

Limited success in patients treated with transanal haemorrhoidal dearterialisation

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ABSTRACT

INTRODUCTION: Transanal haemorrhoidal dearterialisation (THD) is a novel non-excisional technique based on suture closure of the haemorrhoidal arterial flow feeding the haemorrhoidal plexus. The primary objective of this study was to report the first Danish experience with THD.

METHODS: The study was a single-centre, non-controlled retrospective study that comprised consecutive patients from a two-year period. Prior to the study start, THD was introduced in our surgical department as the standard treatment of Grade III-IV haemorrhoids. All patients were clinically examined 4-6 weeks post-operatively. Additionally, a structured telephone interview was conducted within two years after the THD operation.

RESULTS: During the study period (from January 2011 to January 2013), 93 patients underwent a THD procedure. Twenty patients were excluded from the study which left 73 patients for analysis. Treatment success was obtained in 47 patients (64%) after a median follow-up period of nine months (range 1-24 months).

CONCLUSION: We found a relatively low success rate of 64% in patients undergoing THD. Our findings may, in part, reflect a learning curve, patient selection, or that a low success rate is associated with the use of THD per se.

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Haemorrhoid disease is a common benign anal condition with a prevalence rate of 4.4% peaking from 45 to 65 years [1]. The treatment of haemorrhoids is controversial, and the choice of treatment mostly depends on the severity of the haemorrhoid condition (Goligher's class I-IV) [2]. Generally, Grade I haemorrhoids are treated conservatively with dietary modification [2, 3], Grade II with rubber band ligation [3, 4], Grade III and IV with Milligan haemorrhoidectomy [2, 3, 5], stapled haemorrhoidopexy [6], or transanal haemorrhoidal dearterialisation (THD) by strangulation of the haemorrhoidal arterial flow feeding the haemorrhoidal plexus [7]. Milligan haemorrhoidectomy is often beset with intense post-operative pain, whereas stapled haemorrhoidopexy and THD are regarded less painful.

The primary objective of this study was to report the first preliminary Danish experiences with THD.

METHODS

The study was a single-centre, non-controlled retrospective study comprising consecutive patients from January 2011 to January 2013, and the study had a maximum follow-up period of two years.

Prior to the study start, we planned a standardised treatment algorithm. Thus, THD was the primary choice of treatment for Goligher Grade III-IV. THD was also preferred for treatment-resistant Grade II haemorrhoids not responding to rubber band ligation. In case of concomitant mucosa prolapse, we did not consistently include mucopexy in the THD procedure. Milligan haemorrhoidectomy for Grade III-IV was offered to patients who rejected THD treatment.

Patients were identified by the electronic hospital coding system using the THD procedure code (KJHB96A and KJHB96B). Data from medical records included patient demographics, preoperative symptoms, previous treatment of haemorrhoidal disease and the extent of the internal haemorrhoidal disease (Goligher grade). The exclusion criteria were patients previously operated in the anal region (THD, open haemorrhoidectomy, stapled haemorrhoidopexy, etc.). Also, patients suffering from chronic fistulas or fissures were excluded from the study. The operative data included date of surgery, duration of surgery, mucopexy or not, and post-operative complications during the first month (bleeding, haematoma, thrombosis, acute fissure, anal stenosis, faecal incontinence, infection/abscess, acute and chronic pain).

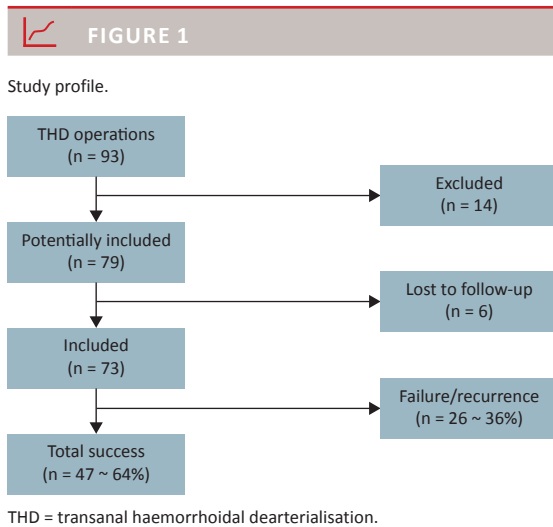
Transanal haemorrhoidal dearterialisation technique

The THD procedure was performed using a specially designed proctoscope with a Doppler probe (Figure 1). The terminal branches of the superior rectal artery [6] were identified by a Doppler signal and the artery was ligated approximately three centimetres above the dentate line. In case of additional prolapsing piles, anopexy was performed with a running suture from the place of ligation to about one centimetre above the dentate line [8]. The operation was performed by two surgeons who had been trained in the THD procedure through a standardised structural training (provided by the manufacturer) consisting of five guided procedures for each surgeon prior to the inclusion period.

