



# Efficacy of a pain therapy protocol following gynaecological surgery

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## Abstract

**Background** An adequate management of postoperative pain is an important guarantee for high quality care. The department of Gynecology at the University Hospital S. Anna in Ferrara (Italy) regularly monitors the intensity and treatment of pain using a dedicated form called "Treating pain together", complying with the recommendations of the local task force on pain "Pain-free Hospital and Land". The purpose is to evaluate the prevalence and intensity of pain in hospitalised women undergoing surgery by using a dedicated form and the efficacy of pain therapy protocols.

**Methods** 156 women undergoing gynecological surgery were examined, according to the type of surgical access (transversal laparotomy TL, longitudinal laparotomy LL, vaginal VAG), anesthesia and pain therapy. Pain was monitored three times a day during the first three days after surgery using NRS. Pain episodes were treated with painkillers when exceeding the intensity threshold NRS=3.

**Results** The prevalence of pain on day 0 was 15.8%, 19% and 31.6% for TL, LL and VAG respectively. During days 1 and 2 the values were respectively: 55.3% and 27.6% for TL, 52.4% and 50% for LL, 26.3% and 23.7% for VAG. The "due hours" painkillers administration scheme is related to a lower percentage of pain episodes, if compared to rescue doses.

**Conclusion** "Treating pain together" is a useful tool to systematically describe the different aspects of pain. It gives insight into this extremely subjective symptom and vital sign and helps improve therapy protocols when necessary.

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## Introduction

Pain is defined by the International Association for the study of Pain (IASP) as "an unpleasant sensory and emotional experience associated with actual or potential tissue damage, or described in terms of such damage" (1). Postoperative pain is the expected, undesirable by-product of all surgical procedures. Despite its universal occurrence, our understanding of its causes and our ability to treat postoperative pain is still incomplete (2). In women undergoing gynaecological surgery, postoperative pain can have different consequences: it can be severe, interfere with sleep and appetite, or result in chronic pain (3;4).

Several studies report that the management of acute postoperative pain is still ineffective and that different pain scales and criteria for assessment are used (4-11).

Most studies about gynaecological surgical procedures describe the outcome in terms of postoperative pain comparing

the different approaches to surgery, from the least to the most invasive one (12-18).

Pain is a complex symptom, influenced by several factors. In the clinical setting, as well as in most published research, the measurement of its "intensity" suggests that this is most important dimension to assess and record (19).

A systematic and adequate management of postoperative pain is an important guarantee for high quality care (20;21). In Italy, particularly in the region of Emilia Romagna, it is a primary aim. S. Anna University Hospital in Ferrara has complied with the recommendations of the national project "Pain-free Hospital and Land" since its foundation, in 2001. The operators who join this project play an active role in improving assistance and treatment for hospitalised people, and the final aim is to promote the diffusion of the so-called "culture of pain" in which pain is handled on the same terms as other medical issues (22;23).



## Research and Best Practice

In order to comply with the recommendations of the “Pain-free Hospital And Land” task force on pain and in agreement with the national law n. 38/2010 (24), the Department of Gynaecology constantly monitors the intensity of pain in women who have undergone surgery, using a dedicated form, called “Treating Pain Together” (25;26;Appendix 1).

### Objective

The aim of the study is to evaluate:

- the prevalence and intensity of pain in hospitalised women who have undergone surgery for gynaecological diseases, using a dedicated form called “Treating pain together”
- the efficacy of pain therapy protocols, based on expected pain.

### Materials and Methods

#### Participants and Procedures

From February to December 2010, all patients referred to the Department of Gynaecology and Obstetrics at the S. Anna University Hospital, for a supposed benign gynaecological condition or a pre-malignancy, were recruited for the present study.

The indications for surgery were: uterine fibroids, benign pelvic masses, endometrial atypia, intraepithelial lesions of the uterine cervix, and uterine prolapse.

Exclusion criteria were: “Treating pain together” form not correctly filled in, patient displacement in other departments after surgery, a second surgery during the postoperative period.

All the surgical procedures were done during hospitalisation. For each patient, the clinical history was recorded.

All patients received an appropriate evaluation by the anaesthetist in accordance with the American Society of Anesthesiologists (ASA) classification in order to choose the most suitable anaesthesiology procedure: general, blended, spinal or combined spinal and epidural (CSE) anaesthesia.

