

Perception of patients and surgeons regarding self-demarcation of surgical sites for elective surgery: a pilot study

Percepção de pacientes e cirurgiões quanto à autodemarcação do sítio cirúrgico para cirurgia eletiva: um estudo piloto

Percepción de pacientes y cirujanos sobre la autodemarcación del sitio quirúrgico para cirugía electiva: un estudio piloto

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ABSTRACT: Objective: To measure the accuracy rate in the self-demarcation of laterality performed by elective surgery patients in the immediate preoperative period and to analyze the perception of patients and surgeons regarding this practice. **Method:** Cross-sectional study developed from June to December 2018, in a private hospital in southern Brazil. The sample consisted of 105 patients undergoing elective surgical procedures for ambiguous organs, who answered a questionnaire about the demarcation of the surgical site. Data were evaluated using descriptive analysis. **Results:** 105 questionnaires were analyzed, of which three were excluded because they were incomplete, thus, the sample consisted of 102 documents. All patients performed the self-demarcation in the correct site. Among participants, 93% of patients and 99% of surgeons reported feeling confident about self-demarcation. **Conclusion:** Self-demarcation may complement care practice, consisting of another safety barrier and promoting the patient's participation as a care agent, but it does not replace confirmation by the surgeon in the preoperative period.

Keywords: Elective surgical procedures. Patient safety. Self care. Surgicenters.

RESUMO: Objetivo: Mensurar a taxa de precisão na autodemarcação da lateralidade realizada pelo paciente cirúrgico eletivo no período pré-operatório imediato e analisar a percepção do paciente e do médico-cirurgião diante dessa prática. **Método:** Estudo transversal desenvolvido de junho a dezembro de 2018, em um hospital privado do Sul do Brasil. A amostra foi composta por 105 pacientes submetidos a procedimentos cirúrgicos eletivos de órgãos ambíguos, que responderam a um questionário sobre a demarcação do sítio cirúrgico. Os dados foram avaliados por meio de análise descritiva. **Resultados:** Foram analisados 105 questionários, dos quais três foram excluídos por estar incompletos, dessa forma, a amostra foi composta por 102 documentos. Todos os pacientes realizaram a autodemarcação no local correto. Dentre os participantes, 93% dos pacientes e 99% dos cirurgiões relataram sentirem-se seguros quanto à autodemarcação. **Conclusão:** A autodemarcação pode constituir uma complementação na prática assistencial, consistindo em mais uma barreira de segurança e promovendo a participação do paciente como agente de cuidado, porém não substitui a confirmação pelo cirurgião no período pré-operatório.

Palavras-chave: Procedimentos cirúrgicos eletivos. Segurança do paciente. Autocuidado. Centros cirúrgicos.

RESUMEN: Objetivos: Medir el índice de acierto en la autodemarcación de lateralidad realizada por el paciente quirúrgico electivo en el preoperatorio inmediato y analizar la percepción del paciente y del cirujano respecto a esta práctica. **Método:** Estudio transversal, desarrollado de junio a diciembre de 2018, en un hospital privado del sur de Brasil. La muestra estuvo conformada por 105 pacientes sometidos a procedimientos quirúrgicos electivos por

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órganos ambiguos, quienes respondieron un cuestionario sobre la demarcación del sitio quirúrgico. Los datos se evaluaron mediante análisis descriptivo. **Resultados:** se analizaron 105 cuestionarios, de los cuales se excluyeron tres por estar incompletos, por lo que la muestra estuvo conformada por 102 documentos. Todos los pacientes realizaron la autodemarcación en el lugar correcto. Entre los participantes, el 93% de los pacientes y el 99% de los cirujanos informaron sentirse seguros con la práctica de la autodemarcación. **Conclusión:** La autodemarcación puede ser un complemento a la práctica asistencial, siendo una barrera más de seguridad y promoviendo la participación del paciente como agente asistencial, pero no reemplaza la confirmación por parte del cirujano en el preoperatorio.

