
III DEGREE HAEMORRHOIDS: PROSPECTIC,
RANDOMISED, MULTICENTRIC SYUDY OF
COMPARISON BETWEEN STAPLED
HAEMORRHOIDOPEXY WITH CIRCULAR
STAPLER AND DOPPLER-GUIDED TRANSANAL
HAEMORRHOIDAL DEARTERIALISATION *(PHASE III)*

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Introduction

According to a recent review of the literature, the incidence of ano-rectal bleeding in the general population is approximately: 20%/year, while the number of people seen by a G.P. for this reason is 6/1000/year and 7/10.000/year are seen by a specialist. Haemorrhoids have, in literature, extremely high ranges of prevalence, 4,4% to 36% [1,2], being influenced by the modality of the survey, if by G.Ps or by specialists.

According to the indications of the Guidelines of the Società Italiana di Chirurgia ColoRettale, and of the most reputed international scientific societies [3, 4] the currently advised treatments for III degree (Goligher) haemorrhoids are:

1. The Stapled Hemorrhoidopexy is indicated in grade III haemorrhoids (degree of recommendation A) due to its advantages vs. other techniques in pain reduction and time before resume of normal activity. Positive results up to 94-96% are reported with a mean follow up of > 18 months [5-7]. However, relapses, such to require a re-intervention in 25% of procedures with a 12 months follow up, are reported in a perspective Belgian study [8]; and, another randomized and perspective study with a minimum follow up of 6 months, confirms a major incidence of relapses (P = 0.008) in the Longo technique vs. haemorrhoidectomy [9]. An evidence of complications, also severe, is given by a study with a review of 550 patients treated with the Longo technique in 12 different surgical departments. [10]; particularly, persistent pain and sepsis are evidenced, as confirmed by other authors [11]. Complications, like bleeding and faecal incontinence have been described following this procedure, at a similar rate to those described after the Milligan Morgan procedure [9]; other complications, infrequent but difficult to treat as recto-vaginal fistulas, rectal stenosis, obstructed defecation, rectal lumen occlusion and persistent anal pain, seem to be more specifically associated with the Longo technique [7, 12-16].
2. The new techniques of Doppler guided trans-anal arterial ligation (HAL e THD), initially proposed for II degree haemorrhoids but successfully applied also to III degree ones, appear to be another important therapeutic tool for the coloproctologist thanks to its scarce complications, the minimally invasive procedure and efficacy of the short term results [17-20]. At the moment, comparative studies and long term results, such to allow a correct evaluation from the viewpoint of evidence based medicine, are lacking (degree of recommendation C). To date, the results are encouraging; in fact in the study by Sohn et al. on 60 patients who underwent THD, bleeding

was resolved in 88%, prolapse in 92% and pain in 71%, with a failure rate of 3%, such to consider THD an alternative to haemorrhoidectomy, mostly in presence of associated continence problems. [21]. Similar results have been presented on 102 patients inclusive also of IV degree haemorrhoids; 82.6% of patients was free of symptoms, with a mean follow up of 22% [22], and in a non comparative, perspective study on 40 patients of II e III degree treated with THD with a > 4 months mean follow up. [23]. In a recent perspective, non randomized study, the Doppler guided ligation of the terminal branches of the superior rectal artery has been performed in III e IV degree patients, with interesting results: 27' the mean procedural time, absence of severe or moderate pain post operatively and a failure in 7 of the 32 patients (3 of II degree and 4 of IV degree) [24]. In a perspective, study randomized between closed haemorrhoidectomy and Doppler guided ligation, on 60 patients, the advantages of the latter were a lesser use of analgesic drugs and a reduced hospital stay with no difference of symptom remittance and relapses, with a 12 months follow up [25]. In a perspective, multi-centre observational study, in the 86 patients with II or III degree haemorrhoids, treated with THD the symptoms: pain, dischertia, bleeding and mucosal soiling were reduced significantly at a mean follow up 14.7±5.1 months (3-24); with no differences in the different degrees of the ailment [26].

Currently, the most commonly accepted classification of the haemorrhoidal disease is the Goligher one [27]; however this classification fails to really evidence the severity of the pathology: in fact, within the same degree, the number of interested nodules and the contemporary presence of hypertone or of associated mucosal prolapse are all variables. For this reason, the use of the more complete PATE 2000 [28] alongside the Goligher classification is proposed for this study. It has been proven that the use of PATE 2000 correlates better both with the gravity of the pathology and with the therapeutical choices [29].

