Anesth Pain Med. 2018 April; 8(2):e68383. doi: 10.5812/aapm.68383.

Published online 2018 April 28. **Research Article**

The Effectiveness of 2% Lidocaine Gel Compared to 0.5% Tetracaine Eye Drop As Topical Anesthetic Agent for Phacoemulsification Surgery

Susilo Chandra,[1,*] Adhrie Sugiarto,[1] Robert Hotasi,[1] Annemarie Chrysantia Melati,[1] and Bondan Harmani[2]

[1]Department of Anesthesiology and Intensive Care, Universitas Indonesia, Jakarta, Indonesia
[2]Department of Ophthalmology, Universitas Indonesia, Jakarta, Indonesia

[*]*Corresponding author*: Susilo Chandra, Department of Anesthesiology and Intensive Care, Universitas Indonesia, Jl. Diponegoro, Jakarta, Indonesia. Tel: +62-213143736, E-mail: susilochandra@gmail.com

Received 2018 March 07; **Revised** 2018 April 02; **Accepted** 2018 April 25.

Abstract

Background: Topical anesthetics have become the primary choice in phacoemulsification procedures for cataract extraction. The most common topical anesthetic drug used is 0.5% tetracaine eye drops. Repeated administration of 0.5% tetracaine drops can cause corneal epithelial damage. Two percent lidocaine gel is latest option which has longer contact time with corneal epithelium.
Objectives: To compare the effectiveness of 2% lidocaine gel with 0.5% tetracaine drops in phacoemulsification surgery.
Methods: The study was a single blinded randomized clinical trial from March to July 2017 in patients underwent phacoemulsification cataract surgery. There were 72 subjects with age $\geq$ 40 years old who received randomization and divided into 2 groups: 2% lidocaine gel group and 0.5% tetracaine eye drop group. Topical anesthetics were applied 5 minutes before surgery. Five minutes after surgery, pain scale perceived during surgery was assessed by using a numerical rating scale. At the end of surgery, the subject filled the satisfaction questionnaire on topical anesthetic drugs administered. The ophthalmologists were also given a satisfactory questionnaire for topical anesthetic drugs selected for the procedure.
Results: The median pain scale for 2% lidocaine gel group pain scale was 1; meanwhile, the median pain scale for 0.5% tetracaine eye drops was 3 ($P < 0.05$).
Conclusions: Two percent lidocaine gel was more effective in relieving pain during phacoemulsification cataract surgery compared with 0.5% tetracaine drops.

Keywords: Phacoemulsification, Corneal Anesthesia, Lidocaine, Tetracaine, Topical Anesthesia

1. Background

Nowadays, cataract surgery has been conducted through phacoemulsification technique. This technique has developed significantly with the aid of topical anesthetic agent. Topical anesthetic agent generates shorter duration of admission with improved comfort, lower cost, and less complications in comparison with general anesthesia (1).

Topical anesthetic agent during cataract surgery may be administered in the form of an eye drop, gel, or intracamera injection (1). The latest agent to be used is 0.5% tetracaine eye drop. This agent is proven to be safe and effective in most cases. However, the absorption and duration of this agent is slower in comparison with gel preparation. Therefore, the 0.5% tetracaine eye drop must be administered repeatedly with the risk of corneal epithelial damage due to its toxic reactions, including punctate keratopathy, persistent epithelial defect, ring shaped stromal infiltration, corneal edema, Descemet's membrane filding, endothelial cell loss to neurotrophic ulcer, stromal melting, secondary infectious keratitis, corneal scarring, and corneal perforation (2, 3).

There were still some contradictory research findings regarding the superiority of 2% lidocaine gel as topical anesthetic agents. Amiel et al., mentioned that postoperative pain between 2% lidocaine gel and 0.5% tetracaine eye drop did not differ significantly (4). Chalam et al., mentioned the superiority of 0.5% tetracaine eye drop during intraoperative pain management in comparison with 2% lidocaine gel (5). However, another study mentioned that 0.5% tetracaine eye drop must be administered at least three times to achive the desired effect (6).

