

A.M.I.® HAL / RAR System

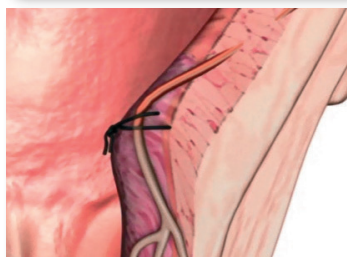
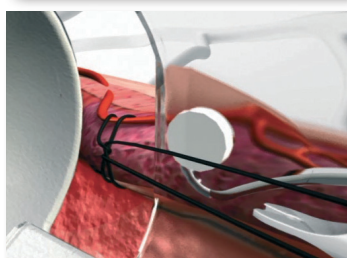
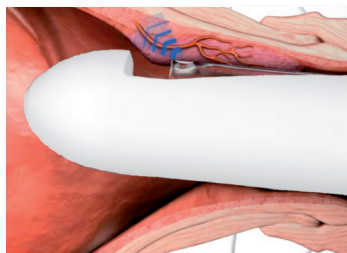
Product Group Coloproctology | Issue 04/2017



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

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The A.M.I. HAL and RAR methods

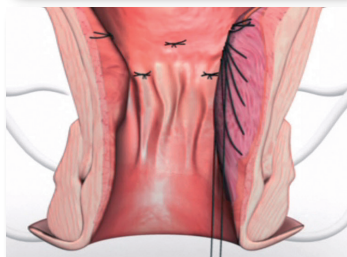


HAL (Haemorrhoidal Artery Ligation)

The HAL method is suitable for treating low to medium grade haemorrhoids, and is extremely effective in addressing the symptoms of haemorrhoidal disease. The ligations serve to reduce the arterial blood supply, causing the haemorrhoidal cushions to shrink back to normal size.

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 centre of the artery.
2. Once the first artery has been found, it is ligated using an A.M.I. Suture with 5/8 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 haemorrhoids in each case.



RAR (Recto Anal Repair)

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

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 Linea Dentata, 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.

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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

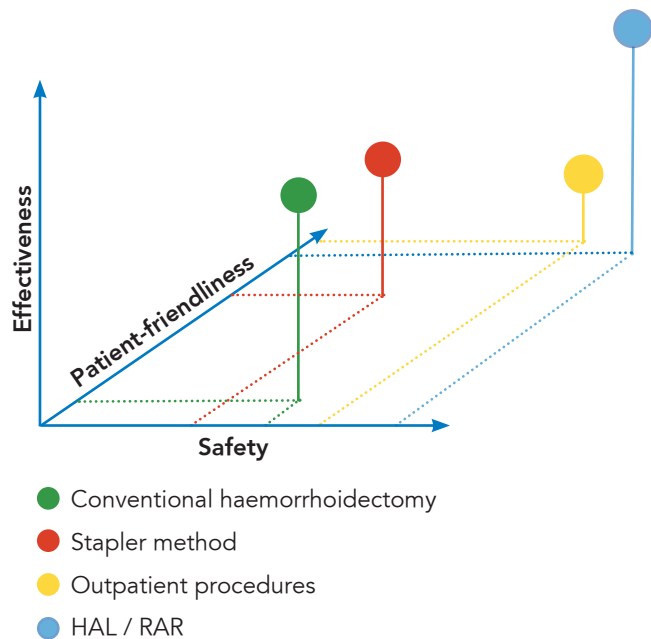
Patient-friendly

- 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.

Roka et al. 2013 - DG-RAR for the treatment of symptomatic grade III and grade IV haemorrhoids; a 12-month multi-centre study
"For the first time in a study concerning DG-HAL/RAR, a multi-variate analysis was carried out to demonstrate the statistically significant influence of various factors on parameters of efficacy. The number of PRSs [RAR, prolapse-reduction sutures] and in particular the number of ligations [HAL] were shown to influence the recurrence of symptoms, whereas the only factor affecting the recurrence of prolapse was the grade of disease. It is interesting to note that the only factor significantly influencing patient satisfaction was the number of ligations [HAL]."