In literature, there are no studies comparing Doppler guided ligation and Stapled Hemorrhoidopexy, although the different Authors seem to report similar results and indications. The feasibility in day or outpatient surgery, the lower cost of the instrument and the lesser complications so far reported, should play a role in favour of Doppler guided ligation, while, the associated reduction of prolapse favours the Stapled Hemorrhoidopexy. The rationale is certainly different; in fact, based on the hypothesis that the mucosal and sub/mucosal resection and stapling of the Stapled Hemorrhoidopexy is effective also due to its interrupting the arterial inflow, a study has been performed mapping by Doppler the terminal branches pre e 1 month after the procedure and its

findings have been that the terminal branches are not interrupted and the postoperative result is independent from their interruption [30].

A few basic problems are still open: a more accurate classification can help in the understanding the reason of the different results published on either technique? The etio-pathogenetical hypothesis of prolapse as the basis of the haemorrhoidal disease is prevailing or the prolapse itself is secondary to a vascular stasis which can be treated by a reduction of the arterial inflow?

Aim of this study is to compare 2 techniques: The doppler guided transanal haemorrhoidal dearterialisation with the THD*¹ device and the stapled Haemorrhoidopexy (according to Longo) for III degree (Goligher) haemorrhoid, not regarding the number of prolapsed piles.

Primary aims:

1. **To Observe and compare the efficacy of the two techniques for the resolution of the haemorrhoidal disease by gathering and quantifying the symptoms.**

Secondary aims:

1. **To evaluate the possible differentiations regarding:**
 - a. **Hospital stay**
 - b. **Back to work time (Resumption of work activity)**
 - c. **Costs**
 - d. **QoL**
 - e. **Postoperative Pain (VAS)**

Methods:

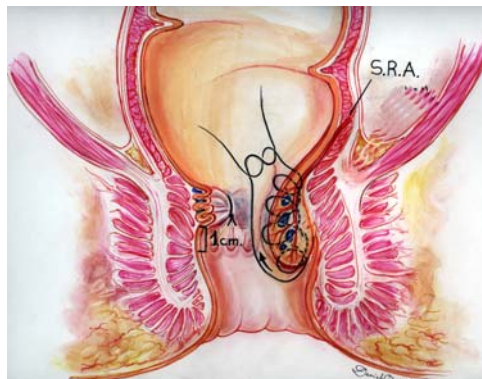
1. **Enrolment of the medical centres for this study:** Centres admitted:
 - a. National and International medical centres that have a previous experience with the two techniques;
 - b. Medical Centres that had obtained the authorisation from the ethical committee.
2. **Patients enrolment, preparation and surgical technique:**
 - a. **Inclusion criteria:**
 - i. Patients with III degree (Goligher) Haemorrhoids (evaluated also with PATE 2000, see annex);
 - ii. Patients of both sexes
 - iii. Age between ≥ 18 and ≤ 70 ;
 - iv. Patients mentally capable to sign the informed consent, given to them at the moment of their acceptance to undergo surgery, and collected the day of the operation;
 - v. Absence of previous proctologic operations;
 - vi. Absence of previous pelvic-perineal radiotherapy;
 - vii. The patient should sign the informed consent.

