A new stomaplasty ring (Koring™) to prevent parastomal hernia: an observational multicenter Swiss study

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Abstract

Background Parastomal hernias (PSH) are one of the most frequent complications of enterostomies with a non-negligible complication rate and a significant socio-economic effect. Therefore, preventing PSH by placing a mesh at the time of primary surgery has been advocated. The aim of our study was to evaluate the safety and feasibility of the new stomaplasty ring [Koring™, (Koring GmbH, Basel, Switzerland)] and investigate the reason why surgeons are reluctant to take preventive measures.

Methods A multicenter observational study was conducted on 30 patients between December 2013 and January 2015. In permanent end colostomies and end ileostomies, the Koring™ was implanted. The primary outcome was the 30-day morbidity (infection and other stoma-related

complications). Secondary endpoints were the technical feasibility and the time needed to fix the ring. In addition, an online survey of 107 surgeons was performed.

Results Twenty-seven patients received permanent end colostomies, and three received end ileostomies. No stoma-related complication was detected within the first 30 days post-operatively. The Koring™ ring was evaluated by the surgeons as easy and very easy to implant in more than half of the patients. Average additional operating time for ring implantation was 19 min.

Conclusions Koring™ implantation at the time of creating the stoma is safe, easy and only adds minimally operating time. A long-term follow-up as well as a randomized controlled study is needed to evaluate the impact of the Koring™ on PSH prevention. The ease and rapidity with which Koring™ can be implanted may help surgeons to overcome their apprehension of using a preventative device.

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Introduction

Parastomal hernia (PSH) is a well-known healthcare issue, and effective treatment remains a challenge for surgeons. It is defined as protrusion of abdominal contents through a weakness in the abdominal wall at the site of the previous hole (trephine) made for delivering the stoma. Many surgeons believe that a PSH is almost inevitable due to the fact that 50 % of all stomas are permanent and up to 76 % of these patients will develop a PSH within the first 3 years after the primary surgery [1]. The incidence rate of PSH varies depending on the type of stoma. It is higher in colostomies compared to ileostomies, and end colostomies

carry the highest risk of PSH [2]. Eighty percent of patients with PSH are symptomatic, and 30 % of patients will require surgery due to incarceration, pain, recurrent constipation or poorly fitting appliances [3]. A wide range of techniques for PSH repair has been described such as primary fascia repair, relocation or mesh placement. The approach can be open or laparoscopic. Despite the effort to improve methods of intervention, the recurrence rate after PSH repair is high, even using a laparoscopic approach (12–25 %) [4]. Due to these unsatisfactory results, prevention of PSH by insertion of a prophylactic mesh at the time of primary surgery has recently been advocated. Several studies have already shown the safety of using a polypropylene mesh during initial stoma creation [5–11]. The mesh was mainly placed in a sublay position. The more relevant trials were included in a meta-analysis, which revealed a reduced incidence of PSH (12.3 vs. 54.7 %, $p = 0.02$) in the mesh group [3]. However, correct mesh placement remains a demanding and time-consuming surgical procedure. Moreover, mesh implants are known to cause problems such as fibrosis, adhesions, implant shrinkage, infections, fistulas and, in rare cases, bowel erosion [2, 12]. So far, only a minority of surgeons use a mesh to prevent PSH. The reason for this reluctance has not been evaluated so far. A new stomaplasty ring called KoringTM (Koring GmbH, Basel, Switzerland) was recently described [13] (Fig. 1). It is easy to implant and does not require tissue dissection. It is not directly in contact with the abdominal cavity and thus potentially reduces the risk of bowel adhesions and mesh infections. It has the potential to prevent PSH, to improve the quality of life of patients and to reduce costs by preventing further surgical interventions.

Therefore, the aim of this study was to evaluate the safety and feasibility of this new device. Furthermore, we used an online questionnaire to evaluate the reason for not using preventive measures during primary stoma formation.

Fig. 1 Stomaplasty ring (KoringTM)

Materials and methods

In a prospective multicenter observational trial, consecutive patients requiring placement of a permanent end colostomy or end ileostomy during an elective operation were included. Exclusion criteria were age under 18 years, any drug or alcohol abuse, mental disorders, pregnant or breastfeeding women, fecal peritonitis, a body mass index (BMI) over 40 kg/m², recurrent PSH and factors limiting the ability to cooperate in the study.

