Comparison of Efficacy Outcomes of Lidocaine Spray, Topical Lidocaine Injection, and Lidocaine General Anesthesia in Nasal Bone Fractures Surgeries: A Randomized, Controlled Trial

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Background: Lidocaine is widely used as a general and local anesthetic in minor or major surgeries. The objective of the study was to compare postoperative pain relief and adverse events using different forms of lidocaine administration in patients following closed nasal bone reduction surgery.

Material/Methods: A total of 381 patients with a solitary nasal fracture that could be managed with closed reduction were included in this study and divided into 3 groups of 127 patients in each group. Patients had received 1% lidocaine HCl with epinephrine (LL group), inserted a mesh impregnated with lidocaine spray (TL group), or 1 mg/kg/h lidocaine infusion (GL group) before surgeries. Patients also received morphine when the pain was not controlled. The postoperative pain was assessed at 6 hours and 48 hours after surgery. Postoperative vomiting and nausea were evaluated. Repeated ANOVA/Tukey-Kramer multiple comparisons test was performed at 95% confidence level.

Results: At 6 hours after surgery, patients in the general lidocaine (GL) group reported decreased postoperative pain compared with those in the topical lidocaine (TL) group ($P<0.001$, $q=6.633$) and LL group ($P<0.001$, $q=8.056$). The morphine consumption within 48 hours was least in GL group than TL group ($P<0.001$, $q=172.9$) and LL group ($P<0.001$, $q=226.42$). Lidocaine infusion caused nausea ($P<0.001$, $q=6.742$) and vomiting ($P<0.001$, $q=4.306$).

Conclusions: Topical lidocaine anesthesia had the same postoperative pain relief and the least adverse events as local and general lidocaine anesthesia.

MeSH Keywords: Anesthesia and Analgesia • Lidocaine • Morphine • Nasal Bone • Nasal Surgical Procedures • Surgery, Oral

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Background

Most facial fractures are nose fractures [1], and more than half of the fractures in the human body are nasal fractures of some type. Nasal bone fractures occur with facial bone fractures or may develop alone [2]. As an anatomic feature, the nose bone is raised or embossed [1]. Moreover, it has a central location on the face and anterior projection [2]. As such, the nasal bone is more susceptible to fracture during accidents.

At present, closed nasal fractures reduction (CNFR) surgeries are performed under general anesthesia, topical anesthesia, and/or local anesthesia [3]. Studies are available on the safe use of general anesthesia [4], topical anesthesia [1], and local anesthesia [5].

Lidocaine is widely used as a general and local anesthetic following minor or major surgeries [6]. It has an analgesic effect, which is more than locally administered analgesic drugs [7]. It decreases the inflammatory response and hyperalgesia because it modulates ectopic neuronal discharges [8]. It blocks sodium channels, modulates G protein-coupled receptors, NMDA receptors, and calcium and potassium-channels [9]; therefore, it is effective in pain control [10].

The objective of the study was to compare postoperative pain relief using different forms of lidocaine administration in patients following CNFR surgeries in a Chinese setting. The secondary objective was to report lidocaine-emergent adverse events.

Material and Methods

Materials

Lidocaine (Xylocaine® 10 mg) spray, 5% lidocaine HCl solution (Xylocaine® heavy injection), and 1% lidocaine HCl with epinephrine (Xylocaine® w/Epi) was purchased from Astra Zeneca, Shanghai, China; 0.5% phenylephrine nasal drops were purchased from Xinhua Pharma, China. The materials for surgeries were purchased by the patients’ relatives.

Inclusion criteria

Patients who had a nasal bone fracture with or without facial traumatic injury admitted to the Oral and Maxillofacial Department of Sir Run Run Shaw Hospital of Zhejiang University, China during January 2012 to November 2017 were included in this randomized, parallel, prospective, experimental anesthetic study. Patients age 18 years and older, who did not required septoplasty in addition to CNFR surgery, and who did not require open reduction of nose fracture surgery were included in this study. Patients who had simple nose fracture and/or minor facial fractures were included in this study.

Exclusion criteria

Patients who were younger than 18 years old, refused to sign an informed consent form, required septoplasty in addition to CNFR surgery or open reduction of nose fracture, did not want to perform CNFR surgery, and preferred cosmetic surgery were excluded from this study. Patients who had simple nose fracture with major facial fractures were excluded from this study.