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Follow-up programme and outcomes

All patients were examined clinically 4-6 weeks after operation to establish treatment success or failure: Patients were asked about symptom relief, no change, or even worse symptoms compared with preoperatively. Before analysing the present study data, we defined that treatment success was a combination of symptom relief and relapse freedom at the follow-up anal examination. No relief of symptoms or worsened symptoms compared with preoperative complaints were defined as treatment failure. When doubt arose (as to treatment success or failure), results were discussed to achieve consensus among the authors. In addition, a structured telephone interview within two years after THD was performed (see results below). For this purpose, we used an international questionnaire that is well-accepted and extensively used in the literature but which has a non-validated structure [5, 9, 10]. The questionnaire included five questions about haemorrhoidal symptoms (pain, itching/discomfort, bleeding, soiling or prolapse). Symptoms were ranked according to never, monthly, weekly, or daily. High scores indicate relatively worse symptoms. The maximum score is 15 (worst results), and the minimum score is 0 (best results). We translated the questionnaire from English into Danish using a linguistic protocol described elsewhere [11]. If patients had a score exceeding 2 or had symptoms once a week or more often, they were offered a follow-up visit to our clinic on suspicion of recurrence [9].

Statistics

We used non-parametric descriptive statistics. Variables are expressed as numbers and percentages, or medians and ranges, when appropriate. Fisher's exact test and the Mann-Whitney test were used to analyse results be-

tween treatment success/failure and haemorrhoids score, Goligher grade, and operation technic, as appropriate. A p-value < 5% was considered significant.

Trial registration: not relevant.

RESULTS

The study profile is shown in Figure 1. During the 2-year study period, a total of 93 patients underwent treatment. Fourteen patients were excluded due to previous operations (11 Milligan, two stapled hemorrhoidopexy and one with complicated fistulas), and six patients were lost to follow-up, which left 73 for analysis. Patient demographics and operation data are shown in **Table 1**. All patients were discharged from hospital on the day of THD, except for four patients who stayed at hospital one night due to conservative treatment of bleeding (n = 2) or pain (n = 2).

In total, treatment success dropped from 74% at the 6-week follow up to 64% at median 9 months post-operatively (3-24 months). Results from the telephone interview showed that the symptom score in the treatment success group was a little, but significantly lower (better) than in the treatment failure group (1 (0-6) versus 1 (0-10), p = 0.012). Five patients in the treatment success group scored > 2 compared with eight patients in the treatment failure group (p = 0.053).

Seven out of ten patients with preoperative Grade IV haemorrhoids experienced treatment failure, which was not significantly higher (p = 0.760) than in the group with Grade III haemorrhoids (**Table 2**). During the 2-year study period, 21 patients undergoing primary THD underwent a subsequent THD re-operation (29%). A total of 58 of the 73 patients had THD, but no mucopexy (**Table 1**).

In the in the group with Grade III and IV haemorrhoids, the difference in treatment success was not significantly larger when mucopexy was performed (p = 0.061) (**Table 3**).

DISCUSSION

This preliminary retrospective study basically found an unacceptably low success rate of 64%.

Haemorrhoids may be asymptomatic or present with bleeding, itching, unspecific discomfort and inconvenience due to mucosal prolapse [2]. One pathophysiological aetiology of haemorrhoids is believed to be a vascular hyperplasia followed by higher blood flow of the submucosal rectal arteries which correlates with the appearance of haemorrhoids [12]. Thus, in patients with haemorrhoids, the terminal branches of the superior rectal artery supplying the anal cushion have a significantly larger diameter and a higher blood flow, peak velocity and acceleration velocity than the terminal



TABLE 1

Patient demographic and results.

