# **Doppler Guided Hemorrhoidal Artery Ligation** and Recto Anal Repair Procedures

What is (DG) HAL/RAR?
Results, Benefits, & Risks
Procedure Time
Pre and Post Procedure
Grade 1 to 4 Hemorrhoids
(DG) HAL/RAR® System
A.M.I. HAL Method
A.M.I. RAR Method
HAL/RAR Publications

## How can (DG) HAL/RAR® help me?

A product of A.M.I. (Agency for Medical Innovations) is the (DG) HAL/RAR® System. It is the first system to utilize minimally invasive surgical techniques to treat the source of hemorrhoidal disease without surgical excision, stapling or banding. It is a single system that offers two procedure options, (DG) HAL (Doppler Guided Hemorrhoidal Artery Ligation) and (DG) RAR (Doppler Guided Recto Anal Repair Proctoplasty/Mucopexy).

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## How many patients have been treated and what are the results?

Available to patients since 2001, the procedures have been successfully performed on tens of thousands of patients worldwide. Physicians report an institutional success rate of 93-96% in treating patients with grades II to IV disease. Complication rates are very low, and any complications that do occur, such as minor bleeding, thrombosis, and defecation pain, are very manageable.

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## How long does the procedure take, will I be hospitalized, and when can I go back to work?

The procedure can take as little as twenty minutes and patients usually leave the same day. Most patients experience only minor pain and discomfort, and return to work the next day.

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## What kind of care will I need before, during, and after the procedure? What medications will the doctor prescribe?

Discuss this in-depth with your physician as your age, weight, and physical condition will influence how you are medicated and managed during and after the procedure. Your surgeon may opt to forgo general anesthesia for conscious sedation. Again, you should discuss these

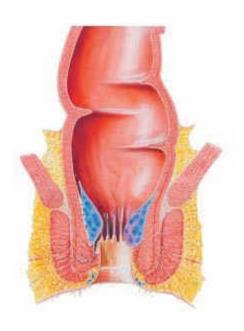
options with your doctor. Results are variable but post-procedural pain medications are usually minimal and for limited duration.

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## **Grade 1 Through 4 Hemorrhoid Prolapse**

## Grade 1 Prolapse

Hemorrhoid protrudes into the anal canal but does not prolapse outside the anus

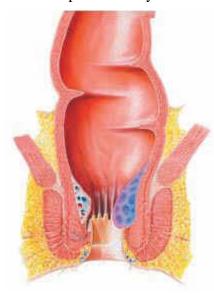


Grade 3 Prolapse

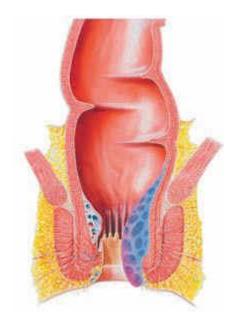
Hemorrhoid protrudes through the anus during straining or evacuation but needs to be manually returned to position

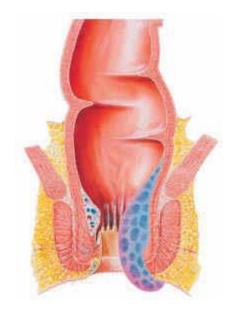
### Grade 2 Prolapse

Hemorrhoid protrudes through the anus during straining or evacuation but returns spontaneously.



Grade 4 Prolapse
Hemorrhoid remains prolapsed outside the anus





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## A.M.I. (DG) HAL/RAR® System

The (DG) HAL/RAR® System is the first system to utilize minimally invasive surgical techniques to treat the source of hemorrhoidal disease without surgical excision, stapling or banding. It is a singlesystem that offers two procedure options, (Doppler Guided) Hemorrhoidal Artery Ligation and Recto Anal Repair (Proctoplasty).

#### Features and Benefits:

#### Good control

- \* Rapid identification of terminal branches of superior hemorrhoidal artery
- \* Precise, accurate ligation
- \* Immediate confirmation

#### Minimal discomfort

- \* Minimally invasive surgery
- \* Ligation sutures are placed 2-3 cm above dentate line
- \* General or MAC sedation

#### High success rate

- \* 90% or greater success rate
- \* No major complications reported
- \* Ratio of inflow to outflow drops significantly

## HAL Doppler II System

Minimally-invasive treatment for lower grades of hemorrhoids.



