



Efficacy of lidocaine vs combination of lidocaine and bupivacaine in management of maxillofacial trauma: a clinical comparative study

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Abstract

Background The COVID-19 pandemic has created an unprecedented situation which the treatment of maxillofacial trauma, especially mandibular fractures that were previously managed using general anaesthesia had to be performed under local anaesthesia. In these cases, there was a requirement for an anaesthetic agent that would have a rapid onset but also provide a prolonged effect. The aim of the study was to evaluate the onset, duration, depth, required volume of anaesthesia of lidocaine with epinephrine versus combination of lidocaine and bupivacaine with epinephrine anaesthetic agents in surgical management of isolated mandibular fracture patients.

Methods A total of 30 patients with isolated mandibular fractures reported to our hospital included the study group. Patients were randomly distributed to two groups, Group A and Group B. Group A received local anaesthesia using 2% Lidocaine with 1:80,000 adrenaline and Group B received 0.5% Bupivacaine with 1:2,00,000 adrenaline combined with 2% Lidocaine with 1:80,000 adrenaline at a ratio of 1:1. The outcome variables were recorded and the data was tabulated and analysed using un-paired students *t* test.

Results The combination of anaesthetic agents had longer duration of action (mean: 182.47 min, *P*-value: 0.001) and required lesser volume of anaesthetic solutions (mean: 5.38 mL, *P*-value: 0.001) as compared to usage of lidocaine alone. Although combination group showed quicker onset (mean: 4 min 8 s), the result was insignificant (*p*-value: 0.345).

Conclusion The study found that the combination of lidocaine and bupivacaine could serve as a potential anaesthetic cocktail in effective surgical management of isolated mandibular fractures.

Clinical relevance Maxillofacial injuries can be managed efficiently under local anaesthesia using combination of lidocaine and bupivacaine.

Keywords COVID-19 · Lidocaine · Bupivacaine · Local anaesthesia

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Introduction

The COVID-19 pandemic created a space to transform the conventional approach for carrying out surgeries [1–4]. The uncertainty created by the pandemic led to a spontaneous introduction of new safety protocols procedures, as well as a shift towards more minimally invasive and virtual surgeries to minimize the risk of exposure and transmission of the virus worldwide. [4] The imposed strict lockdown by the government could help in the reduction of trauma patients reporting to the hospital due to road traffic accident, but there was an enormous hike in the number of facial fractures caused due to interpersonal and domestic violence. Need for immediate intervention was required in many of these cases to avoid lifelong aesthetic and functional morbidity. Performing surgeries under general anaesthesia was

practically not possible during those times due to the shortage of anaesthetists and supporting manpower who were almost completely working in frontline to fight the spread of COVID-19 infection. Facial fractures, falling into the category of elective surgeries were being differed. Under these extreme circumstances, the general anaesthesia workload was reduced by performing maximum possible surgeries under local or regional anaesthesia with strict intra and post operative monitoring following all the safety precautions and protocols in place then.

Lengthy surgical procedures warranted longer depth and duration of anaesthesia. The maximum duration of activity of 2% Lidocaine with 1:80,000 adrenaline, the commonly used anaesthetic agent in oral and maxillofacial procedures, is seen to be for up to 2 h. Following this, subsequent doses are not as effective as the initial anaesthesia and multiple administrations are needed. Almost 70% of lidocaine is metabolised in the liver and repeated, additional dosage can be potentially toxic to the patients [5]. This also leads to the patient experiencing further pain, intra-operative morbidity.

To achieve a satisfying post-operative outcome, good intra-operative anaesthesia is necessary in turn providing a better patient compliance. Combining a short onset and a long-acting local anaesthetic agents were planned to be administered to overcome the shortcoming of lidocaine alone, but there was not enough strong evidence in literature to support the efficacy of this combination in oral and maxillofacial procedures. Our study aims at comparing the onset, depth and duration of anaesthesia provided by administration of lidocaine with epinephrine alone for regional anaesthesia versus the combination of lidocaine and bupivacaine with epinephrine in isolated mandibular fracture fixation surgeries carried out during the pandemic period.

