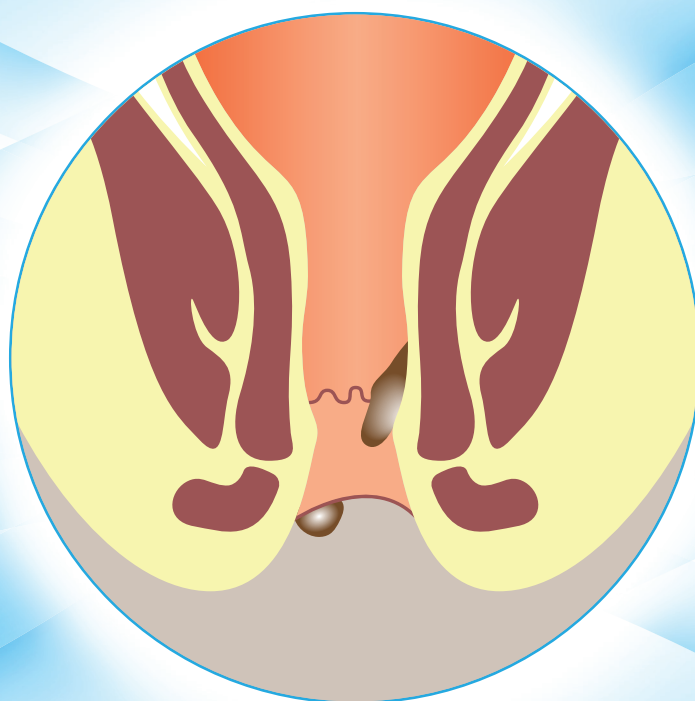




# **The Association of Colon and Rectal Surgeons of India**

(A Section of ASI)



# **HEMORRHOIDS**

## **PRACTICE GUIDELINES 2021**





## The Association Of Colon And Rectal Surgeons Of India

Practice Parameters Consensus Meeting - 11th Nov 2021, Hotel Renaissance Mumbai

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# Foreword

Disorders of the colon and rectum are not only very common but complex too and many a time difficult to treat. The urge to provide best treatment amongst the vast majority available is even more perplexing and frustrating at times. This gets further compounded by the lack of supporting evidences locally. Our members are more guided by evidences produced by other part of the world though it is a well known fact that colorectal disorder occurrences, behaviour and treatment responses may differ across the continents. A need was therefore felt to compile various available literature for some common colorectal disorders and produce them in the form of Practice Guidelines suitable for our members. It is an established fact that treatment modalities guided by the explicit, careful and judicious use of the best evidence available serves as a guide for most appropriate clinical decision making and patient care.

The Association of Colon and Rectal Surgeons of India lead by its team of expert faculties in their respective fields have done some excellent literature search and collated the available experiences to prepare this guidelines for you. We hope this will serve as a ready reckoner for our members in their times of need and help them to combat many litigations too.

I take this opportunity to thank all the contributors for their constant support in this endeavour.

**Dr. Niranjana Agarwal**  
President-ACRSI

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# **HEMORRHOIDS**

## **PRACTICE GUIDELINES 2021**

# Summary of recommendations

## Clinical evaluation and diagnosis

- To diagnose hemorrhoids, detailed patient history-taking and physical examination should be conducted. Proctoscopy and sigmoidoscopy should be used to confirm the diagnosis. Selected patients who are >40 years old and report weight loss and fever, report rectal bleeding, iron deficiency anemia, abdominal pain, diarrhea, positive fecal occult blood, weight loss, fever, or no colonoscopy in the past 10 years, should be subjected to colonoscopy examination. (Strong recommendation based on moderate-quality evidence, 1B)

## Management

### A. Conservative treatment

#### Dietary and lifestyle modifications

- Patients with hemorrhoids should be recommended to follow dietary modifications including increased fiber intake with adequate fluid as a first-line treatment. (Strong recommendation based on moderate-quality evidence, 1B)
- If constipation is a predominant factor, patients should be treated carefully using laxatives such as polyethylene glycol, lactulose, and bulking agents (Strong recommendation based on moderate-quality evidence, 1B)

#### Sitz bath

- No strong evidence supports the use of sitz bath for relieving pain or healing wounds associated with hemorrhoids. However, in practice, sitz bath has been observed to alleviate pain. (Weak recommendation based on low or very-low-quality evidence, 2C)

#### Medical therapy

- Phlebotonics or venoactive agents are recommended for symptomatic hemorrhoids. They serve as an effective adjuvant to surgery and other procedures. (Strong recommendation based on moderate-quality evidence, 1B)
- A majority of the gathered evidence pertains to MPFF. However, there is limited evidence favoring one phlebotonic over another. (Strong recommendation based on very-low-quality evidence, 1C)
- Topical applications may be used as a short-term treatment, but related evidence is limited to low-quality studies. Moreover, long-term use of topical preparations containing steroids should be avoided owing to their detrimental effects. (Weak recommendations based on very-low-quality evidence, 2C)

### B. Non-surgical office-based procedures

- Rubber band ligation, injection sclerotherapy, and infrared coagulation can all be used in the treatment of grade I-II and selective grade III hemorrhoids for patients who do not respond to medical treatment. The success rates are highest with RBL albeit with a higher complication rate. Injection sclerotherapy can be safely performed in high-risk ill moribund patients and in those on anticoagulants. Proper technique should be followed for these procedures, otherwise complications such as necrosis and ulceration can occur. Bipolar diathermy, direct current electrotherapy, and heater probe coagulation are not used routinely but reserved for specific cases (1, 2) (Strong recommendation based on high-quality evidence, 1A)

### C. Surgical management

#### Hemorrhoidectomy

- Hemorrhoidectomy is a suitable option for treating grade III-IV hemorrhoids; however, it may be associated with postoperative complications. The closed procedure has more advantages with respect to postoperative pain and bleeding compared with the open procedure. Advanced techniques such as vessel sealing system, ultrasonic scissor, and monopolar or bipolar modes of electrosurgery could help overcome some disadvantages of conventional hemorrhoidectomy.(3-5) (Strong recommendation based on high-quality evidence, 1A)

#### Stapled hemorrhoidopexy

- Stapled hemorrhoidopexy is recommended for treating grade III-IV (a-c) hemorrhoids, as it is more effective in pain control, wound healing, and decreasing hospital stay and time for return to work compared to conventional hemorrhoidectomy. Newer stapling devices may overcome the complications of stapled hemorrhoidopexy.(6) (Strong recommendation based on moderate-quality evidence, 1B)
- However, stapled hemorrhoidopexy is associated with higher recurrence rates (up to 40%) than open hemorrhoidectomy.(7) (Strong recommendation based on moderate-quality evidence, 1B)

# Summary of recommendations

## Doppler-guided hemorrhoidal artery ligation

- Doppler-guided hemorrhoidal artery ligation (DGHAL)/transanal hemorrhoidal dearterialization (THD) is recommended for treating grade II-IV hemorrhoids. Although recurrence of grade III-IV hemorrhoids may be a limiting factor, a combination of current techniques such as anopexy/mucopexy with DGHAL could address this limitation and broaden the applicability of DGHAL to the grade III-IV hemorrhoids.(8, 9) (Strong recommendation based on moderate-quality evidence, 1B)

## Hemorrhoids in special situation

### A. Patients on anticoagulants

- The choice of treatment should be based on the grade of hemorrhoids with cautious management of anticoagulation such that there is no cardiac compromise. Cardiologist's opinion should be taken before discontinuing anticoagulants. Injection sclerotherapy is preferable over rubber band ligation due to the risk of postoperative bleeding complications in the latter. (Strong recommendation based on low or low-to very-low-quality evidence, 1C)

### B. Patients with immunocompromised status or infected with human immunodeficiency virus

- Conservative treatment should be the first-line approach for management of symptomatic hemorrhoids in HIV-infected patients. If conservative management fails, surgical procedures should be offered with proper management of CD4 counts and prophylactic antibiotics.(10-12) (Strong recommendation based on low or low-to very-low-quality evidence, 1C)

### C. Hemorrhoids during pregnancy

- All pregnant women with symptomatic hemorrhoids should be managed using a conservative approach including diet and lifestyle modifications (intake of fiber-rich diet, high liquid intake, relief from constipation, personal cleanliness, and lying on the left side to relieve pain and other symptoms) and medical therapy. (Strong recommendation based on low or low-to very-low-quality evidence, 1C)
- MPFF is a safe and effective medical therapy in the management of hemorrhoids in pregnant women (usage is not advised during the first trimester in the absence of evidence). In the antenatal period, maintenance treatment with MPFF reduces both the frequency and duration of relapse of symptoms of acute hemorrhoids.(13) (Strong recommendation based on low or low-to very-low-quality evidence, 1C)
- Surgical or non-surgical procedures may be advised for patients who do not respond to conservative management. Surgical procedures should be reserved for strangulated or thrombosed hemorrhoids and performed under local anesthesia. (Strong recommendation based on low or low-to very-low-quality evidence, 1C)

### D. Hemorrhoids in children

- Dietary and lifestyle modifications, proper toilet training, and medical management are the first-line options for hemorrhoids in children. Non-surgical office procedures may be reserved if conservative management fails. (Strong recommendation based on low or low-to very-low-quality evidence, 1C)

### E. Portal hypertension and cirrhosis

- Conservative approach should be tried in all patients with portal hypertension and cirrhosis. (Strong recommendation based on low or low-to very-low-quality evidence, 1C)
- Differentiation between hemorrhoids and rectal varices should be done in portal hypertensive patients with active rectal bleeding. (Strong recommendation based on low or low-to very-low-quality evidence, 1C)
- Management of hemorrhoids associated with portal hypertension remains conservative approach. RBL is contraindicated. (Strong recommendation based on low or low-to very-low-quality evidence, 1C)
- There is lack of robust evidence for surgical management. Only in cases refractory to conservative treatment or in emergency some form of hemorrhoidectomy should be done using newer energy sources like ultrasound scissors or energy sealing systems. (Strong recommendation based on low or low-to very-low-quality evidence, 1C)