Ethical consideration

The study was registered in research registry (http://www.researchregistry.com) UIN is researchregistry3388 dated 31 December 2011. The study protocol on the human subject was approved and maintained by Sir Run Run Shaw Hospital, China Review Board under 1964 Declaration of Helsinki and CONSORT guidelines. Data were available from DICO files of patients of Sir Run Run Shaw Hospital and the referring hospital (Wuyi traditional Chinese Medical Hospital). All patients’ relatives signed an informed consent form before commencement of the surgeries, thus providing their consent to perform anesthesia, surgeries, and publication of the study in all formats (electronic and hard copy) irrespective of time and language.

Design of the study

In total, 381 patients planned for CNFR surgeries were assigned for this randomization (simple randomization) and parallel study design. The patient population was divided into 3 groups. The prior sample size was calculated using OpenEpi 3.01-English (Epidemiologic Statistics for Public Health, USA) with 127 patients in each group. The other parameters were confidence limit of 95% with design effect for cluster survey of 1, hypothesized percentage frequency of 95%, and sample population of 381. CONSORT flow diagram of the experimental anesthetic study is presented in Figure 1. The demographic parameters of enrolled patients are presented in Table 1, which shows that except for etiology of nasal bone fracture, there were no significant differences for demographic parameters among enrolled patients.

Grading of nasal bone fracture before surgery

The history of nasal fracture was taken orally. The bones of the nose were examined by computed tomography (CT) for the presence of fracture and graded as shown in Table 2 [1,2].

Intervention

Patients of local lidocaine (LL) group had infiltrated by 1% lidocaine HCl with epinephrine injection into the nose root and two lateral sides. The volume of 1% lidocaine HCl with epinephrine injection was calculated as per Eq. 1 [11].
Where $V=$ volume of 1% lidocaine HCl with epinephrine injection; $M=$ maximum allowable dose of lidocaine HCl with epinephrine as local anesthetic = 7 mg/kg; $W=$ weight of patient (kg); $C=$ concentration of lidocaine HCl in the used product for anesthesia.

Patients in the topical lidocaine (TL) group received 0.5% phenylephrine nasal drops in both nasal cavities and inserted a lidocaine spray impregnated mesh over an operative area [1] before surgeries. Patients in the general lidocaine (GL) group received 2.5% lidocaine solution in normal saline, 1.5 mg/kg lidocaine as a bolus, followed by 1 mg/kg/h lidocaine infusion before surgeries [12].

**CNFR surgery**

For all patients, the surgeries were performed by oral and maxillofacial surgeons who had experience of at least 5 years and were blinded regarding anesthetic method. During the surgeries, the elevated part was pushed, and fractured part was pulled by elevator. If the depressed part was not fixed, then a doxycycline tampon was used to fix the moving part. The tampon was removed after 3 days. All patients’ noses had a plaster cast applied [1]. After surgeries, no oral painkillers were given to the patients. However, patients also received morphine (10 mg/mL morphine sulfate injection, Hameln Pharmaceuticals Ltd., UK) when pain was not controlled [13].

**Postoperative pain assessment**

All patients were transferred to the general ward on the 4th day. The postoperative pain was assessed at 6 hours and 48 hours after surgery by simple questionnaires using visual analog scale (VAS) score method [14]. In the VAS score method, 0: absent pain, 1: slight pain, 2: mild pain, 3: moderate pain, 4: moderate to severe pain, 5: severe pain, 6: severe to extreme pain, 7: extreme pain, 8: extreme to worst pain, 9: worst pain, and 10: maximum worst. Postoperative pain was considered as pain if it was during a coughing episode [15] and at rest [13].

**Lidocaine-emergent adverse effects**

Postoperative vomiting, nausea, and the total length of hospital stay were evaluated [13].

**Satisfaction**

The plaster cast was removed from the nose on the 25th day. Nose reduction was evaluated by oral and maxillofacial surgeons and one otolaryngologist, who was blinded regarding satisfaction.