Palabras clave: Procedimientos quirúrgicos electivos. Seguridad del paciente. Autocuidado. Centros quirúrgicos.

INTRODUCTION

Patient safety is a relevant topic and has been discussed since the 1970s. However, it was only in the following decade, in 1984, with the publication of “The Harvard medical practice study”, that the dimension of the weaknesses of health services became evident, and with the publication of the report “To err is human”, in 1999, by the Institute of Medicine (IOM), in the United States, strategies and actions aimed at patient safety began in fact to be widely discussed and implemented¹⁻⁴.

In 2004, the World Health Organization (WHO) launched the “World Alliance for Patient Safety”, with the aim of coordinating, disseminating, and promoting better safety in health care, including the patient in care, with the launch of global campaigns aimed at offering safer health care, among which, “Safe Surgery Saves Lives”, defined strategies aimed at reducing harm caused by surgical procedures, including those associated with surgery on the wrong patient or site⁵.

Wrong-site surgical procedure is a potentially devastating complication⁶. In the United States, with the demarcation of laterality (right and left), it is estimated that procedures in wrong patients occur in one in 100,000 surgeries, that is, from 1,500 to 2,500 incidents per year⁷.

In order to minimize the damage caused by these adverse events, numerous strategies continued to be implemented, such as the demarcation of the surgical site, published in 2009 in the guideline for the implementation of the universal protocol for surgical patient safety. This practice aims to unambiguously identify the location of the surgical procedure⁶.

In procedures that involve distinguishing between bilateral structures, multiple structures (such as fingers and toes, or spinal procedures), the site should be demarcated so that it is visible after the patient is prepared for surgery⁷.

In Brazil, with the publication of GM/MS ordinances No. 1.377, of July 9th, 2013, and No. 2.095, of September 24th, 2013, which approved the basic patient safety protocols through

the dissemination of the six goals of international safety standards and determine its implementation throughout the national territory, the movement to implement the safe surgery program gains more weight. In parallel with its wide use, the practice of demarcating the surgical site is one of the important strategies for safe surgery^{8,9}.

With the growth of this movement, the discussion about the importance of the patients’ role in the care process, also known as participatory care, at different moments of their journey, including the pre and postoperative phases, has expanded⁸⁻¹⁰.

Thus, nursing, as a defender of the patients’ interests, must act in order to favor the best practice, which guarantees safety and satisfaction with the experience of the surgical anesthetic experience. In addition, considering the importance of patient participation as an active subject of their care, the following research questions were defined: how accurate is the patient’s laterality demarcation in the immediate preoperative period? What is the perception of patients and surgeons regarding self-demarcation as a safety strategy for the surgical procedure?

OBJECTIVE

The study aimed to measure the accuracy rate in patients’ self-demarcation of laterality in the immediate preoperative period of elective surgeries and to analyze this perception by both the patient and the surgeon.

METHOD

This is a cross-sectional study of patients undergoing surgical procedures of different specialties in a private hospital in the southern region of Brazil, which has two surgical centers intended for the care of procedures of low to high

complexity, encompassing specialties of general surgery, gynecology, chest, mastology, ophthalmology, orthopedics, otolaryngology, and urology.

Data were collected from June to December 2018, with a convenience sample of 105 patients undergoing elective surgical procedures for ambiguous organs that required the demarcation of the surgical site.

Inclusion criteria for the study were: being an assistant surgeon on the clinical staff of the institution; patient aged 18 years old or older, unaccompanied at the time of demarcation, with indication for bilateral organ surgery, such as ophthalmologic, otorhinolaryngologic, thoracic, mastologic, upper urologic and reproductive tract, orthopedic, oncologic, plastic, dermatologic, general, vascular, and neurologic. Patients who received benzodiazepines and/or opioids before demarcation and those with visual or self-care deficits were excluded.