The pre-surgical exams were prescribed on the basis of the hospital protocol: blood sample, electrocardiogram, chest X-Rays, and other procedures depending on the clinical needs of the patient. All received antibiotic prophylaxis with penicillin-derived drugs - if they were not allergic - gastric protection, and antithrombotic prophylaxis if necessary.

All surgical procedures were performed by the surgical team of the Department of Gynaecology and Obstetrics at the S. Anna University Hospital.

For each patient, we assessed: age, indication for surgery, type of surgery, length of postoperative hospitalisation, surgical access, anaesthesia, postoperative analgesic devices, postoperative analgesics administration scheme and number of pain episodes during the hospitalisation, especially during the first 72 hours after surgery.

Patients were divided into three groups depending on the surgical access: transversal laparotomy (TL), longitudinal laparotomy (LL) and vaginal access (VAG).

Surgical procedures were distinguished by being either demolishing or not demolishing, depending on whether hysterectomy was performed or not. All patients received painkillers according to hospital therapy protocols, applied on the basis of the expected pain, according to the Evidence-Based Medicine (EBM) and Evidence-Based Nursing (EBN) criteria. All protocols implied the use of a multimodal therapy with the association of opiates and NSAIDs.

Every patient was given an elastomeric pump containing painkillers (NSAIDs or a combination of NSAIDs and opiates), through continuous, fixed-dose, intravenous or epidural analgesic pump, during the first 24 hours after surgery (renewable). An additional analgesic administration scheme was prescribed to be administered at least during the first day after surgery. This consisted of intravenous painkillers according to a scheduled timetable (due hours) in addition to rescue doses if needed, or rescue doses alone, just in case of pain exceeding the threshold value NRS=3, as explained below. The most suitable scheme was chosen by the anaesthetist according to the patient’s history and needs, the type of surgery and the intensity of the expected pain. After the first 24 hours, painkillers were given as rescue doses exclusively.

#### Pain Assessment

The data was taken from the “Treating Pain Together” form. This tool was introduced in December 2009 in some departments of S. Anna University Hospital, and gradually incorporated in all departments. It has been part of the clinical files of gynaecological patients (both surgical and not surgical) since January 2010.

The form was completed by the health care providers (medical and nursing staff) when the patient is admitted to the ward and updated at least three times a day, until discharge. Patients’ experience of pain is reported in order to document the intensity, characteristics and



## Research and Best Practice

therapy of pain during the whole hospitalisation.

All patients were informed about the project and introduced to the “Treating the Pain together” form. They received information about pain and treatment, both orally and in written material. The members of the “Pain-free Hospital and Land Committee”, represented by operators in every department of the hospital, were available for information when needed.

The chosen pain scale was the Numerical Rating Scale (NRS), on which 0 represents “no pain” and 10 “pain as bad as you can imagine”. Scores 1-3 correspond to mild pain and did not represent need for analgesic therapy; scores 4-7 correspond to moderate pain and scores 8-10 to severe pain. The threshold value is NRS=3: beyond this value, the administration of rescue doses of painkillers is mandatory.

Every episode of pain higher than threshold was reported in a table: according to time, intensity, therapy and to the re-evaluation of the patient’s pain after 30 or 60 minutes from the administration of the analgesic drug.

Pain trend, in terms of number of episodes and intensity, was analysed during the day of surgery (day 0) and the following two days (days 1 and 2). During this period, all groups were comparable within the duration of the hospital stay. For each patient, we considered the highest score on NRS among the three surveys recorded each day by the health care providers. The “mean NRS” value represents the average score among the highest scores of pain intensity of all patients, in the duration of days 0, 1, and 2 after surgery.

### Statistical Analysis

Univariate and multivariate analyses were used to find variables potentially responsible for causing more pain episodes and affecting the need for rescue analgesia: “presence of an over-threshold episode of pain” was considered as a dependent variable. Independent variables were: age, demolition, surgical access, type of anaesthesia, prescription of painkillers every due hour or as a rescue dose.

The statistical analyses were done separately for each day, since the parameters could change over time: during day 1, the painkillers administration scheme changed because some women, who got analgesics every due hour during day 0, received only rescue doses the following days.

All the involved surgical procedures foresee a “moderate intensity” expected pain, classified on the Numerical

Rating Scale with values between 4 and 7.

