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ORIGINAL ARTICLE

Postoperative analgesia using the ERAS® protocol in total mastectomy. A randomized clinical trial

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Abstract

Background: *Up to 60% of patients undergoing mastectomy for breast cancer experience severe postoperative pain. The Enhanced Recovery After Surgery (ERAS®) protocol has demonstrated efficacy in managing postoperative pain.* **Objective:** *To compare postoperative pain in patients undergoing mastectomy for breast cancer with and without the application of the ERAS® protocol.* **Method:** *Women over 18 years of age with breast cancer undergoing mastectomy were included.The ERAS® protocol was implemented during the preoperative, intraoperative, and postoperative phases. Pain intensity was assessed at 0, 30, 60, and 120 minutes postoperatively, as well as at discharge.* **Results:** *A total of 80 patients were enrolled: 43 (53.75%) in the ERAS® group and 37 (46.25%) in the control group. A significant reduction in pain scores was observed in the ERAS® group during immediate postoperative assessment, at 30, 60, 90 minutes, and at discharge ($p < 0.001$). No significant differences were found between groups regarding operative time or intraoperative bleeding.* **Conclusions:** *Implementation of the ERAS® protocol in patients undergoing mastectomy is associated with improved postoperative pain control.*

Keywords: *ERAS®. Breast cancer. VAS. Mastectomy. Postmastectomy chronic pain.*

Analgesia postoperatoria mediante el protocolo ERAS® en la mastectomía total. Un ensayo clínico aleatorizado.

Resumen

Antecedentes: *Hasta un 60% de las pacientes sometidas a mastectomía por cáncer de mama presenta dolor postoperatorio grave. El protocolo Enhaced Recovery after Surgery (ERAS®) ha demostrado su utilidad para el control del dolor postoperatorio.* **Objetivo:** *Comparar el dolor postoperatorio en pacientes sometidas a mastectomía por cáncer de mama cuando se aplica el protocolo ERAS®.* **Método:** *Mujeres mayores de 18 años con cáncer de mama, sometidas a mastectomía. Se aplicó el protocolo ERAS® en las fases preoperatorio, transoperatorio y postoperatorio, y se comparó la intensidad del dolor a los 0, 30, 60, y 120 minutos después del postoperatorio y al egreso.* **Resultados:** *Se incluyeron 80 pacientes, 43 pacientes (53.75%) del grupo ERAS® y 37 para el grupo control (46.25%). Se encontró disminución significativa para el grupo en el*

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que se aplicó el protocolo ERAS® en la evaluación del dolor en el postoperatorio inmediato, a los 30, 60 y 90 minutos y al egreso (p < 0.001). No se encontraron diferencias entre los grupos en el tiempo de cirugía y en sangrado transoperatorio. **Conclusiones:** *La aplicación del protocolo ERAS® en pacientes con mastectomía se asoció a mejor control del dolor postoperatorio.*

Palabras clave: *ERAS®. Cáncer de mama. EVA. Mastectomía. Síndrome posmastectomía.*

Introduction

Breast cancer is the most common neoplasm worldwide, with an age-standardized rate of 47.8 per 100,000 inhabitants[1]. Over the years, there has been an increase in the use of breast-conserving surgery as surgical treatment in early stages, thanks to the 2014 recommendations of the Society of Surgical Oncology (SSO) and the American Society for Radiation Oncology (ASTRO), which consider the absence of tumor cells at the inked margin as an adequate surgical margin, leading also to a reduction in reoperation rates[2]. However, mastectomy remains the surgery of choice in 30-40% of early-stage breast cancer cases, especially in women younger than 40 years[3,4]. An increase in the use of contralateral prophylactic mastectomy has also been demonstrated in recent years[5]. Unfortunately, up to 60% of patients undergoing mastectomy experience intense postoperative pain, which may persist in 22 and 8% of patients at 6 and 12 months, respectively[6]. This type of pain has been described as burning, stinging, and dull, occurring in the chest, axilla, and proximal upper limb, generally attributed to neuropathy secondary to intercostobrachial nerve damage during surgery, hence termed postmastectomy pain syndrome (PMPS)[7]. However, when considering other sources of pain beyond neuropathy, such as lymphedema, musculoskeletal pain, and even the use of adjuvant treatments such as radiotherapy, the more appropriate term is persistent postmastectomy pain syndrome (PPMPS), which is also associated with a significant deterioration in patient quality of life[8,9]. The reported frequency of PMPS ranges from 25 to 60%, and there are multiple risk factors for the development of PPMPS; however, one particularly relevant factor is the presence of acute postoperative pain, which has been shown to increase the risk of PPMPS by 1.16 times (95% CI, 1.03-1.30)[10,11].

