



Short-term outcomes of the over-the-scope clip proctology system for rectovaginal fistula repair: a prospective study

Yiwei Tong^{1,2} · Bertrand Trilling^{1,3} · Pierre-Yves Sage¹ · Edouard Girard^{1,3} · Jean-Luc Faucheron^{1,3}

Received: 30 September 2018 / Accepted: 13 February 2019 / Published online: 1 April 2019
© Springer Nature Switzerland AG 2019

Abstract

Background The over-the-scope clip proctology system is rather new and information regarding its use for the closure of anorectal fistulas is scarce. No study has been designed to focus exclusively on its application in the treatment of rectovaginal fistulas. The aim of the study was to evaluate the feasibility, safety, and effectiveness of the clip for rectovaginal fistula repair.

Methods From September 2014 to November 2017, consecutive patients underwent a rectovaginal fistula repair using the over-the-scope clip proctology system and were enrolled in a non-randomized prospective monocentric study. The primary outcome was fistula healing at 8 months. Secondary outcomes included assessment of morbidity and timing of rectovaginal fistula recurrence.

Results There were 16 patients with a median age of 40.1 years. The most common causes of rectovaginal fistula were adverse events following proctectomy or pelvic radiotherapy (6 patients), obstetric trauma (5 patients) and inflammatory bowel disease (3 patients). Most participants had undergone at least two previous surgical interventions before the clipping procedure. 11 patients had a temporary diverting stoma at time of the clipping procedure. Successful primary healing of the fistula was observed in 7 (43.7%) patients. Short-term complications were rare and included pain, which occurred in 4 patients, and spontaneous clip detachment, which occurred in 2 patients. Most recurrences appeared shortly after the procedure, with a median delay of 45 days (range 16–217).

Conclusions We demonstrated the feasibility, safety, and reproducibility of the Over-The-Scope Clip Proctology system in rectovaginal fistula repair for the patients selected. Further trials should be designed, incorporating comparisons to well-established techniques, a longer follow-up period, and a larger cohort.

Keyword Rectovaginal fistula · OTSC proctology system · Surgery

Introduction

Rectovaginal fistula (RVF), an abnormal connection between the rectum and the vagina, constitutes less than 5% of all anorectal fistulas [1, 2]. RVFs are usually associated with chronic pain, unpleasant secretions, urinary infections, and hygiene problems, resulting in a poorer quality of life and incapacity to work. The main causes of RVF include

obstetric trauma, inflammatory bowel diseases and adverse events following proctectomy or pelvic radiotherapy. Should more conservative treatments prove unsuccessful, a surgical procedure is usually required to cure RVF.

Various surgical techniques are available to treat established fistulas; these include simple fistulotomy, fibrin glue, fistula plug, rectal advancement flap procedure, the Martius procedure, gracilis muscle interposition and more complex abdominal surgical procedures [3]. The surgeon's choice is made according to the location of the fistula, tissue frailty or inflammation, complexity of the fistula tract, and his or her own personal experience. Although various attempts have been described, the closure of RVF is still a significant challenge, and it is not clear what the ideal procedure is [3].

Over the past decade, a new procedure for surgical closure has been developed, using a nitinol clip derived from the over-the-scope clipping system (OTSC[®] Proctology,

✉ Jean-Luc Faucheron
JL.Faucheron@chu-grenoble.fr

¹ Colorectal Unit, Department of Surgery, Michallon University Hospital, CS 10 217, 38 043 Grenoble cedex, France

