HeLP
Painless Outpatient treatment of Hemorrhoids

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biolitec AG
Contents

• The Pathology
• The treatments
• HeLP: the Outpatient treatment option
• The market
• Conclusion and Discussion
Hemorrhoids: the Pathology

• **Hemorrhoids** (AmE), **haemorrhoids** (BrE), or **piles** are varicosities or swelling and inflammation of veins in the rectum and anus. The anatomical term "hemorrhoids" technically refers to "'Cushions of tissue filled with blood vessels at the junction of the rectum and the anus."[1] However, the term is popularly used to refer to varicosities of the hemorrhoid tissue.

• These cushions are part of the normal anatomy and are thought to aid in defecation and assist in closing the anal canal. Hemorrhoids are custom cushions where blood flows in and out to swell or shrink the tissue to provide continence. Over time these cushions can enlarge and even prolapse or protrude from the anus.

• Perianal hematoma are sometimes misdiagnosed and mislabeled as hemorrhoids, when in fact they have different causes and treatments.[2]

2. Perianal hematoma - Medbroadcast
Men and women alike have hemorrhoids, they occur naturally in the body.

Hemorrhoids are common. By age 50, about half of adults have had to deal with the itching, bleeding and pain that often signal the presence of hemorrhoids.

In the USA, the prevalence is about 4.4%. Annually, about 10% to 20% of patients with symptomatic hemorrhoids require surgery. According to a British medical journal of 1972 hemorrhoids "are common in economically developed communities, rare in developing countries, and almost unknown in tribal communities, where the influence of Western countries is slight."
Hemorrhoids: Causes

- Increased straining during bowel movements, by constipation or diarrhea, may lead to hemorrhoids. [7] It is thus a common condition due to constipation caused by water retention in women experiencing premenstrual syndrome or menstruation.

- Hypertension, particularly portal hypertension, can also cause hemorrhoids because of the connections between the portal vein and the vena cava which occur in the rectal wall -- known as portocaval anastomoses. [8]

- Obesity can be a factor by increasing rectal vein pressure. Sitting for prolonged periods of time can cause hemorrhoids. Poor muscle tone or poor posture can result in too much pressure on the rectal veins.

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Hemorrhoids: Causes

- Pregnancy causes hypertension and increases strain during bowel movements, so hemorrhoids are often associated with pregnancy.

- Excessive consumption of alcohol or caffeine can cause hemorrhoids.[9] Both can cause diarrhea. Note that caffeine ingestion increases blood pressure transiently, but is not thought to cause chronic hypertension. Alcohol can also cause alcoholic liver disease leading to portal hypertension.

- Medical experts including the late Dr. Robert Atkins, of 'Atkins Diet' fame, have warned against undertaking acts of a sexual nature involving the anus. The frequent participation in penetrative anal sex with or without the use of a condom or lubricating substances, can perhaps induce the occurrence of haemorrhoids or indeed significantly agitate existing haemorrhoids.[10]

Hemorrhoids: Symptoms

- Many anorectal problems, including fissures, fistulae, abscesses, or irritation and itching, also called pruritus ani, have similar symptoms and are incorrectly referred to as hemorrhoids.

- Hemorrhoids usually are not dangerous or life threatening. In most cases, hemorrhoidal symptoms will go away within a few days. Although many people have hemorrhoids, not all experience symptoms. The most common symptom of internal hemorrhoids is bright red blood covering the stool, on toilet paper, or in the toilet bowl.

- However, an internal hemorrhoid may protrude through the anus outside the body, becoming irritated and painful. This is known as a protruding hemorrhoid.

- Symptoms of external hemorrhoids may include painful swelling or a hard lump around the anus that results when a blood clot forms. This condition is known as a thrombosed external hemorrhoid.
Types of Hemorrhoids

- **External hemorrhoids:** are those that occur outside of the anal verge (the distal end of the anal canal). They are sometimes painful, and can be accompanied by swelling and irritation. External hemorrhoids are prone to thrombosis: if the vein ruptures and a blood clot develops, the hemorrhoid becomes a thrombosed hemorrhoid.[11]

- **Internal hemorrhoids:** are those that occur inside the rectum. As this area lacks pain receptors, internal hemorrhoids are usually not painful and most people are not aware that they have them. Internal hemorrhoids, however, may bleed when irritated. Untreated internal hemorrhoids can lead to two severe forms of hemorrhoids: prolapsed and strangulated hemorrhoids:
  - Prolapsed hemorrhoids are internal hemorrhoids that are so distended that they are pushed outside the anus.
  - If the anal sphincter muscle goes into spasm and traps a prolapsed hemorrhoid outside the anal opening, the supply of blood is cut off, and the hemorrhoid becomes a strangulated hemorrhoid.

