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THORACIC SURGERY

Effects of Transcutaneous Electrical Nerve Stimulation on Pain, Pulmonary Function, and Respiratory Muscle Strength After Posterolateral Thoracotomy: A Randomized Controlled Trial

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Abstract

Purpose To evaluate the effects of transcutaneous electrical nerve stimulation (TENS) compared to placebo TENS and a control group on pain, pulmonary function, respiratory muscle strength, and analgesic medications in the postoperative period of thoracotomy in an Intensive care unit (ICU).

Methods Patients who had undergone posterolateral thoracotomy were randomly allocated to receive TENS during ICU stay, or placebo TENS, or into the control group. All groups received conventional physiotherapy. We analysed the intensity of pain, pulmonary function, respiratory muscle strength, and use of analgesia medications. Outcomes were evaluated before surgery, immediately after, 24 and 48 h after ICU admission.

Results Forty-five patients were included. Regarding pain perception, there was no difference between groups ($p=0.172$), but there was a significant reduction in pain intensity for patients receiving TENS after first physiotherapy session compared to baseline (4.7 ± 3.2 vs 3.3 ± 2.6; $p<0.05$). All groups had a decrease in forced vital capacity (FVC) after surgery ($p<0.001$). There was no difference between the groups regarding the use of analgesic medications, but a higher intake of morphine and acetaminophen were observed for the control ($p=0.037$) and placebo group ($p=0.035$), respectively.

Conclusion The use of TENS provides a little benefit of pain (in the first 12 h) but failed to demonstrate any improvement in the recovery of ICU patients after 48 h of posterolateral thoracotomy.

Trial Registration NCT02438241.

Keywords Pain management · Pulmonary function · Thoracotomy · Transcutaneous electric nerve stimulation

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Abbreviations

TENS	Transcutaneous electrical nerve stimulation
ICU	Intensive care unit
FVC	Forced vital capacity
RCT	Randomized control trials
MAP	Mean arterial pressure
RASS	Richmond agitation-sedation scale
IG	Intervention group
PG	Placebo group
CG	Control group
VAS	Visual analogue scale
PFT	Pulmonary function tests
FEV 1	Forced expiratory volume in 1 second
FVC	Forced vital capacity
IPmax	Maximum inspiratory pressures
EPmax	Maximum expiratory pressures
PC	Epidural catheter
PVC	Paravertebral catheter

Introduction

Thoracotomy is one of the surgical procedures most associated with postoperative pain, a complication related to an increase in morbidity and mortality after surgery [1]. Many factors contribute to post-thoracotomy pain, such as incision of the skin, muscle, and pleura, retraction of ligaments and muscles, irritation of pleura, and intercostal nerves due to chest tubes, and costal fractures [2]. A painful incision generates an increase in muscle tone during inspiration, which reduces volume and complacency of the lungs. These factors can contribute to retention of bronchopulmonary secretions, lung atelectasis, and respiratory infections, also reducing respiratory function and strength [3–5]. For these reasons, adequate management of postoperative pain is essential.

Epidural anaesthesia is considered the gold standard for pain control after thoracic surgeries, but this method is associated with several complications, ranging from hypotension to neurologic injuries [6, 7]. On the other hand, the paravertebral block is a technique that presents less adverse effects [8]. Besides pharmacological analgesia, transcutaneous electrical nerve stimulation (TENS) has been suggested as a possible therapy to manage postoperative pain, improving thorax mechanics, and reducing possible respiratory complications in thoracic surgeries [9, 10].

A meta-analysis by Sbruzzi et al. including 11 randomized control trials (RCT) observed that TENS promoted a reduction in postoperative pain after thoracotomy. However, new RCTs were suggested due to the small sample sizes and low-quality methodology of the studies included [10]. Therefore, our RCT aimed to assess the effects of TENS on the management of pain, pulmonary function, respiratory muscle strength, and pharmacological analgesia in patients admitted in an intensive care unit (ICU) after thoracotomy.

Methods

Study Subjects and Design

Our Institutional Review Board approved this single-centre, randomized, double-blinded, parallel controlled trial (ISC-MPA Committee, IRB00002509; project approval number 086914/2014), registered at ClinicalTrials.gov under the number NCT02438241, following the *Consort Statement* [11].

