

Comparison of continuous epidural block and continuous paravertebral block in postoperative analgesia after video-assisted thoracoscopic surgery lobectomy: a randomised, non-inferiority trial

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Abstract

Background: Video-assisted (VATS) lung lobectomy can be associated with stronger postoperative pain than is commonly believed. It is generally accepted to introduce multimodal analgesic strategies based on regional blockade, opioids and non-steroidal anti-inflammatory drugs. However, there is still no consensus regarding the optimal regional technique. The aim of this study was to compare the analgesic efficacy of continuous thoracic epidural block (TEA) and percutaneous continuous paravertebral block (PVB) in patients undergoing video-assisted lung lobectomy.

Methods: Fifty-one patients undergoing VATS lobectomy were enrolled in the present prospective, randomised clinical trial. The same analgesic regimen in both groups included continuous infusion of 0.25% bupivacaine with epinephrine, intravenous ketoprofen and paracetamol. The doses of local anaesthetics were determined to achieve the spread of at least 4 segments in both groups. Postoperative static and dynamic visual analogue pain scores, as well as patient-controlled morphine usage, were used to compare the efficacy of analgesia. Side effects and failure rates of both blocks were analysed.

Results: Static and dynamic pain scores at 24 postoperative hours were significantly lower in the paravertebral group, as were the static pain score at 36 and 48 postoperative hours ($P < 0.05$). No difference between the treatment groups was identified regarding postoperative morphine usage. The failure rate was higher in the epidural group than in the paravertebral group. No complications were noted in either group, but side effects (urinary retention, hypotension) were more frequent in the epidural group ($P < 0.05$).

Conclusions: Postoperative pain following VATS lung resection procedures is significant and requires the application of complex analgesic techniques. Percutaneous paravertebral block is equally effective as thoracic epidural block in providing analgesia in patients undergoing VATS lobectomy. Paravertebral block has a better safety profile than thoracic epidural block.

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Thoracic epidural anaesthesia (TEA) is generally considered the gold standard of analgesia after thoracotomy [1–3]. Irrespective of the extent of lung resection, the surgery-associated injury to the thoracic wall itself, resulting from the wide opening of the intercostal space, can require the postoperative use of advanced and complex methods of

analgesia and monitoring of life functions in an intensive care unit (ICU) setting.

An increasingly high frequency of anatomical lung resections using video-assisted thoracic surgery (VATS) has been widely discussed in surgical and anaesthesiological circles. Does the benefit-risk ratio of this type of manage-

ment justify the use of technically difficult epidural block? Are alternative methods of postoperative analgesia equally efficient? Finally, is the pain experienced after videothoracoscopic procedures, whose invasiveness is regarded to be low, less severe than thoracotomy?

Epidural and paravertebral blocks show the highest efficacy in pain management after VATS lobectomy [4, 5]. Both blocks were compared with other methods of analgesia in clinical tests, yet only one study has reported on the direct comparison between them [6]. Reviews devoted to the methods of regional anaesthesia after anatomical videothoracoscopic resections have raised more questions than have provided answers [4, 5]. Based on a few literature publications available, it is not possible to determine conclusively the superiority of any type of anaesthesia or formulate for even general recommendations.

The aim of the present trial was to compare the two methods of postoperative regional analgesia — i.e., continuous epidural and continuous paravertebral blocks — in patients undergoing VATS lobectomy. The criteria of inclusion and exclusion were chosen to provide the highest homogeneity of the groups in terms of surgery-related injury, as well as surgical and anaesthetic techniques. Simultaneously, to determine the efficacy of anaesthetic procedures, postoperative pain was measured using the visual analogue scale (VAS), and the patient-controlled analgesia (PCA) morphine dosage was assessed.

METHODS

The study design was approved by the Bioethical Committee at the Oncology Centre in Gliwice and was registered in the ClinicalTrials.gov database (NCT02040662). Each patient provided written informed consent for participation. The clinically significant VAS difference of 20 mm was accepted for sample size calculations. In the pilot study, the standard deviation of the dynamic values was 22.5 mm. At the significance level of 5% and power of 90%, each group should have included a minimum of 26 patients.

