# Efficacy of 0.25% Lidocaine Versus 0.5% Lidocaine in Dermatologic Surgery: A Double-Blind, Randomized Controlled Trial

Yelena Dokic, MD, Nabor Stephen Mireles, BSA, Aileen Y. Hu, BS, Tejas P. Joshi, BS, Ikue Shimizu, MD, and Jennifer Song Ranario, MD, MBA*

**BACKGROUND** Although lidocaine is widely used in dermatologic surgery, no formal standard concentration is established. Previous research indicates that more dilute concentrations may offer equally effective anesthesia while potentially reducing toxicity risks. In addition, diluting commercially available lidocaine conserves supplies—a significant benefit during periods of lidocaine shortage.

**OBJECTIVE** To evaluate the efficacy of 0.25% lidocaine compared with that of 0.5% lidocaine in achieving anesthesia in cutaneous surgery.

**MATERIALS AND METHODS** A prospective, double-blind study with 100 patients undergoing cutaneous surgery (Mohs surgery or excision) randomized to receive either 0.25% or 0.5% lidocaine for their percutaneous anesthesia. Patients completed a postoperative survey assessing pain level, satisfaction, and willingness to undergo future dermatologic surgery.

**RESULTS** This study revealed no statistically significant differences between the 0.25% and 0.5% lidocaine groups regarding pain scores, patient satisfaction, total lidocaine volume, rescue lidocaine volume, or willingness to undergo the procedure again.

**CONCLUSION** 0.25% lidocaine is a safe and effective option for achieving anesthesia during Mohs surgery and standard excisions. The results suggest that 0.25% lidocaine can be used to optimize high-value care and enhance patient safety in dermatologic surgery.

Lidocaine is the most commonly used anesthetic in dermatologic surgery.[1] No formally established standard exists for lidocaine concentration in dermatologic surgery, and the concentration used in practice varies.[2] The FDA recommends 0.5 or 1% for percutaneous infiltration. However, studies show that lower concentrations can be effective, and diluting lidocaine could alleviate the current shortage, doubling supplies when 1% lidocaine is diluted to 0.5% lidocaine and quadrupling supplies when diluted to 0.25% lidocaine. Morganroth and colleagues[3] found 0.5% lidocaine with 1:200,000 epinephrine as effective as 1.0% lidocaine with 1:100,000 epinephrine in Mohs micrographic surgery (MMS). Song and colleagues[4] found no significant differences in median visual analog scale scores, degree of satisfaction, volume of lidocaine consumed, or incidence of complication between groups using 0.25%, 0.33%, and 0.5% lidocaine in hernia repair.

Flint and colleagues[5] further suggested that 0.25% lidocaine can also be used in dermatologic surgery. Their proof-of-concept study showed 0.25% lidocaine to be as efficacious as 1% lidocaine in achieving pain control in 40 healthy volunteers undergoing scheduled provocations over a 2-hour period. However, its extrapolation to clinical settings is limited. In this study, the authors conducted a double-blind, randomized controlled trial to assess the efficacy of 0.25% lidocaine compared with 0.5% lidocaine in dermatologic surgery.

## METHODS

### *Lidocaine Preparation*

The 0.25% and 0.5% lidocaine concentrations were prepared by 2 members of the team the day before use in study participants. The 0.5% concentration was prepared by mixing 50 mL of 0.5% lidocaine with 1:200,000 epinephrine and 5 mL of sodium bicarbonate. The 0.25% concentration was made by mixing 25 mL of 0.5% lidocaine with 1:200,000 epinephrine with 2.5 mL of sodium bicarbonate and 27.5 mL of normal saline. Solutions were drawn into sterile, labeled 3-mL syringes, each label covered with a color-coded tape corresponding to one of the 2 lidocaine concentrations. The surgical team, blinded to the concentration, used syringes based on the

*From the *All authors are affiliated with the Department of Dermatology and Dermatologic Surgery, Baylor College of Medicine, Houston, Texas*

*The authors have indicated no significant interest with commercial supporters.*

*Address correspondence and reprint requests to: Yelena Dokic, MD, Department of Dermatology and Dermatologic Surgery, Baylor College of Medicine, 1977 Butler Boulevard, Houston, TX 77030, or e-mail: yelena.dokic@bcm.edu*

