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ORIGINAL SCIENTIFIC REPORT

Long-Term Results After Stapled Hemorrhoidopexy: A 15-Year Follow-Up

Ralph Schneider[1] · **Pia Jäger**[1] · **Andreas Ommer**[2]

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Abstract

Background The stapled hemorrhoidopexy is reported to have a low recurrence while treating the major hemorrhoidal symptoms of bleeding and prolapse. The aim of this study is to obtain long-term results on the outcome of the stapled hemorrhoidopexy.

Methods All patients with a hemorrhoidal disease grade III, who underwent stapled hemorrhoidopexy from May 1999–December 2003, were included. Data collection was based on a standardized telephone interview. In the questionnaire, we recorded information regarding the postoperative recurrence and severity of hemorrhoidal symptoms (defined as bleeding, prolapse, burning, itching and moisture), further hemorrhoidal treatments and functional results (incontinence, fecal urgency and outlet obstruction) as well as patients' satisfaction.

Results Of the 257 patients, who underwent stapled hemorrhoidopexy, follow-up data were available in 140 patients. In 47.4% of the patients, a recurrence of at least one hemorrhoidal symptom was registered, whereas this recurrence was observed in 47.3% of these patients more than 10 years postoperatively. A surgical re-intervention was necessary in 15.2%. We found a postoperative new incontinence in 15.5%, a fecal urgency in 28.0% and an outlet obstruction in 9.4%. Of all patients, 62.3% were "very satisfied" with the operation.

Conclusions The results of the study revealed a relatively high recurrence of hemorrhoidal symptoms after a mean follow-up of 15 years with a high recurrence rate more than 10 years postoperatively. In consideration of not negligible risk of incontinence, fecal urgency and outlet obstruction, the indication for a stapled hemorrhoidopexy should be made well considered. However, patients' satisfaction is very high.

Introduction

Hemorrhoidal disease is a common pathology with a highly variable incidence [1]. The prevalence of hemorrhoidal symptoms is reported to be between 40 and 80% [2]. In contrast, an American study from 1990 reports a prevalence of 4.4% [3]. In general, an indication for a medical treatment is only given in symptomatic patients [4]. The treatment is based on the clinical severity classified by the four grades by Goligher. In addition, hemorrhoidal symptoms and comorbidities should be considered [5].

The treatments of grade I and II are mostly conservative with dietary modifications and topical therapy using

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✉ Ralph Schneider
r.schneider@kem-med.com

[1] Department of Surgery and Center for Minimal Invasive Surgery, Kliniken Essen-Mitte, Henricistrasse 92, 45136 Essen, Germany

[2] End- und Dickdarm-Zentrum Essen, Essen, Germany

emollients, astringents or hydrocortisone. In case of ongoing symptoms or active bleeding, surgical treatment should be considered. These procedures include ligation, fixation, excision, stapled hemorrhoidopexy or a combination of these approaches. While conventional surgical techniques like the Milligan–Morgan or Ferguson procedures remove the hemorrhoidal tissue, the stapled hemorrhoidopexy, which was introduced by Longo [6], aims to reposition the prolapsed tissue.

Originally, the stapled hemorrhoidopexy was reported to have less postoperative pain, a shorter length of inpatient stay [7–10] and a low recurrence while treating the major hemorrhoidal symptoms of bleeding and prolapse [11, 12]. However, several studies analyzing follow-up of stapled hemorrhoidopexy reveal a higher rate of recurrence and complications in comparison with conventional hemorrhoidectomy [13–16]. Especially, high rates of fecal urgency were observed even in short-term follow-up [17].

The aim of this study is to obtain long-term results on the outcome of the stapled hemorrhoidopexy with a mean observation period of more than 15 years. In addition to symptoms, recurrence rate, follow-up treatments and complications as well as the influence of age and gender were analyzed.

Materials and methods

Patients

All patients with a hemorrhoidal disease grade III, who underwent stapled hemorrhoidopexy from May 27, 1999, through December 31, 2003, were included in this study. We identified patients from a prospectively maintained database containing all patients who underwent stapled hemorrhoidopexy at the Kliniken Essen-Mitte.

