

**Original contribution** 

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# A comparison of spinal anesthesia with small-dose lidocaine and general anesthesia with fentanyl and propofol for ambulatory prostate biopsy procedures in elderly patients

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Keywords: Age factors; Analgesics, opioid: fentanyl; Anesthesia: day-case; Anesthetics, intravenous: propofol; Anesthetics, local: lidocaine	Abstract Study Objective: To compare operating conditions, intraoperative adverse events, recovery profiles, postoperative adverse effects, patient satisfaction, and costs of small-dose lidocaine spinal anesthesia with those of general anesthesia using fentanyl and propofol for elderly outpatient prostate biopsy. Design: Prospective, randomized, blind study. Setting: Outpatient anesthesia unit at a municipal hospital. Patients: 80 ASA physical status I and II patients, aged 65 to 80 years, scheduled for outpatient prostate biopsy. Interventions: Patients were assigned to receive either spinal anesthesia with 10 mg of hyperbaric 1% lidocaine (L group, n = 40) or anesthetic induction with fentanyl 1 $\mu$ g · kg <sup>-1</sup> IV and 1.0 mg · kg <sup>-1</sup> propofol injected at 90 mg · kg <sup>-1</sup> · h <sup>-1</sup> , followed by continuous infusion at 6 mg · kg <sup>-1</sup> · h <sup>-1</sup> (F/P group, n = 40). Measurements and Main Results: Both anesthetic techniques provided acceptable operating conditions for the surgeon. However, a significantly higher frequency of intraoperative hypotension was found in the F/P group than in the L group ( $P < 0.05$ ). Time to home readiness was shorter in the F/P group ( $P < 0.05$ ). Both techniques had no major postoperative adverse effects and resulted in a high rate of patient satisfaction. Total costs were significantly lower in the L group than in the F/P group ( $P < 0.01$ ).
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**Conclusions:** Spinal anesthesia with 10 mg of hyperbaric 1% lidocaine may be a more suitable alternative to general anesthesia with fentanyl and propofol for ambulatory elderly prostate biopsy in terms of safety and costs.

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## 1. Introduction

Prostate biopsy is typically performed during local anesthesia, either alone or in combination with sedation [1]. Periprostatic local anesthetic infiltration, however, often fails to provide optimal surgical conditions and/or comfortable patient experience, mainly because of inadequate pain control [2,3].

Spinal anesthesia may be advocated for elderly patients undergoing prostate biopsy because of its ability to provide adequate sensory block and its minimal effects on brain and cardiac function. In addition, the rapid regression of action obtained by spinal lidocaine may make it a more suitable option on an outpatient basis.

This anesthetic technique for ambulatory surgery has nevertheless fallen into disfavor because of concerns over transient neurologic symptoms (TNS), which are most often associated with the use of intrathecal lidocaine [4-6].

We designed this study to evaluate the usefulness of spinal anesthesia with a small dose of hyperbaric lidocaine as an alternative to general anesthesia with fentanyl and propofol for ambulatory prostate biopsy in elderly patients.

#### 2. Materials and methods

After obtaining approval for the study from the Muroran City General Hospital's ethics committee and written, informed consent from each patient, we enrolled 80 ASA physical status I and II patients, aged 65 to 80 years, and scheduled for elective outpatient prostate biopsy. Exclusion criteria were evidence of clinically significant cardiovascular, respiratory, renal/hepatic, or metabolic disease; contraindications to spinal anesthesia (eg, coagulopathy, localized infection, or neurologic disease); and mental dysfunction or inability to give accurate responses to questions. Patients were randomly assigned by sealed-envelope technique to receive general anesthesia with fentanyl and propofol (F/P group, n = 40).

Patients in both groups received no premedication. On arrival in the operating room (OR), intravenous (IV) infusion of lactated Ringer's solution was begun and standard monitoring was applied. Mean arterial blood pressure (MAP), heart rate (HR), and hemoglobin oxygen saturation (SpO<sub>2</sub>) were recorded at two-minute intervals during surgery.

