ORIGINAL ARTICLE

The Feasibility of Spermatic Cord Block for Bilateral Orchiectomy in Metastatic Prostate Cancer: A Randomized Controlled Trial

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Background: Prostate cancer is the second most common cancer in elderly males worldwide. Orchiectomy is one of the standard treatments, typically performed under spinal anesthesia (SA) or general anesthesia (GA). However, elderly patients often have underlying conditions, which increase perioperative cardiac risks. Spermatic cord block (SCB) is a feasible alternative, but studies comparing its pain outcomes and safety are lacking.

Objective: To compare intraoperative pain scores, morphine consumption at 6- and 12-hours postoperative intervals, and postoperative complications between SA and SCB.

Materials and Methods: The present study was a randomized controlled trial that included prostate cancer patients undergoing orchiectomy between June and December 2023. Patients were randomized into SA and SCB groups. Data were analyzed using the independent t-test and Fisher's exact test.

Results: Eighteen male patients were studied. In the SA group, the mean age was 73.67 years, body mass index (BMI) was 22.29 kg/m^2, and operative time was 30.33 minutes. In the SCB group, the mean age was 73.44 years, BMI was 21.46 kg/m^2, and operative time was 31.11 minutes. The mean pain scores during surgery and 1 hour postoperatively were 0 (0) and 0.33 (1) in the SA group and 0 (0) in the SCB group, with no significant difference (p=1 and 0.347, respectively). Morphine consumption at 6- and 12-hours postoperative intervals was 1.67 (1.5) and 3 (2.69) mg in the SA group, and 1.22 (0.97) and 1.33 (1.12) mg in the SCB group (p=0.466 and 0.115, respectively). No postoperative complications were observed.

Conclusion: There were no significant differences in intraoperative pain scores, postoperative opioid consumption, or complications between SA and SCB. SCB appears to be a safe and effective alternative for bilateral orchiectomy in appropriately selected patients.

Keywords: Spermatic cord block; SCB; Bilateral orchiectomy; Prostate cancer; Pain score; Spinal anesthesia; Local anesthesia; Pain management; Randomized controlled trial

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Prostate cancer is the second most common cancer in elderly males worldwide[1]. Orchiectomy surgery is one of the standard treatments for prostate cancer[2]. This procedure usually requires spinal anesthesia (SA) or general anesthesia (GA). However, anesthesia in elderly patients with underlying medical conditions might increase the risk of perioperative major adverse cardiac events. Spermatic cord block (SCB) is feasible but not widely popular due to lack of studies comparing pain score and safety aspects[3].

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Objective

The objective is to compare intraoperative pain score, morphine consumption at 6- and 12-hours after surgery, and postoperative complications between SA and SCB groups.

Materials and Methods

The present study was a randomized controlled trial, approved by the Ethics Committee of Sunpasitthiprasong Hospital, project code 026/66C, collected data from prostate cancer patients who underwent orchiectomy at the authors' institution between June and December 2023. The present

study protocol was registered at the ClinicalTrials.gov, NCT06313775. Patients were randomly divided into two groups, SA and SCB. Data were collected on intraoperative pain score, 1-hour post-surgery, morphine consumption at 6- and 12-hours after surgery and complications. All data were statistically analyzed using independent t-test and Fisher's exact test.

Inclusion criteria

Patients of all ages that have been diagnosed with prostate cancer undergoing treatment with bilateral orchiectomy.

Exclusion criteria

1. Patients with a history of Xylocaine allergy
2. Patients with uncorrected bleeding disorders
3. Patients with paralysis or neurosensory deficits
4. Patients with dementia or cerebrovascular accidents such as strokes that impair communication.
5. Patients with contraindications for spinal anesthesia, including:

- Patient refusal of SA
- Infection at the site of spinal injection
- Allergy to specific types of local anesthetics, such as hyperbaric bupivacaine
- Inability of the patient to cooperate with the spinal anesthetic procedure
- Suspicion of high intracranial pressure based on abnormal physical examination.
- Aortic stenosis with fixed cardiac output
- Low platelet count