Features and Benefits:

- Displays identified artery depth.
- Displays blood flow velocity in identified arteries.
- New: A built in printer generates a protocol on the number, position and depth of ligated arteries.
- Recto Anal Repair (RAR®) Proctoplasty (Mucopexy)

A mucopexy can be performed through the window of the (DG) HAL proctoscope to treat grades III and IV hemorrhoids.



Features and Benefits:

- No resection of mucosal tissue
- No severe complications reported

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A.M.I. HAL Method









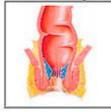
The HAL Method - Doppler Guided Hemorrhoidal Artery Ligation Procedure

- 1. The patient is positioned in Lateral Recumbent or in a Lithotomy Position.
- 2. Ultra Sound Gel is put on the A.M.I. HAL-Doppler Proctoscope before it is fully trans-anally inserted and slowly/gently turned until a typical Doppler sound of arterial blood flow can be heard.
- 3. The identified arteries are ligated in a distance 3 to 4 cm proximal to the Dentate Line through the ligation window of the A.M.I. HAL-Doppler Proctoscope, thus reducing the blood inflow to the inner hemorrhoidal plexus.

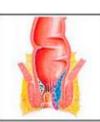
#### Good control

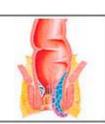
- Rapid identification of terminal branches of superior hemorrhoidal artery
- Precise, accurate ligation
- Immediate confirmation
- Minimum discomfort
- Minimally invasive surgery
- Ligation sutures are placed 2-3 cm above dentate line
- General or MAC (Monitored Anesthesia Care) sedation
- High success rate
- 90% or greater success rate
- No major complications reported
- Ratio of inflow to outflow drops significantly









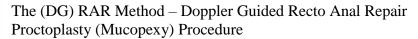


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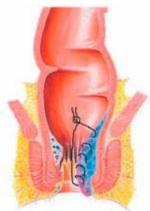
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#### A.M.I. RAR Method





- 1. First, a running stitch is made from the top to the bottom. The device is so designed that only the prolapsing tissue is caught by the needle.
- 2. The ends of the thread are pulled together and knotted at the top. This has the effect of lifting up the hemorrhoids that are hanging down.
- 3. With this "lifting", the hemorrhoids are back where they belong. The tissue scars over and integrates "seamlessly" back into the anal tissue. The stitches are placed not in the anus but in the lower rectum, where there are almost no pain nerves. Patients report little discomfort or pain associated with these procedures.



#### Patient Satisfaction

- "93.75% of patients would recommend treatment with (DG) HAL/RAR® to a friend because of the level of pain and effectiveness"
- "91% of patients would ask for HAL treatment if necessary"
- Recovery normally takes just one to three days



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## HAL/RAR Publications Medical Reports on (DG) HAL/RAR (in chronological order)

Scheyer M. Arnold St

HAL/RAR-A Combination of Doppler-Guided Hemorrhoidal Artery Ligation and Transanal Rectal Mucopexy for the Treatment of all Stages of Hemorrhoidal Disease with the Hemorrhoidal Treatment System

Bludenz State Hospital (LKH), Department of General Surgery Hemorrhoidal disease is one of