Anesthesia in patients in the F/P group was induced with fentanyl 1  $\mu$ g · kg<sup>-1</sup> IV, followed by 1.0 mg · kg<sup>-1</sup> propofol at a rate of 90 mg · kg<sup>-1</sup> · h<sup>-1</sup> for 3 minutes, and

it was maintained with a continuous propofol infusion of 6 mg  $\cdot$  kg<sup>-1</sup>  $\cdot$  h<sup>-1</sup>. All patients received supplemental oxygen via a face mask at a rate of 6 L  $\cdot$  min<sup>-1</sup> throughout the procedures. Patients manifesting signs of inadequate anesthesia such as movement received a supplemental bolus dose of propofol (0.4 mg  $\cdot$  kg<sup>-1</sup> IV). If hypoxemia associated with respiratory depression (defined as SpO2 <92%) occurred in a patient, respiration was assisted via manual ventilation through a face mask. The number of patients requiring supplemental propofol and airway support was recorded. Propofol infusion was discontinued at the completion of the surgical procedure, and the times from discontinuation of propofol to opening of eyes, verbal command, and orientation were recorded. For patients in the L group, lumbar puncture was performed in the lateral position using a 25-gauge Quincke point needle (Top Co, Tokyo, Japan) positioned midline at the L2-3 or L3-4 vertebral interspace. The spinal injectate was prepared by drawing up a mixture of 1 mL of 3% lidocaine and 2 mL of 0.9% normal saline (hyperbaric 1.0% lidocaine). From this solution, 1 mL (10 mg lidocaine) was used for the anesthetic and was injected intrathecally for 10 seconds. In both groups, intraoperative hypotension (defined as a decrease in MAP that exceeds 20% of baseline MAP) and bradycardia (defined as an HR of <50 beats per minute or a decrease of >20% from baseline HR) were treated with 5 mg IV boluses of ephedrine and 0.25 mg IV atropine, respectively, until each variable had increased above the threshold level. Baseline MAP and HR values were each defined as the mean of the two lowest measurements recorded during a 5-minute interval just before the induction of anesthesia. Sensory level and motor response were assessed using pinprick and a modified Bromage scale (0 = full movement, 1 = movement of knees only, 2 = movement of ankles only, and 3 = no movement), respectively, 5 and 10 minutes after lidocaine injection and at the end of surgery. Severity of movement in response to noxious stimulation associated with the insertion of an ultrasound probe and biopsy needle was evaluated according to an ordinal scale (none, mild, or severe), and assessments of operating conditions, including movement to surgical stimulation, were made by the surgeon (all operations were performed by the same surgeon) using a three-point scoring system of poor, good, or excellent. All prostate biopsy procedures were performed via a transrectal approach during ultrasound guidance, and in all cases, up to 10 biopsy cores were obtained.

After surgery, all patients bypassed the postanesthesia care unit (phase I recovery unit) and were transferred directly from the OR to the phase II recovery unit.

Table 1Demographic data		
	F/P group	L group
Number	40	40
Age (y)	$73 \pm 6$	$71 \pm 6$
Weight (kg)	$61 \pm 7$	$61 \pm 9$
Height (cm)	$163 \pm 7$	$164 \pm 5$
ASA physical status (I/II)	30/10	31/9
Surgery duration (min)	8 ± 3	8 ± 3
Anesthesia duration (min)	27 ± 5	31 ± 8*

Values are means  $\pm$  SD or numbers.

\* P < 0.05 compared with the F/P group.

Discharge from the OR to the phase II unit was determined according to the fast-track scoring system of White and Song [7]. On arrival in the phase II unit, patients received oxygen at a flow rate of 3 L  $\cdot$  min<sup>-1</sup> if SpO<sub>2</sub> was less than 92%. Frequency of postoperative hypotension, bradycardia, and complications (eg, nausea, headache, backache, dizziness, and chest pain) was examined. Postoperative recovery was evaluated by the same independent physician-observer who was blinded to study group allocation, and the time to home readiness was defined as a score of 9 or higher in the modified Post-Anesthesia Discharge Scoring System [8]. The modified Post-Anesthesia Discharge Scoring System is based on 5 main criteria: (1) vital signs, that is, blood pressure, HR, and respiratory rate (RR); (2) ambulation; (3) pain; (4) nausea/vomiting; and (5) surgical bleeding. Neither oral intake nor voiding were required for determination of home readiness. The times to ambulation and home readiness were evaluated every 15 minutes by a studyblinded observer.