Data

Data collection was based on the standardized telephone interview. If patients denied a telephone interview, we invited them to an outpatient clinic visit or requested them to fill out the questionnaire sent by mail/post.

Basic data of each patients comprised age, gender, follow-up time. In the questionnaire, we recorded information regarding the postoperative recurrence and severity of hemorrhoidal symptoms (defined as bleeding, prolapse, itching, burning or moisture), further conservative or operative hemorrhoidal treatments and functional results like incontinence, fecal urgency or outlet obstruction. Finally yet importantly, we asked patients about their personal subjective assessment of the operative result.

Surgery

We performed the operating procedure with a PPH-01 stapler from Ethicon Endo-Surgery (Norderstedt, Germany), as described in the literature [6]. The operations were performed under general anesthesia or spinal anesthesia. Additionally, we offered an intraoperative colonoscopy to all patients, who had not undergone recent colonic diagnostic examination.

Statistical analyses

In a first step, we categorized patients as "symptom-free" or "recurrence of the hemorrhoidal symptoms" and analyzed the influence of age and gender on the recurrence. Additionally, we recorded for each symptom "bleeding," "prolapse," "burning," "itching" and "moisture," if the patient had "no symptoms before the operation," "no symptoms after the operation," "symptoms equal," "symptoms better," "symptoms worse," "persisting symptoms after the operation, lower intensity," "persisting symptoms after the operation, equal intensity," "persisting symptoms after the operation, stronger intensity" or "new symptoms after the operation." The time between the operation and recurrence of hemorrhoidal symptoms was categorized as "never," "< 1 year," "1–3 years," "3–5 years," "5–10 years," "> 10 years" and "until now."

We registered further conservative or operative hemorrhoidal treatments as "no further treatment," "surgical therapy," "sclerotherapy" or "topical therapy using emollients, astringents, or hydrocortisone."

As functional results, we analyzed incontinence, fecal urgency and outlet obstruction. We recorded, if the symptoms were evident "neither pre- nor postoperatively," "new postoperatively—persisting," "new postoperatively—transitory," "pre- and postoperatively—equal severity," "pre- and postoperatively—better postoperatively," "pre- and postoperatively—worse postoperatively." The univariate analysis was performed using a χ^2-test for "gender" and a two-sided t test for "age." Additionally, the influence of age and gender on new postoperative symptoms was analyzed. Therefore, a generalized linear model based on a multivariate logistic regression analysis was performed. The created dichotomy variable "recurrence of hemorrhoidal symptoms" that differs between the presence of any symptoms (not symptom-free) and the absence of any symptoms (symptom-free) was defined as independent variable. The variables "age" and "gender" were analyzed as independent variables. In the generalized linear model, "age" was considered as continuous and "gender" as bivariate categorical variable.

Additionally, we evaluated the personal subjective satisfaction of the patients with the result of the operation. The patients could select "very satisfied," "satisfied," "moderately satisfied" or "not at all satisfied."

Continuous variables are presented as mean ± standard deviation (SD). Statistical analysis was performed using the free software environment for statistical computing "*R*." *P*-values < 0.05 were considered as statistically significant.

Ethics

The ethics commission of the Ärztekammer Nordrhein approved the study (No. 2017419).

Results

Of the 257 patients who underwent stapled hemorrhoidopexy from May 27, 1999, through December 31, 2003, we analyzed 224 patients in the first follow-up study with a mean follow-up of 6.3 ± 1.2 years [18, 19]. In 84 of these patients (63 males and 21 females), no actual contact information were available. Therefore, renewed follow-up data were possible to generate in 140/224 patients. In 23 patients, we found out that these patients died within the follow-up period by contacting relatives. Consecutively, we analyzed 117 patients (78 males and 39 females) in the present study. The mean age of these 117 patients was 65.8 ± 10.6 years (range 46–87 years), and the mean follow-up time was 15.2 ± 1.6 years (range 11.8–18.1 years) (Fig. 1).