**Figure 1.** Flow diagram of randomized, parallel, clinical trial. POP – postoperative pain; ANSP – satisfaction regarding anesthetic and surgical procedure; NONS – satisfaction regarding nasal obstruction and nasal shape; AEAE – anesthesia-emergent adverse effects; TLHS – total length of hospital stays; MC – morphine consumption.
Table 1. Demographic parameters of enrolled patients at the time of enrollment.

| Parameters            | LL group | TL group | GL group | Comparison of groups | p-Value | q-Value |
|-----------------------|----------|----------|----------|----------------------|---------|---------|
| Sample size           | 127      | 127      | 127      |                      |         |         |
| Age (years)           | 18–29    | 31 (24.5%) | 43 (33.9%) | 39 (30.7%) |         |         |
|                       | 30–39    | 35 (27.6%) | 42 (33.1%) | 36 (28.3%) |         |         |
|                       | ≥40–49   | 33 (25.9%) | 27 (21.3%) | 35 (27.6%) | 0.0735  | N/A     |
|                       | 50–59    | 18 (14.2%) | 8 (6.3%)   | 11 (8.7%)   |         |         |
|                       | ≥60      | 10 (7.9%)  | 7 (5.5%)   | 6 (4.7%)    |         |         |
| Gender                | Male     | 45 (35.4%) | 55 (43.3%) | 46 (36.2%)  | 0.3194  | N/A     |
|                       | Female   | 82 (64.6%) | 72 (56.7%) | 81 (63.8%)  |         |         |
| Etiology              | Work     | 10 (7.9%)  | 17 (13.4%) | 27 (21.3%)  |         |         |
|                       | Fall     | 13 (10.2%) | 44 (34.6)  | 31 (24.4%)  |         |         |
|                       | Sports   | 15 (11.8%) | 34 (26.8%) | 9 (7.1%)    | <0.0001 | 8.53    | 7.16    | 1.35    |
|                       | Accident | 45 (35.4%) | 12 (9.5%)  | 41 (32.3%)  |         |         |
|                       | Assault  | 44 (34.6%) | 20 (15.7%) | 19 (14.9%)  |         |         |
| Ethnicity             | Non-Chinese | 1 (0.8%)  | 7 (5.5%)  | 2 (1.6%)    | 0.0414  | N/A     |
|                       | Chinese  | 126 (99.2%) | 120 (94.5%) | 125 (98.4%) |         |         |
| Body weight (kg)      | ≥40 but <50 | 25 (19.7%) | 33 (25.9%) | 31 (24.4%)  |         |         |
|                       | ≥50 but <60 | 58 (45.7%) | 42 (33.1%) | 51 (40.2%)  | 0.9537  | N/A     |
|                       | ≥60 but <70 | 33 (25.9%) | 47 (37.0%) | 37 (29.1%)  |         |         |
|                       | ≥70      | 11 (8.7%)  | 5 (3.9%)   | 8 (6.3%)    |         |         |
| Height (cm)           | ≥140 but <155 | 35 (27.6%) | 47 (37.0%) | 37 (29.1%)  |         |         |
|                       | ≥155 but <170 | 66 (51.9%) | 65 (51.2%) | 58 (45.7%)  | 0.265   | N/A     |
|                       | ≥170 but <185 | 26 (20.5%) | 15 (11.8%) | 32 (25.2%)  |         |         |

* All male subjects; ^ The most of the motor vehicle types. ANOVA following Tukey-Kramer multiple comparisons test was used for statistical analysis. p<0.01 and q>4.151 were considered as statistically significant. N/A – not applicable.

Table 2. Grading of nasal bone deformity.

| Type of nasal bone deformity | Position of fracture | Deviation of the width of the nasal bridge |
|-----------------------------|----------------------|------------------------------------------|
| I                           | Inferior half of nasal bone | <½                                      |
| II                          | Entire nasal bone and separation from position | ≥½ but <1                                |
| III                         | Nasal bone and the frontal maxilla | ≥1                                      |
| IV                          | Nasal bone, the frontal maxilla, and facial bones | Touch to cheek                           |
anesthetic method. Satisfaction was measured regarding anesthetic and how the surgical procedure had been performed using a 5-point numerical scale method: 1: least satisfied, 2: fair satisfied, 3: average satisfied, 4: moderate satisfied, and 5: maximum satisfied [1]. Satisfaction was measured regarding how nasal obstruction and nasal shape were performed using a 3-point numerical scale method: 1: no or poor improvement in nose shape, 2: fair improvement in nose shape, and 3: good improvement in nose shape with slight irregularity [16]. X-ray and CT were used to justify satisfaction criteria [17]. If further surgery was required for additional improvement in the nose shape, it was done using topical lidocaine as an anesthetic [1].