Patients were recruited between the December 1, 2013, and January 31, 2015. Six hospitals participated in this study: the University Hospitals of Basel, Zurich, Lausanne and Geneva as well the Limmattal Hospital and the Hospital of Schaffhausen (Switzerland). Eleven surgeons performed KoringTM implantation. The surgical procedure was standardized as described elsewhere [13]. Antibio-prophylaxis was given according to each hospital's guideline. Before the procedure, the surgeon had access to an instruction video and a step-by-step written and illustrated instruction manual. Critical steps of the procedure were documented in an evaluation sheet. The choice of the KoringTM diameter, which depends on the patient's anatomy, was left to the surgeon.

Outcomes

The primary outcome was 30-day morbidity, with particular attention paid to infection, necrosis, retraction and prolapse and any other stoma-related complications. Infections were defined according to the Centers for Disease Control and Prevention (USA) definition. Secondary outcomes were technical feasibility, intraoperative complications and time of KoringTM implantation.

Data collection

The surgeon performing the operation documented the time of implantation, the size of the KoringTM used (diameter 2.5, 3.5 or 4.5) and the impression of technical difficulty (5 items, Likert scale: very easy, easy, moderate, difficult or very difficult) on a standardized evaluation sheet immediately after surgery.

A follow-up document had to be filled in by the surgeon, with information on stoma output, infections, the presence or absence of post-operative ileus and other stoma-related complications on days 3, 7 and 30 post-operatively. Post-operative ileus was defined by placement of a nasogastric tube in the post-operative course. Patient demographics and procedure-related information were also collected.

In a one-year follow-up, the rate of parastomal hernia will be assessed. For this purpose, a clinical examination will be performed as well as an abdominal computed

tomography scan. In the meantime, patients are asked to communicate any signs of infection or stoma dysfunction.

Online survey

In 2012, we performed an online survey of 107 surgeons in Switzerland. After 2 weeks, we sent out one reminder to those who did not respond initially. The questionnaire included 15 items concerning parastomal hernia prevention. The surgeons were consultants or clinic directors.

Statistical analysis

The data were analyzed using descriptive statistics. Since this was an observational study without control group, other statistical hypotheses were not tested.

Results

Procedures and outcomes

Thirty patients were included in the study. Patient baseline characteristics are presented in Table 1. Two-thirds of the procedures were abdominal perianal surgery for rectal or anal cancer. The KoringTM was implanted successfully in all patients requiring permanent colostomies ($n = 27$, 90 %) and terminal ileostomies ($n = 3$, 10 %). The 3.5 cm diameter was used in 80 % of the cases ($n = 24$) whereas the 2.5 cm was used in 20 % ($n = 6$). The time needed to fix the ring was a median 19 min [± 8 min, standard deviation (SD)]. KoringTM implantation was rated as “very easy” and “easy” in 63 % ($n = 19$) of the cases and “moderate” in 30 % ($n = 11$) of the cases. Only 7 % ($n = 2$) were considered “difficult.” The implantation could always be done according to the instruction. There were no surgical site infections or other stoma-related complications reported at 3, 7 and 30 days post-operatively. Eleven patients who underwent abdominoperineal resection developed perineal wound infection or dehiscence. Post-operative paralytic ileus was noted in nine patients (30 %). There were no obstructions due to mechanical problem. BMI had no impact on KoringTM implantation time (Table 2).

Online survey

In the online survey, 70 surgeons out of 107 responded, resulting in a response rate of 65 %. The first question was what they estimated the parastomal hernia rate to be. According to the likelihood of PSH, the majority of surgeons ($n = 31$, 44.3 %) estimated the risk of PSH to be between 25 and 50 %, and 12.9 % ($n = 9$) estimated the

Table 1 Patient characteristics

Mean age in years (SD)	61 (14)
Mean body mass index in kg/m ² (SD)	24 $\pm$ 5
Diabetes, n (%)	
Yes	5 (16.7)
No	25 (83.3)
ASA classification, n (%)	
I	3 (10)
II	13 (43.3)
III	13 (43.3)
IV	1 (10)
Emergency surgery, n (%)	
Yes	2 (6.7)
No	28 (93.3)
Reason for surgery, n (%)	
Rectal cancer	18 (60)
Anal cancer	3 (10)
Defecation or incontinence problem	4 (13.3)
Other	5 (16.7)
Type of surgery, n (%)	
Abdominoperineal resection	20 (66.7)
Lower anterior rectal resection	3 (10)
Other	7 (23.3)

SD standard deviation

PSH risk even higher than 50 %. Most of the surgeons (68.1 %, $n = 47$) think that there is a strong need to prevent PSH. In terms of active prevention of PSH, 17.1 % ($n = 12$) of the surgeons use mesh implantation during stoma formation, 37.1 % ($n = 26$) occasionally and 45.7 % ($n = 32$) never do so. Those surgeons actively trying to prevent PSH either implant conventional synthetic meshes ($n = 27$, 73 %), biological mesh ($n = 2$, 5.4 %) or apply special sutures ($n = 8$, 21.6 %). When a mesh is implanted during stoma formation, the majority of surgeons 73.5 % ($n = 25$) place the mesh intraperitoneally.

