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ORIGINAL ARTICLE

Guidelines, guidelines and more guidelines for haemorrhoid treatment: A review to sort the wheat from the chaff

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Abstract

Aim: Guidelines benefit patients and clinicians by distilling evidence into easy-to-read recommendations. The literature around the management of haemorrhoids is immense and guidelines are invaluable to improve treatment integrity and patient outcomes. We identified current haemorrhoid guidelines and assessed them for quality and consistency.

Methods: A systematic search of the literature from January 2011 to October 2021 was carried out. Guidelines identified were assessed for quality using the AGREE II instrument and for consistency in terms of tabulated treatment recommendations.

Results: During this period nine guidelines were identified worldwide. The general quality was poor with only one guideline considered of high enough quality for use. In general, expert selection criteria for guideline development groups were vaguely defined. There were inconsistencies in the interpretation of the published evidence leading to variation in treatment recommendations.

Discussion: Fewer, higher quality guidelines, with more consistent results, are needed. Particular attention should be given to defining the selection of experts involved.

KEYWORDS

AGREE II, GRADE, Guidelines, Haemorrhoids

INTRODUCTION

Advances in medical research have reduced the level of uncertainty in clinical practice [1]. Guidelines complement this progress by providing recommendations. These recommendations should be informed by a systematic review of the evidence with assessment of the certainty of this evidence, providing the end user with a simple guide to decision making [2]. Such guidelines should be rigorous in their review of evidence, have transparency in their development process and involve appropriate stakeholders [3].

Whilst guideline adherence benefits the patient and clinician by generally improving treatment integrity and patient outcomes [4–8]

the benefit is only as good as the quality of the guidelines themselves. To improve the quality various 'guidelines for guidelines' have been developed and national bodies attempt to coordinate such guidance [9,10]. The AGREE enterprise provides an instrument and a checklist that allows evaluation of the quality of each guideline [11].

A clinical condition where guidelines are essential is haemorrhoidal disease. Haemorrhoids are common and symptoms lead to a significant socioeconomic burden worldwide [12]. Whilst there are numerous treatment options, many have potential drawbacks that include dubious efficacy, high cost or prominent side effects, in particular pain [13]. Perhaps spurred on by the widespread incidence and lack of a universal highly effective and painless treatment, a

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large number of surgical innovations have occurred [14–17]. These have in turn resulted in an overabundance of literature, with over 43 000 publications (search keyword ‘haemorrhoids’) available in PubMed in the last 20 years (accessed 18 November 2021), making guidelines essential to distil this literature and aid practice. However, the plethora of publications has been followed by a plethora of guidelines, with different organizations and countries producing their own interpretation of the literature. Variation in practice may be valid where there are variations in capacity—in terms of resources or proficiency—and where evidence is equivocal or contextually inapplicable [18]. However, there is a danger of confusion to the end user if the guideline development is substandard and variation relates to non-valid reasons such as conflicts of interest and lack of awareness, ignoring or poor appraisal of relevant evidence [19].

The aim of this review were to identify current guidelines for the treatment of haemorrhoidal disease, assess the overall quality of each guideline, and identify whether conflicting advice is prevalent and whether any variation can be justified.

METHODS

Eligibility criteria

Articles were eligible if they were guidelines following the Institute of Medicine definition [20].

We focused on guidelines published from January 2011 to the date of the last search of 1 October 2021, with the most up to date guideline version being selected if there was more than one. We excluded guidelines not focused solely on haemorrhoids, expert reviews, other forms of recommendations (e.g., quality indicators) and guidelines published in a language other than English.

Search

The electronic databases used for the search included Embase, MEDLINE and CINAHL. The search strategy included words relating to haemorrhoids, guidelines, clinical standards and quality standards (combination of keywords tailored to each database). See Data S1 for the exact syntax searches. An additional search of the grey literature was carried out on Guidelines International Network, CPG InfoBase, the Scottish Intercollegiate Guideline Network and Google Scholar (first 80 pages).

Study selection process

Four reviewers (HTM, AC, BB, CG) independently screened the title and abstracts of the papers for eligibility, with questions and disagreements referred to a clinical specialist (SRB). Full texts of potentially eligible papers were retrieved and screened against the eligibility criteria.

