

## ORIGINAL RESEARCH

### Effectiveness Comparison: Saddle Block vs. Low Dose Spinal Anesthesia in Cervical Cancer Brachytherapy

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#### ABSTRACT

**Background:** Brachytherapy plays a role in the management of cervical cancer by delivering radiation to large tumors at the end or in conjunction with chemoradiotherapy. Regional anesthesia is the dominant technique used for brachytherapy. Low Dose Spinal Anesthesia involves injecting local anesthetic into the subarachnoid space. Saddle block anesthesia is a type of low spinal block that provides anesthesia to the saddle area. Low Dose Spinal Anesthesia has the disadvantage of longer motor recovery in the extremities compared to saddle block. This study aims to compare the sensory and motor effectiveness between saddle block anesthesia and Low Dose Spinal Anesthesia in cervical cancer patients undergoing intracavitary brachytherapy.

**Methods:** A non-paired double-blind consecutive clinical trial with cervical cancer patients undergoing elective brachytherapy at Dr. Kariadi Hospital, Semarang. Patients were divided into two groups: Saddle block anesthesia and Low dose spinal anesthesia. Vital signs, NRS pain scale, Bromage motor activity score, side effects including hemodynamics, patient satisfaction level (EVAN-LR), and operator satisfaction level were recorded. The collected data were analyzed using independent t-tests and Mann-Whitney tests, with results considered significant if  $p < 0.05$ .

**Results:** Bromage scores at 30 minutes and 60 minutes in the saddle block anesthesia group were significantly higher than those in the low dose spinal group ( $p=0.000$ ). The numerical rating scale during applicator placement, after moving rooms, and after removing the indicator in the saddle block anesthesia group was better than the low dose spinal group but not significant ( $p=0.054$ ).

**Conclusion:** Sensory and motor effectiveness in patients using Saddle Block Anesthesia is better compared to Low Dose Spinal Anesthesia.

**Keywords:** Brachytherapy; Bromage Score; Cervical Cancer; Low Dose Spinal Anesthesia; NRS; Saddle Block.

## INTRODUCTION

According to the Global Cancer Observatory (GLOBOCAN) WHO 2020 data, cervical cancer ranks 7th in incidence and 4th as the cause of mortality among women, accounting for 7.7% of deaths.<sup>1</sup> In Indonesia, cervical cancer ranks second among the top 10 most common cancers based on Anatomical Pathology data from the Ministry of Health of the Republic of Indonesia in 2010, with an incidence of 12.7%. Currently, it is estimated that the number of new cervical cancer cases ranges from 90-100 cases per 100,000 population, with 40,000 cases occurring annually.<sup>2</sup> Specifically, Central Java Province has the second-highest number of cervical cancer patients, totaling 19,734 cases.<sup>2,3</sup> Brachytherapy is a therapeutic modality that plays an important role in the management of local malignancies, including in the field of gynecology. Brachytherapy is utilized in the treatment of cervical cancer with radiation applied to large tumors either at the end or concurrently with chemoradiotherapy.<sup>4</sup>

The two most common anesthesia techniques in brachytherapy are general anesthesia and neuraxial block anesthesia. The goals of these

techniques are (1) to provide patients with effective initial therapy anesthesia in a cost-effective manner, (2) to achieve sufficient residual analgesia with minimal sedation, and (3) to minimize the risk of hemodynamic instability both during the placement and removal of the applicator.<sup>5</sup> Both techniques also offer varying degrees of adequate post-procedural analgesia.<sup>6</sup>

According to Benrath et al., after reviewing 1,622 brachytherapy procedures, it was found that regional anesthesia is the dominant technique used for brachytherapy due to its advantages in providing adequate analgesia and immobilization, facilitating patient transfer between units, and posing less risk than general anesthesia.<sup>5,7</sup> The study, conducted over 5½ years, also concluded that regional anesthesia is preferred for brachytherapy in the treatment of cancers of the female genital organs, rectum, and prostate, with spinal anesthesia being the most commonly used method.<sup>8</sup>