² School of Medicine, Shanghai Jiao Tong University, Shanghai, China

³ University Grenoble Alps, Grenoble, France

OVESCO Endoscopy GmbH, Tübingen, Germany) for the treatment of complex anorectal fistulas and RVFs. The method was first derived from the endoscopic OTSC[®] system, which has been proven to be effective and safe for the endoscopic interventions for gastrointestinal bleeding and perforations [4–9]. The current data show a success rate of 76–86% in endoscopic closure of leaks and fistulas [4–9]. The theoretical advantage of the OTSC[®] Proctology system over well-established surgical procedures for fistula repair is the maintenance of compression force on the internal fistula opening. In addition, the method can be viewed as a minimally invasive surgical technique avoiding sphincter damage [10]. However, since the OTSC[®] proctology system is still rather new, there is less information available regarding its use for the closure of anal or rectal fistulas. Limited evidence has been obtained from previous studies, with results remaining controversial. Prosst et al. reported a healing rate of about 90% following OTSC[®] proctology system closure in the management of complex anal fistulas with a follow-up of 6 months [10]. Another retrospective study by Menigen et al. showed that with a median follow-up of 72 days, nearly 70% of refractory transsphincteric fistulas could be cured using OTSC[®] Proctology systems [11]. Marinello et al. demonstrated OTSC[®] proctology clip effectiveness, with a 60% success rate for healing at a median follow-up of 15 months [12]. Nevertheless, another recent retrospective study of 17 patients found a relatively low healing rate of 12% after a follow-up period of 4 months [13]. A comprehensive evaluation of this surgical technique is not yet available, and no study has been designed to focus exclusively on its application in the treatment of RVFs. Thus, the objective of this non-randomized prospective study was to evaluate the feasibility, safety, and effectiveness of the OTSC[®] proctology system for RVF repair in consecutive patients at our institution.

Materials and methods

Patients

Between September 2014 and November 2017, consecutive patients treated for RVF repair (primary or recurrent) with the OTSC[®] Proctology system in our institution were prospectively included in this study. All procedures were performed by a senior colorectal surgeon (JLF). Patient clinical details were reported in our prospective single-center institutional review board-approved database. Exclusion criteria were: age younger than 18 years, pregnancy, RVF associated with an active anorectal or vaginal tumor, American Society of Anesthesiologists (ASA) grade of IV or V, high RVF close to the cervix and opening of the RVF beyond the size of the OTSC[®] Proctology device.

The following procedural data were collected: age at RVF occurrence, main cause of RVF, age at first surgical intervention, type and number of previous surgeries before OTSC[®] Proctology system intervention, previous drainage, short-term and long-term outcomes and complications of clip closure.

Surgical procedure

The closure procedure using the OTSC[®] Proctology system begins with the same standardized protocol that has been already described in our ongoing prospective multicenter study for anal fistula [14]. The major steps are as follows: (1) patient under general anesthesia; (2) local exposure using a bivalve spacer; (3) localization of the internal opening of the fistula using a fistula probe; (4) removal of the epithelium around the internal opening to allow the positioning of the OTSC[®] Proctology system on muscular tissue; (5) placement of two U-shaped sutures through the sphincter muscle, uncut, in a cross-like fashion, to center the internal opening; (6) pulling the distal ends of the sutures through the working channel of the clip applicator using the Thread Retriever with a slight tension; (7) insertion of the applicator above the fistula opening and aligning it parallel to the fistula tract; (8) deactivation of the safety-lock and release of the OTSC[®] Proctology device; (9) removal of the applicator; (10) testing for leakage with sterile saline solution injected through the vaginal opening.

Study outcomes

The primary outcome was RVF healing rate at 8 months and at a median follow-up of 10.2 months (range: 8–36 months). Healing was defined as an absence of symptoms of leakage reported by the patient, and confirmed by clinical examination, radiological contrast control through the lower limb of the colostomy if present, and examination under general or epidural anesthesia. Secondary outcomes included morbidity associated with OTSC[®] proctology system placement and delay of RVF recurrence.

The study was conducted in accordance with the principles of the Declaration of Helsinki. According to the recommendations relative to the steps and means to be used for evaluation and diffusion of innovation in surgery published by an international panel of methodologists and surgeons, this study of RVF closure using a nitinol clip for consecutive patients can be classified as a phase 1 study [15]. Therefore, submission of the data to a Committee for the Protection of Individuals was unnecessary.

Statistical analysis

Median values, interquartile range (IQR), and frequency of quantitative variables were computed using standard methods. Descriptive characteristics of categorical variables were tested using the Chi-square tests or Fisher's exact test. The cumulative percentage of RVF recurrence was estimated using the Kaplan–Meier method. All statistical tests were conducted using IBM SPSS statistics software version 23 (SPSS, Inc., Chicago, IL, USA). Two-sided p values < 0.05 were considered statistically significant.

