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European Society of ColoProctology: guideline for haemorrhoidal disease

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Abstract

Aim The goal of this European Society of ColoProctology project was to establish a multidisciplinary, international guideline for haemorrhoidal disease (HD) and to provide guidance on the most effective (surgical) treatment for patients with HD.

Methods The development process consisted of six phases. In phase one we defined the scope of the guideline. The patient population included patients with all stages of haemorrhoids. The target group for the guideline was all practitioners treating patients with haemorrhoids and, in addition, healthcare workers and patients who desired information regarding the treatment management of HD. The guideline needed to address both the diagnosis of and the therapeutic modalities for HD. Phase two consisted of the compilation of the guideline development group (GDG). All clinical members needed to have affinity with the diagnosis and treatment of haemorrhoids. Further, attention was paid to the geographical distribution of the clinicians. Each GDG member identified at least one patient in their country who could read English to comment on the draft guideline. In phase three review questions were formulated, using a reversed process, starting with possible recommendations based on the GDG's knowledge. In phase four a literature search was performed in MEDLINE (Ovid), PubMed, Embase (Ovid) and the Cochrane Database of Systematic Reviews. The search was focused on existing systematic reviews addressing each review question, supplemented by other studies published after the time frame covered by the systematic reviews. In phase five data of the included papers were extracted by the surgical resident (RT) and checked by the methodologist (JK) and the GDG. If needed, meta-analysis of the systematic reviews was updated by the surgical resident and the methodologist using Review Manager. During phase six the GDG members decided what recommendations could be made based on the evidence found in the literature using GRADE.

Results There were six sections: (i) symptoms, diagnosis and classification; (ii) basic treatment; (iii) outpatient procedures; (iv) surgical interventions; (v) special situations; (vi) other surgical techniques. Thirty-four recommendations were formulated.

Conclusion This international, multidisciplinary guideline provides an up to date and evidence based summary of the current knowledge of the management of HD and may serve as a useful guide for patients and clinicians.

What does this paper add to the literature?
This is the first international, multidisciplinary guideline that provides an up to date and evidence based summary of the current knowledge of the management of haemorrhoidal disease and may serve as a useful guide for patients and clinicians.

Introduction

Haemorrhoidal disease (HD) is one of the most frequent anorectal disorders. The prevalence rates vary between 4.4% and 45% [1–4].

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Over the past decades, an enormous amount of HD research, including several national guidelines, has been conducted [5–7]. The most recently published national guideline is from the German guideline committee published in March 2019 (https://www.awmf.org/leitlinien/detail/ll/081-007.html). There is a newly updated guideline from the American Society of Colon and Rectal Surgeons [7]. These guidelines could be improved with more robust methodology on how the recommendations were formulated.

The AGREE Enterprise developed the first instrument to assess the quality and reporting of guidelines [8]. According to the AGREE checklist, existing national HD guidelines do not describe rigorous development methodology. The guidelines often do not report their review questions or the methods used for formulating their recommendations.

The aim of this guideline was to develop an international, multidisciplinary, high quality guideline in collaboration with the European Society of Coloproctology (ESCP) addressing both the diagnosis of and the therapy for HD.

Methodology

The full methodology has been published on the ESCP website https://www.escp.eu.com/images/guidelines/documents/Development-ESCP-Guideline-Haemorrhoidal-Disease.pdf. The development process consisted of six phases.

Phase one: setting the scope

In phase one we defined the scope of the guideline taking into account the patient, the target group and the different treatment modalities.

We decided that the guideline should apply to patients with all stages of HD in whom (surgical) interventions are being considered. The target audience is all practitioners treating patients with HD (e.g. general practitioners, surgeons, gastroenterologists, dermatologists), healthcare workers and patients who desire information about the management of HD. The guideline needed to address both the diagnosis of and the therapy for haemorrhoids.

