HEMORRHOIDS

CHI Formulary Development Project

مجلس الضمان الصحي
Council of Health Insurance

INDICATION UPDATE

ADDENDUM- October 2023

To the CHI Original Hemorrhoids Clinical Guidance- Issued April 2020

Contents

Related Documents

Related SOPs

- IDF-FR-P-02-01-IndicationsReview&IDFUpdates
- IDF-FR-P-05-01-UpdatedIndicationReview&IDFUpdates

Related WI:

- IDF-FR-WI-01-01SearchMethodologyGuideForNewIndications

List of Tables

List of Figures

Abbreviations

CHI	Council of Health Insurance
CPG	Clinical Practice Guideline
DDH	Deranged Defecation Habit
DGHAL	Doppler-Guided Hemorrhoidal Artery Ligation
EMA	European Medicines Agency
FDA	Food and Drug Administration
HD	Hemorrhoids
IDF	Insurance Drug Formulary
IRC	Infrared Coagulation
IS	Injection Sclerotherapy
MPFF	Micronized Purified Flavonoid Fraction
N/A	Not Applicable/Not Available
NSAID	Non-Steroidal Anti-Inflammatory Drug
RBL	Rubber Band Ligation
RCT	Randomized Controlled Trial
SFDA	Saudi Food and Drug Authority
SH	Stapled Hemorrhoidectomy
SICCR	Italian Society of Colorectal Surgery
STARR	Stapled Trans-anal Rectal Resection
THD	Trans-anal Hemorrhoidal Dearterialization

Executive Summary

Hemorrhoids (HD), commonly known as piles, refer to enlarged and irritated veins located in the vicinity of your anus or the lower part of your rectum. There are two distinct varieties of hemorrhoids: external hemorrhoids, which develop beneath the skin surrounding the anus, and internal hemorrhoids, which emerge within the lining of the anus and the lower rectum[1].

Chances of experiencing hemorrhoids are increased if a person strains during bowel movements, prolongedly sits on the toilet, suffers from persistent constipation or diarrhea, consumes low-fiber diet, is over 50 years of age, is pregnant, or frequently engages in heavy lifting[1].

The symptoms can differ from person to person. Some of the typical signs encompass vivid red blood in the stool, discomfort and inflammation around the anus, enlargement, or a firm protrusion around the anus, and itching[2].

Globally, it is estimated that approximately 4.4% of the general population experiences symptomatic hemorrhoids[3].

According to a 2020 study about the prevalence of hemorrhoids and associated complications in the Kingdom of Saudi Arabia, it was reported that 27% of the 1172 participating respondents had hemorrhoids. Of these 27%, 32% had internal hemorrhoids, while 64% had external hemorrhoids, and 5% had thrombosed hemorrhoids, which in other terms, is the formation of a blood clot inside a hemorrhoidal vein, obstructing blood flow and causing a painful swelling of the anal tissues[4].

There are four different grades for hemorrhoids classification: Grade I: Prominent hemorrhoidal vessels, no prolapse, Grade II: Prolapsed hemorrhoids with Valsalva maneuver; spontaneously reduces, Grade III: Prolapsed hemorrhoids with Valsalva maneuver; manual reduction is required and Grade IV: Chronically prolapsed hemorrhoids; manual reduction is ineffective[5].

Treatment varies based on the severity of the hemorrhoids. In short, Grade I hemorrhoids are managed through conservative medical approaches and the avoidance of nonsteroidal anti-inflammatory drugs (NSAIDs), as well as spicy or fatty foods. Grade II or III hemorrhoids are initially addressed with non-surgical methods. Highly symptomatic Grade III and Grade IV hemorrhoids are most effectively managed with a surgical hemorrhoidectomy. The treatment of Grade IV internal hemorrhoids or any incarcerated or gangrenous tissue necessitates immediate surgical consultation[5].

CHI issued Hemorrhoids clinical guidance after thorough review of renowned international and national clinical guidelines in April 2020. Updating clinical practice guidelines (CPGs) is a crucial process for maintaining the validity of recommendations.

This report functions as an addendum to the prior CHI Hemorrhoids clinical guidance and seeks to offer guidance for the effective management of Hemorrhoids. It provides an **update on the Hemorrhoids Guidelines** for CHI Formulary with the ultimate objective of updating the IDF (CHI Drug Formulary) while addressing **the most updated best available clinical and economic evidence related to drug therapies.**

Main triggers for the update are summarized, by being the addition of **new guidelines to the report** such as the Taylor and Francis- recommendations and best practice on the management of hemorrhoidal disease in Saudi Arabia **2022**, the European Society of Coloproctology: guideline for hemorrhoidal disease **2020**, the Consensus statement of the Italian society of colorectal surgery (SICCR): management and treatment of hemorrhoidal disease **2020** and the Belgian consensus guideline on the management of hemorrhoidal disease **2021**.

After carefully examining clinical guidelines and reviewing the SFDA drug list, two medications are no longer SFDA registered: single agent cinchocaine (the combination of cinchocaine with betamethasone is still SFDA registered), as well as the combination of aluminum acetate, hydrocortisone acetate, lidocaine, and zinc oxide.

In general, corticosteroids such as hydrocortisone acetate and betamethasone are no longer recommended as part of the treatment of hemorrhoids.

All recommendations are well supported by reference guidelines, Grade of Recommendation (GoR), Level of Evidence (LoE) and Strength of Agreement (SoA) in all tables reflecting specific drug classes' role in Hemorrhoids management.

Below is a table summarizing the major changes based on the different Hemorrhoids guidelines used to issue this report:

Table 1. General Recommendations for the Management of Hemorrhoids

Management of Hemorrhoids	
General Recommendations	**Level of Evidence/Grade of Recommendation and reference**
Daily oral intake of fiber, either food or supplements, shows a consistent beneficial effect for HD symptoms	Level of evidence: 1; Grade of recommendation: B[6]

reducing the risk of bleeding, in case of an acute event	
Rubber band ligation (RBL) is the most popular non-invasive procedure and should be used for the treatment of I, II, and III-degree HD that fails conservative treatment.	Level of evidence: 1; Grade of recommendation: B[6]
Injection Sclerotherapy (IS) should be used for the treatment of I–II and III-degree HD that fail conservative treatment.	Level of evidence: 1; Grade of recommendation: B[6]
Infrared Coagulation (IRC) should be used for the treatment of I-II and III-degree HD that fail conservative treatment.	Level of evidence: 1; Grade of recommendation: B[6]
Pregnancy: In pregnant and postpartum women basic treatment (i.e., laxatives, topical treatments, phlebotonics and analgesics) should be used.	Expert opinion[7]
Pregnancy: In pregnant and postpartum women with thrombosed hemorrhoids unresponsive to basic treatment, surgical procedures to treat thrombosis can be considered.	Expert opinion[7]
Conservative treatment: Topical preparations such as creams, ointments, and suppositories should be limited. For oral preparation, micronized purified flavonoid fraction (MPFF) are the most common phlebotonic agent used for treating non-complicated Grade I and II hemorrhoidal disease.	N/A[8]
Conservative treatment: Other existing venoactive drugs like calcium dobesilate, heparan sulfate, Euphorbia prostrata, and ginkgo biloba have a low level of evidence in the management of hemorrhoidal disease. Stool softeners must be used.	N/A[8]

At the end of the report, a **key recommendation synthesis section** is added highlighting the latest updates in **Hemorrhoids clinical and therapeutic management.**

Section 1.0 Summary of Reviewed Clinical Guidelines and Evidence

This section is divided into two parts: the first includes recommendations from **updated versions of guidelines** mentioned in the previous CHI Hemorrhoids report, while the second includes **newly added guidelines** that have helped generate this report.