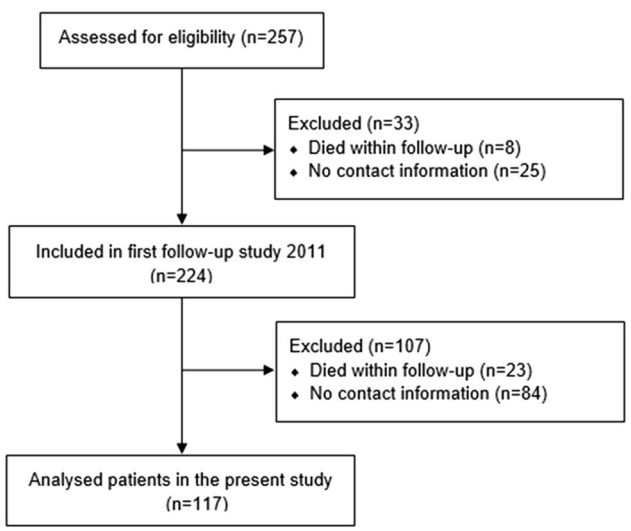

Fig. 1 Analyzed patients

Recurrence and severity of hemorrhoidal symptoms

A total of 116 patients answered the question regarding recurrence of hemorrhoidal symptoms. Of these, 55 patients (47.4%) reported a recurrence of at least one hemorrhoidal symptom, while 61 patients (52.6%; 19 females and 42 males) were symptom-free since the operation.

The univariate analysis of the influence of the gender on the recurrence of hemorrhoidal symptoms found no statistical significant difference. The univariate analysis of the influence of the ages on the recurrence of hemorrhoidal symptoms revealed a slightly, statistically not significant older age in the 61 recurrence-free patients (67.3 years) compared to the 55 patients with recurrent symptoms (64.2 years). In the multivariate analysis, analyzing the influence of age and gender on the probability to gain a recurrence-free follow-up, we found for females a lower—but statistically not significant—probability. This probability for females to achieve no recurrence decreases statistically not significant with increasing age.

We present the symptom-free interval after the operation in Fig. 2. In 26/116 patients with recurrent symptoms (22.4%), a recurrence was observed more than 10 years after the surgery. The mean duration until the recurrence of symptoms was 8.8 years.

We present a detailed summary of recurrence and severity for each symptom in Table 1. Further, postoperative symptoms were pain (16/117 patients; 13.7%), perianal pressure (1/117 patients; 0.9%), an anal edema (1/117 patients; 0.9%), anal tags (1/117 patients; 0.9%) and sanitary problems (1/117 patients; 0.9%).

Further conservative or operative hemorrhoidal treatments

Out of the 112 patients, who answered this question, 88 patients (78.6%) had no further hemorrhoidal treatments. In 24/112 patients (21.4%), further conservative and/or operative treatments were performed within the follow-up time.

A recurrence of hemorrhoidal symptoms with the necessity of a further surgical therapy was recorded in 17/112 patients (15.2%). An open hemorrhoidectomy according to Milligan–Morgan was performed in 13 patients, in two patients another stapled hemorrhoidopexy and in two patient a ligation of the hemorrhoidal artery. A sclerotherapy was performed in the postoperative period in 18/112 patients (16.1%). While 17 of these patients had one sclerotherapy within the last year, one patient hat more than five sclerotherapies within the last 12 months. A topical therapy using emollients, astringents or hydrocortisone was recorded in 20/112 patients (17.9%). Three

