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Effect in Pain Scale of Trocar Insertion, Onset, and Duration of Anesthesia of Subtenon Anesthesia without Premedication Compared with Premedication in Pars Plana Vitrectomy: A Randomized Controlled Trial

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Abstract: Effect in Pain Scale of Trocar Insertion, Onset, and Duration of Anesthesia of Subtenon Anesthesia without Premedication Compared with Premedication in Pars Plana Vitrectomy: A Randomized Controlled Trial. Background: Pars plana vitrectomy (PPV) has traditionally been performed under general anesthesia. However, in recent years, regional anaesthetic techniques such as subtenon block have gained popularity due to their safety and effectiveness, reducing the risk of severe complications associated with needle-based blocks. Patients and Methods: This randomized controlled trial (RCT) was conducted between November 2023 to March 2024 at a tertiary teaching hospital in Indonesia. A total of 30 patients undergoing vitrectomy were randomized assigned to one of two groups: with premedication or without premedication. The primary outcomes evaluated were the pain scale during trocar insertion, the onset of anesthesia, and the duration of anesthesia. Statistical analyses were performed using the Mann-Whitney U test and ANCOVA. Results: No significant differences were observed between the two groups regarding the pain scale during trocar insertion, the onset of anesthesia, or the duration of anesthesia ($p<0.001$). However, after adjusting for diagnosis and type of the therapy, the group without premedication demonstrated a significantly longer duration of anesthesia. Conclusion: Subtenon anesthesia without premedication represents a viable alternative for pars plana vitrectomy. It offers practical benefits, such as eliminating the need for fasting and intravenous line placement, while maintaining patient and operator comfort.

Keyword: Premedication, Subtenon Anesthesia, Pars Plana Vitrectomy, Pain Scale

INTRODUCTION

Pars plana vitrectomy (PPV) is typically performed with the assistance of an anesthesiologist, employing either monitored anesthesia care or general anesthesia combined with eye block anesthesia. In most cases using regional anesthesia, premedication such as intravenous propofol is administered to calm the patient, necessitating the placement of an intravenous line. When sedation anesthesia is used, patients must also adhere to fasting guidelines. Midazolam, a common sedative for PPV procedures, carries potential side effects, including hypotension, apneic spells, sudden movements during recovery, cardiovascular complications, respiratory depression, metabolic acidosis, acute kidney injury, and nausea. Additionally, at the onset of the procedure, patients may have difficulty following instructions and could suddenly awaken in a confused state, resulting in unpredictable and rapid movements of the head or hands (American Academy of Ophthalmology, 2016; Andayani et al., 2023; Licina et al., 2016).

Local anesthesia offers several advantages, allowing patients to continue their routine medications and dietary habits, thereby enhancing comfort and reducing risks such as hypoglycemia in diabetic patients. A study involving 21 patients undergoing PPV with subtenon anesthesia without intravenous premedication reported no intraoperative complications, interruptions to the procedure, or conversions to intravenous sedation.(Almasi et al., 2020; Kumar et al., 2017). In this study, we compared the pain scale during trocar insertion, as well as the onset and duration of anesthesia, between patients receiving subtenon anesthesia without premedication and those receiving premedication during PPV.

Problem formulation:

1. Is there no difference in the pain scale of trocar insertion in subtenon anesthesia without premedication compared to premedication in pars plana vitrectomy?
2. Is there no difference in the onset of anesthesia in subtenon anesthesia without premedication compared to premedication in pars plana vitrectomy?
3. Is there no difference in the duration of anesthesia in subtenon anesthesia without premedication compared to premedication in pars plana vitrectomy?

METHODS

This study was an experimental, analytical investigation utilizing a randomized controlled trial (RCT) design conducted from November 2023 to March 2024. Participants were divided into two groups: premedication and without premedication. The study included all patients undergoing vitrectomy at a tertiary hospital in Indonesia. Inclusion criteria required participants to sign informed consent specific to the research. Exclusion criteria included patients undergoing general anesthesia, those with a history of eye surgery within the past three months, or individuals with uncontrolled hypertension. This research adhered to the principles of the Declaration of Helsinki and received ethical approval from the Research Ethics Committee of the Faculty of Medicine, Udayana University (2437/UN14.2.2.VII.14/LT/2023).

