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An enhanced outpatient modality for the treatment of hemorrhoidal disease: preliminary results

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SUMMARY: **An enhanced outpatient modality for the treatment of hemorrhoidal disease: preliminary results.**

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Surgical treatment of haemorrhoids is, primarily, performed on an outpatient basis, and as so, the reduction of the operative time and the hospitalization duration is necessary. In order to achieve these results, both the surgical procedure and the anaesthesia modality should be optimized. Therefore, in this randomized controlled trial, we proposed the hemorrhoidal arteries ligation under pudendal nerve block, as an enhanced outpatient modality, versus the standard of doppler guided hemorrhoidal arteries ligation under spinal anaesthesia. Preliminary results showed that the experimental group was characterized by a similar to the control arm, symptoms remission rate, a lower operation duration and an improved postoperative recovery.

KEY WORDS: Hemorrhoids - Ligation - Ultrasound - Hemorrhoidopexy.

Reduction of the operative time, enhancement of the postoperative recovery and the subsequent accelerated hospital discharge, have always been key points of paramount importance in outpatient surgical procedures. Surgical treatment of hemorrhoids is one of the commonest operations performed, on an outpatient basis.

Since increased arterial flow in the hemorrhoidal plexus is considered as the main genesis factor of hemorrhoidal disease, Doppler guided (DG) ligation of hemorrhoidal arteries (HAL), has been introduced (1). This technique, however, is characterized by high recurrence rates, especially in Grade IV hemorrhoids (2). Ligation of the hemorrhoidal nodules and hemorrhoidopexy has been proposed as an efficacious alternative. In the RCT by Aigner et al., it was found that the addition of ultrasound did not influence postoperative results (3).

In outpatient settings, spinal anesthesia is often the method of choice. However, spinal anesthesia is related to certain complications such as urinary retention, headache and inhibition of immediate postoperative mobilization. Pudendal nerve block, was also introduced in elective perianal procedures, since it provides adequate postoperative analgesia with lower local and systematic complications (4).

Taking under consideration these facts, the present trial was designed, in order to compare two modalities for hemorrhoids treatment, the ligation and hemorrhoidopexy technique applying pudendal nerve block and the conventional ligation of hemorrhoid arteries using ultrasound with spinal anesthesia. Exclusion criteria included acute or malignant perianal diseases, patient age ≥ 80 years, ASA score ≥ III, inflammatory bowel disease, previous rectoanal

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operation and any clinical significant comorbidity (Figure 1).

In the first group, after placing the patient in the Lloyd-Davies position, a proctoscope combined with a Doppler sensor is inserted in the anus. After locating the hemorrhoidal arteries with the ultra-