Study protocol

All patients participating in the present study were treated as inpatients at Sunprasittiprasong Hospital. The preparation for patients before surgery included the following:

1. Pre-operative evaluation:

- Fasting for at least eight hours prior to surgery (NPO)
- Administration of intravenous fluids during the fasting period
- Basic blood tests before surgery for complete blood count, blood urea nitrogen, creatinine, and electrolytes
- Chest X-ray using plain film, and electrocardiogram (ECG)

2. Patients will be randomized into two groups, one group receiving SA and the other group receiving local anesthesia at the spermatic cord.
3. SA administration guidelines:

- Equipment: 27-gauge spinal needles (BD® Quincke spinal needles 27G)
- Anesthetic agent: 0.5% hyperbaric bupivacaine 10 to 15 mg/dose to achieve T6 dermatome level
- Injection site: Spinal location at L3-L5 using aseptic technique
- Management of hypotension: If hypotension occurs during SA, consider administering vasoactive drugs such as epinephrine, norepinephrine, or ephedrine.
- Supplemental pain management: If SA was ineffective or if the patient experienced moderate to severe surgical pain, with a pain score of 4 to 10, additional analgesics such as fentanyl 1 to 2 mcg/kg/dose or ketamine 0.5 to 1 mg/kg/dose may be given.
- Failure of SA: In the case of SA failure, consider switching to GA. Patients who require this change will be withdrawn from the study, counted as dropout.

4. SCB administration guidelines[4]:

- Anesthetic agent: 1% Xylocaine with adrenaline, maximum 7 mg/kg/dose
- Injection site: Spermatic cord on both sides. The spermatic cord can be located by palpating approximately 1 cm medial and 1 cm inferior to the pubic tubercle. Once identified, the cord should be gently stabilized between the fingers. Using a 24-gauge needle, inject 6 to 8 mL of local anesthetic directly around the spermatic cord. Take care to avoid injury to nearby blood vessels. Always aspirate before injection to ensure the needle is not intravascular[5]. To prevent nerve injury, after needle insertion into the spermatic cord, the patient should be asked whether they experience any sudden tingling sensation or electric shock-like pain, which may indicate direct nerve contact[6,7]. The use of a blunt-tip needle may help reduce the risk of nerve injury, however, in this study, blunt-tip needles were not used due to lack of availability[8,9]. Repeat on the other side. Additionally, inject 3 to 4 mL of the prepared anesthetic into the skin at the surgical site and wait for three to five minutes.
- Testing anesthesia: Test sensation in the scrotum compared to a normal area. If the patient still experiences pain in the scrotum, consider increasing the dose, not exceeding 7 mg/kg/dose, and retest before beginning surgery.
- Supplemental pain management: During surgery, if the patient experiences moderate to severe pain, with a pain score of 4 to 10, administer

additional analgesics such as fentanyl 1 to 2 mcg/kg/dose or ketamine 0.5 to 1 mg/kg/dose.

- Failure of SCB: If the SCB was ineffective, consider switching to GA. Patients requiring this change will be withdrawn from the study, and counted as dropout.

5. Monitoring during pain management and surgery: The patient's vital signs will be monitored every five minutes as per standard protocol.

6. Surgical procedure for bilateral orchiectomy: The surgical incision is made in the median raphe with a single vertical midline incision. Monopolar electrocauterization is used to isolate the vas deferens and spermatic vessels, which are then ligated using silk 2-0 sutures. The surgical wound is closed with absorbable sutures 3-0. A single surgeon performed the entire procedure.

7. Post-surgical pain assessment: After surgery, patients assessed their overall pain level using the verbal numerical rating scale (VNRS) immediately after the procedure and again one hour later in the post-anesthesia care unit (PACU). The pain assessments during and after surgery were conducted by a team of nurse anesthetists who were blinded to the anesthesia method used and were not involved in the research study.

