Efficacy of Unilateral Ilioinguinal Transversus Abdominis Plane Block for Alleviation of Catheter-related Bladder Discomfort in Male Patients after Emergence from General Anesthesia: a Prospective, Randomized Controlled Trial

Xiyue Zhao
Wenzhou Medical University First Affiliated Hospital

Liangrong Wang
Wenzhou Medical University First Affiliated Hospital

Yi Hu
Wenzhou Medical University First Affiliated Hospital

Lei Chen (luckstone009@sina.com)
Wenzhou Medical University First Affiliated Hospital

Research article

Keywords: unilateral ilioinguinal, transversus abdominis plane block, catheter-related bladder discomfort

DOI: https://doi.org/10.21203/rs.2.21364/v2

License: This work is licensed under a Creative Commons Attribution 4.0 International License. Read Full License
Abstract

Background: Urinary catheterization frequently leads to catheter-related bladder discomfort (CRBD) in male patients after general anesthesia. This prospective cohort trial aimed to prove the efficacy of unilateral ilioinguinal transversus abdominis plane block (TAPB) in attenuating CRBD in male patients.

Methods: Male patients with a severe CRBD were randomized to receive unilateral ilioinguinal TAPB with 0.375% ropivacaine 10 mL (group T) or intravenous sufentanil 0.15 µg/kg (group C). The primary outcomes were the incidence rates of moderate-to-severe CRBD at 0.5, 1, 2, and 6 hours after treatment, and the other outcomes were postoperative adverse events related to treatments.

Results: The incidence rates of moderate-to-severe CRBD were significantly lower in group T than in group C at 0.5 hours (11.5% vs 87.4%, P<0.001), 1 hour (7.6% vs 92.3%, P=0.001), 2 hours (7.6% vs 92.3%, P=0.001), and 6 hours (11.5% vs 100%, P<0.001) after treatment. The postoperative incidences of sedation and respiratory depression were decreased significantly in group T compared to group C (P<0.05).

Conclusions: Unilateral ilioinguinal TAPB with ropivacaine can decrease the incidence of moderate-to-severe CRBD and reduce side effects in male patients after general anesthesia compared to intravenous sufentanil administration.

Trial registration: This trial was registered with Clinicaltrials.gov as ChiCTR1900022869 on April 29, 2019, http://www.chictr.org.cn/showproj.aspx?proj=38516.

Introduction

Intraoperative urinary catheterization frequently leads to catheter-related bladder discomfort (CRBD) during the postoperative period, especially in male patients receiving general anesthesia. Different types of surgeries cause CRBD, which occurs predominantly in males with an incidence ranging from 47% to 90%\(^1\). Severe CRBD usually makes the patient agitated, with behavioral responses such as loud complaining, restless extremity movements and attempts to pull out the urinary catheter in the post-anesthesia care unit (PACU)\(^2\).

CRBD is associated with muscarinic receptors, and anticholinergic agents are considered the first line treatment for CRBD\(^3\). However, these medications usually cause dry mouth, facial flushing, and blurred vision. Anesthetics such as sevoflurane, desflurane, tramadol ketamine and dexmedetomidine have also had beneficial effects toward reducing CRBD\(^4,5,6\). However, the administration of these drugs is associated with side effects that may lead to unpleasant complications and decrease the quality of recovery. Hence, new and safer techniques or agents are needed in clinical settings.

With the rapid advancement of nerve blocks in recent years, the dorsal penile nerve block and pudendal nerve block have been demonstrated to be effective in decreasing the incidence and severity of CRBD\(^7,8\).
Moreover, the efficacy of the transversus abdominis plane (TAP) block has been proven in various types of abdominal surgery\(^9\), but reports on the effects of TAPB in CRBD are unavailable. We hypothesized that TAPB could be employed to reduce CRBD in male patients after general anesthesia with fewer side effects.

**Methods**

This prospective, randomized and controlled study was approved by the Research Ethical Committee of the First Affiliated Hospital of Wenzhou Medical University, and written informed consent was obtained from all participants. Before the patients’ enrollment, the trial was registered at the Chinese Clinical Trial Registry (http://www.chictr.org.cn, ChiCTR1900022869; principal investigator: Xiyue Zhao; date of registration: April 29, 2019).