What does this paper add to the literature?

Guidelines on haemorrhoid management are of a generally poor standard with inconsistencies in recommendations. Areas of weakness and inconsistency are highlighted. Adherence to GRADE and AGREE II principles is emphasized.

Data extraction

Four reviewers (HTM, AC, BB, AES) independently reviewed and extracted descriptive data from the guidelines. Data were extracted on organization and country. Recommendations were classified under medical therapy (lifestyle, laxatives, phlebotonics, sitz baths and topical), office therapy (banding, sclerotherapy, others), surgery (excisional haemorrhoidectomy, haemorrhoidopexy, haemorrhoidal artery ligation, others) and special situations (pregnancy, thrombosed haemorrhoids, anticoagulants, impaired immunity, Crohn's, radiation proctitis, portal hypertension).

Risk of bias in individual studies

The quality of the existing guidelines was assessed using the Appraisal of Guidelines for Research and Evaluation (AGREE II) instrument [11]. The quality of guidance is evaluated in different domains: scope and practice, stakeholder involvement, rigour of the development, clarity of presentation, applicability and editorial independence. AGREE II was applied to each guideline by five independent reviewers (SRB, BB, HTM, AC, AES). The appraisers met to discuss results and present information that may have been overlooked by others.

An average score for each domain was calculated to determine if there were differences in quality. A guideline was ‘recommended’ if most of the AGREE II and GRADE principles were reported as having been used and most of the AGREE II domains (≥ 4) scored above 50%. A guideline was ‘recommended with modifications’ if ≥ 4 domain items scored above 50% implying that the guidelines could be relatively easily modified to comply with AGREE II and GRADE principles.

Synthesis of results

A narrative synthesis was presented, providing a descriptive and critical overview of tabulated data. PROSPERO deemed the methods in this review not synonymous with those of a systematic review and therefore registration was not required (reference 212350). The protocol is available on ORDA [21].

RESULTS

Study selection

The searches of bibliographic databases and grey literature yielded 2002 articles, after the elimination of duplicates. After reviewing the title and abstracts, 11 articles were retrieved. After applying the eligibility criteria, nine guidelines in total were deemed eligible for inclusion in this review. Figure 1 shows the PRISMA diagram for study inclusion.

Study characteristics

The included guidelines were published between 2013 and 2021, in Asia ($n = 2$) [22,23], Europe ($n = 6$) [24-29] and North America ($n = 1$) [30]. The profession behind the guidelines was mainly surgeons with only one guideline produced by gastroenterologists alone [26]. As a result, gastroenterology guidelines did not include surgical management. Only one guideline states adherence to the AGREE II principles [27] and only four guidelines stated that they used GRADE to appraise the level of evidence [22,26,27,29].

Risk of bias within studies

Table 1 provides a summary of the characteristics of the guidelines according to the AGREE II instrument. The scores are scaled to a percentage of the maximum score for each domain.

The main criticisms regarding stakeholder involvement include the absence of a methodologist, a gastroenterologist or a patient. Whilst many guidelines described the membership of the guideline development group, the selection criteria for what should be construed as an 'expert' in this group was either not defined or in one guideline vaguely defined as a 'prominent gastroenterologist' [26]. Some guidelines had methodological weaknesses including very brief details of the process of systematic review and of evidence selection and the failure to use the GRADE to appraise level of evidence. The main criticisms for rigour of development were no formal external review (over and above peer review for journal publication) or procedure for updating. Whilst clarity of presentation was generally good for all, applicability was poor with few details about barriers, implementation, resource issues and monitoring. This may be an issue with a mainly surgically oriented guideline (see Discussion). In addition, some guidelines could be criticized for editorial independence, giving few details on funding or conflicts of interest of the authors.