At 24 hours and 7 days after the operation, pain severity and adverse events were assessed by a blinded investigator using a standardized telephone interview method. Patient satisfaction with the anesthetic technique was evaluated using a scoring system: poor, satisfied, or very satisfied. Finally, all patients were asked the question: "If you were coming for the same surgery, would you want the same anesthesia?"

Cost calculation included anesthetic drug and equipment costs in the OR, drug and resources costs in the recovery unit, and labor costs in both areas. Drug and resources that were common to both groups (eg, electrocardiogram leads, pulse oximeter probes, and IV administration sets) were not included, but the costs of wasted drugs were included. Nursing labor costs were based on the actual time spent by the nurse with a patient. The total cost of each anesthetic technique was calculated by summing costs of drugs, nursing labor, and resources.

A power analysis based on previously published data suggested that a minimum of 40 patients in each group would be required to detect a 25% difference in time to home readiness, with a power of 90% at an error of 0.05. This group size would also be adequate to detect a 20% reduction in MAP and HR between the two anesthetic groups with a power of 90% ( $\alpha = .05$ ). Statistical analysis was conducted using StatView 5.0 (SAS Institute, Cary, NC). Data were analyzed using analysis of variance, the Mann-Whitney U test, the  $\chi^2$  test, or Fisher's exact test, as appropriate. A P value of less than 0.05 was considered statistically significant.

### 3. Results

There were no statistically significant differences between the two groups with respect to demographic characteristics, duration of surgery and anesthesia (Table 1), or the amount of IV fluid administered during surgery (Table 2).

After induction of anesthesia, 47.5% of the patients in the F/P group had hypotensive episodes, and 63.2% of those patients developed severe hypotension requiring more than two bolus injections of ephedrine (10 mg). The amount of ephedrine required for patients in the F/P group was significantly greater than that required for patients in the L group (P < 0.01). Twenty percent of patients in the F/P group also experienced respiratory depression and required airway intervention and/or assisted ventilation. Additional bolus doses of propofol to prevent movement were needed in 15% of the patients in the F/P group. However, there was no difference in the surgeon's satisfaction with operating conditions obtained by the two anesthesia methods (Table 2). All patients in both groups bypassed the postanesthesia care unit and went directly to the phase II unit. The discharge time from the end of surgery to the phase

	F/P group	L group
Intravenous fluid (mL)	261.1 ± 55.7	239.4 ± 62.0
Highest level of sensory block	NA	L1 (T10-L3)
Maximum motor blockade score	NA	0 (0-1)
Frequency of adverse eve	ents (n [%])	
Hypotension	19 (47.5)	2 (5)*
Bradycardia	0 (0)	0 (0)
Respiratory depression	8 (20)	0 (0)*
Total doses of supplement	tal agents (mg)	
Propofol	$8.3 \pm 21.1$	NA
Ephedrine	$6.7 \pm 6.7$	$0.5 \pm 2.0^{*}$
No. of patients requiring	supplementation (n	[%])
Propofol (0/1/2/3/4)	34 (85)/4 (10)/1 (2.5)/1 (2.5)/0	NA
Ephedrine (0/1/2/3/4/5)	21 (35)/7	38 (95)/1 (2.5)/1
	(25)/8 (25)/3 (12.5)/1 (2.5)/0	(2.5)/0/0/0
Acceptable operating conditions (%)	100	100

Values are means  $\pm$  SD or median (range) or numbers (percentages). NA indicates not applicable.

\* P < 0.01 compared with the F/P group.