Phase two: compilation of guideline development group (GDG)

In phase two we created the GDG. All clinical members of the GDG had to have an affinity with the diagnosis and treatment of patients with haemorrhoids. In addition, a geographical spread of clinicians from Europe was sought, as the guideline is aimed at an international audience. We asked all international representatives of the ESCP to participate. Most representatives replied that they did not treat HD or felt that they were not experienced enough to provide input. Following their recommendations, healthcare professionals with an in-depth understanding of HD and/or development of guidelines were invited using the so-called 'snowball method'. The GDG included members from six European countries (Denmark, Italy, France, Germany, the Netherlands and the UK) and it consisted of five colorectal surgeons (SB, DA, JJ, NQ, AW), one gastroenterologist (TH), one general practitioner (JM), one surgical resident (RT) and one methodologist (JK) with extensive experience in guideline development. One dermatologist (CH) commented on the guideline drafts but was not a member of the GDG. Each GDG member identified at least one patient in their country who could read English to comment on the draft guideline.

The GDG members were assisted by a team of methodologists (staff at Kleijnen Systematic Reviews Ltd).

Phase three: formulating review questions

In phase three we developed the first set of review questions. The review questions were built up using a reverse process, starting with possible recommendations based on the GDG's knowledge of practice. Budgetary constraints necessitated an efficient and pragmatic process. The review questions functioned as a framework for the design of the literature searches, informed the planning and process of the evidence review, and acted as a guide for the development of recommendations by the GDG. Review questions were altered and clustered into the following six sections: (i) symptoms, diagnosis and classification; (ii) basic treatment; (iii) outpatient procedures; (iv) surgical interventions; (v) special situations (e.g. thrombosed haemorrhoids, coagulation defect, immunodeficiency and pregnant women); and (vi) other surgical techniques.

Phase four: literature searches

In phase four, we performed literature searches based on the review questions in MEDLINE, PubMed, Embase and the Cochrane Database of Systematic Reviews. There were no restrictions concerning publication format or language. The search was limited by date (< 25 years) and conducted in August 2017. See Appendix S1 for the complete search.

Titles and abstracts were screened for inclusion by the surgical resident (RT). All GDG members added relevant studies from their own knowledge to the search.

Inclusion focused on the available systematic reviews addressing each review question, supplemented by further studies published after the time frame covered by the systematic reviews. We used a hierarchy of best available evidence for study selection, i.e. well performed systematic reviews with or without meta-analyses, randomized trials, controlled observational studies, case series and expert opinion. If evidence of a higher level was available, no lower level of evidence was sought or included.

Phase five: reviewing evidence of the literature

In phase five, data of the included papers were extracted by the surgical resident (RT) and checked by the methodologist (JK) and the GDG.

If needed, we updated high quality systematic reviews, or included the primary studies of the review, to create a new review. Meta-analysis from the systematic reviews was updated by the surgical resident and the methodologist using Review Manager (REVMAN, The Nordic Cochrane Centre, Copenhagen, Denmark) (computer program) version 5.3 software.

Quality assessment of the included papers consisted of a systematic process using the ROBIS tool to assess bias by considering the appropriateness of the study design and the methods of the study. The full ROBIS tool and guidance documents are available on the ROBIS website (www.robis-tool.info) or using the link www.jclinepi.com. We used the Cochrane checklist for assessing risk of bias of randomized trials.

Phase six: developing and wording recommendations

In phase six, the GDG members decided what recommendations could be made based on the evidence found in the literature using GRADE [9]. In the case of high evidence, the term 'must' was implemented in the guideline. Concerning moderate evidence, we used the wording 'should or could'. For low graded evidence we used 'could or may', and for very low evidence 'can be considered'. No Delphi process was conducted; GDG reached consensus on all recommendations. In the case of minority dissent, we planned to explicitly report this; however, full consensus was reached on all recommendations. This process is also stated in the development paper (https://www.escp.eu.com/images/guidelines/documents/Development-ESCP-Guideline-Haemorrhoidal-Disease.pdf).

The draft version of the guideline was posted on the ESCP website for 1 month for consultation. In addition, Dutch, British, German, Italian and French patients were asked to read the guideline in its final form and were asked to give feedback.

The ESCP guideline for the management of HD will be updated on an annual basis starting in 2020. This will involve an update of searches and consideration of whether recommendations need to be adapted or changed. The guideline group plans to reconvene at annual ESCP conferences to discuss an updated version of the guideline.

Results

This guideline includes the following six sections: (i) symptoms, diagnosis and classification; (ii) basic treatment; (iii) outpatient procedures; (iv) surgical interventions; (v) special situations (e.g. thrombosed haemorrhoids, coagulation defect, immunodeficiency and pregnant women); and (vi) other surgical techniques. For the extended version of the guideline see https://www.escp.eu.com/images/guidelines/documents/ESCP-Guidelines-Haemorrhoidal-Disease-2019-02.pdf.