1.1 Revised Guidelines

This section contains the **updated versions** of the guidelines mentioned in the April 2020 CHI Hemorrhoids Report and the corresponding recommendations:

Table 2. Guidelines Requiring Revision

Guidelines requiring revision	
Old versions	**Updated versions**
The American Society of Colon and Rectal Surgeons Clinical Practice Guidelines for the Management of Hemorrhoids (2018)	N/A*
American Hemorrhoids: Diagnosis and Treatment Options- American Academy of Family Physicians (2018)	N/A*

*: No updated version available: the existing version is the most recent one and no further updates or revisions have been made or released.

1.2 Additional Guidelines

This part includes the added guidelines to the previous CHI Hemorrhoids report, along with their recommendations.

Table 3. List of Additional Guidelines

Additional Guidelines
Recommendations and Best Practice on the Management of Hemorrhoidal Disease in **Saudi Arabia** (**2022**)[8]
European Society of Coloproctology: Guideline for Hemorrhoidal Disease (2020)[7]

Consensus Statement of the **Italian Society of Colorectal Surgery** (SICCR): Management and Treatment of Hemorrhoidal Disease (**2020**)[6]
Belgian Consensus Guideline on the Management of Hemorrhoidal Disease (**2021**)[9]

1.2.1 Recommendations and Best Practice on the Management of Hemorrhoidal Disease in Saudi Arabia (2022)

To develop consensus recommendations that ensure the best possible diagnosis and treatment of hemorrhoidal disease in Saudi Arabia, the consensus panel consisted of experts in surgery in Saudi Arabia. The main recommendations are summarized below[8]:

Recommendations for dietary and lifestyle modifications:

- Dietary and lifestyle modifications should be used as a first-line treatment which includes:
    1. Having regular physical activity.
    2. Rule of the 4Fs:
        - Drinking enough **f**luids.
        - Having a regular mealtime with food rich in fibers: **f**resh vegetables and **f**ruits.
        - Having regular exercise (**f**itness and feet).
- Deranged defecation habit (DDH) can be corrected with the help of the 'TONE' mnemonic. TONE entails specifying exact treatment goals: T, three minutes at defecation; O, once-a-day defecation frequency; N, no straining during passing motions; E, enough fiber.
- Having a regular bowel habit with non-straining defecation:
    - Insisting on having at least one bowel movement daily.
    - Neglecting the first urge to defecate.
    - Insisting on trying to pass the last portion of stool from the rectum or anal canal.
    - Ensuring proper positioning during defecation.

Recommendations for medical treatments:

- Hemorrhoidal disease and not only hemorrhoid is treated.

Conservative/basic treatment:

- Topical preparations such as creams, ointments, and suppositories should be limited as the published literature lacks strong evidence supporting the true efficacy of topical treatment for symptomatic hemorrhoidal disease.
- For oral preparation, micronized purified flavonoid fraction (MPFF) are the most common phlebotonic agent used for treating non-complicated Grade I and II hemorrhoidal disease. MPFF has been proven to improve venous tone, reduce capillary fragility, decrease capillary permeability, facilitate lymphatic drainage, and has anti-inflammatory effects.
    - MPFF also serves as an effective adjuvant to surgery and other procedures (during the pre- and post-operative periods)
    - Flavonoids should be considered during the referral period from general physicians to specialists, especially in public hospitals, which might be for one month.
    - Other existing venoactive drugs like calcium dobesilate, heparan sulfate, Euphorbia prostrata, and ginkgo biloba have a low level of evidence in the management of hemorrhoidal disease. Calcium dobesilate has been associated with an increased risk of agranulocytosis.
- Stool softeners must be used.

Recommendations for outpatient procedures:

- Persons with Grade I or II hemorrhoidal disease can undergo outpatient procedures after failure of medical and conservative measures.
- Persons with Grade III or IV hemorrhoidal disease can also undergo outpatient procedures if they refuse surgery interventions or in case of contraindication to anesthesia.
- The selection of the procedure depends on the doctor's experience, patient's preferences, and available resources in the medical center.
    1. Laser hemorrhoidoplasty is a minimal invasive procedure determining the shrinkage of the hemorrhoidal piles by diode laser. It can be performed in Grade II and III hemorrhoidal disease. It does not involve any special anal hygienic measures. In parallel, it induces low postoperative pain and slightly significant peri-anal wounds, resulting in negligible postoperative discomfort.
    2. Hemorrhoid banding, also called rubber band ligation, can be performed as a last resort in Grade I and II and in selected cases of Grade III hemorrhoidal disease, when symptomatic and after failure of medical and conservative measures.

3. Infrared photocoagulation is used in bleeding Grade I hemorrhoidal disease.
4. Injectable sclerotherapy can be done in Grade I or II hemorrhoidal disease.

Recommendations for surgical procedures:

- In case of failure of conservative treatment, a safe anal surgery should be performed according to the grade of the hemorrhoidal disease, available medical resources, patient's fitness and preferences, and surgeon's experience.
- The existence of several procedures for one pathology means that none is completely effective yet.
    1. Hemorrhoidectomy can be used in patients with Grade I to III hemorrhoidal disease who failed the outpatient procedures. It is also indicated in circumferential prolapsing Grade III and IV hemorrhoidal disease.
    2. Doppler-guided hemorrhoidal artery ligation (DG-HAL)/transanal hemorrhoidal dearterialization (THD) can be done with or without mucopexy. It can be used in patients with Grade II and III hemorrhoidal disease, is effective and safe.
    3. Stapled hemorrhoidopexy can be used in patients with Grade II and III hemorrhoidal disease or in hemorrhoid refractory to outpatient procedures. This technique requires special expertise to avoid major complications.
    4. New surgical procedures like stapled hemorrhoidopexy and DG-HAL are more effective with less side effects than classic open hemorrhoidectomies as the new procedures are done above the dentate line and cause less pain and less complications.
    5. Surgical hemorrhoidectomy results in fewer recurrences than stapled hemorrhoidopexy.
    6. Lord's manual dilatation must be avoided as it might lead to fecal incontinence, and it is not related to any evidence-base practice.

Recommendations for post-operative treatments and practice:

- Lifestyle modifications (same as above).
- Avoiding constipation.
- Using MPFF (e.g., Daflon 500 mg) to decrease pain and recurrence.