Low Dose Spinal Anesthesia is a type of regional anesthesia involving the injection of local anesthetic medication into the subarachnoid space. The target area for anesthesia is achieved depending on the height of the injection

site on the spine and is particularly effective for surgeries below the umbilicus. In Low Dose Spinal Anesthesia, hyperbaric bupivacaine is the most frequently used agent.<sup>9</sup> Additionally, opioids are commonly used alongside intrathecal bupivacaine to extend intraoperative and postoperative analgesia. Fentanyl, a synthetic  $\mu$ -opioid receptor agonist, is lipophilic and has a rapid onset, providing early postoperative pain relief without causing delayed respiratory depression.<sup>3,10</sup> The recovery time from Low Dose Spinal Anesthesia is closely related to the dose and type of drug used, which is an important consideration for outpatient services.<sup>8,11</sup>

Saddle block anesthesia is a type of low spinal block that provides anesthesia to the saddle area, including the perineum, perianal area, and the medial aspects of the legs and thighs. Various medications can be introduced into the spinal canal using this procedure, including procaine, bupivacaine, cocaine, and other anesthetic agents. Saddle block anesthesia is preferred over general and subarachnoid anesthesia. This procedure is routinely used for various obstetric, urological, anorectal procedures, and

perioperative analgesia. Over time, this technique has gained popularity due to its rapid onset, early patient mobilization, and short hospital stays.<sup>12</sup>

Outpatient intracavitary brachytherapy is essentially feasible if performed on an outpatient basis using the Low Dose Spinal Anesthesia technique. Adequate recovery time from Low Dose Spinal Anesthesia is a key consideration for outpatient services. The main factors influencing spinal anesthesia recovery time include the drug and dosage used.<sup>8,11</sup>

Currently, the anesthesia commonly used for brachytherapy at Dr. Kariadi General Hospital is Total Intravenous Anesthesia (TIVA). However, a recent 2021 study at Dr. Kariadi General Hospital comparing the effectiveness of TIVA and Low Dose Spinal Anesthesia for brachytherapy, particularly in cases of cervical cancer, found that Low Dose Spinal Anesthesia is more effective.<sup>12</sup> Despite this, Low Dose Spinal Anesthesia still has the practical drawback of longer extremity motor recovery compared to the saddle block, although both are types of spinal anesthesia. In brachytherapy applications, saddle block anesthesia has been used in prostate cancer patients and

is commonly used in non-cancer conditions in obstetric gynecology procedures such as curettage and cervical cerclage replacement.<sup>13</sup> This aligns with the principles of regional anesthesia techniques in brachytherapy, which aim to provide adequate analgesia and immobilization, facilitate patient transfer between units, and pose less risk than general anesthesia.<sup>4</sup> Therefore, saddle block anesthesia is a viable option for brachytherapy in cervical cancer patients.

## METHOD

This study used a non-paired double-blind consecutive clinical trial with cervical cancer patients undergoing elective brachytherapy at Dr. Kariadi General Hospital in Semarang. The study was conducted on 52 cervical cancer patients undergoing brachytherapy at Dr. Kariadi General Hospital from June to August 2023. The sample for this study was selected using consecutive sampling that met the inclusion and exclusion criteria. The aim of this study was to compare the sensory and motor effectiveness of saddle block anesthesia and Low Dose Spinal Anesthesia in cervical cancer patients undergoing intracavitary brachytherapy.

Cervical cancer patients who had not metastasized distantly, aged > 18 years, with a Body Mass Index (BMI) of 18.5 – 30 kg/m<sup>2</sup>, physical status ASA I-III, no history of gastric pain, no renal function impairment with serum creatinine > 2 mg/dl, not currently using opioids, and able to use the Numerical Rating Scales (NRS) were included in this study. Patients with shock or major anesthesia or surgical complications during the procedure, allergies to opioids and other anesthetic agents used in the study, more than two spinal needle punctures, negative results on the skin prick test, and post-hysterectomy patients were excluded from this study. Patients who met the inclusion and exclusion criteria were divided into two groups: saddle block anesthesia and Low Dose Spinal Anesthesia.