Between January and June 2016, this single-centred study included adults (30–70 years) without previous knowledge or experience with TENS who would undergo lung resection (segmentectomy, lobectomy) by thoracotomy with posterolateral incision and presence of anterior and posterior chest tubes. After admission in the ICU, subjects were evaluated from 4 to 6 h. They should be haemodynamically stable (mean arterial pressure (MAP), 60–100 mmHg; heart rate, 50–110 bpm; peripheral oxygen saturation, > 90%) and should not present fluid drainage from chest tubes greater than 300 ml in the first six hours after surgery. Participants should be conscious (Richmond agitation-sedation scale (RASS) range, − 1 to + 1), presenting an epidural or paravertebral catheter and have physiotherapy prescribed. Exclusion criteria were: extubation with more than 6 h after the immediate postoperative period, rib fracture (prior, during or after surgery), any cardiovascular diseases (e.g. use of pacemakers, cardiac arrhythmias) or neurological diseases (e.g. stroke, high spinal cord injury), and allergic reaction to self-adhering electrodes.

Interventions

Through stratified random sampling, patients were grouped to receive one of the following different interventions: TENS (intervention group, IG), placebo TENS (placebo group, PG), or control group (CG).

The IG would receive TENS with an electric muscle stimulator (Neurodyn II, IBRAMED, Amparo, Brazil) with four channels and symmetrical biphasic waveform with pulsatile current. The following parameters were used: frequency, 100 Hz; pulse duration, 100 μs; intensity up to the maximum sensory threshold for pain; and total session time, 30 min. Self-adhering electrodes were used (ValuTrode, Axelgaard, Fallbrook, CA, USA), with 5 × 9 cm in size, positioned in the posterolateral portion of the thorax, 2 cm from the surgical incision, superiorly or inferiorly. Also, all patients underwent conventional physiotherapy after TENS.

The PG received a similar protocol to the IG but patients received a sham TENS, according to protocols previously described [12]. In this placebo intervention, the procedure also lasted 30 min but the electrical nerve stimulation was only done for 45 s (in the first 30 s, intensity was increased up to the maximum sensory threshold for pain, followed by a gradual shut down of electrical current during 15 s). During the remaining 29 min and 15 s, the electrical current was kept off [12].

The CG received only conventional physiotherapy, which consisted of in-bed manual resistance active exercises for the lower limbs (triple flexion, abduction, adduction, plantar flexion, and dorsiflexion), in-bed active exercises of the upper limbs (shoulder flexion, horizontal shoulder flexion, and diagonal functional movements), bronchial hygiene therapy, flow redirection, expiratory positive pressure, and insufflating ventilatory patterns.

All patients underwent physiotherapy three times a day (morning, afternoon, and night) during their ICU stay. After 48 h of assistance, all patients were re-evaluated following the same preoperative criteria. Therefore, each patient received support at least six times.

Outcomes and Evaluation

The primary outcome was the magnitude of pain, and secondary outcomes were pulmonary function, respiratory muscle strength, and pharmacological analgesia.

Pain magnitude was assessed through a visual analogue scale (VAS) which consisted of a scale from zero to ten, where zero represented no pain, and ten was the most intense pain ever felt.

Pulmonary function tests (PFT) were performed using a digital spirometer (Datospir Micro C, Sibelmed, Barcelona, Spain). The following parameters were analysed: forced expiratory volume in 1 s (FEV_1), forced vital capacity (FVC), and FEV_1/FVC ratio, according to the guidelines recommended by the American Thoracic Society [13].

Respiratory muscle strength was assessed using a digital manovacuometer (MVD300A, Globalmed, São Paulo, Brazil), and both maximum inspiratory and expiratory pressures (IPmax and EPmax, respectively) were measured following the guidelines recommended by the American Thoracic Society [13]. All examinations were performed by the same operator.