¹ THD[®]: designed by projected by TKC srl and Manufactured by GF srl, Italy

b. **Exclusion criteria:**

- i. Patients previously submitted to a surgical treatment for haemorrhoids.
 - ii. Patients submitted to outpatient treatments for haemorrhoidal disease in the last three months.
 - iii. Patients with faecal incontinence
 - iv. Patients with outlet obstruction resistant to conservative treatment
 - v. Contemporary presence of other ano-rectal disease
 - vi. Patients with irritable bowel syndrome with prevalent constipation or diarrhoea
- c. The patient should sign the informed consent.
- d. The patients enrolled in this study will be randomised in one of the 2 treatment groups with a link and assigned to the stapled haemorrhoidopexy group (SH) and to the transanal haemorrhoidal dearterialisation group (THD).
- e. The patients of both groups will be prepared with a phosphate enema.
- f. The anaesthesia will be chosen according to use of each single centre, with the recommendation to adopt the less aggressive possible.
- g. The patients will be discharged as soon as possible. A telephone number for the eventual emergencies will be given to all patients.
- h. Minor pain-relieving drugs (NSAIDs) or, if not sufficient, major ones (opioids) will be administered only if required and reported in the apposite card.
- i. Normal feeding will be resumed the evening of the operation day and all the patients will be advised to follow a rich fibre diet and Psyllium fibre (> 5 g/die) for at least 4 weeks.
- j. No antibiotic prophylaxis will be adopted, except for the patients with risk factors (Immunodeficiency, endoprosthesis or other particular situations).
- k. **SH technique:** Lithotomy position. Rectal examination and lubrication of the anal canal. The PPH introducer is inserted and fixed with 2 stitches to the perianal skin. The purse string is completed with a monofilament non-absorbable at about 3,5-4 cm., with mucosal stitches distant about 2-3 mm, proximally to the dentate line. Insertion of the PPH in complete open position; closure of the PPH; verification of the purse string; extraction of the suture threads through the apposite holes. Then, placed the head near to the anvil, avoiding to insert in between other tissue than that incorporated in the purse string, fire the stapler. Verification of the mucosal integrity and, in case of possibility of bleeding from the suture line, apposition of haemostatic stitches. Control for an eventual bleeding for at least five minutes.
- l. **THD Technique:** Lithotomy position. Rectal examination and lubrication of the anal canal. Apply lubricant gel liberally to the tip of THD device, being careful to lubricate the black tip of the Doppler probe; this facilitates better transmission of the Doppler signal. Insert the THD proctoscope carefully into the anal canal with gentle rotating movements. The terminal branches of the superior rectal artery are generally located at 1 o'clock, 3 o'clock, 5 o'clock, 7 o'clock, 9 o'clock and 11 o'clock, as observed in lithotomy position. The terminal branches of the superior rectal artery are to be detected 2-3 cm above the dentate line. Slowly rotate the THD until you hear the pulsating Doppler signal corresponding to the arterial pulsation. It may be useful to gently tilt the tip of the instrument creating a to and fro motion inside the anal canal. Ligate the arteries with a "figure 8" stitch with 2/0 absorbable suture with a 5/8 needle through the apposite ligation window. In case of prolapsed the suture

should be continuous with 3 to 5 stitches applied 5 mm from each other taking care that the last one is at least 5mm above the dentate line; then tie the suture realising an haemorrhoidal pexis as shown in the figures



3. Pre-operative, Operative and Post-operative evaluation. A digital card will contain the objective data and the symptoms evaluated with Visual Analogue Scale (10 cm line, without any marks) in rates from 0 to 99 (mm). In particular:
 - a. Pain, bleeding, sphincter tone (PATE 2000)
 - b. Constipation (Wexner score)
 - c. Rectal Tenesmus
 - d. faecal Incontinence (AMS + Wexner score)
 - e. Soiling
 - f. The operation card will contain:
 - i. Type os anesthesia
 - ii. Type of surgical procedure
 - iii. First surgeon
 - iv. Operation time
 - v. Number of ligation and number of stitches for each single pixy procedure, when applicable (THD)
 - vi. Intra-operative Complications
 - vii. Associated procedures
 - g. Use of pain-relieving drugs: type and dose to be reported until 1 month after the operation
 - h. Total days of hospital stay
 - i. Postoperative hospital stay
 - j. The results of some optional tests prescribed by the surgeon will be reported with the mention of the eventual lesions:
 - i. Ano-rectal manometry
 - ii. Endo-rectal Ultrasonography
 - iii. X-Ray defecografy
 - iv. Recto-sigmoidoscopy
 - v. Colonoscopy
 - vi. Barium Enema
 - vii. other.

4. Postoperative evaluation: The patient will be informed on the compilation of the diary that will be given to him at the hospital discharge. Except in case of complications, the controls will be once a weekly for the first month; monthly for the 2nd and 3rd months, at the 6th month and every six months until the 18th postoperative month. The card will contain data on:
 - a. Pain, bleeding, prolapse, sphincter tone (PATE 2000)
 - b. Rectal Tenesmus
 - c. faecal Incontinence (AMS + Wexner score)
 - d. Constipation (Altomare score)
 - e. Tenesmus
 - f. Use of pain-relieving drugs: type and dose to be reported until 1 month after the operation
 - g. The results of some optional tests prescribed by the surgeon will be reported with the mention of the eventual lesions:
 - i. Ano-rectal manometry
 - ii. Endo-rectal Ultrasonography
 - iii. X-Ray defecography
 - iv. Recto-sigmoidoscopy
 - v. Colonoscopy
 - vi. Barium Enema
 - vii. other.
5. Statistical analysis: We start from the hypothesis that the procedure A (SH) has a complete or partial success rate of 85% (literature outcomes), while the treatment B has a complete or partial success rate between 75 and 85% (literature outcomes). If the statistical analysis at the end of the study, will determine a non significant difference, the recognition that the two treatments are equivalent will lead to adopt the new therapeutic protocol in case of less complications and/or better conservation of sphincter function and/or minor cost; if the analysis will be positive, the standard treatment will not be abandoned. Therefore 284 patients should be recruited in about one year, with a confidence interval of 95%, potency of 95% and signifying of 0,1.
6. The paper that will be submitted for publication will report the names of those researchers that will registered and completed the cards of 90% at least of the number of patients assigned to their centre.