In this study, patients underwent spinal anesthesia procedures divided into 2 treatment groups. Before the procedure, patients received premedication with midazolam 0.025 mg/kg (maximum 2 mg) via intravenous injection at least 5 minutes before the induction of anesthesia began. Induction of anesthesia in Treatment Group 1 was performed with saddle block anesthesia, using 5 mg (1 ml) of 0.5% hyperbaric

bupivacaine combined with 25 mcg (0.5 ml) of intrathecal fentanyl. Patients waited for 5 minutes in a sitting position before proceeding to the brachytherapy applicator insertion procedure. Induction of anesthesia in Treatment Group 2 was performed with low dose spinal anesthesia, using 5 mg (1 ml) of 0.5% hyperbaric bupivacaine combined with 25 mcg (0.5 ml) of intrathecal fentanyl. Patients were laid down immediately before the brachytherapy applicator insertion procedure began. Patients' vital signs were evaluated before induction, 3 minutes after induction, and 10 minutes after the start of anesthesia. The Numerical Rating Scale (NRS) scores were assessed during brachytherapy applicator insertion, during patient transfer to the radiology room, and upon brachytherapy applicator removal. Bromage scores were assessed at 30-minute, 60-minute, and more than 60-minute intervals after the procedure was completed. Any side effects were evaluated after anesthesia induction. Intravenous ondansetron 4 mg was administered for nausea and vomiting. If hypotension occurred, intravenous ephedrine 10 mg was given. In cases of bradycardia, intravenous atropine sulfate 0.5 mg was administered. Patient

satisfaction was assessed by the researcher after the brachytherapy procedure was completed. Operator satisfaction was assessed by the researcher immediately after the brachytherapy applicator insertion procedure was completed.

Collected data underwent univariate and bivariate analysis. In univariate analysis, categorical data were presented in frequency and percentage, while numerical data were presented in mean and standard deviation. Bivariate analysis used the unpaired t-test. Data were collected and processed through cleaning, coding, and tabulation using SPSS software. Hypothesis testing to assess the mean difference of ratio-scale variables between the saddle block anesthesia group and the low dose spinal anesthesia group used the independent t-test if the data were normally distributed, or the Mann-Whitney test if the data were not normally distributed.

## RESULTS

The median age of patients in the entire population was 51.5 years, with the youngest being 28 years old and the oldest being 68 years old. The median duration of therapy was 72 minutes, with the shortest duration being 70 minutes and the longest being 75 minutes. Other

results showed that the BMI of patients was normally distributed, with a mean BMI of  $22.381 \pm 2.2290$ .

**Table 1.** The Characteristics of The Research Subjects

Variable	Saddle Block Anesthesia		Low Dose Spinal Anesthesia		Total		P <sup>α</sup>
	Mean ± SD	Min-Max Median	Mean ± SD	Min-Max Median	Mean ± SD	Min-Max Median	
	Age (Years)	49.73 ± 9.434	28-62 51	53.73 ± 10.243	28-68 55.5	51.73 ± 9.957	
Duration of brachytherapy (Minutes)	71.96 ± 1.949	70-75 72	72.08 ± 2.153	70-75 72	72.02 ± 2.034	70-75 72	0.000
BMI (kg/m <sup>2</sup> )	22.719 ± 2.4627	18.3-27 22.4	22.042 ± 1.9576	18.7-25.8 22	22.381 ± 2.2290	18.3-27 22.1	0.114 <sup>#</sup>

Note: Group 1 = Saddle Block Anesthesia; Group 2 = Low Dose Spinal Anesthesia; α = Shapiro-Wilk Test, #sig if p>0.05

**Table 2.** Bromage

Variable	Saddle Block Anesthesia		Low Dose Spinal Anesthesia		P <sup>α</sup>	P <sup>m</sup>
	Mean ± SD	Min-Max Median	Mean ± SD	Min-Max Median		
30 minutes	0.7 ± 0.37	0-1 1	2 ± 0	2-2 2	0.000	0.000*
60 minutes	0.5 ± 0.23	0-1 0	2 ± 0	2-2 2	0.000	0.000*
>60 minutes	0 ± 0	0-0 0	0 ± 0	0-0 0	0.000	1.000

Note: α = Shapiro-Wilk Test, #sig if p>0.05; m = Mann Whitney Test, sig if p<0.05

The results of this study showed that the Bromage score at 30 minutes in the saddle block anesthesia group was  $0.7 \pm 0.37$ , while in the low dose spinal group it was  $2 \pm 0$ . There was a significant difference, with the mean

Bromage score being higher in the low dose spinal group (p=0.000).