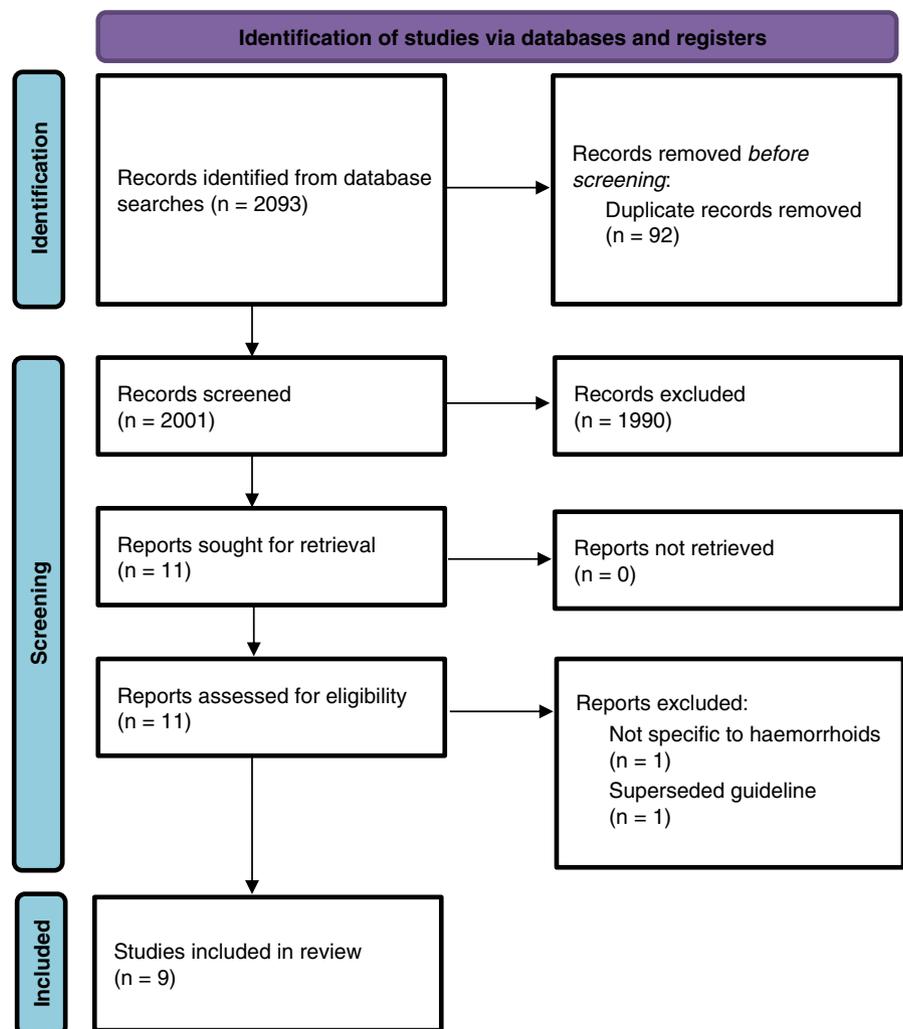


FIGURE 1 PRISMA flow diagram

The European Society of Coloproctology guidelines scored the highest out of all the guidelines, with high scores in all AGREE II domains, and was recommended for use [27]. We considered that the American, Japanese and Italian guidelines could easily be modified to become recommended. Such modifications would include more detail about stakeholders, use of GRADE methodology and confirmation of editorial independence.

Synthesis of results

There was significant variation in all aspects of key recommendations for each of the nine guidelines and these are summarized in Table 2. Particular areas are commented on below.

Non-operative management

Topical agents are recommended for symptom relief by all guidelines except the Belgian guidelines [29,30]. Only the Portuguese and Indian guidelines emphasize avoiding long-term topical agents [22,26]. A sitz bath is only recommended by four guidelines [23,24,26,28].

Whilst the use of phlebotonics is recommended by most guidelines the European and Belgian guidelines comment on the weakness of the evidence and phlebotonics are not mentioned in the Japanese or Danish guidelines [23,24].

Office procedures

Rubber band ligation is mentioned by all. However, there is some variation in recommendation based on individual grade of haemorrhoids. All appear to agree that grade II haemorrhoids are an

indication. The treatment is recommended for grade I haemorrhoids by some [22,23,25,27,30] but not by others [24,26,29]. Whilst some guidelines recommend rubber band ligation for all grade III haemorrhoids [23,28,29], others recommend selective treatment [22,26,27] or treatment is not recommended [24,25,30].