The included patients were randomly allocated into the groups administered paravertebral block (PVB) or thoracic epidural anaesthesia (TEA). Both patients and investigators were blinded to the type of analgesia.

The following inclusion criteria were used: patients qualified for VATS lobectomy due to cancer, aged 18–85 years, of both genders, ASA I–III, an understanding of the principles of VAS pain assessment and no chronic pain. The exclusion criteria included the following: technical failures to insert an epidural or paravertebral catheter, abandonment of resection (e.g., in cases of neoplastic dissemination), conversion of VATS to thoracotomy, anatomical obstacles to drug distribution found intraoperatively, cases in which the VAS assessment of pain severity was infeasible (e.g.,

postoperative delirium), use of other drugs affecting pain sensations, artificial lung ventilation, discontinuation of local anaesthesia for technical reasons (e.g., catheter slipping out or damage), and the use of drugs or doses that were not included in the study protocol.

Resections were carried out under general anaesthesia, which was induced using propofol or etomidate with fentanyl and was maintained with the mixture of N₂O/O₂/sevoflurane and analgesic doses of fentanyl administered every 30–60 min. Neuromuscular blockade (for intubation and intraoperatively) was provided with pancuronium or rocuronium using a relaxation monitor. Patients were intubated with a double-lumen tube; after verification of its position, patients were placed in lateral decubitus. The ventilation of one lung was provided with the model sparring the lungs and using the tidal volumes < 6–7 mL kg⁻¹ as well as a maximum airway pressure up to 30 cm H₂O. After the surgical procedures, all patients recovered from anaesthesia in the operating theatre. The effects of muscle relaxants were reversed with neostigmine at a dose of 1.5–2 mg preceded by 1 mg of atropine. After extubation, the patients were transferred to the ICU for at least 72 h.

The basic protocol of postoperative analgesia included the methods of regional analgesia as well as IV ketoprofen (Ketonal, Sandoz), 100 mg every 12 h, IV paracetamol (Paracetamol, Kabi), 1000 mg every 8 h and IV morphine (Morphinum sulfuricum, Polfa Warsaw) using PCA without a background infusion at a dose of 2–2.5 mg every 10 min (with the lock-up time) and a maximum hour dose of 10 mg without an induction dose (emergency analgesia).

Epidural blocks were performed using the classic paramedian approach technique, whereas paravertebral blocks were performed according to the Eason and Wyatt method. In both groups, the suitable space was identified using the loss-of-resistance method: in the TEA group using air and in the PVB group with 0.9% NaCl. Both blocks were provided using standard sets for epidural anaesthesia (Epidural Minipack, Portex). The induction dose of a local anaesthetic was administered to the catheter during skin suturing, several minutes before the completion of surgery. In both groups, 0.25% bupivacaine with the addition of adrenaline was applied — 1:200 000. The induction doses — i.e., 20 mL for PVB and 6 mL for TEA — were tailored to provide analgesia for a minimum of 4 segments and a maximum of 6 segments. The maintenance infusion flow was 0.08–0.1 mL kg⁻¹ h⁻¹ in group PVB and 0.06–0.08 mL kg⁻¹ h⁻¹ in group TEA and was modified to obtain the optimal range of anaesthesia and to avoid the adverse effects associated with too extensive blocks. The catheters for local anaesthetics were identically fixed to the patient's skin in both groups to prevent possible identification of the type of block. The extent of anaesthesia was determined 4, 24, 48 and 72 h after the procedure using ethyl chloride.