Pain management is one of the cornerstones during the preoperative, intraoperative, and postoperative periods. Opioid-sparing pain treatment plans are initiated before surgery using a combination of oral drugs and regional anesthesia. Oral drugs include acetaminophen, gabapentin, and celecoxib. The use of multimodal opioid-sparing analgesia provides pain control without the side effects of narcotics, thereby accelerating the patient's return to functionality[12]. The Enhanced Recovery After Surgery (ERAS®) protocol has demonstrated its usefulness in many types of surgery for controlling postoperative pain, reducing opioid consumption, shortening the length of stay, and controlling nausea and vomiting[13]. In a recent meta-analysis, ERAS® protocols in major surgery were shown to reduce recovery time and length of stay by 2-3 days and complications by 30-50%[14]. This utility has been demonstrated in breast reconstruction surgery, and since 2017, recommendations have been issued by international expert panels based on meta-analyses regarding each component of this protocol in breast reconstruction[15]. However, few studies have evaluated the application of the ERAS® protocol in mastectomy for breast cancer. In 2020, Cortina et al. demonstrated that the ERAS® protocol in patients undergoing mastectomy for breast cancer leads to faster recovery, reduced opioid analgesic use, and greater patient satisfaction, with the possibility of same-day hospital discharge. However, to date, the use of the ERAS® protocol in immediate postoperative pain has not been objectively evaluated. The aim of this study was to determine postoperative pain outcomes in patients undergoing mastectomy for breast cancer when the ERAS® protocol was applied compared with those in whom it was not applied.

Methods

This report follows the CONSORT guidelines for reporting randomized clinical trials. A prospective, randomized, double-blind study was conducted in women older than 18 years undergoing mastectomy for breast cancer or aggressive tumors (phyllodes tumor), or risk-reducing surgery, at a high-specialty breast cancer center between January 2022 and January 2023. The primary endpoint was to evaluate postoperative analgesia outcomes in patients undergoing mastectomy when the ERAS® protocol was applied compared with those who did not receive it. Secondary objectives were

1) compare the need for opioid analgesics in the postoperative period; 2) compare postoperative hospital length of stay; 3) compare postoperative complication rates: hematoma, seroma, infection, dehiscence, and flap necrosis; and 4) compare hospital readmission.

Participants

All women were invited to participate in the study, and after signing informed consent, they were randomized 1:1 to ERAS® protocol vs. no protocol. Patients were excluded if they had known allergies to local anesthetics, pregabalin or gabapentin, and opioid or non-opioid analgesics. Patients with conditions affecting pain threshold, such as fibromyalgia, neuropathy, and psychiatric disorders, were also excluded. Patients with severe neurological diseases, renal insufficiency, chronic opioid use, liver failure, or chronic liver disease with significant functional impairment were excluded.

Intervention

The study protocol was conducted in two stages. The first consisted of a pilot study in five patients in whom the ERAS® protocol was applied and five patients in whom it was not. A primary evaluation was performed to identify adverse effects or complications attributable or suspected to be related to the procedure. After no adverse events related to the protocol were identified, stage 2 of the protocol was continued. After informed consent, adaptive randomization or automated minimization was performed. The first 20 patients meeting inclusion criteria were randomized simply; thereafter, the probability of assignment to each group was adjusted based on imbalance between groups, considering age and decision for immediate reconstruction to balance groups and avoid selection bias.