the most common diseases of the anal region. Ten percent of patients require surgical intervention. At our department, we have performed hemorrhoidal artery ligation (HAL) since 2000 and have further refined the technique of Doppler ultrasound-guided recto-anal repair (RAR), the combination of HAL and transanal rectal mucopexy (TRM). From January 2000 to July 2006, we applied HAL in 656 patients. Our results show that HAL can be performed successfully and with high patient comfort in patients with grade 2, grade 3, and grade 4 hemorrhoidal disease. Merely the recurrence rate for prolapse (13%) in grade 3 patients and a far too high rate of prolapse recurrence (almost 60%) in grade 4 patients were not satisfactory. Based on our own experience and references in the literature, we developed RAR, a combination of Doppler-guided HAL and TRM. A proctoscope, specially designed for this purpose (HTS Hemorrhoidal Treatment System), enables the standardized application of HAL and the use of continuous sutures for narrowing the prolapse. The Doppler-guided HAL leads to a reduction of the blood flow and a shrinking of existent hemorrhoidal cushions, while TRM leads to a lifting of the prolapse. On the whole, this standardized technique allows for the restoration of the normal anatomy using minimally invasive surgery with substantially reduced patient pain and discomfort. We report our first 110 cases treated with Doppler-guided RAR. The results show that with this new technique we can refer to a minimally invasive procedure for the treatment of all stages of hemorrhoidal disease that achieves high patient satisfaction and has a success rate of over 90%.

B.M. Wallis de Vries . E.S.J. van der Beek . L.R.H. de Wijkerslooth . W.C. van der Zwet . J.A.B. van der Hoeven . M.Eeftinck Schattenkerk . E.H. Eddes

Treatment of Grade 2 and 3 Hemorrhoids with Doppler-Guided Hemorrhoidal Artery Ligation Abstract

Aim: We evaluated the results of the Doppler-guides hemorrhoidal arterial ligation (DG-HAL) method in the management of symptomatic grade 2 and 3 hemorrhoids. Patients and Methods:

Between June 2005 and March 2006, 110 consecutive patients with symptomatic grade 2 and 3 hemorrhoids according to the DG-HAL method were treated. All procedures were preformed in daycare under spinal anaesthesia. The primary objective was the reduction in hemorrhoidal gradation as determined by proctscopy; the secondary was patient satisfaction This was measured by interviewing patients over the telephone. Results: The average age as 47,6 years. 42 patients had grade 2 hemorrhoids, 58 grade 2. An average of 7.3 ligations were placed. Proctoscopy showed that, after 6 weeks, 97 (88%) patients had a significant improvement in their hemorrhoidal gradation. After an average follow-up of 37 weeks, 93 of the 110 (84,5%) patients ware satisfied with the postoperative result. Mortality was 0% and morbidity 3%.

Conclusion: DG-HAL is a safe and effective treatment in the management of symptomatic grade 2 and 3 hemorrhoids.

September 2007

#### M. Pescatori, F. Aigner

Stapled transanal rectal mucosectomy ten years after Tech Coloproctol 2007 Stapled mucosectomy (SM) was first proposed for the management of patients with rectal internal mucosal prolapse and obstructed defecation, but gained popularity worldwide for the treatment of hemorrhoids. The present review highlights the advantages and disadvantages of the operation. SM tends to decrease postoperative pain and shortens convalescence after hemorrhoid

surgery, but may be followed by severe complications, e.g. rectal obliteration and pelvic sepsis requiring a diverting stoma, more frequently than after standard hemorrhoidectomy. Moreover it carries a higher recurrence rate in the treatment of fourth-degree piles. A recent Cochrane metaanalysis demonstrated that SM is less effective than standard hemorrhoidectomy since it carries a higher recurrence rate (OR=3.6) and reintervention rate (OR=2.3). When used for rectal mucosal prolapse and obstructed defecation, SM is reported to have variable results. A better outcome is likely to be achieved in patients without anismus and psychoneurosis operated on by specialists trained with this technique.

February 2007

M. Scheyer, E. Antoneietti, G. Rollinger, H. Mall, S. Arnold

Doppler-guides hemorrhoidal artery ligation.

Excerpta Medica – The American Journal of Surgery, 2006

Background: In 1995, Morinaga reported a new technique for the treatment of hemorrhoids, hemorrhoidal artery ligation (HAL), which uses a specially designed proctoscope coupled with a Doppler transducer for identification and ligation of hemorrhoidal arteries.

Methods: Because the arteries carrying the blood inflow are ligated, internal pressure of theplexus hemorrhoidalis is decreased.

Results: We report the results of the first 308 patients (189 male and 119 female; median age 50.1 years) who have been treated at our department since 2002 and followed-up for a median period of 18 months. Eighty-nine patients had grade II, 192 patients had grade III, and 27 patients had grade IV hemorrhoids. The acute symptoms of hemorrhoids were treated immediately by performing HAL.