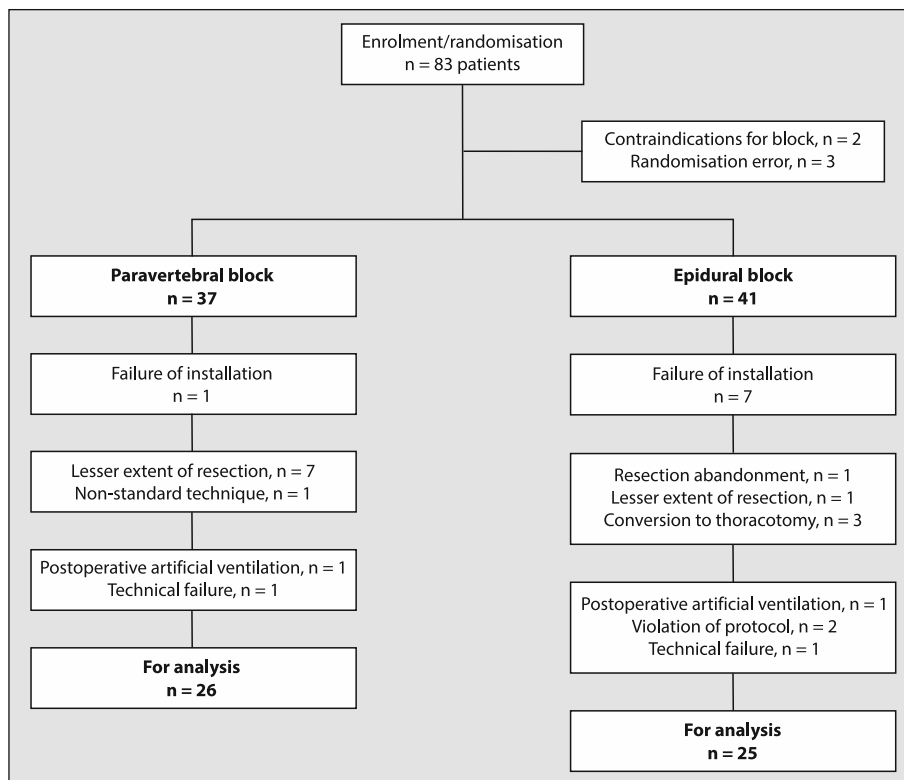


Figure 1. Protocol for patient enrolment in the study groups

The intensity of pain according to VAS was evaluated 1, 4, 8, 24, 36, 48 and 72 h after the procedures using a standard ruler. In each case, static (at rest) and dynamic assessments (on cough) were performed. Whenever the measurement was to be carried out at night (according to the schedule), it was postponed in sleeping patients until they spontaneously woke up. The doses of morphine on individual days were expressed in milligrams per hour and were read from the PCA memory.

The adverse side effects and complications were monitored systematically, and their nature and extent were recorded in the patient’s records and study questionnaire. Hypotension was considered at a systolic arterial pressure below 90 mm Hg and/or SAP decrease by > 20% compared with the pre-surgery value. The following criteria of respiratory depression were assumed: respiration rate < 10 per min and/or SpO₂ < 90%. Atelectasis was diagnosed in cases whenever a new opacification was observed in roentgenogram corresponding to the anatomical lung unit. In case of doubt, differentiation with pleural exudate was based on transthoracic US and/or bronchoscopy. Urinary retention was diagnosed when there was no spontaneous miction for 8 h after surgery or when the US-assessed volume of the urinary bladder was > 500 mL.

STATISTICA 10 software was applied (StatSoft, Inc.). Groups were compared using Student’s t-test with separate estimation of variance and the Mann-Whitney U test. Changes in the pain severity in the study groups were analysed using the general linear model (GLM) in the system of repeatable measurements. *P* < 0.05 was considered statistically significant. Analysis of the first-line end-point of pain intensity was performed using the method of non-inferiority or equivalence according to the CONSORT recommendations [7].

RESULTS

Eighty-three patients were enrolled in the study; the final analysis involved the data of 51 of them (Fig. 1).