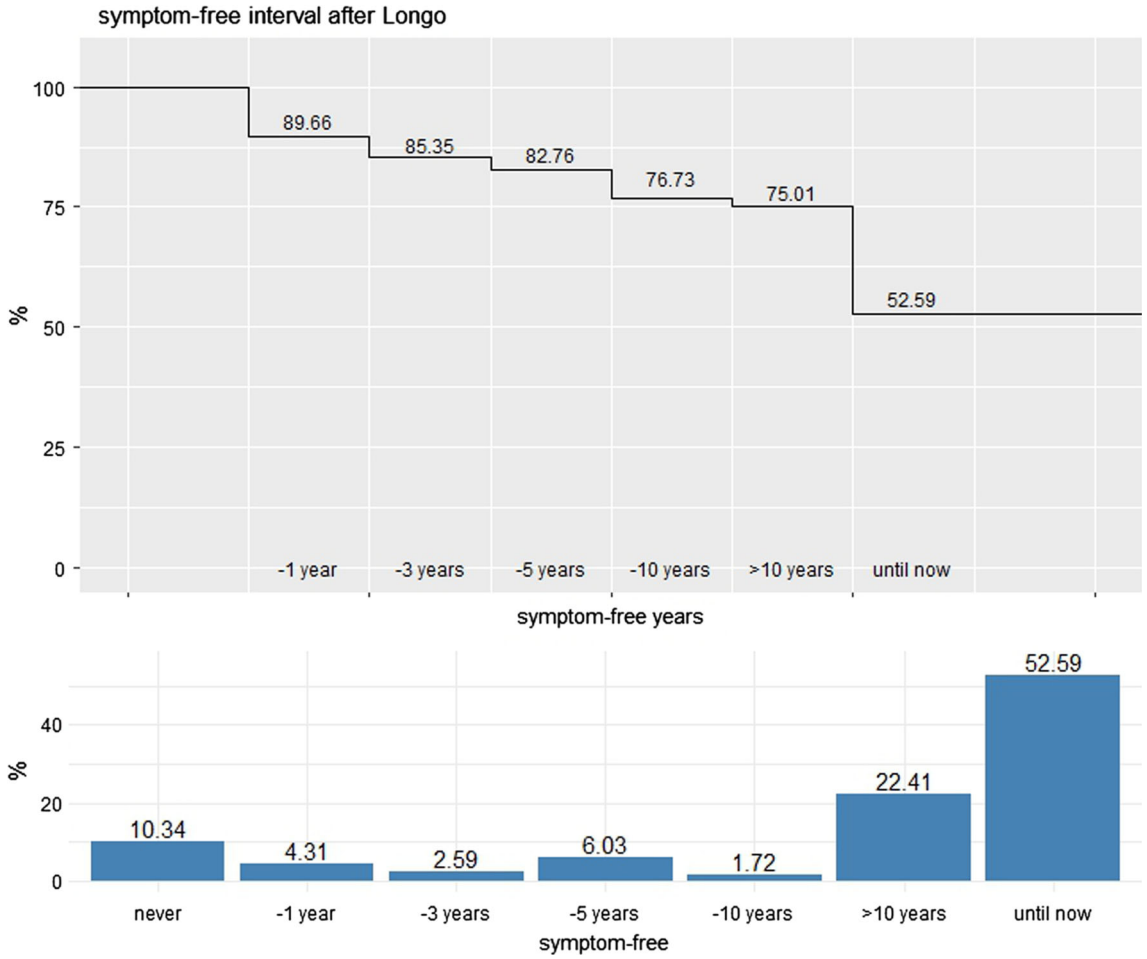

Fig. 2 Symptom-free interval after the operation

Table 1 Summary of recurrence and severity for each symptom

	Bleeding (n = 112) n (%)	Prolapse (n = 112) n (%)	Itching (n = 109) n (%)	Burning (n = 111) n (%)	Moisture (n = 106) n (%)
No symptoms before the operation	5 (4.5)	8 (7.1%)	37 (34.0)	31 (27.9)	38 (35.9)
No symptoms after the operation	70 (62.5)	64 (57.1)	53 (48.6)	59 (53.2)	53 (50.0)
Symptoms equal	1 (0.9)	2 (1.8)	1 (0.9)	1 (0.9)	1 (0.9)
Symptoms better	7 (6.3)	6 (5.4)	3 (2.8)	4 (3.6)	1 (0.9)
Symptoms worse	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Persisting symptoms after the operation, lower intensity	23 (20.5)	26 (23.2)	9 (8.3)	8 (7.2)	8 (7.6)
Persisting symptoms after the operation, equal intensity	4 (3.6)	5 (4.5)	4 (3.7)	6 (5.4)	4 (3.8)
Persisting symptoms after the operation, stronger intensity	2 (1.8)	1 (0.9)	1 (0.9)	1 (0.9)	1 (0.9)
New symptoms after the operation	0	0	1 (0.9)	1 (0.9)	0 (0)

patients reported a regular use. Thirteen patients used emollients only when needed and in four patients, and an intermittent (but not actual) use for a few months within the follow-up time was registered.

