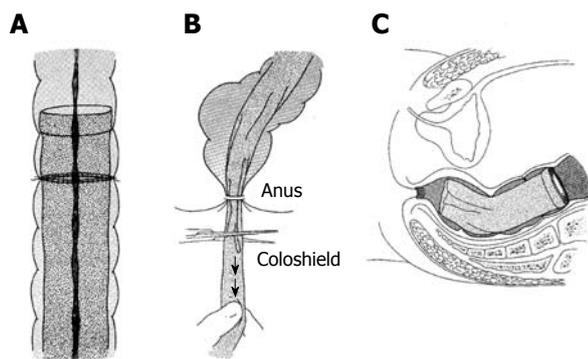
Figure 2 The Coloshield. A: The coloshield is sutured to the submucosa of the bowel proximal of the anastomosis; B and C: Slight traction is placed on the coloshield and it is cut so that it lies in the rectal ampulla.

tion, patients were randomised to the TAS group or the control group. After inclusion of 194 patients (of the planned 448 patients) an interim analysis was performed because of the occurrence of several leaks over a short time. Clinically significant leakage was diagnosed in 25 patients (13%), of whom seven were treated with drainage only and 18 with relaparotomy. AL occurred more frequently in the TAS groups (17%) than in the control group (8%). Although the difference in leak rate appears to be clinically relevant, the difference was not statistically significant because of the small sample size ($P = 0.09$). The study was stopped prematurely for ethical reasons because of this trend. Although this study was unable to demonstrate a statistical difference in AL between the groups, it seems unlikely that inserting the TAS reduces the incidence of AL (Figure 1).

INTRALUMINAL DEVICES

Intracolonic devices do not aim at preventing anastomotic dehiscence. However, they may prevent the faecal load from contacting the anastomotic site, thereby preventing leakage of faeces into the peritoneal cavity when the walls of the anastomosis have become dehiscent. When the faecal stream is bypassed from contacting the bowel mucosa, a gap in the anastomosis will not lead to extravasation of intraluminal content. Shielding the anastomosis from contact with faeces might also reduce the incidence of AL[22].

Animal studies

Coloshield: In the 1980's, Ravo and Ger developed an intraluminal colonic tube to prevent anastomotic leakage. The application procedure is illustrated in Figure 2. After the bowel resection, the proximal loop is inverted for 4-6 centimetres. The proximal end of the tube, reinforced with a cloth strip, is fixed to the proximal bowel loop using polyglycolic acid sutures. The inverted intestinal portion is overturned to its normal anatomic position and the posterior half of the anastomosis is performed. Then, a rectal probe is introduced through the anus and

is connected to the tube by a built-in connector. The probe is drawn outside the intestinal lumen through the distal bowel and the anastomosis is completed by suturing the anterior part. The tube is then cut at the level of the anal orifice after a light traction, spontaneously returning inside. In cases where the mid-or lower rectum is resected, the tube is left protruding from the anus and an incontinence bag is attached to the perineum[23]. Studies on dogs were performed using different tubes varying in width and length, material (latex, silicone, rubber), and suture technique. The colon tube placement was found to be a safe, uncomplicated procedure and none of the dogs (three studies, 14 dogs per study) developed AL (evaluated by laparotomy and barium studies). All tubes were expelled naturally together with the faecal stream[24-26]. Even when an intentionally incomplete anastomosis was made after inserting the tube, no AL occurred. In 1985, the bypass tube was successfully tested on five dogs using a (circular) stapler[27].

Silicone prosthesis: In 1992, Serra *et al*[28] studied the efficacy of intracolonic silicone prosthesis in 42 dogs. The use of the prosthesis is similar to the technique described by Ravo and Ger[23,26,29]. The primary objective of the study was to evaluate the efficacy of the intracolonic silicone prosthesis in protecting the anastomosis. Three groups of 14 dogs each (colonic occlusion, diverticulitis, and control) were randomized to undergo resection and anastomosis with or without the silicone prosthesis. A significant difference in mortality was found: six dogs without prosthesis developed anastomotic failure, of which three died. No deaths or AL occurred in the prosthesis groups.