There is variation in the recommendation of injection sclerotherapy, with one guideline not recommending use at all [29]. There was no consensus amongst the other guidelines as to which grade of haemorrhoid that injection sclerotherapy should be used.

Surgical management

Surgical management was mentioned in all but one guideline [26]. However, there was significant variation in the grade of haemorrhoid recommended for surgical interventions. This included haemorrhoidopexy being recommended for only grade III haemorrhoids [22,29], only grades II–III haemorrhoids [23,24,26] or all grades [27]. Similarly, haemorrhoidectomy was recommended for grades III–IV haemorrhoids in some guidelines [21,22,27,29], yet recommended for all grades in another [24]. For Doppler-guided haemorrhoidal artery ligation, half the guidelines recommended this procedure for grades III–IV haemorrhoids [22,24,28], one suggested the procedure was not appropriate for grade IV [29] two guidelines recommended the procedure for grades II and III haemorrhoids [25,27] and one made no recommendation [23,30].

Special situations

In general, there was consensus that conservative management was recommended for special situations, such as haemorrhoids in pregnancy, inflammatory bowel disease, portal hypertension,

TABLE 1 The AGREE II scores for each guideline

	Year	Scope and purpose	Stakeholder involvement	Rigour of development	Clarity of presentation	Applicability	Editorial independence	Recommended for use	Average
USA	2018	74	48	71	69	30	100	Yes, with modifications	65
Japan	2017	86	40	40	64	25	61	Yes, with modifications	53
Portugal	2019	74	21	45	69	29	68	No ^a	51
Italy	2020	74	50	71	67	39	64	Yes, with modifications	61
India	2017	50	21	43	52	29	54	No	42
Europe	2020	100	81	100	100	66	93	Yes	90
France	2016	26	17	29	24	21	61	No	30
Denmark	2013	52	19	34	67	32	18	No	37
Belgium	2021	55	38	61	88	25	14	No	47
Average		66	37	62	71	33	53		

^aExcluded because does not include surgical options.



immunocompromised, post irradiation therapy and thrombosed external haemorrhoids. Nevertheless, mention of these situations was completely absent in one guideline [30]. The detail within recommendations varied. For example, recommendations for the treatment for patients on anticoagulants ranged from extensive [27,29] to brief [22,25,28] to absent [23,24,26,30].

DISCUSSION

This review has allowed us to identify nine English language guidelines for the treatment of haemorrhoids published over the last 8 years. Most are produced by stakeholders of a particular country. However, one was international, claiming to represent views from stakeholders throughout Europe. The underlying motivation and the overall need for production of so many guidelines worldwide is questionable. We know that the presence of a guidelines committee, routine guideline output and adhering to GRADE methodology are associated with higher guideline quality in the field of surgery [31]. Perhaps those organizations not meeting these criteria should consider adopting guidelines by those that do or journal editors should consider carefully the need for publication.

Despite peer review publication of all identified articles, the standard according to the AGREE II criteria was poor for almost all. Only one guideline mentioned use of the AGREE II instrument and in our assessment this was the only guideline that we would recommend for use without modification [24]. Even this guideline could be criticized for its failure to adequately involve patients as stakeholders and the brevity of the economic analysis. In addition to the AGREE instrument another standard for guidelines is GRADE methodology for appraising level of evidence [32,33]. This was absent in the majority of guidelines. Others mention GRADE but it was unclear if all except one [24] had used the methodology framework comprehensively and fully.

Cost-effectiveness is pertinent when considering barriers to implementation of the more expensive haemorrhoid interventions. Some countries, even within Europe, will have variation in practice due to variation in resources, perhaps explaining variation in recommendations. Rigorous economic evaluation provides greater guidance particularly to policy makers [34]. Nevertheless it is well known that cost-effectiveness studies in surgery are scarce and recommendations difficult to make [35,36]. Economic evaluation was limited throughout all of the guidelines analysed.