Results

Patients

Patient baseline characteristics are summarized in Table 1. All 16 women treated for RVF from September 2014 to November 2017 were included in the current study. Median age at first OTSC[®] proctology surgery was 40.1 years

Table 1 Characteristics of patients undergoing RVF repair surgery using the OTSC[®] proctology system

Characteristics	Full cohort ($n = 16$)	
	No.	%
Cause of RVF		
Iatrogenic (proctectomy or radiotherapy)	6	37.50
Obstetric trauma	5	31.25
Inflammatory bowel diseases	3	18.75
Unknown	2	12.50
OVESCO as first surgical intention		
Yes	3	18.75
No	13	81.25
Median number of surgeries before OVESCO		
0	3	18.75
1–3	7	43.75
> 3	6	37.50
Seton drainage before OVESCO		
Yes	6	37.50
No	10	62.50
Diverting stoma before OVESCO		
Yes	11	68.75
No	5	31.25
Other surgical procedures before OVESCO		
Simple fistulotomy	5	31.25
Fistula plug	6	37.50
Fibrin glue	2	12.50
Rectal/vaginal advancement flap	3	18.75

OTSC over-the-scope clip, RVF rectovaginal fistula

(range: 27–56 years). The RVFs appeared at a median age of 35.4 years (range: 25–56 years). The main causes of RVFs were adverse events following proctectomy or pelvic radiotherapy in 37.5% (6/16), obstetric trauma in 31.3% (5/16) and inflammatory bowel diseases in 18.8% (Crohn's disease: $n = 2$, and ulcerative colitis: $n = 1$) of the patients. Most participants had undergone at least two previous surgical interventions before the clipping procedure (fistulotomy, plug, fibrin glue, or rectal advancement flap). Three patients were operated on with the OTSC[®] proctology device as the first surgical intervention. The fistula tract was drained by loose setons in 6 patients and 11 patients had a temporary diverting stoma for a median period of 6.5 months (range: 1–21 months) prior to the clipping procedure. The placement of the OTSC[®] proctology system was technically successful in all cases.

Primary outcome

No patient was lost during follow-up. Successful primary healing of the fistula was observed in 7 (43.7%) patients at 8 months and this result persisted at a median follow-up of 10.2 months (range 8–36 months) after the OTSC[®] proctology system procedure. 9 out of 16 (56.3%) patients reported recurrence of RVF (Fig. 1). We found that the success rate was comparable when the clip was placed as the first surgical intervention or following multiple attempts (33.3% versus 46.2%, $p = 0.952$). Moreover, no significant difference was observed when comparing the healing rate of RVFs due to different factors (66.7% for inflammatory bowel diseases, 66.7% for iatrogenic etiology and 20.0% for obstetric trauma, $p = 0.247$), or with or without the presence of a stoma ($p = 0.85$).

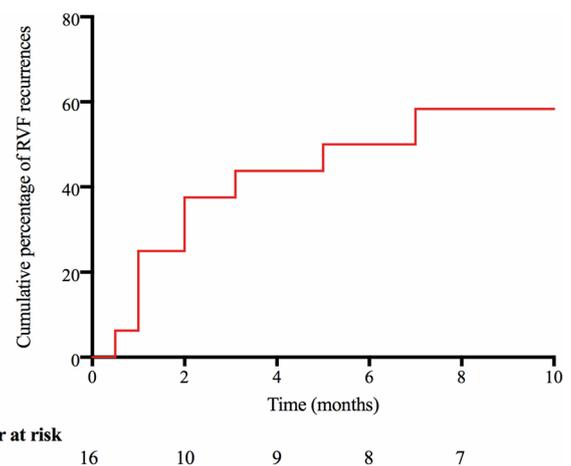


Fig. 1 Recurrence of rectovaginal fistula (RVF) following OTSC[®] proctology system

Secondary outcomes

Short-term postoperative complications were rare in the study population. Only one patient reported pain due to a perianal abscess that required an immediate removal of the clip and drainage. Two cases of spontaneous detachment were also observed at 1-month follow-up. Chronic pain and ulceration around the clip led to surgical removal of the clip in three further patients.

Most RVFs reoccurred shortly after the OTSC[®] proctology procedure with a median delay to recurrence of 45 days (range 16–216 days): 7 patients presented with a recurrence within the first 2 months after the insertion of the clip, including the 6 patients who lost their clip spontaneously or surgically. A further surgical procedure was needed in 8 of the 9 patients with recurrence (supplementary sutures around the clip in 2 and rectal or vaginal advancement flap in 6 patients) with success in 5 of 8 (62.5%). One patient with recurrence was asymptomatic and refused surgery. No patients reported postoperative incontinence.