Soft latex tube: Intraluminal colonic tubes were studied by Ross[30] in a rat model. The rats were divided in four groups; all underwent colon diversion with creation of an incomplete anastomosis. The first group consisted of rats treated with an intracolonic tube made from rat duodenum. In the second group, an intracolonic soft latex tube was introduced. The third group had a tube placed outside the colon lumen, and the last group was a control group with an incomplete anastomosis. The tubes were attached 1.5 cm above the incomplete anastomosis. The tubes remained inside the rectum, barely reaching the dentate line and were removed after five or six days. Rats treated with latex and rat duodenum tubes showed a better survival compared to controls (52% and 71%, respectively *vs* 25% in controls). Rats treated with rat duodenum showed a significant better survival compared to the control group ($P < 0.02$). A mortality rate of 100% was found in rats with a tube placed outside the lumen of the colon. The results suggest that only intraluminal tubes have a survival advantage compared to controls. This finding may be explained by the fact that tubes will prevent faecal contamination of the anastomotic site and allow time for secondary healing of the anastomosis.

Figure 3 Polyflex stents with a proximal flare.

Polyflex self-expandable covered plastic stent: As a result of achievements in biomedical technology, in 2008 Tsereteli *et al*[31] performed a randomized controlled trial in 16 pigs comparing the incidence of AL after open rectosigmoid resection with or without a 21 mm Polyflex self-expandable covered plastic stent (Figure 3). The stent was placed over a guidewire with use of a flexible colonoscope and deployed under fluorescence control. A 2-cm anastomotic gap was created. After 6-9 d, stents were spontaneous expelled. At autopsy, none of the animals in the study group (*n* = 8) showed leak-related complications, although two pigs developed an unrelated postoperative complication (evisceration and bladder necrosis) and died. Five out of eight control animals (63%) showed intra-abdominal infection around the anastomosis at autopsy, with four abscesses and one fistula. This demonstrated a significant beneficial effect of the stent group *vs* controls (*P* = 0.002). The authors stated that the stent could be a breakthrough solution for the complicated colorectal anastomosis, avoiding the necessity of a stoma during the healing process. A potential new indication for this stent was also to seal an acute anastomotic leak, which is supported by one case report describing the successful use of a coated stent in healing a 1-cm fistula from a rectosigmoid anastomosis two weeks after surgery[32].

Human studies
Coloshield: The development of the intraluminal tube led to the final version of the Coloshield: a soft, pliable tube like a surgical glove. This intraluminal protective device, developed by Ravo, was first used in humans in 1984[25,33]. Indications for use include perforated diverticulitis, colonic obstruction, volvulus, carcinoma, and fistula. Several non-randomized studies were performed in patients (ranging from *n* = 6 to *n* = 98) undergoing colon surgery with the Coloshield. The reported anastomosis-related complication rates varied between 0% and 8.7%[23,25,34-37]. The Coloshield related complications included two anastomotic dehiscences (from a group of 98 patients) following low anterior resection, both attributed to technical errors[23]. Egozi *et al*[38] described a case with a complicated course after insertion of a rigid

intracolonic bypass. On the 8th postoperative day, the Coloshield was found to have eroded through the colon. Castrini *et al*[33] tested an intracolonic latex bypass in 19 patients undergoing left colon or rectal resection. None of these patients developed anastomotic complications. Regrettably, no detailed information concerning procedures, patients, and complications was reported.

The last article concerning the Coloshield was published by Ravo in 1991. Ravo described a method of inserting the Coloshield in the proximal colon after completion of the anastomosis by performing a longitudinal colostomy on the antimesenteric border of the afferent loop, proximal to the anastomosis[39]. Ravo and Ger pioneered the use of intracolonic stents, testing different materials (silicone, rubber, and latex) before developing and, finally, filing the patent of the latex Coloshield[40]. They concluded that the one-stage intracolonic bypass procedure is a viable alternative to the two- or three-stage procedure because it reduces the length of hospital stay and the length of disability. Despite its promise, the Coloshield has not been widely accepted. Ravo still uses the Coloshield (personal communication).

Condom: In 1994, Yoon *et al*[41] used a condom instead of a Coloshield to protect the colo-anal anastomosis. Ten patients with rectal carcinoma undergoing LAR received this condom. The ring of the sterilised condom was sutured to the mucosal and submucosal layer of the proximal colon before completing the anastomosis. The condom was brought to the exterior and transected with scissors. The device is expelled naturally from the anus between the 10th and 14th postoperative day. No anastomotic dehiscence, leakage, or colonic necrosis occurred. In 1995, Ruiz *et al*[42] described the same method using a condom (termed a skinless skin) as a protective device in a colonic anastomosis. When using a stapler, the distal end of the condom is attached to the anvil of the EEA stapler with two stay sutures, permitting it to be pulled through the anastomosis. Ruiz *et al* hypothesized that a latex condom is a cheap and safe device that decreases the risk of dehiscence and permits the performance of a large number of primary anastomoses. Unfortunately, for both studies, no detailed information on the procedures and patients are available.

