# Patients' satisfaction with the implementation of the concept of pain as the fifth vital sign to control postoperative pain\*

Satisfação dos pacientes com a implantação do conceito dor o quinto sinal vital, no controle da dor pós-operatória

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## **SUMMARY**

**BACKGROUND AND OBJECTIVES**: There is an increasing concern of health institutions with patients' satisfaction. This study aimed at evaluating patients' satisfaction in the postoperative period of a medium-sized hospital in terms of controlling pain and implementing the concept of pain as the fifth vital sign, faced to the importance of the theme and the scarcity of prospective studies on the subject.

**METHOD**: Open randomized clinical trial. Postoperative patients were divided in two groups. In the group with intervention, pain scales were made available to the assisting team and verbally informed when applied. For the group with no intervention, there were no pain scales. Satisfaction measurements were evaluated once a day until, at the utmost, the fifth postoperative day.

**RESULTS**: There has been predominance of females (83.5%) and mean sample age was 36.7 years. Most surgeries were C-sections (57.1%). Patients referred pain in 75.6% of measurements and considered it from moderate to severe in 23% of measurements. As to satisfaction, most (54%) have considered pain control excellent. In

comparing groups there has been no significant difference in the level of satisfaction.

**CONCLUSION**: There has been no difference in patients' satisfaction when pain as the fifth vital sign was implemented. The study suggests that several components contribute to patients' satisfaction, although we have just evaluated the physiological aspect of pain.

**Keywords**: Hospitalization, Pain measurement, Patients' satisfaction, Postoperative pain.

# **RESUMO**

JUSTIFICATIVA E OBJETIVOS: Há uma preocupação crescente das instituições de saúde com a satisfação do paciente no seu atendimento. O objetivo deste estudo foi avaliar a satisfação dos pacientes em pós-operatório, em hospital de médio porte quanto ao controle da dor, após implantar o conceito dor como quinto sinal vital, vista a importância do tema e a escassez de estudos prospectivos sobre o assunto.

**MÉTODO**: Ensaio clínico aleatório aberto. Os pacientes em pós-operatório foram divididos em dois grupos. No grupo com intervenção, as escalas de dor foram disponibilizadas para a equipe assistencial e informadas verbalmente no momento da aplicação. Já no grupo sem intervenção, as escalas de dor não estiveram disponíveis. Foram então avaliadas as medidas de satisfação uma vez ao dia até, no máximo, o quinto dia de pós-operatório.

**RESULTADOS**: Ocorreu predomínio do sexo feminino (83,5%) e a média de idade da amostra foi de 36,7 anos. A maioria das cirurgias foi cesariana (57,1%). Os pacientes referiram dor em 75,6% das medições e a consideraram de moderada a intensa em 23% das medições. Quanto ao grau de satisfação, a maioria (54%) considerou ótimo o controle álgico. Comparando os grupos, não houve diferença significativa quanto ao grau de satisfação.

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CONCLUSÃO: Observou-se que não houve diferença na satisfação dos pacientes quando colocada em prática a dor como quinto sinal vital. O estudo sugere que vários componentes contribuem para a satisfação do paciente, embora tenha sido avaliado apenas o aspecto fisiológico da dor.

**Descritores**: Dor pós-operatória, Internação, Medição da dor, Satisfação do paciente.

## INTRODUCTION

Acute postoperative pain is the result of local surgical trauma and is protective, since it informs the body that there is an injury. During this period, pain is very uncomfortable causing not only anatomic but also physiologic changes, in addition to negative psychological symtoms<sup>1</sup>. Studies show that up to 90% of patients submitted to surgeries feel some type of pain, indicating that postoperative pain is frequent<sup>1</sup>.

Surveys in 36 North-American hospitals about the experiences of 3 thousand patients submitted to different surgical procedures have shown that, in average, 60% of them referred pain, 33% had pain throughout the hospitalization period or a major part of it and 87% had moderate to severe pain<sup>2</sup>. Other studies show that, in average, 40% to 60% of postoperative patients refer moderate to severe pain<sup>1,3</sup>.

Although so prevalent, pain is inadequately managed. One reason for its under treatment, in addition to subjectivity, individual variability to painful stimulations and wrong understanding of therapy, is the inadequate evaluation<sup>4</sup>. In addition to increasing costs and decreasing quality of life, inadequately treated pain may result in inpatients increased morbidity and mortality<sup>1</sup>. Postoperative pain control is critical for patients' integral assistance and its adequate management depends on a correct evaluation<sup>5</sup>.