Classification of Hemorrhoids

- The most common grading system was developed by Banov: [3][12]

- Grading of Internal Hemorrhoids by degree of prolapse:
  - Grade I: The hemorrhoids do not prolapse.
  - Grade II: The hemorrhoids prolapse upon defecation but spontaneously reduce.
  - Grade III: The hemorrhoids prolapse upon defecation and must be manually reduced.
  - Grade IV: The hemorrhoids are prolapsed and cannot be manually reduced.

Hemorrhoids: prevention

• Prevention of hemorrhoids includes drinking more fluids, eating more dietary fiber (such as fruits, vegetables and cereals high in fiber), exercising, practicing better posture, and reducing bowel movement strain and time. Food considered "probiotic", such as yogurt with active culture, may help keep the gut functioning normally and thus prevent flare-ups.

• Hemorrhoid sufferers should avoid using laxatives and should strictly limit time straining during bowel movement. Wearing tight clothing and underwear will also contribute to irritation and poor muscle tone in the region and promote hemorrhoid development.

• Women who notice they have painful stools around the time of menstruation would be well-advised to begin taking extra dietary fiber and fluids a couple days prior to that time.

• Kegel exercises for the pelvic floor may also prove helpful.
Treatment of Hemorrhoids

- Treatments for hemorrhoids vary in their cost, risk, and effectiveness. Different cultures and individuals approach treatment differently. Of course also according to the degree of the disease.

- First, we could talk about **Non Surgical Treatments**: divided in **Natural** or **Pharmacological** treatments;

- For many people, hemorrhoids are mild and temporary conditions that heal spontaneously or by the same measures recommended for prevention. There is no medicine that will cure hemorrhoids but local treatments can also provide temporary relief.

- Especially in the case of external hemorrhoids with a visible lump of small size, the condition can be improved with warm bath causing the vessels around rectal region to be relaxed. Consistent use of medicated creams during the early stages of a hemorrhoid flare-up will also provide relief and may stave off further development and irritation. However, creams containing steroid preparations weaken the skin and may contribute to further flare-ups. Ointment or suppositories can also relieve the symptoms.
Surgical Treatment of Hemorrhoids

- Reassurance and exclusion of serious disease is important in some cases.

- Some people require the following medical treatments for chronic or severe hemorrhoids:
Rubber Band Ligation

- Elastic bands are applied onto an internal hemorrhoid to cut off its blood supply.[28]
- Within several days, the withered hemorrhoid is sloughed off during normal bowel movement.
- Possible complications:
  - Pain
  - Bleeding
  - Band slippage or breakage
  - Infection and pelvic sepsis
  - Thrombosed hemorrhoids
  - Anal fissure
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  ▪ Thrombosed hemorrhoids
  ▪ Anal fissure
Sclerotherapy (injection therapy)

- Sclerosant or hardening agent is injected into hemorrhoids.
- This causes the vein walls to collapse and the hemorrhoids to shrivel up.

**Complications**, while rare include:

- Venous thromboembolism, thrombophlebitis, skin necrosis,
- Hyper-pigmentation and visual disturbances
- Allergic reaction
- A recent report attributed a stroke to foam treatment [13], although this involved the injection of an unusually large amount of foam

Hemorrhoidectomy

- A true surgical procedure to excise and remove hemorrhoids.
- An in-patient stay is often required (average of 3 days).
- For this reason is often now recommended only for severe (grade IV) hemorrhoids.