8. Post-operative care: All patients will receive patient-controlled analgesia (PCA) for pain management, with the following setting, a PCA dose of 1 mg per bolus, a lockout interval of five minutes, and a maximum limit of 10 mg per hour, and opioid consumption will be recorded at 6- and 12-hours post-surgery. Complications occurring post-operatively will also be assessed, including complications from SA, such as acute urinary retention and neurological complications such as radiculopathy, neurological deficits, cauda equina syndrome, or paraplegia, within 24 hours before discharge from the inpatient unit.

Intervention

All patients participating in the present study were treated as inpatients at Sunprasittiprasong Hospital. Preoperative preparation was conducted for GA. Patients were then randomized into two groups, one receiving SA and the other receiving local anesthesia via SCB.

Anesthetic techniques:

- SA: Administered using 0.5% hyperbaric bupivacaine at a dose of 10 to 15 mg to achieve a T6 dermatome level[10].

- SCB: Performed using 1% Xylocaine with adrenaline, with 6 to 8 mL injected on each side at the spermatic cord while carefully avoiding blood vessels. Additionally, 3 to 4 mL was injected at the incision site. Awaiting period of three to five minutes was observed before testing for anesthesia[4,11].

If hypotension occurred during SA, vasoactive drugs were administered as needed.

Pain management and anesthesia failure protocol:

- Supplemental pain management: If SA or SCB was ineffective, or if patients experienced moderate to severe surgical pain with a pain score of 4 to 10, additional analgesics such as fentanyl with 1 to 2 mcg/kg/dose or ketamine with 0.5 to 1 mg/kg/dose were administered.

- Anesthesia failure: If SA or SCB failed, GA was initiated. Patients requiring this transition were withdrawn from the study and counted as dropout.

Surgical procedure: All patients underwent a simple bilateral orchiectomy, performed by the same surgeon[12].

Postoperative monitoring and pain assessment:

- Vital signs monitoring: Recorded every five minutes as per standard protocol.

- Pain assessment: Patients evaluated their pain levels using the VNRS[13] immediately after the procedure and again one hour later in the PACU.

- Pain management: All patients received PCA for pain control. Opioid consumption was recorded at 6- and 12-hours postoperative intervals.

- Postoperative complications: Assessed for any complications, particularly those related to SA, such as acute urinary retention and neurological complications such as radiculopathy, neurological deficits, cauda equina syndrome, or paraplegia. Complications were monitored within 24 hours before discharge from the inpatient unit.

Outcome

Primary outcome measure: Intraoperative pain score assessed immediately postoperatively.

Secondary outcome measures:

1. One-hour post-operative pain score
2. 6- and 12-hours post-operative morphine consumption
3. Twenty-four-hour post-operative complications

Sample size

The sample size was calculated using the n4Studies application for a non-inferiority trial with continuous outcome variables. The assumptions included standard deviation of 3.01, non-inferiority margin of 0.1, expected mean difference of 3.789[11],

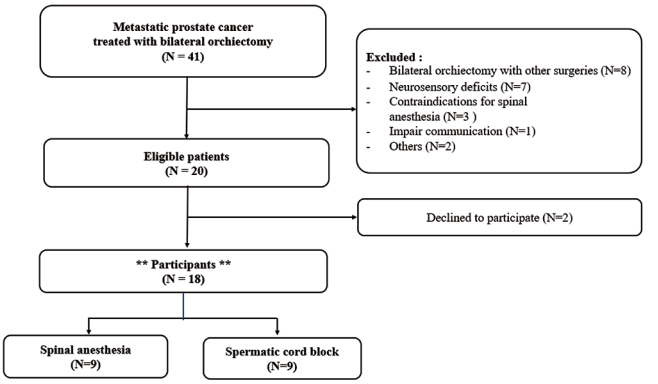

Figure 1. Participant flow.

one-sided alpha level of 0.05, and power of 80%. According to the formula below:

$$n_1 = \kappa n_2, \text{ and}$$
$$n_2 = \frac{(z_\alpha + z_\beta)^2 \, \sigma^2 \, (1 + 1/\kappa)}{(\varepsilon - \delta)^2}$$

Based on the calculations, the total sample size was 18 people, equally divided with nine in the control group and nine in the experimental group[14].