Table 3 Recovery unit data

	F/P group	L group
Adverse effects (n [%])		
Pain (none-mild-	30 (75)-10	32 (80)-8
moderate-severe)	(25)-0-0	(20)-0-0
Headache	0 (0)	0 (0)
Backache	0 (0)	0 (0)
Nausea	0 (0)	0 (0)
Respiratory depression	2 (5)	0 (0)
(SpO <sub>2</sub> < 92%)		
Dizziness	0 (0)	0 (0)
Chest pain	1 (2.5)	0 (0)
Urinary retention	0 (0)	0 (0)
Pain medication required	0 (0)	0 (0)
Recovery times (min)		
Phase II recovery unit	$9.8 \pm 2.5$	0**
Ambulation	$30.0~\pm~8.0$	$38.0 \pm 14.7*$
Home readiness	$30.0~\pm~8.0$	$38.0 \pm 14.7^*$

Values are numbers (percentages) or means  $\pm\,$  SD. NA indicates not applicable.

\* P < 0.05 compared with the F/P group.

\*\* P < 0.01 compared with the F/P group.

II unit was significantly shorter in the L group compared with the F/P group (P < 0.01) (Table 3).

In the phase II recovery unit, none of the patients experienced moderate or severe pain, and 75% of patients in the F/P group and 80% in the L group had no pain. Two patients (5%) in the F/P group experienced respiratory depression (SpO<sub>2</sub> <92%) and required oxygen supplementation, but no patient who received lidocaine did so. Other postoperative complications such as nausea, headache, and backache did not occur in either group. The time to home readiness was significantly shorter in the F/P group than in the L group (P = 0.012) (Table 3).

Neither postoperative pain nor headache at home occurred in any of the patients in either group. Two patients in the L group experienced persistent mild backache at three days, but this pain did not have radicular symptoms

Table 4 Adverse events at home		
	F/P group	L group
Adverse effects (n [%])		
Pain (none-mild)	38 (95)-2 (5)	40 (100)-0 (0)
Headache	0 (0)	0 (0)
Backache	0 (0)	2 (5)
Chest pain	0 (0)	0 (0)
TNS	0 (0)	0 (0)
Patient satisfaction	0-8 (20)-32	0-12 (30)-28
(with anesthetic technique)	(80)	(70)*
(poor-satisfied-very		
satisfied) (n [%])		
Choose same anesthetic? (%)	100	100
Values are numbers (percentages)		

Values are numbers (percentages).

TNS transient neurologic symptoms.

\* P < 0.05 compared with the F/P group.

Table 5	Incremental costs in the two anesthetic techniques

	F/P group	L group
Intraoperative costs		
Drugs		
Fentanyl, 100 µg	1.89	NA
Propofol, 500 mg	24.85	NA
Lidocaine 3%	NA	0.64
Ephedrine	$0.54 \pm 0.49$	$0.06 \pm 0.24^{**}$
Oxygen	$1.78 \pm 0.45$	0**
Equipment	11.81	10.54
Labor costs	$22.70 \pm 3.93$	$25.68 \pm 6.44*$
Total costs (US\$)	$61.68 \pm 4.28$	$36.18 \pm 6.56^{**}$
Recovery costs		
Drugs		
Oxygen	$0.10 \pm 0.30$	0
Equipment	2.55	0
Nursing labor costs	$10.00 \pm 2.67$	12.66 ± 4.92*
Total costs (US\$)	$12.65 \pm 2.76$	$12.66 \pm 4.92$
Total perioperative	$74.32 \pm 4.69$	48.84 ± 7.91**
costs (US\$)		

Values are means  $\pm$  SD or numbers (in US dollars). NA indicates not applicable.

\* P < 0.05 compared with the F/P group.

\*\* P < 0.01 compared with the F/P group.

consistent with a diagnosis of TNS. None of the patients in the L group developed TNS (Table 4). The degree of satisfaction with the anesthesia was high for all patients. However, the degree of patient satisfaction in the F/P group was significantly higher than that in the L group (P < 0.05). None of the patients in either group reported a score of poor. All patients in both groups were willing to accept the same anesthesia again (Table 4). Total costs of drugs and supplies used in the OR were significantly lower in the L group than in the F/P group (P < 0.01). However, because the average time spent in the OR was significantly longer in the L group than in the F/P group (P < 0.05), the time-related costs of labor in the OR were significantly higher in the L group (P < 0.05).