The authors developed a questionnaire to record patients' self-demarcation, which was signed by all those involved at each stage of data collection. The instrument contained sociodemographic data extracted from the patients' electronic medical record and others, which were collected in the preoperative phase, through an interview conducted by duly trained collectors. The research took place in two stages:

Step 1: Data collection in the preoperative environment:

- a. nurses evaluated patients to exclude self-care deficit;
- b. nurse researchers explained the research, read the informed consent, and requested it to be signed;
- c. the technician read the original medical order, checking it with patients and their companions;
- d. after confirmation, patients, with a skin marker pen, marked oneself in the presence of their companion with the word YES; and
- e. patients completed the security perception survey on self-demarcation.

Step 2: Data collection in the operating room, before the incision:

- a. the doctor marked the patient with a skin marker pen (double demarcation) and confirmed the self-marking, according to the proposed surgery and the methodology of each team;

- b. together with the team, while the safe surgery checklist items were applied, prior to anesthetic induction, the physician-surgeon confirmed that the demarcated site complies with the site to be operated;
- c. after this step, the physician completed the survey on the perception of safety on self-demarcation; and
- d. the nurse researcher confirmed that the surgery was performed in the correct place, as well as the surgeon.

Before data collection, the collection instrument was pre-tested with five patients and five surgeons, who were not included in the research. There was no need to modify the instrument.

The data were organized in electronic spreadsheets in the Excel[®] program, according to the previously established variables. The sociodemographic variables were tabulated after searching the Tasy[®] system using the data contained in the patient's label, contained in the patient's record performed at the time of admission.

To assess the perception of patients and surgeons, a five-point Likert scale was applied with the options MII (very unsafe or unsafe) N (neutral) S (safe) MS (very safe), in which 4 was considered the goal (safe). A significance level of $p \leq 0.05$ was established for confidence interval of 95%. The following study variables were defined: sociodemographic: age (measured in complete years) and gender (male and female); surgical procedure (procedure name and specialty); outcome (number of total procedures and procedures performed with correct laterality, with wrong laterality; and percentage of responses on patient and surgeon safety).

The project was approved by the Research Ethics Committee, under Opinion No. 2.908.265, and developed in accordance with Resolution No. 466/2012 of the National Health Council/Ministry of Health. Patients and surgeons were invited to voluntarily participate in the study after clarifying the objectives and methodology of the study, risks and benefits, and freedom to withdraw at any time, registering their agreement to participate by signing the Informed Consent.

RESULTS

A total of 105 questionnaires were applied, of which three were excluded due to failure to fill in and lack of information determining the study variables. Therefore, the sample consisted of 102 participants, most of them male (55.8%), with a mean age of 48.90 years, undergoing orthopedic procedures (74.5%), as shown in Table 1.

All patients included in the study had the correct location marked and the procedure performed on the correct side (Table 2).

Regarding the perception of safety reported by patients and surgeons, most of them considered themselves safe or very safe with the practice of self-demarcation (Table 3).

Table 1. Clinical-surgical profile of study participants (n=102). Florianópolis (SC), Brazil, 2018.

| Characteristic | n (%) | Mean | Standard deviation | Variation (min.-max.) |
|------------------------|------------|-------|--------------------|-----------------------|
| Gender | | | | |
| Male | 57 (55.90) | | | |
| Female | 45 (44.10) | | | |
| Age (years) | | 48.90 | 16.62 | 18-79 |
| Surgical procedure | | | | |
| Orthopedic | 76 (74.50) | | | |
| General | 9 (8.80) | | | |
| Mastological | 8 (7.80) | | | |
| Thoracic | 3 (2.90) | | | |
| Ophthalmic | 2 (2.00) | | | |
| otorhinolaryngological | 2 (2.00) | | | |
| Urological | 1 (1.00) | | | |
| Gynecological | 1 (1.00) | | | |

min.: minimum; max.: maximum

Table 2. Number of procedures performed in the correct place and side (n=102). Florianópolis (SC), Brazil, 2018.

