

**EudraCT number: 2016-002824-98**

**Title:** Comparison of three techniques in the management of the postoperative acute pain, after a general anesthesia based on the control of the nociception.

**Code:** ANE\_HEPUNOX

**Sponsor:** Servicio de Anestesiología y Reanimación Hospital Universitari Vall d'Hebron

**Principal Investigator:** Ana Abad Torrent

### **Justification of termination of the trial**

This was a prospective, randomized, non-invasive clinical trial oriented to better handle postoperative pain after general anesthesia, according to three different analgesic monitorization techniques: pupilometry, electroencephalography, and hemodynamic parameters of arterial tension and cardiac rate.

The main goal was to analyse the subjective pain perception and opioid consumption in patients undergoing prostatectomy and hysterectomy according to their sex, race, study level, and socioeconomic status. The telephonic interview conducted a month after the surgery was the method used to examine the demographic factors. It was intended to raise information to treat postoperative pain not only pharmacologically, but considering psychosocial aspects.

A recruitment of 204 patients was proposed, including those elected for abdominal hysterectomy by laparoscopy, and robotic prostatectomy. Patient recruitment was proposed in two different surgical areas of the Vall d'Hebron Hospital at Barcelona (Spain): Hospital General and Hospital Materno Infantil. This had the advantage of having the same type of equipment, and thus homogeneous conditions for the study.

Recruitment scenario changed as a consequence of general management policies in the hospital, derived from Hospital general guidelines:

- Robotic surgery was chosen as the preferred gynecological election. This implied important changes in the initial scenario, with a loss of homogeneity criteria.
- Different surgical equipment was used from the initially considered, with its corresponding learning curves.
- Surgical periods were longer, and pharmacological administration changed in dose and could affect trial results, as well as the post-operative overall period.
- Robotic surgery was moved to a different building than considered, conforming a whole different scenario, with different conditions and personnel involved in data collecting with different training.

### **RESULTS**

For the above mentioned reasons, it was impossible to have statistically validated data regarding postoperative quality of patients. However, the second part of the study considered

a phone interview one month after the surgery procedure, in order to have a subjective perception of pain, and opioid consumption in the initial 24 hours, considering differences in sex, age, ethnics, and socio-economical factors. These results have been published at Austin Journal of Anesthesia and Analgesia (Open-Access):

*Abad-Torrent A, de Miguel M, Sanaú B, Cortiella P, Suescun MC, Suárez-Edo E. Influence of Demographic Factors on Pain Perception and Postoperative Opioid Consumption. Austin J Anesthesia and Analgesia. 2020; 8(3): 1093.*

## **Abstract**

### **Purpose:**

The purpose of this study was to analyse the influence of demographic factors on pain perception and opioid consumption in patients undergoing robotic prostatectomy and laparoscopic hysterectomy.

### **Methods:**

A total of 93 patients were included in this observational, prospective study. A telephone interview was carried out after one month of the surgery. The patients were asked about demographic information, academic training, employment situation and the perception of their pain by assessing the Visual Analogue Scale (VAS) before and after the intervention. During their hospital stay, the total consumption of morphine and VAS were collected.

### **Results:**

There were no statistically significant differences in VAS scores on the first postsurgical day and one month after the operation by sex, origin, and academic training. On multivariate logistic regression analysis, qualified work and inactive status were independent protective factors for moderate-severe postoperative pain on the first day after surgery. There was higher morphine consumption in men compared with women in the first four postoperative hours (mean difference: 0.029 mg/kg; 95% CI: 0.006 to 0.05).

### **Conclusion:**

Sex, race, and academic formation did not influence the perception of the intensity of postoperative pain and the opioid consumption, except for the first 4 hours of the postoperative period, in which women required fewer doses of morphine than men. Qualified work and inactive status were independent protective factors for moderate-severe postoperative pain on the first day after surgery. Before surgery, inactive patients had higher VAS scores than retired and active workers.