The guideline includes 34 recommendations which provide guidance on the most effective management of patients with HD.

1. Evaluation: symptoms, diagnosis and classification

We found little useful evidence for this section and the recommendations were predominantly based on expert opinion. The strongest wording used in the recommendations was 'should'.

1.1 Healthcare providers should make a provisional diagnosis of HD based on the clinical history whilst also thinking about the presence of other diseases such as colorectal cancer and inflammatory bowel disease (IBD).
Expert opinion, upgraded by the GDG.

1.2 Inspection and physical examination of the anorectal region should be performed to exclude other anorectal pathology.
Expert opinion, upgraded by the GDG.

1.3 A procedure (e.g. rigid anoscope, proctoscope or rectoscope) to visualize the entire anal canal must be performed in order to diagnose and to classify the severity of HD and to exclude other anal pathology.
Expert opinion, upgraded by the GDG.

1.4 If any indications are found during history taking or physical examination of colorectal cancer or IBD, the relevant (inter)national guidelines for these conditions should be applied.
Expert opinion, upgraded by the GDG.

1.5 Physical examination should be performed in a position that facilitates reliable diagnosis and comfort for the patient, i.e. the left lateral position. The lithotomy and the knee–chest position may be alternatives.
Expert opinion, upgraded by the GDG.

1.6 If a provisional diagnosis of HD has been made, basic treatment (i.e. toilet training, laxatives, local anaesthetics and phlebotonics) can be started. Patients with refractory symptoms should be referred.
Expert opinion, upgraded by the GDG.

See the next section 'Basic treatment' for evidence regarding toilet training, dietary changes (specifically high fibre diet), topical treatments and pharmacological treatments which may include phlebotonics susch as flavonoids.

1.7 For docusmentation and classification, the Goligher classification has been used most widely and could be used in order to help healthcare providers choose the best therapeutic option for each patient.
Expert opinion, upgraded by the GDG.

Other recently developed classifications include PATE, the Single Pile Classification and a classification by Lunniss *et al.* [10–12]. These classifications might be interesting but are clinically less usable than the Goligher classification. Altogether, we found no evidence favouring one classification over another.

2. Basic treatment

When a patient visits the outpatient clinic with anorectal symptoms which may include bleeding, pain, prolapse, itching and/or soiling and the healthcare provider has diagnosed haemorrhoids and excluded the presence of colorectal cancer or IBD, patients can be first reassured that surgical treatment is not mandatory. Indeed, the first management step should consist of basic treatments and advice for all grades of HD.

Basic treatments could be used for symptom relief and to prevent prolapse and include toilet training, dietary changes (specifically high fibre diet), and topical and pharmacological treatments which may include phlebotonics such as flavonoids. In addition, it will be important to manage the patients' expectations about symptom control.

These interventions are given in addition to advice about adequate water intake, healthy diet and encouraging physical activity.

2.1 Healthy lifestyle measures, such as sufficient water intake, a healthy diet and physical activity should be encouraged.
Expert opinion, upgraded by the GDG.

No systematic reviews or (randomized) trials were found regarding healthy lifestyle measures.

2.2 Toilet training including adopting the correct body position during defaecation should be advised. Straining and prolonged defaecation sessions should be avoided.
Expert opinion, upgraded by the GDG.

No systematic reviews or (randomized) trials were found regarding toilet training.

2.3 The use of laxatives could be considered for symptom relief and to reduce bleeding.
Low level of evidence.

Analysis of the literature revealed only one systematic review evaluating the use of laxatives (fibre – high fibre diet or bulking agents such as bran, ispaghula, psyllium; stimulant laxatives – senna and bisacodyl; faecal softeners – liquid paraffin, seed oils; osmotic agents – lactulose, magnesium hydroxide, sorbitol and lactitol) [13]. In this systematic review seven randomized clinical trials (RCTs) and a total of 378 patients were evaluated.