### Statistical analysis

All data were represented as mean ±SD. Repeated measure analysis of variance (ANOVA) [4] following Tukey-Kramer multiple comparisons test [18] was used to compare anatomical conditions of patients at the time of enrollment (considering critical value (q) >4.151 as significant), morphine consumption, postoperative pain assessment 48 hours after surgery, satisfaction regarding the anesthetic procedure, satisfaction regarding nasal obstruction and nasal shape, lidocaine-emergent adverse effects, and the total length of hospital stay (considering q>3.327 as significant). One-way ANOVA [19] following Tukey-Kramer multiple comparisons test (considering q>3.327 as significant) [18] was used to compare postoperative pain assessment 6 hours after surgery. All analysis was performed using InStat (GraphPad Software, Inc, USA). Anatomical conditions of patients at the time of enrollment were considered significant at 99% and the rest of results were considered significant at 95% of confidence level [20].

### Results

There were no significant discriminations for the type of nasal bone deformity and nasal fracture symptoms between the enrolled patients (Table 3).

Three patients in the GL group failed to complete the VAS score after 6 hours of surgeries. At 6 hours after surgery, patients in the GL group reported decreased postoperative pain compared to patients in the TL group (P<0.001, q=6.633) and the LL group (P<0.001, q=8.056). However, the factors of time and morphine injection had significance effect on the decrease of postoperative pain in all groups (Table 4). The morphine consumption within 48 hours (Figure 2) was least in the GL group (10.1±0.12 mg) compared to the TL group (40.63±0.22 mg; P<0.001, q=172.9) and the LL group (50.08±0.18 mg; P<0.001, q=226.42).

All methods of lidocaine anesthesia provided equal satisfaction regarding anesthetic procedure (Figure 3), nasal obstruction, and nasal shape (Figure 4) to patients.

General lidocaine anesthesia caused nausea (P<0.001, q=6.742) and vomiting (P<0.001, q=4.306). Operation time was reported in the following order of local lidocaine anesthesia > topical lidocaine anesthesia > general lidocaine anesthesia. The method of anesthetic administration had no effect on bone reduction failure (Table 5). The total length of hospital stay was in the following order of general lidocaine anesthesia (5.09±0.36 days) > local lidocaine anesthesia (5.03±0.18 days) > topical lidocaine anesthesia (5.01±0.09 days; Figure 5).

### Table 3. Anatomical conditions of patients at the time of enrollment.

| Parameters                | LL group | TL group | GL group | Statistical analysis |
|---------------------------|----------|----------|----------|----------------------|
| Sample size               | 127      | 127      | 127      |                      |
| Type of nasal bone deformity |          |          |          |                      |
| I                         | 35 (27.6%) | 36 (28.3%) | 37 (29.1%) |                      |
| II                        | 33 (25.9%) | 31 (24.4%) | 29 (22.8%) | <0.0001 \(q\)-Value 2.019 3.69 1.582 |
| III                       | 38 (29.9%) | 35 (27.6%) | 33 (25.9%) |                      |
| IV                        | 21 (16.6%) | 25 (19.7%) | 28 (22.2%) |                      |
| Nasal tenderness          | 101 (79.5%) | 95 (74.8%) | 103 (81.1%) | 0.013 N/A N/A N/A     |
| Bone depression           | 91 (71.7%) | 88 (69.3%) | 86 (67.7%) | 0.0218 N/A N/A N/A   |
| Nasal deviation           | 66 (51.9%) | 61 (48.0%) | 60 (47.2%) | 0.0053 3.595 4.315 0.7191 |
| Nasal swelling            | 58 (45.7%) | 61 (48.0%) | 55 (43.3%) | 0.0106 N/A N/A N/A   |

For statistical analysis of nasal fracture parameters, the presence of symptom was considered as 1 and absent of that was considered as 0. Repeated measures ANOVA following Tukey-Kramer multiple comparisons test was used for statistical analysis. A \(p<0.01\) and \(q>4.151\) was considered as significant. N/A – not applicable.

