General Anaesthesia Combined with Bilateral Paravertebral Blockade (T11-T12-L1) vs General Anaesthesia for Bilateral Varicocelectomy
A Randomized Double-Blind Clinical Trial

To the control group. Higher surgeon and patient satisfaction compared to general anaesthesia in combination with placebo paravertebral nerve block. Blocks could provide better postoperative pain relief compared to general anaesthesia in combination with placebo paravertebral nerve block.

Methods: Sixty patients scheduled for varicocelectomy were randomized prospectively. Thirty patients each in either the active group (general anaesthesia combined with nerve stimulator guided paravertebral block) or the control group (general anaesthesia combined with normal saline nerve stimulator-guided paravertebral block). Postoperative pain was assessed by visual analogue scale scores at predetermined time intervals.

Results: The active group was found to have better postoperative pain-relief \((p < 0.005)\), reduced need for analgesics \((p < 0.05)\), and also a more rapid return to normal activities \((p < 0.001)\) compared to control group. Higher surgeon and patient satisfaction \((p < 0.001)\) were noted in the active group compared to the control group.

Conclusion: Preoperative paravertebral blockade combined with general anaesthesia showed significantly reduced postoperative pain scores and analgesic consumption, earlier return to normal activity and was associated with better patient and surgeon satisfaction during varicocelectomy surgery.

INTRODUCTION

Open varicocelectomy (OV) is a common operation in Lebanese urology practice. Its indications include: infertility, arrest of testicular growth in children and persistent testicular pain [1-2]. However, this technique is associated with high postoperative pain scores, necessitating good pain control regimens [1-4].

Based on this background, peripheral nerve block may provide an alternative anaesthetic technique to general anaesthesia (GA), since it has been reported to produce high quality, long lasting, intra- and postoperative analgesia in different surgical settings [5]. Effectiveness of paravertebral blocks (PVB) in various urological and non-urological operations was demonstrated in many clinical trials [6-7].
The aim of this prospective, randomized, double-blind study was to investigate whether a combination of general anaesthesia and bilateral nerve stimulator guided paravertebral nerve blocks could provide better postoperative pain relief compared to general anaesthesia in combination with placebo bilateral paravertebral nerve block.

Our primary outcome measure of the study was postoperative pain scores. Secondary outcome measures includes postoperative analgesic needs, time to discharge from the Postanesthesia Care Unit (PACU) and time needed to return to regular daily activities.

**METHODS**

The study was approved by the Institutional Review Board and written informed consents were obtained from all participants. Sixty male patients classified as ASA physical status I, aged between 18-61 years old and scheduled for ambulatory bilateral OV were enrolled in this prospective randomized double-blind study. Data characteristics included age, height, weight, body mass index (BMI, kg/m²) and ASA status (Table I). Exclusion criteria were history of allergic reaction to local anaesthetics, spinal abnormality and patient’s refusal.

Patients were randomized to either active group (GA combined with bilateral PVB using local anaesthetics; n = 30) or control group (GA combined with bilateral PVB using normal saline; n = 30) using a sealed envelope containing randomly generated numbers. PVB was performed preoperatively and the operation was performed by the same surgical team. Patients, surgeons, anaesthesiologists, and nurses responsible for data collection were all blind to patients’ assigned groups.

Postoperative data included recovery room stay, postoperative nausea and vomiting (PONV), time to first urination, passing gas and defecation, patient and surgeon satisfaction, and time needed to return to normal activity (Table II). The criteria to return to normal activity was defined as ability to return to work and/or carry on routine tasks. The data was then collected during follow-up phone calls. The period of follow-up lasted up to 8 days. Neither the surgeons nor the anesthesiologists were aware of the content of the injected solution. The decision to discharge the patient from the hospital was entirely made by the surgeon in charge, according to established clinical routine, blind to the patient’s group.

**General anaesthesia technique**

General anaesthesia was induced by intravenous fentanyl (1.5 mcg kg⁻¹) and thiopentone (3-5 mg kg⁻¹) followed by endotracheal intubation facilitated by atracurium (0.5 mg kg⁻¹). Anaesthesia was subsequently maintained with isoflurane 1-3%, fentanyl (3-4 mcg kg⁻¹), nitrous oxide 70% and oxygen 30%. The isoflurane concentration was adjusted with the intention of keeping heart rate and blood pressure within ± 25% of pre-induction values. At the end of the operation, residual neuromuscular blockade was antagonized with neostigmine (0.05 mg kg⁻¹) and atropine (0.01 mg kg⁻¹).

