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ORIGINAL RESEARCH REGIONAL ANESTHESIA

# A randomized controlled trial comparing the recovery time after spinal anesthesia with 2% hyperbaric prilocaine 50 mg vs. 0.5% hyperbaric bupivacaine 12.5 mg for cystoscopic procedures

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## ABSTRACT

**Background:** Cystoscopy is a urologic procedure performed as a diagnostic or a therapeutic intervention, usually requiring spinal anesthesia (SA). Bupivacaine is a frequently used spinal anesthesia agent. However, the prolonged duration of its effect is a disadvantage. Prilocaine may be an alternative for spinal anesthesia in cystoscopy, which has a shorter duration of action compared to bupivacaine. We compared recovery time of 2% hyperbaric prilocaine 50 mg vs. 0.5% hyperbaric bupivacaine 12.5 mg for cystoscopic procedures under spinal anesthesia.

**Methods:** This study was a randomized controlled trial involving 66 patients who underwent cystoscopy in Dr. Cipto Mangunkusumo National General Hospital under SA. Subjects were randomized into two groups, i.e. prilocaine group to receive SA with hyperbaric prilocaine 2% 50 mg + fentanyl 25 µg and bupivacaine group to receive hyperbaric bupivacaine 0.5% 12.5 mg + fentanyl 25 µg. Following SA, the time to lift the leg 45 degrees and time to regain the ability to walking unsupported were noted in both groups and statistically compared. Hemodynamic changes in SpO2 and NIBP at fixed periods, as well as adverse effects were recorded.

**Results:** Hemodynamic changes and adverse effects were comparable between the two groups. The mean time to lift a leg 45 degrees (93.88 min vs. 180.36 min; $P < 0.001$) and the time until the patient walked (144.91 min vs. 259.76 min; $P < 0.002$) were significantly short in the prilocaine group. The mean regression time for prilocaine and bupivacaine SA was $69.36 \pm 35.85$ and $131.88 \pm 79.43$ min respectively; the difference being significant ($P < 0.001$).

**Conclusion:** Hyperbaric prilocaine 2% has a shorter recovery period when compared to hyperbaric bupivacaine 0.5% for spinal anesthesia and is appropriate for the length of the cystoscopy, making it a viable spinal anesthetic option.

**Keywords**: Bupivacaine; Cystoscopy; Prilocaine; Anesthesia, Spinal; Recovery Time

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## 1. INTRODUCTION

Cystoscopy is a short surgical procedure in the field of urology that is very frequently performed. In the United States, approximately 173,000 women and 286,000 men underwent cystoscopic procedures in 2014.[1] Most of the cystoscopy procedures are performed for diagnostic purposes but can also be performed for therapeutic purposes, with a procedure duration of

 

between 60-90 min. At the time of cystoscopy, the patient will feel mild-moderate pain and discomfort that requires anesthesia.[2,3] Spinal anesthesia (SA) is the choice because it has an easy implementation technique, fast onset, and low complications compared to general anesthesia.[4]

SA as a form of regional anesthesia has been widely used in short surgical procedures, including cystoscopy. SA has several advantages compared to general anesthesia, including reduced stay in the post-anesthesia care unit (PACU), as well as better postoperative pain and less nausea / vomiting.[5] The short recovery time for SA allows patients to go home immediately after the procedure.[6]

One of the spinal anesthetic regimens often used is 0.5% hyperbaric bupivacaine with a two-segment regression time of around 65 min and requires 164 min for complete regression to the sacral dermatomes. A systematic review by Nair et al., showed that the patient's recovery time ranged from 180-240 min, calculated from anesthesia until the patients were ready to go home.[7] Bupivacaine, when used for relatively short procedures, causes various disadvantages including prolonged effects.