Cards:

Annex 1: data collection cards

Annex 2: PATE 2000, Pain relieving drugs consumption scale , Bleeding scale, Altomare score for Ostructed defecation, Cleveland Clinic Score for incontinence; AMS score

Annex 3: Card for informed consent

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III DEGREE HAEMORRHOIDS: COMPARISON STUDY (PROSPECTIC, RANDOMISED, MULTICENTRIC) BETWEEN STAPLED HAEMORRHOIDOPEXY VS DOPPLER GUIDED TRANSANAL HAEMORRHOIDAL DEARTERIALISATION (FASE 3)

Centre: _____ Surgeon: _____

FORENAME.....SURNAME.....Sex.....
Age..... Date of Birth..... Tel.....

PREOPERATIVE Date _____

Goligher degree: III []

PATE 2000 degree: _____

PREOPERATIVE SYMPTOMS

<i>PATE 2000</i>	
<i>Spontaneous pain (VAS)</i>	
<i>Pain at evacuation (VAS)</i>	
<i>Pain relieving drugs : Type and dosage</i>	
<i>Bleeding</i>	
<i>Mucosal exceeding</i>	

Randomization: Mucoprolassectomy [] THD []

Results of some exams prescribed by the researcher (optional), should be reported, with the specification of the eventual lesions:

<i>Ano-rectal manometry</i>	
<i>Endo-rectal ultrasonography</i>	
<i>Dynamic proctogram</i>	
<i>Rectosigmoidoscopy</i>	
<i>Colonoscopy</i>	
<i>Barium enema</i>	
<i>Other</i>	

Other _____

OPERATION

- type _____ date _____
- duration (m') [_ _] if THD: n° Ligations [_ _] Surgeon _____

Concomitant operations _____

NOTES: _____

Postoperative

Complications:

- *early (within 3 days)*

BLEEDING THAT NEEDS: TRANSFUSION <input type="checkbox"/> ₁ REOPERATION <input type="checkbox"/> ₂	
SUBMUCOUSAL HAEMATOMA	
Urinary retention	
HAEMATURIA	
THROMBOSIS	
Other	

- *late (within 30 days)*

SEPTIC COMPLICATIONS	
EVACUATION PROBLEMS	
URINATION PROBLEMS	
LATE BLEEDING THAT NEEDS READMISSION	Yes/No post-op day __/ __
Other	

PATE 2000

	I	II	III	IV	
P	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	Left lateral
	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	Anterior
	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	Right posterior
	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	Circonfential
A	<input type="checkbox"/> 0	A0: no acute features			
	<input type="checkbox"/> 1	AE: Oedema	<input type="checkbox"/> P	<input type="checkbox"/> E	
	<input type="checkbox"/> 2	AT: Thrombosis	<input type="checkbox"/> P	<input type="checkbox"/> E	
T	<input type="checkbox"/> 1	T-1: Hypotonic sphincter			
	<input type="checkbox"/> 0	T-0: Normotonic sphincter			
	<input type="checkbox"/> 2	T+1: Hyoertonic sphincter			
E	<input type="checkbox"/> 0	E0: No pile			
	<input type="checkbox"/> 1	E1: External piles			
		<input type="checkbox"/> 2	Left lateral		
		<input type="checkbox"/> 2	Anterior		
		<input type="checkbox"/> 2	Right Posterior		
Q D V	QoL		<input type="text" value="0 - 99"/>		
S C O R E	P				
	A				
	T				
	E				
	Totale				

Pain relieving drugs consumption scale

1.	None
2.	1-3/day for less than 2 days
3.	1- 3/day for more than 2 days
4.	>3/day for more than 2 days

Bleeding scale:

1.	Never
2.	Sporadic
3.	Moderate at evacuation
4.	Abundant at evacuation
5.	Without evacuation

VAS: from 0 to 99 mm

Constipation Score:

The Obstructed Defecation Score is a standard scoring system which can be used to evaluate the patient with constipation, to monitor progression of symptoms and to assess response to therapy.