Despite the same literature resource and data available there is significant variation in many recommendations. Rubber band ligation is an example. Treatment for grade I haemorrhoids is recommended by some but not by others. The same is true for grade III haemorrhoids. In each case the variation occurs when the evidence is poor and recommendations rely more on expert interpretation and consensus opinion. Variation presumably reflects the values, preferences, acceptability and affordability within the country of origin [18].

Given the paucity of data in some elements of practice, the reliance on expert opinion becomes important. Yet selection of appropriate 'experts' is challenging [37]. Such selection should be open and transparent, but those that are elected onto such panels have qualifications that may not indicate the predictive capability needed to be an expert or they may have significant cognitive bias [38]. Their views may then reinforce dogma, explaining an alternative cause of recommendation variation. In all of the guidelines produced, the 'expert' was poorly defined or not defined at all and many guidelines fall into the variety that has been termed GOBSAT (Good Old Boys Sat At Table) [39]. There have been tools developed to aid guideline panel selection and participation. Introduction of such should be considered mandatory [40]. A robust process should exist to manage academic and financial conflicts of interest in a fair, judicious, transparent manner, in line with the nine core principles of the Guidelines International Network [41].

This review is based on a rigorous search strategy which will have identified all relevant English language guidelines. Restricting reviews to English language publications rarely affects conclusions [42] and will not do so in this case, where the finding was general low quality and probably unwarranted variation. The subjective element in using the validated AGREE II instrument was mitigated by the use of two or more reviewers for each paper with meetings allowing appraisers the opportunity to present information that may have been overlooked. The majority of our assessors had not previously been involved in guideline development and may have therefore been considered too stringent in assessment. However, guideline developers have been shown to give even lower quality ratings than clinicians or policy makers using the AGREE II instrument [11]. A final potential weakness is the fact that the AGREE II instrument has not been designed specifically for surgical guidelines and compliance with all aspects of several parameters of the instrument is not always possible [43]. We support the concept of an extension to the instrument specific to surgical guidelines.

The problem of redundant and overlapping guidelines is similar to that observed in systematic reviews, where variable methodological quality and coverage result in different estimates of effect sizes for the same question [44]. There is often overlap between the scopes of different systematic reviews, without them being coterminous, because some cover broad and other narrow topic areas [45]. In our review even guidelines that were restricted to surgery had different patterns of attention, while other guidelines also covered alternative management strategies. In systematic reviews there are legitimate reasons for overlapping reviews, including differences in purpose, emergence of new evidence, concern about the robustness of previous work and differences in methodological standards. A broader scope does not necessarily equate to quality, because simple clinical guidelines can be more effective than complex guidelines [46]. Like systematic review authors [45], guideline committees should acknowledge the existence of previous or ongoing work and justify the need for new guidance. Whilst guidelines have the potential to underpin safe practice and provide safeguards for both patients and

TABLE 2 Summary of guideline variation for individual recommendations

	USA	Japan	Portugal	Italy
Classification	Grades I–IV	Goligher	Goligher Sodergren score	Goligher Nystrom score
Evaluation	Symptoms	Symptoms	Symptoms	Symptoms
	Physical examination	Physical examination	Physical examination	Physical examination
	Colonoscopy	Colonoscopy	Flexible sig/colonoscopy	Colonoscopy
Non-operative				
Lifestyle	Adequate fibre and fluid Counselling	Adequate fibre and fluid Avoid straining	Fibre and fluid Avoid straining	Fibre
Laxatives	-	-	-	Effective for symptom relief
Phlebotonics	For acute and chronic haemorrhoids	-	Recommended	Effective for symptom relief
Sitz bath	-	Recommended	Recommended in pregnancy	Recommended (weak evidence)
Topicals	-	Recommended	May be useful short term	Recommended for pregnancy
Office therapy				
Banding	Grades I–II, selective grade III	Grades I–III	Grade II, selective grade III	Grades I–III
Sclerotherapy	Grade I	Grades II–IV	Grade I	Grades I–III
Infrared coagulation	Grades I–II	-	Grades I–II	Grades I–III
Surgery				
Excisional haemorrhoidectomy	Grades III–V, open and closed	Grades III–IV, open and closed	-	Grades III and IV, open and closed
Haemorrhoidopexy	-	Grade III	-	Effective treatment
DG HAL	-	-	-	Grades II–III, possibly grade IV
Special situations				
Pregnancy	-	Careful consideration	Conservative	Conservative haemorrhoidectomy
Thrombosed external haemorrhoids	Possibly early excision	Conservative surgery if needed	Conservative surgical	Conservative excision

Note: Countries down the columns and interventions across the rows.