As shown in Fig. 2, most surgeons do not use preventive measures, because they fear for a mesh infection ($n = 31$, 59.6 %), are not convinced of its benefit (40.4 %, $n = 21$), do not accept prolonged operating time (21.2 %, $n = 11$) or are trying to avoid additional costs (17.3 %, $n = 9$).

Discussion

PSH is the most frequent complication after stoma creation with a high impact on a patient’s quality of life. Surgical repair is indicated in 30 % of the cases. A variety of techniques used for PSH repair have therefore been described but even with a mesh insertion the PSH recurrence rate remains high. Prevention seems to be the best

Table 2 Perioperative data

Complications, <i>n</i> (%)	
Infection (SSI)	None
Stoma retraction	None
Stoma prolapse	None
Perception of the ring	None
Average time for implantation (minutes), mean (SD)	19 (8)
BMI < 30 kg/m ² , <i>n</i> (%)	18.9 (8.0)
BMI > 30 kg/m ² , <i>n</i> (%)	19.2 (8.2)
Colostomies, <i>n</i> (%)	27 (90)
Ileostomies, <i>n</i> (%)	3 (10)
Used diameter (KORING TM), <i>n</i> (%)	
2.5 cm	6 (20)
3.5 cm	24 (80)
4.5 cm	0
Feasibility rating, <i>n</i> (%)	
>BMI 30 kg/m ²	
Very easy	0
Easy	3 (60)
Moderate	1 (20)
Difficult	1 (20)
Very difficult	0
<BMI 30 kg/m ²	
Very easy	4 (16)
Easy	12 (48)
Moderate	8 (32)
Difficult	1 (4)
Very difficult	0

SSI surgical site infection, BMI body mass index

Fig. 2 Online survey of 107 surgeons

approach to the management of PSH [2], and to date, there is good evidence for placing a mesh at the time of stoma creation [4, 14]. The results seem promising, with a PSH rate of 10 %. However, the ideal material and site of implantation have yet to become standardized. Placing the mesh in the intraperitoneal space reduces the risk of contamination but can lead to adhesions with subsequent intestinal obstruction, intraperitoneal abscess or fistula

[15]. Lately, most publications have been based on sublay techniques, and no significant mesh-related complications were detected [5, 7, 8, 10]. Even in the study of Jänes et al. [6], using a lightweight mesh, with a follow-up of 5 years, no complications were documented.

In the online survey we carried out, the main reason given by the surgeons for not using a preventive measure is the fear of infection. Our results are similar to the recent literature with no occurrence of infection. Therefore, we can say that this fear is unfounded. Another reason highlighted in the survey was that the surgeons were not convinced of the benefit of a mesh. One recent retrospective study has just confirmed the previous results. In this study, a three-dimensional funnel mesh was implanted in an intraperitoneal in-lay position in 80 patients. The recurrence rate was 3.8 % with a median follow-up of 21 months [16]. In our study, the KoringTM was placed in a sublay position posterior to the rectus muscle. It is braided out of Dacron, a lightweight and non-absorbable material (polyethylene terephthalate). In contrary to the polypropylene, which was used in most of the early studies, it is flexible and not abrasive. It has the advantage of being available in 3 diameters allowing it to perfectly fit the bowel size. Moreover, it is designed to have a minimal surface area, diminishing contact with surrounding tissue, thus minimizing the risk of fibrosis, contraction and infection. Compared to other meshes, it does not necessitate any additional tissue dissection reducing the potential risk of seroma and hematoma and decreasing operating time. KoringTM implantation appears to be a technically easy procedure, which does not dramatically increase operating time. The BMI does not seem to have an impact on the technical difficulty of the surgery. In fact, the mean time for KoringTM implantation was similar in patients with a BMI > 30 kg/m² and those with a BMI ≤ 30 kg/m². However, surgeons have rated the surgery more difficult in patients with BMI > 30 kg/m².

Conclusions

This observational study gives us the first encouraging results regarding the safety and feasibility of KoringTM implantation. It is easy to implant and does not increase surgical time significantly. Moreover, the recent literature strongly supports application of a preventative measures. A long-term follow-up study is planned to evaluate the PSH rate and long-term rates of infection, fistula formation and other complications after KoringTM implantation.

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Compliance with ethical standards

Conflict of interest The authors declare that they have no conflict of interest.

Ethical approval The Koring is CE certified (EU1306403) and the KORING company is ISO 14385 certified.

Informed consent Informed consent was obtained at each center.

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