Pharmacological analgesia was evaluated in milligrams per patient per day through nursing records in the medical prescription during the first 48 h after surgery. The following medications were analysed: acetaminophen (oral), dipyrone (oral), tramadol (intravenous), and morphine (intravenous). In case of pain referral, patients received analgesia in the following order: (1) acetaminophen (oral); (2) dipyrone (oral); (3) tramadol (intravenous); and (4) morphine (intravenous). Patients were offered an alternative medication in case of pain maintenance at least one hour after the last given drug and respecting each drug's posology and maximum daily intake dosage.

Pulmonary function and respiratory muscle strength were analysed before, immediately after, and 48 h after the surgery. Pharmacological analgesia was evaluated within the first 24 and 48 h of the procedure. Pain magnitude was assessed before and after each session of TENS and physiotherapy. The physiotherapists who assessed the outcomes after interventions were blinded to treatment allocation. Also, physiotherapists responsible for TENS application were blinded to whether the procedure was full or sham TENS.

Sample Size Calculation

The sample size was estimated based on results from previous studies analysing the pain VAS measured within the first 48 h after surgery between the intervention (3 ± 1.5) versus the control (1.5 ± 1.5) groups [14]. Accepting a type I error rate (α) of 0.05 and power ($1–\alpha$) of 90%, a sample size of 10 subjects was estimated for each group. A total of 45 patients was included to prevent possible losses or exclusions of patients (20%),

Randomization and blinding

The stratified randomized sampling was electronically created for 45 subjects using a ratio of 1:1:1 to create three distinct and homogeneous groups with 15 patients each, based on the following criteria for stratified randomized allocation: (1) VAS; (2) FEV_1; (3) FVC; (4) IPmax; and (5) EPmax.

Statistical Analysis

Data were presented as means ± standard deviations or means (95% confidence interval (CI)) and median (interquartile range). Data were tested for normality of distribution using the Shapiro–Wilk test. Comparisons of proportions were made using χ-squared tests. One-way ANOVA was used for comparison of baseline characteristics between the groups. Generalized estimation equations (GEE) were utilized to determine whether there were significant differences between the groups and between the periods of evaluation. A p value < 0.05 was set for statistical significance. All statistical analyses were conducted in commercial software (Statistical Package for the Social Sciences, ver. 18, SPSS Inc., Chicago, IL, USA).

Results

In total, 45 patients underwent posterolateral thoracotomy. All subjects concluded the study, and there were no losses or exclusions (Fig. 1). Also, baseline characteristics were similar between all groups (Table 1). There was no difference between the groups for the kind of catheter used after thoracotomy (epidural catheter (PC) and paravertebral catheter (PVC)) (Table 1). Besides, all patients received the same analgesia medications (bupivacaine and fentanyl).

Pain Scale

Regarding pain perception, there was no difference between the groups ($p = 0.172$). However, there was a significant reduction in pain intensity for patients in the IG after the first physiotherapy session compared to baseline (4.7 ± 3.2 vs 3.3 ± 2.6; $p < 0.05$) (Fig. 2).

Pulmonary Function and Respiratory Muscle Strength

There were no significant differences for pulmonary function tests (FEV_1 and FVC) and respiratory muscle strength between the groups. All groups presented decrease of FEV_1, FVC, IPmax, and EPmaxin within the first 48 h after surgery ($p < 0.001$) (Fig. 3). On the other hand, for patients who received placebo TENS, median EPmax also increased in the 48-h evaluation compared to immediate postoperative.

Pharmacological Analgesia

There were no statistically significant differences between the groups in the use of pharmacological analgesia (acetaminophen; $p = 0.742$; dipyrone; $p = 0.445$; tramadol; $p = 0.706$; and morphine; $p = 0.564$). Comparing 24 vs. 48 h after surgery, use of morphine increased in the CG [respectively, 0.87 (95%CI 0.20–1.53) mg, vs. 1.80 (95%CI 0.87–2.73)