2.4 Phlebotonics could contribute to symptom reduction.
Low level of evidence.

Analysis of the literature revealed two systematic reviews regarding the use of phlebotonics [14,15]. The first systematic review [15] included 14 trials (of which four trials are not reported in the review of Perera *et al.*) with a total of 1514 patients. The other systematic review [14] included 24 RCTs with a total of 2344 patients.

2.5 Nonsteroidal anti-inflammatory drugs (NSAIDs) and non-opioid analgesics could be prescribed for pain.
Expert opinion.

There are no scientific data evaluating NSAIDs, cortisone and its derivates for the treatment of haemorrhoids.

3. Outpatient procedures

In patients where basic treatment has not resulted in acceptable symptom reduction, further procedures should be considered. As some treatments are less invasive, have fewer and/or less serious reported

complications and are quicker and cheaper than others, we propose that clinicians first consider outpatient procedures [i.e. rubber band ligation (RBL), sclerotherapy (SCL) or infrared coagulation (IRC)]. Nevertheless, patients with circular prolapsing Grade III and especially Grade IV HD may be treated with primary surgical interventions such as haemorrhoidectomy, stapled haemorrhoidopexy (SH) or Doppler-guided haemorrhoidal artery ligation + mucopexy (DG-HAL). However, it seems justifiable to use repeat RBL for Grade III prolapsing haemorrhoids, recognizing that surgical procedures will be necessary for patients whose symptoms are not relieved with RBL and those with circular prolapse. Equally, outpatient procedures could be performed in patients with Grades III and IV HD when primary surgery is contra-indicated or the patient refuses primary surgery. This is represented in Fig. 1.

3.1 Choice of the outpatient procedure (i.e. RBL, injection SCL and IRC) should be informed by shared decision-making, taking into account patient preferences, availability of procedures and fitness for further procedures.
Expert opinion, upgraded by the GDG.
3.2 RBL should be performed in Grade I–III HD. Repeat banding may be necessary.
Moderate level of evidence.

Analysis of the literature revealed one meta-analysis (MacRae and McLeod, [16]) comparing RBL, IRC and SCL and including 18 RCTs and observational studies. The following comparisons were made: RBL *vs* surgical haemorrhoidectomy (three observational studies), Lord procedure (e.g. manual dilatation) *vs* surgical haemorrhoidectomy (six observational studies), SCL *vs* IRC (one RCT and one observational study), SCL *vs* RBL (three observational studies and one RCT) and RBL *vs* IRC (three RCTs) [16].

The meta-analysis by Shanmugam *et al.* [17], including three trials (Murie 1980 [18], Cheng 1981 [19] and Lewis 1983 [20]) and 216 patients, compared RBL with haemorrhoidectomy.

Two RCTs (Shanmugam *et al.*, [21]; Peng *et al.*, [22]) including a total of 105 patients compared RBL with SH [21,22].

One RCT (Brown *et al.*, [23]), including 372 patients, compared RBL with DG-HAL.

3.3 IRC could be used as the first option in bleeding Grade I haemorrhoids.
Low level of evidence.

Analysis of the literature revealed five RCTs comparing RBL and IRC. These RCTs included a total of 680 patients [24–28].

3.4 Injection SCL could be used in patients with Grade I–II HD.
Low level of evidence.

Analysis of the literature revealed three RCTs comparing RBL and SCL. These RCTs included a total of 606 patients [29–31].

4. Surgical treatment

In patients where basic treatment and/or outpatient procedures have not resulted in acceptable outcomes or in Grades III and IV HD, surgical procedures could be considered. These include haemorrhoidectomy, SH and/or a mucopexy with or without DG-HAL.

4.1 Choice of surgical treatment should be informed by shared decision-making, taking into account patient preferences, availability of procedures and fitness for surgical procedures.
Expert opinion, upgraded by the GDG.
4.2 DG-HAL +/− mucopexy could be used in patients with Grade II–III haemorrhoids and/or in patients who are refractory to outpatient procedures (*low level of evidence*). However, because the effectiveness of using a Doppler is currently questioned, mucopexy alone could be considered.
Very low level of evidence, upgraded by the GDG.

Analysis of the literature revealed two RCTs that assessed the efficacy of the Doppler transducer, the addition of a mucopexy and ligation under visual control followed by a mucopexy [32,33].