Implementation of the ERAS® protocol followed the recommendations issued by the ERAS Society in 2017[16]. These included: 1) preadmission information and counseling; 2) preadmission optimization, including at least one month of smoking cessation and alcohol abstinence; 3) no prolonged preoperative fasting, allowing clear liquids up to 2 hours before surgery; 4) preoperative carbohydrate loading with 600 ml of a carbohydrate-rich liquid; 5) venous thromboembolism prophylaxis with compression stockings intraoperatively and pneumatic devices and low-molecular-weight heparin in high-risk patients 12 hours after surgery; 6) antimicrobial prophylaxis with a third-generation cephalosporin administered 30 minutes before incision; 7) prophylaxis for nausea and vomiting; 8) pre- and intraoperative analgesia consisting of 1 g intravenous paracetamol at least one hour before surgery and 300 mg gabapentin; 9) multimodal anesthesia using total intravenous anesthesia; 10) prevention of intraoperative hypothermia by maintaining temperature > 36 °C; 11) perioperative intravenous fluid management using balanced crystalloids, avoiding over- or under-resuscitation; and 12) postoperative pain management with paracetamol, gabapentin, and nonsteroidal anti-inflammatory drugs, with opioids used only when necessary. Figure 1 illustrates ERAS® protocol recommendations at each phase.

Pain assessment was performed in a blinded manner using the visual analog scale, validated for Latin American countries, consisting of 10 points, where 0 represents no pain and 10 unbearable pain[17]. Assessment was performed at 30, 60, and 120 minutes after admission to the postoperative care unit and prior to hospital discharge.

Statistical analysis

A sample size calculation was performed for comparison of independent means, with a statistical power of 80% and a confidence level of 95%, assuming 15% losses, resulting in a minimum recruitment of 21 patients per group. However, after completing the sample, it was decided to continue including patients until reaching a total of 80 patients. For inferential statistics, the chi-square test was used to compare qualitative variables, as well as the Mann-Whitney U test and Student's t test for quantitative variables, according to their distribution. Comparison between groups for pain at each assessment time point was performed using the Mann-Whitney U test. For the variable "opioid use," relative risk (RR) with 95% CI was calculated. Statistical significance was considered when the level of significance (p) was < 0.05.

Results

From August 2021 through November 2022, a total of 86 patients were recruited who agreed to participate in the study. Of these, three from the experimental group were excluded after randomization due to failure to strictly comply with ERAS protocol guidelines. After the intervention, three additional patients were excluded (one from the experimental group and two from the control group) due to incomplete postoperative analgesia evaluation. Therefore, the total number of patients included in the