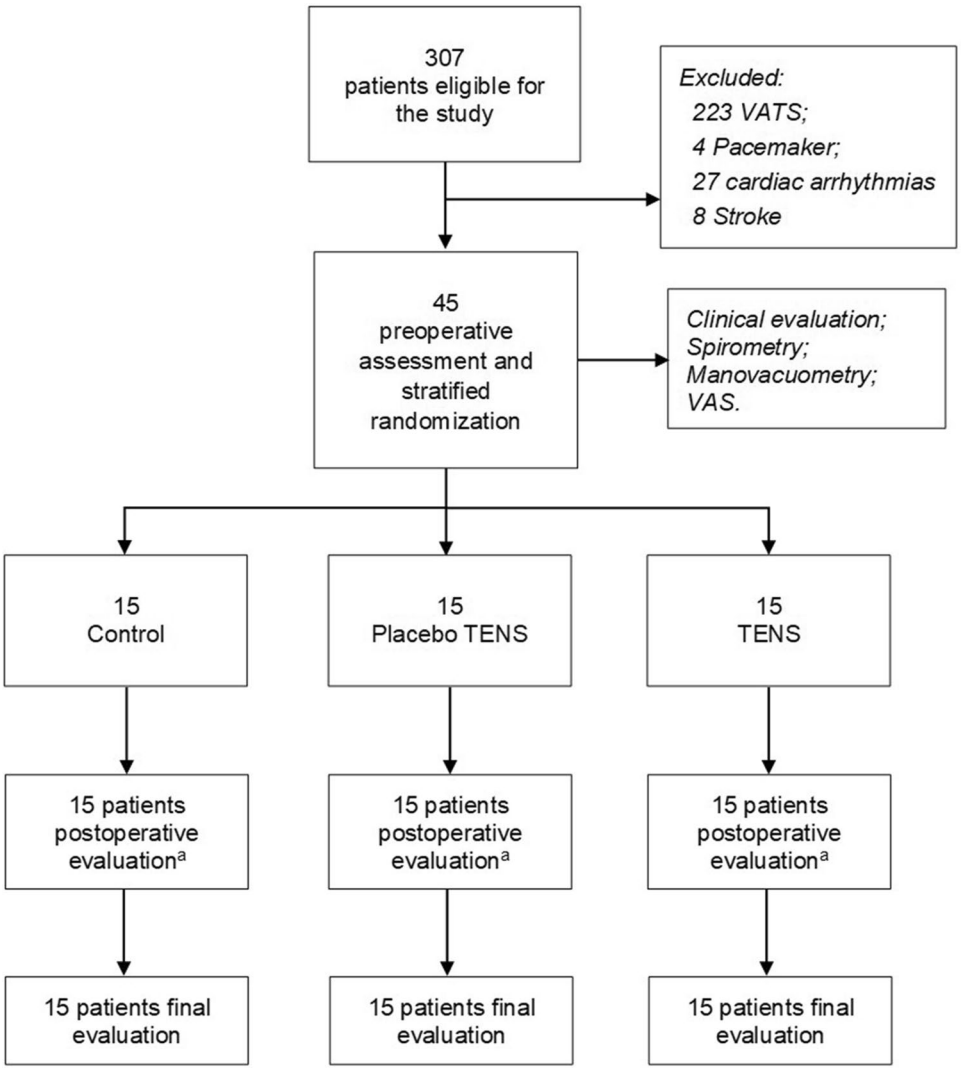

Fig. 1 Flow diagram. [a]Same preoperative evaluation. [b]Protocol of three service shifts (morning, afternoon and evening) for 48 h. *VATS* video-assisted thoracic surgery