Two systematic reviews compared DG-HAL and SH. The first systematic review (Pucher *et al.*, [34]) included 28 trials and 2904 patients (six trials were RCTs). Another systematic review (Sajid *et al.*, [35]) included three randomized trials (two of these were also reported in the review mentioned above) and 150 patients [34–36].

One meta-analysis (Xu *et al.*, [37]), including four RCTs and 316 patients, and one RCT (Bursics *et al.*, [38]), including 60 patients, compared DG-HAL + mucopexy with haemorrhoidectomy [37,38].

4.3 SH could be used in patients with Grade II–III haemorrhoids and/or in patients who are refractory to outpatient procedures.
Low level of evidence.

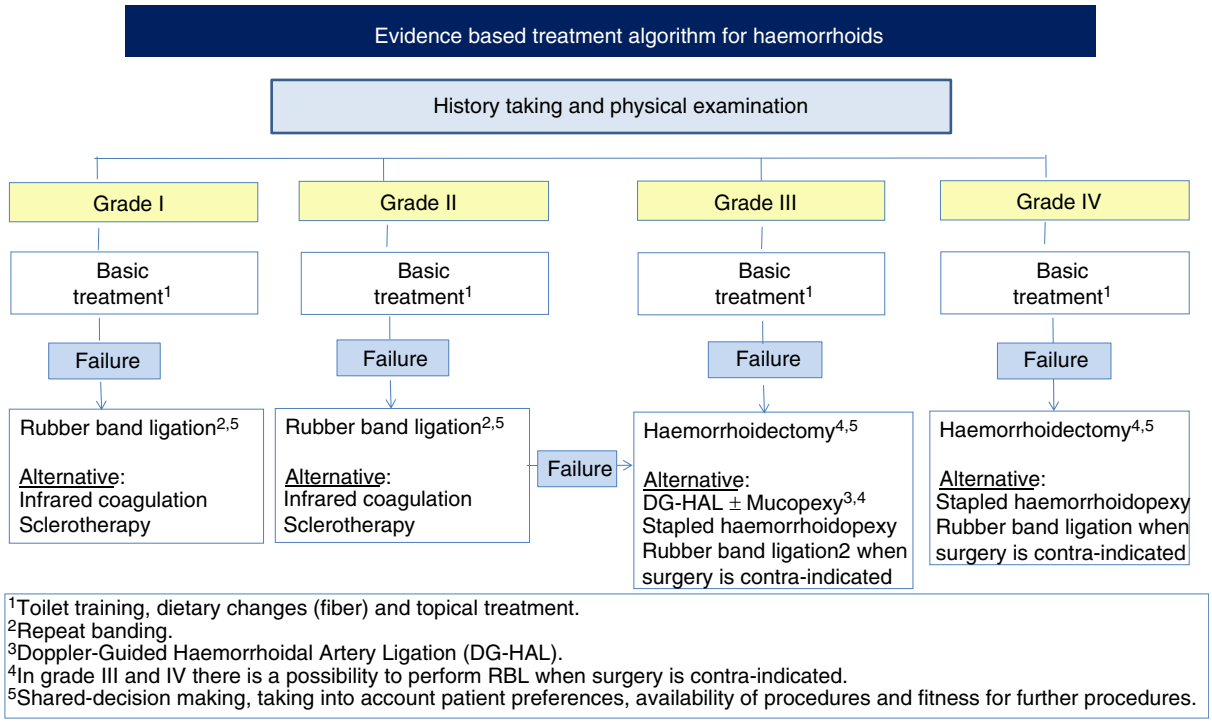

Figure 1 Flow diagram grade I-IV HD.

4.4 Haemorrhoidectomy could be used in patients with Grade II–III haemorrhoids and/or should be used in patients who are refractory to outpatient procedures.
Moderate level of evidence.
4.5 Haemorrhoidectomy should be used for Grade IV haemorrhoids.
Moderate level of evidence.

Three meta-analyses, four systematic reviews and one RCT were found comparing haemorrhoidectomy with SH [39–46].

5. Special situations

Thrombosed haemorrhoids

In the anocutaneous junction there is a venous plexus (anatomically called plexus haemorrhoidalis externa) and here perianal thromboses or perianal haematomata may develop, which can cause severe pain and swelling. In these cases, the thrombosed vessels are covered by skin and there is no prolapsed mucosa. We suggest this phenomenon is called 'perianal thrombosis' to make it distinguishable from thrombosed haemorrhoids since it is also possible for haemorrhoids to become incarcerated/thrombosed. This may happen with Grade II, III and/or IV haemorrhoids. In this guideline, we focus on thrombosed haemorrhoids.