- Using combined analgesia for 5 days of paracetamol, non-steroidal anti-inflammatory drugs, and opioids.
- Using laxatives to ensure a soft and regular bowel movement.
- Post-operative rehabilitation for wound healing and improving the quality of life of patients with defecation problems, starting with patient reeducation on muscular synergy (chest, abdomen, vertebral column, and perineum).

1.2.2 European Society of Coloproctology: Guideline for Hemorrhoidal Disease (2020)

The recommendations of the European society of coloproctology are listed below[7]:

Table 4. European Society of Coloproctology Level of Evidence

Level of evidence	Implementation
High evidence	The term 'must' was implemented
Moderate evidence	The term 'should or could' was implemented
Low evidence	The term 'could or may' was implemented
Very low evidence	The term 'can be considered' was implemented

- Inspection and physical examination of the anorectal region **should** be performed to exclude other anorectal pathology. - Expert opinion
- A procedure (e.g., rigid anoscope, proctoscope or rectoscope) to visualize the entire anal canal **must** be performed to diagnose and to classify the severity of HD and to exclude other anal pathology. - Expert opinion
- If a provisional diagnosis of HD has been made, basic treatment (i.e., toilet training, laxatives, local anesthetics and phlebotonics) **can** be started. Patients with refractory symptoms **should** be referred. - Expert opinion
- Healthy lifestyle measures, such as sufficient water intake, a healthy diet and physical activity **should** be encouraged. - Expert opinion
- Toilet training, including adopting the correct body position during defecation **should** be advised. Straining and prolonged defecations sessions **should** be avoided. - Expert opinion
- The use of laxatives **could** be considered for symptom relief and to reduce bleeding. (Low level of evidence)

- Phlebotonics **could** contribute to symptom reduction. (Low level of evidence)
- Nonsteroidal anti-inflammatory drugs (NSAIDs) and non-opioid analgesics **could** be prescribed for pain. Expert opinion.
- Choice of the outpatient procedure (i.e., RBL, injection sclerotherapy (IS) and IRC) **should** be informed by shared decision-making, considering patient preferences, availability of procedures and fitness for further procedures. Expert opinion, upgraded by the GDG.
- RBL **should** be performed in Grade I–III HD. Repeat banding may be necessary. (Moderate level of evidence)
- IRC **could** be used as the first option in bleeding Grade I hemorrhoids. (Low level of evidence.)
- IS **could** be used in patients with Grade I–II HD. (Low level of evidence)
- DG-HAL +/- mucopexy **could** be used in patients with Grade II–III hemorrhoids 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)
- Stapled hemorrhoidopexy **could** be used in patients with Grade II– III hemorrhoids and/or in patients who are refractory to outpatient procedures. (Low level of evidence)
- Hemorrhoidectomy **could** be used in patients with Grade II–III hemorrhoids and/or **should** be used in patients who are refractory to outpatient procedures. (Moderate level of evidence)
- Hemorrhoidectomy **should** be used for Grade IV hemorrhoids. (Moderate level of evidence)
- Primarily, basic treatment (i.e., toilet training, laxatives, NSAIDs and non-opioid analgesics) **can be considered** in patients with thrombosed hemorrhoids (expert opinion). Phlebotonics **could** be considered in patients with thrombosed hemorrhoids (low level of evidence). In selected cases, surgical options **may be discussed** with the patient. (Very low level of evidence)
- Surgical procedures (i.e., SH and hemorrhoidectomy) **can be considered** in patients with thrombosed hemorrhoids. (Very low level of evidence)
- Outpatient procedures (including RBL and IS) in immunocompromised patients seem to be safe, but very limited data is available. (Very low level of evidence.)

Pregnancy population:

- In pregnant and postpartum women basic treatment (i.e., laxatives, topical treatments, phlebotonics and analgesics) **should** be used. Expert opinion
- In pregnant and postpartum women with thrombosed hemorrhoids unresponsive to basic treatment, surgical procedures to treat thrombosis **can be considered**. Expert opinion.
- 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)
- Both closed and open hemorrhoidectomy (not using energy devices) **could** be used (low level of evidence). Closed hemorrhoidectomy is associated with less pain and bleeding. (Low level of evidence)
- Surgical energy devices (LigaSure and Harmonic scalpel) **could** be used for hemorrhoidectomy. (Low level of evidence)
- Alternative procedures (laser and radiofrequency ablation procedures) **could** be used/can be considered. (Low level of evidence)
- Rectal resection using a stapler device [including stapled transanal rectal resection (STARR)] **should** not be used to treat hemorrhoids. (Low level of evidence, downgraded by the experts)

1.2.3 Consensus Statement of the Italian Society of Colorectal Surgery (SICCR): Management and Treatment of Hemorrhoidal Disease (2020)

The recommendations of the Italian society of colorectal surgery are listed below[6]:

Table 5. Grades of Recommendation, Assessment, Development, and Evaluation System Grading Recommendations

Class	Description	Benefit vs risk and burdens	Methodological quality of supporting evidence	Implications
1A	Strong recommendation, high-quality evidence	Benefits clearly outweigh risk and burdens or vice versa	RCTs without important limitations or overwhelming evidence from observational studies	Strong recommendation, can apply to most patients in most circumstances without reservation

1B	Strong recommendation, moderate-quality evidence	Benefits clearly outweigh risk and burdens or vice versa	RCTs with important limitations (inconsistent results, methodological flaws, indirect or imprecise) or exceptionally strong evidence from observational studies	Strong recommendation, can apply to most patients in most circumstances without reservation
1C	Strong recommendation, low- or very-low-quality evidence	Benefits clearly outweigh risk and burdens or vice versa	Observational studies or case series	Strong recommendation but may change when higher quality evidence becomes available
2A	Weak recommendation, high-quality evidence	Benefits closely balanced with risks and burdens	RCTs without important limitations or overwhelming evidence from observational studies	Weak recommendation, best action may differ depending on circumstances or patient or societal values
2B	Weak recommendations, moderate-quality evidence	Benefits closely balanced with risks and burdens	RCTs with important limitations (inconsistent results, methodological flaws, indirect or imprecise) or exceptionally strong evidence from observational studies	Weak recommendation, best action may differ depending on circumstances or patients' or societal values

2C	Weak recommendation, low- or very-low quality evidence	Uncertainty in the estimates of benefits, risks, and burden; benefits, risks, and burden may be closely balanced	Observational studies or case series	Very weak recommendations: other alternatives may be equally reasonable

1. **Conservative treatments**

Fiber and/or laxatives:

Daily oral intake of fiber, either food or supplements, shows a consistent beneficial effect for HD symptoms reducing the risk of bleeding, in case of an acute event, and as the risk of not improving symptoms in about 50% and 47% of patients, respectively. Several trials show a lack of evidence regarding a direct effect on prolapse, pain and itching (Level of evidence: 1; Grade of recommendation: B).

Sitz bath:

There is a lack of RCTs defining the role of sitz bath with warm water in the treatment of HD-related pain (Level of evidence 2; Grade of recommendation C).