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**TABLE 1. Demographics and Baseline Characteristics of Patients Undergoing Dermatologic Surgery With 0.25% Versus 0.5% Lidocaine ($N = 100$)**

| | 0.25% Lidocaine | 0.5% Lidocaine | *p* |
|---|---|---|---|
| Age, yrs (SD) | 66.2 (13.2) | 69.0 (12.3) | .28 |
| Female (%) | 17 | 15 | .12 |
| Body mass index (SD) | 27.2 (5.8) | 27.2 (5.2) | 1.00 |
| Blood thinner use | | | .53 |
| Yes | 18 | 18 | |
| Procedure type | | | .95 |
| Excision | 18 | 24 | |
| Mohs micrographic surgery | 38 | 35 | |
| Lesion location | | | .67 |
| Extremities | 12 | 18 | |
| Hands and feet | 2 | 4 | |
| Head and neck | 35 | 25 | |
| Trunk | 7 | 10 | |
| Other | 0 | 1 | |
| Lesion type | | | .83 |
| Basal cell carcinoma | 22 | 13 | |
| Dysplastic nevus | 4 | 9 | |
| Melanoma | 3 | 2 | |
| Squamous cell carcinoma | 23 | 30 | |
| Other | 3 | 4 | |
| Excision area, $cm^2$ (SD) | 2.5 (3.2) | 2.3 (1.4) | .59 |
| Repair area, $cm^2$ (SD) | 5.9 (10.1) | 4.5 (3.3) | .37 |
| Visit time, min (SD) | 119.4 (96.5) | 91.0 (57.5) | .08 |
| Perceived increase in bleeding | | | .22 |
| Yes | 34 | 27 | |
| No | 16 | 23 | |

color assigned to each patient. Only those preparing the lidocaine knew the concentration in each syringe.

## Outcome Measures

The primary end points were patient pain level, patient satisfaction, and willingness to undergo dermatologic surgery again (all assessed through a survey administered at the end of the procedure). Dosage and volume of total and rescue lidocaine used constituted secondary end points. Pain level was assessed using the 11-point numerical rating scale (NRS-11). The NRS-11 was chosen for its demonstrated ease of use, low failure rates, and strong support within evidence-based dermatologic surgery literature.[6] Patient satisfaction was assessed using an 11-point Likert scale, with 0 representing the lowest level of satisfaction with the procedure and 10 indicating the highest level of satisfaction with the procedure. Rescue lidocaine volume represented the volume of additional lidocaine delivered in response to and until resolution of any sharp pain the patient reported during the procedure. Total lidocaine volume was calculated as the volume of initial lidocaine used to anesthetize the surgical field plus the volume of rescue lidocaine delivered during the procedure. For each procedure, the primary surgeon also documented whether any increase in bleeding was perceived (yes or no) to see if a difference could be appreciated between the 2 different epinephrine concentrations.

## Patients

Using a minimal clinically significant difference of 1.39 on the NRS-11[7] and SD of 2.3,[8] the authors calculated a sample size of 89 patients to detect a statistically significant difference at a 5% significance level and 80% power. In total, 100 patients, scheduled for MMS or standard excision surgery with the primary surgeon (senior author) during the period November 16, 2023, to March 8, 2024, were recruited over phone calls made by a dermatology resident to explain the study. Once in the clinic, informed consent was obtained, and patients were enrolled by the primary surgeon. This study included patients 18 years and older, excluding those allergic to lidocaine, with reported sensitivity to epinephrine, on anxiolytics, pregnant, or breastfeeding. Patients recruited for this double-blind, randomized controlled trial were assigned a patient ID



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| TABLE 2. Outcomes of Patients Undergoing Dermatologic Surgery With 0.25% Versus 0.5% Lidocaine ($N$ = 100) | | | |
|---|---|---|---|
| | **0.25% Lidocaine** | **0.5% Lidocaine** | ***p*** |
| NRS-11 pain level (SD) | 0.44 (0.79) | 0.40 (1.0) | .39 |
| Patient satisfaction (SD)* | 9.8 (1.0) | 9.8 (0.54) | .99 |
| Total lidocaine volume, mL (SD) | 15.0 (26.6) | 13.0 (12.5) | .38 |
| Rescue lidocaine volume, mL (SD) | 0.65 (2.17) | 0.17 (0.38) | .11 |
| Total lidocaine dose, mg (SD) | 13.9 (11.8) | 26.5 (12.7) | <.001 |