BIODEGRADABLE DEVICES
Animal studies
In 1993, Winkeltau tested the protective effect of biodegradable bipolymer intraluminal stents in 90 rats under the adverse condition of induced general peritonitis (verified by inspection, microbiology, and histology)[43]. Peritonitis was induced using the cecal ligation and puncture model[44]. Stents of various shapes and biodegradable materials were compared to controls with no stents, in rats undergoing jejuno-jejunostomy. The survival rate in the control group was 25% and rats receiving a tube had a significantly better survival, varying between

Figure 4 Murphy's button. John Benjamin Murphy developed his device in 1892 as a quick and safe method of intestinal anastomosis. The steel Murphy button had two rounded heads mounted on hollow shafts. After the intestinal ends were tied on the shafts, the heads were screwed together to compress the tissue.

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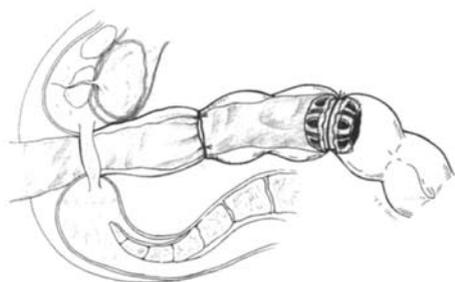
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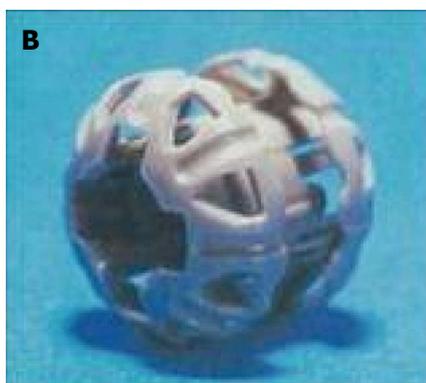
Figure 5 Valtrac-secured intracolonic bypass device. A: Rough colorectal anastomosis with large gaps between sutures protected by the intracolonic bypass; B: Biofragmentable anastomosis ring.

65% and 90%. The best results were obtained in rats with a funnel shaped BCL-004 tube, mainly composed of polyhydroxybutyric acid (PHB). The use of degradable materials is not restricted to the distal parts of the gastrointestinal tract, since it does not carry the risk of causing an obstruction.

Valtrac secured intracolonic bypass (VIB): Chen[45] introduced the VIB, which consists of a soft vinyl tube attached to a biofragmentable anastomosis ring (BAR). The

BAR was introduced by Hardy *et al*[46] in 1985 (inspired by Murphy's button). The BAR realises a sutureless intestinal anastomosis composed of two identical segments. The two components interdigitate and can be approximated to a semi-closed position with a 6 mm gap between the two edges of the ring (Figures 4 and 5).

Chen attached the BAR to the lumen of a pig's colon, 5-10 cm proximal from the anastomotic site, by putting a simple suture encircling the colon at the site of the BAR gap. The tube attached to the BAR passed through the anastomosis to the anus, thereby preventing contact between the anastomotic site and the faecal stream. Eighteen pigs underwent colonic resection with the deliberate creation of an incomplete anastomosis. Six pigs received the bypass, six received the bypass under the condition of a colonic outlet obstruction (created by tying a purse string suture at the level of the anus) and six pigs were controls. All pigs with the bypass had no anastomotic leakage (checked by a barium enema) and survived. Temporary anorexia and abdominal distension were noted in pigs with a colonic outlet obstruction. Four of six controls developed anastomotic leakage, of which three died.

Human studies

Valtrac secured intracolonic bypass: In 2002, the VIB was tested on 83 patients undergoing LAR for rectal cancer[47]. After inclusion, the patient decided whether he/she wanted to be treated with the VIB or with a loop ileostomy (LI) to protect the anastomosis. The VIB was attached to the colon 5-7 cm proximal of the anastomosis by the same method Chen *et al* used in their experimental study. The fragmentation and excretion of the BAR occurred 12-22 d postoperatively. Fifty-three percent of patients chose the VIB and 47% chose the LI as treatment. Four subclinical anastomotic dehiscences were diagnosed, two in each group. Total hospital stay and costs were significant lower in the VIB group ($P = 0.001$); no readmission for a take down of the stoma was indicated. In two patients, the BAR detached en-bloc, which led to a difficult expulsion. In these cases the BAR was manually crushed and excreted through the anus. The authors concluded that the VIB is a safe and effective diverting technique to protect an elective low colorectal anastomosis; it avoids stoma-related complications and lowers the cost. This study can be criticized because the lack of randomization and high probability of introduction of bias.

