

# The use of EVRF (Radiofrequency) in the treatment of Haemorrhoids (HaemoRF)

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## Introduction :

At the Kriocentrum facility in Poland, Dr Klos and Dr Batijewski have been treating haemorrhoids for several years. Both doctors have significant experience with all possible solutions since there is not one modality which guarantees 100% success. Of course, medicine is not like mathematics so there is no ultimate solution.

In Kriocentrum, they perform sclerotherapy, rubber bandaging or legation, HaemoRF, laser, freezing and surgical methods such as the Milligan-Morgan method or Bipolar diathermy. Together with the patient, they decide which is the most suitable treatment.

Four years ago, Dr. Klos and Dr. Batijewski began to use EVRF's monopolar energy for the treatment of haemorrhoids as a test case because they already had experience with laser. They started treating grade II haemorrhoids and concluded after 160 patients that the method is effective, minimally invasive and that is was safe to move on to grade III and IV.

HaemoRF (Haemorrhoid Radiofrequency) is a method for haemorrhoid treatment using the FCare's monopolar radiofrequency device EVRF and their proprietary specially designed HPR45i probe. This treatment can be used for all stages or grades of internal haemorrhoids.

## The patient:

Several factors are important when treating haemorrhoids:

1. Available methods : sclero, laser, HemoRF, rubber legation,...
2. Cost of the treatment (for the physician and the patient)
3. Safety and complications
4. Exclusion of a patient from professional life and everyday activity.

The problem of exclusion from everyday activities is extremely important to a patient. We have to remember that haemorrhoids are not cancer. We do not save a patient's life, we only free them from larger or smaller complaints. Based on the doctors experiences patients want to have their haemorrhoids treated when the opportunity occurs, like a dental treatment. Patients don't want general anesthesia, sedation or hospitalization. They want a simple, quick, lunch-break procedure in an outpatient setting.

Patients, in general, are embarrassed about this condition which is why the treatment has to be quick, effective and without a lot of preparation. Avoiding eye contact with the medical staff during the procedure and not seeing the equipment being used helps to create less stress.

### Selecting the treatment:

Haemorrhoids are, simply speaking, blood filled bubbles with arteriovenous connections inside. They are fed (vascularized) by small arterioles coming from the top (in their upper part). Enlarged grade II, III and IV haemorrhoids are filled with an excessive amount of blood and therefore move downwards.

Grade II: Slip out of place through straining but spontaneously retracts

Grade III: move out of position, are prolapsed, manual reduction

Grade IV: fixed, non-reducible lesions, permanently prolapsed.

In general, the treatment of haemorrhoids is based on three rules:

1. Elimination of the prolapse
2. Reduction of the haemorrhoids (removal of excessive tissue)
3. Reduction of the blood flow into the haemorrhoid

Rubber banding eliminates the excessive tissue of the haemorrhoids, whereas other elements are left unchanged and artery feeding remains as it was. Therefore, after several (2-3) years the recurrence rate is high.

The DGHAL method is based on the fact that an ultrasound sensor locates the arterioles and sutures are placed in this location. This method is based on the fact that the artery feeding of haemorrhoids is decreased. However, it does not eliminate the excessive tissue and sufficient shrinkage of hypertrophic tissues doesn't always occur. An additional problem is the fact that multiple arterioles feed the upper part of one hemorrhoid and 8-10 sutures have to be placed in most of the cases. We might as well place several sutures around the intestine without visualization and this will have a similar effect.

Dr Klos and Dr Batijeswki rarely use sclerotherapy because it is generally effective only in cases of very small grade I and II haemorrhoids or at the end of treatment when there are residues of haemorrhoids tissue after HaemoRF treatment.

For 20 years the doctors used rubber bandaging in combination with freezing and performed several thousands of procedures because the method is simple, quick and safe. The disadvantage of this method is the high recurrence rate after 2-3 years. Also severe bleeding occurs when the rubbers come loose and the arterioles are all exposed at once. It still is a common used method.

Laser therapy is similar to the HaemoRF method. Laser releases a lot of energy (heat) on a small area and theoretically it may be more dangerous and less predictable but it more a question of experience. Laser fibers often break whereas the HaemoRF HRP45 probe is rigid and very easy to use. Laser is more expensive than the EVRF systems and often static whereas the EVRF is easily transportable.