Conclusions: Our study showed the HAL is painless, effective and has a low rate of complications. It can be applied on a outpatient setting and is on good alternative to all other haemorrhoid treatment methods.

#### G. Felice, A. Privitera, E. Ellul and M. Klaumann

Doppler-Guided Hemorrhoidal Artery Ligation: An Alternative to Hemorrhoidectomy Department of General Surgery, St. Luke's Hospital, Gwardamangia, Malta Springer New York, Diseases of the Colon & Rectum, September 2005

### M. Lienert, B. Ulrich;

Doppler-guided ligation of the hemorrhoidal arteries

Early results of DH-HAL in 248 patients are presented. 171 patients (69&) needed no anaethesia. 147 patients (Without additional interventions) were free of symptoms. A total of 87,7& were at least improves. The complication rate was low. Hospital Geeresheim, Düsseldorf, Germany, 2005

Original Report: German

#### A. Hardy, C.L.H. Chan, C.R.G. Cohen

The surgical Management of Haemorrhoids - A Review

A number of new surgical treatments have led to a reappraisal of haemorrhoid disease over the last few decades. Despite a range of treatment modalities, the options are limited in their effectiveness and can lead to a number of complications. An inadequate classification system

based on appearance rather than symptoms makes the choice of appropirate therapy difficult. More recent techniques have led to a move away from surgical excision. However, further research is required to establish their precise indications and long-term efficacy. Digestive Surgery, 2005

St. Mark's Hospital, Harrow UK

W. Wen, X. Li, J. Wang, H. Liu, B. Ma, C. Zang, W. Xu, D.Shen, W. Zhen, R. Li, Values of clinical application of Doppler-guided hemorrhoid artery ligation (Dg-HAL) in treatment of hemorrhoids (a report of 40 cases) General Surgery Department of PLA General Hospital (Bejinig)

The objective of this article was to evaluate the efficacy of procedure for Doppler-guided hemorrhoid artery ligation DG• |HAL in treatment of hemorrhoids. The 40 patients with the symptomatic hemorrhoids underwent a DG/HAL. The mean operation time was 26.5minutes and postoperative hospital stay was 1.15 days; the time of returning to work was 2.15 days and 94.2% of patients were satisfied with the results. There were no recurrence, and no faecal incontinence after short-up (2 weeks-3 months). Results show that DG/HAL for symptomatic hemorrhoids is a safe procedure with good results, low complications, shorter hospital stay and earlier recovery. Doppler-guided hemorrhoid artery ligation seems to be ideal for 1-day surgery, and it fulfills the requirements of minimally invasive surgery. But long-term effect is to be investigated.

J. L. Narro, Doctor for Surgery, Germany, Cologne, Titel: Hemorrhoid Therapy with Doppier Guided Hemorrhoidal Artery Ligation via Proctoscope KM-25. A New Alternative to Hemorrhoidectomy and Rubber Band Ligation?

Issue: Zentralbl Chir 2004,

Original article in German, 2004

Zagrjadsky Eugeny Alekseevich, Chief of the department colorectal surgery of the medical center, Moscow, Russia;

Title: doppler guided hemorroidal artery ligation (HAL) for the treatment of hemorrides-result in 169 patients.

Orginal report in English, October 2003 and September 2004

A. Bursics, K. Morvay, P. Kupcsulik, L. Flautner, First Department of Surgery, Semmelweis University, 1082 Budapest, Hungary.

Title: Comparison of early and 1-year follow-up results of conventional hemmorrhoidectomy and hemorrhoid artery ligation: a randomized study.

Issued in the "International Journal of Colorectal Disease", accepted May 2003

F. Corno, P. Almerigi, F. Corno, F. Gabrielli, N. Gallese, E. Guarino, M. Mungo, V. Landolfi, F., Poncina, R. Riccardi, P. Setti

Multicentric Study, HAL Doppler method in patients with II and III dagress bleeding haemorrhoids.

Year 2002-2003, Italy