**Paravertebral nerve block technique**

After placement of regular anaesthetic monitors, all patients received 2-3 mg of intravenous midazolam as a premedication. In order to perform the preoperative bilateral PVB, patient was put in lateral decubitus position and the sites of injection were identified 2.5-3 cm lateral to the midline on both sides according to body mass index, corresponding to T11, T12 and L1. After aseptic preparation of the skin, the injection sites were each infiltrated with 0.5-1.0 ml of 1% lignocaine by 29-gauge needle to facilitate the penetration of the nerve stimulation needle (Stimuplex, B. Braun AG, Melsungen, Germany).

In order to identify the muscular response appropriate

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**TABLE I**

**PATIENTS’ CHARACTERISTICS & PERIOPERATIVE DATA**

<table>
<thead>
<tr>
<th></th>
<th>Control Group</th>
<th>Active Group</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of patients</td>
<td>30</td>
<td>30</td>
<td></td>
</tr>
<tr>
<td>Age (years)</td>
<td>27.5 (9.8)</td>
<td>30.1 (8.1)</td>
<td>0.28</td>
</tr>
<tr>
<td>Height (cm)</td>
<td>174.6 (6.2)</td>
<td>174.2 (5.3)</td>
<td>0.79</td>
</tr>
<tr>
<td>Weight (kg)</td>
<td>78.4 (11.2)</td>
<td>76.4 (11.8)</td>
<td>0.51</td>
</tr>
<tr>
<td>Body mass index (kg/m²)</td>
<td>[20-25]</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>10 (33.3%)</td>
<td>14 (46.7%)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>19 (63.3%)</td>
<td>13 (43.3%)</td>
<td>0.25</td>
</tr>
<tr>
<td></td>
<td>1 (3.3%)</td>
<td>3 (10.0%)</td>
<td></td>
</tr>
<tr>
<td>ASA</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>I</td>
<td>11 (38.7%)</td>
<td>13 (43.3%)</td>
<td></td>
</tr>
<tr>
<td>II</td>
<td>19 (63.3%)</td>
<td>17 (56.7%)</td>
<td>0.79</td>
</tr>
</tbody>
</table>

Data reported as mean (± SD), and number (%).

**TABLE II**

**POSTOPERATIVE DATA**

<table>
<thead>
<tr>
<th></th>
<th>Control Group</th>
<th>Active Group</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of patients</td>
<td>29</td>
<td>30</td>
<td></td>
</tr>
<tr>
<td>Recovery room (min)</td>
<td>223.62 (57.9)</td>
<td>61.8 (19.4)</td>
<td>&lt; 0.01</td>
</tr>
<tr>
<td>PONV</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>5 (17.2%)</td>
<td>9 (30.0%)</td>
<td>0.39</td>
</tr>
<tr>
<td>No</td>
<td>24 (82.8%)</td>
<td>21 (70.0%)</td>
<td></td>
</tr>
<tr>
<td>Time to first</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Urination</td>
<td>5.19 (0.68)</td>
<td>5.18 (0.84)</td>
<td>0.98</td>
</tr>
<tr>
<td>Passing gas</td>
<td>5.23 (0.85)</td>
<td>5.24 (0.83)</td>
<td>0.97</td>
</tr>
<tr>
<td>Defecation</td>
<td>17.6 (2.56)</td>
<td>17.2 (2.19)</td>
<td>0.46</td>
</tr>
<tr>
<td>Patient’s satisfaction</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>16 (55.2%)</td>
<td>27 (90.0%)</td>
<td>&lt; 0.01</td>
</tr>
<tr>
<td>No</td>
<td>13 (44.8%)</td>
<td>3 (10.0%)</td>
<td></td>
</tr>
<tr>
<td>Surgeon’s satisfaction</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>22 (75.9%)</td>
<td>29 (96.7%)</td>
<td>0.05</td>
</tr>
<tr>
<td>No</td>
<td>7 (24.1%)</td>
<td>1 (3.3%)</td>
<td></td>
</tr>
<tr>
<td>Return to regular daily life (days)</td>
<td>5.4 (1.4)</td>
<td>2.0 (0.5)</td>
<td>&lt; 0.01</td>
</tr>
</tbody>
</table>