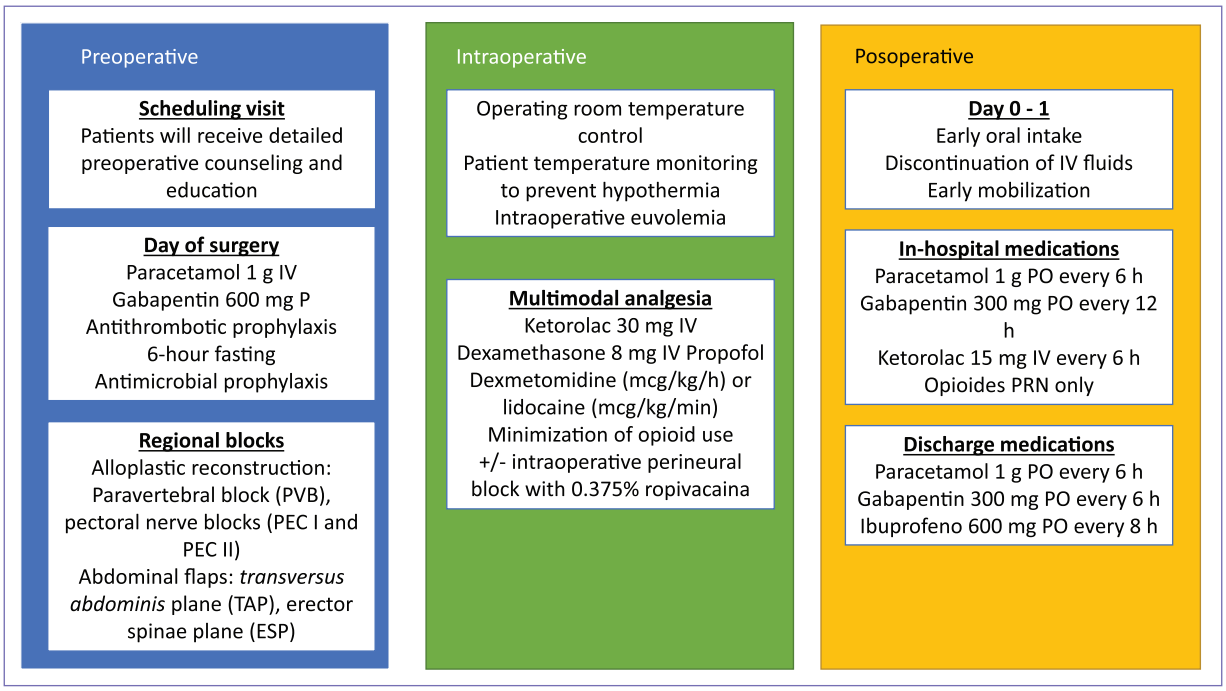


Figure 1. ERAS® (Enhanced Recovery After Surgery) protocol applied to the experimental group in the preoperative, intraoperative, and postoperative phases.

study was 80, with 43 in the experimental group and 37 in the control group (Fig. 2). The mean age of the population was 53.9 ± 10.9 years, and the mean body mass index was 27.7 kg/m². No statistically significant differences were found in age (p = 0.08) or body mass index (p = 0.22). Regarding medical history, 32.5% (n = 26) of the population reported at least one comorbidity. No statistically significant differences in comorbidities were found between groups (p = 0.35), with hypertension and diabetes being the most frequent. Regarding treatment, 20% (n = 16) received neoadjuvant therapy, 17.5% (n = 14) reconstruction, 57.5% (n = 46) sentinel lymph node biopsy, and 37.5% (n = 30) axillary dissection. The mean surgical time was 120 minutes, and mean blood loss was 150 ml, with no differences between groups. No significant differences were found in the use of neoadjuvant therapy (p = 0.012), reconstruction surgery (p = 0.28) (Fig. 3), axillary staging surgery (p = 0.29) (Fig. 4), surgical time (p = 0.49) (Fig. 5), or intraoperative bleeding (p = 0.64). Only one patient in the control group (2.70%) required reintervention due to postoperative bleeding greater than 200 mL. Regarding histological subtype, 81.3% (n = 65) were invasive ductal carcinoma, 7.5% (n = 6) ductal carcinoma *in situ*, 3.8% (n = 3) invasive lobular carcinoma, and 2.5% (n = 2) atypia. No differences in histological subtype were found between groups

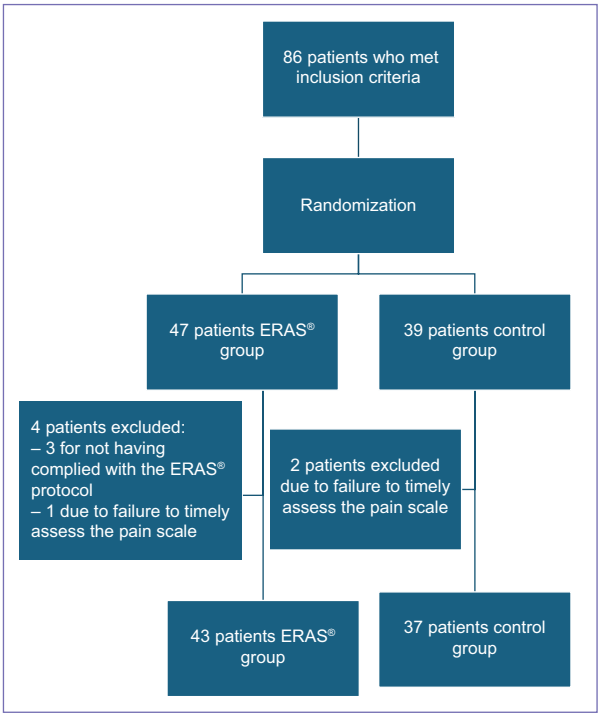


Figure 2. Flow diagram of patients included for final analysis.

