Original article

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Doppler-guided transanal haemorrhoidal dearterialization for haemorrhoids: results from a multicentre trial

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Abstract

Aim This multicentre study, based on the largest patient population ever published, aims to evaluate the efficacy of Doppler-guided transanal haemorrhoidal dearterialization (THD Doppler) in the treatment of symptomatic haemorrhoids and to identify the factors predicting failure for an effective mid-term outcome.

Method Eight hundred and three patients affected by Grade II (137, 17.1%), III (548, 68.2%) and IV (118, 14.7%) symptomatic haemorrhoidal disease underwent THD Doppler, with a rectal mucopexy in patients with haemorrhoidal prolapse. The disease was assessed through a specifically designed symptom questionnaire and scoring system. A uni- and multivariate analyses of the potential predictive factors for failure were performed.

Results The morbidity rate was 18.0%, represented mainly by pain or tenesmus (106 patients, 13.0%). Acute bleeding requiring surgical haemostasis occurred in seven patients (0.9%). No serious or life-threatening complications occurred. After a mean follow-up period of 11.1 ± 9.2 months, the overall success rate was 90.7% (728 patients), with a recurrence of haemorrhoidal prolapse, bleeding, and both symptoms in 51 (6.3%), 19 (2.4%) and 5 (0.6%) patients, respectively. Sixteen out of 47 patients undergoing re-operation had a conventional haemorrhoidectomy. All the symptoms were significantly improved in each domain of the score ($P < 0.0001$). At multivariate analysis the absence of morbidity and performance of a distal Doppler-guided dearterialization were associated with a better outcome.

Conclusion THD Doppler is a safe and effective therapy for haemorrhoidal disease. If this technique is to be employed, an accurate distal Doppler-guided dearterialization and a tailored mucopexy are mandatory to contain and reduce the symptoms.

Keywords Haemorrhoids, haemorrhoidal disease, rectal bleeding, prolapse, transanal haemorrhoidal dearterialization, multivariate

What does this paper add to the literature?
To our knowledge this is the largest series ever published on the topic of Doppler-guided transanal haemorrhoidal dearterialization. This paper describes the changes in the technique that there have been over the years, and their impact on the results in short- and long-term follow-up. A detailed multivariate analysis of the potential predictive factors of failure is provided.

Introduction

Haemorrhoidal disease represents the most common condition presenting to proctology units, with its prevalence ranging from 5% to about 35% in Western populations [1,2].

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Over the past two decades traditional excisional procedures, such as Milligan–Morgan haemorrhoidectomy, have been questioned, mainly because of the risk of postoperative pain and complications [3]. In 1995 Morinaga *et al.* [4] described Doppler-guided transanal ligation of haemorrhoidal arteries to reduce the arterial hyperflow to haemorrhoids. More recently, a new technique was introduced, Doppler-guided transanal haemorrhoidal dearterialization (THD Doppler). By means of specifically designed proctoscopes it also allows the performance of a rectal mucopexy to reduce

the prolapse [5]. Several studies have shown the safety and efficacy of THD for symptomatic haemorrhoidal disease [6–9], in fourth-degree haemorrhoids [10] and in an emergency setting [11]. Therefore, the UK National Institute for Health and Care Excellence (NICE) has recently provided a clinical guideline, which considers haemorrhoidal artery ligation as 'an efficacious alternative to conventional haemorrhoidectomy or stapled haemorrhoidopexy', without 'major safety concerns' [12].

Based on the largest patient population ever published, this multicentre observational study aims to: evaluate the efficacy of THD Doppler in the treatment of symptomatic haemorrhoidal disease, with a detailed description of early and late morbidity; and identify the factors predictive of failure for mid-term follow-up (FU).

Method

A total of 803 patients (502 men, mean age 49.4 ± 13.0 years, range 18–87) affected by symptomatic haemorrhoids who failed a conservative approach (diet modifications and pharmacological therapy) were treated primarily with the THD Doppler procedure at seven Italian colorectal units from June 2005 to October 2011 (Table 1). The leading centre (Rome) coordinated the study, and a prospective database was collected by each participating centre. Institutional review board approval was obtained in all departments and all patients gave written informed consent.

Table 1 Baseline demographic and clinical features.

	No. of patients (%)
Sex	
Male	502 (62.5)
Female	301 (37.5)
Age (years)*	49.4 (13.0) (range 18–87)
Haemorrhoid grade†	
I	0
II	137 (17.1)
III	548 (68.2)
IV	118 (14.7)
Recurrent disease	
Yes	82 (10.2)
No	721 (89.8)
Previous surgical treatment	
Stapled haemorrhoidopexy	32 (39.0)
Haemorrhoidectomy	29 (35.4)
THD	10 (12.2)
Rubber band ligation	9 (11.0)
Cryotherapy	2 (2.4)
Total	82 (100)

THD, transanal haemorrhoidal dearterialization.
*Values are mean (SD).
†Goligher classification [13].