Table 1 Sample characteristics

Groups	Total $N=45$	Control $n=15$	PlaceboTENS $n=15$	TENS $n=15$	P^a
Sex					0.06
Male	20 (44)	3 (7)	8 (18)	9 (20)	
Female	25 (56)	12 (27)	7 (16)	6 (13)	
Age, years	60 ± 12	60 ± 12	62 ± 10	58 ± 16	1.00
BMI, Kg/m^2	26 ± 6	27 ± 7	26 ± 4	25 ± 7	1.00
Spirometry					
FEV_1,L	2.04 ± 0.8	1.89 ± 0.7	1.93 ± 0.9	2.29 ± 0.8	0.34
FVC, L	2.63 ± 1.0	2.27 ± 0.8	2.65 ± 1.1	2.99 ± 1.1	0.15
FEV_1,%	75 ± 22	76 ± 25	71 ± 26	79 ± 15	0.66
FVC, %	79 ± 22	77 ± 25	79 ± 26	82 ± 15	0.83
FEV_1/FVC	78.05 ± 13.8	82.77 ± 13.8	72.36 ± 15.1	79.01 ± 11.1	0.11
Manovacuometer					
IPmax, cmH2O	61.43 ± 32.4	52.06 ± 28.4	56.80 ± 27.3	76.42 ± 37.8	0.10
EPmax, cmH2O	87.06 ± 40.8	89.66 ± 61.6	79.46 ± 22.3	92.42 ± 28.1	0.67
Smoking status					0.28
Smoker	11 (24)	2 (4)	6 (13)	3 (7)	
Non-smoker	16 (36)	8 (18)	3 (7)	5 (11)	
Former smoker	18 (40)	5 (11)	6 (13)	7 (16)	
Surgery					0.18
Segmentectomy	20 (44)	9 (20)	7 (16)	4 (9)	
Lobectomy	25 (56)	6 (13)	8 (18)	11 (24)	
Catheter					0.14
Epidural	37 (82)	13 (29)	14 (31)	10 (22)	
Paravertebral	8 (18)	2 (5)	1 (2)	5 (11)	
Lung					0.52
Right	28 (62)	11 (24)	9 (20)	8 (18)	
Left	17 (38)	4 (9)	6 (13)	7 (16)	
Lobe					0.84
Upper	26 (58)	8 (18)	10 (22)	8 (18)	
Middle	2 (4)	1 (2)	0 (0)	1 (2)	
Lower	17 (38)	6 (13)	5 (11)	6 (13)	

Data presented as frequency and percentages or mean ± standard deviations

BMI body mass index, *FEV_1* forced expiratory volume in 1 s, *FVC* forced vital capacity, *FEV_1/FVC* FEV_1/FVC ratio, *IPmax* maximum inspiratory pressure, *EPmax* maximum expiratory pressure

[a]Chi-squared test or ANOVA

mg; $p=0.037$]. Likewise, in the PG, the use of acetaminophen significantly increased from 24 to 48 h after surgery [respectively, 1900 (95%CI 1348–2452) mg, vs 2500 (95%CI 2116–2884) mg; $p=0.035$] (Fig. 4).

Discussion

The results of this clinical trial demonstrated that the use of TENS only provided a little benefit on pain relief in the first 12 h after posterolateral thoracotomy but failed to show any benefit on the recovery of ICU patients 48 h after the procedure.

Most studies that evaluated TENS for pain management after thoracic surgery with posterolateral incision have found favourable results [14–21]. However, some methodology issues in these papers could compromise the results, such as lack of information about randomisation [14, 20–22], pain assessment only during rest [16, 20, 21] or cough [14, 15, 19], TENS technical variability [16–21], no comparison of parameters between the evaluations before and after TENS [14–22], and no placebo group [15, 20, 21]. Also, in most of these studies, there were no protocols described for conventional daily physiotherapy [14, 22], what could weaken data on pulmonary function reported in some [14–16, 20]. Moreover, data on