### F. Inflammatory bowel disease

- Management should primarily be conservative; in particular, avoid surgery in acute conditions. (Strong recommendation based on low or low-to very-low-quality evidence, 1C)
- Hemorrhoidectomy should be done in selective cases only. (Strong recommendation based on low or low-to very-low-quality evidence, 1C)



#### **G. Thrombosed external hemorrhoids**

- Thrombosed piles are an extremely painful condition and are an emergency. Prompt medical treatment is required. If the patient does not respond to medical therapy within 48 hours, then surgical excision should be performed. (Strong recommendation based on low or low-to very-low-quality evidence, 1C)

# Introduction

Hemorrhoids are a common anorectal condition with a projected prevalence of 5%. A peak prevalence occurs in the age group of 45-65 years. In fact, about 50% of the population (age >50 years) experiences hemorrhoids at least once.(14, 15) Hemorrhoids manifest as engorgement of blood vessels within the hemorrhoid venous plexus and disintegration of the supporting connective tissue within the anal cushions. They are usually found at 3 main locations: left lateral, right anterior, and right posterior columns of the anal canal.(16)

The pathophysiology of hemorrhoidal development is multifactorial. It includes

- Disintegration of the supporting connective tissue within the anal cushions (theory of sliding anal cushions) or
- Their downward displacement/prolapse that causes venous dilatation, redundancy of the rectal mucosa.
- Hyperperfusion and neovascularization with abnormal distensions of arteriovenous anastomoses and veins of the internal hemorrhoidal venous plexuses, overexpression of inflammatory mediators, and increase in resting anal pressure.(16, 17)

# Methodology

This practice guideline for the management of hemorrhoids is an updated version of the earlier Association of Colon and Rectal Surgeons of India (ACRSI) guidelines.(14) An organized literature search for English language articles was performed in PubMed, the Cochrane database of collected reviews, and Google Scholar. The following keyword combinations were used: hemorrhoids, hemorrhoidal diseases, anoscopy, anorectal examination, thrombosed hemorrhoid, medical therapy for hemorrhoids, rubber-band ligation, sclerotherapy, infrared coagulation, hemorrhoidectomy, Doppler-guided hemorrhoidal artery ligation, procedure for prolapsing hemorrhoids, stapled hemorrhoidopexy, and Milligan–Morgan, Ferguson, and laser hemorrhoidoplasty. The draft was shared with expert committee members through email and a consensus was reached during a consensus meeting conducted over video conferencing. A method adopted by American Society of Colon and Rectal Surgeons (ASCRS) was used to derive quality of evidence, wherein 1 was assigned to strong recommendation and 2 was assigned to weak recommendations. These recommendations were again categorized based on the level of evidence as A for RCTs without important limitations or overwhelming evidence from observational studies, B for RCTs with important limitations (inconsistent results, methodologic flaws, indirect or imprecise) or exceptionally strong evidence from observational studies, and C for observational studies or case series or consensus opinion of the expert group.(18)

**Table 1 The GRADE system for grading recommendations**

Supporting evidence	Quality of evidence	Grade of recommendation	Quality of evidence
RCTs without important limitations or overwhelming evidence from observational studies	Benefits clearly outweigh risk and burdens or vice versa	1	A
	Benefits closely balanced with risks and burdens	2	A
RCTs with important limitations (inconsistent results, methodologic flaws, indirect, or imprecise) or exceptionally strong evidence from observational studies	Benefits clearly outweigh risk and burdens or vice versa	1	B
	Benefits closely balanced with risks and burdens	2	B
Observational studies or case series or consensus opinion of the panel	Benefits clearly outweigh risk and burdens or vice versa	1	C
	Uncertainty in the estimates of benefits, risks and burden; benefits, risks, and burden may be closely balanced	2	C

# Classification and grading of hemorrhoids

Internal hemorrhoids arise from the superior hemorrhoidal venous plexus above the dentate line and are covered by a relatively less sensitive mucosa. They rarely thrombose and are typically not painful. However, sometimes, they bleed, prolapse, and cause perianal

itching and irritation. External hemorrhoids are covered with sensitive squamous epithelium and are located below the dentate line. Hemorrhoid-associated pain generally accompanies thrombosed external hemorrhoids (TEHs); these present as an acutely painful perianal swelling resulting from rapid distension of the innervated skin because of clots and surrounding edema.(16, 19) Table 2 represents the classification of hemorrhoids as per the previous ACRSI guidelines.(14)

**Table 2. Association of Colon and Rectal Surgeons of India (ACRSI) classification of hemorrhoids**

Grade	Characteristics
I	Remains inside the anal canal
II	Protrudes during defecation and reduces spontaneously
III	Protrudes during defecation but needs manual repositioning
IV	Remains prolapsed outside; external hemorrhoids

Each primary grade (I to IV) of hemorrhoids is further categorized depending on the number of hemorrhoids and presence of circumferential hemorrhoids or thrombosis by using the suffixes (a to d), as mentioned below.

a	Single pile mass
b	Two piles but with <50% circumference
c	Circumferential piles occupying >50% circumference of the anal canal
d	Thrombosed or gangrenous piles (complicated)

## Clinical evaluation and diagnosis

Patient history and physical examination are important aspects of clinical evaluation and diagnosis.

The most common symptom of hemorrhoids is painless bleeding usually while defecation, wherein bright red blood either coats the stool at the end of defecation or falls as drops and soils the pan. It is different from bleeding in fissures wherein the blood streaks the stool. Pain may be a symptom of complicated hemorrhoids such as thrombosed piles, or its presence may indicate other common concomitant painful conditions like fissures, perianal abscess, and anorectal neoplasm. Other major symptoms of hemorrhoids include tissue prolapse (something coming out per rectum), swelling, and itching and irritation of the perianal skin. Swelling is characteristically seen external to the anus in grade III and IV hemorrhoids. Prolapsing hemorrhoids cause perianal irritation, mucoid discharge, and itching, and are more prone to strangulation. Symptoms such as sensation of perianal fullness, change in bowel habits, and weight loss need further examination to rule out other pathological conditions such as anorectal carcinomas, anal condylomata, and inflammatory bowel disease.(14, 15, 20, 21)

Hemorrhoids may be a presenting feature in carcinoma of the rectum, pregnancy, stricture urethra, benign prostate hyperplasia, chronic constipation, and portal hypertension (rectal varices).

**Patient history-taking** should be conducted with the intent to gather information on risk factors such as constipation, low-fiber diet, hygiene, low water intake, sedentary lifestyle, and pregnancy. In patients with bleeding per rectum detailed family history should be taken to rule out colorectal cancer, inflammatory bowel disease (IBD), angiodysplasia, and diverticular disease.(14, 15, 17, 22, 23) Furthermore, details regarding past or present anticoagulant treatment for a coexisting cardiac problem and any fecal incontinence (wexner score) should be noted.

**Anorectal examination** is performed with the patient in the left lateral position; other less commonly used positions are lithotomy or the knee-elbow position. Primary piles are seen at the 3, 7, and 11 o'clock positions. Secondary piles are seen between these primary positions. External (local) inspection helps in diagnosing Thrombosed External Hemorrhoids, anal skin tags, perianal dermatitis, fistula-in-ano, anal fissure, abscess, or any evidence of Crohn disease. Internal hemorrhoids appear as dilated purplish-blue veins, whereas external hemorrhoids are less pink. Thrombosed External Hemorrhoids commonly appears as a firm, purplish nodule that is tender on palpation and may be ulcerated with bloody drainage.(21, 23, 24) Rectal varices must be differentiated from hemorrhoids. Rectal varices originate >4 cm above the anal verge, are not contiguous with anal columns, collapse with pressure, and do not prolapse into the scope (as piles do).

Digital examination helps rule out distal rectal mass and anorectal abscess or fistula. Digital examination also helps assess anal sphincter integrity.

Proctoscopy should be routinely performed to identify internal hemorrhoids and for ruling out distal rectal masses, because digital examination alone may not be sufficient.(25) Suspicion of sporadic or hereditary colon and rectal cancer indicates the need for extended colonic evaluation. In patients >40 years of age who have bleeding per rectum and a family history of rectal cancer, the guidelines recommend colonoscopic evaluation.(26) Flexible sigmoidoscopy, rectal contrast enema, and other diagnostic modalities can be occasionally offered to patients who cannot undergo colonoscopic evaluation.

### ACRSI recommendation

- To diagnose hemorrhoids, detailed patient history-taking and physical examination should be conducted. Proctoscopy and sigmoidoscopy should be used to confirm the diagnosis. Selected patients who are >40 years old and report weight loss and fever, report rectal bleeding, iron deficiency anemia, abdominal pain, diarrhea, positive fecal occult blood, weight loss, fever, or no colonoscopy in the past 10 years, should be subjected to colonoscopy examination. (Strong recommendation based on moderate-quality evidence, 1B)

## Management

### A. Conservative treatment

#### Dietary and lifestyle modifications

Constipation, bowel habits such as straining during defecation, prolonged time in the toilet, passing hard stools, and feeling of incomplete defecation are the well-recognized precipitating factors for hemorrhoids.(27) Patients with any degree of hemorrhoids should be advised lifestyle modifications, including avoiding sitting in toilet for a long time, performing yoga and other exercises, and dietary modifications to include more fiber and fluids. Fiber restores the normal frequency of bowel movements by increasing fecal mass, volume, and softness. Increasing dietary fiber (in food or as supplements) and fluid intake improves stool consistency and decreases rectal bleeding. This is an effective first-line, non-surgical treatment for acute episodes of hemorrhoids, which also prevents recurrence of hemorrhoidal symptoms.(15, 17) Consumption of commonly available fiber-rich foods such as oats, lentils, flax seeds, chia seeds, prunes, raisins, broccoli, spinach, figs, pears, grapes, and papaya can be advised to patients with constipation.