In Indonesia, 0.5% tetracaine eye drop was the current choice of topical anesthesia in the daily practice. There was no past study that mentioned the use of 2% lidocaine gel as

the other choice of topical anesthesia for phacoemulsification surgery. Therefore, this study was conducted to measure the effectiveness of 2% lidocaine gel as topical anesthesia for phacoemulsification surgery.

2. Objectives

This present study aimed to understand the effectiveness as well as patient satisfaction of 2% lidocaine gel as a topical anesthetic agent in comparison with the 0.5% tetracaine eye drop during phacoemulsification cataract surgery.

3. Methods

This was a single blind randomized clinical trial held in the tertiary hospital in Jakarta, Indonesia. The population included patients scheduled for phacoemulsification surgery from February to August 2017 following ethical approval from the ethics committee. Additionally, this study passed the approval from the department of ophthalmology Universitas Indonesia.

The inclusion criteria included patients age $\geq$ 40 years old who were scheduled for phacoemulsification surgery with intraocular lens implantation, underwent local anesthesia, and agreed to participate in this study. The exclusion criteria included patients with an allergic history towards 2% lidocaine gel and/or 0.5% tetracaine eye drop, history of past phacoemulsification surgery, with communication problems, dementia, and anxiety disorder. The drop out criteria included surgery longer than 30 minutes and required additional intravenous anesthesia agent.

There were 36 subjects for each group with block randomization conducted by a third independent party. The randomization result was secured inside the enclosed envelope. The envelope was revealed moments before topical anesthetic application. The researcher was blinded towards the results of randomization.

Five minutes before the surgery, topical anesthesia selected for the subject were administered. Five minutes following the incision, the pain scale was asssed with the numerical pain scale from scale 1 - 10 (scale 1 - no pain; scale 10 - severe pain). This was measured as the primary outcome of the present study. If the patient complained of untolerable pain in the middle of the procedure, the same anesthetic agent chosen was administered repeatedly. At the end of the procedure, patient satisfaction was measured by using a questionnaire filled after the surgery. Similarly, surgeon satisfaction was also measured by using a questionnaire filled postoperatively.

Patient satisfaction questionnaire consisted of: any painful administration of the anesthetic agent, any painful experience during the surgery, and any side effect of the anesthetic agent. Surgeon satisfaction questionnaire consisted of: the onset of action of the anesthetic agent, comfort during the surgery, side effects of the anesthetic agent, and the neef of additional anesthetic agent. Both questionnaire results were classified into: not satisfied, satisfied, and very satisfied. These questionnaires were constructed and validated by three senior anesthesiologist consultants. The statistic analysis was conducted by using the SPSS program version 21.0.

4. Results

This study was conducted in patients scheduled for phacoemulsification surgery. As seen in Table 1, overall demographic data between two groups were comparable. The distribution of pain scale data was abnormal so that it was displayed as median pain score and minimal-maximal score. Based on Table 2, the statistical test showed that there was a significant pain scale difference between two groups ($P < 0.05$).

This study measured that the 2% lidocaine gel group had a less number of additional topical anesthetic agent in comparison with 0.5% tetracaine eye drop; this difference was statistically significant. This study also recorded no side effect in relation with any topical anesthetic agent. This study showed that all subjects and surgeons were either satisfied or very satisfied; there was no subject or surgeon who were not satisfied with both topical anesthetic agents.

5. Discussion

Cataract remains a major cause of blindness worldwide, especially in developing countries. Based on the national health survey in Indonesia in the year 2014, the number of blindness reached 1.8% with 0.78% of all cases being caused by cataract. Data from the world health organization estimated that 253 million people live with vision impairment in 2017 with 35% of blindness being caused by unoperated cataract (7). Therefore, cataract surgery is one of the most common surgeries held in many health centres. In most cases, cataract surgery is conducted on a one-day care basis.

Based on the result of this study, both topical anesthetic agents provided excellent analgesic properties during phacoemulsification surgery. However, the 2% lidocaine gel was statistically more superior in reducing pain during phacoemulsification surgery. The mean pain scale for group of patients with the 2% lidocaine gel was lower than group of patients with the 0.5% tetracaine eye drop.