5.1 In patients with thrombosed haemorrhoids, treatment should be informed by shared decision-making, taking into account patient preferences, availability of procedures and fitness for further procedures.
Expert opinion, upgraded by the GDG.

There is a remarkable paucity of studies reporting on thrombosed haemorrhoids and even fewer studies provided high level of evidence. No systematic reviews were found regarding this subject.

5.2 Primarily, basic treatment (i.e. toilet training, laxatives, NSAIDs and non-opioid analgesics) can be considered in patients with thrombosed haemorrhoids (*expert opinion*). Phlebotonics could be considered in patients with thrombosed haemorrhoids (*low level of evidence*). In selected cases, surgical options may be discussed with the patient.
Very low level of evidence.

There were no scientific data evaluating NSAIDs for the treatment of thrombosed haemorrhoids. However, analgesics could be prescribed for pain.

Analysis of the literature revealed one RCT (Giannini *et al.*, [47]), including 134 patients, assessing the efficacy of the oral intake of flavonoids *vs* placebo in patients with acute 'haemorrhoidal crisis'.

5.3 Surgical procedures (i.e. SH and haemorrhoidectomy) can be considered in patients with thrombosed haemorrhoids.
Very low level of evidence.

Three RCTs compared SH with haemorrhoidectomy. The first RCT (Lai *et al.*, [48]) included 80 patients. Another RCT (Brown *et al.*, [49]) included 35 patients and a third RCT (Wong *et al.*, [50]) included 41 patients.

Immunodeficiency
Immunocompromised patients have an increased risk of anorectal sepsis and poor tissue healing after any intervention. Therefore an operation should be avoided, or should be performed only after careful consideration [51]. Also, antibiotic prophylaxis should be given before performing any intervention.

5.4 Outpatient procedures (including RBL and SCL) in immunocompromised patients seem to be safe, but very limited data are available.
Very low level of evidence.

Analysis of the literature revealed that two studies assessed whether SCL can be safely performed in patients with acquired immunodeficiency syndrome (HIV). One observational study included 22 patients with HIV who underwent SCL. Another observational study included a total of 76 patients with haemorrhoids (36 positive HIV and 40 negative HIV) (Scaglia, 2001) [52].

One observational study assessed whether RBL can be safely performed in select HIV-positive patients [53].

Pregnant women
(Thrombosed) haemorrhoids are a common condition in pregnant women due to an increased endopelvic pressure. The exact prevalence is unknown. One study reported that 8% of women during the last trimester of pregnancy and 20% of women immediately after delivery develop thrombosed haemorrhoids [54,55]. A survey, including 165 obstetricians, showed that only 42% of obstetricians refer these women to the consultant for HD treatment [56]. For many women, symptoms will resolve spontaneously soon after birth, and so the primary goal of treatment is to relief acute symptoms mostly by means of dietary and lifestyle modification (Abramowitz, 2011) [51].

5.5 In pregnant and postpartum women basic treatment (i.e. laxatives, topical treatments, phlebotonics and analgesics) should be used.
Expert opinion, upgraded by the GDG.

Analysis of the literature revealed one review, including two trials and 150 pregnant women, that compared oral hydroxyl ethylrutosides, a flavonoid drug given to improve the microcirculation in venous insufficiency, with placebo [57].

Two studies evaluated the effectiveness of Proctofoam-HC®, a combination of corticosteroid and a local anaesthetic, in 292 pregnant women [58,59].

One observational study, including 495 pregnant women, compared three times per day salty warm sitz bath (using 20 g of commercial salt) ($n = 284$) with topical cream (containing corticoid and anaesthetic) twice daily [60].

5.6 In pregnant and postpartum women with thrombosed haemorrhoids unresponsive to basic treatment, surgical procedures to treat thrombosis can be considered.
Expert opinion.

One cohort study assessed the efficacy of haemorrhoidectomy among 25 pregnant women with HD [61].

Inflammatory bowel disease (IBD)
Haemorrhoids are relatively uncommon in IBD patients [62]. However, this anal problem could be underestimated because of a bias due to the higher attention paid to the other clinical features of IBD.