**Patients**

Patients with CRBD after various surgeries performed under general anesthesia between May and September 2019 were enrolled into our study. Specifically, the patients received general anesthesia induction using sufentanil 0.5 mg/kg, propofol 2 mg/kg and rocuronium 0.6 mg/kg, and anesthesia was maintained with propofol and remifentanil in TCI mode under the monitoring of BIS. Intraoperative medications currently known to affect the severity of CRBD, including glycopyrrolate, dexmedetomidine, paracetamol, tramadol and sevoflurane plus desflurane, were avoided. Additionally, the patients had a 16-gauge catheter that had been lubricating with tetracaine-lidocaine gel. After admission to the PACU, the severity of CRBD was evaluated. The inclusion criteria were severe CRBD, adult male, and American Society of Anesthesiologists physical status I–III. The exclusion criteria were a history of urological surgery, renal insufficiency, prostate hyperplasia, bladder outflow obstruction, neurogenic bladder, overactive bladder (>8 times in 24 hours or frequency>3 times in the night), bleeding disorder, or inability to communicate.

**Randomization, concealment, and blinding**

After screening, fifty-two patients were included in our study and randomly divided into the intervention group (group T) and control group (group C) by computer. Patients in group T received unilateral TAPB with 0.375% ropivacaine 10 mL (Ilio-inguinal TAP, near the iliac crest lateral to the anterior superior iliac spine\(^{10}\)), and patients in group C received intravenous sufentanil 0.15 μg/kg (doses of sufentanil administered were converted to intravenous morphine equianalgesic doses according to published conversion factors, with intravenous morphine 10 mg = sufentanil 10 μg = tramadol 100 mg)\(^{11,12}\). The investigator who assessed the severity of CRBD was blinded to the group allocation.

**Outcomes**

The primary outcomes were the incidence of moderate-to-severe CRBD at 0.5, 1, 2, and 6 hours after treatment. All patients were questioned about their symptoms of CRBD by investigators in the PACU and
surgical ward. The severity of CRBD was assessed with a 4-point scale: none (no discomfort when asked); mild (reported by the patient only when asked); moderate (reported by patient without being asked and without any behavioral response); or severe (reported by the patient independently along with behavioral responses such as flailing limbs, strong vocalization, and attempts to remove the catheter). The severity of CRBD was scaled using the methods described above.

Other secondary outcomes were evaluated as follows:

1. Sedation: Postoperative sedation was evaluated by the Ramsay sedation scale, which has been well described. Patients with a sedation scale score >4 were considered sedated.

2. Postoperative nausea and vomiting (PONV): PONV was evaluated with a 4-point ordinal scale from 0 to 3, where 0 meant no nausea, 1 meant mild nausea, 2 meant moderate nausea, and 3 meant severe nausea with vomiting.

3. Respiratory depression: Respiratory depression was defined as oxygen saturation < 90% or respiratory frequency < 8 bpm.

Sample size calculation and randomization

We conducted a pilot study to determine the sample size, and after intervention. With 10 patients per group, CRBD was relieved in 80% of patients in group T and 20% of patients in group C postoperatively. For $\alpha=0.05$ and $\beta=0.90$, 18 patients in each group were required. We estimated a dropout rate of 20%, and 15 patients in each group were needed. We planned to enroll 60 patients, and 26 patients in each group were enrolled.

Statistical analysis

All analyses were conducted using SPSS software (version 17.0). The normality test of the data was performed using the Shapiro-Wilk test, and continuous data with normal distribution are expressed as the mean ± standard deviation (SD), and enumeration data were expressed as a number or ratio. The surgery type, the incidences of moderate-to-severe CRBD, and the side effects in each group were analyzed with the $\chi^2$ test, whereas CRBD severity (none, mild, moderate, or severe) was analyzed by Fisher's exact test. Comparisons of continuous data between two groups were performed by $t$ test. A $P$ value <0.05 was considered significant.