Abbreviations: DG-HAL, Doppler guided Haemorrhoidal artery ligation; LA, Local Anaesthetic; RBL, Rubber band ligation.

clinicians [47], expert and consensus approaches can go beyond high quality evidence, sometimes resulting in inappropriate recommendations [48]. However, evidence-based medicine demands 'the integration of best research evidence with clinical expertise and patient values' [49] while basing recommendations on small-scale or poorly designed trials without the application of expertise and patient values, leading to poor policy [50–53].

We hope that journal editors will carefully consider the need for publication of guidelines when adequate guidelines may already exist, and will ensure the guidelines that they publish follow the most rigorous standards available. Professional bodies and journal editors should consider mandatory registration of guidelines using facilities such as the Guidelines International Network library [41]

to avoid unnecessary duplication. For 'end users' we urge consideration of available high quality haemorrhoid guidance in preference to mainly national guidelines that do not meet current standards, taking into account availability and affordability in different health-care systems. Finally given the difficulties in selection of 'expert' panels we encourage further quality research in haemorrhoids to reduce the reliance on 'expert' opinion, allowing more consistent recommendations.

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SRB, DH, HTM and AC designed the review and search strategy. CG, BB, HTM and AC were involved in the acquisition of data and study selection. HTM, AC, SRB and AES extracted and synthesized



India	Europe	France	Denmark	Belgium
Novel	Goligher	Grades I–IV	Goligher	Goligher
Symptoms	Symptoms	–	Symptoms	Symptoms
Physical examination	Physical examination		Physical examination	Physical examination
Sigmoidoscopy	Endoscopy		Endoscopy	Colonoscopy
Adequate fibre and fluid	Healthy diet Sufficient water Physical activity	Fibre	Fibre	Fibre Avoid straining
Use if constipation is predominant	Effective for symptom relief	Effective for symptom relief	Recommended to soften stool	
Grades I–II and selected grade III	Reduce symptoms	Effective for symptom relief	–	May reduce bleeding Not for long term
–	–	–	Recommended	
Avoid long-term use	Pregnant and post-partum	Effective for symptom relief	Reduce symptoms	No proven effect
Grades I–II, selective grade III	Grades I–III	Grades I–II	Grade II	Grade II
Grades I–II, selective grade III	Grades I and II	Grades I and II	–	Avoid
Grades I–II, selective grade III	Grade I	Grades I–II		Grades I–II
Grades III–IV, open and closed	Grades II–IV, open and closed	All grades, open and closed	Grades III–IV, open only	Grades II–III after office therapy fails Large grade III and IV first line
Grades III–IV	Grades II–III	Grades II–III	Grades II–III	Not grade IV
Grades II–IV	Grades II–III (± mucopexy)	Grades II and III	Grades II–IV	Not grade IV
Conservative phlebotonics Surgery if needed	Conservative phlebotonics Surgery if needed	Conservative phlebotonics Surgery for severe cases	Conservative	Conservative phlebotonics Not RBL
–	Conservative Surgery can be considered	Conservative phlebotonics Excision/incision	Incision with LA	

the data, using the AGREE II guidelines. All authors contributed to drafting the paper and provided feedback and revisions. All authors approved the final version to be published.

CONFLICT OF INTEREST

The authors have no conflicts of interest to declare.

AUTHOR CONTRIBUTIONS

SB and DH conceived the project. DH developed methodology, administered, resourced and supervised the project. SB provided the first draft of the manuscript. SB,CG,HTM, AC,BB,AS DH contributed to investigation, analysis, writing, reviewing and final editing of the manuscript.

DATA AVAILABILITY STATEMENT

Data sharing is not applicable to this article as no new data were created or analysed in this study.

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SUPPORTING INFORMATION

Additional supporting information may be found in the online version of the article at the publisher's website.

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