(p = 0.31) (Table 1). No differences were found in hospital length of stay or hospital readmission.

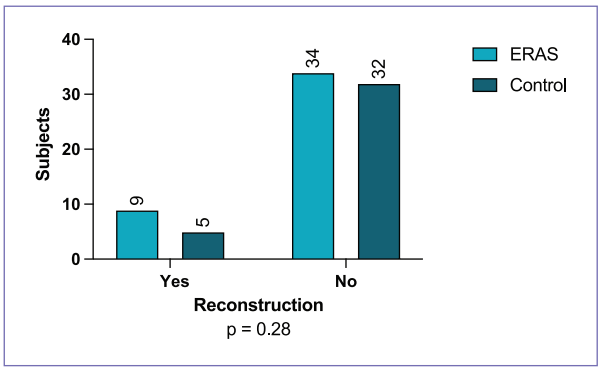


Figure 3. Comparison of reconstruction frequency between the ERAS® (Enhanced Recovery After Surgery) group and the control group.

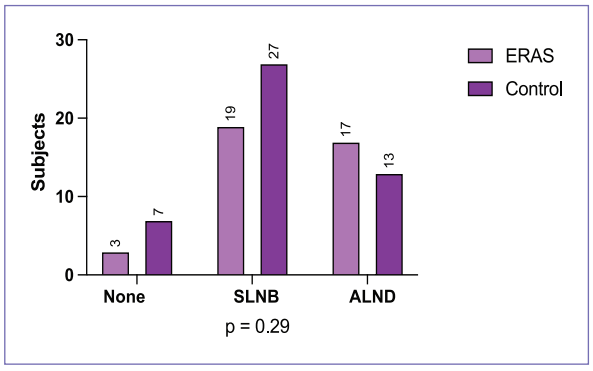


Figure 4. Comparison of axillary staging type between the ERAS® (Enhanced Recovery After Surgery) group and the control group. SLNB: sentinel lymph node biopsy; ALND: axillary lymph node dissection.

Postoperative pain was assessed using the numerical visual scale immediately after surgery, at 30 minutes, 1 hour, 2 hours, and at discharge. In the comparison of postoperative pain between groups, measured using the numerical scale, a significant difference was found in favor of the ERAS® group in the immediate phase, with a median of 0 (range, 0-5) compared with the control group with a median of 5 (range, 0-10) ($p < 0.001$). At 30 minutes, the ERAS® group had a median of 1 (range, 0-7) and the control group a median of 5 (range, 0-10) ($p < 0.001$). At 1 hour, the ERAS® group had a median of 2 (range, 0-8) and the control group a median of 4 (range, 0-10) ($p = 0.002$). At 2 hours, the ERAS® group had a median of 2 (range, 0-7) and the control group a median of 4 (range, 0-9) ($p = 0.001$). At discharge, the ERAS® group had a median of 2 (range, 0-5) and the control group a median of 4 (range, 0-7) ($p < 0.001$) (Fig. 6 and Table 2). A trend toward lower opioid use for postoperative pain was also observed in the ERAS® group (n = 2) vs. the control group (n = 4), although this difference did not reach statistical significance (RR, 0.43; 95% CI, 0.08-2.21; $p = 0.40$).

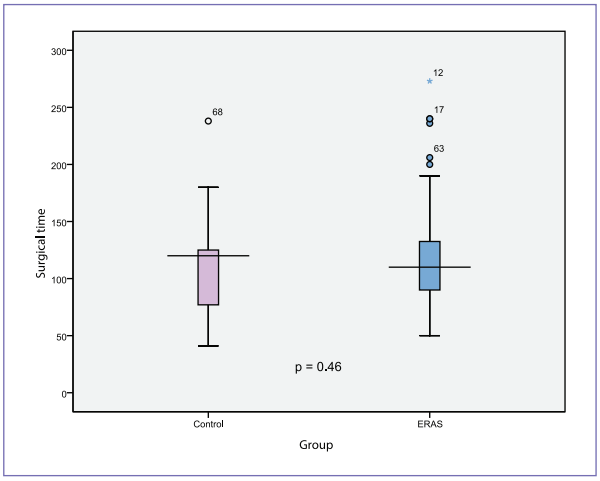


Figure 5. Comparison of surgical time between the ERAS® (Enhanced Recovery After Surgery) group and the control group.