**Complications:**
- Has possible correlation with incontinence issues later in life;
- Many patients complain that pain during recovery is severe and recovery time long.
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Stapled Hemorrhoidectomy

- Also called **PPH**: Procedure for Prolapse and Hemorrhoids
- This procedure was first described by an Italian surgeon – Dr. Antonio Longo, Department of Surgery, University of Palermo – in 1993
- Employs a unique circular **stapler** which reduces the degree of prolapse by excising a circumferential strip of mucosa from the proximal anal canal. This has the effect of pulling the hemorrhoidal cushions back up into their normal anatomical position.
- PPH is generally indicated for the **more severe cases of hemorrhoidal prolapse** (3rd and 4th degree) where surgery would normally be indicated.
- It's meant for hemorrhoids that fall out or bleed and is not helpful for painful outside conditions.
- The procedure may be contra-indicated when only one cushion is prolapsed or in severe cases of fibrotic piles which cannot be physically repositioned.
- Usually the patient will be under general anesthetic, but only for 20-30 minutes. Many cases have been successfully performed under local or regional anesthesia and the procedure is suited to day case treatment.
Stapled Hemorrhoidectomy
Stapled Hemorrhoidectomy

- Post Operative **complications:**
  - Urinary retention in the immediate post-operative period appears to be the most common complication.
  - Should there be some post-operative bleeding, this can be dealt with either by the district nurse or in the GP surgery. If it is still a concern, refer the patient back to the hospital.
  - Cheetham et al conclude that a disturbingly high proportion of patients developed persistent, severe pain and fecal urgency following stapled hemorrhoidectomy, and the long-term complications following this procedure outweigh the benefits of decreased postoperative pain. [14]

Doppler Guided Hemorrhoidectomy

- Performed using a modified proctoscope in conjunction with a Doppler ultrasound flowmeter.
- A needle and thread is passed beneath the artery, and a knot is externally tied, to stop the blood flow to the hemorrhoid.
- It does not involve cutting tissues but could help with a retraction component due to the suture.
- It is performed normally under local anesthesia and patients are usually back to work on the same day.
- Indicated in management of Grade II & Grade III Hemorrhoids
- HAL Doppler and THD - Transanal Hemorrhoidal Dearterialization - are the more popular systems.
Doppler Probe: Signal

Ligation

2 - 3 cm

Petinate Line

Doppler Probe: Signal
Doppler Guided Hemorrhoidectomy

• **Complications:**
  - The procedure requires a very high manual training by the surgeon as a suture needs to be done through an anus-scope. It could take very long time for inexperienced surgeon.
  - Some patients refer persistent significant pain after the procedure.
  - Swelling and thrombosis of the hemorrhoids and a secondary hemorrhage occurred in some patients. [15]

15. Felice George et al. Doppler-guided hemorrhoidal artery ligation : An alternative to hemorrhoidectomy
Other Treatments

- **Photocoagulation:** a device called a photocoagulator focuses infrared light into a fine point at the end of a probe, which spot-welds the hemorrhoid in place. This is used for hemorrhoids that are actively bleeding. Only effective for Grades I & II.

- **Hemorrhoidolysis:** Consists of the application of a small probe (electrode) to each hemorrhoid using manual pressure under direct vision (commonly known as the "Ultroid" method). This causes a gentle electrolysis that results in progressive, complete and permanent shrinkage of the hemorrhoid tissue. More than one hemorrhoid site may be treated at each visit with the actual treatment lasting only a few minutes. The average hemorrhoid case will require 3 treatments for symptomatic resolution. Mainly used on internal hemorrhoids.

- **Cryotherapy:** application of extreme cold to the hemorrhoid. This causes the affected tissue to slough off, so that new healthy tissue can grow in its place. Mainly used on external hemorrhoids.

- **Cryosurgery:** A frozen tip of a cryo-probe is used to destroy hemorrhoidal tissues.[29] Rarely used anymore because of side effects.

- **Laser Hemorrhoidectomy:** Uses laser energy for vaporizing or excising giving the only advantage of hemostasis against surgical hemorrhoidectomy. **Not to be confused with HeLP**
HeLP™
Painless Out-Patient treatment of hemorrhoids

HeLP: the Outpatient treatment option
HeLP: Painless Outpatient Treatment of Hemorrhoids

- A new minimally invasive surgical technique for treating hemorrhoids using a 980nm diode laser guided by Doppler for photocoagulation of the distal branches of hemorrhoidal arteries.
- Based on Doppler guided ligation of the distal branches of hemorrhoidal arteries
- Minimally invasive procedure, Painless, Outpatient basis, No anesthesia or sedation
HeLP™ Platform

