

## **SDC1 - Text.1**

### **Exclusion criteria – LigaLongo RCT**

- Acute hemorrhoidal disease
- Previous hemorrhoidal surgery
- History of congenital or acquired anal stenosis
- Anal fissure
- Perianal abscess
- Inflammatory bowel disease
- Colorectal cancer
- Rectal or sigmoid resection
- Rectal prolapse
- Portal hypertension
- Hemophilia
- Current pregnancy

## **SDC2 - Text.2**

### **Randomization**

Subjects were randomly allocated to the two groups in a 1:1 ratio using a blocked randomization technique.

Web-based randomization software (TENALEA Software, Amsterdam, The Netherlands) was used to generate random sequence blocks of size 6.

The randomization was stratified on the grade of the HD (GII / GIII).

**SDC3 - Table 1: Symptoms and quality of life assessment**

| <i>Variable category</i>              | <i>Time scale</i> |           |           |           |
|---------------------------------------|-------------------|-----------|-----------|-----------|
|                                       | Baseline          | D.90      | M.6       | M.12      |
| Pain VAS (0-10)                       |                   |           |           |           |
| DGHAL                                 | 4.2±2.6           | 1.1±1.9   | 1.0±1.8   | 1.0±1.9   |
| SH                                    | 3.9±2.6           | 1.2±1.8   | 0.9±1.6   | 0.9±1.6   |
| Symptom Severity (0-19) [15]          |                   |           |           |           |
| DGHAL                                 | 6.6±2.4           | 2.0±2.5   | 2.0±2.2   | 2.1±2.4   |
| SH                                    | 6.5±2.5           | 2.3±2.7   | 2.1±2.5   | 2.0±2.7   |
| Disease Severity (0-4)*[7]            |                   |           |           |           |
| DGHAL                                 | 2.4±0.8           | 0.7±0.9   | 0.5±0.8   | 0.6±0.9   |
| SH                                    | 2.4±0.9           | 0.7±1.0   | 0.6±0.9   | 0.6±0.9   |
| Physical composite SF36 score (0-100) |                   |           |           |           |
| DGHAL                                 | 48.4±8.0          | 53.2±7.0  | -         | 53.5±6.8  |
| SH                                    | 49.3±8.0          | 52.8±8.2  | -         | 53.2±7.8  |
| Mental composite SF36 score (0-100)   |                   |           |           |           |
| DGHAL                                 | 47.1±10.8         | 48.7± 9.3 | -         | 48.2±10.2 |
| SH                                    | 44.6±11.2         | 47.2±11.2 | -         | 48.0±10.1 |
| Patient satisfaction (0-100)          |                   |           |           |           |
| DGHAL                                 | -                 | 85.3±23.9 | 83.8±25.2 | 82.1±25.6 |
| SH                                    | -                 | 82.9±23.1 | 86.0±19.6 | 83.0±25.1 |
| Would recommend (% patients)          |                   |           |           |           |
| DGHAL                                 | -                 | 93.6%     | 96.0%     | 92.6%     |
| SH                                    | -                 | 96.0%     | 96.3%     | 94.5%     |

\*Discomfort related to hemorrhoidal disease: from none (0) to max. (4) independently graded by the patient [7]