### Evidence

A meta-analysis of 7 randomized trials (N = 378) that compared fiber diet with non-fiber diet (control) showed that fiber intake (7-20 gm/day) reduced the risk of bleeding by 50% (relative risk [RR] 0.50, 95% confidence interval [95% CI]: 0.28-0.89), and persistent symptoms by 47% (RR 0.53, 95% CI: 0.38-0.73). However, fiber intake did not improve symptoms of prolapse, pain, or itching.(28) Along with sufficient fiber intake, proper bowel habits (avoiding strain during defecation, reducing the time in the toilet, etc.) and once-a-day frequency of defecation have shown beneficial effects as they improved prolapse (56.5%) and decreased bleeding (71.8%).(29) A Cochrane systematic review reported beneficial effects of stimulant laxatives (bisacodyl), osmotic agents (polyethylene glycol and lactulose), and bulking agents (isabgol husk powder with senna) in treating hemorrhoidal symptoms.(30)

### ACRSI recommendations

- Patients with hemorrhoids should be recommended to follow dietary modifications including increased fiber intake with adequate fluid as a first-line treatment. (Strong recommendation based on moderate-quality evidence, 1B)
- If constipation is a predominant factor, patients should be treated carefully using laxatives such as polyethylene glycol, lactulose, and bulking agents ( Strong recommendation based on moderate-quality evidence, 1B)

### Sitz bath

Sitz bath with warm water (not exceeding 40-42 °C for 3 minutes) is a traditional and often recommended treatment for various anal disorders including hemorrhoids; however, proper instructions should be given to patients to ensure proper execution and to avoid infection.(15, 31)

Pain relief after a sitz bath may be attributed to internal anal sphincter relaxation via neural pathways through a "thermosphincteric reflex" and decrease in anal resting pressure.(32)

### Evidence

A systematic review of 4 randomized controlled trials (RCTs) evaluating the effect of sitz bath in treating anorectal diseases suggested lack of strong evidence for its role in relieving pain.(33) Moreover, some complications associated with sitz bath included burns, dissemination of herpes, and maternal–neonatal Streptococcus outbreak.(34, 35) A prospective comparative study showed complete healing of



hemorrhoids in pregnant women who received Sitz bath compared to ano-rectal cream.(36) In an RCT (N = 50; average age, 45 years) with patients in the post-hemorrhoidectomy period conducted in India, sitz bath offered neither pain relief nor wound healing and did not reduce analgesic consumption compared to the group that was not given sitz bath.(37) A prospective study, however, showed it to be effective in patients with hemorrhoids.(38)

### ACRSI recommendation

- No strong evidence supports the use of sitz bath for relieving pain or healing wounds associated with hemorrhoids. However, in practice, sitz bath has been observed to alleviate pain. (Weak recommendation based on low or very-low-quality evidence, 2C)

### Medical therapy

Phlebotonics are a heterogeneous class of drugs made using plant-derived products such as flavonoids (either synthetic or extracted from *Euphoria prostrata*, *Ginkgo biloba*, etc.) or synthetic compounds such as calcium dobesilate. They are used to treat both acute and chronic hemorrhoidal disease, because of their effects of strengthening blood vessel walls, increasing venous tone, promoting lymphatic drainage, and normalizing capillary permeability. However, their exact mechanism of action is not well-established.(16, 26, 39) Optimum dose of MPFF is 1000 mg TDS for 4 days then 1000 mg BD for 3 days then maintenance dose of 1000 mg daily for 60 days.

For symptomatic control, topical treatments (ointments/creams and suppositories) containing analgesics/anesthetics (e.g., cinchocaine, xylocaine) and steroids (e.g., hydrocortisone), antiseptics, and emollients, either isolated or in combination, are available. However, adequate evidence for these treatments is not available.(17) Their prolonged use may cause allergic reactions or sensitization and, hence, these should be used with caution.(40)

### Evidence

A Cochrane review of 24 RCTs (N = 2344) that compared phlebotonics with a control showed a statistically significant beneficial effect of phlebotonics on the outcomes of pruritus (odds ratio [OR] 0.23; 95% CI: 0.07-0.79,  $P = 0.02$ ), bleeding (OR 0.12; 95% CI: 0.04-0.37,  $P = 0.0002$ ), post-hemorrhoidectomy bleeding (OR 0.18; 95% CI: 0.06-0.58,  $P = 0.004$ ), discharge and leakage (OR 0.12; 95% CI: 0.04-0.42,  $P = 0.0008$ ), and overall improvement in symptoms (OR 15.99; 95% CI: 5.97-42.84,  $P < 0.00001$ ). However, the results were not statistically significant for pain, pain scores post-hemorrhoidectomy, or postoperative

analgesic consumption.(41) A meta-analysis of 14 randomized trials (N = 1514) compared flavonoids (diosmin, micronized purified flavonoid fraction [MPFF], and rutosides) with placebo or no therapy in patients with symptomatic hemorrhoids. Flavonoids decreased the risk of persisting symptoms by 58% (risk ratio[RR] 0.42; 95% CI: 0.28-0.61). In addition, they also reduced the risk of bleeding (RR 0.33; 95% CI: 0.19-0.57), persistent pain (RR 0.35; 95% CI: 0.18-0.69), itching (RR 0.65; 95% CI: 0.44-0.97), and recurrence (RR 0.53; 95% CI: 0.41-0.69).(42) A meta-analysis of 10 RCTs (N = 1164) evaluated the efficacy and tolerability of MPFF in hemorrhoids and reported statistically significant reduction in rectal bleeding in patients receiving MPFF (RR 1.46; 95% CI: 1.10-1.93,  $P = 0.008$ ).(43) In a recent meta-analysis by Sheikh et al., MPFF showed significant benefits for bleeding (OR: 0.082; 95% CI: 0.027-0.250,  $P < 0.001$ ), discharge/leakage (OR 0.12; 95% CI: 0.04-0.42,  $P < 0.001$ ), pain (OR 0.11; 95% CI: 0.01-1.11,  $P = 0.06$ ), and overall improvement according to patients (OR 5.25; 95% CI: 2.58-10.68,  $P < 0.001$ ) and investigators (OR 5.51; 95% CI: 2.76-11.0,  $P < 0.001$ ).(44) Furthermore, phlebotonics have shown beneficial effects in hemorrhoidal diseases after surgery.(45) Calcium dobesilate along with fiber supplements has provided effective symptomatic relief from acute bleeding and has significantly reduced inflammation of hemorrhoids.(46) However, its use has also been associated with an increased risk of agranulocytosis.(47)

Another RCT (N = 36) showed benefits of a gel containing hyaluronic acid, tea tree oil, and methyl-sulfonylmethane in treating hemorrhoids compared to placebo.(48) However, these studies do not provide a strong evidence to provide a clear recommendation.

### ACRSI recommendations

- Phlebotonics or venoactive agents are recommended for symptomatic hemorrhoids. They serve as an effective adjuvant to surgery and other procedures. (Strong recommendation based on moderate-quality evidence, 1B)
- A majority of the gathered evidence pertains to MPFF. However, there is limited evidence favoring one phlebotonic over another. (Strong recommendation based on very-low-quality evidence)
- Topical applications may be used as a short-term treatment, but related evidence is limited to low-quality studies. Moreover, long-term use of topical preparations containing steroids should be avoided owing to their detrimental effects. (Weak recommendations based on very-low-quality evidence)

## B. Non-surgical office-based procedures

Office-based treatments are generally used for internal hemorrhoids. Non-operative procedures are usually considered primarily for grade I-II (a-c) and selective grade III (a-c) hemorrhoids. These procedures can be performed on an outpatient basis without anesthesia. The goal of all non-surgical hemorrhoid therapies is to decrease vascularity and promote fixation of tissue to the rectal wall, thus minimizing prolapse. These treatments are considerably well tolerated and less painful than excisional treatments of external hemorrhoids because there is relative lack of somatic innervation in internal hemorrhoids. However, these methods are associated with variable recurrence rates and may require repeated applications.(26, 49)

### Rubber band ligation

Rubber band ligation (RBL) is the most popular and effective office-based treatment, wherein constricting bands are placed around the base of hemorrhoids in single or multiple sittings; the bands cause ischemic necrosis with subsequent scar fixation of the tissue to the underlying tissue. It is suitable for grade I-II (a) and selective grade III (a) hemorrhoids and should be avoided in patients with anorectal sepsis. It can be done either using a rigid proctoscope or during flexible endoscopy. Minor complications such as anal pain, band slippage, and mild bleeding occur in about 5% of patients. Major complications are rare and include delayed massive rectal bleeding and sepsis.(50-53) Severe complications are also rare but massive gastrointestinal hemorrhage, liver abscess, endocarditis, perineal sepsis, and death have been reported after RBL.(15, 54-57)

It is contraindicated in patients on anticoagulants patients with a bleeding disorder, thrombosed hemorrhoids, concomitant anorectal sepsis, anal fissures, abscess and fistula, colitis, colorectal tumors, pregnancy, immunodeficiency conditions, and diabetes mellitus.(15)