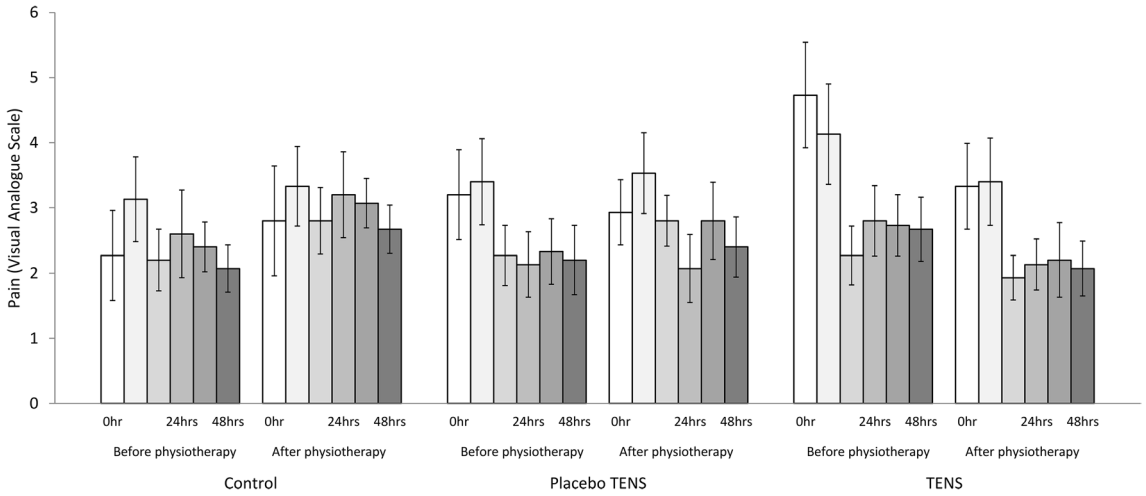

Fig. 2 Pain perception between groups. There was no difference between groups ($P = 0{,}172$). [a]Significant reduction in pain after first care compared with baseline ($4{,}73 \pm 3{,}2$ vs $3{,}33 \pm 2{,}6$; $P < 0{,}05$)

pharmacological analgesia were missing in a few manuscripts [16, 17, 19–21].

TENS for pain management after thoracic surgery has been investigated for decades [14–22]. In our study, TENS did not change pain magnitude in 24 and 48 h after surgery. However, comparing all evaluations done for patients who received TENS therapy after thoracotomy, reduction in pain scale was more effective for these patients after the first intervention. The results we found are in accordance with previous studies. In a similar study that compared TENS with epidural analgesia versus placebo TENS with epidural analgesia, favourable results were found towards TENS use in the first 8 h of treatment [21]. Another study that evaluated pain control immediately after thoracotomy found that pain was less intense up to one hour after TENS compared to patients who received placebo TENS [22].

Besides pain control, pulmonary function was also evaluated. There were no significant differences between the groups, and a global reduction in FEV_1 was observed, keeping with data from previous studies on pulmonary function after thoracotomy [23]. In this study, there was no change in the FVC of the patients in 48 h. In a study by Fiorelli et al. patients presented postoperative changes in the FCV but only 5 days after the thoracotomy.

To our knowledge, this was the first study that evaluated respiratory muscle strength in patients that received TENS after thoracic surgery with a posterolateral incision. We found a reduction in IPmax and EPmax in all groups in the first 48 h after surgery, and six sessions of TENS in the postoperative period could not interfere on this reduction.

Thoracic epidural analgesia is considered the gold standard for pain management after thoracic surgery [7, 24], and it can be combined with analgesic medications through oral intake and intravenous injection. In our Department of Thoracic Surgery, acetaminophen, dipyrone, tramadol, and morphine are the standard analgesic medications used. In our study, we observed a higher intake of morphine for the CG and acetaminophen for the PG, compared to the IG. Such findings are parallel with previous studies that analysed opioid use after thoracic surgery and demonstrated a lower intake for patients receiving TENS compared to control groups [14, 16, 19].

Our limitations include the concomitant use of thoracic epidural/paravertebral analgesia that could contribute to overlapping on the activation of analgesia pathways due to TENS mechanisms on pain perception. Besides, the use of standard medications in the postoperative period could have limited the variation in analgesic intake, despite the VAS pain perception or the use of thoracic epidural/paravertebral analgesia.

In summary, our results show that the use of TENS provided a little benefit in the reduction of pain (only in the first 12 h) after posterolateral thoracotomy that was not persistent nor different from the dummy intervention or control after 48 h.