Discussion

Mastectomy is the main surgical treatment for breast pathology related to breast cancer. Most studies on complications of this procedure are closely linked to breast cancer, with particular clinical relevance given to chronic postmastectomy pain.

The introduction of Enhanced Recovery After Surgery (ERAS®) protocols has revolutionized preoperative and postoperative care. Arsalani-Zahed et al. conducted a review of ERAS® implementation in patients undergoing breast surgery and described the 12 main interventions that we used. Their study suggests that enhanced recovery principles can be adopted in breast surgery.[18] In the study by Jogerst et al., it was demonstrated that with ERAS protocol implementation, patients could be discharged on the same day of surgery without increased morbidity[19]. Additionally, multiple studies and a meta-analysis have shown that ERAS® significantly reduces opioid analgesic use, leading to faster recovery without increasing morbidity in patients undergoing mastectomy with reconstruction.[20-24] Similar to these studies, we did not find a significant

Table 1. General data

Variable	Total (n = 80)	ERAS® (n = 43)	Control (n = 37)	p*
Age, years $\tilde{x}$ (SD)	53.9 (10.9)	55.9 (11.1)	51.6 (10.4)	0.08‡
BMI, kg/m² $\tilde{x}$ (SD)	27.7 (4.7)	28.3 (4.9)	27.1 (4.5)	0.22‡
Comorbidities, yes n (%)	26 (32.5)	16 (37.2)	10 (27)	0.35
Axillary surgery, n (%)				
None	4 (5)	3 (7)	1 (2.7)	
SLNB	46 (57.5)	27 (62.8)	19 (51.4)	0.29
ALND	30 (37.5)	13 (30.2)	17 (45.9)	
Reconstruction, yes n (%)	14 (17.5)	9 (21)	5 (13.5)	0.28
Neoadjuvant treatment, yes n (%)	16 (20)	4 (9.3)	12 (32.4)	0.012
Complications, yes n (%)	1 (1.3)	0 (0)	1 (2.7)	0.46
Surgical time, min Md (range)	120 (41-273)	110 (50-273)	120 (41-238)	0.46†
Intraoperative bleeding, ml Md (range)	150 (50-700)	200 (50-700)	150 (50-600)	0.64†
Histological type, n (%)				
Phyllodes	3 (3.8)	1 (2.3)	2 (5.4)	0.31
DCIS	6 (7.5)	5 (11.6)	1 (2.7)	
LCIS	1 (1.3)	0 (0)	1 (2.7)	
IDC	65 (81.3)	33 (76.7)	32 (86.5)	
ILC	3 (3.8)	2 (4.7)	1 (2.7)	
Others	2 (2.5)	2 (4.7)	0 (0)	
Local anesthesia technique, n (%)				
Intraoperative block	18 (41.9)	18 (41.9)	-	
Preoperative block	25 (58.1)	25 (58.1)	-	

*Chi-square test used.
†Mann-Whitney U test used.
‡Student's t test used.
SLNB: sentinel lymph node biopsy; IDC: invasive ductal carcinoma; DCIS: ductal carcinoma in situ; ILC: invasive lobular carcinoma; LCIS: lobular carcinoma in situ; ALND: axillary lymph node dissection; ERAS®: Enhanced Recovery After Surgery; BMI: body mass index; Md: median.