Preoperatively, all patients underwent full clinical and physical examination, including digital rectal examination and anoscopy; the severity of the haemorrhoidal disease was graded according to the Goligher classification [13]. Associated conditions (skin tags, anal fissure, anal fistula) were scrupulously identified. Overall, 137 (17.1%), 548 (68.2%) and 118 (14.7%) cases were classified as Grade II, III and IV haemorrhoids, respectively (Fig. 1). In 82 out of 803 patients (10.2%) the disease was recurrent; Table 1 reports previous surgical procedures in these cases.

A symptom questionnaire and scoring system, specifically designed for patients affected by haemorrhoidal disease, was also administered to all subjects [14]. This questionnaire, although not yet validated, scores the frequencies of five different parameters which characterize haemorrhoidal disease (from 0 to 4, with 0 being no symptom and 4 daily presence of the symptom): bleeding, prolapse, manual reduction, impact on quality of life, discomfort/pain. A final score of 0 indicates the total absence of symptoms, while a score of 20 represents the worst condition. A screening colonoscopy was performed before the operation, if necessary; patients affected by colorectal cancer or other neoplasms were excluded.

Equipment

The THD Doppler device (THD S.p.A., Correggio, Italy) consists of a proctoscope equipped with a Doppler probe on the lateral profile of the device and a light source. During the study period the device evolved twice (July 2007 and September 2008), so that three different devices were used to treat patients (Fig. 2).

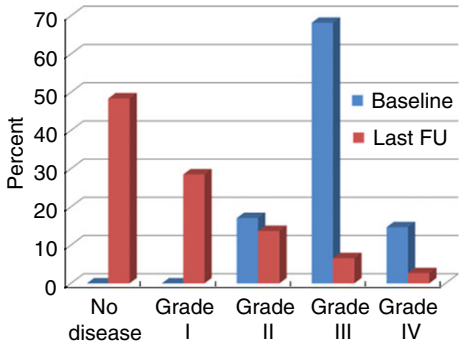

Figure 1 Proportion of patients classified according to the Goligher classification [13] at baseline and at the last follow-up evaluation.

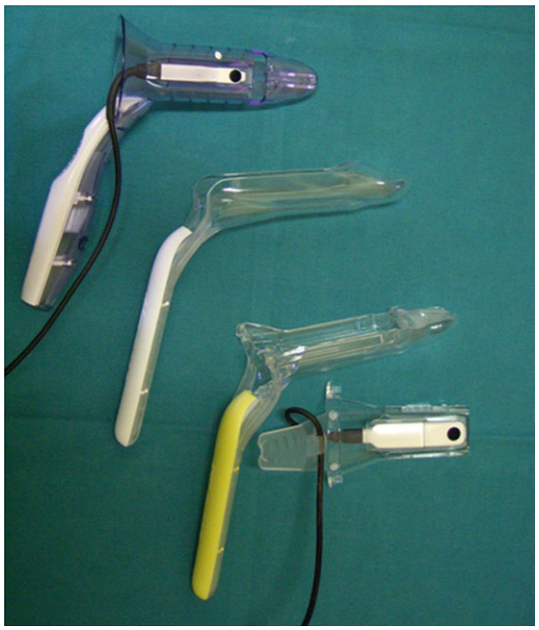

Figure 2 Proctoscopes used in the transanal haemorrhoidal dearterialization (THD) procedure over time. From top left to bottom right: traditional THD proctoscope (the 'first device'); THD Surgy® (the 'second device'), used since July 2007 together with the first device to make the mucopexy; THD Slide® (the 'current device'), in used since September 2008.

Surgical technique

On the day of the surgery, two enemas were given as bowel preparation. No antibiotic prophylaxis was given. All patients were treated under general or spinal anaesthesia.

A detailed description of the surgical technique has already been published [15]. With the patient in the lithotomy position, the proctoscope was fully introduced transanally to reach the lower rectum. Under Doppler guidance, six arterial signals were found at 6–7 cm from the anal verge, mostly at 1, 3, 5, 7, 9, 11 o'clock of the rectal circumference. The traditional approach to make the 'dearterialization' involves the transfixion of rectal mucosa and submucosa with a 'Z-stitch' to entrap the artery; this dearterialization modality is here defined as 'high ligation'. In patients affected by haemorrhoidal prolapse, mucopexy was performed after the artery ligation with the same suture used for the dearterialization, making a series of passages in increments of about 0.5 cm. Finally, the suture was tied to fix the mucopexy. Since 2009, dearterialization has been modified by introducing 'distal Doppler-guided dearterialization' (DDD) [5,8]. After the identification of the main arterial trunks at 6–7 cm from the anal verge, the proctoscope was moved distally and, when the best Doppler signal was obtained (usually within the most distal 2 cm of rectum, above the anorectal junction), a small 'marker point' was placed on the mucosa using electrocautery. In patients who needed the dearterialization alone, a Z-shaped stitch was placed to entrap the artery, and the knot tied. In patients with prolapsing haemorrhoids needing a mucopexy, after placement of the 'marker point' the proctoscope was fully re-introduced and the mucopexy started at 6–7 cm from the anal verge and continued distally (including the 'marker point' which was surrounded by two Z-shaped suture passages). The last mucopexy suture was placed at the apex of the internal haemorrhoidal pile (which was never included within the mucopexy suture), and the knot tied (Fig. 3). When six sutures were performed the mucopexy was defined as