## HaemoRF treatment:

### Principal:

The HPR45 probe is placed inside the Haemorrhoid by inserting the sharp tip, fast waves create a friction between the molecules causing heat energy. As a result the tissue coagulates and necrosis can be observed. A hard scar is formed in this area and even if feeding vessels are not treated, a hard scar does not have the arteriovenous connections, therefore a hard bubble, creating a surface area which can not stretch and grow. A reasonable analogy can be made by imagining how difficult it would be to inflate a rubber balloon which has thick and hard walls.

Closing the feeding vessel is the aim but like the DGHAL technique much harder in practice than in theory.

### Ultrasound :

An ultrasound sensor can be used to detect arterioles with the diameter of 1mm. The problem is your limited treatment area. In anoscopy, an anoscope needs approx. 2cm<sup>2</sup>. It's not possible to use the ultrasound detector and the HPR45i probe simultaneously. Even if you introduce the detector and locate the vessel, you have to remove the device in order to apply anesthesia which changes everything – you don't know the exact location of the artery.

### Position of the patient :

The haemorrhoid treatment with the HPR45i probe can be performed in 3 positions:

1. Knee-elbow position
2. Left lateral position
3. Gynecological position

In both doctors opinion the Knee-elbow position is the most comfortable working for them and for the patients. It is less time consuming than working with sterile drapes. The patient doesn't see anything happening and there is no eye-contact. But it all depends on the physician's preference.

### Anaesthesia:

Local anaesthesia is administered (3-5ml of 1% lidocaine or 3-4 Klein solution plus 1-2ml lidocaine 1%). With the Klein solution effective anaesthesia is not immediately observed and you have to wait longer.

### Procedure:

- An anoscope with a 2cm diameter and tapered opening is inserted.
- 4-6 ml of anaesthesia is administered deep below the haemorrhoid area of the muscle layer in order to lift and separate the vessel layer and muscle layer.
- The HPR45i is inserted to the center and deep in the upper part of the haemorrhoid, where the feeding arteries should be located.
- Lift the HPR45i tip to the intestinal center in order to separate it from the muscle layer, give 10 sec of 25 Watt energy (3 – 4 cycles) in this area.

Withdraw the HPR45i and place its tip, centrally, in a few spots of the haemorrhoid (2-3 spots) or 12 sec. (2 cycles).

Sometimes it's possible to observe that a haemorrhoid starts to contract.

At the end, take the HPR45i out of the haemorrhoid and place its tip against the haemorrhoid surface and give energy - observe the tissue whitening and coagulating.

Bleeding may occur therefore coagulate it superficially with the tip of the HPR45i at the site of the bleeding.

During the procedure a nurse checks whether the HPR45i is clean and not covered by haemolyzed blood otherwise the probe will lose its effect.

It is very important to cool down the treated area with cold gauze. Moistened gauze with cold water cooled in the fridge.

Check with your finger if the area is not too hot otherwise cool down again with the gauze.

End of procedure

Sometimes small haemorrhage is observed at the end of the procedure. Touching the surface with the tip of the probe can stop the bleeding and it is usually enough. However if a mild haemorrhage is still observed, it can be left like this. There have never been any problems with haemorrhage after the procedure and during the recovery. Even between day 7-14 larger haemorrhages can be observed and a follow-up could be necessary but such an additional intervention has never been required.

In theory the procedure principle is as follows: heat energy from the HPR45i results in tissue coagulation and lesion. Lesion of the haemorrhoid tissue leads to necrosis. Necrotic tissue becomes exfoliated and a wound is formed on the location of the haemorrhoid, generally creating scar tissue. This area will become a scar or covered with mucous membrane. As a result of the heat energy effect on the tissue 2 zones are formed:

1. Zone of irreversible tissue lesion – necrotic zone – a scar forms while healing
2. Zone of reversible tissue lesion – around- edema is formed while healing

The trickiest part of the procedure is finding the right balance between quantity and duration of applied energy. Less energy might not be effective enough while too much and unevenly applied energy could cause complications (intestinal mucosa, deep muscle and sphincter damage). Placing the probe at different locations for a short period of time is better than longer in one place. This theory is observed in reality and confirmed by both doctors. During the first days after the procedure swelling occurs. Patients may think that the haemorrhoid has grown bigger. The following days necrosis and exfoliation can be observed. At this stage the patient might feel pain and experience mild bleeding as a result of the wound but this will be the generation, and eventual detachment, of the hard tissue scar. The complete healing process might take 3-4 weeks and up to 6 weeks in case of grade III and IV haemorrhoids.