### Evidence

A Cochrane review of 3 RCTs (N = 216) evaluated the efficacy of RBL versus excisional hemorrhoidectomy depending on the grade of hemorrhoids. No significant difference was reported between the 2 methods for grade II hemorrhoids (1 trial, 32 patients; RR 1.07; 95% CI: 0.94-1.21,  $P = 0.32$ ); excisional hemorrhoidectomy was superior to RBL for grade III hemorrhoids (2 trials, 116 patients; RR 1.23; 95% CI: 1.04-1.45,  $P = 0.01$ ). The rate of recurrence was also less with excisional hemorrhoidectomy (3 trials, RR 0.20; 95% CI: 0.09-0.40,  $P < 0.00001$ ). The use of RBL was suggested as the choice of treatment for grade II hemorrhoids.(50) In a retrospective study (N = 890) of patients treated with RBL, 76% were cured ( $P = 0.31$ ) after treatment and 4% experienced minor complications such as pain (2.6%), rectal bleeding (1%), and vasovagal symptoms (0.4%) that did not require hospitalization; however, after 2

years, 20% of patients reported symptomatic recurrence.(58) Patients with anticoagulants are reported to have an incidence of on table bleeding to be 7.5%.(52) Multiple bandings in the same session may result in better control of bleeding and symptoms but could also lead to relatively more pain and tenesmus.(59) A prospective comparative study for the use of RBL and injection sclerotherapy with 50% dextrose in water for treating symptomatic internal hemorrhoids demonstrated statistically significant superiority ( $P = 0.03$ ) of RBL in resolution of complete (64.4%) or partial (40.9%) symptoms compared to injection sclerotherapy (28% and 22.7%, respectively).(60) A meta-analysis compared RBL with other office procedures and excisional hemorrhoidectomy: RBL had a higher cure rate albeit with more complications, mainly pain and urinary retention.(49) It is less effective than excisional hemorrhoidectomy in Goligher's grade III hemorrhoids but is better tolerated and has fewer complications.(2, 50)

The efficacy of RBL has been also proven in other studies in the Indian population.(61-64)

### Injection sclerotherapy

In injection sclerotherapy, liquid sclerosants are injected into the submucosa at the apex of a hemorrhoidal bundle, aiming to induce an inflammatory reaction and fibrosis with subsequent fixation of the hemorrhoidal tissue. Various sclerosing agents such as 5% phenol in vegetable or almond oil, sodium tetradecyl sulfate, and 3% polidocanol are used. Sclerotherapy is safe and effective and, thus, should be used in selective bleeding grade I-II (a-c) hemorrhoids. It may be considered for patients who are at a high risk of bleeding, such as those receiving anticoagulants, old, and morbid patients who are not fit for surgery.(26)

A misplaced injection during sclerotherapy may manifest an iatrogenic risk; in particular, an anteriorly misplaced injection in male patients may produce urological complications.(65) Other rare complications of injection sclerotherapy include rectovaginal fistula,(66) sepsis,(67, 68) adult respiratory distress syndrome,(69) and necrotizing fasciitis.(70, 71)

### Evidence

Injection sclerotherapy is economical and easy to perform but has a higher failure rate as compared to RBL.(1) Newer sclerosing agents such as aluminum potassium sulfate and tannic acid have shown fewer recurrence rates compared to the traditionally used phenol in almond/vegetable oil.(72-75) In an RCT (N = 130) assessing the efficacy of foam or liquid sclerotherapy (polidocanol 3%) for treating first-grade hemorrhoidal disease, 3% polidocanol foam was found to be superior to liquid polidocanol after a 12-week follow-up in terms of effectiveness (88% vs. 69%;  $P = 0.01$ ), number of sessions required for successful treatment (1.08 [ $\pm 0.32$ ] vs. 1.42 [ $\pm 0.64$ ];  $P < 0.001$ ), and

total amount of injected polidocanol (35 mg ( $\pm 10$ ) vs. 85 mg ( $\pm 38$ );  $P < 0.001$ ).<sup>(76)</sup> More than 90% of prolapses were reported to resolve in grade II hemorrhoidal disease in an RCT and case series.<sup>(53)</sup>

Several studies in India also showed similar findings.<sup>(77-79)</sup>

### **Infrared coagulation**

Infrared coagulation involves direct application of infrared waves to internal hemorrhoids, causing protein coagulation, consequent necrosis, and finally fixation of the mucosa. The degree of tissue destruction depends on the duration of contact and the number of applications. This method is most useful for grade I-II (a-c) hemorrhoids.<sup>(26)</sup>

#### **Evidence**

Infrared coagulation is more effective than injection sclerotherapy in non-prolapsing hemorrhoids; however, when used for prolapsing hemorrhoids, the rate of recurrence of prolapse is higher.<sup>(80)</sup> In various RCTs, infrared coagulation had similar outcomes as RBL. The side effects of infrared coagulation are less than that of RBL.<sup>(81-83)</sup> In an RCT for grade I and II internal hemorrhoids, the use of infrared coagulation controlled symptoms in 81% patients, postoperative complication rate was 13%, and repeat procedure was required in 28% patients.<sup>(84)</sup> In another randomized trial, infrared coagulation led to bleeding cessation in 78.4%, 51.6%, and 22.2% of patients with grade I, II, and III acute internal hemorrhoids, respectively.<sup>(85)</sup> In an RCT in India, despite RBL being more effective, infrared coagulation was suggested as the preferred technique given the high pain and discomfort associated with RBL.<sup>(86)</sup>

### **Bipolar diathermy, direct current electrotherapy, and heater probe coagulation**

These technologies are based on coagulation and cauterization of the base of the hemorrhoidal vessel, above the anal transition zone, which subsequently forms the fibrotic tissue at the treatment site. Bipolar diathermy encompasses cauterization with a 1-second pulse of 20 W of heater energy. The direct current probe utilizes 110 V direct current applied for varying durations depending on the size of hemorrhoids. A biochemical reaction driven by sodium hydroxide produced at the negative electrode of the device causes regression of the hemorrhoidal cushion. Similarly, heater probe uses a direct heat transfer mechanism to coagulate the tissue.

#### **Evidence**

Although direct current application results in an early return to work and less post-procedure pain, higher recurrence rates and longer procedure are major issues.<sup>(87)</sup> A line of evidence shows that all these treatments compare favorably with RBL and other forms of outpatient procedures.<sup>(88, 89)</sup>

### **Cryotherapy**

Cryotherapy initially exhibited some promise for both hemorrhoids and anal fissures. Later, however, it was recognized to be associated with low response rates and increased complications such as rectal pain and discharge, which led to abandoning of the procedure for management of hemorrhoids.<sup>(19)</sup>

### **ACRSI recommendation**

- Rubber band ligation, injection sclerotherapy, and infrared coagulation can all be used in the treatment of grade I-II and selective grade III hemorrhoids for patients who do not respond to medical treatment. The success rates are highest with RBL albeit with a higher complication rate. Injection sclerotherapy can be safely performed in high-risk ill moribund patients and in those on anticoagulants. Proper technique should be followed for these procedures, otherwise complications such as necrosis and ulceration can occur. Bipolar diathermy, direct current electrotherapy, and heater probe coagulation are not used routinely but reserved for specific cases (1, 2) (Strong recommendation based on high-quality evidence, 1A)

### **C. Surgical management**

Surgery remains the gold standard treatment for grade III and IV hemorrhoids. Surgery is also recommended in grade II hemorrhoids that do not respond well to medical treatment.

### **Hemorrhoidectomy**

Hemorrhoidectomy can be open or closed. Open hemorrhoidectomy is the commonly preferred approach for treating severe acute gangrenous hemorrhoids where tissue edema and necrosis precludes closure of mucosa.<sup>(21)</sup> The open procedure is preferred in Europe, whereas the closed one is more commonly performed in North America.<sup>(90)</sup> Numerous instruments and techniques such as ultrasonic scissors, mono- or bipolar modes of electrosurgery, and CO<sub>2</sub>/YAG laser significantly contribute to improved outcomes of hemorrhoidectomy.

Contraindications: Generally, there are no absolute contraindications for hemorrhoidectomy. Relative contraindications would include anticoagulant treatment and unfitness for surgery. Owing to the risk of inducing labor, surgery is avoided during pregnancy. However, excision of complicated hemorrhoids can be

performed in necessary cases.(91)

Complications: Common complications, primarily seen in the early postoperative period, include bleeding, pain, and urine retention. The later, rare complications include incontinence, fissure, fistula, and stenosis.(92)

### **Evidence**

Several studies have estimated outcomes of hemorrhoidectomy in patients with Goligher's grades II-IV hemorrhoids. In a meta-analysis of 11 RCTs comparing open versus closed hemorrhoidectomy (N = 1326), the closed procedure had advantages in terms of wound healing (OR 0.08; 95 % CI: 0.02, 0.24;  $z = 4.33$ ;  $P < 0.0001$ ), postoperative pain (standardized mean difference,  $-0.36$ ; 95 % CI:  $-0.64$ ,  $-0.07$ ;  $z = 2.45$ ;  $P = 0.01$ ), and bleeding (OR 0.50; 95 % CI: 0.27: 0.91;  $z = 2.27$ ;  $P < 0.02$ ). In both the methods, postoperative complications, hemorrhoid recurrence, and risk for infection were similar.(3) Continuous efforts have been invested to develop new techniques and modifications that promise a less painful course and rapid recovery. One such technique is the vessel sealing system that has shown superiority to the conventional procedure in a Cochrane systematic review and a meta-analysis.(4, 5) Similarly, the use of a ultrasonic scissors is another strategy associated with less pain score and 50% fewer complications than the conventional procedure.(93) Bipolar diathermy, however, reported similar outcomes and postoperative pain scores when compared to ultrasonic scalpel for closed hemorrhoidectomy in an RCT.(94)

Hemorrhoidectomy compared to office procedures remains effective, especially for treating grade III hemorrhoids; however, high complication rate and postoperative pain are major drawbacks of surgery.(1, 95) Therefore, the benefit-to-risk ratio of each procedure should be contemplated during decision-making.

Efforts have been invested to reduce complications associated with hemorrhoidectomy. Different systematic reviews or meta-analyses have shown beneficial effects of topical metronidazole, glyceryl trinitrate, diltiazem, and sucralfate in decreasing postoperative pain following excisional hemorrhoidectomy. Some researchers have also tried locally methylene blue injection in selected cases (96-100) In 2 meta-analyses (including 9 and 7 RCTs), local anesthesia in patients undergoing hemorrhoidectomy was associated with significantly better results for postoperative pain, need for rescue analgesia, urine retention, headache, and intraoperative hypotension compared to regional or spinal anesthesia.(101, 102) Radiofrequency hemorrhoidectomy is a suture-less technique that enrolls a modified electrosurgical unit to achieve tissue and vessel sealing. It has less blood loss, postoperative pain, and complications, and is technically simple because suturing is not required and hemostasis is easy to achieve. Radiofrequency hemorrhoidectomy has the potential of making hemorrhoidectomy a day-care

regimen.