Hypotension after SA is a side effect of concern and is associated with myocardial infarction and decreased cerebral blood flow, especially in geriatric patients.[8] The incidence of hypotension after SA using bupivacaine is reported to be quite high but varies. Reports in Thailand showed an incidence of hypotension to be 57.9% after bupivacaine SA.[9,10] Based on data from Anesthesia Sprint Audit of Practice-2 (ASAP-2) in England in 2016, perioperative hypotension was associated with postoperative mortality in 10,489 cases of hip surgery with spinal anaesthesia.[11]

Prilocaine is an alternative to bupivacaine in short surgical procedures, including cystoscopy. It has a profile similar to lidocaine, but with less neurotoxicity.[12] The Camponovo study demonstrated a relatively short onset of sensory block in 2% hyperbaric prilocaine. Similar results were also seen in the onset of prilocaine motor blockade, where the onset of motor blockade with a Bromage score ≥ 2 was achieved at 8 ± 5 min and 8 ± 3 min after administration of 2% hyperbaric prilocaine doses of 40 mg and 60 mg respectively.[13] Prilocaine 2% hyperbaric in a dose of 40-60 mg can provide a block to T10 dermatome for 100-130 min.[14,15] Therefore, hyperbaric prilocaine doses above 40 mg are suitable for cystoscopic surgery.

Data regarding the comparison of SA recovery time between prilocaine and bupivacaine is still relatively limited. This study compared the recovery time for SA with hyperbaric prilocaine 2% 50 mg compared to hyperbaric bupivacaine 0.5% 12.5 mg in cystoscopy procedure.

# 2. METHODOLOGY

This study was a double-blind, randomized clinical trial. This study compared the recovery time of SA with 2% hyperbaric prilocaine 50 mg compared to 0.5% hyperbaric bupivacaine 12.5 mg for cystoscopic procedures. The research was conducted in the urology operating room of Dr. Cipto Mangunkusumo National General Hospital from May to October 2022.

The study protocol was carried out in accordance with the relevant guidelines and regulations and was approved by the Ethics Committee of Medical Faculty, the University of Indonesia (KET-1158/UN2.F1/ETIK/PPM.00.02/2021). It was registered at ClinicalTrial.gov (NCT05610007). Informed consent for study participation was obtained from all patients and/or their legal guardian(s). Guidelines of the Helsinki Declaration were adhered to during the informed consent and data acquisition period.

Patients of both genders, over the age of 18, ASA physical status I-III, normal body mass index according to Quetelet's index, willing to participate in the research, and compliance with research rules were included according to the consecutive sampling method. Patients with a history of allergy to a study drugs, a history of impaired gait before, and contraindications to SA, were excluded. Patients were dropped out / excluded if they developed complications of SA, such as shock, anaphylactic reaction, seizures, severe respiratory distress, or failure of SA technique. Also if a duration of action extended to more than 90 min, circumstances during surgery requiring special measures, such as active bleeding and ruptured bladder, the concerned patients were excluded.

## Sample size calculation

The combined standard deviation can be determined from previous studies regarding the recovery time of prilocaine compared to bupivacaine[15] SA, and is calculated by the following formula:

$$Sg^2 = \frac{S_1{}^2(n_1 - 1) + S_2{}^2(n_2 - 1)}{n_1 + n_2 - 2}$$

Sg = combined standard deviation
$s_1$ = standard deviation of recovery time in the prilocaine group
$s_2$ = standard deviation of recovery time in the control group
$n_1$ = the sample size of the prilocaine group
$n_2$ = the sample size of the control group

 

We determined that the sample size per group was 30 subjects. By estimating a drop out of 10%, this study required a minimum of 33 subjects per group.

### Procedures

The selected patients were given a number in the order of the patient's arrival. Randomization was carried out by block randomization followed by concealment using the sequentially numbered, opaque, sealed envelope (SNOSE) technique. The envelopes were opened by the chief anesthesiologist on duty in the patient's operating room after the patient agreed to participate.

The patient and the patient's family were asked to do an hourly assessment and record the time the patient could lift his leg 45 degrees and the time the patient could walk after the procedure.

Patients age, height, and weight were recorded. Patients were allocated into one of the two groups. Bupivacaine Group received 0.5% bupivacaine hyperbaric (2.5 ml) + fentanyl 25 µg (0.5 ml) and Prilocaine Group received hyperbaric 2% prilocaine (2.5 ml) + fentanyl 25 µg (0.5 ml).

The syringe containing the drug was placed in a sterile aluminum box with a lid and labeled with the patient's name, participant number, and the patient's medical record number. The SA was performed by a blinded anesthesiologist.