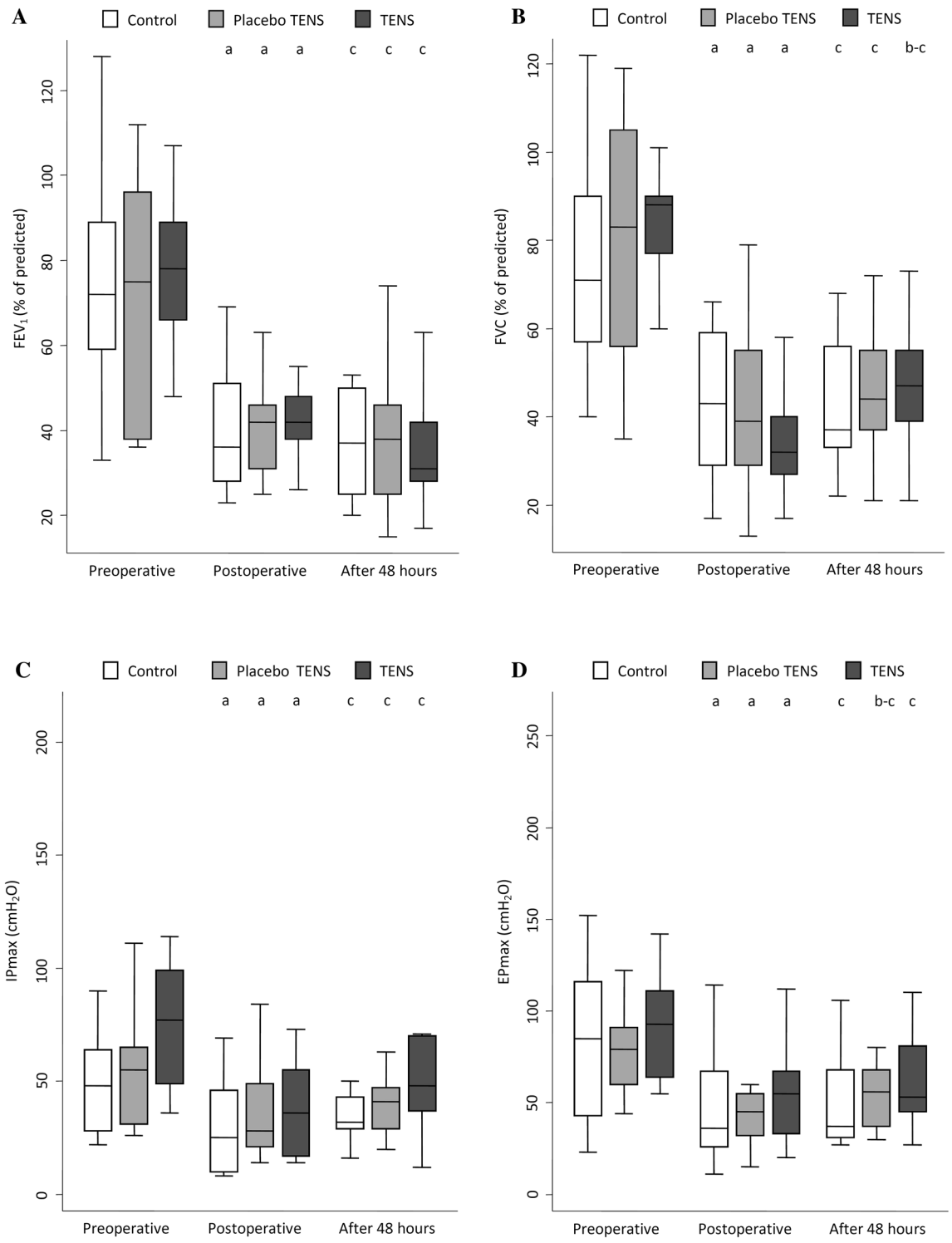

Fig. 3 Pulmonary function tests and respiratory muscle strength. **a** VEF_1, forced expiratory volume in 1 s; **b** FVC, forced vital capacity; **c** IPmax, maximum inspiratory pressures; **d** EPmax, maximum expiratory pressures (test: Generalized estimation equations). [a]Preoperative vs postoperative; $P<0.001$. [b]Postoperative vs after 48 h; $P<0.001$. [c]Preoperative vs after 48 h; $P<0.001$

