

A.M.I.® HAL / RAR System

Product Group Coloproctology | Issue 05/2011



- Safe, gentle and effective treatment for all grades of hemorrhoids in one procedure
- Doppler ultrasound technology for the precise, customised detection of hemorrhoidal arteries in each patient
- Handle with high-performance LED's for bright, even illumination and a clear view

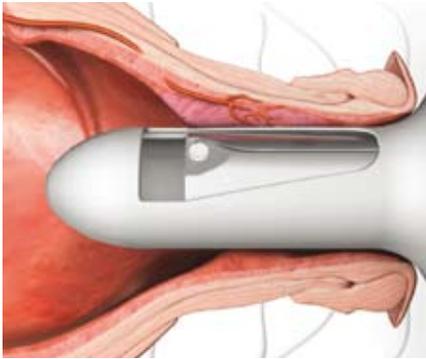
NEW
PROBE
TECHNOLOGY

A.M.I.® HAL / RAR System

The A.M.I. HAL and RAR methods

HAL (Hemorrhoidal Artery Ligation)

The HAL method is suitable for treating low to medium grade hemorrhoids, and is extremely effective in addressing the symptoms of hemorrhoidal disease. The ligations serve to reduce the arterial blood supply, causing the hemorrhoidal cushions to shrink back to normal size. This method can be carried out with ease using the RAR Flexi Probe.

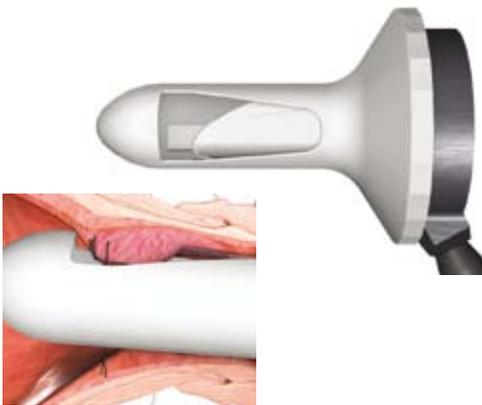


1. The handle with the RAR Flexi Probe is introduced into the rectum, then rotated slowly to search for arteries. The loudest Doppler signal indicates the center of the artery.
2. Once the first artery has been found, it is ligated using a Vicryl suture with UR 6 needle.
3. The handle is then turned again to locate further arteries. Once found, each artery is ligated as described in step 2.

As a rule, between five and eight arteries will be found during the procedure. However, this number can vary from patient to patient, and will also depend on the severity of the hemorrhoids in each case.

RAR (Recto Anal Repair)

The RAR method is used to treat the prolapsing hemorrhoids that occur during more advanced stages of the disease. RAR involves one or more mucopexies of prolapsing mucosa, carried out after the hemorrhoidal arteries have been ligated.



RAR Flexi Probe

1. The handle is placed in the starting position as for ligation. The ligation window - and hence the handle - point towards the prolapse position requiring treatment.
2. First, an initial stitch is made as far proximal as possible. The handle is then turned slightly to reveal more mucosa distally.
3. Now a running suture is started, and then continued with gradual turning of the handle, leaving 7 to 10 mm between each stitch. After the last stitch, which ends proximal of the dentate line, the needle is cut off and the suture material knotted up near the initial stitch. This causes the prolapsing tissue to be pulled up towards the initial stitch, where it is then secured in place with a sliding knot.

New probe technology

The RAR Flexi Probe offers surgeons several key advantages for both the HAL and RAR procedures:



1. New Doppler ultrasound technology: quicker, more precise detection of arteries
2. White sleeve: highly improved illumination
3. 18% larger inner diameter at the ligation window: easy, quick suturing

Advantages of HAL and RAR

Since the introduction of these minimally-invasive methods, many tens of thousands of patients have been treated with them and excellent results achieved in terms of effectiveness, patient-friendliness and safety.