Basic demographic data of the patients, extent and duration of surgery and dosage of intraoperative opioids are presented in Table 1. Selected details of surgical technique are summarized in Table 2. The dermatomal extent of blocks on the day of surgery were mean 4.4 in TEA group and 4.2 in PVB group. On POD1 the loss of sensation extended on average 4.0 (TEA group) and 3.7 (PVB group) dermatomes and on POD2 3.7 and 3.5 dermatomes respectively (Table 3).

The comparative analysis of pain sensations demonstrated slight inter-group differences (Fig. 2). Significant

Table 1. Characteristics of the study groups

Parameter	Group TEA	Group PVB
Number of patients	25	26
Age(years); mean (range)	59.9 (28–78)	64.7 (44–73)
Body mass (kg); mean (range)	73.6 (55,5–102)	76.3 (54–100)
Female gender; number (%)	10 (40%)	12 (46%)
Extent of pulmonary parenchyma resection		
right upper lobe	12	13
left lower lobe	5	7
right lower lobe	4	3
left upper lobe	4	1
middle lobe	0	1
Duration of surgery (min); mean (range)	187.4 (115–330)	188 (105–305)
Total intraoperative dose of fentanyl(μ g); mean (range)	370 (100–700)	340 (200–500)

Table 2. Characteristics of surgical procedures

		Group TEA	Group PVB
		n	n
Utility thoracotomy incision	5 th intercostal space	24	22
	6 th intercostal space	1	4
Placement of a posterior port	6 th intercostal space	17	12
	7 th intercostal space	2	3
	8 th intercostal space	6	11
Number of ports	two	17	18
	three	8	8
Number of inserted drains	one	9	5
	two	16	21

Table 3. Ranges of blocks

Day	Range	Group TEA	Group PVB	P-value
		Thoracic dermatomes — mean (range)	Thoracic dermatomes — mean (range)	
0	Upper	4.4 (2–6)	4.7 (4–7)	0.1097
	Lower	7.8 (5–10)	7.9 (6–10)	0.4010
1	Upper	4.9 (3–6)	4.7 (4–7)	0.1220
	Lower	7.8 (6–9)	7.7 (7–10)	0.6550
2	Upper	5 (2–7)	5 (4–7)	0.9010
	Lower	7.7 (5–9)	7.6 (6–10)	0.7257

differences were found in the measurements at 24 h — both at rest and on coughing ($P = 0.01$ and $P = 0.023$, respectively) — and in static pain at 36 h and 48 h ($P = 0.025$ and $P = 0.026$, respectively). Moreover, the U test showed a significant difference in pain on coughing at 48 h ($P = 0.045$).

The comparative analysis of both groups did not reveal any significant differences in the postoperative morphine

dosage (Fig. 3). The mean dose was 0.4 mg h^{-1} on day 0, 0.37 mg h^{-1} on day 1, 0.21 on day 2 and 0.14 mg h^{-1} on day 3.

None of the patients developed severe, anaesthesia-characteristic complications. Otherwise, the incidence of hypotension and urinary retention was found to be higher in TEA patients. The incidence of respiratory complications — i.e., atelectasis and pneumonia — was low and compa-