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Table 4. Postoperative pain assessment.

| Time after surgery (h) | Anesthesia | Group | LL group | TL group | GL group | SA between groups |
|------------------------|------------|-------|----------|----------|----------|------------------|
|                        |            |       | Local lidocaine | Topical lidocaine | Lidocaine Infusion | *p-Value | q-Value |
| 6                      |            |       | 127      | 127      | 124      | LL vs. TL | LL vs. GL | TL vs. GL |
|                        |            |       | 0 (0.0%) | 0 (0.0%) | 3 (2.4%) | <0.0001 | 1.342   | 8.056     | 6.633     |
| VAS score              |            |       | 5 (14.9%) | 18 (14.2%) | 12 (9.8%) | <0.0001 | 1.342   | 8.056     | 6.633     |
| 48                     |            |       | 0 (0.0%) | 0 (0.0%) | 0 (0.0%) | <0.0001 | 1.342   | 8.056     | 6.633     |
|                        |            |       | 1 (0.8%) | 7 (5.5%) | 21 (16.5%) | <0.0001 | 12.359  | 51.71     | 39.351     |
| VAS score              |            |       | 5 (13.4%) | 17 (13.4%) | 9 (7.3%)  | <0.0001 | 12.359  | 51.71     | 39.351     |
| 48                     |            |       | 0 (0.0%) | 0 (0.0%) | 0 (0.0%) | <0.0001 | 1.342   | 8.056     | 6.633     |

*VAS score – visual analogue scale score; SA – statistical analysis. A 0: Absent pain and 10: maximum worst pain. * Repeated measures of ANOVA or ¶ One-way ANOVA following Tukey-Kramer multiple comparisons test was used for statistical analysis. A p<0.05 and q>3.327 was considered as significant.
Discussion

The anesthetic experimental study reported postoperative adverse effects due to lidocaine-anesthetic infusion. In the topical lidocaine (TL) anesthetic group, patients had edema and pain at the injection site due to inert of lidocaine impregnated mesh. General lidocaine anesthesia is the preferred method [3] in CNFR surgeries because of hospital protocols [21], less postoperative pain [1], and greater accuracy of surgery [22]. However, this method requires major operation theater and high total length of hospital stay for patients [1]. Besides these factors, local lidocaine administration is not associated with pain and inflammation at the site of injection [22]. With respect to the lidocaine-emergent adverse effects associated with anesthetic methods of this study, the local lidocaine-anesthetic method had the most acceptable parameters for surgeons and patients during CNFR surgeries.

The present study showed that the type of anesthetic method had no effect on outcomes of CNFR. The results of the experimental anesthetic study were in the line with available studies [1,16,22]. With respect to the success rate of surgeries, topical, local, and/or general lidocaine-anesthetic methods can be used as anesthetics for CNFR surgeries.

General-lidocaine anesthesia required the least morphine consumption. Intravenous lidocaine can reduce postoperative pain [23,24] and postoperative opioid(s) consumption [19]. Regarding study results on postoperative pain, general-lidocaine anesthesia was more effective in managing post-surgical pain syndromes than topical and local-lidocaine anesthesia.
All lidocaine anesthesia methods had an equal risk of second surgeries, patients’ satisfaction regarding the anesthetic procedure, surgical procedure, nasal obstruction, and nasal shape. The available published studies have reported a high risk of second surgeries and least satisfaction regarding anesthetic and surgical procedure and functional results (satisfaction regarding nasal obstruction and nasal shape) in topical [1] and local [25,26] lidocaine anesthesia compared to a general-lidocaine anesthesia method following CNFR surgeries. With respect to the results of this study, all lidocaine anesthetic methods performed the anesthesia in an equal manner.

There were several limitations to this study. The blood plasma lidocaine levels after performing all method of anesthesia was not evaluated. To manage postoperative pain only morphine injection was used, which is absolute in practice. Neither fentanyl, meperidine, piritramide, or sufentanil were used in postoperative pain management nor the equivalent of morphine calculations was performed regarding the other opioids. A single, experienced oral and maxillofacial surgeon approach was used. Double, experienced surgeon approach was not used. Only one otolaryngologist and one oral and maxillofacial surgeon evaluated the size and shape of the nose after surgeries and any dispute of opinions was resolved through discussion to reach a final decision. Preoperative pain scores were not evaluated. The study enrolled more female than male patients; however, sex also been identified as having a potential effect on the pharmacokinetics of anesthetic used.

**Conclusions**

This randomized parallel experimental anesthetic study concluded that the topical lidocaine anesthesia method had the same postoperative pain relief and the least lidocaine-emergent adverse events as local and general lidocaine anesthesia method in closed nasal bone reduction surgeries. However, at the time of surgery, fracture condition also has an important role in the success of the operation and the risk for second surgery. The study results recommend the double surgeon (oral and maxillofacial surgeon and ENT surgeon) approach for reducing the risk of bone reduction failure.
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Conflicts of interests

None.