In the operating room, after routine preparation, the patient was positioned sitting. The injection site was identified in the L4-5 intervertebral space, prepped and the dura was punctured with a 27G spinal needle. After confirming free flow of cerebrospinal fluid, the research drug was injected. Immediately after the injection, the patient's position is changed to a flat supine position using a pillow under the head. Blood pressure, pulse rate, respiratory rate and oxygen saturation were monitored every 3 min for the first 15 min. In case of hypotension, ephedrine 5 mg was given repeatedly until the mean arterial pressure returned to the basal value. If the hypotension persisted, the patient was resuscitated with fluids and vasopressors, and excluded from the study.

The researchers recorded the maximal sensory block height achieved by using the pinprick test. Pain was assessed during the cystoscopic procedure, using VAS 0-10 (0 = no pain, 10 = very severe pain). Fentanyl 25 µg IV was used if VAS > 3. Five min later VAS pain was reassessed, if it has not decreased < 3, then additional fentanyl 25 µg was given until the patient felt comfortable. A failed spinal needed fentanyl 1 µg/kg IV, repeated as needed and propofol 1 mg/kg IV bolus followed by 25 µg/kg/min IV drip. Total analgesic use was recorded and included in the analysis. The time taken for the surgical procedure was recorded and the patient sent to the recovery room. Time to lift the leg by 45 degrees at the hip joint and the time the patient could walk were recorded. The sensory level was assessed every 15 min, as well as side effects such as hypotension, nausea, vomiting, chills, and pain.

### Statistical analysis

The basic characteristics of the patients are described in the form of frequency tables, mean distributions and standard deviations. Maximum sensory block height data and the side effects data are displayed in the form of frequency and percentage tables. The patient's ambulation time and recovery time data are displayed in the form of a distribution table of the mean and standard deviation. Data that has been evaluated for completeness wase coded, processed, and analyzed using the SPSS version 20 program.

The research establishes a two-way hypothesis, with an $\alpha$ value of 5%, $\beta$ of 10%, and a significant $P < 0.05$. Data analysis used an unpaired comparative-numeric type design. The mean comparison between the two groups was seen using the unpaired T-test if the data followed a normal distribution. In contrast, if the data distribution was not normal, the Mann-Whitney test was used. Comparisons in the two groups of categorical data were tested by Chi-square, Fisher, or Kolmogorov-Smirnov tests.

## 3. RESULTS

This study obtained 66 samples of patients who underwent cystoscopy. Patients, who met the inclusion criteria, were randomly selected and divided into two study groups.

The number of study subjects in the prilocaine group and the bupivacaine group was 33 people each. No subjects were excluded or dropped out, so the number of research subjects who qualified to be analyzed was 33 in each group. The demographic characteristics of the subjects are shown in Table 1.

Time to maximum sensory level achieved with hyperbaric prilocaine and hyperbaric bupivacaine are given in Table 2. The median time for prilocaine and bupivacaine groups were 11.00 and 12.00 min, respectively.

The recovery time for SA with hyperbaric prilocaine 2% 50 mg and hyperbaric bupivacaine 0.5% 12.5 mg in this study was assessed from the time the patient could lift his leg by 45 degrees and the time it took for the patient to walk. The mean time to lift the leg 45 degrees (93.88 min vs. 180.36 min) and the time until the patient walked (144.91 min vs. 259.76 min) were significantly more in the bupivacaine group ($P < 0.05$) (Table 2).

 

**Table 1: Comparative demographic characteristics of the subjects**

| Variable | Prilocaine group (n = 33) | Bupivacaine group (n = 33) |
|---|---|---|
| Age (y) | 45.61 (13.53) [a] | 46.94 (9.22) [a] |
| Sex | | |
| Male | 10 (30.30%) | 11 (33.33%) |
| Female | 23 (69.70%) | 22 (66.67%) |
| BMI (kg/m$^2$) | 23.10 (4.11) [a] | 22.99 (4.27) [a] |
| ASA | | |
| 1 | 3 (9.09%) | 1 (3.03%) |
| 2 | 20 (60.61%) | 17 (51.52%) |
| 3 | 10 (30.30%) | 15 (45.45%) |
| Procedure duration [c] (min) | 40.00 (15.00-90.00) [b] | 55.00 (30.00-90.00) [b] |

*[a] Normal data distribution is stated in mean (SD); [b] Abnormal data distribution is stated in median (Min-Max); [c] Time was assessed from the time SA was completed.*

Most of the study subjects achieved the maximum sensory level to T6, e.g., 42.42% vs. 48.48% in the prilocaine group and the bupivacaine group (Table 3).