Functional results

Out of 110 patients, who answered the question regarding an incontinence, 92 patients (83.6%, mean age 65.2 years) suffered neither pre- nor postoperatively from an incontinence. Further 17/110 patients (15.5%; mean age 68.8 years; 8/36 females [22.2%]; 9/74 males [12.2%]; gender difference not significant) developed an incontinence postoperatively. In one more patient (0.9%), the incontinence was only evident for a few months. A multivariate analysis found a higher—but statistical not significant—probability to develop an incontinence postoperatively for older females.

A fecal urgency, which developed postoperatively and was still evident at the time of the re-evaluation, was recorded in 21/75 patients (28.0%; mean age 67.9 years; 7/26 females [26.9%]; 14/49 males [28.6%]; gender difference not significant). In 2/75 patients (2.7%), a transitory postoperative fecal urgency was reported. In 13/75 patients, an already preoperative existent fecal urgency was still reported in the postoperative period, whereas in 12/75 patients (16.0%), the pre- and postoperative severity was equal, while in 1/75 patients (1.3%) the severity aggravated postoperatively. The multivariate analysis found a higher—but statistically not significant—rate of fecal urgency in older males.

A new postoperative outlet obstruction was registered in 9/96 patients (9.4%). In further 12/96 patients (12.5%), this symptom was pre- and postoperative evident in the same severity. The preoperative already existing outlet obstruction aggravated postoperatively in 1/96 patients (1.0%) and improved postoperatively in 6/96 patients (6.3%).

Figure 3 shows the frequency of new postoperative incontinence, fecal urgency and outlet obstruction.

Patients' satisfaction

We present the satisfaction of the patients with the stapled hemorrhoidopexy in Fig. 4. Out of 114 patients, who answered this question, 71 patients (62.3%; 46/114 males [40.4%], 25/114 females [21.9%]) were "very satisfied" and 22 patients (19.3%; 18/114 males [15.8%]; 4/114 females [3.5%]) were "satisfied." Of the remaining patients, 9 patients (7.9%; 6/114 males [5.3%]; 3/114 females [2.6%]) were "moderately satisfied" and 12 patients (10.5%; 5/114 males [4.4%]; 7/114 females [6.1%]) were "not at all satisfied."

Discussion

The stapled hemorrhoidopexy has gained wide popularity because of its many advantages like less severe postoperative pain, shorter hospital stay and fewer working days lost compared to conventional open hemorrhoidectomy [20–22]. However, several studies reported high rates of recurrence [23–25], perforations of the rectum [13, 14, 16] and chronic pain [26, 27]. Recently, two studies presenting a long-term follow-up of 10 years and 12 years have been published. Both studies demonstrated that stapled