Results

Study population

Sixty-four patients were assessed for eligibility in this study, and 4 patients were excluded (Figure 1). After randomization, 4 patients in both groups were excluded because the patients were not compliant with treatment. Therefore, a total of 52 patients were enrolled and analyzed.
Patient characteristics, types of surgery, durations of surgery and anesthesia, and rates of intraoperative sufentanil, remifentanil and propofol use were similar between groups (Table 1).

**Outcomes**

The incidences of moderate-to-severe CRBD were significantly lower in group T than in group C at 0.5 hours (11.5% vs 87.4%, P<0.001), 1 hour (7.6% vs 92.3%, P=0.001), 2 hours (7.6% vs 92.3%, P=0.001), and 6 hours (11.5% vs 100%, P<0.001) after treatment (Table 2).

There were no differences in PONV in the PACU between the two groups (P>0.05), but the incidences of sedation and respiratory depression were decreased significantly in group T compared with group C (P<0.05) (Table 3).

**Discussion**

This study demonstrated that unilateral ilioinguinal TAPB with ropivacaine can be used as a rescue therapy for severe CRBD in male patients. This approach reduces not only the incidence of moderate-to-severe CRBD but also the occurrence of the side effects associated with opioid analgesic drugs for CRBD, including sedation and respiratory depression.

Anticholinergic drugs such as tolterodine and butylscopolamine are the mainstay of treatment for CRBD, but these muscarinic antagonists usually have several side effects. Newer antimuscarinic drugs, which are selective M3-receptor antagonists, are well established in the management of CRBD. Srivastava et al. found that pretreatment with solifenacin, darifenacin or trospium can reduce the incidence and severity of CRBD with far fewer side effects. However, these drugs cannot be used as emergency measures for postoperative severe CRBD.

Tramadol, which activates μ-opioid receptors and inhibits M1 and M3 muscarinic receptors, is also used to decrease the incidence and severity of CRBD. However, as a rescue medication for severe CRBD, tramadol has a relatively slow onset and easily causes nausea and vomiting. Here, we chose an equivalent dose of sufentanil instead of tramadol as the control medication, which rapidly relieves CRBD, to test our hypothesis that unilateral ilioinguinal TAPB can provide better effects toward reducing CRBD with fewer side effects.

TAPB was first introduced by Rafi as a landmark-based technique via the triangle of Petit in 2001. TAPB has been widely applied in recent years and has become technically easier and safer to perform due to ultrasound guidance. In the field of urology, TAPB has been used as a multimodal analgesic strategy to improve postoperative pain and reduce opioid consumption. Upon analyzing ten randomized clinical trials, De Oliveira GS Jr found that TAPB can reduce pain after laparoscopic surgical procedures. However, there is no evidence supporting the use of TAPB as a rescue technique for CRBD.
Mechanistically, CRBD is mediated by M3 muscarinic receptor activation, which induces involuntary contractions of the bladder detrusor. The bladder receives the pelvic nerves from the S2~S4 spinal nerves and the hypogastric nerves from T11~L1 and L2 spinal nerves; thus, blockage of these nerves would theoretically relieve CRBD. Growing evidence has demonstrated TAPB, which mainly covers T12 and L1, is effective for various abdominal surgeries; however, its analgesic effect is limited to the abdominal wall, and it is less effective in addressing visceral pain. Our present study found that unilateral ilioinguinal TAPB with ropivacaine can have better effects toward decreasing the severity of CRBD than intravenous sufentanil, but the exact mechanisms have been unexplored. The authors suspected that unilateral ilioinguinal TAPB may act by directly blocking the ilioinguinal-iliohypogastric nerve or via permeation of local anesthetics through the transverse abdominis into the transversalis fascia, which spread to the much wider retroperitoneal space that blocks the nerves. Moreover, our results demonstrated that TAPB decreased the severity of CRBD but had no effects on the incidence of CRBD. After TAPB treatment, most patients still complained of mild CRBD. This may imply that the simple TAPB was incomplete. Specifically, it did not block the dorsal penile nerve that covers the glans penis, and extradorsal penile nerve block may be considered as a supplemental therapy. In addition, we found that unilateral ilioinguinal TAPB had a similar desired effect to that of bilateral ilioinguinal TAPB in the preliminary test (data not shown). Thus, we decided to perform unilateral block, which was more convenient and practical. In addition, we found that the incidences of sedation and respiratory depression were significantly decreased in patients who received TAPB, which suggested that TAPB could be a safe therapy for CRBD treatment.