The sensory level gains of SA with 2% 50 mg hyperbaric prilocaine and 0.5% 12.5 mg hyperbaric bupivacaine at the end of cystoscopy in this study can be seen in Table 3. Most of the subjects in the prilocaine group reached sensory level at the T10 level (42, 42%) at the end of cystoscopy, while most of the subjects in the bupivacaine group achieved sensory level at T8 (39.39%) at the end of cystoscopy.

The mean regression time of normal SA based on the Kolmogorov-Smirnov test for prilocaine and bupivacaine SA was 69.36 ± 35.85 and 131.88 ± 79.43 min respectively, and there was a significant difference between the regression time for SA in the two groups (P < 0.001) (Table 3).

Comparison of the side effects of hyperbaric prilocaine SA 2% 50 mg with hyperbaric bupivacaine 0.5% 12.5 mg and the need for additional analgesia in this study can be seen in Table 7. The side effect of shivering was the most common, namely 9.09% in both drug groups. Meanwhile, additional analgesia was given to two subjects (6.06%) in the prilocaine group.

# 4. DISCUSSION

Cystoscopy requires SA to facilitate the procedure so that the patient remains comfortable without pain. SA recovery time is greatly influenced by the type of local anesthetic drug used.[16-18] In this study, the types of spinal anesthetic drugs used were prilocaine and bupivacaine. Bupivacaine is an anesthetic drug that has been commonly used in cystoscopic procedures.[19-23] Prilocaine is an anesthetic drug with a relatively short duration of action and can be an alternative spinal anesthetic for a short-duration procedure such as cystoscopy.[24-27]

Our study showed that the recovery time for hyperbaric prilocaine 2% was significantly shorter than bupivacaine 0.5% (Table 2), to lift leg at 45 degrees (P < 0.001) and the time before the subject could walk (P = 0.002). Faster recovery time was also reported by Hampl et al. where the resolution of motor blockade was shorter in the prilocaine 2% group compared to bupivacaine 0.5% (P < 0.05).[36,37] This is also supported by the study by Etriki et al. where the time for subjects to walk was shorter in the prilocaine group than bupivacaine (P < 0.001).[15] Thus, the recovery time for hyperbaric prilocaine 2 % is superior to hyperbaric bupivacaine 0.5 mg as a spinal anesthetic agent in cystoscopic procedures. The time of onset of maximum sensory level did not differ between the prilocaine and bupivacaine groups (Table 3).

The onset time of reaching maximum sensory level is difficult to predict because it is influenced by many factors.[31-33] The most influential aspect of the onset of nerve conduction block is the physicochemical properties of the local anesthetic drug itself. In order to prevent depolarization of the nerve cell membrane, local anesthetic drugs must be able to enter the intracellular space and adhere to the intracellular surface of the

**Table 2: Comparative time to maximum sensory level and recovery times**

| Variable | Prilocaine group (n = 33) | Bupivacaine group (n = 33) | P value |
|---|---|---|---|
| Time to maximum sensory level (min) | 11.00 (3.00-25.00)[a] | 12.00 (3.00-42.00)[a] | 0.346 [b] |
| Regression time to T12 (min) | 69.36 ± 35.85 | 131.88 ± 79.43 | < 0.001* |
| Time to lift the leg 45° (min) | 93.88 ± 35.48 | 180.36 ± 76.55 | < 0.001* |
| Time until the patient walks (min) | 144.91 ± 47.11 | 259.76 ± 81.58 | 0.002* |

*[a] Abnormal data distribution is stated in median (Min-Max); [b] Mann-Whitney test; * Unpaired T test; Data presented as mean ± SD or median (range)*

 