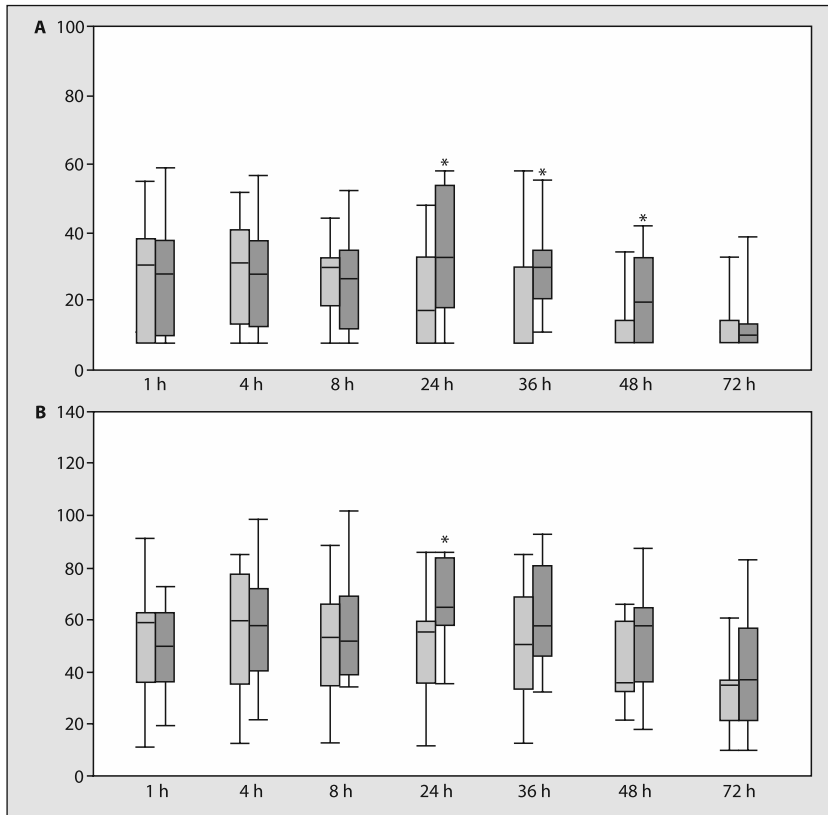


Figure 2. Static (A) and dynamic (B) pain intensity (mm) at subsequent measurements. Whiskers — range between the 5th and 95th percentiles; box — IQR; horizontal line — median; light grey colour — group PVB; dark grey colour — group TEA; *statistically significant differences

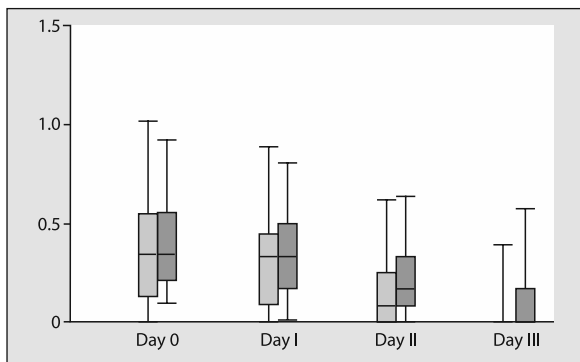


Figure 3. Emergency PCA-administered morphine doses (mg h⁻¹). Light grey colour — group PVB; dark grey colour — group TEA; whiskers — range between the 5th and 95th percentiles; box — IQR; horizontal line — median

nable in both groups. There were no respiratory depression symptoms observed in any patient (Table 4).

The comparative analysis of both methods of postoperative analgesia demonstrated the superiority of PVB over TEA on postoperative days 1 and 2.

DISCUSSION

Video-assisted thoracoscopic surgery lobectomies have been performed for more than 20 years and have become the method of choice in some centres. Postoperative pain is managed using multimodal strategies based on various ways of regional anaesthesia; however, the majority of centres elaborated their own protocols of analgesia. The choice of a particular block depends on numerous factors — e.g.,

Table 4. Adverse effects of blocks

Parameter	Group TEA n (%)	Group PVB n (%)	P-value
Urinary retention	16 (64)	9 (34.6)	0.0036
Hypotension	8 (32)	2 (7.7)	0.0031
Respiratory depression	0	0	
Atelectasis	1 (4)	2 (7.7)	0.0542
Pneumonia	0 (0)	1 (3.8)	0.0331