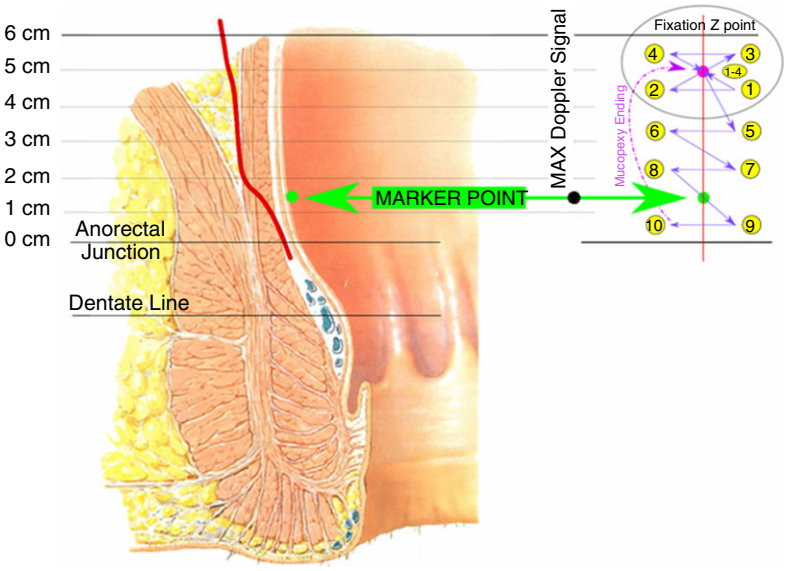

Figure 3 Schema of THD Doppler procedure including dearterialization and mucopexy.

'total'; on the contrary, if fewer than six sutures were adopted it was defined as 'partial'.

Follow-up

During the postoperative period, patients were advised to avoid straining and physical effort, while a fibre- and fluid-rich diet was prescribed. Stool softeners, analgesics and anti-inflammatory drugs were given for three postoperative days, and thereafter only if necessary; no antibiotics were administered.

Routine FU visits were scheduled at 2 weeks, 1 month and 3 months and then a year after the operation. In this study, the FU visit with the longer period of observation (at least 3 months) was defined as 'last FU'. Postoperative symptoms occurring in the first 24 h (early morbidity) and then within 30 days (late morbidity) were all noted. The required medical or surgical therapies adopted were also registered. At the last FU visit, the symptom questionnaire was re-administered (and compared with the preoperative data), and patients were submitted to anoscopy. Failure was defined as the presence of recurrent bleeding or recurrent haemorrhoidal prolapse needing a medical or surgical therapy, so an 'intention-to-treat' analysis was carried out.

Statistical analysis

The following baseline variables were evaluated as factors predictive of failure: age, gender, haemorrhoid grade, recurrent disease, type of THD procedure performed, morbidity, need for therapy, FU period, use of first or second device, use of 'high ligation'. Continuous data were analysed as means (with SD and range) and compared using the paired samples *t*-test; categorical data were analysed as frequencies and percentages and compared using the chi-square test test or the marginal homogeneity test as necessary. To assess factors potentially predictive of failure univariate and multivariate logistic regression models were applied. A $P < 0.05$ was considered statistically significant. Analyses were carried out with SPSS® version 17.0 software for Windows® (SPSS, Chicago, Illinois, USA).

Results

Average surgery time was 34.3 ± 5.9 (range 24–47) minutes, and postoperative stay was 0.6 ± 0.53 days. The THD Doppler procedure consisted of a dearterialization without a mucopexy, a dearterialization plus a partial mucopexy, and dearterialization plus a total mucopexy in 112 (13.9%), 52 (6.5%) and 639 (79.6%) patients, respectively. Another concomitant surgical procedure was carried out in 199 out of 803 patients (24.8%); skin tag removal (66 patients, 8.2%) was the most frequent associated procedure. In 53 patients (6.6%) with anal fissure, an internal lateral sphincterotomy was performed before starting the THD Doppler procedure (Table 2). Concerning the type of device used, 67 patients (8.3%) were treated with the first device, 77 (9.6%) with the second one, and 659 (82.1%) with the final one. In 523 out of 803 patients (65.1%), dearterialization was performed according to the 'high ligation' modality, while 280 (34.9%) underwent the 'DDD'.

One intra-operative complication occurred in four cases (0.5%): two transient submucosal haematomas, one tearing of the rectal mucosa and one case of bleeding; these events were always easily managed by placing a haemostatic suture (Table 2).