Nursing labor cost in the phase II unit was also significantly higher in the L group because of a longer stay in this unit (P < 0.05). The two anesthetic techniques were, however, comparable with respect to total costs in the phase II unit because of the need for the cost of equipment in the F/P group. Total perioperative costs were, therefore, significantly lower in the L group than in the F/P group (P < 0.01) (Table 5).

### 4. Discussion

This study shows that intraoperative hemodynamic lability and anesthesia-related increased costs are more common in anesthetic induction with fentanyl 1  $\mu$ g · kg<sup>-1</sup> IV and propofol 1.0 mg · kg<sup>-1</sup> followed by maintenance with continuous infusion with 6 mg · kg<sup>-1</sup> · h<sup>-1</sup> than in spinal anesthesia with 10 mg of 1% lidocaine, but recovery

processes and patient satisfaction are comparable between the two anesthetic techniques for ambulatory elderly prostate biopsy.

The criteria for ideal ambulatory anesthesia are excellent operating conditions, rapid recovery, no postoperative adverse effects, high degree of patient satisfaction, and good cost-effectiveness. In the present study, unpredictable movement of the patient during surgery and/or insufficient relaxation of the rectal sphincter muscle could have made the surgical procedures difficult and entailed the risk of intraoperative complications. The two main contributors to the acceptable operating conditions, therefore, appeared to be adequate reduction of movement to noxious stimulation and adequate reduction of rectal sphincter spasms. Accordingly, the smallest dose of intrathecal lidocaine or IV propofol that could achieve reductions of movement and rectal sphincter spasms was used for each anesthetic technique in the present study.

Lidocaine used in spinal anesthesia has been reported to cause TNS in 0% to 40% of patients [4-6]. Although the exact etiology of TNS is unknown, data suggest that limiting the total dose may be helpful for prophylaxis against TNS [4]. Despite the use of intrathecal lidocaine and lithotomy positioning, which have been suggested to be factors contributing to the development of TNS [4-6], no patient developed TNS. This may be due to the minimal dose of lidocaine used. However, failure to detect a low frequency of TNS is one of the potential limitations of this study. The study population size was selected to determine equivalency of hemodynamic changes associated with the two anesthetic techniques and was probably too small to detect a very low frequency of TNS.

The major contributors to determining discharge time in the F/P and L groups were emergence time and time to regression of motor block, respectively. Although the difference between emergence time in the F/P group and time to block regression in the L group would, therefore, have led to a statistically significant difference in time to home readiness, an 8-minute difference between the two groups was really unlikely to be clinically relevant.

The patient dissatisfaction also may be related to inadequate control of postoperative pain and a high frequency of adverse effects [9]. However, because there were few adverse effects in either group in this study, the anxiety and discomfort during spinal and/or surgical procedures might be associated with the slightly lower degree of satisfaction in the L group than in the F/P group.

The results mentioned previously suggest that small-dose spinal lidocaine is an acceptable alternative to fentanylpropofol anesthesia for ambulatory surgery with respect to operating conditions, recovery profile, postoperative complications, and patient comfort. However, as for intraoperative hemodynamic and respiratory depression, even the minimal dose of propofol used for anesthetic induction that is required to provide acceptable operating conditions could not prevent hypotension during surgery. Fortunately, the lability of perioperative hemodynamics and respiratory function in the F/P group did not increase the frequency of postoperative complications in this study. However, hemodynamic instability during general anesthesia greatly increases the risk of myocardial infarction or stroke, especially in patients with a labile cardiovascular system [10,11]. In addition, a previous study [12] suggested that general anesthesia using fentanyl and propofol produced a strong suppressive effect on left ventricular mechanical performance in the elderly. Special attention should, therefore, be paid to the combined use fentanyl and propofol in elderly patients, which may have a latent attenuated physiological reserve. Thus, in consideration of fewer effects on hemodynamics, respiratory function, and costeffectiveness, spinal anesthesia with 10 mg hyperbaric 1% lidocaine may be a more suitable alternative to general anesthesia with fentanyl and propofol for elderly ambulatory prostate biopsy.

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