Table 1. Demographic Data (N = 36)[a]

Variables	2% Lidocaine Gel	0.5% Tetracaine Eye Drop
Age, y	58.39 ± 8.84	58.61 ± 8.90
Sex		
Male	21 (58.3)	16 (44.4)
Female	15 (41.7)	20 (55.6%)
Education		
Low-middle	30 (83.3)	32 (88.9)
High	6 (16.7)	4 (11.1)

[a]Values are expressed as mean ± S or No. (%).

Table 2. The Comparison of Pain Scale, Patient Satisfaction, Surgeon Satisfaction, and Topical Anesthetic Additive Between 2% Lidocaine Gel Group and 0.5% Tetracaine Eye Drop Group (N = 36)[a]

Variables	2% Lidocaine Gel	0.5% Tetracaine Eye Drop	P Value
Pain scale	1 (0 - 3)	3 (2 - 5)	< 0.001[b]
Patient satisfaction			0.004[c]
Satisfied	14 (38.9)	26 (72.2)	
Very satisfied	22 (61.1)	10 (27.8)	
Surgeon satisfaction			0.028[d]
Not satified	0 (0)	0 (0)	
Satisfied	28 (77.8)	35 (97.2)	
Very satisfied	8 (22.2)	1 (2.8)	
Topical anesthetic additive			< 0.001[c]
Additional	5 (13.9)	32 (88.9)	
No additionion	31 (86.1)	4 (11.1)	

[a]Values are expressed as No. (%).
[b]Mann-Whitney test.
[c]Chi-Square test.
[d]Fisher test.

This finding was in accordance with another study by Berequet et al., who found that single use of quarter-inch of the 2% lidocaine gel was significantly effective as anesthetic agent for cornea (7). However, this finding was inconsistent with other studies. Amiel et al., also found similar effectiveness between both anesthetic agents (4). Conversely, Chalam et al., found that the 0.5% tetracaine eye drop was more superior that the 2% lidocaine gel (5). In general, both anesthetic agents were equally effective as analgesia for cataract phacoemulsification surgery (6).

In this study, there were 88.9% participants receiving the 0.5% tetracaine eye drop that required additional topical anesthetic agents intraoperatively. Meanwhile, only 13.9% participants receiving the 2% lidocaine eye gel required additional topical anesthetic agents. Based on the literature, the 2% lidocaine gel did not require additional anesthetic agent due to its gel preparation. Gel has thick concentration, which has prolonged contact with the cornea. Therefore, this will increase the penetration into the cornea epithel to achieve better analgesic effect (7). Based on the literature, the duration of action of one drop of the 0.5% tetracaine eye drop is lasting for 15 - 20 minutes; meanwhile, lidocaine gel may provide ocular anesthesia up to 30 minutes (8, 9).

Topical anesthetic agent from the surface of cornea is cleared through nasolacrimal drainage system. Additionally, there is some drug absorption through nasal mucosa into the systemic circulation. Liu et al., mentioned that systemic concentration of lidocaine, following lidocaine gel administration, did not increase significantly following topical administration. This is due to high penetration from the gel preparation into the corneal epithel and its thick preparation creates long duration in the cornea despite of tears (10).

Pain was assessed by using the numerical rating scale, which was measured by the subject following administration of topical anesthetic agent. Perception of pain is highly influenced by many factors, including age, gender, race/ethnicity, and education. Similar surgical stimulus might not be perceived as a similar degree of pain for different patients (11).

This study found that all participants were satisfied with both preparations. This level of satisfaction was influenced by many factors, including intraoperative pain, preparation of local anesthetics, additional topical anesthetics, and other external factors, such as patients' expectation and hospitality of any medical staffs (12). The level of satisfaction of the patient might influence the choice of which topical anesthetics to be used in the surgery, regardless its similar effectiveness.

In addition to the level of satisfaction of the patient, this study also measured the satisfaction level of the surgeon. This study concluded that all surgeons were satisfied with both topical anesthetic agents. However, some respondents were more satisfied with 2% lidocaine gel due to the fact that they did not have to add more topical anesthetics intraoperatively.

This study had some limitations, including inability to blind the patient and surgeon regarding the type of topical anesthetic given due to different drug preparation. Another limitation was that the use of numerical rating scale was a subjective measurement of pain. Similarly, the questionnaires for both subjects and surgeons were also subjective. Further studies should include more objective measurements.