Randomization

Simple random sampling: The researchers would prepare sealed envelopes equal to the sample size in each group, divided into those receiving SA and those receiving local anesthesia at the spermatic cord. The envelopes were opened on the morning of the surgery by individuals who were not involved in evaluating the research outcomes.

Statistical analysis

Demographic data were analyzed using descriptive statistics, including frequency, percentage, mean and standard deviation. Analytical statistics were used to compare the SA and SCB groups. An independent t-test was applied for continuous data, while the Fisher's exact test was used for categorical data. A p-value of less than 0.05 was considered statistically significant.

Results

Participant flow

Forty-one patients were assessed, as shown in Figure 1, with 21 excluded for various reasons. Of the 20 eligible patients, two declined to participate. The remaining 18 patients were equally allocated to the SA group with nine participants and the SCB group, also with nine participants.

Table 1. Demographic data

	Spinal anesthesia (n=9)	Spermatic cord block (n=9)	p-value
Age (years); mean±SD	73.67±2.96	73.44±9.34	0.947
Body weight (kgs); mean±SD	58.44±20.18	56.89±12.7	0.847
Height (cm); mean±SD	160.67±10.45	162.22±6.36	0.708
BMI (kg/m^2); mean±SD	22.29±5.84	21.46±3.78	0.722
Underlying disease; n (%)	2 (22.2)	5 (55.6)	0.335
DM	0 (0.0)	2 (22.2)	0.471
HT	0 (0.0)	3 (33.3)	0.206
CKD	1 (11.1)	1 (11.1)	1
OSA	1 (11.1)	0 (0.0)	1
DLP	0 (0.0)	1 (11.1)	1
COPD	0 (0.0)	1 (11.1)	1
Gleason grade group; n (%)			
1	0 (0.0)	1 (11.1)	1
2	2 (22.2)	1 (11.1)	1
3	2 (22.2)	2 (22.2)	1
4	0 (0.0)	1 (11.1)	1
5	5 (55.6)	4 (44.4)	1
Volume of metastasis; n (%)			
Low volume	5 (55.6)	2 (22.2)	0.335
High volume	4 (44.4)	7 (77.8)	0.335
Prior ADT; n (%)			
No ADT	7 (77.8)	8 (88.9)	1
Received ADT	2 (22.2)	1 (11.1)	1

BMI=body mass index; DM=diabetic mellitus; HT=hypertension; CKD=chronic kidney disease; OSA=obstructive sleep apnea; DLP=dyslipidemia; COPD=chronic obstructive pulmonary disease; ADT=androgen deprivation therapy; SD=standard deviation

Recruitment

Single center: Sunprasittiprasong Hospital. Data was collected between June and December 2023.

Baseline data

The baseline demographic and clinical characteristics of the SA and SCB groups were

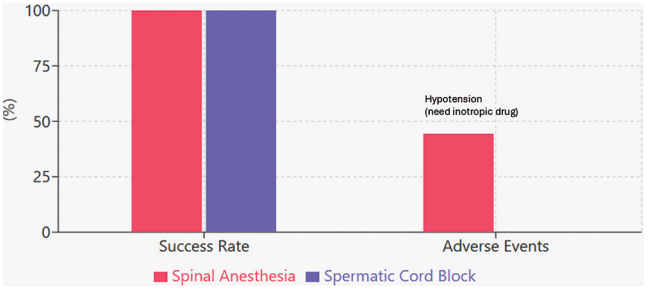

Figure 2. Success rate of surgery and intraoperative adverse event.