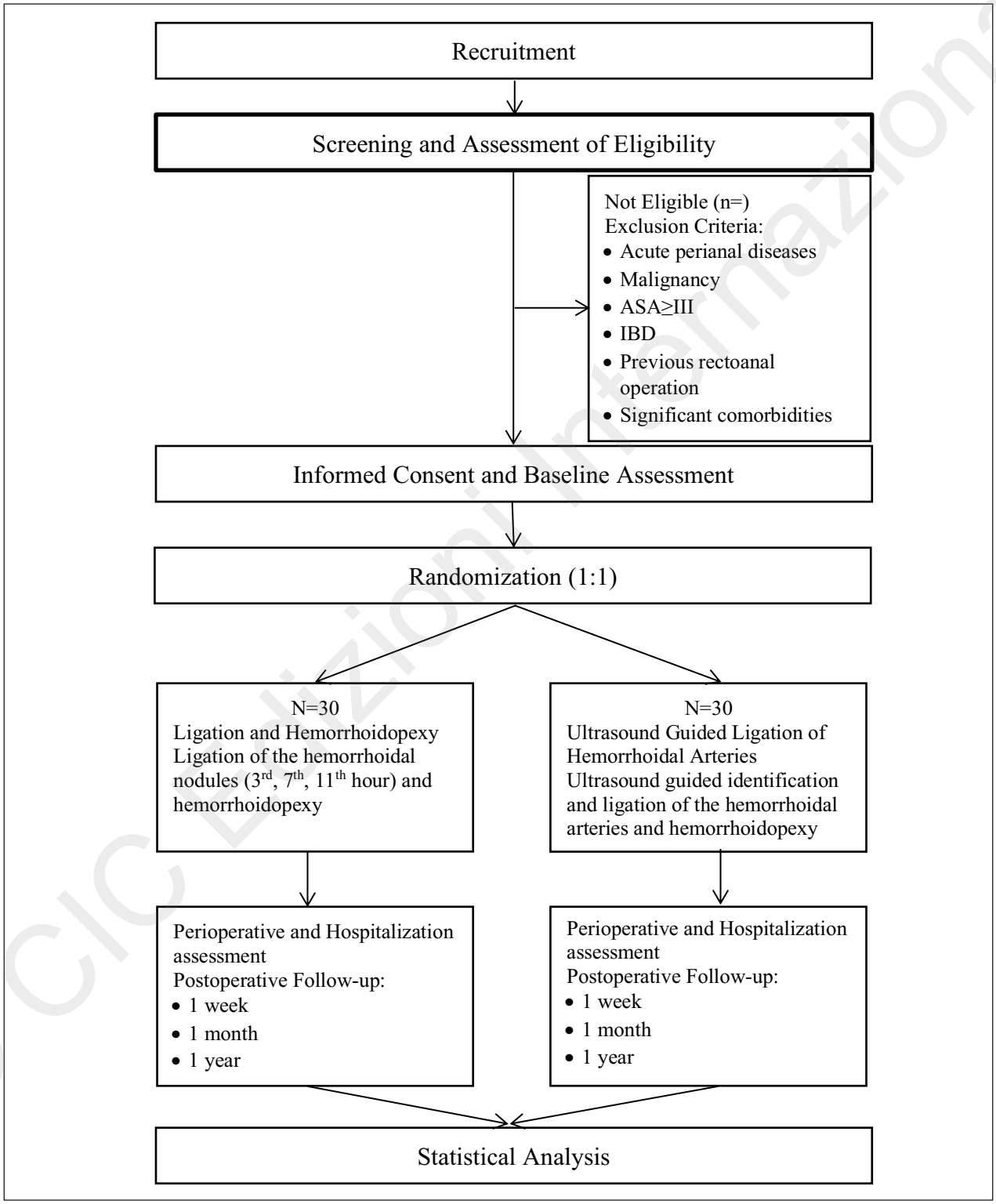

Figure 1 - Study Flow Diagram.

sound guidance, using an absorbable polyglycolic acid suture, Z ligations is placed. Confirmation of devascularization is based on the absence of a Doppler signal. In the presence of residual hemorrhoidal tissue, hemorrhoidopexy is performed, through application of a continuous suture from the hemorrhoidal stalk and distally. Prior to the operation, a L2-L3 or L3-L4 spinal anesthesia is administered, using a levobupivacaine 5 mg/ml and fentanyl 25 mg solution.

In the experimental arm, respectively, a conventional proctoscope is utilized. Identification of the hemorrhoids (3rd, 7th, 11th hour), is followed by the ligation of the nodules using an absorbable polyglycolic acid suture. After placing a fixative suture in the nodule, hemorrhoidopexy is performed by applying a continuous suture from the stalk and distally. In this group the patient is submitted to pudendal nerve block, using a 20 ml lidocaine solution (diluted with saline in a 1:1 rate).

As primary endpoint was considered the difference in the symptoms remission rate between the two groups, at one month after the operation (Figure 2). Other endpoints included operative time, postoperative mobilization time and onset of oral feeding, postoperative pain levels, short, medium and long-term adverse events, recurrence rates, patient satisfaction and changes in the postoperative quality of life, on the basis of the SF-36 questionnaire.