There are some limitations to this study. First, the use of TAPB for alleviation of CRBD was based only on the author’s recent clinical experience and lacked a theoretical foundation. Second, a double-blind assessment could not be achieved due to the completely different route of administration. Third, CRBD predominantly occurs in male patients, and thus, the sample size of female patients who suffered from CRBD was not sufficient. In addition, a few of the patients with severe CRBD in this trial were unable to tolerate the treatment, which may have resulted in treatment failure. Further studies should focus on CRBD prevention.

Conclusions

In summary, unilateral ilioinguinal TAPB with ropivacaine can decrease the incidence of moderate-to-severe CRBD and reduce side effects in male patients after general anesthesia compared to intravenous sufentanil administration.

List Of Abbreviations

CRBD = Catheter-related Bladder Discomfort; ChiCTR = Chinese Clinical Trial Registry; PACU = Post-anesthesia Care Unit; PONV = Postoperative Nausea and Vomiting; SD = Standard Deviation; TAPB = Transversus Abdominis Plane Block.
Declarations

Ethics approval and consent to participate

This study was approved by the ethics committee of the First Affiliated Hospital of Wenzhou Medical University, and written informed consent was obtained from all patients according to international guidelines.

Consent for publication

Not applicable.

Availability of data and materials

The datasets generated and/or analyzed during the current study are not publicly available due to them containing information that could compromise research participant privacy, but they might be made available from the corresponding author on reasonable request.

Competing interests

The authors declare that they have no competing interests.

Funding

This project was supported by Science and Technology Bureau of Wenzhou City, Zhejiang Province, China (No.Y20180565). Funding agencies had no role in the decision-making; design of the study; collection, analysis, or interpretation of data; or the writing of the manuscript.

Authors’ contributions

Study concept and design: XYZ and LC. Acquisition of data: YH and XYZ. Analysis and interpretation of data: LRW. Drafting of the manuscript: XYZ and LRW. Statistical analysis: LC. Administrative, technical, and material support: XYZ and LC. XYZ and LRW are co-first authors and contributed equally to this study. All authors have read and approved the manuscript for publication.

Acknowledgments

We thank Ms. Lina Lin (Department of Anesthesiology, The First Affiliated Hospital of Wenzhou Medical University) for her help in overseeing the project conception.

References


**Tables**

**Table 1. Clinical and Surgical Characteristics**
<table>
<thead>
<tr>
<th></th>
<th>Group T (n=26)</th>
<th>Group C (n=26)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>N</td>
<td>65 ±8</td>
<td>63 ±13</td>
<td>0.573</td>
</tr>
<tr>
<td>N</td>
<td>23.8±2.5</td>
<td>22.6±3.2</td>
<td>0.192</td>
</tr>
<tr>
<td>N</td>
<td>6</td>
<td>6</td>
<td></td>
</tr>
<tr>
<td>N</td>
<td>5</td>
<td>7</td>
<td></td>
</tr>
<tr>
<td>N</td>
<td>15</td>
<td>13</td>
<td></td>
</tr>
<tr>
<td>N</td>
<td>186±22</td>
<td>183±26</td>
<td>0.779</td>
</tr>
<tr>
<td>N</td>
<td>220±24</td>
<td>219±29</td>
<td>0.876</td>
</tr>
<tr>
<td>N</td>
<td>30.1±3.7</td>
<td>32.2±4.5</td>
<td>0.120</td>
</tr>
<tr>
<td>N</td>
<td>1641±445</td>
<td>1857±403</td>
<td>0.072</td>
</tr>
<tr>
<td>N</td>
<td>1311±279</td>
<td>1457±400</td>
<td>0.133</td>
</tr>
</tbody>
</table>

*p* expressed as the mean ± standard deviation. Group T, TAP block; Group C, C.