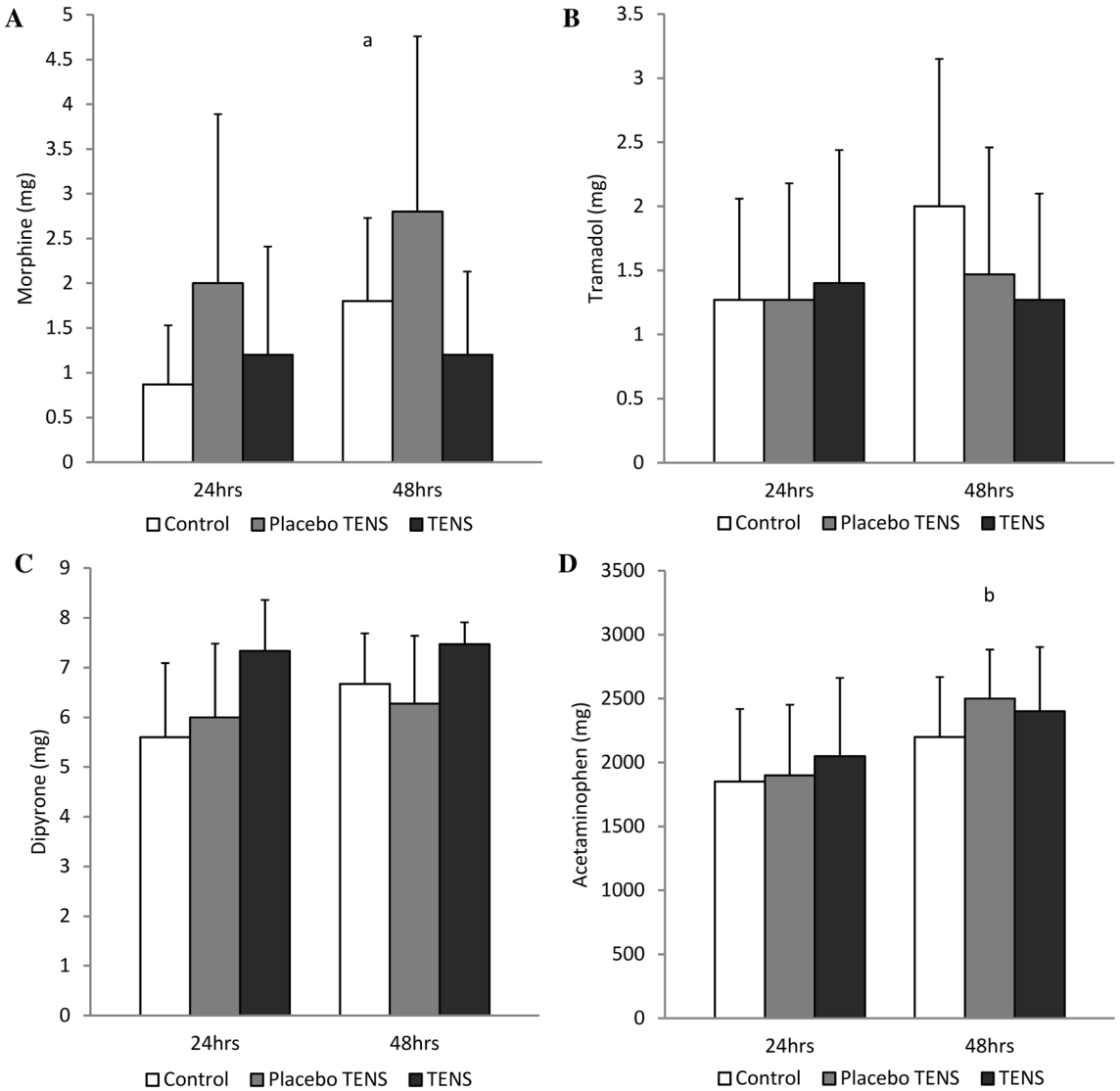

Fig. 4 Comparison of analgesic medication between groups. There was no difference between groups ($P=1{,}000$). **a** Morphine in mg; **b** Tramadol in mg; **c** Dipyrone in mg; **d** Acetaminophen in mg. [a]Control showed an increase in morphine consumption between 24 vs 48 h postoperative ($P=0{,}037$). [b]Placebo TENS had an increase in acetaminophen consumption between 24 vs 48 h postoperative ($P=0{,}035$)

Compliance with Ethical Standards

Conflict of interest The authors declare that they have no conflict of interest.

Informed Consent Informed consent was obtained from all individual participants included in the study.

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