The statistical analysis was performed using StatGraphics statistical package v.4 Rockwell (MA) USA and SYSTAT v. 5 Evanston, (IL) USA. Contingency tables  $m \times n$  were tested by the Chi-square test, or by the Fisher’s exact test if needed.

The trends of numerical variables on an interval-scale were checked with simple linear regressions, while the differences between mean values of groups and subgroups were compared using one way Analysis of Variance (1-way ANOVA) or, for non-normal distribution by mean value comparison, using the graphical Notched Box & Whiskers test. The contribution of different variables referring to single binary variables was calculated by univariate and multivariate logistic regression.

Differences in mean or median values were considered significant when the alpha error (type I error) held less than 0.05.

### Results

From 1 February to 31 December 2010, 169 women underwent gynaecological surgery by laparotomic or vaginal access, with a moderate expected pain (NRS 4-7).

13 patients were excluded: 10 because of the absence of the Treating pain together form in the clinical file (at the very beginning of introducing the tool); 2 were displaced in the Intensive Care department because of general comorbidity, and 1 needed a second surgery during the postoperative period.

The accepted sample consisted of 156 women.

The sample was divided into three groups, according to the surgical access:

1. Transversal laparotomy (TL),  $n=76$ .
2. Longitudinal laparotomy (LL),  $n=42$ .
3. Vaginal access (VAG),  $n=38$ .

The sample is presented in Table 1.

Anaesthetists decided on different kinds of painkillers administration in addition to continuous infusion, based on the hospital therapy protocol, influenced by the history, the characteristics of the patients, surgical procedures and expected pain. In the TL group, 41 (54%) received painkillers every due hour and 35 (46%) received rescue doses. In the LL group, 21 received due hour (50%) and 21 rescue administration (50%). In the VAG group, 20 received due hour (53%) and 18 rescue (47%) administration.



## Research and Best Practice

**Table 1** Age and duration of postoperative hospitalisation description in different surgical accesses

| Surgical access            | n°         | %            | Age         |               |                     | Postoperative hospitalisation (days) |              |                 |
|----------------------------|------------|--------------|-------------|---------------|---------------------|--------------------------------------|--------------|-----------------|
|                            |            |              | mean        | SD*           | median (range)      | mean                                 | SD*          | median (range)  |
| Transversal laparotomy TL  | 76         | 48.7         | 48.6        | ± 11.7        | 48.0 (19-81)        | 4.8                                  | ± 1.1        | 5 (2-8)         |
| Longitudinal laparotomy LL | 42         | 26.9         | 63.2        | ± 13.1        | 62.5 (35-83)        | 6.7                                  | ± 2.7        | 6 (4-17)        |
| Vaginal access VAG         | 38         | 24.4         | 65.8        | ± 7.9         | 66.5 (47-78)        | 4.4                                  | ± 1.9        | 4 (2-13)        |
| <b>TOTAL</b>               | <b>156</b> | <b>100.0</b> | <b>56.7</b> | <b>± 13.8</b> | <b>55.0 (19-83)</b> | <b>5.2</b>                           | <b>± 2.1</b> | <b>5 (2-17)</b> |

\*SD = standard deviation

The chi-square analysis did not reveal any significant difference between the three surgical accesses in terms of demolition.

Only one major complication associated with surgery occurred: one episode of febrile morbidity during day 2 after a transversal laparotomy. Results obtained from “Treating pain together” did not show any evidence of any association with increased pain.

### Post-Operative Pain Episodes

#### Day 0

The pain prevalence and mean intensity during day 0 is described in Table 2.

Most women did not complain of pain episodes. However, in the VAG group, a higher number of pain episodes is evident when compared to both laparotomies (TL, LL) and the p value indicates some borderline significance ( $p = 0.14$ ) about this relation.

The mean value of pain intensity was higher in the VAG access ( $p < 0.01$ ) considering only women who complained of at least one episode of over-threshold pain (Figure 1).

Univariate analyses did not highlight any significant relation. A borderline, close to significance result has been observed between the VAG access and the possibility of having more pain episodes if compared to laparotomies ( $p = 0.06$ ), with Odds Ratio (OR 95%) of 2.5.

The multivariate analysis were inconclusive. However, a borderline relation between the presence of hysterectomy and the possibility of having more pain, if compared to non-demolishing surgery ( $p < 0.09$ ) was observed.

#### Day 1

The pain prevalence and mean intensity during day 1 is described in Table 3.