Methodology

A prospective single blinded randomized control study was performed in patients reporting to our hospital with isolated mandibular fractures during a period from March 2020 to August 2020. Institutional Review Board clearance was taken for the study and informed written consent was obtained from all the patients involved in the study.

Inclusion criteria:

- Isolated displaced simple or complex mandibular fractures. (Complex fractures involve at least two fracture lines and three or more fragments in the same region of the mandible)
- Fractured fixed using miniplate osteosynthesis/semi-rigid fixations.

Exclusion criteria:

- Fractures requiring rigid fixations like, reconstruction plates or locking plates.
- Condylar fractures
- Mandibular fractures associated with other concomitant fractures.
- COVID-19, RTPCR positive patients or patients who had recent COVID-19 infection.
- Malunited fractures.
- Infected fractures.
- Patients contraindicated for surgery under local anaesthesia.
- Patients who were uncooperative intra-operatively. (Such patients were sedated using intravenous Injection. Midazolam 1 mg before carrying out further procedures.)

Patients satisfying the above-mentioned criteria were randomly allocated by lottery method to two different groups, Group A and Group B, demographic details were collected (Table 1). Group A consisted of patients who received 2% Lidocaine with 1:80,000 adrenaline only for achieving local anaesthesia while Group B patients received 0.5% Bupivacaine with 1:2,00,000 adrenaline as well as 2% Lidocaine with 1:80,000 adrenaline together at a ratio of 1:1.

All patients underwent open reduction and internal fixation of the fractures under local anaesthesia by two experienced surgeons only using the standard protocol which includes:

Table 1 Demographic details and study variables

		Group A	Group B
Number of patients		15	15
Age (years)	Youngest	18	29
	Oldest	64	58
Sex	Male	13	12
	Female	2	3
Location of fracture	Unilateral parasymphysis	9	7
	Unilateral angle	2	1
	Bilateral parasymphysis	1	1
	Unilateral body	0	2
	Symphysis	1	2
	Parasymphysis and angle	2	2
Onset (min)	Minimum	3	3.5
	Maximum	5.5	6
Duration (min)	Minimum	80	155
	Maximum	110	210
Volume (ml)	Minimum	6	4.5
	Maximum	11	7
VAS score	Minimum	7	7
	Maximum	9	9

I. Pre-operative

- Imaging: dental panoramic radiograph and PA view of mandible.
- Routine blood investigations: complete blood count, serology, and bleeding profile.
- Liver, renal, and thyroid profiles if indicated.
- Adequately hydrated.
- Intravenous medications (administered half an hour before the surgery):
 - Inj. amoxicillin 1.2 g
 - Inj. metronidazole 500 mg
 - Inj. hydrocortisone 100 mg

II. Intra-operative

- Monitoring vitals: blood pressure, pulse, SpO₂, and respiratory rate.
- Draped under aseptic conditions.
- **Administration of local anaesthesia:** Group A and Group B patients received different aesthetic agents as mentioned above. Bilateral mental nerve blocks for symphysis region and bilateral Inferior Alveolar Nerve Block along with long buccal nerve block were administered for para symphysis, body, and angle fracture of mandible cases. All patients were administered with lingual nerve block. Inferior border of mandible was anesthetised using local infiltration with the same local anaesthetic agent(s) through extra-oral injection in all patients.
- Placement of Ivy's eyelets in upper and lower arches. Maxillary eyelets were placed under local anaesthetic infiltration.
- Intra-oral vestibular incision for fracture site exposure.
- Callus between fracture segments removed if present.
- Manual reduction of fractured segments.
- Intermaxillary fixation (IMF).
- Fixation of fractures segments using miniplate osteosynthesis.
- Release IMF and recheck occlusion.
- Thorough irrigation using normal saline.
- Closure of incision using resorbable suture materials.

III. Post-operative

- Monitoring vitals.
- Intramuscular analgesics as and when anaesthesia wears off.
- Discharge on post-operative day.

Total volume of anaesthetic solution injected in both the groups were recorded. The primary outcome

measures included onset of anaesthesia evaluated by a blinded observer using pin prick test immediately after administration of anaesthetic agent till the onset of anaesthesia at an interval of 30 s, duration of anaesthesia, measured by calculating the time between the onset of anaesthesia to the point when patient starts experiencing pain in pin prick test performed at an interval of 5 min starting after 15 min of placement of the last suture and the volume of anaesthetic solution injected to achieve the desired depth of anaesthesia.