The sample size for the study was determined using the formula presented in Figure 1. A clinical judgment criterion and a standard deviation of 1.5 were applied for the calculation. The Z values corresponding to a significance level α of 5% and a power of 95% were 1.96 and 1.64, respectively. According to the formula, the minimum required sample size per group was calculated to be 13 subjects. Accounting for a potential 10% dropout rate, a total of at least 15 participants per group was deemed necessary. Consequently, the study required a total of 30 participants across both groups. Subjects were randomized using permuted block randomization with a double-blind design, ensuring that participants, surgeons, and anesthesiologists were blinded to the assigned medications. Maximal pupil dilation was achieved using topical drops of 1% tropicamide and 5% phenylephrine. In the premedication

group, participants received intravenous midazolam at a dose of 0.05 mg/kg, along with 0.5% proparacaine hydrochloride as local anesthetic drops administered to the cul-de-sac. Participants in the without premedication group received 0.9% NaCl. Both solutions were prepared in identical 3 mL syringes coded by operating room staff. All participants received subtenon anesthesia, consisting of a mixture of 2.5 mL lidocaine 2% and 2.5 mL bupivacaine 0.5%, injected into the inferomedial subtenon space. A 23G trocar and cannula system was used for transconjunctival sclerotomies in the inferotemporal, superotemporal, and superonasal quadrants, positioned 3.5 mm from the limbus. Pars plana vitrectomy was performed using a Dutch Ophthalmic Research Center (DORC) vitrectomy machine.

$$n = 2\left[\frac{(Z\alpha + Z\beta)s}{(x1 - x2)}\right]^2$$

Description:

n : number of samples or subjects in a group

x1- x2 : desired clinical judgement

$Z\alpha$: Z value for α of 5%

$Z\beta$: Z value for power of 95%

Figure 1. Sample size formula

The study primarily examined variables including the pain scale during trocar insertion (measured using the Numeric Rating Scale [NRS]), anesthetic onset, and anesthesia duration for each group. Additional surgical characteristics were recorded, including pain scale during surgery, the need for supplemental anesthesia or sedation, and complications. The need for supplemental anesthesia was defined as the administration of additional anesthetic agents beyond those specified in the study protocol, while supplemental sedation referred to sedatives administered beyond protocol requirements.

All data were documented in study worktables and analyzed using IBM® SPSS® Statistics 26.0 (International Business Machines Corporation, Armonk, New York). Normality was assessed using the Shapiro–Wilk test. Differences in trocar insertion pain and anesthetic onset were analyzed using the Mann–Whitney U test for non-normally distributed data and the independent t-test for normally distributed data. Multivariate analysis was performed using analysis of covariance (ANCOVA). A p-value <0.05 was considered statistically significant.

RESULTS & DISCUSSION

The total number of subjects in this study was 30, with 15 participants in the without premedication group and 15 in the premedication group. The characteristics of the sample are summarized in Table 1. Surgical characteristics, including the pain scale during surgery, the need for additional anesthesia, the need for additional sedation, and complications, are presented in Table 2.