The prevalence of pain episodes in VAG was significantly lower if compared to both laparotomies ( $p < 0.02$ ).

The univariate logistic regression, considering surgical access, showed an OR 95% of 0.29 in VAG during day 1. Pain incidents were three to four times less probable if compared to both the laparotomy groups ( $p < 0.005$ ).

A preventive effect was also evident in the use of pain-killers every due hour if compared to rescue doses ( $p < 0.001$ ), with an OR 95% of 0.20, demonstrating that incidents of pain are about 5 times less likely to occur when following the due hour administration scheme.

Multivariate logistic regression showed a connection between the same two parameters: surgical access and method of analgesics administration. Both the “due hour” administration and the vaginal access during day 1 reduced the risk of experiencing pain, with an OR 95% of 0.17 ( $p < 0.01$ ) for the first parameter, and an OR 95% of 0.23 ( $p < 0.005$ ) for the second one.

#### Day 2

The values of day 2 are represented in Table 4.

During day 2, the clinical condition of patients in both the TL and VAG groups improved, while the percentage of women feeling pain remained high in LL, with over-threshold pain episodes in 50% of the sample ( $p < 0.05$ ).

There were no significant differences among the three groups in terms of pain intensity.

The pain prevalence and intensity is described in Figure 2a, 2b.



## Research and Best Practice

**Table 2** Pain episodes and average intensity during day 0

| PAIN ON DAY 0 | TL<br>(tot 76) |      |              | LL<br>(tot 42) |    |              | VAG<br>(tot 38) |      |              |
|---------------|----------------|------|--------------|----------------|----|--------------|-----------------|------|--------------|
|               | n°             | %    | mean<br>NRS* | n°             | %  | mean<br>NRS  | n°              | %    | mean<br>NRS  |
| NO episodes   | 64             | 84.2 | -            | 34             | 81 | -            | 26              | 68.4 | -            |
| ≥1 episodes   | 12             | 15.8 | 5.6<br>(4-7) | 8              | 19 | 6.3<br>(5-7) | 12              | 31.6 | 7.2<br>(5-9) |

Chi-square distribution: pain episodes–surgical access  $p < 0.14$ ; Chi-square distribution: pain intensity–surgical access  $p < 0.01$   
 \*Numerical Rating Scale

**Table 3** Pain episodes and average intensity during day 1

| PAIN ON DAY 1 | TL<br>(tot 76) |      |              | LL<br>(tot 42) |      |               | VAG<br>(tot 38) |      |              |
|---------------|----------------|------|--------------|----------------|------|---------------|-----------------|------|--------------|
|               | n°             | %    | mean<br>NRS  | n°             | %    | mean<br>NRS   | n°              | %    | mean<br>NRS  |
| NO episodes   | 34             | 44.7 | -            | 20             | 47.6 | -             | 28              | 73.7 | -            |
| ≥1 episodes   | 42             | 55.3 | 5.7<br>(4-8) | 22             | 52.4 | 6.09<br>(4-9) | 10              | 26.3 | 6.5<br>(5-8) |

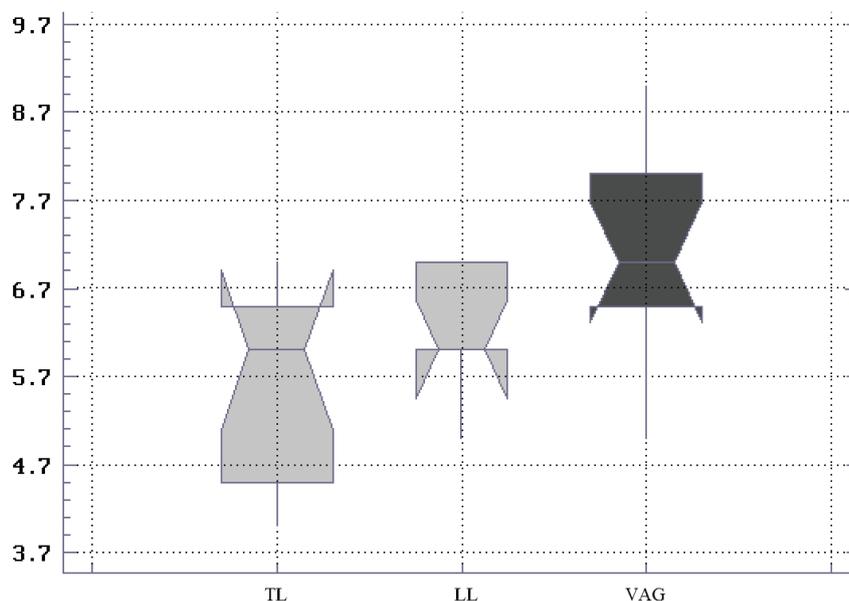
Chi-square distribution: pain episodes–surgical access  $p < 0.02$   
 Chi-square distribution: pain intensity–surgical access  $p < 0.14$