| Step | n (%) |
|--|-----------|
| Key safety criteria for self-demarcation | |
| Confirmation of the two safety markers | 102 (100) |
| Confirmation with the patient of the procedure to be performed | 102 (100) |
| Total patients without self-care deficit | 102 (100) |
| Total patients who performed self-demarcation | 102 (100) |
| Total patients with confirmation of laterality with the companion | 102 (100) |
| Post-demarcation outcome | |
| Total patients double-checked by the surgeon | 102 (100) |
| Total patients in which laterality was correctly demarcated | 102 (100) |
| Total number of patients in whom the procedure was performed on the correct side | 102 (100) |

Table 3. Percentage of safety perceived by the patient and the surgeon (n=102). Florianópolis (SC), Brazil, 2018.

| Step | *MII | N [†] | S [‡] | MS [§] |
|---|---------|----------------|----------------|-----------------|
| | n (%) | n (%) | n (%) | n (%) |
| How patients felt making the demarcation themselves | 2 (2.0) | 7 (6.9) | 58 (56.8) | 35 (34.3) |
| How surgeons felt after the demarcation performed by patients | 3 (2.9) | - | 33 (32.4) | 66 (64.7) |

*MII: very unsafe and unsafe; †N: neutral; ‡S: safe; §MS: very safe.

DISCUSSION

The study demonstrated safety in relation to the self-demarcation of the surgical site by patients undergoing elective surgeries that involve laterality, in the same way, patients and surgeons considered the procedure as safe. Therefore, self-demarcation can be an additional safety tool in preventing wrong-site surgical procedures.

It is important to highlight that this practice did not replace the surgeon's preoperative confirmation, as recommended in the surgical checklist⁶, as well as the pause before the surgical incision for final confirmation of the procedure and laterality, however it adds another safety barrier in the immediate preoperative period to avoid surgery at an incorrect surgical site, in addition to encouraging patient participation in their care process.

A study with 200 patients undergoing orthopedic surgeries indicated that 67.2% of them adhered to self-demarcation, with the correct execution of the signaling of the surgical site to be operated¹¹. In addition, this initiative is one of the goals of the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) to improve patient safety, involving them as an active agent of their care¹².

Considering that in many realities the demarcation of laterality still represents a challenge for surgical patients and professionals involved in the process, given the absence or fragility of protocols related to surgical safety and limited adherence of surgeons¹³, new strategies must be developed, generating scientific evidence that encourage team members to understand the demarcation of laterality as a multidisciplinary practice since their academic training.

The relevance of demarcating the surgical site in orthopedic procedures was evidenced in a study with 502 orthopedists, which identified that 40% of the professionals did not demarcate the surgical site and confirmed that they had already performed surgery in the wrong place, in addition to most of them never having been trained on safe surgery protocol¹⁴.

Another study evaluated the knowledge of the nursing team about adverse events and found that only 55% of professionals classified the absence of laterality demarcation as an adverse event¹⁵. Thus, there is a need for continuing education of professionals about safety protocols related to surgical patients, in order to strengthen the development and implementation of these processes in health services.

A previous investigation evaluated adherence to the ten objectives proposed by the world safe surgery program from the perspective of operating room nurses, of which 89% reported applying practices that ensure adherence to the objective of operating on the right patient in the right place, however,

since operating the wrong site is considered a catastrophic event (never events), the adherence of only 89% of nurses is less than ideal to guarantee a safe practice¹⁶.

The difficulty of adherence may be related to the lack of specific training of the medical and nursing staff in the application of patient safety protocols. In a study with 86 physicians, including 35 residents and 33 professors, it was found that 58% denied having participated in any training on safe surgery and only 51% reported having specific content on safe surgery protocol in the college curriculum¹⁷.