The secondary variable, the depth of anaesthesia or the patient pain experience during the surgical procedure was recorded using Visual Analogue Scale (VAS) ranging from 0 to 10. This intra-operative data was evaluated later and recorded as patient reports from the recall of pain experienced during the surgical procedure especially during the miniplate fixation being done.

The data obtained was tabulated and evaluated using unpaired students *t* test (Table 1 and 2).

Results

A total of 30 patients were included in the study and was equally distributed among Group A and Group B. Female patients included in the study was only 5 and rest were male patients. The duration of the surgery depended on the complexity of the procedures, site and number of fractures addressed. The primary outcome variables, onset of anaesthesia in Group A ranged from 3 to 5 min 30 s with a mean of 4 min 8 s. On the other hand, in Group B it ranged from 3.9 min with a mean of 4.2 min. On statistical analysis using un-paired students *t* test, the *p*-value was 0.345, not significant. The mean duration of anaesthesia was 94.3 min and 187 min in Group A and Group B respectively. Group A patients received an average of 5.8 ml of anaesthetic solution for achieving adequate depth of anaesthesia while it was only 9.1 ml in Group B. *P*-value as calculated was 0.001, proving the results to be significant. The mean volume of anaesthetic solution injected in Group A was 9.07 ml while it was only 5.83 ml in Group B. The result was significant with a *p*-value of 0.001. The secondary variable, depth of anaesthesia observed using VAS score of the experience during the procedure as recalled by the patient was a mean of 8 irrespective of the groups. None of our patients had any adverse reactions to any of the local anaesthetic solutions administered.

Discussion

Since Nils Lofgren and Bengt Lundquist invented Lidocaine in 1943 [6, 7], it is the most widely used anaesthetic agent in oral and maxillofacial procedures performed under local anaesthesia. It is an amide local anaesthetic agent which is most soluble in water and has demonstrated a rapid onset of anaesthetic effect and intermediate duration of action. In clinical applications, it is required to re-administer multiple times with the lidocaine in

Table 2 Comparison of onset, duration, volume of LA needed, and VAS scores between the two groups by un-paired *t* test

Group		<i>N</i>	Mean	Std. deviation	<i>p</i> -value	Mean difference	95% Confidence interval of mean difference		Power analysis for the comparison
Onset	Group A	15	3.90	0.74	0.345	− .30	− .94	.34	17%
	Group B	15	4.20	0.96					
Duration	Group A	15	94.33	8.84	0.001	− 92.67	− 102.94	− 82.39	99%
	Group B	15	187.00	17.30					
Volume	Group A	15	9.07	1.36	0.001	3.23	2.40	4.07	99%
	Group B	15	5.83	0.79					
VAS	Group A	15	8.00	0.76	1.000	.00	− .53	.53	Same mean values- power not calculated
	Group B	15	8.00	0.65					

Duration of local anaesthesia was significantly higher for group *B* when compared by unpaired *t* test. Volume of local anaesthesia needed was significantly lower for group *B* when compared by unpaired *t* test. There was no significant differences for the other variables

case of performing a longer duration procedure. Bupivacaine, a long-acting amide local anaesthetic agent was formulated by Bo af Enkenstam et al. in 1957 [8]. It is the choice of anaesthesia in oral and maxillofacial surgeries requiring longer duration of anaesthesia. Attributed to its higher lipid solubility and high protein binding capacity, it provides a long duration of action and higher potency than lidocaine.

Onset of action for lidocaine is approximately 3 min while bupivacaine demonstrates a delayed onset of action of approximately 15 min. 2% Lidocaine with 1:80,000 adrenaline has an average duration of action about 108.5 ± 13.7 min [9]. Action of 0.5% bupivacaine with 1:2,00,000 adrenaline lasts approximately for an average of 252.8 ± 34.3 min [9] which is more than two times as that of lidocaine. In terms of toxicity, Bupivacaine is reported to have less than one fourth of that of lidocaine [10]. However, it is more toxic compared to other longer acting anaesthetic agents, especially regarding its cardiotoxicity [11]. Bupivacaine showed high potential for accumulation in the sodium channel, as it enters rapidly during the action potential but exited slowly during recovery. Lidocaine is known for its cardiotoxicity as well as proconvulsant effect at higher doses [11].