Patients, n (female:male)	73 (33:40)
Age, yrs, median (range)	47 (22-82)
Grade of haemorrhoid, n (%)	
II	24 (33)
III	39 (53)
IV	10 (14)
THD with mucopexy, n	
Grade II	0
Grade III	9
Grade IV	6
Operation time, min., median (range)	18 (10-42)
Success at 6-week follow-up, n (%)	54 (74)
Success after a median of 9 months ^a , n (%)	47 (64%)
Patients with treatment failure, n (male:female)	26 (14:12)

THD = transanal haemorrhoidal dearterialisation.

a) Telephone interview.

branches in healthy volunteers [13]. The THD technique aims to modify this by restoring the normal anatomy of the haemorrhoidal cushions through reduction or strangulation of the arterial in-flow in a technically simple manner via the accurate localisation by a Doppler signal and transfixion of the terminal branches of the superior rectal artery [7]. The reduction in blood flow to the haemorrhoids should therefore lead to shrinkage of the haemorrhoidal cushions and to symptomatic improvement [14].

Randomised trials have indicated that stapled haemorrhoidopexy and THD should be less painful and just as effective [6] as Milligan haemorrhoidectomy with no important difference in the long-term treatment success and recurrence rate [5, 14]. In our study, we did not register pain. Our success rate is unsatisfactory compared with other uncontrolled case series of THD, which reported success rates of 71-96% after varying follow-up periods from 1.5 to 60 months [6], but the treatment success reported from three randomised trials was 82% with a recurrence rate of 18% [6], which is still far superior to our modest 64% success rate. Our unsatisfactory results may, in part, be explained by a learning curve effect, the relatively low frequency of mucopexy in patients with Grade 3 and 4 haemorrhoids, and the fact that THD was used also for Grade IV haemorrhoids. It is generally recommended that THD should be combined with mucopexy when prolapsing piles are present [8, 15, 16]. We did not find a significant difference between success and failure in patients with or without mucopexy, but this may be due to type II statistical error in this relatively small study.

Milligan haemorrhoidectomy is often used for Grade III and IV haemorrhoids [2] and has a clinical suc-



TABLE 2

Outcome for Grade III and IV haemorrhoids.

Grade	Failure, n	Success, n
III	14	25
IV	7	3



TABLE 3

Outcome of mucopexy in Grade III and IV haemorrhoids.

	Failure	Success
Mucopexy, %	18	16
Mucopexy performed, %	4	11

cess rate of 84% and a recurrence rate of 1.9% [17]. However, Milligan haemorrhoidectomy is often painful, and complications such as anal stenosis occur [3]. A comparison of THD with Milligan haemorrhoidectomy revealed no significant differences regarding treatment success rate, complications and recurrence, but patients treated with THD had less pain and a more rapid return to normal daily activities [5, 14].

In the present study, seven out of ten patients with Grade IV haemorrhoids experienced treatment failure, although differences were not significant between Grade III and IV. Despite this, we believe that Grade IV should be treated with Milligan haemorrhoidectomy, because Grade IV haemorrhoids may have a relatively higher risk of recurrence [7, 8] than lower grades, and a careful patient selection is necessary; this involves excluding those with firm and fibrous haemorrhoids when using THD [10]. In our study, we had only few minor complications (pain and bleeding) during the first 4 weeks post-operatively, which is in accordance with a recent systematic review including 1,996 patients [7]. However, a recent case study reported a patient undergoing THD who suffered a brain abscess [18].

Our study has many limitations. It is a small retro-



Transanal haemorrhoidal dearterialisation proctoscope with a Doppler probe.

spective uncontrolled study using a non-validated questionnaire. However, a prospective follow-up was performed, and the study probably reflects the efficacy of THD when implemented in the daily clinical setting.

In future, THD studies should use mucopexy in patients with Grade III and IV haemorrhoids. A large randomised study would be desirable. It should compare THD with Milligan haemorrhoidectomy in the treatment of Grade III haemorrhoids with endpoints such as success rate, post-operative pain, complications, time to normal daily activity and recurrence after one year.

CONCLUSION

We found an unacceptably low success rate (64%) using THD. More evidence should establish the future role of THD in the standard treatment of patients with haemorrhoids.

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