difference in surgical time, suggesting that protocol implementation does not significantly increase operative duration. When comparing pain in patients undergoing mastectomy in whom the ERAS® protocol was applied, significant reductions in pain were observed, with a median of 2, very similar to previously reported results. This suggests that protocol implementation not only leads to faster recovery but is also more effective in reducing pain than traditional treatment[20,23,25]. Although most patients underwent intraoperative blockade, those who received blockade also showed reduced pain compared with thoracic blockade. In our study, no significant difference was found in the reduction of opioid use as rescue analgesia for postoperative pain, although there was a trend toward lower use, consistent with other studies[12,20]. This was likely due to sample size, as the study was not designed for this secondary outcome. Finally, this study included patients undergoing immediate reconstruction, with a higher proportion in the ERAS® group, although without statistical significance. While not designed for this purpose, the results support the benefit of protocol application in patients undergoing immediate reconstruction.

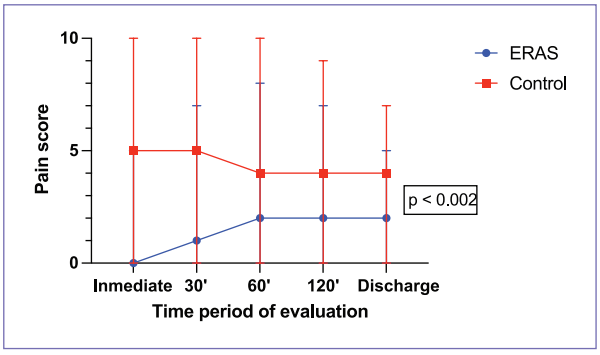


Figure 6. Comparison between groups for pain scores assessed using the visual analog scale at different time points.

Limitations and scope: Since most patients underwent surgery in the afternoon shift, early discharge safety (same-day discharge) could not be evaluated; however, this was not a study objective. Preoperative

Table 2. Comparison of postoperative pain by group, measured using the numerical scale*

Postoperative pain Md (range)	Total	ERAS®	Control	p*
Immediate	0 (0-10)	0 (0-5)	5 (0-10)	< 0.001
30 minutes	3 (0-10)	1 (0-7)	5 (0-10)	< 0.001
60 minutes	3 (0-10)	2 (0-8)	4 (0-10)	0.002
120 minutes	3 (0-9)	2 (0-7)	4 (0-9)	0.001
At discharge	3 (0-7)	2 (0-5)	4 (0-7)	< 0.001

*Mann-Whitney U test.
ERAS®: Enhanced Recovery After Surgery; Md: median.

education depended on each physician, as well as the time dedicated to it. A higher number of patients in the control group received neoadjuvant therapy, which was statistically significant; however, neoadjuvant chemotherapy has not been shown to be associated with increased postoperative pain. In Mexico, liposomal bupivacaine is not available; therefore, ropivacaine was used, which has a shorter half-life (6.8 hours). The perspective of this study is to follow these patients and compare the incidence of chronic postmastectomy pain in those who received the ERAS® protocol in the long term, as evidence suggests that reduction in acute postoperative pain decreases chronic postmastectomy pain at 3 and 6 months[26].

Conclusions

The application of the ERAS® protocol in patients undergoing mastectomy was associated with better postoperative pain control compared with patients who did not receive the protocol. Protocol implementation is safe, as it was not associated with an increased number of complications. Our results are consistent with previously published studies. To our knowledge, this is the first study in Mexico designed to evaluate the usefulness of the ERAS® strategy in breast surgery. Since ERAS® is designed for rapid recovery, it will be important to evaluate the safety of early discharge (same day of surgery) in Mexican women in whom it is applied.

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Conflicts of interest

The authors declare no conflicts of interest.

Ethical considerations

Protection of humans and animals. The authors declare that the procedures followed complied with the ethical standards of the responsible human experimentation committee, in accordance with the World Medical Association and the Declaration of Helsinki. The procedures were approved by the institutional Ethics Committee.

Confidentiality, informed consent, and ethical approval. The authors followed their institutional protocols for accessing clinical record data. Informed consent was obtained from patients, and Ethics Committee approval was granted. SAGER guidelines were followed.

Statement on the use of artificial intelligence. The authors declare that no generative artificial intelligence was used in the writing or creation of this manuscript.

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