Table 1. Characteristics of research subjects

Characteristics of research subjects	Premedication (n = 15)	Without Premedication (n = 15)
Age, median (IQR)	49 (34-66)	54 (31-63)
Gender, n (%)		
Male	8 (53.3)	5 (33.3)

Female	7 (46.7)	10 (66.7)
Visual acuity (logmar chart), median (IQR)	1.3 (0.3-2.3)	2.3 (0.4-2.7)
Diagnosis, n (%)		
Retinal Detachment	4 (26.7)	5 (33.3)
Attached Retinal + SO Filled Eye	7 (46.7)	2 (13.3)
Vitreous Hemorrhage	2 (13,3)	5 (33.3)
PDR	0	2 (13.3)
IOL Drop	0	1 (6.7)
Posterior Uveitis	1 (6.7)	0
Cataract + Vitreomacular Traction	1 (6.7)	0
Type of surgery, n (%)		
PPV	7 (46.7)	9 (60.0)
PPV + SO evacuation	6 (40.0)	1 (6.7)
PPV + Membrane Peeling	0	2 (13.3)
PPV + phacoemulsification	0	1 (6.7)
PPV + IOL Drop evacuation	0	1 (6.7)
PPV + SO evacuation + phacoemulsification	1 (6.7)	0
PPV + Membrane Peeling + phacoemulsification	1 (6.7)	1 (6.7)

Sumber: Data Penelitian

(IQR: interquartile range, PDR: Proliferative diabetic retinopathy, PPV: Pars plana *vitrectomy*, IOL: Intraocular lens, SO: silicone oil)

Table 2. Surgical characteristics (pain scale intraoperative, additional anesthesia, additional sedation, and complications)

Surgical characteristics	Premedication (n = 15)	Without Premedication (n = 15)
Intraoperative NRS	0 (0-2)	1 (0-2)
Additional anesthesia, *n* (%)		
No	15 (100.0)	15 (100.0)
Yes	0 (0.0)	0 (0.0)
Additional sedation, *n* (%)		
No	14 (93.3)	15 (100.0)
Yes	1 (6.7)	0 (0.0)
Complications*, *n* (%)		
No	10 (66.7)	11 (73.3)
Yes	5 (33.3)	4 (26.7)

Sumber: Data Penelitian

NRS: numerical rating scale

*In the form of nausea

Differences in pain during trocar insertion and the onset of anesthesia were analyzed using the Mann–Whitney U test, as the data were not normally distributed. Differences in the duration of anesthesia were analyzed using the independent t-test, as this data followed a normal distribution. The results of these tests, shown in Table 3, revealed no significant differences in pain during trocar insertion, anesthetic onset, or the duration of subtenon anesthesia compared with peribulbar anesthesia.

Table 3. Differences in numerical rating scale of trocar insertion, onset of anesthesia, and duration of anesthesia in subtenon with premedication and without premedication groups

Variables	Premedication (n = 15)	Without Premedication (n = 15)	p
NRS of trocar insertion, median (IQR)	0 (0-0)	0 (0-1)	0.141**

Anesthesia onset (minutes), median (IQR)	5 (4-6)	5 (4-6)	0.570**
Anesthesia duration (minute), mean ± SD	64.27 ± 27	96.67 ± 33	0.343*

Sumber: Data Penelitian
*independet t-test; ** Mann-Whitney test

As shown in Table 4, multivariate analysis indicated no significant differences in the pain scale during trocar insertion, anesthetic onset, or duration of anesthesia. However, after adjusting for diagnosis and type of therapy, a significant effect was observed on the duration of anesthesia.

Table 4. Covariate analysis of anesthesia types to NRS of trocar insertion, onset and duration of anesthesia with covariates age, gender, diagnosis, type of surgery

Variable	NRS		Onset of Anesthesia		Duration of Anesthesia	
	F	p	F	p	F	p
Without premedication	1.086	0.385	0.753	0.565	4.805	0.005
Age (years)	0.006	0.937	1.406	0.247	0.472	0.498
Male gender	1.136	0.297	1.030	0.320	0.587	0.451
Diagnosis	0.443	0.512	0.214	0.648	10.962	0.003
Type of surgery	0.566	0.459	0.006	0.941	14.680	0.001