The ODS score

VARIABLES	SCORE	0	1	2	3	4
Mean time spent at the toilet	≤ 5 min	6-10min	11-20 min	21-25 min	>25 min	
N° attempts to defecate per day	one	two	Three	Four	> five	
Anal/vaginal digitation	Never	> 1/month, < 1/week	Once a week	2-3 per week	Every defecation	
Use of laxatives	Never	> 1/month, < 1/week	Once a week	2-3 per week	Every day	
Use of enemas	never	> 1/month, < 1/week	Once a week	2-3 per week	Every day	
Incomplete/fragmented defecation	Never	> 1/month, < 1/week	Once a week	2-3 per week	Every defecation	
stool consistency	soft	hard	Hard and few	Fecaloma formation		

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Faecal incontinence score:

The severity of faecal incontinence can be assessed by a scoring system which takes into account the type and frequency of incontinence as well as the extent to which it alters the patient's life. This can also be used to monitor the patient over time, especially after interventions.

Finding	Never	Rarely	Some-times	Usually	Always
solid stool incontinence	0	1	2	3	4
liquid stool incontinence	0	1	2	3	4
gas	0	1	2	3	4
wears pad	0	1	2	3	4
lifestyle alteration	0	1	2	3	4

definitions	per month	per week	per day
rarely	< 1 time		
sometimes	>= 1 time	<= 1 time	
usually		>= 1 time	< 1 time
always			>= 1 time

incontinence score =

= (points for solid stool) + (points for liquid stool) + (points for gas) + (points for wearing pad) + (points for lifestyle alteration)

Interpretation:

A score of 0 indicates perfect control.

A score of 20 indicates complete incontinence.

Physician Name	Patient Name	Date of Evaluation ____/____/____
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FECAL INCONTINENCE SCORING SYSTEM - PATIENT QUESTIONNAIRE - Page 1 of 1

This questionnaire is designed to be completed by the patient.

Evaluation: Preoperative _____ after operation

PATIENT DIRECTIONS: Please check the one best response for each question.

1. In the past 4 weeks, how often did you experience accidental bowel leakage of gas?

- (0) Never
- (1) Rarely *(one time in the past four weeks)*
- (7) Sometimes *(greater than one time in the past four weeks, but less than one time per week)*
- (13) Weekly *(greater than or equal to one time per week, but less than one time per day)*
- (19) Daily *(one time per day)*
- (25) Several Times a Day *(greater than one time per day)*

2. In the past 4 weeks, how often did you experience minor bowel soiling or seepage?

- (0) Never
- (31) Rarely *(one time in the past four weeks)*
- (37) Sometimes *(greater than one time in the past four weeks, but less than one time per week)*
- (43) Weekly *(greater than or equal to one time per week, but less than one time per day)*
- (49) Daily *(one time per day)*
- (55) Several Times a Day *(greater than one time per day)*

3. In the past 4 weeks, how often did you experience *significant* accidental bowel leakage of liquid stool?

- (0) Never
- (61) Rarely *(one time in the past four weeks)*
- (73) Sometimes *(greater than one time in the past four weeks, but less than one time per week)*
- (85) Weekly *(greater than or equal to one time per week, but less than one time per day)*
- (97) Daily *(one time per day)*
- (109) Several Times a Day *(greater than one time per day)*

4. In the past 4 weeks, how often did you experience *significant* accidental bowel leakage of solid stool?

- (0) Never
- (67) Rarely *(one time in the past four weeks)*
- (79) Sometimes *(greater than one time in the past four weeks, but less than one time per week)*
- (91) Weekly *(greater than or equal to one time per week, but less than one time per day)*
- (103) Daily *(one time per day)*
- (115) Several Times a Day *(greater than one time per day)*

5. In the past 4 weeks, how often has this accidental bowel leakage affected your lifestyle?

- (0) Never
- (1) Rarely *(one time in the past four weeks)*
- (2) Sometimes *(greater than one time in the past four weeks, but less than one time per week)*
- (3) Weekly *(greater than or equal to one time per week, but less than one time per day)*
- (4) Daily *(one time per day)*
- (5) Several Times a Day *(greater than one time per day)*