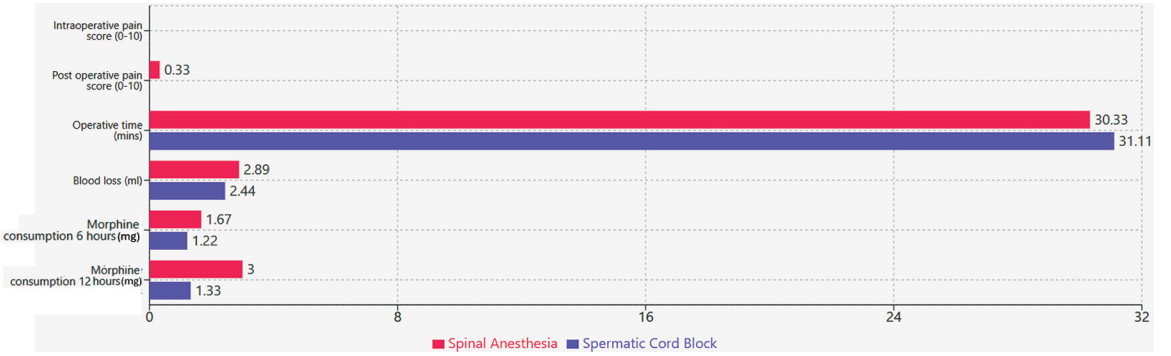

Figure 3. Outcomes.

comparable (Table 1). The mean age of participants was similar between the groups at 73.67±2.96 versus 73.44±9.34 years (p=0.947). Other demographic parameters, including body weight, height, and body mass index (BMI), also did not differ significantly with p-values ranging from 0.708 to 0.847. Although the overall prevalence of comorbidities was higher in the SCB group, at 55.6%, compared to the SA group, at 22.2%, this difference was not statistically significant (p=0.335). Specifically, hypertension and diabetes mellitus were more commonly observed in the SCB group at 33.3% and 22.2%, respectively. Additionally, no significant differences were found between the groups regarding Gleason grade, volume of metastasis, or prior androgen deprivation therapy (all p≥0.335), indicating well-balanced baseline characteristics.

Perioperative and post operative outcomes

The perioperative measures showed that SA patients received an average of 2.87±0.1 mL of 0.5% hyperbaric bupivacaine, while patients in the SCB group received 17.11±1.83 mL of 1% Xylocaine with adrenaline. This difference reflects the distinct medications used in each group. There were no significant differences between the two groups in terms of operative time (p=0.859) or blood loss (p=0.612), indicating that the procedures were similar in both groups. The success rate of surgery was 100% in both groups as shown in Figure 1. Intraoperative pain scores were also identical, with both groups reporting a score of 0, and no additional pain medication or conversion to GA was required.

However, a notable difference occurred in the incidence of hypotension requiring inotropic drug intervention, which was observed in 44.44% of patients in the SA group but not in the SCB group. This suggested that SA may carry a higher risk of hypotension compared to SCB as shown in Figure 2.

Post-operative outcomes revealed that the post-operative pain scores were low in both groups, with no significant difference between them (p=0.347). The amount of morphine consumed within six hours and twelve hours after surgery was also similar between groups, with no significant differences in opioid use (p=0.466 and 0.115, respectively) as shown in Figure 3.

Regarding complications, there were no scrotal hematomas, infections, or neurological complications in either group. However, there were specific complications related to the anesthesia technique. In the SA group, two patients (22.2%) experienced

acute urinary retention, a known complication of SA. Conversely, no complications were noted in the SCB group, though there was one case of spermatic cord hematoma and vascular injury.

Discussion

Orchiectomy is a common surgical procedure performed for various indications, including testicular cancer, androgen deprivation therapy for prostate cancer, and severe testicular trauma[15]. Adequate perioperative analgesia is crucial for patient comfort, reduced opioid consumption, and improved postoperative recovery. Local anesthetic blocks have gained popularity as an adjunct or alternative to GA in orchiectomy due to their efficacy in pain control, reduced side effects, and potential benefits in outpatient settings[4,16].