Phlebotonics:

Phlebotonics has a statistically significant effect on HD-related symptoms (bleeding, pain, itching, and symptoms recurrence) if compared with a control group (Level of evidence: 1; Grade of recommendation: B).

2. **Outpatient treatments**

Rubber band ligation (RBL)

RBL is the most popular non-invasive procedure and should be used for the treatment of I, II, and III-degree HD that fails conservative treatment (Level of evidence: 1; Grade of recommendation: B).

Sclerotherapy

Injection Sclerotherapy (IS) should be used for the treatment of I–II and III-degree HD that fail conservative treatment (Level of evidence: 1; Grade of recommendation: B)

Infrared coagulation

Infrared Coagulation (IRC) should be used for the treatment of I-II and III-degree HD that fail conservative treatment (Level of evidence: 1; Grade of recommendation: B)

3. Non-excisional procedures

Stapled hemorrhoidopexy

SH is an effective technique for the treatment of HD. When compared with conventional hemorrhoidectomy, SH is associated with less operating time, earlier return of bowel function, shorter hospital stays, less pain, a faster functional recovery with shorter time of work, an earlier return to normal activities, and better wound healing (Level of evidence 1; Grade of recommendation: A). However, the incidence of recurrence and the need for additional operations are also significantly higher when compared to conventional hemorrhoidectomy (Level of evidence 1; Grade of recommendation: A).

Transanal hemorrhoidal dearterialization (THD) or Doppler-guided hemorrhoidal artery ligation (DGHAL) THD or DGHAL is a treatment option for II- and III-degree hemorrhoids and in experienced hands possibly also for IV degree (Level of evidence: 1; Grade of recommendation: A).

THD/DGHAL is associated with decreased postoperative pain, reduced postoperative events, and faster recovery than excisional hemorrhoidectomy, but carries higher recurrence rates (Level of evidence: 1; Grade of recommendation: A).

4. Excisional procedures

Excisional hemorrhoidectomy

The traditional excisional methods (Milligan-Morgan, Ferguson procedures) remain the first choice and the most common indication for symptomatic III- and IV-degree HD (Level of evidence: 1; Grade of recommendation: A).

5. Management of HD in special conditions

Pregnancy

Patients with I- and II-degree HD may benefit from oral rutosides for symptom relief. However, their use cannot be recommended until new evidence about their safety is available (Level of evidence: 1; Grade of recommendation: B)

Conservative treatment for prolapsed thrombosed internal hemorrhoids, if compared with urgent hemorrhoidectomy, is associated with a shorter inpatient stay and less anal sphincter damage than operative treatment (Level of evidence: 1; Grade of recommendation: B)

SH is a feasible treatment for selected patients with an acute hemorrhoidal crisis and has a similar complication rate if compared with a conventional excisional hemorrhoidectomy. SH is associated with less postoperative pain, shorter operation time, a shorter hospital stays, and an earlier return to normal activities (Level of evidence: II; Grade of recommendation: B

Immunosuppressed patients

Even if the indications for hemorrhoidectomy in patients with AIDS need to be considered extremely carefully because of the high incidence of delayed wound healing, nowadays, there is no significant increase in complication rate for patients with a low CD4+T-cell count (level of evidence 1: grade of recommendation C)

1.2.4 Belgian Consensus Guideline on the Management of Hemorrhoidal Disease (2021)

The recommendations of the Belgian guidelines are listed below[9]:

Table 6. Grade System Used to Score the Strength of Evidence

Grade	Statement
High (A)	We are very confident that the true effect lies close to that of the estimate of the effect.
Moderate (B)	We are moderately confident in the effect estimate: The true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different.
Low (C)	Our confidence in the effect estimate is limited: The true effect may be substantially different from the estimate of the effect.
Very low (D)	We have very little confidence in the effect estimate: The true effect is likely to be substantially different from the estimate of effect.

Risk Factors

1. The most important risk factors to develop hemorrhoidal disease are straining, constipation, diarrhea, pregnancy, and obesity. (100% agreement- grade C)

Treatment of symptomatic hemorrhoids: general approach

2. Every treatment for symptomatic hemorrhoids should be tailored to patient profile and expectations. (100% agreement- grade D)

Conservative treatment

3. Fiber therapy improves hemorrhoidal symptoms and bleeding in grade I-II hemorrhoids. (85% agreement- grade A)
4. Topical treatment has no proven effect in the treatment of hemorrhoidal disease. (92% agreement- grade B)

5. Venotropics can influence bleeding in symptomatic hemorrhoids. (83% agreement- grade A)
6. There is no rationale for long-term treatments with venotropics; their use is recommended in acute hemorrhoidal disease for a short period. (92% agreement- grade D)
7. Venotropics have no proven effect on hemorrhoidal thrombosis and should not be used for this indication. (92% agreement- grade B)

Instrumental therapy

8. IR coagulation is indicated in grade 1 or 2 symptomatic hemorrhoids not responding to conservative treatment. (100% agreement- grade A)
9. Sclerosing injections can cause severe adverse events, are not superior to IR coagulation and should therefore be avoided. (83% agreement- grade B)
10. Rubber band ligation (RBL) should be placed just proximal to the hemorrhoid. (Agreement 100%- grade D)
11. RBL can be used for grade 2 to 3 internal hemorrhoids. (92% agreement- grade A)
12. For grade 2 hemorrhoids, rubber band ligation seems the logical first choice of treatment. (92% agreement- grade A)

Surgical therapy

13. Surgical treatment of hemorrhoids can be proposed after failure of medical and instrumental treatments (infra-red, sclerosis, elastic band ligations) for grade 2 and 3 hemorrhoidal disease. (92% agreement- grade A)
14. Surgery is indicated as first line therapy for grade 4 and large grade 3 hemorrhoids. (100% agreement- grade A)
15. Surgery is indicated for acute complications (pain/necrosis/thrombosis) if conservative therapy fails. (92% agreement- grade D)
16. Surgery is indicated for hemorrhoidal bleeding resulting in severe and otherwise unexplained anemia, irrespective of the anatomical stage of disease. (85% agreement- grade D)
17. Surgery is indicated for symptomatic internal hemorrhoids that are associated with symptomatic external hemorrhoidal disease resistant to conservative therapy: recurrent external hemorrhoidal thrombosis resistant to conservative therapy or bothersome hypertrophic tags. (92% agreement-grade D)
18. Conventional hemorrhoidectomy is the gold standard in surgical therapy for grade 3-4 hemorrhoids. (100% agreement-grade A)

19. Compared to rubber band ligation conventional hemorrhoidectomy has a superior long-term efficacy for grade 3 hemorrhoids at the cost of more side effects. (100% agreement-grade A)
20. Conventional hemorrhoidectomy is the preferred procedure for noncircumferential hemorrhoids and in case of concomitant bothersome external hemorrhoids/skin tags. (92% agreement-grade D)
21. Stapled hemorrhoidopexy is associated with less pain and faster recovery compared to conventional hemorrhoidectomy but suffers from higher recurrence rates. (100% agreement-grade A)
22. Doppler-guided hemorrhoidal artery ligation has a significantly higher persistence/recurrence rate compared to stapled hemorrhoidopexy. (Agreement 92%- grade A)
23. Stapled hemorrhoidopexy and Doppler-guided hemorrhoidal artery ligation are not recommended in cases of grade 4 hemorrhoidal disease. (100% agreement- grade B)