There was no mortality. Early morbidity (within 24 h) consisted mainly of pain or tenesmus, which occurred in 96 patients (12.0%) and required medical therapy; however, the rate of prescription of analgesics or nonsteroidal anti-inflammatory drugs (NSAIDs) was higher. Catheterization was necessary in 69 patients (8.6%) with urinary retention. Only one case of early bleeding requiring surgical haemostasis was registered (Table 2). The 30-day morbidity rate was 18.0%, and it was represented mainly by pain or tenesmus (104 patients, 13.0%). Acute bleeding occurred in 18 patients (2.2%): it stopped spontaneously in four cases, in seven patients (0.9%) a rectal washout was performed with bleeding resolution without further treatments and surgical haemostasis was needed in the remaining seven patients (0.9%) (Table 2). Four cases (0.5%) of haemorrhoidal thrombosis were reported. Three patients (0.4%) suffered from an anal abscess which was drained in two cases; only one case of postoperative anal fissure was reported (Table 2).

Last follow-up evaluation

The mean FU period was 11.1 ± 9.2 months (median 7, range 3–57). No patients were lost to FU. At the last FU evaluation, recurrence of haemorrhoidal prolapse, of bleeding and of both haemorrhoidal prolapse and bleeding requiring a medical or surgical therapy was seen, respectively, in 51 (6.3%), in 19 (2.4%) and 5 (0.6%) patients. Therefore, the overall failure rate was 9.3% (75 patients) (Table 2). Conversely, on an 'intention-to-treat' basis, the success rate was 90.7%. However, about a third of recurrent patients (28 patients, 37.3%) underwent a conservative treatment consisting of diet and drugs. Consequently, the overall

Table 2 Perioperative and last follow-up results.

	No. of patients (%)
Perioperative results	
Type of THD procedure	
Dearterialization	112 (13.9)
Dearterialization + partial mucopexy	52 (6.5)
Dearterialization + total mucopexy	639 (79.6)
Concomitant surgical procedure	
Skin tag removal	66 (8.2)
Internal lateral sphincterotomy	53 (6.6)
Single pile removal	42 (5.2)
Anorectal polyp excision	24 (3.0)
Fistulotomy	2 (0.3)
Other	12 (1.5)
Total	199 (24.8)
Mortality	0
Intra-operative complications	
Transient submucosal hematoma	2 (0.3)
Rectal mucosa tearing	1 (0.1)
Bleeding	1 (0.1)
Total	4 (0.5)
Early (≤ 24 h) morbidity	
Pain/tenesmus	96 (12.0)
Urinary retention	69 (8.6)
Bleeding	1 (0.1)
Total	166 (20.7)
Required therapy for early morbidity	
Analgesics	188 (23.4)
Catheterization	69 (8.6)
Other drugs	53 (6.6)
NSAIDs	27 (3.4)
Surgical haemostasis	1 (0.1)
Total	338 (42.1)
Late (≤ 30 days) morbidity	
Pain/tenesmus	104 (13.0)
Bleeding	18 (2.2)
Urinary retention	7 (0.9)
Haemorrhoidal thrombosis	4 (0.5)
Constipation	3 (0.4)
Anal abscess/infection	3 (0.4)
Anal fissure	1 (0.1)
Other	4 (0.5)
Total	144 (18.0)
Required therapy for late morbidity	
Analgesics	116 (14.4)
NSAIDs	37 (4.6)
Other drugs	28 (3.5)
Catheterization	7 (0.9)
Surgical haemostasis	7 (0.9)
Rectal washout	7 (0.9)
Anal abscess drainage	2 (0.3)
Fissurectomy	1 (0.1)
Other	1 (0.1)
Total	206 (25.7)
Last follow-up results	
Failure	
Haemorrhoidal prolapse	51 (6.3)
Recurrent bleeding	19 (2.4)
Haemorrhoidal prolapse and bleeding	5 (0.6)
Total	75 (9.3)
Required therapy for failure	
Drugs	28 (3.5)
Repeat-THD	18 (2.2)
Haemorrhoidectomy	16 (2.0)
Rubber band ligation	12 (1.5)
Other	1 (0.1)
Total	75 (9.3)
Condition or symptom referred	
Skin tags	67 (8.3)
Chronic rectal pain/discomfort	3 (0.4)
Post-defecation soiling	3 (0.4)
Anal fistula	1 (0.1)
Anal fissure	1 (0.1)
Recurrent haemorrhoidal thrombosis	1 (0.1)
Other	11 (1.4)
Total	87 (10.8)
Required therapy for referred symptom	
Skin tag removal	41 (5.1)
Analgesics	3 (0.4)
Biofeedback	2 (0.3)
Fistulectomy	1 (0.1)
Haemorrhoidal thrombosis incision	1 (0.1)
NSAIDs	1 (0.1)
Other	4 (0.5)
Total	53 (6.6)

THD, transanal haemorrhoidal dearterialization; NSAID, non-steroidal anti-inflammatory drug.

re-operation rate was 5.6% (47/803 patients). Among the re-operated patients, 18 underwent the THD Doppler procedure again, 16 patients a conventional haemorrhoidectomy and 12 patients a rubber band ligation (Table 2). No statistical difference emerged when a subgroup analysis was carried out. The success rate was, respectively, 92.7, 90.3 and 89.8% in Grade II, III and IV haemorrhoids; it was respectively 88.4, 92.3 and 90.9% in patients who underwent dearterialization alone, dearterialization plus partial mucopexy, and dearterialization plus total mucopexy. A detailed analysis of the failure rate by degree of disease and symptoms is provided in Table 3. Residual skin tags were the most frequent conditions detected or referred at the last FU physical examination (67 patients, 8.3%); three patients

Table 3 Failure rate by degree of disease and symptoms reported.