Due to the relevance of this clinical symptom, both the Agency for Healthcare Research and Quality and the American Society of Pain and the Joint Commission on Accreditation on Healthcare Organizations (JCAHO) recommend that, to optimally control pain, it should be regularly and adequately measured and in the same clinical environment of vital signs, being defined as the "fifth vital sign" Considering pain as the fifth vital sign is a way to systematize pain perceived by patiens<sup>5</sup>. Pain documentation may, alone, improve communications among professionals assisting patients<sup>7</sup>.

Among the scales used to estimate pain, the numeric verbal scale (using grades from zero to 10, where zero is

absence of pain and 10 represents the worst imaginable pain) is the most popular method to measure pain as the fifth vital sign, because it is a simple, easy, practical and fast method<sup>7</sup>.

In the opinion of postoperative patients, priority should be given to pain intensity measurement and evaluation of analgesia. So, postoperative pain management should be considered a priority for hospitals, since it is one of the major components of patients' satisfaction with the treatment, and also because its relief is a human right<sup>8</sup>. In addition, the American Pain Society proposes that patients' satisfaction with analgesia received during hospitalization should be an indicator of the quality of the institution.

There is increasing concern of health institutions with patients' satisfaction. Although not being the single factor, pain control is a fundamental aspect to evaluate satisfaction with the treatment received. This study aimed at evaluating patients' satisfaction, during the postoperative period in a medium-sized hospital, with pain control after the implementation of pain as the fifth vital sign, due to the importance of the theme and the scarcity of compared and prospective studies on the subject.

#### **METHOD**

After the approval of the Ethics Committee on Research in Human Beings and Animals, Lutheran University of Brazil (protocol CEP/ULBRA 2009-250H), and the approval of the legal responsible and of the Ethics Committee, *Santa Casa de Misericórdia*, São Lourenço do Sul, this randomized study based on Consort criteria (Consolidated Standards of Reporting Trials) was carried out. Target-population were patients above 18 years of age, submitted to surgical procedures who were admitted to the *Hospital Santa Casa de Misericórdia*, São Lourenço do Sul (RS). This is a medium-sized hospital which predominantly assists patients from the Unified Health System (SUS).

After the signature of the Free and Informed Consent Term (FICT) participated in this study 266 patients divided in two groups: group with intervention, with 131 patients where pain was evaluated according to the concept of pain as the fifth vital sign; and group without intervention, with 135 patients, to whom the concept of pain as the fifth vital sign was not applied.

Patients submitted to surgeries, who remained hospitalized for at least 24 hours, above 18 years of age and alert were included. Patients with postoperative sensory changes and without cognitive ability to answer to the

pain numeric verbal scale were excluded. Randomization between groups was made using a list with randomized numbers. Different researchers received data and distributed patients between groups, thus assuring randomization blindness.

Sample size was calculated using the PS (Power Statistics) version 2009 software, indicating a total of 226 patients (113 for each group). The team in charge of assisting patients was trained with presentations about the definition of the fifth vital sign and its importance. The same professionals participated in the two studied groups.

In the group with intervention, pain scales were made available to the assisting team and were verbally informed when applied. In the group without intervention, pain scales were not available to the assisting team, being only available to the researcher in charge of data collection. This way, intervention group patients received more adjusted analgesic intervention and more adapted to the pain referred by the numeric verbal scale.

Pain was evaluated twice a day and the level of satisfaction was evaluated once a day, until hospital discharge or a maximum period of five days. For patients remaining in the hospital for a shorter period, evaluations until patients' discharge were considered. Two intermediate formal efficacy analyses were performed when 50%

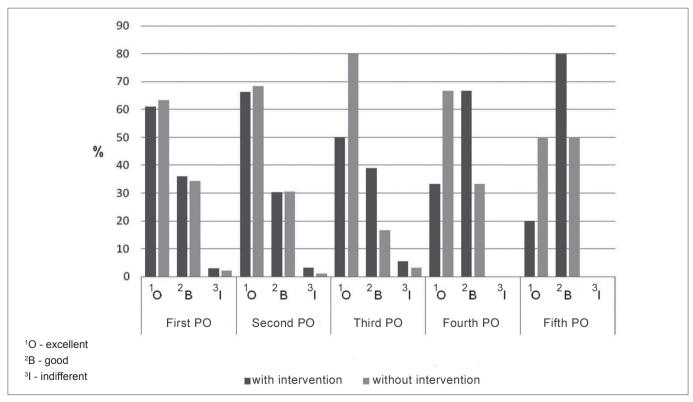
and 75% of data collections had been made, comparing groups and without difference in the p value reported for these intermediate tests.