**Table 3: Comparative maximum sensory level. Data presented as n (%)**

| Dermatome | Prilocaine group (N=33) | | Bupivacaine group (N=33) | |
|---|---|---|---|---|
| | maximum sensory level | Sensory level at the end of cystoscopy | maximum sensory level | Sensory level at the end of cystoscopy |
| T4 | 5 (15.15%) | 0 (0%) | 4 (12.12%) | 0 (0%) |
| T6 | 14 (42.42%) | 1 (3.03%) | 16 (48.48%) | 6 (18.18%) |
| T8 | 8 (24.24%) | 4 (12.12%) | 9 (27.27%) | 13 (39.39%) |
| T10 | 6 (18.18%) | 14 (42.42%) | 4 (12.12%) | 11 (33.33%) |
| T12 | | 10 (30.30%) | | 3 (9.09%) |
| L1 | | 3 (9.09%) | | 0 (0%) |
| L2 | | 1 (3.03%) | | 0 (0%) |

sodium channels. Local anesthetic drugs are non-ionized anesthetic drugs ready to penetrate lipid-soluble cell membranes.[28-30]

The number of local anesthetic drug molecules in a non-ionized form in plasma is affected by the pKa of the drug. Local anesthetic drugs with a pKa close to the body's pH will have a greater number of non-ionized molecules in the plasma, so the drug's onset time is also faster. Prilocaine has a pKa of 7.9 while bupivacaine has a pKa of 8.1, thus the onset time of prilocaine should be faster than that of bupivacaine.[29,33] However, it should be noted that the actual onset times of prilocaine and bupivacaine can only be assessed if researchers compare the onset times at the same dermatome level.

This study showed no difference in maximum sensory level between the prilocaine group and the bupivacaine group (Table 2). This can be explained because of the treatment of the same position in all subjects of this study. Studies by Kaban et al. reported similar results, where there was no difference in maximum sensory level between hyperbaric prilocaine 2% 30 mg

(T9 [6-12]) and hyperbaric bupivacaine 0.5% 7.5 mg [T9 (6-12)].[17]

**Table 4: Side effects and the need for additional analgesia**

| Variable | Prilocaine (n = 33) | Bupivacaine (n = 33) |
|---|---|---|
| Nausea | 1 (3.03%) | 1 (3.03%) |
| Shivers | 3 (9.09%) | 3 (9.09%) |
| Hypotension | 1 (3.03%) | 1 (3.03%) |
| Additional analgesia | 2 (6.06%) | 0 (0%) |

*Data presented as numbers (percentage)*

The achievement of maximum sensory level in SA is strongly influenced by the process of drug distribution in the intrathecal cavity. Factors that influence the spreading process include posture and baricity. The position of the patient receiving SA affects the process of spreading spinal anesthetic drugs. The spread of SA in patients in a sitting position will be different compared to those in the lateral decubitus or supine position, so the patient's postural changes will also affect the maximum sensory level of SA.[32,34] To reduce bias due to postural factors, in this study, all research subjects were treated in the same position, namely a flat supine position using a pillow under their head after SA. In addition, baricity also affects the process of spreading spinal anesthetic drugs. Hyperbaric drugs have a greater specific gravity than cerebrospinal fluid. Different specific gravity with isobaric or hypobaric preparations will affect the distribution pattern of anesthetic drugs in the intrathecal cavity, which also depends on changes in the patient position.[29]

In this study, it was found that the majority of subjects with hyperbaric prilocaine 2% (42.42%) still experienced sensory blockade up to T10 at the end of the procedure (Table 2). Five subjects (15.15%) in the prilocaine group also experienced sensory blockade above T10. Sensory block at the end of the procedure is a vital parameter to consider when choosing SA for cystoscopic procedures. There were not enough studies that reported sensory blockade at the end of the procedure and comparisons between spinal anesthetics. Nonetheless, sensory blockade as high as T10 was assessed as suitable for all cystoscopic procedures.[34] The sensory blockade level results at the end of the procedure in this study indicated that hyperbaric 2% prilocaine 50 mg could still provide adequate sensory blockade for cystoscopic procedures.