### **ACRSI recommendation**

- Hemorrhoidectomy is a suitable option for treating grade III-IV hemorrhoids; however, it may be associated with postoperative complications. The closed procedure has more advantages with respect to postoperative pain and bleeding compared with the open procedure. Advanced techniques such as vessel sealing system, ultrasonic scissor, and monopolar or bipolar modes of electrosurgery could help overcome some disadvantages of conventional hemorrhoidectomy.(3-5) (Strong recommendation based on high-quality evidence, 1A)

### **Stapled hemorrhoidopexy**

Stapled hemorrhoidopexy uses a circular stapling device to resect the mucosal membrane above the dentate line, aiming to interrupt the blood supply to the prolapsed tissue and allow shrinkage of the hemorrhoidal cushion and restoration to their anatomical position. As the surgery occurs above the dentate line, it is associated with less postoperative pain compared to hemorrhoidectomy.(103-105) Despite its effectiveness in internal prolapsing hemorrhoids, this method does not address external hemorrhoids.(26)

Indications: It is indicated in patients with grade III-IV (a-c) hemorrhoids, as well as in patients who are refractory or intolerant to office procedures.

Contraindications: Stapled hemorrhoidopexy is contraindicated in patients with anal stenosis, previous anorectal surgery, intra-anal fibrosis, and anal incontinence.(106)

Complications: Apart from general complications such as bleeding, pain, and fissure, stapled hemorrhoidopexy is associated with several postoperative complications such as rectal obliteration, rectal perforation, retroperitoneum, pneumomediastinum, pelvic sepsis, rectovaginal fistula, intra-abdominal bleeding, rectal diverticulum, instrument failure, rectal stricture, and Fournier's gangrene.(106, 107)

### **Evidence**

Stapled hemorrhoidopexy exhibits several advantages such as less operation time, shorter hospitalization, and early return to work.(108) However, higher recurrence and more postoperative complications limit its efficacy when compared to conventional or vessel sealing system hemorrhoidectomy.(7, 109-113) A systematic review of complications associated with stapled



hemorrhoidopexy reported overall complication rates ranging from 3.3% to 81% along with 5 cases of mortality.(114)

In a prospective randomized trial comparing stapled hemorrhoidectomy with conventional hemorrhoidectomy in India, the mean intraoperative time, mean hospital stay, and postoperative pain were significantly less ( $P < 0.001$ ) in the stapled group after 1 to 2 days compared to the conventional group, but pain after 7 days was not statistically different between stapled and conventional hemorrhoidectomy groups.(115) Availability of novel staplers such as end-to-end anastomosis (EEA), double purse string, and tissue selecting therapy (TST) has reduced postoperative complications and improved patient satisfaction. In Goligher's grade III patients, the EEA stapler had better hemostatic properties and offered a larger area for resection of mucosal prolapse, which was associated with potential benefits with respect to the recurrence rate, compared with the procedure for prolapse and hemorrhoids (PPH) staplers.(116) Similarly, use of TST staplers also showed quick recovery and less postoperative complications.(117) A meta-analysis of 22 RCTs (N = 3511) indicated superior clinical effects of TST for grade III and IV hemorrhoids compared to hemorrhoidectomy: TST had lower rates of urine retention and fecal incontinence and fewer incidences of anal stenosis compared to hemorrhoidectomy.(118) Suture hemorrhoidopexy without using staplers has been described; however, long-term data are awaited.(119, 120) Partial stapled hemorrhoidopexy (PSH) deploys fewer staples, thereby potentially reducing some morbidities associated with the conventional method, and helps preserve the mucosal bridges. PSH has shown similar outcomes in patients with grade III-IV hemorrhoids, namely, reduced postoperative pain and urgency, better postoperative anal continence, and minimal risk of rectal stenosis compared to circumferential stapled hemorrhoidopexy.(121)

### ACRSI recommendations

- Stapled hemorrhoidopexy is recommended for treating grade III-IV (a-c) hemorrhoids, as it is more effective in pain control, wound healing, and decreasing hospital stay and time for return to work compared to conventional hemorrhoidectomy. Newer stapling devices may overcome the complications of stapled hemorrhoidopexy.(6) (Strong recommendation based on moderate-quality evidence, 1B)
- However, stapled hemorrhoidopexy is associated with higher recurrence rates (up to 40%) than open hemorrhoidectomy.(7) (Strong recommendation based on moderate-quality evidence, 1B)

### Doppler-guided hemorrhoidal artery ligation

Doppler-guided hemorrhoidal artery ligation (DGHAL) or transanal hemorrhoidal dearterialization (THD) is a relatively new and minimally invasive procedure, which uses a Doppler probe combined with a distinctive proctoscope for detecting and ligating superior hemorrhoidal arteries and its branches. Ligating arteries decreases blood flow to the hemorrhoidal cushions, subsequently reducing bleeding and causing shrinkage of the internal piles. Minimal postoperative complications and no tissue excision are the main benefits of this procedure.(8, 16, 122)

**Indications:** This technique is indicated in patients with grade II-IV (a-c) hemorrhoids and in patients unresponsive or intolerable to non-surgical procedures. Furthermore, DGHAL could be an excellent option for patients with previous anal surgeries, problems pertaining to fecal continence, and definitive incontinence risk with other methods.(123)

**Contraindications:** There are no absolute contraindications for DGHAL/THD procedures, although patients in whom anesthesia is contraindicated should not undergo this procedure,(124) although the procedure can be performed under local anesthesia.

**Complications:** This procedure is not associated with any serious complications. Tenesmus, bleeding, pain, and prolapse are its rare complications.(125)

### Evidence

A systematic review (N = 1996) established that THD is associated with shorter operation time and hospital stay, early resumption to work, and less postoperative pain. Nevertheless, higher recurrence rate with THD performed in grade IV hemorrhoids is a cause for concern.(8) A systematic review evaluating 28 studies included patients with grade I to IV hemorrhoids (N = 2904); it reported a recurrence rate of 3% to 60% (pooled recurrence rate, 17.5%), with the highest recurrence for grade IV hemorrhoids. Postoperative analgesia was required in 0% to 38% of patients. Overall postoperative complication rates were low, with an overall bleeding rate of 5.0% and an overall re-intervention rate of 6.4%. Operative time ranged from 19 to 35 minutes.(126) Addition of anopexy/mucopexy to DGHAL reduced recurrences in grade III-IV hemorrhoids.(9, 127, 128) A randomized prospective trial compared the effectiveness of THD (N = 185) with RBL (N = 187) in the treatment of grade II and III hemorrhoids; 49% patients in the RBL group and 30% patients in the HAL group had hemorrhoid recurrence at 1 year post-procedure. This difference was due to the number of subsequent extra procedures required (32% in RBL vs. 14% in HAL) to control hemorrhoids. Symptom severity score, complications, quality of life, and continence score were similar in both the groups. Although recurrence after HAL was lower than that after a single RBL, patients felt more pain after HAL than RBL in the early postoperative

period. In a meta-analysis of 8 RCTs (N = 977), no statistically significant differences in total complications were noted between hemorrhoidal dearterialization and stapled hemorrhoidectomy (OR 0.93; 95% CI: 0.69-1.25), postoperative pain (OR 0.43; 95% CI: -0.43-1.29), operative time (OR: -3.12; 95% CI: -7.01--0.77), duration of hospital stay (OR -0.00; 95% CI, -0.21-0.20), time to resuming work (OR -0.50; 95% CI, -4.42-3.43), and reoperation rate (OR 1.81; 95% CI: 0.93-3.54), but significant differences were noted in bleeding (OR 1.85; 95% CI: 1.10-3.10). This indicated equal effectiveness for DGHAL and stapled hemorrhoidectomy for the treatment of hemorrhoids.(129)

### ACRSI recommendation

- Doppler-guided hemorrhoidal artery ligation (DGHAL)/transanal hemorrhoidal dearterialization (THD) is recommended for treating grade II-IV hemorrhoids. Although recurrence of grade III-IV hemorrhoids may be a limiting factor, a combination of current techniques such as anopexy/mucopexy with DGHAL could address this limitation and broaden the applicability of DGHAL to the grade III-IV hemorrhoids.(8, 9) (Strong recommendation based on moderate-quality evidence, 1B)

### Emerging technologies

#### Laser hemorrhoidoplasty

Laser hemorrhoidoplasty (LHP) is a minimally invasive technique in which a laser beam is applied inside the hemorrhoidal tissue. Laser in surgery is based on the principles of photo ablation, which breaks cellular chemical bonds; photocoagulation, which induces protein denaturation leading to shrinkage of the arterial wall; and photo vaporization, which causes shrinkage and fibrosis that aids in fixing the prolapsing element. LHP reduces postoperative pain, intraoperative bleeding, and the need of postoperative analgesics. LHP is also associated with shorter operative time and causes less postoperative pain compared to excisional surgery.(15, 130)

Indications: LHP can be used for treating grade II-IV hemorrhoidal disease.(131)

A conical laser fiber is introduced inside the hemorrhoidal mass through the dentate line in pulse mode. At the time of insertion, a 6 W pulse is given for 1 second, and, at the time of coagulation, another 6 W

pulse is given for 3 seconds. It is advisable to withdraw the fiber at every 5 mm. The total energy required is 150-200 J per pile mass. At the end of the procedure, an ice finger is placed for 20 minutes to reduce edema that might have occurred as a result of cellular injury by thermal energy. Submucosal application of controlled laser emission causes the hemorrhoidal mass to shrink. Moreover, fibrotic reconstruction generates new connective tissue, ensuring that the mucosa adheres to the underlying tissue and thus prevents the occurrence or recurrence of prolapse.(15, 132)

Additional procedure of DGHAL along with laser has also been tried with better efficacy and results.