The analysis of the existence of association between categorical variables and the outcome variable was performed with Pearson's Chi-square test. For quantitative analysis, central trend and dispersion measures were calculated and compared to groups means with Student's t test, considering significant p < 0.05.

## **RESULTS**

There has been predominance of females (83.5%). Mean age was  $36,74 \pm 16,2$  years. Predominant surgical procedure was C-section (57.1%), followed by hernioplasty (7.9%). Most surgeries were performed in the morning (61.7%). The group without intervention had more surgeries performed in the evening (p = 0.012). The other variables were no significantly different.

Patients had few associated co-morbidities; only 2 (0.8%) patients had diabetes *mellitus*, 1 (0.4%) had neoplasia and no patient had psychiatric disorder or rheumathological disease. Patients referred pain in 75.6% of measurements and, with regard to pain intensity, they considered it from moderate to severe in 23% of measurements.



Graph 1 – Percentage of level of satisfaction with pain control stratified by postoperative day.

As to the level of satisfaction, most patients (64%) considered pain control excellent. Among those classifying it as excellent, 54.5% were from the group without intervention (Graph 1). When stratified between groups with and without intervention, the level of satisfaction was not statistically different. In comparing groups, there were no statistically significant differences in the level of total satisfaction even when the level was stratified by postoperative day (Graph 2).

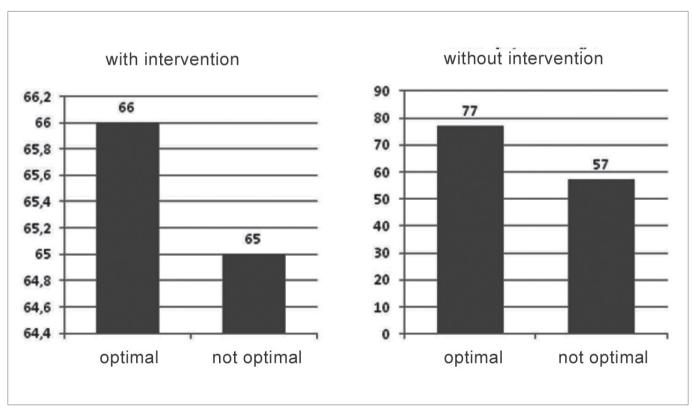
As to pain relief drugs prescription, most were fixed doses for both groups. With regard to pharmacological group, most prescriptions were non-steroid anti-inflammatory drugs (NSAIDs) or opioids, such as dipirone, paracetamol and the combination of dipirone, adifenin and promethazine. There has been a higher use of muscular drugs in the intervention group, while in the group without intervention, the majority was venous. However, when comparing groups, there has been no statistically significant difference in any variable.

## DISCUSSION

The profile of the studied sample has to be considered because it may have been influenced by the high number of C-sections. Literature shows that females have lower pain threshold and different responses to painful stimulation as compared to males<sup>9</sup>. Our study has shown that females and younger patients referred more problems when asked<sup>2</sup>, fact which may have interfered with results. Other relevant aspect was the low prevalence of co-morbidities, which could have interfered with the level of pain perception.

There has been no difference between groups in route of administration and pharmacological class of analgesics, or with regard to dose, whether necessary or fixed, although that, for better pain control, the use of fixed drugs is more indicated to prevent painful peaks, with additional analgesic doses (if needed) for rescue and not its isolated use<sup>1</sup>.

This study has shown that most patients considered pain management excellent, although in most measurements there have been reports of pain and in 23% of measurements pain was considered from moderate to severe. There has been no difference in patients' satisfaction regardless of the use of the pain scale as fifth vital sign. There may be many reasons for the inability to detect differences between groups, different from just controlling pain. Studies show that there is a paradox between



Graph 2 – Patients' satisfaction with pain control.