The regression time of SA to T12 was faster in the prilocaine group than in the bupivacaine group (Table 2). This result is also supported by the sensory level at the end of cystoscopy (Table 3). It can be seen that at the end of the cystoscopy procedure, 42.42% of the subjects in the prilocaine group had reached a dermatome below T10. Meanwhile, in the bupivacaine group, only three subjects (9.09%) had reached a sensory level of T10 and none of them had reached a level of L1 or L2. Kaban et al. showed that the regression time for prilocaine was

 

shorter than that for bupivacaine, both for L1 and S3 regression.[17]

The duration of SA depends on several factors. The type of molecule, potency, protein binding, and vascularity at the injection site affect the duration of action of spinal anesthetic drugs. The tendency of spinal anesthetic drugs to bind to proteins will prolong the duration of action of spinal anesthetic drugs. Prilocaine has a tendency to bind to protein by 53% compared to bupivacaine by 96%.[29,38]

The two local anesthetic drugs in the study can affect the vascularity of the injection site. Prilocaine tends to be a vasodilator, whereas bupivacaine tends to be a vasoconstrictor. Consequently, the uptake of prilocaine from the injection site into the circulation is greater than bupivacaine. Weaker protein binding and greater uptake from injection sites are the theoretical basis for prilocaine's shorter duration of action than bupivacaine.[29,38]

Side effects and rescue analgesic needs with hyperbaric prilocaine 2% were relatively the same as hyperbaric bupivacaine 0.5% (Table 4). Kaban et al. reported similar side effects between prilocaine and bupivacaine.[17] Based on the need for analgesia, the study by Camponovo et al. also showed similar results.[21] The need for additional analgesia appears to have an inverse relationship with increased hyperbaric prilocaine dose. This shows that hyperbaric prilocaine 2% has the potential to be a spinal anesthetic agent in cystoscopic procedures, with side effects comparable to bupivacaine 0.5% and a relatively minimal need for additional analgesia.

All study subjects in the prilocaine group achieved a maximum sensory level greater than or equal to the T10 dermatome (Table 3) so that hyperbaric prilocaine can be used for cystoscopy. At the end of the cystoscopy procedure, the majority of sensory levels of hyperbaric prilocaine 2% 50 mg were still in the T10 dermatome.

The advantage of hyperbaric prilocaine 2% is the shorter recovery time than hyperbaric bupivacaine 0.5% 12.5 mg. The recovery time or duration of SA varies widely and is difficult to predict in practice. Selection of the type of spinal anesthetic drug is important to note so that the duration of anesthesia can be estimated, which can include the duration of the operation and recovery time. Demographic factors in this study, both the prilocaine group and the bupivacaine group, were relatively the same so the duration of the blockade obtained could be due to the selection of the type of spinal anesthetic drug. Shorter SA recovery time can reduce patient congestion in the PACU, improve service quality, and reduce the risk of post-anesthesia complications.[17]

# 5. LIMITATIONS

This study has several limitations. We did not evaluate the ability to void urine which is one of the discharge criteria after SA and commonly used in daily practice. However. cystoscopies are very commonly followed by catheterization.

This study also could not assess the length of hospital stay after SA. The benefits of shorter recovery time of hyperbaric prilocaine 2% can be seen more clearly if the study is conducted on outpatient surgical patients.

# 6. CONCLUSION

Prilocaine can be used as a spinal anesthetic for cystoscopy because it has a short recovery time and is suitable for the duration of cystoscopy. It is necessary to research the use of prilocaine as SA in addition to cystoscopy. It is necessary to conduct research with a more significant, larger number of samples and in outpatient surgery services to be able to assess the length of stay and cost analysis studies on the use of hyperbaric prilocaine 2% 50 mg in cystoscopic procedures.

## 7. Data availability

The numerical data generated during this research is available with the authors.


## 8. Acknowledgement

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## 9. Conflict of interest

The study utilized the hospital resources only, and no external or industry funding was involved.

## 10. Authors' contribution

1. AT: Concept and design; analysis and interpretation data; critical revision of the manuscript.

2. JM, AH: Concept and design; statistical analysis and interpretation data; drafting the manuscript.

All authors have read the final manuscript and approved for publishing.

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