MULTICENTRIC STUDY

HAL DOPPLER method

in patients with II and III degree bleeding haemorrhoids

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The multicentric study has been supervised by Dr. Franco Corno, who works at Le Molinette Hospital in Turin, Italy.

Aims of this study

The aims of the multi-centric study are listed below:

1. To establish the effectiveness of the haemorrhoidal artery ligation in patients with II and III degree haemorrhoids by means of the HAL-DOPPLER device.

2. To define the ideal patients for this treatment.

3. To establish whether this procedure can be done without local regional anaesthesia and if it allows patients to be dismissed immediately.

4. To establish whether HAL can be an effective alternative to ambulatory procedures in para-surgical haemorrhoid therapies (i.e. rubber band ligation, sclerotherapy).

5. To establish whether HAL can have a therapeutic function in treating patients with haemorrhoids who, according to standard practice, would be candidates to a surgical treatment.

Enrolment

Every centre participating to the study should enrol ten patients with II and III degree haemorrhoids with bleeding as main symptom.

Definition of the symptom "bleeding"

The symptom "bleeding" will be subdivided into:

- Bleeding once per day*
- Bleeding once per week*
- Bleeding once per month*

* Evaluations given by the patients

Exclusion criteria

Are excluded from this study:

- Patients with IV degree haemorrhoids
- Patients with other concurrent proctological diseases (fistula, chap, abscess, IBD,..)
- Patients with ascertained coagulation diseases.
- Patients under therapy with anticoagulant drugs (anti-aggregant and dicumarolic).

Method

For every patient a special patient form will be filled in.
The goods used will be:

- HAL DOPPLER device
- Long needle carrier
- HM-50 absorbable suture, 1 mt. length
- Knot-pusher

The device is made by an anoscope with a doppler sound nearby a side window on the tip of the probe. The device must be inserted for all its length in the anal canal after a good lubrication.

A light enables the surgeon to see distinctly the anoscope tip and the mucosa prolapsing into the window.
The procedure is made performing a slow rotation of the proctoscope in order to spot out under the Doppler signal, the noise of the superior haemorrhoidal artery.

The branches thus detected are then ligated through the window and every ligature effectiveness is evaluated by the disappearing of the Doppler signal. After the procedure, no medication or analgesia is prescribed to patients.

The enrolled patients will have a follow up after 1 month, after 6 months and after 1 year from the treatment. During this time the patient form will be updated and completed.

GENERAL RESUME
100 PATIENTS

Subdivision by age	
From 20 to 30	n. 5
From 31 to 40	n. 18
From 41 to 50	n. 49
From 51 to 60	n. 23
From 61 to 70	n. 5
Total treated patients	n. 100

Subdivision by sex	
Male	n. 66
Female	n. 34

Goligher degrees treated	
II	n. 62 patients
III	n. 38 patients

Of the 100 patients considered in this study, 94 had never undergone a treatment for the pathology relative to this study.

Number of ligatures

Numbers of Ligatures	Number of patients
5	9
6	50
7	15
8	15
9	5
10	4
12	2

Table of re-operations

Period	Tot. Patients	n. Patients	%
1 month	100	6	6,00%
6 months	66	6	9,09%
12 months	46	1	2,17%

Table of complications

	Post operation n. Patients 100		1 month n. Patients 100		6 months n. Patients 66		12 months n. Patients 46	
Pain	2	2,00%	1	1,00%	1	1,51%	1	2,17%
Slight pain	15	15,00%	0	0	0	0	0	0
Tenesmus	13	13,00%	1	1,00%	1	Nodule	1	Proctalgy
Thrombosis	3	3,00%	3	3,00%	1	1,51%	0	0
Infections	0	0	0	0	0	0	0	0

All cases of pain or slight pain have been treated either with oral analgesics or with analgesic injections (Toradol in 2 cases).
All have been solved in a very short while.

Patient's evaluation

	1 month n. Patients 100		6 months n. Patients 66		12 months n. Patients 46	
Very satisfied	70	**70,00%**	48	**72,72%**	39	**84,78%**
Satisfied	21	**21,00%**	14	**21,21%**	5	**10,87%**
Not satisfied	9	**9,00%**	4	**6,07%**	2	**4,35%**

	1 month n. Patients 100		6 months n. Patients 66		12 months n. Patients 46	
Very satisfied **Satisfied**	91	**91,00%**	62	**93,93%**	44	**95,65%**
Not satisfied	9	**9,00%**	4	**6,07%**	2	**4,35%**

Centres presently active in Europe.