Failure type	Haemorrhoid grade, * no. of patients (%)				
	II	III	IV	Overall	$P^{\dagger}$
Failure: bleeding	2 (1.5)	16 (2.9)	1 (0.9)	19 (2.4)	0.302
Failure: prolapse	7 (5.1)	33 (6.0)	11 (9.3)	51 (6.3)	0.332
Failure: bleeding + prolapse	1 (0.7)	4 (0.7)	0	5 (0.6)	0.648
Overall failure	10 (7.3)	53 (9.6)	12 (10.2)	75 (9.3)	0.657

*Goligher classification [13].
†Chi-square test.

(0.4%) complained of chronic rectal pain or discomfort, while a further three patients (0.4%) referred to postdefaecation soiling (two of them underwent biofeedback therapy); one anal fistula was detected in one patient (0.1%) submitted to a fistulectomy; one patient (0.1%) affected by recurrent haemorrhoidal thrombosis was submitted to an incision of thrombosed piles. A detailed description of the results of the last FU visits is given in Table 2.

At the last FU physical evaluation, the haemorrhoid grades changed, showing a significant 'downstaging' of the disease compared with the baseline condition ($P < 0.0001$) (Table 4, Fig. 1). Each symptom changed significantly ($P < 0.0001$), so that each score parameter and the total score (from 13.1 at the baseline to 1.5 at the last FU, $P < 0.0001$) significantly decreased (Table 4).

Twelve months' follow-up

Two hundred and ninety-eight patients (180 men, mean age 48.6 ± 13.1 years, range 20–86) were evaluated after a minimum FU of 12 months (mean 20.7 ± 8.5; median 18; range 12–57). Recurrence of haemorrhoidal prolapse, bleeding and both prolapse and bleeding requiring a medical or surgical therapy was seen in 26 (8.7%), 10 (3.4%) and 3 patients (1.0%), respectively.

Factors predictive of failure

At univariate analysis, age < 40 years, absence of morbidity within 30 days and a FU period shorter than 12 months were all variables significantly protecting from failure; a THD procedure performed using the first or second device or with a 'high ligation' were factors significantly associated with a higher failure rate. The haemorrhoid grade and recurrent disease were not significantly associated with failure (Table 5).

At multivariate analysis, absence of morbidity within 30 days was the only protective factor that did not lose its significance (OR 0.396, CI 95% 0.158–0.992, $P = 0.048$); patients who underwent a 'high ligation' had a failure risk about three times greater than that of patients treated by DDD (OR 2.846, CI 95% 1.240–6.532, $P = 0.014$) (Table 5).

Discussion

Despite the high prevalence of haemorrhoidal disease, to date no surgical technique can be considered the 'gold-standard' of treatment [16]. The most innovative approaches are stapled haemorrhoidopexy [17] and Doppler-guided dearterialization [mostly performed by either THD Doppler or Doppler-guided haemorrhoidal artery ligation (DG-HAL)]; both are considered valid alternatives to conventional excision [5,18,19]. However, recurrence is the most concerning issue. A large meta-analysis by Jayaraman *et al.* [20] showed that stapled haemorrhoidopexy was associated with a higher risk of symptom recurrence and prolapse compared with haemorrhoidectomy; these two procedures were comparable in terms of pain, urgency and pruritus ani.

In a recent systematic review the pooled recurrence rate of Doppler-guided dearterialization was 17.5%, with a surprisingly wide range of 3–60% [21]. However, in our opinion, an accurate literature review reveals that, to date, it is not trivial to produce a robust systematic review of the success rate of Doppler-guided dearterialization due to: (i) differences in the adopted device (DG-HAL or THD Doppler), (ii) techniques (dearterialization alone or with mucopexy), (iii) length of FU, and (iv) the definition of 'success' or 'recurrence'.

Also, Tiernan *et al.* [22] suggested the need for 'a standardized definition' of recurrence. In this study 'failure' was defined as the presence of recurrent bleeding or prolapse needing medical or surgical therapy: the overall success rate was 90.7%, with no significant differences between haemorrhoid grade (Tables 2 and 3). Other series showed similar good results for advanced grades of haemorrhoids [7,10,23]. In a randomized trial, patients affected by Grade III and IV haemorrhoids were assigned to THD Doppler or stapled haemorrhoidopexy; both techniques were equally effective at short-term FU, but it was concluded that THD should be the preferred option because of less postoperative pain [7].

Table 4 Clinical symptoms at baseline and at the last follow-up (FU).