#### Evidence

A prospective study compared LHP with open surgical procedure in patients with symptomatic grade III or IV hemorrhoids. LHP was significantly more effective than open hemorrhoidectomy with respect to shorter operative time and less postoperative pain. The procedure time for LHP was 15.94 minutes versus 26.76 min for open surgery ( $P < 0.01$ ). (130)

In a cohort study with 497 patients, long-term symptom relevance was 86% and patient satisfaction was 91% with LHP. Complications were reported in 9.9% of patients and included bleeding (1.8%), infection (1%), urine retention (1.8%), and edema/thrombosis/prolapse (6.6%). Relapse was reported in 8.8% of patients during the 6 months after the procedure.(131)

In an RCT, postoperative pain was significantly lower in the laser group than in the Milligan-Morgan (MM) group ( $P < 0.01$ ). Operative time and intra-operative blood loss were more in the MM group ( $P < 0.001$ ). Administration of analgesics was significantly less in the laser group ( $P < 0.05$ ). Only 2 patients from the laser group (N = 30) compared to no patient in the MM group (N = 30) presented with TEHs 7 to 10 days after the procedure; these resolved with medical treatment. At the 1-year follow-up, resolution of symptoms and sustainable cure were similar between the groups.(133)

Although LHP achieves a high short-term success rate (88%) with respect to stage reduction and symptom improvement, it is associated with a high rate (18%) of minor postoperative complications such as fistulas, incontinence, perianal thrombosis, eczema, local bleeding, and anal fissure. After a mean follow-up of 5.4 years, recurrences were reported in 39% and 33% of patients with grades II and III hemorrhoids, respectively.(134)

Brusciano et al., in a study involving 50 patients with grade II-III hemorrhoids, observed a quick return to daily activity at day 1 (40%) and day 2 (100%) after LHP.(135)

## Hemorrhoids in special situation

### A. Patients on anticoagulants

Management of hemorrhoids in patients on anticoagulants such as warfarin and enoxaparin and those on antiplatelet agents such as aspirin and clopidogrel presents a special challenge. Given the risk of bleeding, cessation of anticoagulation therapy before or after some hemorrhoid management procedures is advisable. However, withdrawal of the therapy in chronic anticoagulated patients may precipitate new adverse cardiac events.(136, 137)

Iyer et al. reported more instances of rectal bleeding after RBL in patients on warfarin (25%) and aspirin or nonsteroidal anti-inflammatory drugs (7.5%), compared to that in patients who were on neither therapy (2.9%).(138) A review by Albuquerque et al. suggested that secondary bleeding normally occurs 10-14 days after banding and patients taking anti-platelet or anti-coagulant medication have a higher risk, with some reports of massive life-threatening hemorrhage.(52) However, Hite et al. demonstrated no significant difference in rectal bleeding post-RBL between patients taking or not taking clopidogrel bisulfate.(139) A retrospective study by Atallah et al. also revealed that THD can be performed on patients taking anticoagulants without cessation of the oral agents and that this did not increase morbidity from postoperative bleeding.(140) Therefore, whether patients on anticoagulant therapy should or should not undergo the procedure remains unclear.

Hence, surgeons must appraise factors such as patient medical history, risk-benefit ratio of anticoagulant withdrawal, outcomes of invasive procedure, and degree of hemorrhoids during decision-making in order to prevent further complications. Predicting the procedure-associated bleeding risk is the foremost step in anticoagulation management. In patients undergoing a procedure with low bleeding risk, vitamin K antagonists such as warfarin and acenocoumarol should be temporarily interrupted approximately 5 days before surgery and resumed approximately 12-24 h after surgery and in case of adequate hemostasis. Moreover, in patients at a high risk for thromboembolism (mechanical valve, atrial fibrillation, or venous thromboembolism), bridging anticoagulation (with either low-molecular-weight heparin or unfractionated heparin) should be implemented when vitamin K antagonists are stopped.(141) Such an interruption of anticoagulation is reported in patients undergoing non-surgical and surgical procedures for hemorrhoid management.(140, 142, 143) In view of the high postoperative bleeding risk, the American Society of Colon and Rectal Surgeons (ASCRS) contraindicate RBL and favors injection sclerotherapy in patients on

anticoagulants.(26)

### ACRSI recommendation

- The choice of treatment should be based on the grade of hemorrhoids with cautious management of anticoagulation such that there is no cardiac compromise. Cardiologist's opinion should be taken before discontinuing anticoagulants. Injection sclerotherapy is preferable over rubber band ligation due to the risk of postoperative bleeding complications in the latter. ( Strong recommendation based on low or low-to very-low-quality evidence, 1C)

### B. Patients with immunocompromised status or infected with human immunodeficiency virus

Approximately 15% patients with human immunodeficiency virus (HIV) infection have hemorrhoidal disease.(144) Wound healing, peri-operative infections, and anorectal sepsis are the common complications observed in these patients and this risk necessitates careful management of hemorrhoids. Owing to dysfunctional wound healing, conservative treatment should be the mainstay of hemorrhoid management in this category of patients. If conservative management fails, operative procedures should be executed with proper management of CD4 counts and antibiotic prophylaxis.(145) Compelling outcomes of RBL, injection sclerotherapy, and hemorrhoidectomy have been demonstrated in HIV-infected patients.(10-12) Further medical therapy can be used as a first-line treatment option in HIV-infected patients and hemorrhoidectomy should be reserved for necessary cases.

Stapler hemorrhoidectomy should be avoided in homosexual patients because of the risk of trauma by the staple line. Selective management is recommended as it may result in high rates of symptomatic relief and complete wound healing after hemorrhoid surgery without excessive morbidity and mortality.(15) A retrospective study showed the effectiveness and safety of TST in prolapsing hemorrhoids (grade III-IV) in HIV-infected patients;(146) however, this is low-quality evidence.

### ACRSI recommendation

- Conservative treatment should be the first-line approach for management of symptomatic hemorrhoids in HIV-infected patients. If conservative management fails,



surgical procedures should be offered with proper management of CD4 counts and prophylactic antibiotics.(10-12) (Strong recommendation based on low or low-to very-low-quality evidence, 1C)

### C. Hemorrhoids during pregnancy

Hemorrhoids are reported in about 25%-35% of pregnant women, mostly in their third trimester.(147) A retrospective study reported that up to 21.8% women complaining of dyschezia may present with a TEH at some point during their pregnancy, and 7.8% of pregnant women may experience a TEH during their third trimester.(148) Etiological factors such as elevated progesterone level, high iron intake, developing uterus, constipation, and increased blood flow to the uterus predispose women to develop hemorrhoids or intensify the pre-existing hemorrhoids.(149) Management of hemorrhoids in these patients should rely on the type and severity of hemorrhoids, the preference of the patient, and expert opinion.(145) Conservative treatment should be the first-line approach, focusing on relief of symptoms, mostly pain.(150) Conservative therapy includes a diet rich in fibers, high liquid intake, treating constipation, personal cleanliness, and lying on the left side to relieve pain and other symptoms. Sitz bath has been reported to have statistically significant benefits in achieving healing of hemorrhoids in pregnant women compared to conservative treatment with an anorectal cream ( $P < 0.05$ ). (36) Medical therapy with MPFF has been very effective in treating hemorrhoids during pregnancy. In an intention-to-treat trial, MPFF was found to be safe and effective in treating internal hemorrhoids during pregnancy. The study showed that 66% patients had relief of their symptoms by the fourth day of treatment (95% CI: 79.1-52.9).(13) Surgical options should be reserved for the pregnant women who do not respond to conservative therapy.(147) Surgical procedures should be employed in the presence of strangulated, gangrenous hemorrhoids.(151)

#### ACRSI recommendations

- All pregnant women with symptomatic hemorrhoids should be managed using a conservative approach including diet and lifestyle modifications (intake of fiber-rich diet, high liquid intake, relief from constipation, personal cleanliness, and lying on the left side to relieve pain and other symptoms) and medical therapy. (Strong recommendation based on low or low-to very-low-quality evidence, 1C)
- MPFF is a safe and effective medical therapy in the management of hemorrhoids

in pregnant women (usage is not advised during the first trimester in the absence of evidence). In the antenatal period, maintenance treatment with MPFF reduces both the frequency and duration of relapse of symptoms of acute hemorrhoids.(13) (Strong recommendation based on low or low-to very-low-quality evidence, 1C)

- Surgical or non-surgical procedures may be advised for patients who do not respond to conservative management. Surgical procedures should be reserved for strangulated or thrombosed hemorrhoids and performed under local anesthesia. (Strong recommendation based on low or low-to very-low-quality evidence, 1C)

### D. Hemorrhoids in children

Children with hemorrhoids should be treated immediately and monitored carefully in order to prevent the development of infections. Common causes of hemorrhoids in children are constipation, prolonged sitting on a chair, low-fiber and junk diet, and faulty toilet training. Conservative management of hemorrhoids in children includes control of constipation, increasing the intake of fiber and decreasing consumption of spicy and oily food, use of anti-pruritus drugs, use of hemorrhoidal cream, and sitz bath. Some case reports describe the successful management of hemorrhoids in children by radiofrequency ablation, injection sclerotherapy, RBL, and hemorrhoidectomy.(152-154)

#### ACRSI recommendation

- Dietary and lifestyle modifications, proper toilet training, and medical management are the first-line options for hemorrhoids in children. Non-surgical office procedures may be reserved if conservative management fails. (Strong recommendation based on low or low-to very-low-quality evidence, 1C)