Sumber: Data Penelitian
NRS: numerical rating scale

This study demonstrated no significant differences in Numeric Rating Scale (NRS) scores for trocar insertion pain, anesthesia onset, and anesthesia duration between the two groups. The average age of patients in the premedication group was 49 years, compared to 54 years in the group without premedication. Similarly, previous studies reported that patients undergoing vitrectomy with premedication had an average age of 58 years (Kumar et al., 2017). The overall pain scale indicated an acceptable level of analgesia during surgery, with most patients experiencing only mild pain or slight discomfort at various stages of the procedure. These findings align with prior research showing that patients reported mild discomfort without significant pain (Andayani et al., 2023). One notable advantage of omitting premedication is the simplified and cost-effective administration, as it eliminates the need for fasting and intravenous line placement. This study reported an additional sedation rate of 6.7% in the premedication group, with no additional anesthesia required in either group. This sedation rate is significantly lower than a previous study, which reported that 13.3% of patients in the premedication group required additional anesthesia (Ribeiro et al., 2020).

No complications related to vision loss were observed in either group. Postoperative nausea occurred in 33.3% of patients in the premedication group and 26.7% in the group without premedication. Other studies have reported conjunctival chemosis or swelling as minor complications of subtenon anesthesia, though these rarely interfere significantly with surgery. For ocular surgery, local anesthesia is often preferred over general anesthesia due to its minimal physiological impact and lower risk of postoperative nausea and vomiting (PONV) (Andayani et al., 2023; Lerch et al., 2020; Ribeiro et al., 2020).

Subtenon anesthesia provided an acceptable level of analgesia during surgery, with most patients experiencing only mild pain or discomfort. In this study, the median onset of subtenon anesthesia was 5 minutes. The mean duration of vitrectomy was 64.27 ± 27 minutes in the premedication group and 96.67 ± 33 minutes in the group without premedication. This difference may reflect the more complex diagnoses and therapies in the group without premedication, which extended treatment duration and influenced the overall pain score. Other research has reported a median onset of subtenon anesthesia of 6 minutes.(Guise, 1996) Studies comparing 1% plain lidocaine, 0.25% plain bupivacaine, and a mixture of 1% lidocaine with

0.25% bupivacaine found no significant differences in onset time, although bupivacaine alone had the longest duration of action (Guise, 1996, 2003, 2012)

The duration of vitrectomy procedures varies widely, typically ranging from 30 to 45 minutes for vitreous hemorrhage caused by a single retinal tear without retinal detachment, and exceeding two hours for complex traction retinal detachment. (Guise, 2012; Jacobi et al., 2000; Morgan et al., 2006; Ribotsky et al., 1996). When combined with cataract extraction (phacoemulsification), the procedure may require an additional 15 to 20 minutes. (Morgan et al., 2006; Ribotsky et al., 1996).

In this study, ANCOVA analysis demonstrated a significant effect of diagnosis and therapy type on the overall pain scale duration ($p < 0.05$). Multivariate analysis confirmed no significant differences in trocar insertion pain scores, anesthesia onset, or anesthesia duration between subtenon anesthesia with or without premedication. Sedation was correlated with anxiety, highlighting the importance of comprehensive preoperative education to reduce patient anxiety. In cases of persistent anxiety despite counseling, intravenous sedation remains an option.

Limitations of this study include the small sample size, lack of follow-up on postoperative outcomes, and insufficient data regarding the degree of pain or patient comfort during anesthesia. This study concludes that subtenon anesthesia without premedication is a viable alternative for vitrectomy, offering operator comfort while balancing the advantages and disadvantages of premedication.

CONCLUSSION

Based on the results of the study, it can be concluded there is no difference in pain scale during trocar insertion in subtenon anesthesia without premedication compared to premedication in pars plana vitrectomy. There is no difference in the onset of anesthesia in subtenon anesthesia without premedication compared to premedication in pars plana vitrectomy. There is no difference in the duration of anesthesia in subtenon anesthesia without premedication compared to premedication in pars plana vitrectomy. There is an effect of duration after being controlled by diagnosis and type of therapy. Based on these conclusions, subtenon anesthesia without premedication can be used as an alternative for simple pars plana vitrectomy surgery without disturbing operator comfort.

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