Data reported as mean (± SD), and number (%). PONV: postoperative nausea & vomiting.
for each dermatome, a 21-gauge insulated needle (Stimuplex) was introduced perpendicularly to the skin at the site of the upper injection points using the following nerve stimulator settings: 5 mA, 9 v and 1 Hz. Initial contractions of the paraspinal muscles were seen as a result of direct muscle stimulation. After the paravertebral space had been entered, at a needle’s depth from the skin between 5 to 8 cm, the stimulating needle was gently manipulated into a position to allow an adequate muscular response with a stimulating current of 0.4-0.6 mA. The manipulation of the needle tip within the paravertebral space is not an in-out movement; it is rather an angular manipulation and circumferential rotation around the axis of the needle in order to orient the tip of the needle into close proximity of the corresponding nerve root. At this point, 0.1 ml kg⁻¹ of either normal saline or the anaesthetic mixture, based on the patient’s group, was given at each of the three paravertebral levels. Each 20 ml of the injected mixture contain 6 ml lignocaine 2%, 6 ml lignocaine 2% with adrenaline 1/200000, 6 ml bupivacaine 0.5%, 1 ml fentanyl 50 mcg.ml⁻¹, 0.7 ml of normal saline and 0.3 ml clonidine 150 mcg ml⁻¹.

To block the opposite side the patient was not moved and a similar approach was used with one exception; the needle was inserted in an oblique downward angle of 45 degrees in relation to the spine with a depth from the skin to the PVS usually 0.5-1.5 cm less than the upper injection site. The time taken to position the patient, perform aseptic preparation of the injection site and to perform both PVB injections ranged between 8-12 minutes.

**Postoperative pain assessment**

Pain was assessed during the first three postoperative days at predetermined time intervals (0 h, 6 h, 12 h, 24 h) during the first day, then once daily, using Visual Analogue Scale (VAS) where 0 represents no pain and 10 the worst possible pain. After hospital discharge, patients were contacted daily by telephone to assess their postoperative pain scores. VAS pain scores were obtained both at rest and during attempted activity. Pain during activity was assessed by asking the patient to: 1) Move from the supine to the sitting position, 2) walk approximately 5 m inside the room and 3) cough (patients were asked to take a deep breath and cough). VAS during first urination, passing gas and defecation were also recorded.

**Postoperative analgesics**

Intravenous Tramal (1 mg.kg⁻¹, Grunenthal GmbH, Aachen, Germany) was administered in the recovery. During follow-up Zaldiar (Grunenthal GmbH, Aachen, Germany) was administered if the VAS pain score was ≥ 4, whereas Naproxen (Grunenthal, Swissmedic, Switzerland) at a dose of 500 mg was given if VAS < 4.

**Postoperative nausea and vomiting (PONV)**

The number of patients free of nausea or vomiting was recorded at the same predetermined time intervals as used for assessing pain scores. No distinction was made between vomiting and retching. The degree of nausea was measured using a numeric rating scale (0 : no nausea, 10 : worst possible nausea).

**Surgeons’ and patients’ satisfaction**

Surgeons’ satisfaction based on their patients overall comfort and patients’ satisfaction based on their comfort and activity were assessed postoperatively at the end of follow-up period.

**Statistical analysis**

In order to detect a 23% reduction in the primary outcome measure (VAS score at rest 24 h postoperatively) with an alpha-value and power of 0.05 and 0.90 respectively, a sample size of 30 patients in each group was found to be needed. Data were reported as mean, standard deviation (SD), median (range) or numbers (percentage). Data were statistically analyzed by contingency tables, t-test and two-way ANOVA for repeated measurements as appropriate. P-values < 0.05 were considered statistically significant.

**RESULTS**

Fifty-nine male patients were enrolled for final data analysis, of whom 30 in the active group and 29 patients in the control group. One patient in the control group was not included in the final data analysis due to loss of follow-up after hospital discharge. No incidence of unintentional vascular puncture or pneumothorax occurred during the performance of the PVB. The day of discharge was the same for all patients.

No statistical significant differences in patients’ characteristics such as age, height, weight, body mass index and ASA were recorded between the two groups (Table I).