Following side effects might be observed:

- Swelling lasting for a few days: Diosmin
- Mild pain: Ibuprofen or Ketoprofen
- Mild bleeding ( up to 2 weeks) : no additional medication or intervention has been required

Rule:

The rule is to operate on the haemorrhoids only in their upper part, above the dentate line. There is no sensational innervation, only autonomic. Above the dentate line a patient does not feel pain, it is possible to cut, place rubber rings or a suture. However in case of HaemoRF a patient does not feel pain as such, only the effect of the heat. Therefore only local anaesthesia is required.

#### Planning the treatment with the patient:

On the first visit Dr. Klos and Dr. Batijewski collect the medical history of the patient and examine the haemorrhoid through an anoscopy to determine the treatment. A first procedure date is scheduled. Before the treatment they perform a rectoscopic analysis to look for serious diseases ie rectal cancer (carcinoma) or polyps. The rectoscopy is not performed if the patient recently had a rectoscopy or colonoscopy.

During the second visit a second rectoscopy will be performed and if there are no tumors, polyps or other diseases, the first haemorrhoid will be treated with HaemoRF. The whole procedure takes between 8-10 minutes, the visit itself 15 minutes. Complete healing will be observed after 3-4 weeks in grade II and 6 weeks in case of a grade III and IV.

1. Visit - Medical history , examination , anoscopy
2. Visit – rectoscopy + 1<sup>st</sup> HemoRF treatment of one hemorrhoid
3. Visit – 2<sup>nd</sup> HemoRF treatment of 2<sup>nd</sup> hemorrhoid after 4-6 weeks
4. Visit – 3<sup>rd</sup> HemoRF treatment of 3<sup>rd</sup> Hemorrhoid after 4-6 weeks
5. Visit – Follow-up after 4-6 weeks

In case of small haemorrhoids and the patient didn't have any complaints after the 2<sup>nd</sup> visit, you can treat the other two in one session.

The whole haemorrhoid procedure may take 3-4 months and includes up to 4-5 visits of 15 minutes.

After the procedure the patient may experience mild pain and for up to 3-4 weeks they may observe bleeding between days 7-14. This is a normal procedure process and not alarming. This is when you would expect the necrotic tissue to detach.

Medication: Ibuprofen or Ketoprofen and Lidocaine ointment gel 10% to prevent pain and Diosmin to reduce the edema, swelling and hyperemia. Lactulose is recommended when the patient is constipated.

A patient can return immediately to their everyday activities, socially and professionally. 70-80% of the patients take a few painkillers and report discomfort and mild pain for a few days only.

Recurrence rate: Since Dr. Klos and Dr. Batijewski started the HemoRF treatment 4 years ago they didn't observed any recurrences. Between them, they have now treated well over 1000 patients using EVRF.

They do not do a 2 year follow-up of the patients. In actual fact therefore, it could be that there are unknown recurrences. However, in their opinion, this is rather unlikely because the hard scar tissue doesn't allow recurrent blood-flow. Secondly, patients would come back to complain about the recurrence of their discomfort and, thus far, none have.

#### Complications :

Complications are very rare, indeed very unlikely, but these could be listed as:

1. Recurrences of an earlier treatment with laser, Bipolar diathermy or a surgical method.
2. Marginal Haematoma, marginal clot – single or multiple. (Treatment with Diosmin plus excision or incision plus evacuation).
3. Anal fissure (Treatment with Dilzem 2% or botox, dilatator, hemagel).
4. Penetration of the muscle layer, surrounding tissue of the hemorrhoid or anal canal with the HPR45i creating a deep wound. Or applying energy in these areas for too long. Prolonged healing process.  
Treatment : dilatator, lidocaine ointment and hemagel.  
To avoid unnecessary tissue damage with the insertion of the probe it is import to administer anaesthesia from the haemorrhoid base deep into the muscle layer. The fluid would separate the vessel layer and the muscle layer. During the procedure, hold the HPR45i in the center of the intestine away from the muscle layer.
5. Late Complications : To much energy in the same area, energy could be distributed to the anal canal and might result in damaging the internal sphincter. This will take more time to heal. Sphincter damage leads to sphincter fibrosis and increased tension of the anal canal but it doesn't lead to dilation or bowel incontinence.