Specific conditions

24. During pregnancy, conservative options are treatment of choice and hemorrhoidal disease should be reevaluated after delivery. (100% agreement-grade C)
25. Venotropics are probably safe during pregnancy, safety during lactation is unknown. (100% agreement- grade C)
26. IR coagulation should be avoided during pregnancy. (85% agreement- grade B)
27. Pregnancy is an absolute contraindication for rubber band ligation. (92% agreement- grade B)
28. Rubber band ligation can safely be performed in compensated liver cirrhosis (Child-Pugh A). (85% agreement- grade C)

Section 2.0 Drug Therapy

This section comprises three subsections: the first one contains the newly recommended drugs SFDA registered, the second one covers drug modifications, the third one outlines the drugs that have been withdrawn from the market.

2.1 Additions

After April 2020, there have been no new drugs that have received FDA and EMA approval and are SFDA registered for hemorrhoidal disease treatment.

2.2 Modifications

No modifications were made to the drugs mentioned in the previous hemorrhoids report.

2.3 Delisting

Please refer to ***section 2.1.7*** *in the* **CHI Hemorrhoids original clinical guidance**

Cinchocaine is delisted from the market.

Please refer to ***section 2.4.1*** *in* **CHI Hemorrhoids original clinical guidance**

The combination of aluminum acetate, hydrocortisone acetate, lidocaine, and zinc oxide is delisted from the market.

Table 7. Delisted Medications

Delisted medications	Reason	Medication status	Alternative
Topical Cinchocaine (Single agent)	Withdrawn from SFDA	No longer used in Saudi. The guidelines do mention: If a provisional diagnosis of HD has been made, basic treatment (i.e., toilet training, laxatives, local anesthetics and phlebotonics) can be started[7]. Other local anesthetics are found on the market.	Topical Lidocaine (Single agent)
Topical	Withdrawn from SFDA	No guidelines recommend the use of corticosteroids	Topical Aluminum

Aluminum acetate, hydrocortisone acetate, lidocaine, zinc oxide (Combination)			actetate, lidocaine, prednisolone, ruscus extr, zinc oxide (Combination)

Section 3.0 Key Recommendations Synthesis

Healthy lifestyle measures, such as sufficient water intake, a healthy diet and physical activity should be encouraged (expert opinion)[7].

Toilet training, including adopting the correct body position during defecation should be advised. Straining and prolonged defecations sessions should be avoided (expert opinion)[7].

Choice of the outpatient procedure (i.e., RBL, injection SCL and IRC) should be informed by shared decision-making, considering patient preferences, availability of procedures and fitness for further procedures (expert opinion, upgraded by the GDG)[7].

RBL should be performed in Grade I–III HD. Repeat banding may be necessary (moderate level of evidence)[7].

IRC could be used as the first option in bleeding Grade I hemorrhoids (low level of evidence)[7].

IS could be used in patients with Grade I–II HD (low level of evidence).

DG-HAL +/- mucopexy could be used in patients with Grade II–III hemorrhoids and/or in patients who are refractory to outpatient procedures (low level of evidence)[7].

In pregnant and postpartum women basic treatment (i.e., laxatives, topical treatments, phlebotonics and analgesics) should be used (expert opinion)[7].

In pregnant and postpartum women with thrombosed hemorrhoids unresponsive to basic treatment, surgical procedures to treat thrombosis can be considered (expert opinion)[7].

Section 4.0 Conclusion

This report serves as **an annex to the previous CHI Hemorrhoids report** and aims to provide recommendations to aid in the management of Hemorrhoids. It is important to note that these recommendations should be utilized to support clinical decision-making and not replace it in the management of individual patients with

hemorrhoids. Health professionals are expected to consider this guidance alongside the specific needs, preferences, and values of their patients when exercising their judgment.

Section 5.0 References

1. Johns Hopkins. definition of hemorrhoids. Published online 2016. Accessed August 23, 2023. https://www.niddk.nih.gov/health-information/digestive-diseases/hemorrhoids/definition-facts#:~:text=complications%20of%20hemorrhoids%3F-,What%20are%20hemorrhoids%3F,the%20anus%20and%20lower%20rectum
2. John Hopkins. signs of hemhorroids. Accessed August 23, 2023. https://www.hopkinsmedicine.org/health/conditions-and-diseases/hemorrhoids
3. medscape. hemorrhoids prevalence worldwide . Published online 2022. Accessed September 1, 2023. https://emedicine.medscape.com/article/775407-overview#:~:text=Worldwide%2C%20the%20prevalence%20of%20symptomatic,million%20related%20prescriptions%20per%20year.
4. Ahmad Al Ghamdi M, Jehad Abousada H, Mohammed Awadh Al Qahtani S, et al. PREVALENCE OF HEMORRHOIDS AND ASSOCIATED COMPLICATIONS IN KINGDOM OF SAUDI ARABIA. *Int J Adv Res (Indore)*. 2020;8(1):55-67. doi:10.21474/IJAR01/10267
5. medscape. grades of hemhorroids. Published online 2022. Accessed September 7, 2023. https://emedicine.medscape.com/article/775407-clinical
6. Gallo G, Martellucci J, Sturiale A, et al. Consensus statement of the Italian society of colorectal surgery (SICCR): management and treatment of hemorrhoidal disease. *Tech Coloproctol*. 2020;24(2):145-164. doi:10.1007/s10151-020-02149-1
7. van Tol RR, Kleijnen J, Watson AJM, et al. European Society of ColoProctology: guideline for haemorrhoidal disease. *Colorectal Disease*. 2020;22(6):650-662. doi:10.1111/codi.14975
8. El-Kelani MZ, Kerdahi R, Raghib S, et al. Recommendations and best practice on the management of hemorrhoidal disease in Saudi Arabia. *Hosp Pract*. 2022;50(2):104-109. doi:10.1080/21548331.2022.2042150
9. De Schepper H, Coremans G, Denis MA, et al. *Belgian Consensus Guideline on the Management of Hemorrhoidal Disease*.