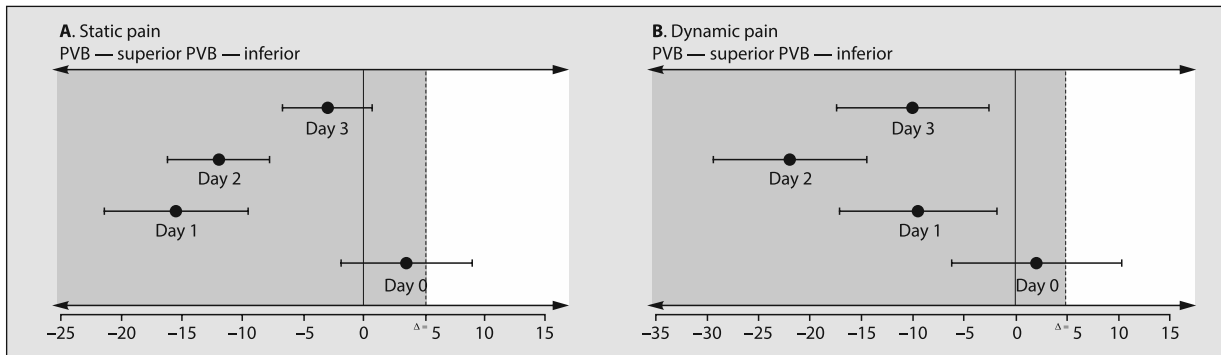


Figure 4. Evaluation of the non-inferiority of the postoperative analgesia methods used according to the CONSORT guidelines. VAS differences at rest and on coughing during the postoperative period. The error bars represent 95% confidence intervals; Δ — non-inferiority margin; the light colour area — inferiority

previous experiences, principles of cooperation between the surgical and anaesthetic teams, patient status and accepted rules of postoperative management. The video-thoracoscopic methods, which cause less severe surgical injuries, are often addressed in older patients with chronic diseases and lower functional reserves [8]. In such groups of patients, the ICU postoperative treatment, duration of rehabilitation and hospitalisation are frequently prolonged. Therefore, it is reasonable and justified to use the methods of regional anaesthesia with continuous drug infusions providing even and long-term analgesic effects, enabling continuous and steady convalescence.

Continuous epidural thoracic anaesthesia is considered the gold standard of analgesia after thoracotomy and is routinely used after VATS in many centres [6, 9–11]. The results of meta-analyses and reviews have demonstrated that paravertebral anaesthesia is characterised by comparable (if not higher) efficacy and a more favourable safety profile [1, 2]. Therefore, the guidelines of postoperative pain management after thoracic surgical procedures currently recommend continuous paravertebral blocks [12]. However, it is worth noting that some authors question the conclusions of available meta-analyses emphasising the differences in the methodology of studies [3]. Likewise, in our opinion, when competently performed, TEA allows the achievement of optimal postoperative analgesia with minimum side effects.

The results of our study indicate that pain sensations after VATS lobectomy were severe, especially during the first 48 postoperative hours. The analysis of the non-inferiority of blocks performed according to the CONSORT criteria [7] on the surgery day was inexplicit — i.e., no superiority of one method was demonstrated — yet a trend for epidural block superiority was observed. On the other hand, on postoperative day 1 and 2, paravertebral block seemed to be superior to epidural anaesthesia, both under static and dynamic conditions. Moreover, the analysis performed on

postoperative day 3 at rest was found to be ambiguous; on coughing, however, better analgesic effects were provided with paravertebral anaesthesia. At comparable emergency doses of opioids in both groups, it can be assumed that the analgesic effect was better in the PVB group. Of note, there were no significant differences in the distribution of both blocks, which could affect the interpretation of study results.

Some authors believe that continuous paravertebral block using the classical landmark puncture technique is not satisfactorily predictable and effective [13–15]. A single injection technique can be fully controlled, yet the continuous block may be unstable. Despite the methods of visualisation or identification of the spinal nerve that can be applied, the major issue is the final location of catheters in relation to the endothoracic fascia and parietal pleura [6, 13]. The surgical method of catheter insertion into the paravertebral space under the parietal pleura with fenestration of the endothoracic fascia is preferable in some centres [16]. However, the latest review of meta-analyses has revealed comparable efficacy of blocks using both techniques [4].