Multiple attempts of combining these anaesthetic agents in various proportions were reported by few authors, but in obstetrics, ophthalmology, general surgery etc. [12–14]. Few authors have reported the usage of similar combinations in minor oral and maxillofacial region but are found to be having insufficient data to derive proper evidence to prove its advantage over usage of a single long-acting anaesthetic agent [15]. There are variations in methods employed and the conclusions derived in various studies reported earlier [12–14]. However, there is no safety or efficacy concerns reported regarding mixing of these agents.

Onset of anaesthesia were nearly similar in both the groups (4 min 8 and 4 min 2 s in Group A and B respectively). This

hypothesized to be the property lidocaine's rapid onset of anaesthesia which is responsible for the similar property in combining lidocaine and bupivacaine. But it was interesting to note that combination of anaesthetic agents has demonstrated a slightly more rapid onset than lidocaine alone, the reason is unknown. Duration of anaesthesia was much longer in Group B (mean-187 min) as compared to the Group A (Mean- 94.3 min); these figures are in accordance with the previous studies reported in the literature highlighting the property of bupivacaine. Group B patient received 5.8 ml, considerably lesser volume of local anaesthetic solution as compared to lidocaine alone (9.1 ml) in our patients. Combining both lidocaine and bupivacaine can reduce the total volume of anaesthetic solution required, which can help in marginally reducing the adverse effects of these anaesthetic agents and need for giving multiple injections.

However, the depth of anaesthesia as evaluated by VAS score for the experience of pain during the procedure revealed similar figures in both the groups. The experience of pain was minimal in all the study patients. Few patients were confused between tactile sensation experienced during the miniplate fixation as pain. Even though there could be recall bias by the patients, the inference was quite significant. Combination of anaesthetic agents have not provided any advantage in terms of depth of anaesthesia in our study patients. Individual agents would be sufficient to achieve an adequate depth of anaesthesia for these kinds of relatively short-duration procedures.

It is also imperative to provide adequate antibiotic cover to the patient's undergoing mandibular fracture fixation irrespective of complexity of fracture. Considering the common mode of injury as road traffic accidents, the fracture is usually associated with superficial to deep contaminated soft tissue injuries it would be sensible to administer three day course of IV antibiotics. Also, this protocol would prevent any chances of post-operative surgical site infection in the patient who does

not follow post-operative care as instructed if discharged without post-operative care. Post-operative hospital stay for at least three days would aid in monitoring the surgical site, occlusion and soft tissue injuries if present. There are no evidence documented in literature for the rationale of administering 3 days IV antibiotics after simple mandibular fracture fixation surgeries but our experience with following this protocol has definitely helped in reducing the number of patients returning with post-operative surgical site infections as well as long-term hardware failures. Further research is required on this to proof the efficacy or provide an evidence for this practice.

Conclusion

The need for a conservative approach during the COVID-19 pandemic has steered us to inculcate the basics of pain management using local anesthetic agents in oral and maxillofacial surgery for managing maxillofacial trauma, providing the patient a smoother treatment experience during the extreme conditions created by the pandemic. The advantage of administering a combination of lidocaine and bupivacaine with epinephrine has given the major advantage of elimination of the complications of general anesthesia, reduced toxicity, shorter onset and longer duration of action as compared to individual anesthetic agents, better depth of anesthesia, longer post-operative analgesia, shorter hospital stays, cost-effective and finally eliminating the morbidity that can be caused by delay in intervention. This can be considered as a viable clinical alternative for routine management of appropriately selected cases.

Author contribution

Authors 1, 3: design of the study, data interpretation.
Authors 1, 2: conducting the study, collection of data, writing manuscript.
Authors 4, 5, 6: conducting the study and collection of the data.

Declarations

Competing interests The authors declare no competing interests.

Ethics and consent to participate IRB approval obtained: Shri Dharmasthala Manjmatheshwara Medical College Ethical Committee.

Verbal and written informed consent obtained from all the patients participated in the study.

Conflict of interest The authors declare no competing interests.

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