Section 6.0 Appendices

Appendix A. Prescribing Edits Definition

I. Prescribing Edits (ensure consistent use of abbreviations, e.g., CU, ST)

Some covered drugs may have additional requirements, rules, or limits on coverage. These requirements and limits may include:

Prescribing edits Tools	Description
AGE (Age):	Coverage may depend on patient age
CU (Concurrent Use):	Coverage may depend upon concurrent use of another drug
G (Gender):	Coverage may depend on patient gender
MD (Physician Specialty):	Coverage may depend on prescribing physician's specialty or board certification
PA (Prior Authorization):	Requires specific physician request process
QL (Quantity Limits):	Coverage may be limited to specific quantities per prescription and/or time
ST (Step Therapy):	Coverage may depend on previous use of another drug
EU (Emergency Use only):	This drug status on Formulary is only for emergency use
PE (Protocol Edit):	Use of drug is dependent on protocol combination, doses, and sequence of therapy

Appendix B. Hemorrhoids Scope

Section	Rationale/Updates

Taylor and Francis-recommendations and best practice on the management of hemorrhoidal disease in Saudi Arabia 2022[8]	**Recommendations for dietary and lifestyle modifications:**
	• Dietary and lifestyle modifications should be used as a first-line treatment which includes:
	  ○ (1) Having regular physical activity.
	  ○ (2) Rule of the 4Fs:
	  ▪ Drinking enough **f**luids.
	  ▪ Having a regular mealtime with food rich in fibers: **f**resh vegetables and **f**ruits.
	  ▪ Having regular exercise (**f**itness and feet).
	• Deranged defecation habit (DDH) can be corrected with the help of the 'TONE' mnemonic. TONE entails specifying exact treatment goals: T, three minutes at defecation; O, once-a-day defecation frequency; N, no straining during passing motions; E, enough fiber.
	• Having a regular bowel habit with non-straining defecation:
	  ○ Insisting on having at least one bowel movement daily.
	  ○ Neglecting the first urge to defecate.
	  ○ Insisting on trying to pass the last portion of stool from the rectum or anal canal.
	  ○ Ensuring proper positioning during defecation.
	
	Recommendations for medical treatments:
	• Hemorrhoidal disease and not only hemorrhoid is treated.
	• <u>Conservative/basic treatment</u>:
	Topical preparations such as creams, ointments, and suppositories should be limited as the published literature lacks strong evidence supporting the true efficacy of topical treatment for symptomatic hemorrhoidal disease.
	For oral preparation, micronized purified flavonoid fraction (MPFF) are the most common phlebotonic agent used for treating non-complicated Grade I and II hemorrhoidal disease. MPFF has been proven to improve venous tone, reduce capillary fragility, decrease capillary permeability, facilitate lymphatic drainage, and has anti-inflammatory effects.

	• MPFF also serves as an effective adjuvant to surgery and other procedures (during the pre- and post-operative periods) • Flavonoids should be considered during the referral period from GPs to specialists, especially in public hospitals, which might be for one month. • Other existing venoactive drugs like calcium dobesilate, heparan sulfate, Euphorbia prostrata, and ginkgo biloba have a low level of evidence in the management of hemorrhoidal disease. Calcium dobesilate has been associated with an increased risk of agranulocytosis. Stool softeners must be used. **Outpatient procedures:** • Persons with Grade I or II hemorrhoidal disease can undergo outpatient procedures after failure of medical and conservative measures. • Persons with Grade III or IV hemorrhoidal disease can also undergo outpatient procedures if they refuse surgery interventions or in case of contraindication to anesthesia. • The selection of the procedure depends on the doctor's experience, patient's preferences, and available resources in the medical center. o (1) Laser hemorrhoidoplasty is a minimal invasive procedure determining the shrinkage of the hemorrhoidal piles by diode laser. It can be performed in Grade II and III hemorrhoidal disease. It does not involve any special anal hygienic measures. In parallel, it induces low postoperative pain and slightly significant peri-anal wounds, resulting in negligible postoperative discomfort. o (2) Hemorrhoid banding, also called rubber band ligation, can be performed as a last resort in Grade I and II and in selected cases of Grade III hemorrhoidal disease, when symptomatic and after failure of medical and conservative measures. o (3) Infrared photocoagulation is used in bleeding Grade I hemorrhoidal disease. o (4) Injectable sclerotherapy can be done in Grade I or II hemorrhoidal disease. **Surgical procedures:** • In case of failure of conservative treatment, a safe anal surgery should be performed according to the grade

	of the hemorrhoidal disease, available medical resources, patient's fitness and preferences, and surgeon's experience.
	• The existence of several procedures for one pathology means that none is completely effective yet.
	  ○ (1) Hemorrhoidectomy can be used in patients with Grade I to III hemorrhoidal disease who failed the outpatient procedures. It is also indicated in circumferential prolapsing Grade III and IV hemorrhoidal disease.
	  ○ (2) Doppler-guided hemorrhoidal artery ligation (DG-HAL)/transanal hemorrhoidal dearterialization (THD) can be done with or without mucopexy. It can be used in patients with Grade II and III hemorrhoidal disease, is effective and safe.
	  ○ (3) Stapled hemorrhoidopexy can be used in patients with Grade II and III hemorrhoidal disease or in hemorrhoid refractory to outpatient procedures. This technique requires special expertise to avoid major complications.
	  ○ (4) New surgical procedures like stapled hemorrhoidopexy and DG-HAL are more effective with less side effects than classic open hemorrhoidectomies as the new procedures are done above the dentate line and cause less pain and less complications.
	  ○ (5) Surgical hemorrhoidectomy results in fewer recurrences than stapled hemorrhoidopexy.
	  ○ (6) Lord's manual dilatation must be avoided as it might lead to fecal incontinence, and it is not related to any evidence-base practice.
	
	Post-operative treatments and practice:
	• Lifestyle modifications (same as above).
	• Avoiding constipation.
	• Using MPFF (e.g., Daflon 500 mg) to decrease pain and recurrence.
	• Using combined analgesia for 5 days of paracetamol, non-steroidal anti-inflammatory drugs, and opioids.
	• Using laxatives to ensure a soft and regular bowel movement.
	• Post-operative rehabilitation for wound healing and improving the quality of life of patients with defecation problems, starting with patient reeducation on muscular synergy (chest, abdomen, vertebral column, and perineum).