**Table 2. Severity of Catheter-related Bladder Discomfort**
### Table 2. Incidences of Pain Intensity 0-10

<table>
<thead>
<tr>
<th>Severity of CRBD</th>
<th>Group T (n=26)</th>
<th>Group C (n=26)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Post-treatment hour</td>
<td></td>
<td></td>
<td>0.000</td>
</tr>
<tr>
<td>0.5</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>None</td>
<td>5 (19.2)</td>
<td>0 (0.0)</td>
<td></td>
</tr>
<tr>
<td>Mild</td>
<td>18 (69.2)</td>
<td>4 (15.4)</td>
<td></td>
</tr>
<tr>
<td>Moderate</td>
<td>1 (3.8)</td>
<td>20 (77)</td>
<td></td>
</tr>
<tr>
<td>Severe</td>
<td>2 (7.7)</td>
<td>2 (7.7)</td>
<td></td>
</tr>
<tr>
<td>Post-treatment hour  1</td>
<td></td>
<td></td>
<td>0.001</td>
</tr>
<tr>
<td>None</td>
<td>5 (19.2)</td>
<td>0 (0.0)</td>
<td></td>
</tr>
<tr>
<td>Mild</td>
<td>19 (73.1)</td>
<td>2 (7.7)</td>
<td></td>
</tr>
<tr>
<td>Moderate</td>
<td>1 (3.8)</td>
<td>19 (73.1)</td>
<td></td>
</tr>
<tr>
<td>Severe</td>
<td>1 (3.8)</td>
<td>5 (19.2)</td>
<td></td>
</tr>
<tr>
<td>Post-treatment hour  2</td>
<td></td>
<td></td>
<td>0.001</td>
</tr>
<tr>
<td>None</td>
<td>5 (19.2)</td>
<td>0 (0.0)</td>
<td></td>
</tr>
<tr>
<td>Mild</td>
<td>19 (73.1)</td>
<td>2 (7.7)</td>
<td></td>
</tr>
<tr>
<td>Moderate</td>
<td>1 (3.8)</td>
<td>19 (73.1)</td>
<td></td>
</tr>
<tr>
<td>Severe</td>
<td>1 (3.8)</td>
<td>5 (19.2)</td>
<td></td>
</tr>
<tr>
<td>Post-treatment hour  6</td>
<td></td>
<td></td>
<td>0.000</td>
</tr>
<tr>
<td>None</td>
<td>2 (7.7)</td>
<td>0 (0.0)</td>
<td></td>
</tr>
<tr>
<td>Mild</td>
<td>21 (80.8)</td>
<td>0 (0.0)</td>
<td></td>
</tr>
<tr>
<td>Moderate</td>
<td>1 (3.8)</td>
<td>21 (80.8)</td>
<td></td>
</tr>
<tr>
<td>Severe</td>
<td>2 (7.7)</td>
<td>5 (19.2)</td>
<td></td>
</tr>
</tbody>
</table>

Data are expressed as numbers (%). Group T, TAP block; Group C, intravenous sufentanil. Data were compared using the χ² test or Fisher's exact test.

### Table 3. Incidences of Side Effects

<table>
<thead>
<tr>
<th>Side Effect</th>
<th>Group T (n=26)</th>
<th>Group C (n=26)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Postoperative nausea and vomiting</td>
<td>1 (3.8)</td>
<td>3 (11.5)</td>
<td>0.610</td>
</tr>
<tr>
<td>Respiratory depression</td>
<td>0 (0.0)</td>
<td>8 (30.8)</td>
<td>0.002</td>
</tr>
<tr>
<td>Sedation</td>
<td>0 (0.0)</td>
<td>7 (26.9)</td>
<td>0.005</td>
</tr>
</tbody>
</table>

Data are expressed as numbers (%). Group T, TAP block; Group C, intravenous sufentanil.

---

**Figures**
Figure 1

CONSORT 2010 Flow Diagram

Supplementary Files

This is a list of supplementary files associated with this preprint. Click to download.

- BLVZGN8FtobeeditedCONSORT2010Checklist.doc