The present study results comparing bilateral orchiectomy performed under SA and SCB showed that the pain score was 0 in both groups, with no statistically significant difference (p=1, 95% CI 0). This is consistent with the fact that the anatomy of the testis and scrotum is innervated by the ilioinguinal, genitofemoral, and pudendal nerves, which originate from the L1-L2 and S2-S4 nerve roots. When the nerves supplying the scrotum and testis are blocked at any location, it can lead to successful surgery. In SA, the blockade occurs at the level of the T6 dermatome. Below the T6 dermatome, both motor and sensory functions are completely blocked. During a SCB, the ilioinguinal nerve and the genital branch of the genitofemoral nerve, located in the spermatic cord, are blocked. Additionally, infiltration is performed at the scrotal skin incision site to block the posterior scrotal nerves that originate from the perineal nerve, and the perineal branch of the posterior cutaneous nerve of the thigh. These findings suggest that there is supporting evidence indicating no difference in pain levels during surgery between the two groups. Furthermore, although there were no statistically significant differences between groups in morphine consumption after surgery, the difference at 12 hours postoperatively approached significance (p=0.115), indicating a trend. Operative time and estimated blood loss were similar between the two groups.

A notable finding in the present study is the significantly higher incidence of intraoperative hypotension in the SA group, at 44.4%, compared to none in the SCB group. This difference reflects a well-recognized complication of SA, which causes sympathetic blockade leading to vasodilation and decreased systemic vascular resistance, resulting in hypotension[17]. This is especially concerning for elderly patients or those with cardiovascular comorbidities, as intraoperative hypotension has been associated with increased risks of myocardial injury, stroke, and mortality in high-risk populations[18,19]. In contrast, SCB provides localized anesthesia without significant autonomic involvement, thereby preserving hemodynamic stability. This advantage suggests that SCB may be a safer alternative for patients at risk of hemodynamic compromise, particularly in outpatient or resource-limited settings where managing hypotension may be more challenging.

A previous study on the results and safety of orchiectomy under SCB by Saelim et al. reported a success rate of 94.74%. Most patients (52.63%) experienced moderate pain, while 10.53% reported severe pain and required conversion to GA. No immediate postoperative complications were observed[11]. These findings are consistent with the present study, which also supports the idea that orchiectomy can be performed under SCB. However, a key difference is that the study by Saelim et al. focused solely on patients receiving SCB, whereas the present study compared pain levels between the two groups, those receiving SA and those receiving SCB. In both groups, the intraoperative pain score was 0, and no immediate complications occurred. Additionally, the present study evaluated morphine consumption as an objective indicator to support subjective pain score data. The protocol also allowed for additional pain medication before considering conversion to GA, ensuring patient comfort during the procedure. Another difference is the choice of local anesthetic. Xylocaine was used in the present study due to its short duration of action, lower systemic toxicity, and suitability for minor procedures with short operative times[5,20]. It was also selected for its wide availability across all levels of healthcare facilities.

Despite the benefits, there are challenges and limitations associated with the use of local anesthetic blocks. One of the primary concerns is the variability in the success of the block, which depends on clinician expertise, anatomical variations, and appropriate technique. Incomplete blocks may necessitate supplemental anesthesia or analgesia, potentially diminishing the intended benefits. Furthermore, while complications from local anesthetic blocks are rare, potential risks such as hematoma, infection, and nerve injury must be considered.

One limitation of the present study is the inability

to implement a double-blind design, due to differences in the methods of anesthesia administration, variations in anesthetic level testing, and the inherent distinctions between the two techniques. Another limitation is the insufficient sample size, which limits the ability to draw statistically significant conclusions regarding the equal effectiveness of both methods. Future research should consider increasing the sample size to improve the power to detect meaningful differences between groups.

In conclusion, local anesthetic blocks represent a valuable option for analgesia in orchiectomy, offering effective pain relief, reduced opioid consumption, and enhanced recovery. While challenges exist, the benefits outweigh the risks, making these techniques a promising avenue for improving perioperative care in orchiectomy patients.

What is already known about this topic?

Orchiectomy surgery is one of the standard treatments for prostate cancer. This procedure is usually required for SA or GA. However, elderly patients with underlying medical conditions have an increased risk of perioperative major adverse cardiac events. SCB is feasible but not widely popular due to a lack of studies comparing pain score and safety aspects.

What does this study add?

This study found that a SCB provided pain relief during orchiectomy comparable to that of SA. Additionally, no surgical complications were observed, suggesting that orchiectomy can be safely performed using a SCB.

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The present research did not receive any funding.

Conflicts of interest

The authors declare no conflict of interest.

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