* Patient satisfaction assessed using an 11-point Likert scale.
NRS, numeric rating scale.

until 100 entries were reached, with 50 patient IDs randomized to receive 0.25% lidocaine with 1:400,000 epinephrine and 50 to receive 0.5% lidocaine with 1:200,000 epinephrine. The patients were assigned a color-coded syringe corresponding to either 0.25% or 0.5% lidocaine. The surgical team, blinded to the specific concentrations, administered the local anesthetic based on the assigned color. Local anesthesia was achieved through direct infiltration into the surgical field by 3 members of the surgical team (the primary surgeon, a surgical technician, and a medical assistant; the latter two were trained in injection techniques by the primary surgeon). No patients withdrew or dropped out of the study. The study was approved by the Baylor College of Medicine Institutional Review Board (Protocol #H-53145). Patient demographics and baseline characteristics are presented in Table 1.

### Data Analysis

Baseline patient characteristics in both groups were compared using the chi-squared test or Fisher exact test for categorical variables and *t* test for continuous variables, as appropriate. NRS pain scores and satisfaction scores in both groups were compared using the Wilcoxon rank-sum test. All analyses were conducted using R v4.3.1.

## RESULTS

All 100 patients, undergoing a total of 114 surgeries, were included in the analysis. Both the 0.25% and 0.5% lidocaine groups were well-matched about age, sex, body mass index, and blood thinner use ($p > .05$). Procedure type, lesion location, lesion type, excision area, repair size, and total visit time (measured from the time informed consent to participate in the study was obtained to completion of the procedure) also did not show significant intergroup differences (Table 1). Most procedures in both groups were MMS, most lesions were keratinocyte skin cancers, and most procedures were performed on the head and neck. None of the patients experienced an epinephrine reaction.

The authors found no significant difference in the NRS pain scores between the 0.25% and 0.5% concentration groups ($p = .39$). The average pain scores were 0.44 (SD 0.79) for the 0.25% group and 0.40 (SD 1.0) for the 0.5% group. Similarly, both groups reported nearly identical levels of satisfaction using the 11-point Likert scale, with scores of 9.8 (SD 1.0) for the 0.25% group and 9.8 (SD 0.54) for the 0.5% group ($p = .99$). In addition, there were no significant differences between the mean total volume of lidocaine per patient ($p = .38$) and the mean volume of rescue lidocaine administered during the procedures ($p = .11$). Notably, patients undergoing surgery with 0.25% lidocaine required almost half the dose of lidocaine compared with patients undergoing surgery with 0.5% lidocaine (13.9 vs 26.5 mg, $p < .001$; Table 2). All 100 patients indicated that they would undergo dermatologic surgery again.

## Discussion

The study findings offer compelling evidence that 0.25% lidocaine is a safe, effective, and valuable option for dermatologic surgery, including both MMS and standard excisions, enhancing patient safety and optimizing resource utilization. Using 0.25% lidocaine instead of more concentrated percentages of lidocaine has several advantages, such as reduced toxicity risk, the ability to perform larger procedures in-office without sedation or general anesthesia, and the potential to extend lidocaine supplies during shortages. In addition, the lower epinephrine concentration in diluted solutions decreases epinephrine exposure, potentially reducing related adverse reactions.