C-seal: A recent development from the Groningen group is the C-seal: a thin walled tube like a soft sheet or condom, with a diameter of 4 cm, a length of 25 cm and a wall thickness of 70 μm (Figure 6). The C-seal is a tubular device composed of a biodegradable synthetic material. Two flaps with adhesive tape are located at one end of the tube. These flaps are used to attach the C-seal to the stapler cap, to facilitate an easy pull-through of the C-seal after the anastomosis is made (http://www.jove.com/index/details.stp?ID=2223). The C-seal remains
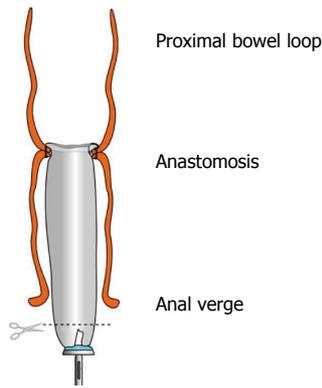
Figure 6 C-seal: A biodegradable drain protecting the anastomosis.

in place for about 10 d, according to the engineered composition of the biodegradable material. Thereafter, it looses strength, degrades, and is secreted from the body together with the gastrointestinal natural contents. In 2007, a pilot study was performed testing the C-seal in 15 patients diagnosed with colorectal carcinoma undergoing LAR with stapled anastomoses[48]. No (sub) clinical AL was diagnosed in these 15 patients. Currently, the C-seal is being tested in a second phase study of 35 patients undergoing (colo-)rectal resection with stapled colorectal anastomosis.

CONCLUSION

The relative high incidence of anastomotic leakage after colorectal surgery, with its major consequences for morbidity and mortality, remain of great concern. Some authors concentrate on early detection of anastomotic dehiscence to reduce the consequences of AL[49-52]. The ideal situation, however, would be prevention of anastomotic leakage. Many devices have been developed to prevent AL by protecting the anastomotic site. We categorised these devices as transanal decompression, intraluminal, and biodegradable protective devices. A number of studies concerning intraluminal tubes demonstrate low leakage rates[18,33-35,48]. Despite these positive results, the use of protective devices has not been widely implemented. Clinicians are probably reluctant to use these devices in clinical practice for a number of reasons.

First, the use of intraluminal devices has only a small basis of evidence in the literature. Most papers are either animal studies or small, non-randomized human studies, often without a control group. Furthermore, most studies are heterogeneous and use different devices[33,37,41,53]. Only two randomized, controlled studies are published, both on decompression devices. Amin *et al*[20] compared a defunctioning stoma with the transanal stent. This study does not show a benefit of the transanal stent. The study suffers from unclear eligibility criteria and a non-transparent randomisation process: one-third of the registered patients were not randomised. With 76 evaluable patients, the study is not sufficiently powered to detect significant differences in leakage rate between

the groups. A similar study by Bülow[21] was prematurely stopped due to a high overall leakage rate, with a trend for a higher leakage rate in the TAS group.

Contrary to the transanal stent, a number of papers suggest that the Coloshield may help to reduce AL, though this beneficial effect has only been demonstrated in small studies with no control group[33-35,39,41,53]. Unfortunately, no proper, randomised trial comparing the Coloshield to the standard of care has been performed until now.

Another aspect of the Coloshield is that it is considered time-consuming and tedious to apply, making it less attractive than the standard procedure. Tsereteli hypothesized that the Coloshield never found wide acceptance because of its technical difficulties and the requirement of a laparotomy for placement[31]. Finally, medical devices are often only successfully introduced by companies who can organize an optimal marketing campaign and a widespread network of representatives. According to Ravo, the Coloshield was never widely accepted because it lacked these factors. Nevertheless, Ravo still uses the Coloshield in daily practice (personal communication).

We conclude that there is currently no high-level evidence demonstrating a benefit of intraluminal devices to reduce AL. Based on the literature, we think that the intraluminal device holds clinical promise to reduce or prevent early leakage of colo-rectal anastomoses and concomitant sequelae (Table 1). Although a number of very innovative approaches have been reported, not all devices have been appropriately studied in a randomized, controlled fashion with sufficient power to rule out chance or bias.

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