### E. Portal hypertension and cirrhosis

The most common consequence of portal hypertension is rectal varices. Flexible sigmoidoscopy should be performed in patients with portal hypertension with active rectal bleeding and rectal varices should be differentiated from hemorrhoids. Hemorrhoids do not extend proximal to the dentate line, are purple, do not collapse with digital pressure, and may prolapse during proctoscopy. In contrast, rectal varices extend more than 4 cm above the anal verge, are dark blue, and collapse



with digital pressure but do not prolapse.(155) The use of conservative measures with correction of any coagulopathy is the preferred initial approach in these patients. Zaher T et al. reported significant improvement in the Goligher's grades of internal hemorrhoids and in the bleeding, with no difference between RBL versus stapled hemorrhoidopexy, in patients with portal hypertension.(156) Although anorectal varices can be managed by suture ligation, RBL is generally contraindicated due to the risk of profound secondary bleeding in patients with advanced cirrhosis.(145) Injection sclerotherapy is effective and safe for treating bleeding hemorrhoids in this situation.(157) Further, hemorrhoidectomy should be reserved for patients who are refractory to other approaches.(145)

No significant difference in the occurrence of hemorrhoids was noted between normal and cirrhotic patients. Generally, RBL is contraindicated in patients with advanced cirrhosis because of the risk of secondary bleeding post-procedure. Conservative measures and correction of coagulopathy should be advised in these patients. Injection sclerotherapy is effective and safe to treat patients with concomitant bleeding hemorrhoids and cirrhosis. In a refractory case, suture ligation at the bleeder or hemorrhoidectomy can be advised.(145) (Grade A Evidence level 3)

#### ACRSI recommendations

- Conservative approach should be tried in all patients with portal hypertension and cirrhosis. (Strong recommendation based on low or low-to very-low-quality evidence, 1C)
- Differentiation between hemorrhoids and rectal varices should be done in portal hypertensive patients with active rectal bleeding. (Strong recommendation based on low or low-to very-low-quality evidence, 1C)
- Management of hemorrhoids associated with portal hypertension remains conservative approach. RBL is contraindicated. (Strong recommendation based on low or low-to very-low-quality evidence, 1C)
- There is lack of robust evidence for surgical management. Only in cases refractory to conservative treatment or in emergency some form of hemorrhoidectomy should be done using newer energy sources like ultrasound scissors or energy sealing systems. (Strong recommendation based on low or low-to very-low-quality evidence, 1C)

#### F. Inflammatory bowel disease

IBD is associated with perianal complications including abscess, fistula, hemorrhoids, diarrhea, skin tags, and fissures. The management of hemorrhoids and fissures in IBD patients may be difficult and could vary from that in their non-IBD counterparts.(158)

Two main types of IBD are ulcerative colitis and Crohn disease. Symptoms of hemorrhoids can be exacerbated in patients with Crohn disease owing to frequent diarrhea. Moreover, in Crohn disease, patients may have problems associated with wound healing or active anorectal inflammation; therefore, treatment for hemorrhoids should be as conservative as possible, because hemorrhoidectomy and other surgery may exacerbate the disease and worsen symptoms.(21, 159) A review by D'Ugo et al. suggested that the first-line management for patients with IBD should be medical therapy, considering the possibility of spontaneous healing.(158) In non-responding patients, hemorrhoidectomy can be performed on a highly selective basis to get acceptable results,(160, 161) while maintaining a high guard for possible complications.(15, 162) The goal of surgery should be to avoid intervention in the presence of asymptomatic complications and active inflammation.

#### ACRSI recommendations

- Management should primarily be conservative; in particular, avoid surgery in acute conditions. (Strong recommendation based on low or low-to very-low-quality evidence, 1C)
- Hemorrhoidectomy should be done in selective cases only. (Strong recommendation based on low or low-to very-low-quality evidence, 1C)

#### G. Thrombosed external hemorrhoids

TEHs are usually associated with acute anal pain along with a newly enlarged or tender bluish lump at the anal verge that can be easily seen on physical examination. Some patients may present with a history of constipation or prolonged staining. Symptom severity depends on the size of the thrombus. Pain and discomfort are greater in the first few days but gradually subside without any intervention over several weeks. High pressure within the thrombus may cause erosion of the overlying skin, resulting in bleeding. Patients can either be treated with conservative therapy or surgically,

depending on the severity of symptoms. Conservative therapy including anti-inflammatory analgesics, sitz bath, and stool softeners is often beneficial.(15, 163)

In a prospective RCT, local application of nifedipine ointment was effective in healing acute TEHs in patients (N = 43).(164) In another RCT, pain intensity in patients with TEH was significantly reduced within 24 hours of BOTOX treatment ( $P < 0.001$ ) compared to placebo.(165) For perianal thrombosis, excision showed significantly better results in terms of decreasing pain, recurrence, and number of skin tags when compared with incision or topically applied 0.2% glyceryl trinitrate ointment ( $P < 0.001$ ). (166)

Gallo et al. recommended surgical excision for patients who are diagnosed within 72 hours of onset of symptoms of TEHs. If the diagnosis happens after 72 hours, conservative treatment is recommended.(167) In a randomized trial, stapled hemorrhoidectomy was found to be safe and effective in patients with acute thrombosed hemorrhoids compared to conventional hemorrhoidectomy.(168) Zuber et al. performed hemorrhoidectomy through an elliptic incision over the site of thrombosis after removal of the entire diseased

hemorrhoidal plexus in one piece. However, caution must be exercised to avoid cutting into the muscle sphincter below the hemorrhoidal vessels.

They also reported a rare risk of infection after closing sutures that are secondary to the rich vascular network in the anal area. Stool softeners must be prescribed postoperatively to help prevent tearing at the suture line. They emphasized on training and experience in general and the need for skin surgery before the physician attempts this procedure unsupervised.(169)

#### ACRSI recommendations

- Thrombosed piles are an extremely painful condition and are an emergency. Prompt medical treatment is required. If the patient does not respond to medical therapy within 48 hours, then surgical excision should be performed. (Strong recommendation based on low or low-to very-low-quality evidence, 1C)

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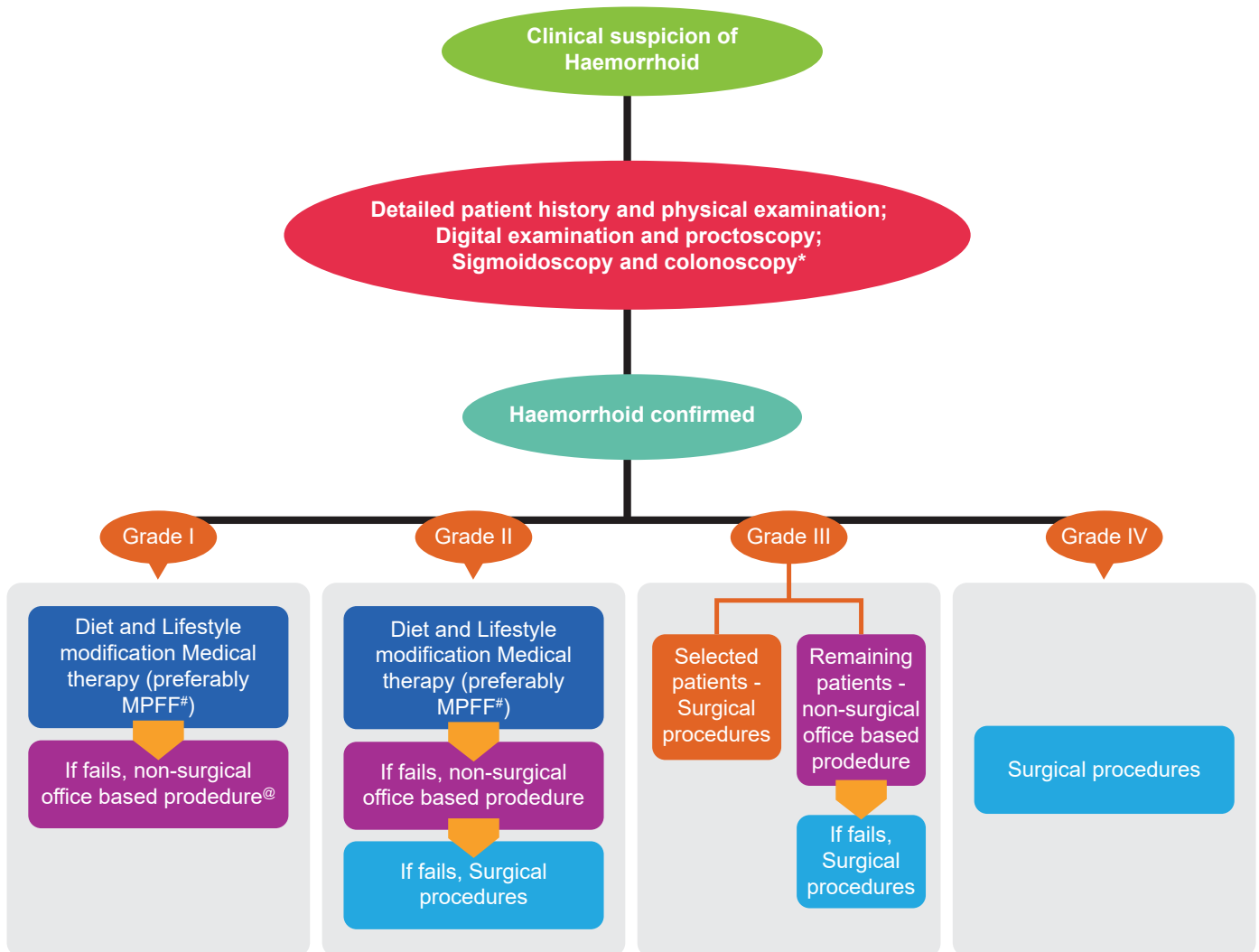
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\*Not advised routinely, and recommended in selected patients with age  $\geq 50$  years and who have not had a complete colon examination within past 10 years; or when alarming symptoms are present i.e. suspicion of underlying malignancy

#Micronized purified flavonoid fraction; MPFF also serves as an adjuvant for procedures and surgery

- Rubber band ligation (RBL), Sclerotherapy, Infrared coagulation (IRC);
- Preferably rubber band ligation. Choice of methods can be made depending on patient characteristics like anticoagulation, pregnancy, portal hypertension etc.