Discussion

The first RVF closure with the OTSC[®] Proctology system was performed and reported by Dr. Prosst in 2015 [10]. To the best of our knowledge, there are no published series of patients treated for RVF with the use of a nitinol clip. This study constitutes the first evaluation of the therapeutic effects and safety of the application of OTSC[®] proctology system in RVF cases.

As shown in the current study, the OTSC[®] proctology system was frequently not chosen as the first surgical intervention to close RVFs (3 out of 16). Six patients underwent drainage by loose setons, and 11 had primary repair in combination with stool deviation by temporary stoma as a first-line procedure before clip insertion. At a median of 10.2 months after the OTSC[®] Proctology system procedure, more than half of the patients experienced recurrence of RVF, in most cases shortly after surgery, with a median delay of recurrence of 45 days. It is difficult to explain why the success rate was comparable when the clip was placed as the first surgical intervention or following multiple attempts, or why no difference was observed when comparing the healing rate of RVFs due to the different factors, or why the presence of a stoma did not influence the outcome. These findings may be due to the limited number of patients and the relatively short follow-up time. An explanation might be that only minor defects were considered for placement of the clip in this series.

The OTSC[®] Proctology system is an innovative technique for use in fistula repairs. Previous studies have been carried out with conflicting results concerning its use in

the treatment of anorectal fistulas. The reported success rate of anorectal fistula healing ranges from 12 to 90% [10–13]. However, no study to date has been designed to focus on the use of the OTSC[®] proctology system in the treatment of RVFs and its importance in RVF repair remains undetermined. Currently, the limited data available indicate generally unfavorable results. Prosst et al. demonstrated that the healing rate of RVFs was only 20% at 6 months after surgery, which was much lower than that of transsphincteric or suprasphincteric anal fistulas [16]. In a study by Gautier et al., all seven of the patients included with RVFs had persistent fistula at the end of the follow-up; four of those patients presented new abscesses requiring drainage [13]. In our series, we observed a healing rate of 43.7% in RVF patients treated with the OTSC[®] Proctology clip system at a median follow-up of 10.2 months; our results are thus the most encouraging data available. According to the literature, the healing rate of anorectal fistulas was 79% when the clip was used as a first-line therapy, much higher than the 26% when applied in recurrent fistulas [16]. In contrast, we found that the success rate was comparable when the clip was placed as the first surgical intervention or after multiple attempts. When comparing the efficacy of the OTSC[®] Proctology system with other surgical options in RVFs, studies using a rectal or vaginal advancement flap, a Martius flap and a fistula plug reported success rates of 60–90%, 65–100% and 49%, respectively [3, 17, 18]. However, a healing rate of 43.7% in such complicated fistulas appears to be fairly good and quite convincing. The results of the OTSC[®] Proctology clip system cannot directly be compared with those of advancement flaps, Martius flaps, or gracilis flaps, because these techniques are much more invasive and associated with higher morbidity rate.

Short-term postoperative complications were rare and not severe in the study population; the most frequent postoperative events we observed were chronic pain and spontaneous detachment or migration of the clip. This finding is comparable to that of another series in which the clip was asymptotically in situ in 72.2% patients with healed fistulas [10]. Due to the fact that the nitinol material is generally biocompatible, the OTSC[®] proctology device can be left in place as long as the patient remains asymptomatic. In contrast, we observed a spontaneous detachment of the clip in 2 out of 16 patients at 1 month after insertion, with the persistence of the fistula requiring a second operation. Similarly, Prosst et al. found that all spontaneous detachments resulted in fistula persistence after reviewing 100 cases of anorectal fistula repair [16]. We believe that the removal of the OTSC[®] proctology device might reopen the internal fistula opening. Therefore, it would be better to keep the clip in situ until the fistula has completely healed, except in cases of intolerable discomfort.

Limitations of this single-armed prospective study are the small number of patients, a relatively short follow-up time and lack of evaluation of quality of life. Future trials must be conducted to confirm our results and further determine the role of the OTSC[®] Proctology system in the management of RVFs. Randomized controlled studies will be needed to compare the OTSC[®] Proctology system with other well-established surgical techniques.

Conclusions

We demonstrated the feasibility, safety, and reproducibility of the OTSC[®] Proctology system in rectovaginal fistula repair for the selected patients. Further trials should be designed, incorporating comparisons to well-established techniques, a longer follow-up period, and a larger cohort.