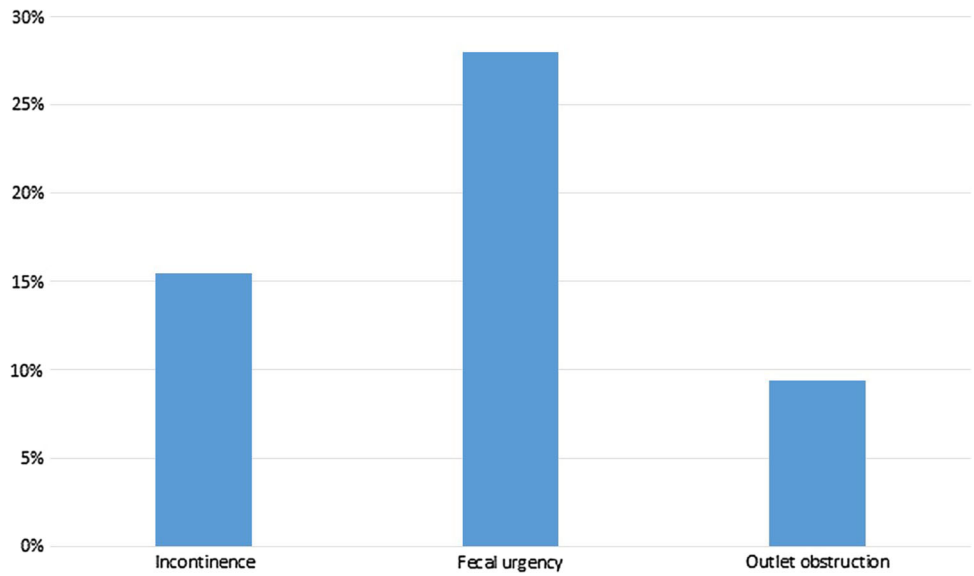

Fig. 3 Frequency of new postoperative incontinence, fecal urgency and outlet obstruction

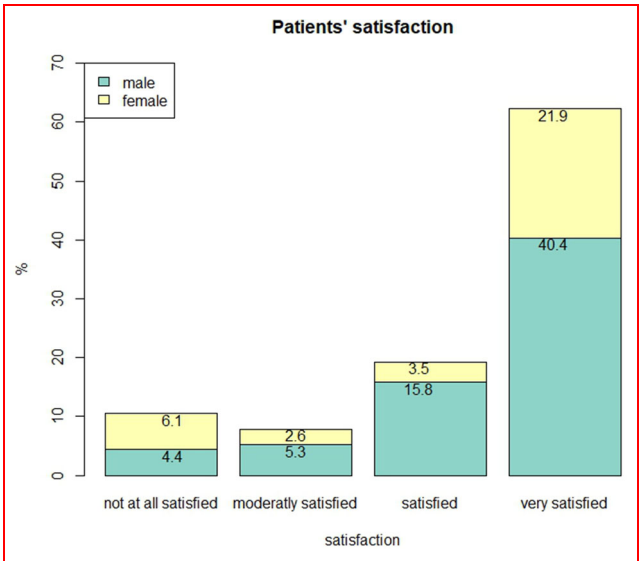

Fig. 4 Satisfaction of the patients with the operation

hemorrhoidopexy is a feasible and safe procedure but associated with a high recurrence and incontinence rate [28, 29].

In the first follow-up analysis of our patients with a follow-up of about 6 years, we found a complete freedom from hemorrhoidal symptoms in about 80% of patients. Further 15% found their symptoms improved, and a re-operation was necessary in 3.6% [18, 19]. Now, more than 15 years after the operation 55/116 patients (47.4%) of the patients reported a recurrence of at least one hemorrhoidal symptom. The extension of the follow-up led to a decrease in symptom-free patients from 69.9% (155/222 patients) [18, 19] to 52.6% (61/116 patients) in the present study. Interestingly, these hemorrhoidal symptoms recurred in 26/116 patients (22.4%) more than 10 years after the operation.

A recently published study analyzed 86 patients, who underwent stapled hemorrhoidopexy. Seventy-seven patients completed the expected follow-up, with a median duration of 119 months. Of them, 30 patients (39%) had a recurrent hemorrhoidal prolapse. Eight patients (10.4%) required a re-operation [28]. Another study with a follow-up of 12 years included 194 patients. Of them, 171 patients answered the questionnaire revealing an anatomical self-reported prolapse recurrence in 70/171 patients (40.9%) [29]. These results are similar to the recurrence rate of 47.4% in the present study taking into consideration that we defined recurrence as the renewed presence of at least one hemorrhoidal symptom. However, in common to all three studies we can observe a reliable recurrence rate in the long-term follow-up.

The rate of a new postoperative incontinence was 15.5% in the present study. However, we did not differentiate between gas, liquid and stool leakage as performed by Bellio et al. [28] who found a gas leakage in 8% (6/77 patients) 10 years postoperatively. An impaired incontinence 12 years postoperatively of 39% (67/171 patients) was reported by Sturiale et al. [29].

The rate of postoperative fecal urgency, which was 28.0% (21/75 patients) in the present study, is although comparable to a review reporting 3–31% [30]. Bellio et al. [28] reported a fecal urgency of 44% (34/77 patients) after a follow-up of 10 years.