The results also indicated that the Bromage score at 60 minutes in the saddle block anesthesia group was  $0.5 \pm 0.23$ , while in the low dose spinal group

it was  $2 \pm 0$ . There was a significant difference, with the mean Bromage score at 60 minutes being higher in the low dose spinal group ( $p=0.000$ ). However, the results showed that the mean Bromage score for more than 60 minutes

in both the saddle block anesthesia group and the low dose spinal group was  $0 \pm 0$ , with no significant difference in the mean Bromage score for more than 60 minutes ( $p=1.000$ ).

**Table 3.** Motor effectiveness

Side Effects	Group		p
	Saddle Block Anesthesia	Low Dose Spinal Anesthesia	
<b>Bromage Score</b>	26 (50%)	26 (50%)	.
<b>Leave the hospital</b>			

Note: Chi-square Test, \*sig if  $p<0.05$

Regarding motor effectiveness as described by Bromage score in terms of being able to leave the hospital, the study results showed that there were 26 patients in the saddle block anesthesia

group and 26 patients in the low dose spinal anesthesia group. Since only patients with a Bromage score that allowed them to leave the hospital were considered, this variable was constant.

**Table 4.** Numerical Rating Scale

Numerical Rating Scale	Saddle Block Anesthesia		Low Dose Spinal Anesthesia		p <sup>α</sup>	p <sup>m</sup>
	Mean ± SD	Min-Max Median	Mean ± SD	Min-Max Median		
<b>Applicator insertion</b>	0.35 ± 0.485	0-1 0	0.62 ± 0.496	0-1 1	0.000	0.054
<b>After room transfer</b>	0.35 ± 0.485	0-1 0	0.62 ± 0.496	0-1 1	0.000	0.054
<b>After applicator removal</b>	0.35 ± 0.485	0-1 0	0.62 ± 0.496	0-1 1	0.000	0.054

Note: α = Shapiro-Wilk Test, #sig if  $p>0.05$ ; m = Mann Whitney Test, sig if  $p<0.05$

The Shapiro-Wilk normality test results showed that the numerical rating scale scores at applicator insertion, after room transfer, and after applicator removal were not normally distributed in both the saddle block anesthesia group and the low dose spinal group. The study results indicated that the numerical rating scale score at applicator insertion in the saddle block anesthesia group was  $0.35 \pm 0.485$ , while in the low dose spinal group it was  $0.62 \pm 0.496$ , with no significant difference ( $p=0.054$ ).

The study results also indicated that the numerical rating scale score after

room transfer in the saddle block anesthesia group was  $0.35 \pm 0.485$ , while in the low dose spinal group it was  $0.62 \pm 0.496$ , with no significant difference in the mean numerical rating scale score after room transfer ( $p=0.054$ ).

Furthermore, the study results indicated that the mean numerical rating scale score after applicator removal in the saddle block anesthesia group was  $0.35 \pm 0.485$ , while in the low dose spinal group it was  $0.62 \pm 0.496$ , with no significant difference in the mean numerical rating scale score after applicator removal ( $p=0.054$ ).

**Table 5.** Sensory effectiveness

Side Effects	Group		p
	Saddle Block Anesthesia	Low Dose Spinal Anesthesia	
NRS Successful anesthesia	26 (50%)	26 (50%)	.

Note: Chi-square Test, \*sig if  $p < 0.05$

Regarding sensory effectiveness as described by the NRS, in terms of successful anesthesia, the study results showed that there were 26 patients in the saddle block anesthesia group and 26 patients in the low dose spinal anesthesia group. Since only patients with successful anesthesia were included, the NRS variable was constant.

Regarding patient satisfaction, the study results showed that in the saddle block anesthesia group, the satisfaction score was  $33.19 \pm 1.201$ , whereas in the low dose spinal anesthesia group, it was  $27.69 \pm 4.671$ . There was a significant difference, with higher patient satisfaction in the saddle block group ( $p=0.028$ ).

**Table 6.** Patient and Operator Satisfaction

	Saddle Block Anesthesia		Low Dose Spinal Anesthesia		P <sup>α</sup>	P <sup>m</sup>
	Mean ± SD	Min-Max Median	Mean ± SD	Min-Max Median		
<b>Patient Satisfaction</b>	33.19 ± 1.201	31-35 33	27.69 ± 4.671	16-34 29.5	0.000	0.000*
<b>Operator Satisfaction</b>	33.58 ± 1.447	30-35 34	31.42 ± 1.770	28-35 32	0.002	0.000*

Note: α = Shapiro-Wilk Test, #sig if p>0.05; m = Mann Whitney Test, sig if p<0.05

Regarding operator satisfaction, the study results showed that in the saddle block anesthesia group, the satisfaction score was 33.58 ± 1.447, whereas in the low dose spinal anesthesia group, it was 31.42 ± 1.770. There was a significant difference, with higher operator satisfaction in the saddle block group (p=0.000).