5.7 In patients with IBD, outpatient procedures and/or surgical procedures can only be considered when there is no sign of active disease.
Expert opinion, upgraded by the GDG.

Analysis of the literature revealed one prospective study (D'Ugo *et al.*, [63]) which included 86 patients with Crohn's disease and compared outpatient and surgical procedures. Another retrospective study (Cracco and Zinicola, [64]) included 11 retrospective studies including 135 patients with IBD.

Irradiation

Radiation therapy has a major role in the treatment of a number of malignancies arising in the pelvis (i.e. carcinoma of the prostate, bladder, rectum and gynaecological malignancies).

5.8 Outpatient and/or surgical procedures in patients who have undergone pelvic radiotherapy cannot generally be considered.
Expert opinion.

In the literature there is no evidence regarding the outcome of haemorrhoidal treatment in irradiated patients. However, there are some papers indicating that surgical treatment in patients who have undergone pelvic radiotherapy can have catastrophic sequelae. The study by Hayne *et al.* showed that more than three-quarters of patients receiving pelvic radiotherapy experience acute anorectal symptoms and up to one-fifth suffer from late phase radiation proctitis [65].

Coagulation disorder

Conservative measures are the mainstay of treatment for patients with a coagulation disorder.

5.9 If an outpatient procedure and/or surgical procedure is scheduled, appropriate cessation of anticoagulant therapy should be followed according to national guidance.
Very low level of evidence, upgraded by the GDG.

One retrospective review identified 364 patients undergoing RBL while on antithrombotic therapy (AT) [66].

One controlled study, including 37 patients with HD, compared patients undergoing SCL while on AT *vs* patients who were not on AT [67].

One retrospective cohort study compared AT patients ($n = 36$) *vs* non-AT patients ($n = 70$) with symptomatic haemorrhoids who underwent DG-HAL [68].

Other surgical techniques (closed/open haemorrhoidectomy, LigaSure® etc.)

6. Other techniques

6.1 Both closed and open haemorrhoidectomy (not using energy devices) could be used (*low level of evidence*). Closed haemorrhoidectomy is associated with less pain and bleeding.
Low level of evidence.

One meta-analysis (Xu *et al.*, [69]), including five RCTs and 318 patients, compared the LigaSure® with the Ferguson (closed) haemorrhoidectomy.

6.2 Surgical energy devices (LigaSure® and Harmonic scalpel®) could be used for haemorrhoidectomy.
Low level of evidence.

Analysis of the literature revealed one meta-analysis (Mushaya *et al.*, [70]), including eight studies and 468 patients, that compared Harmonic scalpel® haemorrhoidectomy with haemorrhoidectomy.

6.3 Alternative procedures (laser and radiofrequency ablation procedures) could be used/can be considered.
Low level of evidence.

Three RCTs (Naderan *et al.*, [71]; Maloku *et al.*, [72]; Giamundo *et al.*, [73]), including a total of 160 patients, compared the outcomes of intra-haemorrhoidal coagulation with 980-nm diode laser with haemorrhoidectomy.

6.4 Rectal resection using a stapler device [including stapled transanal rectal resection (STARR)] should not be used to treat haemorrhoids.
Low level of evidence, downgraded by the experts.

Three RCTs (Corsale *et al.*, [74]; Zanella *et al.*, [75]; Boccasanta *et al.*, [76]), including a total of 691 patients, compared SH with the STARR procedure.

One RCT (Renzi *et al.*, [77]), including 425 patients, compared the clinical and functional results of STARR performed with two staplers (PPH-01 *vs* PPH-03, Ethicon, Somerville, New Jersey, USA).

Discussion

This is a multidisciplinary, international guideline for the management of HD. According to this guideline,

for Grade I and II haemorrhoids, RBL appears to be the treatment of choice, because patients who undergo RBL show a significantly better response compared to patients treated with SCL and/or IRC. In addition, patients treated by RBL have significantly less recurrence compared to patients treated with SCL or IRC. IRC may be the first treatment option in bleeding Grade I haemorrhoids because it causes less pain and complications [28]. Complication rates were similar between RBL, IRC and SCL [78–80]. For Grade III and IV haemorrhoids, haemorrhoidectomy remains the treatment of choice. Comparing SH and haemorrhoidectomy, the efficacy of SH is generally lower than haemorrhoidectomy [81], especially in Grade IV HD [81]. DG-HAL + mucopexy may be considered in patients with Grade II–III HD. However, more research regarding this technique is necessary. The additional effect of the Doppler is currently being questioned since two studies showed that significantly more complications and unscheduled postoperative events were reported in the DG-HAL + mucopexy group compared to the mucopexy alone group [32,33].