- biolitec “Ceralas Laser - 15W”
- HeLP™ Doppler Transceiver (P/N AB2530)
HeLP™ Procedure Kit

- HeLP™ Procedure Kit (P/N 500400510) comprising:
  - HeLP™ Proctoscope
  - HeLP™ Proctoscope introducer with Working Channel
  - HeLP™ Doppler Probe
  - HeLP™ Laser Fiber with Handpiece
HeLP™ Proctoscope

- Reduced dimensions (for patient comfort!)
- Channel used for illumination of the treatment site
- Multipurpose working channel
- Small operation window for performing the procedure, placed about 5-7 cm from the skin line
- Viewing window
HeLP™ Proctoscope
HeLP™ Doppler & Handpiece

- Exclusive 20MHz Doppler unit to identify the small hemorrhoidal branches
- Both probes disposable and single use
- Reduced dimensions (for patient comfort!)
- Working on the same channel
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HeLP: Step-by-Step Procedure

- Insertion of the HeLP Proctoscope into the anal canal above the hemorrhoidal cushions
- Artery detection assessed by ultrasound Doppler (3 mm diameter, 20MHz probe).
- Application of focalized laser energy for photo-coagulating the submucosal branches of hemorrhoidal arteries
- Suggested parameters:
  - Laser on pulsed mode
    - 14W - 1.3 sec
    - 4 pulses / hemorrhoidal branch
    - Total energy of aprox. 70J x branch
- Verification of artery closure using Doppler
- Proctoscope is rotated for each of the submucosal branches of the superior hemorrhoidal arteries and the procedure is repeated until all are treated and closure verified
HeLP: Advantages

- Minimally invasive procedure,
- Painless both during the procedure and after,
- Outpatient basis,
- No anesthesia or sedation,
- Easy and quick to perform,
- No risk of cross contamination
- High level of success
- Advantages against most of the established procedures:
<table>
<thead>
<tr>
<th>Treatment</th>
<th>Characteristics</th>
<th>Procedure</th>
<th>Sutures</th>
<th>Pain during treatment</th>
<th>Pain post treatment</th>
<th>Bleeding (Post treatment)</th>
<th>Efficacy (@ 2 years)</th>
<th>Degree</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sclerotherapy</td>
<td>Inexpensive</td>
<td>Operator dependent</td>
<td>No</td>
<td>Sometimes</td>
<td>Often (12.5 - 70%)</td>
<td>Rare (5%)</td>
<td>Fare (21%)</td>
<td>I - II</td>
</tr>
<tr>
<td>Rubber Band Ligation</td>
<td>Inexpensive</td>
<td>Operator dependent</td>
<td>No</td>
<td>Localized Pain</td>
<td>Very Painful sometimes (5.2 - 60%)</td>
<td>Follow up visit @ 1 wk (12%)</td>
<td>Good (43%)</td>
<td>II - III (Limited IV)</td>
</tr>
<tr>
<td>Surgery</td>
<td></td>
<td></td>
<td>Yes</td>
<td>Yes</td>
<td>Rare (4.5 - 8%)</td>
<td>Sometimes (15%)</td>
<td></td>
<td>III - IV</td>
</tr>
<tr>
<td>Stapler</td>
<td></td>
<td>(Yes)</td>
<td>Yes</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>III - IV</td>
</tr>
<tr>
<td>THD / HAL</td>
<td>Arterial Ligation</td>
<td>Simple if experienced</td>
<td>Yes</td>
<td>Low</td>
<td>Low</td>
<td>Low (7%)</td>
<td>Very Good (70%)</td>
<td>II - III</td>
</tr>
<tr>
<td>HeLP</td>
<td>Laser Arterial Photo-coag.</td>
<td>Very simple</td>
<td>No</td>
<td>Very Low</td>
<td>Very Low</td>
<td>Low</td>
<td>NA</td>
<td>II - III</td>
</tr>
</tbody>
</table>
Market Discussion

- Comparison (marketing / SWOT)
- Prices
- Reimbursement
- Positioning
SOWT

- Strength: Clinical Advantages
- Opportunities: Market need for effective and less invasive treatment
- Weaknesses: Low clinical data/history
- Threats: Other inexpensive procedures
Conclusions & Discussion