Effective

- Treatment of the three main symptoms - bleeding, itching and pain - with HAL
- Treatment of the prolapse with RAR

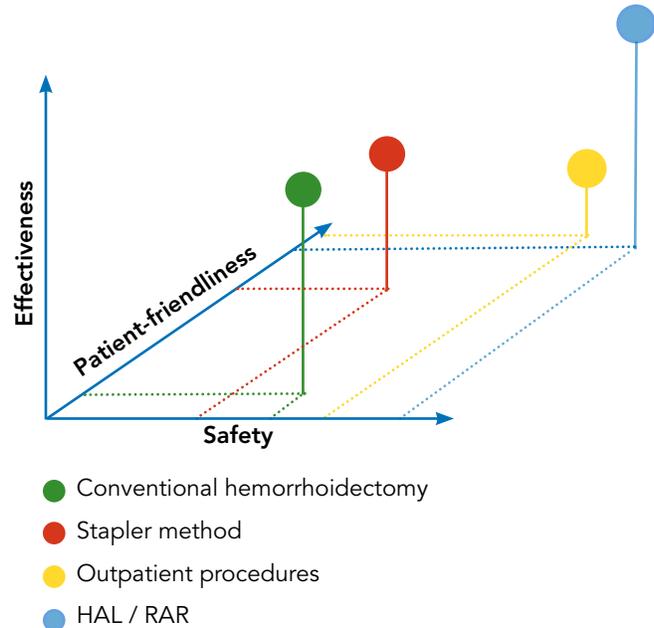
Patient-friendly

- Minimal pain
- Quick recovery

Safety

- Fewer intra-operative complications
- Fewer post-operative complications

Furthermore, the operation can be tailored to suit each individual patient.



This diagram represents an assessment made by A.M.I. based partly on published data and partly on evaluations by surgeons who have experience with the HAL and RAR methods.

Publications with long-term results

Over the last few years, many interesting publications have appeared showing long-term results achieved with HAL and RAR. The literature currently available covers several thousands of patients.

Faucheron 2011– RAR with 34-month follow-up

“One of the advantages of the HAL-RAR procedure is that it can be tailored to best treat each individual case, because the number of arterial ligations depends on the blood pulsations detected, and the number of mucopexies depends on the number of prolapses identified. Particularly in this respect, the HAL-RAR technique would appear to be more suitable than many other methods.”

Satzinger 2009 – 83 RAR operations – prospective study with 1-year follow-up

“The present study confirms that the RAR procedure is a very effective technique for treatment of high-grade hemorrhoids. RAR offers a variety of advantages including improved treatment of symptoms ...”

Zagriadskiy 2008 – 85 RAR operations for high-grade hemorrhoids

“The use of RAR will lower or eliminate invasive operations, it is a painless and minimally invasive procedure that offers an excellent alternative to hemorrhoidectomy.”

Theodoropoulos 2010 – RAR with 15-month follow-up

“DG-HAL with the selective application of RAR is a safe and effective technique for advanced grade hemorrhoids.”

Dorn 2007 - 5-year results after HAL

“HAL is superior to sclerotherapy in stage I and more effective than rubber band ligation in stage II regarding the success rate as well as the relapse rate.”

Wilkerson 2009 - Long-term results and patient satisfaction after HAL

“Given the low complication rates and therefore the low risk, it may well be reasonable to offer DG-HAL as a first line treatment.”

A.M.I.® HAL / RAR System

Order Code		
<p>AHH 001</p> 	<p>A.M.I. HAL Handle</p> <p>Reusable aluminum handle for use with the A.M.I. HAL-II Electronic System and probes</p>	<p>1 handle</p> <p>Delivered non-sterile, steam autoclavable</p>
<p>RAR 2081</p> 	<p>RAR Flexi Probe</p> <p>Disposable probe and sleeve set for performing HAL and RAR procedures Probe with asymmetric design for the gradual release of mucosa</p>	<p>5 sets / box</p> <p>Delivered sterile</p>
<p>AHN 006</p> 	<p>A.M.I. HAL Needleholder</p> <p>Stainless steel needleholder designed specially to fit the ligation groove inside the A.M.I. probes</p>	<p>1 instrument</p> <p>Delivered non-sterile, steam autoclavable</p>
<p>AHK 007</p> 	<p>A.M.I. HAL Knotpusher</p> <p>Stainless steel knotpusher to facilitate knot tying inside the A.M.I. probes</p>	<p>1 instrument</p> <p>Delivered non-sterile, steam autoclavable</p>

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