	Bleeding, no. (%)		Prolapse, no. (%)		Manual reduction, no. (%)		Discomfort/pain, no. (%)		Impact on QoL, no. (%)	
Frequency	Baseline	Last FU*	Baseline	Last FU*	Baseline	Last FU*	Baseline	Last FU*	Baseline	Last FU*
Never	24 (3.0)	619 (77.1)	4 (0.5)	638 (79.5)	99 (12.3)	721 (89.8)	53 (6.6)	598 (74.5)	3 (0.4)	570 (71.0)
At least once/year	78 (9.7)	151 (18.8)	84 (10.5)	88 (11.0)	99 (12.3)	54 (6.7)	110 (13.7)	140 (17.4)	19 (2.4)	176 (21.9)
At least once/month	240 (29.9)	27 (3.4)	160 (19.9)	56 (7.0)	130 (16.2)	21 (2.6)	184 (22.9)	53 (6.6)	209 (26.0)	45 (5.6)
At least once/week	335 (41.7)	6 (0.7)	357 (44.5)	17 (2.1)	331 (41.2)	6 (0.7)	319 (39.7)	10 (1.2)	415 (51.7)	9 (1.1)
Every day	126 (15.7)	0	198 (24.7)	4 (0.5)	144 (17.9)	1 (0.1)	137 (17.1)	2 (0.2)	157 (19.6)	2 (0.2)

	Baseline	Last FU†
Total score	13.1	1.5

Haemorrhoid grade‡	Baseline	Last FU§
No disease	0	389 (48.4)
I	0	229 (28.5)
II	137 (17.1)	110 (13.7)
III	548 (68.2)	53 (6.6)
IV	118 (14.7)	22 (2.7)

*$P < 0.0001$ (marginal homogeneity test).
†$P < 0.0001$ (paired samples *t*-test).
‡Goligher classification [13].
§$P < 0.0001$ (marginal homogeneity test).

Table 5 Predictive factors for failure in univariate and multivariate analysis.

Factor	Univariate analysis Relative risk (95% CI)	*P*-value	Multivariate analysis Relative risk (95% CI)	*P*-value
Age < 40 years	0.932 (0.879–0.988)	0.007	0.987 (0.963–1.012)	0.308
Male gender	0.806 (0.522–1.244)	0.330		
Haemorrhoid grade	1.057 (0.546–2.047)	0.869		
Recurrent disease	0.662 (0.364–1.203)	0.181		
Type of THD procedure	1.198 (0.417–3.441)	0.737		
No morbidity within 30 days	0.542 (0.328–0.894)	0.018	0.396 (0.158–0.992)	0.048
Need for therapy within 30 days	0.852 (0.499–1.456)	0.560		
Follow-up < 12 months	0.541 (0.352–0.831)	0.005	1.021 (0.980–1.063)	0.322
Device: first device	2.222 (1.021–4.837)	0.044	0.779 (0.247–2.455)	0.670
Device: second device	2.269 (1.231–5.613)	0.012	1.228 (0.492–3.065)	0.660
High ligation	3.091 (1.702–5.614)	0.000	2.846 (1.240–6.532)	0.014

THD, transanal haemorrhoidal dearterialization.

In the present study, at last FU the most frequent findings were residual skin tags, needing excision in about two-thirds of cases because of pruritus ani or discomfort (Table 2). However, a 'skin tag-pexy' is not a target for the THD Doppler procedure; that should be made clear to patients in order to avoid false expectations.

In this series, the overall morbidity rate was 18.0%, mainly represented by pain or tenesmus (13.0%) (Table 2). This should be related to the fact that about 85% of patients were subjected to mucopexy, which inevitably creates oedema and/or inflammation of the rectal mucosa/submucosa layers. Administration of NSAIDs and analgesics can easily control pain and tenesmus. Similarly, Theodoropoulos *et al.* [24] found that these symptoms were more pronounced in patients undergoing DG-HAL plus haemorrhoidopexy or recto-anal repair. Data from this study are encouraging with regard to postoperative pain, confirming that THD Doppler resulted in less postoperative pain than stapled haemorrhoidopexy [7,9] or haemorrhoidectomy [25].

It is well known that stapled haemorrhoidopexy can be associated with some serious and life-threatening complications or disabling long-term conditions [26,27]. In this study, no serious event occurred. At last FU visit, only three patients (0.4%) complained of chronic rectal pain, while three (0.4%) reported postdefaecation soiling (Table 2). The low incidence of these conditions is probably due to the absorbable nature of the suture: nerves or the smooth muscle layer are not trapped by the suture indefinitely and no anatomical changes are created in the rectum. Moreover, during the procedure, the needle penetrated the rectal wall at a maximum depth of 6 mm, avoiding perforation of the entire rectal wall; for this reason, perirectal sepsis after THD Doppler was not reported.

Generally, postoperative bleeding is one of the most feared complications after surgery for haemorrhoids. Only one case of early postoperative bleeding (within 24 h) was registered in this study, while the remaining 18 cases (2.2%) occurred within 30 days, but surgical haemostasis was needed only in seven patients (0.9%). These percentages are similar, or actually a little better, than other reports, from which emerged a pooled rate of 5% for postoperative bleeding [21].