European Society of ColoProctology: guideline for haemorrhoidal disease [7]	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.' **29.** Inspection and physical examination of the anorectal region should be performed to exclude other anorectal pathology. - Expert opinion **30.** A procedure (e.g., rigid anoscope, proctoscope or rectoscope) to visualize the entire anal canal must be performed to diagnose and to classify the severity of HD and to exclude other anal pathology. - Expert opinion **31.** If a provisional diagnosis of HD has been made, basic treatment (i.e., toilet training, laxatives, local anesthetics and phlebotonics) can be started. Patients with refractory symptoms should be referred. - Expert opinion **32.** Healthy lifestyle measures, such as sufficient water intake, a healthy diet and physical activity should be encouraged. - expert opinion **33.** Toilet training, including adopting the correct body position during defecation should be advised. Straining and prolonged defecations sessions should be avoided. - expert opinion **34.** The use of laxatives could be considered for symptom relief and to reduce bleeding. Low level of evidence **35.** Phlebotonics could contribute to symptom reduction. Low level of evidence. **36.** Nonsteroidal anti-inflammatory drugs (NSAIDs) and non-opioid analgesics could be prescribed for pain. Expert opinion. **37.** Choice of the outpatient procedure (i.e., RBL, injection SCL and IRC) should be informed by shared decision-making, considering patient preferences, availability of procedures and fitness for further procedures. Expert opinion, upgraded by the GDG. **38.** RBL should be performed in Grade I–III HD. Repeat banding may be necessary. Moderate level of evidence. **39.** IRC could be used as the first option in bleeding Grade I hemorrhoids. Low level of evidence. **40.** Injection SCL could be used in patients with Grade I–II HD. Low level of evidence. **41.** DG-HAL +/- mucopexy could be used in patients with Grade II–III hemorrhoids 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. **42.** SH could be used in patients with Grade II– III hemorrhoids and/or in patients who are refractory to outpatient procedures. Low level of evidence. **43.** Hemorrhoidectomy could be used in patients with Grade II–III hemorrhoids and/or should be used in patients who are refractory to outpatient procedures. Moderate level of evidence. **44.** Hemorrhoidectomy should be used for Grade IV hemorrhoids. Moderate level of evidence. **45.** Primarily, basic treatment (i.e., toilet training, laxatives, NSAIDs and non-opioid analgesics) can be considered in patients with thrombosed hemorrhoids (expert opinion). Phlebotonics could be considered in patients with thrombosed hemorrhoids (low level of evidence). In selected cases, surgical options may be discussed with the patient. Very low level of evidence. **46.** Surgical procedures (i.e., SH and hemorrhoidectomy) can be considered in patients with thrombosed hemorrhoids. Very low level of evidence. **47.** Outpatient procedures (including RBL and SCL) in immunocompromised patients seem to be safe, but very limited data is available. Very low level of evidence. **Pregnancy:** **48.** In pregnant and postpartum women basic treatment (i.e., laxatives, topical treatments, phlebotonics and analgesics) should be used. Expert opinion **49.** In pregnant and postpartum women with thrombosed hemorrhoids unresponsive to basic treatment, surgical procedures to treat thrombosis can be considered. Expert opinion. **50.** 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. **51.** Both closed and open hemorrhoidectomy (not using energy devices) could be used (low level of evidence). Closed hemorrhoidectomy is associated with less pain and bleeding. Low level of evidence. **52.** Surgical energy devices (LigaSure and Harmonic scalpel) could be used for hemorrhoidectomy. Low level of evidence **53.** Alternative procedures (laser and radiofrequency ablation procedures) could be used/can be considered. Low level of evidence.

	54. Rectal resection using a stapler device [including stapled transanal rectal resection (STARR)] should not be used to treat hemorrhoids. Low level of evidence, downgraded by the experts.
Consensus statement of the Italian society of colorectal surgery (SICCR): management and treatment of hemorrhoidal disease[6]	**55. Conservative treatments** **Fiber and/or laxatives:** Daily oral intake of fiber, either food or supplements, shows a consistent beneficial effect for HD symptoms reducing the risk of bleeding, in case of an acute event, and as the risk of not improving symptoms in about 50% and 47% of patients, respectively. Several trials show a lack of evidence regarding a direct effect on prolapse, pain and itching (Level of evidence: 1; Grade of recommendation: B). **Sitz bath:** There is a lack of RCTs defining the role of sitz bath with warm water in the treatment of HD-related pain (Level of evidence 2; Grade of recommendation C). **Phlebotonics:** Phlebotonics has a statistically significant effect on HD-related symptoms (bleeding, pain, itching, and symptoms recurrence) if compared with a control group (Level of evidence: 1; Grade of recommendation: B). **Outpatient treatments:** **Rubber band ligation (RBL)** RBL is the most popular non-invasive procedure [56] and should be used for the treatment of I, II, and III-degree HD that fails conservative treatment (Level of evidence: 1; Grade of recommendation: B). **Sclerotherapy** Injection Sclerotherapy (IS) should be used for the treatment of I–II and III-degree HD that fail conservative treatment (Level of evidence: 1; Grade of recommendation: B) **Infrared coagulation** Infrared Coagulation (IRC) should be used for the treatment of I-II and III-degree HD that fail conservative treatment (Level of evidence: 1; Grade of recommendation: B) **Non-excisional procedures** **Stapled hemorrhoidopexy** SH is an effective technique for the treatment of HD. When compared with conventional hemorrhoidectomy, SH is associated with less operating time, earlier return of bowel function, shorter hospital stays, less pain, a faster functional

	recovery with shorter time of work, an earlier return to normal activities, and better wound healing (Level of evidence 1; Grade of recommendation: A). However, the incidence of recurrence and the need for additional operations are also significantly higher when compared to conventional hemorrhoidectomy (Level of evidence 1; Grade of recommendation: A). Transanal hemorrhoidal dearterialization (THD) or Doppler-guided hemorrhoidal artery ligation (DGHAL) THD or DGHAL is a treatment option for II- and III-degree hemorrhoids and in experienced hands possibly also for IV degree (Level of evidence: 1; Grade of recommendation: A). THD/DGHAL is associated with decreased postoperative pain, reduced postoperative events, and faster recovery than excisional hemorrhoidectomy, but carries higher recurrence rates (Level of evidence: 1; Grade of recommendation: A). **Excisional procedures** **Excisional hemorrhoidectomy** The traditional excisional methods (Milligan-Morgan, Ferguson procedures) remain the first choice and the most common indication for symptomatic III- and IV-degree HD (Level of evidence: 1; Grade of recommendation: A). **Management of HD in special conditions** **Pregnancy** Patients with I- and II-degree HD may benefit from oral rutosides for symptom relief. However, their use cannot be recommended until new evidence about their safety is available (Level of evidence: 1; Grade of recommendation: B) Conservative treatment for prolapsed thrombosed internal hemorrhoids, if compared with urgent hemorrhoidectomy, is associated with a shorter inpatient stay and less anal sphincter damage than operative treatment (Level of evidence: 1; Grade of recommendation: B) SH is a feasible treatment for selected patients with an acute hemorrhoidal crisis and has a similar complication rate if compared with a conventional excisional hemorrhoidectomy. SH is associated with less postoperative pain, shorter operation time, a shorter hospital stays, and an earlier return to normal activities (Level of evidence: II; Grade of recommendation: B **Immunosuppressed patients**