Bristol classification measured at baseline: 3.7±1.3 vs 3.7±1.4

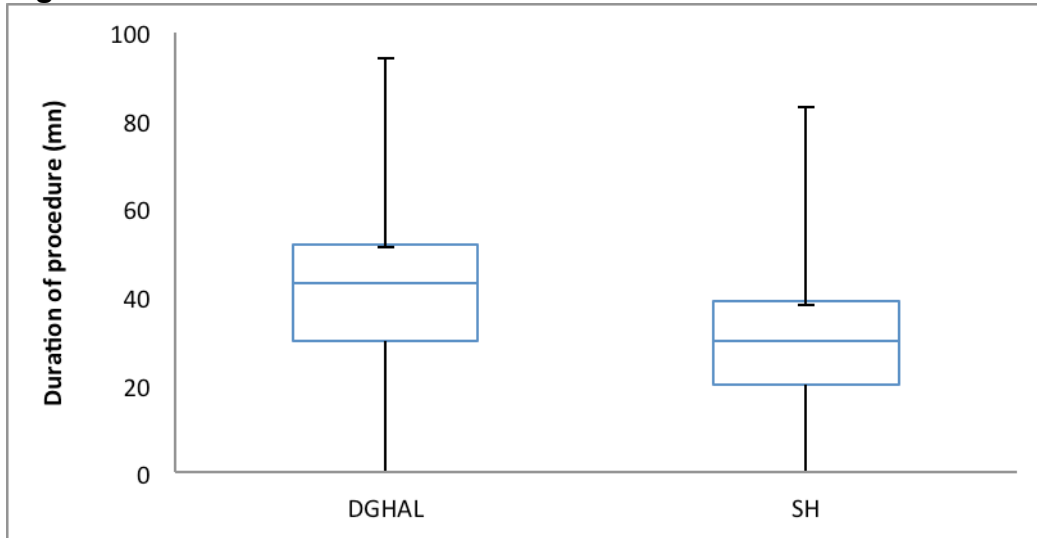
Respectively in the all series, 24% and 5% of the patients complained of evacuation difficulties regularly or always

DGHAL: Doppler-Guided Hemorrhoidal Arterial Ligation ± mucopexy. SH: circular Stapled Hemorrhoidopexy

## SDC4 - Fig.1

### Title: Duration of procedures

Fig.1



DGHAL: Doppler-guided Hemorrhoidal Arterial Ligation ± mucopexy

SH: Circular Stapled Hemorrhoidopexy

mean±SD [median] for DGHAL and SH respectively: 44±16 [42] and 30±14 [30] min;  
p<0.001

For the occupation time of the operating room(OR): mean±SD [median] for DGHAL and SH  
respectively: 82±25[80] and 68±24[64] min; p<0.001

### **SDC5 - Text.3**

#### **Deviations in random assignment (12 patients)**

In one patient randomized to DGHAL, an extensive hemorrhoidal prolapse led to SH.

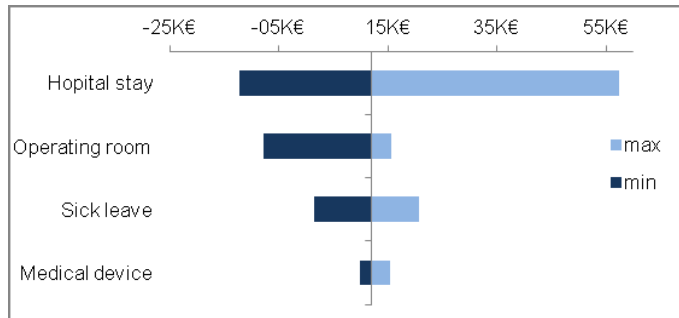
In 3 cases randomized to SH, the anal canal did not permit a safe entry of the stapler and an excisional hemorrhoidectomy was decided and performed.

In 8 cases, the investigator chose for clinical preference to ignore the randomization and performed the other procedure.

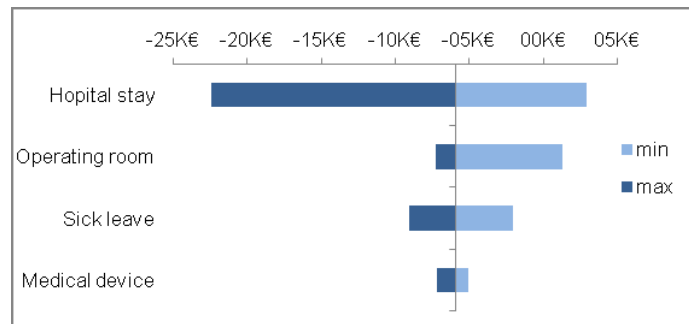
These cases have been included in their randomization arm according to mITT.

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**F Q 2**



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### **SDC7 – Role of the funder**

No companies were involved into the trial. The normal hospital funding method was applied for the reference procedure arm. Prices have been negotiated for the trial procedures by the funder. The trial being supported by the French Ministry of Health regular reports were submitted to the “Direction Générale de l’Offre de Soins”.