**Table 4** Pain episodes and average intensity during day 2

| PAIN ON DAY 2 | TL<br>(tot 76) |      |              | LL<br>(tot 42) |    |              | VAG<br>(tot 38) |      |              |
|---------------|----------------|------|--------------|----------------|----|--------------|-----------------|------|--------------|
|               | n°             | %    | mean<br>NRS  | n°             | %  | mean<br>NRS  | n°              | %    | mean<br>NRS  |
| NO episodes   | 55             | 72.4 | -            | 21             | 50 | -            | 29              | 76.3 | -            |
| ≥1 episodes   | 21             | 27.6 | 5.7<br>(4-9) | 21             | 50 | 5.8<br>(4-7) | 9               | 23.7 | 6.3<br>(5-8) |

Chi-square distribution: pain episodes–surgical access  $p < 0.02$   
 Chi-square distribution: pain intensity–surgical access  $p < 0.35$

**Figure 1** Maximum pain intensity in women with intensity value >3 on NRS (Day 0). Graphical Notched Box & Whiskers test





## Research and Best Practice

64% (100/156) of the women complained of at least one episode of postoperative pain during the first three days after surgery, independently of the type of surgical access. In this group, the 89% (89/100) had moderate pain (NRS 4-7) and the 11% (11/100) reported severe pain (NRS 8-10).