To date, several national guidelines have been published, including the American Society of Colon and Rectal Surgeons guideline [7] and the Italian [82] and French HD guidelines [6]. The overall methodological quality of these guidelines for HD is suboptimal. In most guidelines, the review questions and methods for formulating their recommendations are not reported. The AGREE Enterprise is the first initiative which developed an instrument diminishing variability in practice guideline quality [83–86]. The extensive processes following the AGREE II instrument and using GRADE are the main strengths of this guideline [87–89].

However, several limitations remain. The first limitation of this guideline is that patients were only partially involved in the development of the guideline. We invited two patients to be GDG members but they were unable to attend any of the meetings. Besides, we asked Dutch, British, German, Italian and French patients to read the guideline in its final concept and asked them for feedback. The patients did not have substantial comments that resulted in a change of the guideline. For the coming update, which is planned in 2020, a patient will be a member of the GDG. A separate patient information section describing the different techniques was added to the current guideline. Further, we asked all international representatives of the ESCP to participate. Most representatives replied that they did not treat HD or they felt that they were not experienced enough to provide input. Following their recommendations, healthcare professionals with an in-depth understanding of HD and/or development of guidelines were invited using the so-called 'snowball method'. This strategy resulted in a dedicated group of experts with knowledge of the field but smaller in size than initially planned, which may be a limitation of the study. The third limitation of this guideline is the minimal guidance regarding economic data. The financial reimbursement for HD is different for each country. Therefore, it is difficult to indicate what the best economic option is per country. The GDG chose to give an overview of the published economic data, so that these data can inform local decisions. The fourth limitation is that debate regarding the best treatment option for each grade of HD remains as high level of evidence is lacking. Despite the large volume of HD research that has been conducted over the past decade, only a few studies are of high quality. New procedures emerge with often the same low quality evidence. For future guidelines to have more robust recommendations, new interventions need to be evaluated with more rigorous methodologies.

In addition, the lack of uniform outcome, measurement and reporting in HD research data hampers the ability to compare studies and the creation of optimal treatment guidelines [17,90,91]. A Core Outcome Set was recently developed in cooperation with the ESCP [92].

Furthermore, since the evaluation of patient experiences can be very useful in several decision-making contexts, there is a growing chorus of support from clinicians and researchers to embrace patient-reported outcome measures in clinical care [93–95]. In a clinical setting, it can provide a more complete understanding of the impact of a therapy on a patient's life and aid treatment choices [96]. In addition, it could also provide scientific evidence for guideline development that incorporates the patient's perspective [97–99]. Attempts have been made to develop such a tool. Examples include the Symptom-based Severity Score of Pucher *et al.* [100], the Haemorrhoid Severity Score introduced by Nyström [101], the Haemorrhoid Symptom Score recently used in the eTHoS trial [102] and the Hemorrhoidal Disease Symptom Score and Short Health Scale HD used by Rørvik *et al.* [103]. However, these scoring systems have not gained wide acceptance in the clinical and research setting which may be due to a lack of robust validation and/or the extensive length of the instrument.

We plan to update the guideline on a regular basis starting in 2020. This will involve update of all searches and assessment of any relevant research found in relation to the current recommendations.

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Conflicts of interest

All GDG members including Dr Henquet declared that they had no conflicts of interest. Jos Kleijnen (Kleijnen Systematic Reviews Ltd) has cooperated in the development and is co-author of the ROBIS, PRISMA, QUADAS, STARD and PROBAST tools.

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Ethics approval

Since this study does not use health data of individuals, ethics approval was not required according to the Dutch Federal Act on research involving human beings.

Data availability statement

All data generated are available in the guideline document and the appendices.

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Supporting Information

Additional Supporting Information may be found in the online version of this article:

Appendix S1. Search strategy.