Patients undergoing surgery with 0.25% lidocaine and 0.5% lidocaine required similar total and rescue lidocaine volumes, resulting in patients in the 0.25% lidocaine group to require almost half the total dose of lidocaine compared with those in the 0.5% lidocaine group (13.9 vs 26.5 mg, $p < .001$). Such volume parity has also been observed in other studies comparing different concentrations of lidocaine. It was observed in a previous study comparing the efficacy of 1% versus 0.5% lidocaine in achieving anesthesia for MMS.[3] Song and colleagues[4] observed this volume equivalency (and concomitant total dose reduction) when comparing 0.25% versus 0.5% lidocaine for inguinal hernia repair. Flint and colleagues[5] also recently published that the same volume of diluted 0.25% lidocaine with 1:400,000 provided a noninferior anesthetic effect when compared with commercially available 1% lidocaine with 1:100,000 in a study. They found that patients reported no pain with either solution during scheduled provocation at 4



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different sites; this was tested over a period of 2 hours in 40 healthy volunteers. This study is the first to show the efficacy of 0.25% lidocaine with 1:400,000 epinephrine for local anesthesia during dermatologic surgeries in the clinical setting for patients undergoing MMS or excision.

## Implications

This study has important clinical implications. During times of lidocaine shortage, diluting commercially available 0.5% lidocaine with normal saline to 0.25% would allow surgery practices to double the available supply, whereas diluting 1% lidocaine would effectively quadruple lidocaine supply. The shortages are what led to more regular use of diluted lidocaine at the authors' institution, and Flint and colleagues recently published an article highlighting the clinical utility of diluting commercially available lidocaine preparations to extend supply in the setting of lidocaine shortages. They reported the successful use of 0.25% lidocaine with 1:400,000 epinephrine for 10 years in their Mohs surgery practice.

Moreover, using lower doses of lidocaine without adversely affecting patient care advances a key tenet of high-value care: optimizing patient outcomes while mitigating health care costs.[9] Morganroth and colleagues[3] previously projected that their academic Mohs practice would save $9,360.00 per year if instead of 1% lidocaine, 0.5% lidocaine were used. With the current costs at the authors' academic institution, 3 mL of buffered 0.5% lidocaine with 1:200,000 epinephrine costs approximately $0.70 and 3 mL of buffered 0.25% lidocaine with 1:400,000 epinephrine costs approximately $0.39. Consistently diluting the 0.5% lidocaine supplies to 0.25% would theoretically save $4,836.00 a year if the authors assumed the same volume of lidocaine use as that of Morganroth and colleagues. Savings would be compounded over time and even more pronounced at the national level.

Furthermore, using lower doses of lidocaine can assuage both surgeon and patient concerns of systemic lidocaine toxicity, especially when performing multisite surgeries or undertaking repairs for larger defects. Diluting 0.5% lidocaine with 1:200,000 epinephrine to 0.25% lidocaine also halves the epinephrine concentration to 1:400,000, thereby blunting the risk of epinephrine toxicity. This, coupled with the study finding of volume parity between 0.25% and 0.5% lidocaine concentrations, is also valuable for surgeries involving the digits, where one should be more cautious with epinephrine and volumes must be limited due to the relatively confined space. In addition, in the absence of contraindications and with patient consent, the primary surgeon uses this dilution in patients with reported epinephrine sensitivity and has been able to perform procedures safely and comfortably in many of these patients. Being able to use epinephrine is especially helpful in more vascular areas because of the vasodilating properties of lidocaine, which leads to increased bleeding, decreased visibility of the surgical field, and decreased anesthesia duration. In this study, the primary surgeon did not perceive any difference in bleeding between the 2 concentrations ($p > .05$). However, there was a significant difference in perceived bleeding between patients on blood thinners (61.1%) and those not on blood thinners (26.6%; $p = .001$).

## Limitations and Future Directions

This study is subject to certain limitations. It was performed at a single institution, and only one surgeon performed all the procedures. Another limitation is that the pain score and patient satisfaction were only assessed at the conclusion of surgery. However, pain levels may have varied during the surgery (e.g., with additional lidocaine injections or additional Mohs stages). Future multicenter studies incorporating intraoperative pain monitoring (e.g., through smartwatch software) would offer additional evidence to support the use of 0.25% lidocaine for dermatologic surgeries.[10]

## Conclusion

In summary, the authors show that 0.25% lidocaine with 1:400,000 epinephrine can be used for dermatologic surgeries without compromising pain control or patient satisfaction. The use of 0.25% lidocaine offers a myriad of benefits, including decreased toxicity, increased procedural scope without heavy sedation, and resource conservation—all ultimately contributing to improved patient safety and experience.


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