Based on current literature, patients submitted to ultrasound guided HAL, had a 72.5% remission rate of symptoms, while the respective rate in the ligation and hemorrhoidopexy technique was 90% (5). Thus, for a non-inferiority randomized controlled trial design, with alpha: 2.5%, beta: 80% and a 10% non inferiority limit, the estimated sample in each group was 30 patients.

Since the start of the trial, 40 patients were included, 20 in each group. The demographics were comparable between the two groups. Preliminary analysis did not reveal a significant difference in terms of the primary endpoint (50 *vs* 42.1%, p=0.071). However, the experimental arm was characterized by a shorter operation duration (18.5 *vs* 31.95 min, p<0.001) and a faster postoperative mobilization (5.1 *vs* 9.35h, p=0.007) and onset of oral feeding time (5.9 *vs* 11.2h, p<0.001). Moreover, the level of pain at 12h (6.5 *vs* 2.75, p<0.001) and 7 days (4.58 *vs* 1.63, p<0.001) postoperatively, was significantly higher in the group where DG-HAL and spinal anesthesia were performed. Although vomiting (0 *vs* 10%, p=0.035) and urinary retention (2.5 *vs* 20%, p=0.008) were more frequent in the control group, there was no difference in the medium term adverse events. Similarly return to work was longer in the control arm (4.58 *vs* 1.63, p<0.001). Concerning the quality of life, a significant improvement was reported in both groups, one month postoperatively, at all SF-36 sections. Finally, a superiority of the experimental arm was recorded, in terms of energy (p<0.001), emotional well-being (p=0.001), social functioning (p=0.031) and general health (p=0.006).

Primary results of our trial show that the combination of ligation of hemorrhoidal nodules under pudendal nerve block is at least, comparable to the standard DG-HAL under spinal anesthesia, in terms of postoperative recovery and quality of life. However, completion of the enrollment and full-term analysis, is still required, before final conclusions are drawn. The amalgam of a simple, low cost, but, efficient surgical technique and an anesthesia method will provide a novel, safe and effective outpatient modality for the treatment of hemorrhoids.

Conflict of interest

The Authors declare that they have no conflict of interest.

Author contributions

Conception and design of the study: Perivoliotis, Tepetes

Drafting the article: Perivoliotis

Critical revision: Spyridakis, Zintzaras, Arnaoutoglou

Final approval: Pramateftakis, Tepetes

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		STUDY PERIOD						
	Enrolment	Allocation	Post-allocation					Close-out
TIMEPOINT**	*-1 Day*	0	*Post-operatively*	*12 hours*	*24 hours*	*48 hours*	*1 week*	*1 month*	*1 year*
ENROLMENT:									
Eligibility screen	X								
Informed consent	X								
Demographics	X								
Medical History	X								
Physical and laboratory examinations	X								
ASA Score	X								
Randomization		X							
Allocation		X							
INTERVENTIONS:									
Ligation and Hemorrhoidopexy		X							
Ultrasound Guided Ligation of Hemorrhoidal Arteries		X							
ASSESSMENTS:									
Symptoms Remission Rate								X	
Operative time			X						
Postoperative mobilization time			♦—	—	—♦				
Onset of oral feeding			♦—	—	—♦				
Postoperative pain level				X			X		
Short-term adverse events			♦—	—	—♦				
Postoperative Discharge time			♦—	—	—	—♦			
Medium-term adverse events			♦—	—	—	—	—♦		
Return to work								X	
Long-term adverse events			♦—	—	—	—	—	—	—
Recurrence			♦—	—	—	—	—	—	—
Patient Satisfaction									X
SF-36	X							X	X

Figure 2 - SPIRIT Diagram.

Ethical Approval

All procedures reported in this study involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

This article does not contain any studies with animals performed by any of the Authors.

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Clinicaltrials.gov identifier: NCT03298997

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Ethics Committee

University Hospital of Larissa Ethics Committee
Protocol: 26761, 9/7/14-06-2017
Chairperson: Prof. Tsilimigas

Informed consent

Informed consent was obtained from all individual participants included in the study.

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