## DISCUSSION

Pain is a crucial aspect in comparing saddle block anesthesia and low dose spinal anesthesia. In this study, the analysis of the average Numerical Rating Scale (NRS) scores during applicator insertion showed no significant difference between the saddle block anesthesia group and the low dose spinal anesthesia group (p=0.054). The same applies to the NRS scores after room transfer and after applicator removal. Saddle block anesthesia can provide effective pain control for

approximately 2-4 hours after administration. This method is suitable for shorter procedures or when longer pain control is not required. However, its limitation is its short duration, making it less suitable for longer surgeries or procedures.<sup>3,9,12</sup>

This study found that the average Bromage Score at 30 minutes was higher in the low dose spinal anesthesia group (p=0.000). Similarly, the average Bromage Score at 60 minutes and beyond 60 minutes was also higher in the low dose spinal anesthesia group (p=0.000). Regarding motor effectiveness as described by the Bromage Score in terms of the ability to leave the hospital, the results showed that there were 26 patients in both the saddle block anesthesia and low dose spinal anesthesia groups. Since only patients with a Bromage Score that allowed them to leave the hospital were

considered, this variable was constant and did not show differences between the two groups. Generally, saddle block anesthesia provides better and more localized motor control, as reflected in lower Bromage Scores. Low dose spinal anesthesia may cause more significant motor impairment, reflected in higher Bromage Scores. Saddle block anesthesia has the advantage of maintaining motor control in most body areas, allowing patients to remain active during or after the procedure.<sup>3,9,12,13</sup>

### **Patient and Operator Satisfaction**

Patient and operator satisfaction are crucial factors in evaluating the overall quality of medical care and anesthesia procedures. The results of this study, as detailed in section 5.1, support a comparison of patient and operator satisfaction between the saddle block anesthesia group and the low dose spinal anesthesia group. The findings indicate that patient satisfaction was higher in the saddle block anesthesia group ( $33.19 \pm 1.201$ ) compared to the low dose spinal anesthesia group ( $27.69 \pm 4.671$ ). This difference was statistically significant ( $p=0.028$ ), suggesting that patients in the saddle block anesthesia group were generally more satisfied with their anesthesia experience. Higher patient

satisfaction in the saddle block anesthesia group may be attributed to several factors, such as potentially lower pain levels and fewer motor side effects, which could provide a more comfortable experience for patients. Additionally, greater confidence in safety, fewer complications, and efficient administration of anesthesia may also contribute to higher satisfaction levels. Recovery times were also found to be faster in patients who received saddle block anesthesia.<sup>3,4,9,12,14</sup> Clarke et al. reported that patient satisfaction with saddle block anesthesia was very high, with an average satisfaction score of  $9.18 \pm 1.08$  (on a scale of 0-10) for all patients ( $n=591$ ).<sup>3</sup>

The study also indicated that operator satisfaction was higher in the saddle block anesthesia group ( $33.58 \pm 1.447$ ) compared to the low dose spinal anesthesia group ( $31.42 \pm 1.770$ ). This difference was statistically significant ( $p=0.000$ ), suggesting that operators in the saddle block anesthesia group were more satisfied with the anesthesia procedures they performed. Factors influencing operator satisfaction may include ease of administering anesthesia, precise control, and positive outcomes. An easier administration process and

effective results may provide a more positive experience for the operator.<sup>14</sup>

One limitation of this study is the relatively small sample size. Additionally, the study was conducted at only one hospital, which may limit the generalizability of the results to a broader population.

## CONCLUSION

The sensory and motor effectiveness in patients using Saddle Block Anesthesia is better compared to Low Dose Spinal Anesthesia. Patient and operator satisfaction is higher with Saddle Block Anesthesia compared to Low Dose Spinal Anesthesia.

## CONFLICT OF INTEREST

The author declared no conflict of interest.

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