In the United Kingdom, a survey involving 120 surgeons showed that only 36% demarcate patients' surgical site, while 69% delegate this activity to a member of the team. The results also revealed that surgeons are resistant to this safety practice¹³.

Although the world regulations and the studies presented suggest that the demarcation can be delegated by the surgeon to any other member of the team, especially in the immediate preoperative period, it is clear that he is primarily responsible for the final verification of the place to be operated, that is, before the incision, therefore it is an indelegable and insurmountable responsibility.

In Switzerland, when the demarcation by trained nurses was analyzed in 150 patients, the observed success rate was 90%, 10% of the cases demarcated by surgeons. Also, according to the analysts, during the three years of the study, there was no surgery on the wrong side¹⁸.

In Brazil, in turn, the practice is still a matter of discussion. According to COREN-SP CT No. 052/2013¹⁹, surgeons are responsible for the demarcation process, with the active participation of the nursing team in all stages of the safe surgery protocol, under the leadership of professional nurses. Their performance and patients themselves during the demarcation process is also described in the recommendation of the WHO safe surgery guideline^{6,19}.

Safety commissions in the United Kingdom and Australia highlight the importance not only of nurses, but also encourage the fundamental and active role of patients in this safety process²⁰.

In the present study, 100% of patients eligible for self-demarcation correctly confirmed the site to be operated on and 93% considered themselves safe or very safe with the practice. These aspects seem to indicate the importance and predisposition of patients for their active inclusion in the care process.

In this sense, the study evaluated 78 patients undergoing procedures eligible for laterality demarcation and identified that 93.58% of them could clearly and correctly say the place where they would be operated on, but 71.9% of these patients were not demarcated in the preoperative phase. In addition, in

70.51%, the demarcation was performed only before the surgical incision by the physician responsible for the procedure¹⁷.

A study carried out in Pennsylvania showed that patient involvement in the care process in the surgical process increased their satisfaction and safety and improved the results related to the surgical process. Three key factors are also highlighted in the context of education/guidance of the surgical patient: consistency of information, involvement of the patients' family members and/or support groups, and clear explanations regarding the postoperative period²¹.

Thus, the active participation of patients in the safe surgery protocol, especially in the steps that precede the procedure, should be further explored and encouraged by health professionals²².

Although the surgeons included in the present study reported feeling safe or very safe regarding the self-demarcation of laterality by the patient and the self-demarcation does not exclude the responsibility of the professionals involved in the conference, the adoption of this practice without due clarification to patients may sound to them and their family members as a lack of concern with their case by the surgical team. And even if this behavior is not related to safety failures that result in procedures in the wrong place, it does not contribute to transforming patient safety culture²³.

In this sense, nursing plays a fundamental role, including, educating and strengthening the participation of patients and their families in the surgical process, in addition to playing a leading role in the construction of safety protocols that include all the characters involved and based on the most relevant scientific evidence.

The limitations of this study are the low sample of participants, little time for data collection, and low diversification of medical specialties.

CONCLUSION

The study demonstrated that the practice of self-demarcation was accurate and considered safe by patients and surgeons, constituting an additional alternative as a safety measure during perioperative care.

The development of new studies, in different scenarios and surgical specialties, is recommended, in order to allow evaluating the impact of this intervention in the prevention of adverse events related to procedures in the wrong surgical site.

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CONFLICT OF INTERESTS

The authors declare there is no conflict of interests.

AUTHORS' CONTRIBUTION

LSG: Project administration, Writing — review & editing. **SBDPR:** Conceptualization, Data curation, Writing — original draft, Writing — review & editing. **VBP:** Formal analysis, Writing — review & editing, Supervision. **CSL:** Writing — review & editing, Validation, Visualization. **CB:** Investigation, Methodology, Resources, Writing — review & editing. **GDP:** Investigation, Methodology, Resources, Writing — review & editing.

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