- Conventional haemorrhoidectomy using ligasure/ harmonic procedure; Procedure for prolapse and haemorrhoids; Doppler-guided haemorrhoidal artery ligation with rectopexy.
- Closed procedure has more advantage than open haemorrhoidectomy
- Procedure for Prolapsing Haemorrhoids (PPH) and Doppler-guided haemorrhoidal artery ligation (DGHL) are associated with less complication, but, high recurrence





# COMPREHENSIVE MEDICAL MANAGEMENT OF ANORECTAL DISORDERS<sup>1,2,3</sup>

In Chronic Constipation<sup>3</sup>

## Duphalac<sup>®</sup>

Lactulose

HEMORRHOIDS

ANAL FISSURES

For Management of Acute Hemorrhoids<sup>1</sup>

## Dezoflav<sup>™</sup>

Micronized Purified Flavonoid Fraction of Rutaceae 1000 mg Tablets


For Management of Anal Fissures<sup>2</sup>

## FIDONAL<sup>™</sup>

Nifedipine &amp; Lidocaine Cream



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Ref.: 1. Dezoflav Prescribing Information, Dec 2018. | 2. Fidonanal Prescribing Information | 3. Duphalac Prescribing Information

**DEZOFLAV:** Abbreviated Prescribing Information

MICRONIZED PURIFIED FLAVONOID FRACTION OF RUTACEAE 1000 MG TABLETS DEZOFLAV 1000mg

**LABEL CLAIM:** Each film coated tablet contains: Micronized Purified Flavonoid fraction of Rutaceae composed of Diosmin 900 mg, Flavonoids expressed as Hesperidin 100 mg. **INDICATION:** Acute hemorrhoid (piles). **DOSAGE AND ADMINISTRATION:** For the treatment of acute haemorrhoidal attacks: MPFF 1000 mg 3 tablets daily for 4 days followed by 2 tablets daily for 3 days. For the treatment of haemorrhoids: the maintenance dose is 1 tablet daily for a duration according to the physician's discretion. **CONTRAINDICATIONS:** Hypersensitivity to the micronized purified flavonoid fraction or to any of the excipients. **WARNINGS & PRECAUTIONS:** Hemorrhoidal attack: The administration of this product does not preclude treatment for other anal conditions. The treatment must be short-term. If symptoms do not subside promptly; a proctological examination should be performed and the treatment should be reviewed. **PREGNANCY AND LACTATION:** Experimental studies performed in animals have not revealed any teratogenic effect. Moreover, no harmful effects have been reported to date in humans. Breastfeeding is not recommended during treatment. **ADVERSE REACTIONS:** Side effects reported with MPFF in clinical trials are of mild intensity. They consist mainly in gastro-intestinal events (diarrhea, dyspepsia, nausea, vomiting). Issued on: 24th December 2018 Source: Prepared based on full prescribing information, version v1.0, dated: 27th November 2018

For full prescribing information, please contact: Medical Sciences Division, Abbott India Limited, Floor 16, Godrej BKC, Plot No. C - 68, BKC, Near MCA Club, Bandra (E), Mumbai - 400 051.

**Abbreviated Prescribing Information**

Lactulose Solution USP; Duphalac<sup>®</sup>; Duphalac<sup>®</sup> Enema COMPOSITION: Each 5 ml contains: Lactulose Solution USP, equivalent to Lactulose 3.335 g

**Reconstitution for Duphalac<sup>®</sup> Enema:** To be reconstituted to 20% before use. **INDICATIONS:** Constipation: regulation of the physiological rhythm of the colon | Where a soft stool is considered of medical benefit (haemorrhoids, post colonic/anal surgery) | Hepatic encephalopathy (HE): treatment and prevention of hepatic coma or precoma (adults). **DOSAGE AND ADMINISTRATION:** Duphalac<sup>®</sup> The lactulose solution, may be administered diluted or undiluted. The posology should be adjusted according to the individual needs of the patient. A single dose of lactulose should be swallowed in one and should not be kept in the mouth for an extended period of time. In case of single daily dose, this should be taken at the same time, e.g. during breakfast. During the therapy with laxatives it is recommended to drink sufficient amounts of fluids (1.5 - 2 litres, equal to 6-8 glasses) during the day. Dosing in constipation or where a soft stool is considered of medical benefit Lactulose may be given as a single daily dose or in two divided doses, for which measuring cup may be used. After a few days the starting dosage may be adjusted to the maintenance dose based upon treatment response. Several days (2-3 days) of treatment may be needed before treatment effect occurs.

	Duphalac <sup>®</sup>	Duphalac <sup>®</sup> Enema
	Starting dose daily	Maintenance dose daily
Adults and adolescents	15-45 ml	15-30 ml
Children (7-14 years)	15 ml	10-15 ml
Children (1-6 years)	5-10 ml	5-10 ml
Infants under 1 year	upto 5 ml	upto 5 ml

Dosing in HE (for adults only) For oral administration: Starting dose: 3 to 4 times daily 30-45 ml.

This dose may be adjusted to the maintenance dose to achieve 2 to 3 soft stools per day. For rectal administration: In acute cases (impending coma or coma stage) Trademark may be administered as a retention enema (300ml Trademark/700ml water). The enema is to be retained for 30-60 minutes; the procedure is to be repeated every 4-6 hrs until oral medication can be administered. Duphalac<sup>®</sup> Enema: The administration of Duphalac as a retention enema is an alternative technique. This can be done by diluting Duphalac and is of considerable value especially in unconscious patient. In such cases 300 ml of Duphalac may be mixed with 700ml of potable water to be used as retention enema; the enema is to be retained for 30 - 60 minutes and repeated every 4 - 6 hours until the patient is able to take oral medication. Paediatric population: The safety and efficacy in children (newborn to 18 years of age) has not been established. No data are available. Elderly patients and patients with renal or hepatic

insufficiency: No special dosage recommendations exist, since systemic exposure to lactulose is negligible. **CONTRAINDICATIONS:** Hypersensitivity to the active substance or to any of the ingredients | Galactosaemia | Gastrointestinal obstruction, digestive perforation or risk of digestive perforation. **PRECAUTIONS:** Consultation of a physician is advised in case of Painful abdominal symptoms of undetermined cause before the treatment is started, insufficient therapeutic effect after several days. Lactulose should be administered with care to patients who are intolerant to lactose. The dose normally used in constipation should not pose a problem for diabetics. The dose used in the treatment of HE is usually much higher and may need to be taken into consideration for diabetics. Chronic use of undiluted doses and misuse can lead to diarrhea and disturbance of the electrolyte balance. This product contains lactose, galactose and small amounts of fructose. Therefore, patients with the hereditary problems of galactose or fructose intolerance, total lactase deficiency or glucose-galactose malabsorption should not take this medicine. When administered as a retention enema, due to the strong cathartic effect, fecal incontinence, bedsores, and peri-anal irritation due to the acidic stool can be expected. The hydration status of the patient should be observed carefully. This product contains sulphite from the route of production. **PREGNANCY AND LACTATION:** No effects during pregnancy are anticipated, since systemic exposure to lactulose is negligible. No effects on the breastfed newborn/infant are anticipated since the systemic exposure of the breast-feeding woman to lactulose is negligible. **ADVERSE REACTIONS:** Flatulence may occur during the first few days of treatment. As a rule, it disappears after a few days. When dosages higher than instructed are used, abdominal pain and diarrhoea may occur. In such a case the dosage should be decreased. If high doses (normally only associated with hepatic encephalopathy (HE)) are used for an extended period of time, the patient may experience an electrolyte imbalance due to diarrhea. Hypersensitivity reactions mainly limited to the skin have been observed and identified as potential adverse reactions during post approval use. Because these reactions were reported spontaneously from a population of uncertain size, it is not possible to reliably estimate their frequency. Issued on: 13th May 2021; Source: Prepared based on full prescribing information (version v8.0) dated 13th May 2021. \* Trademark of the Abbott Group of Companies | For full prescribing information, please contact: Medical Sciences Division, Abbott India Limited, Floor 17, Godrej BKC, Plot No. C - 68, BKC, Near MCA Club, Bandra (E), Mumbai - 400 051.

**FIDONAL:** Abbreviated Prescribing Information: Nifedipine & Lidocaine Cream

**LABEL CLAIM:** Nifedipine I.P. 0.3% w/w; Lidocaine I.P. 1.5% w/w; Benzyl Alcohol I.P. (As a preservative) 1.0% w/w; In a Cream Base q.s. **INDICATION:** For the treatment of anal fissures. **DOSAGE AND ADMINISTRATION:** Apply the cream twice daily for at least 3 weeks. Please refer full prescribing information for detailed method of administration. **CONTRAINDICATIONS:** Hypersensitivity to the active ingredient and in particular to Lidocaine and other anesthetics of similar type/structure or any of the excipients, pregnancy - ascertained or presumed, & lactation. **WARNINGS & PRECAUTIONS:** Excessive doses and / or usage for prolonged periods of time can give rise to phenomena of sensitization and reactions of local hyperaemia and bleeding that disappear with discontinuation of treatment. Caution in patients who have severely damaged mucosa and inflammation in the region to be treated. **PREGNANCY AND LACTATION:** Usage is advised only if substantial benefit justifies the potential risk. **ADVERSE REACTIONS:** Local reactions may occur such as pain, burning, itching, hyperemia and bleeding. These effects resolve after discontinuation of treatment.

Issued on: 05th March 2019 Source: Prepared based on full prescribing information, version v1.0, dated: 07th February 2019

For full prescribing information, please contact: Medical Sciences Division, Abbott India Limited, Floor 16, Godrej BKC, Plot No. C - 68, BKC, Near MCA Club, Bandra (E), Mumbai - 400 051.

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