A uni- and multivariate analysis performed in this study on potential predictive factors of failure found that the haemorrhoidal grade was not statistically significant. This finding probably demonstrates that a tailored mucopexy is mandatory for successful treatment of patients with prolapse. Other studies seem to confirm this interpretation. Pol *et al.* [28] treated 244 patients with DG-HAL without mucopexy or recto-anal repair; patients with Grade III and IV haemorrhoids had a higher risk of recurrence at multivariate analysis. On the contrary, an Italian multicentre study [6] in which mucopexy was added to dearterialization to treat patients with grades II and III haemorrhoids, showed that haemorrhoid grade was not predictive of failure. In the present study, only the absence of morbidity and use of 'high ligation' were statistically predictive of failure at multivariate analysis; other confounding variables (age, length of FU and type of device) lost significance at univariate analysis (Table 5).

As previously described, the THD Doppler procedure has evolved over time; initially, the dearterialization was performed at 6–7 cm from the anal verge (high ligation). Recent studies have shown that haemorrhoidal arteries at 4–6 cm from the anorectal junction are located outside the rectal wall, while at 2 cm from the anorectal junction they are almost always detected in the submucosa [29,30]. Therefore the technique has been modified to obtain a more effective

dearterialization, introducing the DDD [5,8]. In this context it is not surprising that at multivariate analysis patients who underwent 'high ligation' showed a three times higher risk of failure (Table 5).

Analysis of patients with a minimum FU of 12 months gave a success rate of 86.9%; this percentage was slightly lower than the 92.9% observed in patients with a FU shorter than 12 months. This difference could be explained by the consideration that a greater proportion of patients with a 12-months minimum FU underwent the operation with the old devices and 'high ligation'. As stated above, these two variables were the only significant independent factors predictive of failure. On the other hand, a longer FU period increased the recurrence rates, but only very slightly. For this reason, a FU shorter than 12 months was significant only at univariate analysis and it has lost its significance at multivariate analysis, when the two confounding variables (type of device and modality of artery ligation) were considered.

Conclusions

THD Doppler is a valid therapeutic option in patients affected by haemorrhoidal disease, irrespective of the grade of their disease. An accurate distal Doppler-guided dearterialization and a tailored mucopexy are mandatory to control symptoms. This procedure is associated with a low morbidity rate. However, it is necessary to be very careful to avoid complications, as this could affect the long-term outcome.

Author contributions

Carlo Ratto: conception and design, extraction of data, review of the Literature. Angelo Parello, Ezio Veronese, Eugenio Cudazzo, Elio D'Agostino, Claudio Pagano, Emanuel Cavazzoni and Luigi Brugnano: design, extraction of data, review of the Literature. Francesco Litta: design, extraction of data, review of the Literature, writing of manuscript.

Conflicts of interest

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References

1 Johanson JF, Sonnenberg A. The prevalence of hemorrhoids and chronic constipation. An epidemiologic study. *Gastroenterology* 1990; **98:** 380–6.
2 Loder PB, Kamm MA, Nicholls RJ, Phillips RK. Haemorrhoids: pathology, pathophysiology and aetiology. *Br J Surg* 1994; **81:** 946–54.
3 Shanmugam V, Thaha MA, Rabindranath KS, Campbell KL, Steele RJ, Loudon MA. Rubber band ligation versus excisional haemorrhoidectomy for haemorrhoids. *Cochrane Database Syst Rev* 2005; **3:** CD005034.
4 Morinaga K, Hasuda K, Ikeda T. A novel therapy for internal hemorrhoids: ligation of the hemorrhoidal artery with a newly devised instrument (Moricorn) in conjunction with a Doppler flowmeter. *Am J Gastroenterol* 1995; **90:** 610–3.
5 Ratto C. THD doppler procedure for hemorrhoids: the surgical technique. *Tech Coloproctol* 2014; **18:** 291–8.
6 Infantino A, Bellomo R, Dal Monte PP *et al.* Transanal haemorrhoidal artery echodoppler ligation and anopexy (THD) is effective for II and III degree haemorrhoids: a prospective multicentric study. *Colorectal Dis* 2010; **12:** 804–9.
7 Festen S, Van Hoogstraten MJ, Van Geloven AA, Gerhards MF. Treatment of grade III and IV haemorrhoidal disease with PPH or THD. A randomized trial on postoperative complications and short-term results. *Int J Colorectal Dis* 2009; **24:** 1401–5.
8 Ratto C, Donisi L, Parello A, Litta F, Zaccone G, De Simone V. 'Distal doppler-guided dearterialization' is highly effective in treating haemorrhoids by transanal haemorrhoidal dearterialization. *Colorectal Dis* 2012; **14:** e786–9.
9 Sajid MS, Parampalli U, Whitehouse P, Sains P, McFall MR, Baig MK. A systematic review comparing transanal haemorrhoidal de-arterialisation to stapled haemorrhoidopexy in the management of haemorrhoidal disease. *Tech Coloproctol* 2012; **16:** 1–8.
10 Ratto C, Giordano P, Donisi L, Parello A, Litta F, Doglietto GB. Transanal haemorrhoidal dearterialization (THD) for selected fourth-degree haemorrhoids. *Tech Coloproctol* 2011; **15:** 191–7.
11 Cavazzoni E, Bugiantella W, Graziosi L *et al.* Emergency transanal haemorrhoidal Doppler guided dearterialization for acute and persistent haemorrhoidal bleeding. *Colorectal Dis* 2013; **15:** e89–92.
12 National Institute for Health and Clinical Excellence. *Interventional Procedure Guidance 342: Haemorrhoidal Artery Ligation.* http://www.nice.org.uk/nicemedia/live/12236/48673/48673.pdf (accessed August 10, 2013).
13 Goligher JC, Leacock AG, Brossy JJ. The surgical anatomy of the anal canal. *Br J Surg* 1955; **43:** 51–61.
14 Giordano P, Nastro P, Davies A, Gravante G. Prospective evaluation of stapled haemorrhoidopexy versus transanal haemorrhoidal dearterialisation for stage II and III haemorrhoids: three-year outcomes. *Tech Coloproctol* 2011; **15:** 67–73.
15 Ratto C, Donisi L, Parello A, Litta F, Doglietto GB. Evaluation of transanal hemorrhoidal dearterialization as a minimally invasive therapeutic approach to hemorrhoids. *Dis Colon Rectum* 2010; **53:** 803–11.
16 Kaidar-Person O, Person B, Wexner SD. Hemorrhoidal disease: a comprehensive review. *J Am Coll Surg* 2007; **204:** 102–17.