A multicenter study from 2001 found an new postoperative outlet obstruction in 4/69 patients (5.8%) [31]. In the present study, the rate was slightly higher (9/96 patients, 9.4%). However, 6/96 patients (6.3%) reported an improved postoperative outlet obstruction, which is usually observed only in the "stapled transanal rectal resection" (STARR) and not in stapled hemorrhoidopexy [32–34]. Considering the improved symptoms in 6.3% and the new outlet obstruction in 9.4%, no reliable influence of the stapled hemorrhoidopexy on the outlet obstruction can be reported.

The correlation between the individual satisfaction of the patients and the recurrence of hemorrhoidal symptoms and the functional outcome seems to be very low. Although we observed a recurrence of hemorrhoidal symptoms in 55/116 patients (47.4%), 71/114 patients (62.3%) were "very satisfied" with the operation. These results are in concordance with the study of Bellio et al. [28] and Sturiale et al. [29], who had similar recurrence rates and reported satisfaction rates of 68% at 10-year follow-up [28] and 81% at 12-year follow-up [29]. A major point for the satisfaction seems to be the expectant attitude of the patients. Several patients told us that they expected to be symptom-free for the rest of their lives. Even if a recurrence occurred more than 10 years after the operation, these patients were not satisfied. Therefore, an extensive and honest patient consent is necessary.

A large, multicenter, parallel-group, pragmatic randomized trial comparing stapled hemorrhoidopexy with traditional excisional surgery for hemorrhoidal disease was published in 2016 and analyzed 777 patients [35]. As summary, the authors recommend the traditional excisional surgery as the surgical treatment of choice. Although the authors found less pain in the short-term follow-up after stapled hemorrhoidopexy, the rates of surgical complications were similar between the groups (7% after stapled hemorrhoidopexy versus 9% after traditional excisional surgery). Further surgical interventions could be observed in 34/364 patients (9%) after stapled hemorrhoidopexy and in 23/371 patients (6%) after tradition excisional surgery ($p = 0.11$). A recurrence of hemorrhoidal symptoms 12 months after the surgery was reported in 94/295 patients (32%; stapled

hemorrhoidopexy) and in 39/278 patients (14%; traditional excisional surgery). A long-term follow-up 24 months after surgery found even higher rates of 42% after stapled hemorrhoidopexy (134/317 patients) and of 25% after traditional incisional surgery (76/300 patients). Both results after 12 month after 24 months were statistically significant [35].

Limitations of this study are the high number of patients lost to follow up. We could analyze only 117/224 patients (52.2%). As the mean age of our analyzed patients is 65.8 years, we assume that several patients, who were lost to follow-up, were dead or moved to a rest home. As we contacted the patients based on the personal information deposited in the medical information system of our hospital, these information may be more up to date in patients with recent hospital visits due to symptoms. Therefore, the rate of recurrent hemorrhoidal symptoms may be overestimated in this study.

Another limitation of this study is the way of the data acquisition based on a telephone interview. As hemorrhoidal symptoms are something very private, it can be suspected that not all patients answered the questions honestly—resulting in an underestimation of the hemorrhoidal symptoms. It has also to be taken into consideration that not all reported symptoms or complications have to be a result of the operation. Moreover, the analysis of the severity of the symptoms 15 years after the operation may be imprecise, as patients do not remember the severity from the preoperative time.

Finally yet importantly, RCTs, especially those funded by NIHR, have extensive resources and will tend to find higher rates of many symptoms, because they look more assiduously, systematically and are meticulous in the use of appropriate data collection tools. Therefore, the difference in recurrence rates is not a factor of surgical quality, more of methodological quality difference.

Conclusion

In summary, the present study found a high rate of recurrent hemorrhoidal symptoms and functional problems like fecal urgency and incontinence within follow-up of 15 years. Stringent selection criteria for a stapled hemorrhoidopexy should be defined. However, patients' satisfaction is very high.

Compliance with ethical standards

Conflict of interest All authors have declared that they have no conflicts of interest.

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