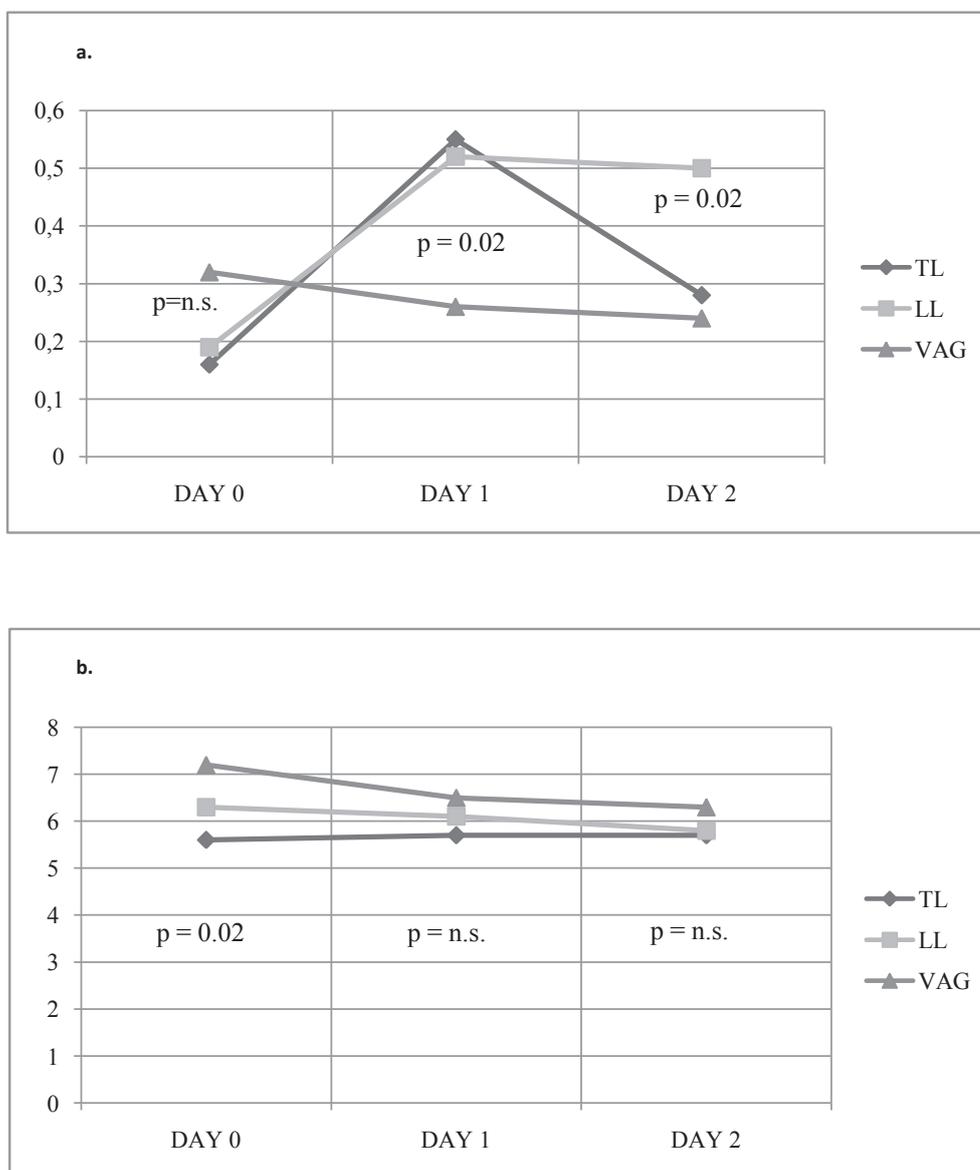
### Discussion

The increasing attention on pain and its treatment, confirmed by the recent Italian legislation (24), has inevitably started actions and initiatives in order to improve the evaluation and monitoring of this problem and to reduce

its occurrence. In our department, we applied the guidelines of the national project called “Pain-free Hospital and Land” (21).

This study on pain episodes in women after gynaecological surgery gave important results: the prevalence of pain (NRS>3) during the first three days after surgery was 64% (100/156), independently of the surgical access. The pain intensity ranged from moderate to severe, on the NRS. However, it is difficult to compare our results to other studies, because of the characteristics of the sample and the surgical area.

**Figure 2** a. Pain prevalence and surgical access during the first three days after surgery;  
 b. Pain intensity in the Numerical Rating Scale and surgical access during the first three days after surgery.





## Research and Best Practice

Prevalence of pain varies considerably in the literature: 25% by Good (4), 78% by Shen (5), 76% by Svensson (6), 80% by Apfelbaum (7), 62% by Costantini (8), 46% by Coucierio (9), 59% by Melotti (10), 2,2% by Moizo (11).

Other studies about pain after gynaecological surgery are not comparable with our results, because of the differences between the type and extension of the surgery, analgesic therapy, time after surgery and presence of other promoting factors (12-18). All these studies use different measuring scales, so it is difficult to assess and compare pain intensity systematically.

Our results regarding intensity seem important: women complained about severe pain only in few cases, generally in the VAG group during day 0. However, the final results showed that the VAG access had the best outcome in terms of percentage of pain episodes, if compared to laparotomies, coherent with the literature (27;28).

The continuous, regular and careful monitoring of pain (its intensity, development and treatment), allowed the detailed description of the postoperative care situation in women in the gynaecological department. The use of the "Treating Pain Together" form in every department of Ferrara University Hospital and dedication to treating and minimising post-operative pain was useful in order to reach this aim.

This study shows that patients undergoing gynaecological surgery suffer sufficient post-operative pain to be in need of intervention.

A further goal could be to attend to these critical points identified in this study: to relieve pain in women in the VAG group during day 0, in the TL group on day 1 and in the LL group on day 2.

### Conclusions

The current study demonstrates that the reduction of postoperative suffering is an important indicator of a high level of health care and life quality.

The strength of this study is the use of the dedicated form "Treating pain together", a useful tool to assess and monitor pain intensity and find the adequate response to its treatment, regularly and continuously. Pain is an extremely subjective symptom and a vital sign, and its detailed description can help with the improvement of therapy protocols when necessary.

Adequate information dedicated to women hospitalised in a gynaecological department and the awareness of

postoperative pain among the sanitary operators gave important results in terms of relief from suffering in operated women.

### Contribution Details

Conception and design: TM, RM, CB

Acquisition of data: CB

Analysis and interpretation of data: CB, TM, RM, PC

Drafting the article: TM, RM, CB

Revising the article critically for important intellectual content: TM, RM, FG, PC, RZ, AP

Final approval of the version to be published: TM, RM, CB, FG, PC, RZ, AP

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## Research and Best Practice

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