In our study, the differences in the dermatomal extent of both types of anaesthesia did not achieve the significance threshold; nevertheless, the tendency for better and more predictable drug spread in epidural block was observed. Moreover, the number of interventions involving changes in infusion rates was higher in the PVB group of patients. Based on the evaluation of block dynamics, it should be assumed that the catheter tips in 5–6 patients could have been located in the ventral subpleural area or outside the paravertebral space. Nonetheless, considering satisfactory clinical effects of the block according to the multimodal protocol, the anatomical issues fade into the background. Of note, Luyet *et al.* [13] have demonstrated satisfactory efficacy and extensive range of continuous paravertebral block in 3 of 5 patients with catheter tips in the dorsal extensor muscle.

Analysis of the literature revealed only five randomised and two observational clinical trials concerning the lung resections of comparable extents that can be compared with our findings. Four of those mentioned above focused exclusively on lobectomy [9, 10, 16, 17], and three dealt with mixed procedures (lobectomies, segmentectomies, and wedge resections) [6, 11, 18]. Continuous paravertebral block and continuous epidural anaesthesia have been compared in only one of the cited studies [6]. In all of the above studies, different protocols and different drugs were used, although analgaesic efficacy was comparable to that in our study.

Compared with the other studies regarding videothoracoscopic lobectomies, the incidence of atelectasis in both study groups appears to be high (Table 4) [19, 20]. It is worth noting that our protocol considered the evaluation of this complication based only on a radiological criterion. All patients suspected of atelectasis underwent bronchofiberoscopy impaired patency of the bronchus caused by the accumulated secretions was confirmed only in two PVB patients (7.7%) and in one TEA patient (4%).

Because extensive VATS resections are followed by severe and long-term pain and in a certain proportion of cases, the perioperative trauma unexpectedly intensifies (e.g., conversion to thoracotomy, insertion of additional ports, prolonged drainage), continuous paravertebral block may be preferable to regional anaesthesia within the multimodal protocols of postoperative analgaesia.

LIMITATIONS

The surgical procedures carried out were not homogeneous. The surgeries were performed by the same team of surgeons, yet the individual characteristics of patients and anatomical conditions necessitated some modifications of the techniques used that can be associated with slight differences in the extent of surgical injuries. Likewise, although only patients requiring lobectomies were enrolled, the distribution of the excised lobes differed; due to the randomisation, the differences were unavoidable.

The solutions used for blocks did not contain opioids. The study protocol involving the comparison of emergency morphine doses excluded the use of the optimal composition of solutions. The study was conducted in the ICU, where the intensity of pain is routinely assessed every 1–4 h. However, the interval characteristics of the individual days were chosen for analysis considering the schedule of nursing and rehabilitation responsibilities. It is most likely that more data could have been gathered considering the higher numbers of pain intensity measurements, but the results could then be associated with a higher risk of errors resulting from different study conditions.

The study design did not include the intraoperative assessment of blood loss or a uniform regimen of intra- and postoperative fluid therapy, which can result in the mis-evaluation of the incidence of hypotension in both groups, assuming that the groups were not homogeneous in terms of fluid balance. Likewise, the extent of sedation was not evaluated in the study; thus, slight symptoms indicating the toxicity of local anaesthetics could have been overlooked.

In some cases, pain assessment in older patients was difficult. Although the patients were informed regarding how to use the VAS ruler and their understanding of the method was checked, some preferred Wong-Baker faces and adjusted the slider's position to them, which could lead to some miscalculations; however, considering the comparable mean ages of patients, the errors, if any, were probably equally distributed.

CONCLUSIONS

1. Pain following VATS lobectomy is severe and requires the use of complex techniques of postoperative analgaesia, including the methods of regional anaesthesia.
2. Continuous paravertebral block using the classical landmark puncture technique is as equally effective as epidural block for multimodal analgaesia.
3. Continuous paravertebral block has a better profile of safety than epidural block, which is particularly visible in the lower incidences of hypotension and urinary retention.

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