Time to discharge from PACU was significantly longer in the control group (Table II). Number of postoperative nausea and vomiting episodes, time needed to first urination, to first passing of gas and to first defecation were not statistically different between the two groups (Table II). Patient and surgeon overall postoperative satisfaction scores were significantly higher in the active group (Table II). The active group also demonstrated a significant shorter time to return to regular daily activity (Table II). Pain scores during first urination and first defecation were lower in the active group compared to the control group (Table II).

Two-way analysis of variance for repeated pain scores measurements during the follow-up period and the t-test at each time interval showed that pain scores at all time intervals were significantly lower in the active group compared to the control group at rest and during activity (moving, coughing and walking) (Figure 1). Concerning consumption of analgesics such as Naproxen for those who scored VAS < 4, the active group demonstrated significantly reduced analgesic consumption compared to the control group (Figure 2). As for the Tramal consumption for those who scored VAS > 4 the active group showed significantly less opioid consumption than the control group (Figure 3).
DISCUSSION

The main finding of this clinical trial was significant improvement in postoperative pain scores at rest and during activities such as moving, coughing and walking and significant reduction in analgesic consumption during bilateral retroperitoneal high ligation varicocelectomy done under GA combined with preoperative bilateral PVB using local anaesthetics and that during the entire follow-up period. Active group experienced significantly faster discharge from PACU and faster return to daily regular activities.

Pain scores obtained in our study for patients receiving only GA were very similar to those recorded by Yazigi and colleagues [8]; patients who received PVB had significantly lower pain scores and consequently less analgesic consumption. Moreover, the duration of improved postoperative analgesia in the active group extended beyond the expected duration of the anaesthetic mixture. This was in accordance with our previous experience using this anaesthetic mixture under different types of surgeries, which resulted in prolonged duration of postoperative analgesia [7].

PVB has been reported to provide high quality afferent blockade with abolishment of somatosensory evoked potentials [9-10]. However, the extended pain-relief period obtained in this study may be due to many factors. First the use of nerve stimulator facilitated the injection of the anaesthetic mixture in close proximity to the nerve resulting in complete block to the incision area [11]. Consequently this resulted in intraoperative hemodynamic stability and postoperative pain relief.

Another factor that may contribute to reducing the analgesic consumption may be the addition of adrenaline, fentanyl and clonidine which markedly enhance pain relief in the postoperative period [12-13]. Fentanyl may be of benefit for the relief of postoperative pain once added to a local anaesthetic. Tverskoy et al. have shown that fentanyl can significantly enhance analgesia peripherally [14]. Addition of clonidine to local anaesthetic solutions has been found capable of prolonging and intensifying peripheral nerve blocks [15-16]. Clonidine brings about this effect by an interaction with the immune system resulting in reduced recruitment of macrophages and lymphocytes at the nerve injury site, and a shift in the propor-

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**Figure 1**
Average pain scores with 95% CI over the follow-up period

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**Figure 2**
Analgesic consumption during the follow-up period (VAS < 4)

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**Figure 3**
Tramal consumption during the follow-up period (VAS > 4)
tion of macrophages from the pro- to the anti-inflammatory phenotype [17]. This will decrease the peripheral nociceptive stimulus with consequent suppression of peripheral hypersensitivity and hyperalgesia [18]. In this study no incidence of unintentional vascular puncture, pneumothorax or other major complications occurred during the performance of the PVB, confirming the results obtained from other studies that guided PVB techniques using the nerve stimulator or ultrasound appear to improve the accuracy and success rate of the PVB technique [10-11, 19].

Third, the duration of postoperative analgesia observed in the present study may be more consistent with a preemptive analgesic effect. The analgesic action of a local anaesthetic-clonidine mixture applied before incision has recently been reported in various experimental pain models [17-18] and in clinical settings among children and adults [9, 16].

Surgeons in the follow-up period were significantly more satisfied in the active group. Moreover, the regional technique of PVB did not change the anatomy of the incision since it was performed far away from the incision area. Patient’s satisfaction was statistically in favor of the active group.

In conclusion, preoperative paravertebral blockade combined with general anaesthesia have showed to safely provide reduction in analgesics consumption, better control of postoperative pain scores and faster functional recovery in males undergoing bilateral varicocelectomy.

ACKNOWLEDGEMENTS

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REFERENCES