Instructions to Physician: Calculating the Fecal Incontinence Score

- a) Choose the Single Highest Valued Response to Questions 1 thru 4 _____
- b) Value of Response to Question 5 _____
- c) Fecal Incontinence Score (Sum of a + b) _____

Informed Consent

PATIENT INFORMATION SHEET

III DEGREE HAEMORRHOIDS: COMPARATIVE STUDY (PERSPECTIVE, RANDOMISED, MULTICENTRIC) ON STAPLED ANUPEXIS VS DOPPLER GUIDED LIGATURE OF THE TERMINAL BRANCHES OF THE SUPERIOR RECTAL ARTERY (PHASE 3)

Dear Madam/Sir,

This department participates in a study finalised to gather evidential data to assess which of the two procedures offers better results in the treatment of III degree haemorrhoidal disease.

This study is organised by SICCR (Società Italiana di Chirurgia ColoRettale) and includes about 12 centres, Italian and international.

In the SICCR Guidelines and, also, by the most reputed international scientific societies, Stapled Anupexis and Transanal Haemorrhoidal Dearterialization are suggested procedures for the treatment of III degree haemorrhoidal disease (Goligher):

- Stapled Hemorrhoidopexy is indicated in grade III haemorrhoids (degree of recommendation A) due to its advantages vs. other techniques in pain reduction and time before resumption of normal activity. Positive results up to 94-96% are reported with a mean follow up of > 18 months. However, relapses requiring re-intervention in 25% of procedures with a 12 months follow up are reported in a perspective Belgian study. Another randomized and perspective study with a minimum follow up of 6 months, confirms a major incidence of relapses (P = 0.008) in the Longo technique vs. haemorrhoidectomy. Persistent pain and sepsis are evidenced as rare complications.
- The new technique of Doppler guided trans-anal haemorrhoidal dearterialisation (THD) has been successfully applied to III degree haemorrhoids with very few complications. It is a minimally invasive procedure, with a good efficacy of the short term results: in the study by Sohn et al. on 60 patients who underwent THD, bleeding was resolved in 88%, prolapse in 92% and pain in 71%, with a failure rate of 3%, suggesting that THD should be considered as an alternative to haemorrhoidectomy, mostly in presence of associated continence problems. [21]. Similar results have been presented on 102 patients inclusive also of IV degree haemorrhoids. In a recent perspective, non randomized study, the Doppler guided ligature of the terminal branches of the superior rectal artery has been performed in III e IV degree patients, with interesting results: 27 minutes the mean procedural time, absence of severe or moderate pain post operatively and a failure in 7 of the 32 patients. In a perspective, study randomized between closed haemorrhoidectomy and Doppler guided ligature, on 60 patients, the advantages of the latter were a lesser use of analgesic drugs and a reduced hospital stay with no difference in symptom remittance and relapses, with a 12 months follow up [25]. In a perspective, multi-centre observational study, in the 86 patients with II or III degree haemorrhoids, treated with THD the symptoms, pain, dischertia, bleeding and mucosal soiling were reduced significantly at a mean follow up 14.7±5.1 months (3-24).

Currently, studies comparing long term results of the two techniques to clarify if one proves better than the other, are lacking.

The study, which you are requested to participate in, is randomised, thus we will know which of the two procedures you will be submitted to only after having inserted your initial data. Afterwards, we will observe and record any specific information relevant to the outcome of the procedure, duration of hospital stay and the subsequent follow-up.

The following information will be inserted in an electronic data base and will be utilised only for research purposes.

- Some data relevant to your clinical history;
- The symptoms and the diagnosis at the time of entering the hospital and after the procedure;
- Some data relevant to the surgical procedure.

In all of the files recorded during this study, you will be identified by a progressive number, the initials and your year of birth; however, personal information, such as your clinical history, could be reviewed by authorised representatives of SICCR. By signing the Informed Consent form, you authorise the above mentioned personnel to have direct access to your clinical data. In no circumstance, your identity will be divulged.

This study has been notified to the relevant Authorities and will be carried out in agreement with the current norms regulating clinical studies.

Your participation in this study is strictly voluntary; You will be able to withdraw your consent to utilise your data at any moment without any alteration of your relationship with your referring Doctor.

You can request and obtain any further information about this study by applying to:

Doctor. _____ (phone. _____), in this department.

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Given on _____

Patient's signature _____

Doctor's signature _____

=====

Received on _____

Patient's signature _____

Doctor's signature _____