	Even if the indications for hemorrhoidectomy in patients with AIDS need to be considered extremely carefully because of the high incidence of delayed wound healing, nowadays, there is no significant increase in complication rate for patients with a low CD4+T-cell count (level of evidence 1: grade of recommendation: C)
Belgian consensus guideline on the management of hemorrhoidal disease 2021[9]	**56.** The most important risk factors to develop hemorrhoidal disease are straining, constipation, diarrhea, pregnancy, and obesity. (100% agreement- grade C) **57.** Every treatment for symptomatic hemorrhoids should be tailored to patient profile and expectations. (100% agreement- grade D) **58.** Fiber therapy improves hemorrhoidal symptoms and bleeding in grade I-II hemorrhoids. (85% agreement- grade A) **59.** Topical treatment has no proven effect in the treatment of hemorrhoidal disease. (92% agreement- grade B) **60.** Venotropics can influence bleeding in symptomatic hemorrhoids. (83% agreement- grade A) **61.** There is no rationale for long-term treatments with venotropics; their use is recommended in acute hemorrhoidal disease for a short period. (92% agreement- grade D) **62.** Venotropics have no proven effect on hemorrhoidal thrombosis and should not be used for this indication. (92% agreement- grade B) **63.** IR coagulation is indicated in grade 1 or 2 symptomatic hemorrhoids not responding to conservative treatment. (100% agreement- grade A) **64.** Sclerosing injections can cause severe adverse events, are not superior to IR coagulation and should therefore be avoided. (83% agreement- grade B) **65.** Rubber band ligatures should be placed just proximal to the hemorrhoid. (Agreement 100%- grade D) **66.** Rubber band ligation can be used for grade 2 to 3 internal hemorrhoids. (92% agreement- grade A) **67.** For grade 2 hemorrhoids, rubber band ligation seems the logical first choice of treatment. (92% agreement- grade A) **68.** Surgical treatment of hemorrhoids can be proposed after failure of medical and instrumental treatments (infra-red, sclerosis, elastic band ligations) for grade 2 and 3 hemorrhoidal disease. (92% agreement- grade A) **69.** Surgery is indicated as first line therapy for grade 4 and large grade 3 hemorrhoids. (100% agreement- grade A)

	70. Surgery is indicated for acute complications (pain/necrosis/thrombosis) if conservative therapy fails. (92% agreement- grade D) **71.** Surgery is indicated for hemorrhoidal bleeding resulting in severe and otherwise unexplained anemia, irrespective of the anatomical stage of disease. (85% agreement- grade D) **72.** Surgery is indicated for symptomatic internal hemorrhoids that are associated with symptomatic external hemorrhoidal disease resistant to conservative therapy: recurrent external hemorrhoidal thrombosis resistant to conservative therapy or bothersome hypertrophic tags. (92% agreement-grade D) **73.** Conventional hemorrhoidectomy is the gold standard in surgical therapy for grade 3-4 hemorrhoids. (100% agreement-grade A) **74.** Compared to rubber band ligation conventional hemorrhoidectomy has a superior long-term efficacy for grade 3 hemorrhoids at the cost of more side effects. (100% agreement-grade A) **75.** Conventional hemorrhoidectomy is the preferred procedure for noncircumferential hemorrhoids and in case of concomitant bothersome external hemorrhoids/skin tags. (92% agreement-grade D) **76.** Stapled hemorrhoidopexy is associated with less pain and faster recovery compared to conventional hemorrhoidectomy but suffers from higher recurrence rates. (100% agreement-grade A) **77.** Doppler-guided hemorrhoidal artery ligation has a significantly higher persistence/recurrence rate compared to stapled hemorrhoidopexy. (Agreement 92%- grade A) **78.** Stapled hemorrhoidopexy and Doppler-guided hemorrhoidal artery ligation are not recommended in cases of grade 4 hemorrhoidal disease. (100% agreement- grade B) **79.** During pregnancy, conservative options are treatment of choice and hemorrhoidal disease should be reevaluated after delivery. (100% agreement- grade C) **80.** Venotropics are probably safe during pregnancy, safety during lactation is unknown. (100% agreement- grade C) **81.** IR coagulation should be avoided during pregnancy. (85% agreement- grade B) **82.** Pregnancy is an absolute contraindication for rubber band ligation. (92% agreement- grade B)

	83. Rubber band ligation can safely be performed in compensated liver cirrhosis (Child-Pugh A). (85% agreement- grade C)

Appendix C. MeSH Terms PubMed

Query	Filters	Search Details	Results
(Hemorrhoids [MeSH Terms]) OR (Hemorrhoid [Title/Abstract])	Guideline, in the last 5 years	("hemorrhoids"[MeSH Terms] OR "Hemorrhoid"[Title/Abstract]) AND ((y_5[Filter]) AND (guideline [Filter]))	4

Appendix D. Treatment Algorithm

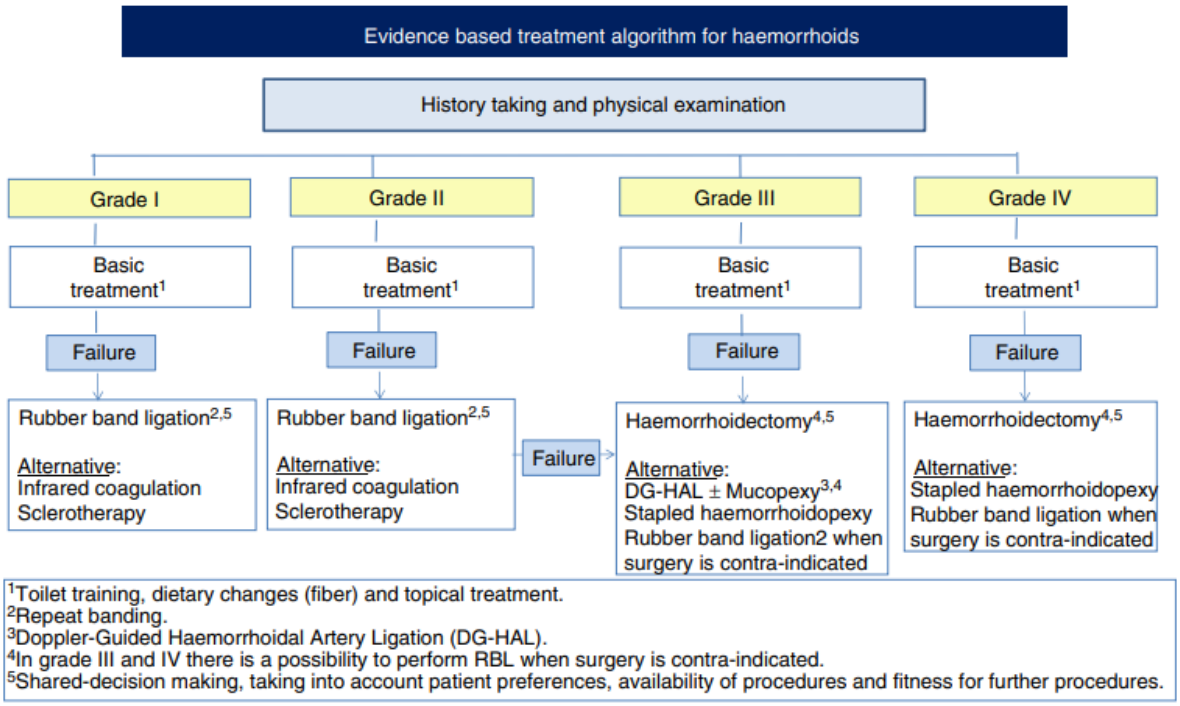

Figure 1. *Treatment Algorithm for the Management of Hemorrhoids. Retrieved from van Tol RR, Kleijnen J, Watson AJM, et al. European Society of ColoProctology: guideline for haemorrhoidal disease. Colorectal Disease. 2020;22(6):650-662. doi:10.1111/codi.14975.*