Acknowledgements The authors thank Wolters Kluwer and Editage for language, grammar, and terminology checking.

Funding None.

Compliance with ethical standards

Conflict of interest Jean-Luc Faucheron has a consulting agreement with AMI, Covidien, Medtronic, Ethicon, MSD, Legrand, and Johnson & Johnson Beauté Santé France. This has had no impact on the results of this study. Yiwei Tong, Bertrand Trilling, Pierre-Yves Sage, and Edouard Girard declare that they have no conflict of interest.

Ethical approval The study has been performed in accordance with the ethical standards as laid down in the 1964 Declaration of Helsinki and its later amendments.

Informed consent For this type of study formal consent is not required.

References

1. Tsang CB, Rothenberger DA (1997) Rectovaginal fistulas. Therapeutic options. *Surg Clin North Am* 77:95–114
2. Browning A, Whiteside S (2015) Characteristics, management, and outcomes of repair of rectovaginal fistula among 1100 consecutive cases of female genital tract fistula in Ethiopia. *Int J Gynaecol Obstet* 131:70–73
3. Corte H, Maggiori L, Treton X et al (2015) Rectovaginal fistula: What is the optimal strategy? An analysis of 79 patients undergoing 286 procedures. *Ann Surg* 262:855–861
4. Kirschniak A, Subotova N, Zieker D et al (2011) The Over-The-Scope Clip (OTSC) for the treatment of gastrointestinal bleeding, perforations, and fistulas. *Surg Endosc* 25:2901–2905
5. Weiland T, Fehlker M, Gottwald T et al (2013) Performance of the OTSC System in the endoscopic closure of iatrogenic gastrointestinal perforations: a systematic review. *Surg Endosc* 27:2258–2274
6. Keren D, Eyal O, Sroka G et al (2015) Over-the-Scope Clip (OTSC) system for sleeve gastrectomy leaks. *Obes Surg* 25:1358–1363
7. Magdeburg R, Kaehler G (2016) Natural orifice transluminal endoscopic surgery in humans: feasibility and safety of transgastric closure using the OTSC system. *Surg Endosc* 30:73–77
8. Winder JS, Kulaylat AN, Schubart JR et al (2016) Management of non-acute gastrointestinal defects using the over-the-scope clips (OTSCs): a retrospective single-institution experience. *Surg Endosc* 30:2251–2258
9. Niland B, Brock A (2017) Over-the-scope clip for endoscopic closure of gastrogastroic fistulae. *Surg Obes Relat Dis* 13:15–20
10. Prosst RL, Joos AK, Ehni W et al (2015) Prospective pilot study of anorectal fistula closure with the OTSC Proctology. *Colorectal Dis* 17:81–86
11. Mennigen R, Laukotter M, Senninger N et al (2015) The OTSC(®) proctology clip system for the closure of refractory anal fistulas. *Tech Coloproctol* 19:241–246
12. Marinello F, Kraft M, Ridaura N et al (2018) Treatment of fistula-in-ano with OTSC(®) proctology clip device: short-term results. *Cir Esp* 96:369–374
13. Gautier M, Godeberge P, Ganansia R et al (2015) Easy clip to treat anal fistula tracts: a word of caution. *Int J Colorectal Dis* 30:621–624
14. Dubois A, Carrier G, Pereira B et al (2015) Therapeutic management of complex anal fistulas by installing a nitinol closure clip: study protocol of a multicentric randomised controlled trial—FIS-CLOSE. *BMJ Open* 5(12):e009884
15. McCulloch P, Altman DG, Campbell WB et al (2009) No surgical innovation without evaluation: the IDEAL recommendations. *Lancet* 374:1105–1112
16. Prosst RL, Joos AK (2016) Short-term outcomes of a novel endoscopic clipping device for closure of the internal opening in 100 anorectal fistulas. *Tech Coloproctol* 20:753–758
17. Gottgens KW, Smeets RR, Stassen LP et al (2014) The disappointing quality of published studies on operative techniques for rectovaginal fistulas: a blueprint for a prospective multi-institutional study. *Dis Colon Rectum* 57:888–898
18. Kniery KR, Johnson EK, Steele SR (2015) Operative considerations for rectovaginal fistulas. *World J Gastrointest Surg* 7:133–137

Publisher's Note Springer Nature remains neutral with regard to jurisdictional claims in published maps and institutional affiliations.