The primary outcome in this study was the effectiveness of topical anesthetic agents, measured by the pain scale. However, duration of both anesthetic agents was not compared and analyzed. Further studies should also compare the duration of both anesthetic agents.

5.1. Conclusion

The 2% lidocaine gel was more effective as an analgesic agent during phacoemulsification surgery. Additionally, both patient and surgeon satisfaction were higher in the 2% lidocaine gel group.

Footnote

Funding/Support: This study was supported by Department of Ophthalmology, Universitas Indonesia, Jakarta.

References

1. Waheeb S. Topical anesthesia in phacoemulsification. *Oman J Ophthalmol*. 2010;**3**(3):136–9. doi: 10.4103/0974-620X.71892. [PubMed: 21120050]. [PubMed Central: PMC2992161].
2. Rafailov L, Kulak A, Weedon J, Shinder R. Comparison of Lidocaine Gel-Assisted Transconjunctival and Transcutaneous Local Anesthesia for Outpatient Eyelid Surgery. *Ophthalmic Plast Reconstr Surg*. 2015;**31**(6):470–3. doi: 10.1097/IOP.0000000000000391. [PubMed: 25675169].
3. Soliman MM, Macky TA, Samir MK. Comparative clinical trial of topical anesthetic agents in cataract surgery: lidocaine 2% gel, bupivacaine 0.5% drops, and benoxinate 0.4% drops. *J Cataract Refract Surg*. 2004;**30**(8):1716–20. doi: 10.1016/j.jcrs.2003.12.034. [PubMed: 15313296].
4. Amiel H, Koch PS. Tetracaine hydrochloride 0.5% versus lidocaine 2% jelly as a topical anesthetic agent in cataract surgery: comparative clinical trial. *J Cataract Refract Surg*. 2007;**33**(1):98–100. doi: 10.1016/j.jcrs.2006.09.013. [PubMed: 17189801].
5. Chalam KV, Murthy RK, Agarwal S, Gupta SK, Grover S. Comparative efficacy of topical tetraVisc versus lidocaine gel in cataract surgery. *BMC Ophthalmol*. 2009;**9**:7. doi: 10.1186/1471-2415-9-7. [PubMed: 19686592]. [PubMed Central: PMC2736919].
6. Irle S, Luckefahr MH, Tho Seeth T. [Tetracaine drops versus lidocaine gel for topical anaesthesia in cataract surgery]. *Klin Monbl Augenheilkd*. 2003;**220**(9):625–8. doi: 10.1055/s-2003-42811. [PubMed: 14533061].
7. Barequet IS, Soriano ES, Green WR, O'Brien TP. Provision of anesthesia with single application of lidocaine 2% gel. *J Cataract Refract Surg*. 1999;**25**(5):626–31. [PubMed: 10330634].
8. Flach AJ. Ophtahalmics therapeutics. In: Riordan-Eva P, Cunningham Jr ET, editors. *Vaughan Asbury's general ophthalmology*. 18th ed. United States of America: McGraw-Hill; 2017.
9. Busbee BG, Alam A, Reichel E. Lidocaine hydrochloride gel for ocular anesthesia: results of a prospective, randomized study. *Ophthalmic Surg Lasers Imaging*. 2008;**39**(5):386–90. doi: 10.3928/15428877-20080901-03. [PubMed: 18831420].
10. Shah H, Reichel E, Busbee B. A novel lidocaine hydrochloride ophthalmic gel for topical ocular anesthesia. *Local Reg Anesth*. 2010;**3**:57–63. [PubMed: 22915870]. [PubMed Central: PMC3417949].
11. Liu B, Ding L, Xu X, Lin H, Sun C, You L. Ocular and systemic pharmacokinetics of lidocaine hydrochloride ophthalmic gel in rabbits after topical ocular administration. *Eur J Drug Metab Pharmacokinet*. 2015;**40**(4):409–15. doi: 10.1007/s13318-014-0218-5. [PubMed: 25031074].
12. Ploghaus A, Narain C, Beckmann CF, Clare S, Bantick S, Wise R, et al. Exacerbation of pain by anxiety is associated with activity in a hippocampal network. *J Neurosci*. 2001;**21**(24):9896–903. doi: 10.1523/JNEUROSCI.21-24-09896.2001. [PubMed: 11739597].