17 Burch J, Epstein D, Sari AB *et al.* Stapled haemorrhoidopexy for the treatment of haemorrhoids: a systematic review. *Colorectal Dis* 2009; **11:** 233–43.
18 Scheyer M, Antonietti E, Rollinger G, Mall H, Arnold S. Doppler-guided hemorrhoidal artery ligation. *Am J Surg* 2006; **191:** 89–93.
19 Rivadeneira DE, Steele SR, Ternent C, Chalasani S, Buie WD, Rafferty JL. Standards practice task force of the American society of colon rectal surgeons. Practice parameters for the treatment of hemorrhoids (revised 2010). *Dis Colon Rectum* 2011; **54:** 1059–64.
20 Jayaraman S, Colquhoun PH, Malthaner RA. Stapled versus conventional surgery for hemorrhoids. *Cochrane Database Syst Rev* 2006; **4:** CD005393.
21 Pucher PH, Sodergren MH, Lord AC, Darzi A, Ziprin P. Clinical outcome following doppler-guided haemorrhoidal artery ligation: a systematic review. *Colorectal Dis* 2013; **15:** e284–94.
22 Tiernan JP, Hind D, Brown SR. Evaluating the efficacy of treatments for haemorrhoids: time for a standardised definition of recurrence? *Colorectal Dis* 2013; **15:** 1449–50.
23 Walega P, Krokowicz P, Romaniszyn M *et al.* Doppler guided haemorrhoidal arterial ligation with recto-anal-repair (RAR) for the treatment of advanced haemorrhoidal disease. *Colorectal Dis* 2010; **12:** e326–9.
24 Theodoropoulos GE, Sevrisarianos N, Papaconstantinou J *et al.* Doppler-guided haemorrhoidal artery ligation, recto-anal repair, sutured haemorrhoidopexy and minimal mucocutaneous excision for grades III-IV haemorrhoids: a multicenter prospective study of safety and efficacy. *Colorectal Dis* 2010; **12:** 125–34.
25 Denoya PI, Fakhoury M, Chang K, Fakhoury J, Bergamaschi R. Dearterialization with mucopexy vs haemorrhoidectomy for grade III or IV haemorrhoids: short-term results of a double-blind randomized controlled trial. *Colorectal Dis* 2013; **15:** 1281–8.
26 Pescatori M, Gagliardi G. Postoperative complications after procedure for prolapsed hemorrhoids (PPH) and stapled transanal rectal resection (STARR) procedures. *Tech Coloproctol* 2008; **12:** 7–19.
27 Faucheron JL, Voirin D, Abba J. Rectal perforation with life-threatening peritonitis following stapled haemorrhoidopexy. *Br J Surg* 2012; **99:** 746–53.
28 Pol RA, van der Zwet WC, Hoornenborg D *et al.* Results of 244 consecutive patients with hemorrhoids treated with doppler-guided hemorrhoidal artery ligation. *Dig Surg* 2010; **27:** 279–84.
29 Schuurman JP, Go PM, Bleys RL. Anatomical branches of the superior rectal artery in the distal rectum. *Colorectal Dis* 2009; **11:** 967–71.
30 Ratto C, Parello A, Donisi L, Litta F, Zaccone G, Doglietto GB. Assessment of haemorrhoidal artery network using colour duplex imaging and clinical implications. *Br J Surg* 2012; **99:** 112–8.