Zagriadskiy et al. 2011 - Randomized trial comparing HAL-RAR and Closed Haemorrhoidectomy (CH); mean follow-up of 15 months
"Patients undergoing HAL-RAR derive greater short-term benefits, while being subject to less pain and a much lower risk of severe complications [in comparison to CH]. Furthermore, they are hospitalized for a shorter length of time and may return to work earlier."

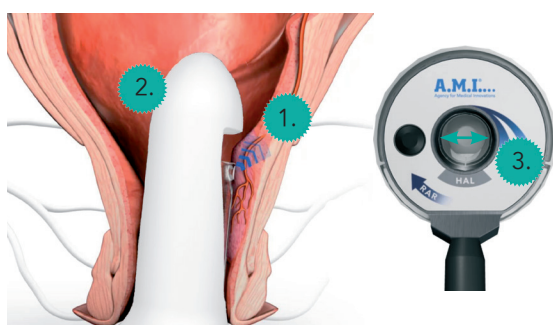
Faucheron et al. 2011 - Prospective study for treatment of grade IV haemorrhoids; mean follow-up of 34 months
"One of the advantages of the HAL-RAR procedure is that it can be tailored to best treat each individual case, because the number of arterial ligations depends on the blood pulsations detected, 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."

Testa et al. 2010 - Safety and low invasivity of HAL; mean follow-up of 36.5 months
"Low discomfort during the operation and the absence of complications justify the use of HAL Doppler also in patients affected by the most precocious degree of haemorrhoidal illness. With this technique both a therapeutic procedure and prophylaxis of the most advanced degree of hemorrhoidal illness may be performed at the same time."

Wilkerson et al. 2009 - Long-term results and patient satisfaction after HAL; 30-month follow-up
"Given the low complication rates and therefore the low risk, it may well be reasonable to offer DGHAL as a first line treatment."

Dorn et al. 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."

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

A.M.I.® HAL / RAR System

Order Code	Product	Technical Details
AHD 204 	A.M.I. HAL-Doppler II System Set consists of: - AHE 203 A.M.I. HAL-II Electronic System, incl. rechargeable battery - AHH 001 A.M.I. HAL Handle - AHK 007 A.M.I. HAL Knotpusher - AHN 006 A.M.I. HAL Needleholder - RAR2081 RAR Flexi Probe - AHAL 70 A.M.I. HAL Suture - AHA 00x A.M.I. HAL-II Adapter (x = 1,2,3,4,5)	230 V adapter or battery operation 1 unit (385 mm x 140 mm x 260 mm) 2 handles 2 instruments 2 instruments 1 box 1 box 2 adapters
AHH 001 	A.M.I. HAL Handle Reusable aluminium handle for use with the A.M.I. HAL-II Electronic System and probes	1 handle Delivered non-sterile, steam autoclavable
RAR2081 	RAR Flexi Probe Disposable probe and sleeve set for performing HAL and RAR procedures. Probe with asymmetric design for the gradual release of mucosa	5 sets / box Delivered sterile
RAR2181 	HAL-RAR Procedure Kit Flexi The kit consists of: - RAR Flexi Probe - A.M.I. HAL Suture (8) - Single-use knotpusher made of polycarbonate For use with the A.M.I. HAL-Doppler II System (AHD 204)	1 set Delivered sterile
AHN 006 	A.M.I. HAL Needleholder Stainless steel needleholder designed specially to fit the ligation groove inside the A.M.I. probes	1 instrument Delivered non-sterile, steam autoclavable
AHK 007 	A.M.I. HAL Knotpusher Stainless steel knotpusher to facilitate knot tying inside the probes	1 instrument Delivered non-sterile, steam autoclavable
AHAL 70 	A.M.I. HAL Suture Suture material for HAL and RAR procedures	36 sutures / box 5/8 circle needle Synthetic, absorbable, 2/0 75 cm long

A.M.I. Headquarters

A.M.I. GmbH
Im Letten 1
6800 Feldkirch
Austria
t +43 5522 90505-0
f +43 5522 90505-4006
e info@ami.at
www.ami.at



A.M.I.®