Without statistically significant difference (by Pearson's  $x_2$  test)

pain and satisfaction with analgesia. Although 50% to 76% of patients referred moderate to severe pain, 75% to 81% of them were happy with pain management<sup>5</sup>. This shows the complexity of such symptom. People may be happy with a higher level of pain for several reasons, such as culture and religion<sup>5</sup>. A study reports that local culture tolerates a high pain level and that very often complaints are considered weakenesses<sup>4</sup>. There are studies showing that patients with pain may have a passive personality, believing that "this is the way", that the team "will do their best" and so they do not inform their pain, even when there is no restriction for verbalization. On the other hand, the health professional, for not prioritizing pain relief, being afraid of adverse analgesic effects and even for believing that patients should tolerate pain, may encourage patients to tolerate it. It is also possible that patients do not manifest dissatisfaction with pain control because they feel vulnerable for being hospitalized. Other studies consider the pain-satisfaction paradox, among them the way patient is taken care of by the team, and the physician-patient relationship. Patients report that the relationship with the nursing team is one of the most important aspects of care<sup>5</sup>. Most studies suggest that it seems to be no correlation between satisfaction and pain control<sup>5,10</sup>. However, a different study showing correlation observes that satisfaction is an insensitive method for adequate pain management<sup>11</sup>.

One should also consider that for most patients, satisfaction encompasses other factors different from just pain relief, such as: be able to relax and move, read, watch TV, receive the visit of relatives and sleep well. To help adequate pain evaluation it is important to consider pain experiences and the objective of individual relief<sup>12</sup>. Researchers propose a theory of balance and coherence of different factors where satisfaction is the result of their congruence<sup>5</sup>. Although this study is a randomized clinical trial, we have not evaluated predictors such as those described, which may have influenced the equity of groups.

A study evaluating factors affecting patients' satisfaction with postoperative pain management in major orthopedic and vascular surgeries showed that 80% of patients were happy with pain management and satisfaction correlated to pre-surgical information and preoperative treatment<sup>10</sup>. A different study has shown that interventions changing the cognitive aspect of patients about pain, such as knowledge, previous experiences and other aspects, are able to influence pain perception and has shown evidences

that they improve postoperative pain control<sup>13</sup>. These variables were not evaluated in our study and may have influenced results.

A study has shown that asking questions about satisfaction brings very positive results and hides institutions' problems, suggesting that results about satisfaction cannot be singly analyzed<sup>2</sup>.

A study evaluating pain management before and after putting into practice pain as the fifth vital sign in a sample including several postoperative patients of different procedures with wide pain spectrum and other co-morbidities has concluded that the evaluation of pain as the fifth vital sign is less accurate than the ideal since there has been no difference in clinical assistance<sup>7</sup>. The explanation for this failure is the need to better understand the accuracy of the numeric verbal scale since nurses tracking pain as the fifth vital sign may underestimate it because when they use it, most of the times they do not follow the formal question pattern<sup>7</sup>. Another study also evaluating pain management before and after the implementation of the fifth vital sign has shown that management was not changed when treating pain and changing analgesia, suggesting that pain measurement as the fifth vital sign does not routinely change pain management. Results have shown the inability to obtain improvements in pain control after the implementation of the fifth vital sign, concluding that the implementation of the fifth vital sign, that is, the documentation of pain intensity, is necessary to follow-up care, but is not enough to improve pain management<sup>14</sup>.

Other factors related to methodology may have interfered with the undetection of differences between groups, for example: the possibility of contamination between groups in open randomized clinical trials, which in this study may have happened because patients not submitted to intervention were in the same environment of intervention patients. Other aspect to be considered is that patients and teams learning could bring information biases, an inherent limitation to open studies.

One should take into consideration the difference between efficacy and efficiency, that is, in well-controlled situations the application of the fifth vital sign has good results, but when put into more realistic practices, such as in this study, it may loose part of this efficacy. The evaluation of health services cannot be made based on patients' satisfaction only, because although patients with moderate to severe pain refer they were happy with pain management, there is the fact that satisfaction includes other factors, different from just pain control.

## CONCLUSION

There has been no difference in patients' satisfaction when the concept of pain as the fifth vital sign was put into practice. This study is consistent with the hypothesis that several components contribute to patients' satisfaction. This study has only evaluated the physiological aspect of pain and its influence on patients' satisfaction with regard to its control.

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