ORIGINAL RESEARCH

Can Regional Anesthesia be an Alternative Option to General Anesthesia in the Management Of Le Fort I and Le Fort II Fracture Maxilla by Open Reduction and Internal Fixation? - A Randomized Controlled Trial

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ABSTRACT

Background: The incidence of maxillofacial injuries is on rise due to the increase in the number of motor vehicle accidents. Fracture maxilla constitute about 11.5% to 18.6%[1,2] of total fractures in maxillofacial region. Open Reduction and Internal Fixation (ORIF) under general anaesthesia (GA) with endotracheal intubation is the preferred method for its management. However, along with the advantages of GA, this technique exposes patients to the risks associated with GA. A randomised controlled study was conducted to evaluate the efficacy of regional anaesthesia (RA) as compared to general anaesthesia (GA) for the management of Le Fort I and Le Fort II fracture maxilla by ORIF.

Material and Method: Patients were divided in to two groups. Group I was treated under LA with Injection Articaine hydrochloride 4% as local anaesthetic agent and injection Tramadol 1mg/kg dose as pre-emptive analgesic agent. Group II was treated under standard care that is general anaesthesia.

Observation and Results: Evaluation was done with various criteria like vital parameters (pulse rate, blood pressure, oxygen saturation), behavioural assessment scoring during regional anaesthesia, immediate post operative complications like nausea/vomiting, post operative edema, duration of hospital stay etc. From the study it is observed that mean time required for surgical procedure under RA was significantly less in group I with less complications rate, 90% of the patients could tolerate the procedure well under RA and procedure was done on day care basis.

Conclusion: Le Fort I and Le Fort II fracture involving maxilla can be managed satisfactorily using regional anaesthesia technique. The advantages of regional anaesthesia being a technique for day care procedure with minimal post operative complication and cost effective.

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INTRODUCTION

The incidence of maxillofacial injuries is on rise due to the increase in the number of motor vehicle accidents. Fracture maxilla constitute about 11.5% to 18.6%of total fractures in maxillofacial region[1,2]. Of these maxillary fractures, Le Fort I constitutes about 32.7% while Le Fort II in about 31.8% cases[1,2]. Open reduction and internal fixation (ORIF) under General anaesthesia (GA) with endotracheal intubation is the preferred method for management of Le Fort I and II Fracture Maxilla [3].

However, along with the advantages of GA , this technique exposes patients to multiple risks associated with a difficult intubation, polypharmacy, and potential postoperative complications like residual sedation, problems of airway maintenance, nausea, vomiting and aspiration pneumonia [3]. Besides this, it requires skilled manpower and operation theatre setup leading to higher cost[4]. Regional Anaesthesia (RA) has been successfully used for various maxillofacial surgical procedures in the past as well [6,7.8].

Aim and Objectives:

Aim of the study was to evaluate the efficacy of RA as compared to GA in the management of Le Fort I and Le Fort II fracture maxilla (low level) by ORIF. The objectives the study was to evaluate the ease and comfort of operative surgeon and patient's comfort during surgical procedure, incidence of post operative complications in both the groups.

Research Question:

Can Regional anaesthesia (RA) be an alternative to general anaesthesia (GA) for the management of Le Fort I and Le Fort II fracture maxilla by open reduction and internal fixation?

Null hypothesis:

RA cannot be an alternative to GA for the management of maxillary Le Fort I/II fractures with Open Reduction and Internal Fixation.

PICOTS criteria:

(P) Type of patients: those patients with Le Fort I or Le Fort II fracture maxilla.
(I) Type of intervention: Manipulation under RA
(C) Type of comparator: Manipulation under GA
(O) Type of Outcomes: Patients comfort with the procedure - type of Anaesthesia
(S) Type of Study: Randomise Control Clinical Trial

MATERIALS AND METHOD

It was a Randomised Control Study conducted after Institutional ethical committee approval. Inclusion criteria includes adult patients with age group 18 to 50, isolated maxillary Le Fort I and II fractures (low level), fractures less than 2 weeks old with indications for ORIF, who are in category ASA I and ASA II to undergo surgery under General anaesthesia/ Regional Anaesthesia. After consent patients were divided into two groups with sample size of 20 each. Group I (Patients treated under regional anaesthesia with local anaesthetic agent,

Articaine hydrochloride 4% with 1:100,000 epinephrine). Group II (Patients treated under General Anaesthesia.

Exclusion criteria includes patients with sensitivity to local anaesthetic agent (articaine), comminuted facial fractures, fractures or major trauma in other body parts, Le forte fractures more than 2 weeks old, patients within head injury, ASA III/IV category patients and those who are not willing to consent.

Lottery system was used to select the type of anaesthesia used during the surgical procedure. Baseline readings for the parameters like blood pressure, Heart rate, SpO_2, temperature were noted preoperatively. Informed consent taken on day of surgery. All preanesthetic protocols were followed like 8 hrs nil by mouth status, prophylactic antibiotic cover. Eyelets were applied for intraoperative intermaxillary fixation in all patients preoperatively. Sensitivity testing was done for local anaesthetic agent Articain for Group I patients.

In case of patients treated under RA, multipara monitor is attached to patients and after wide bore IV access is obtained, injection Tramadol was given with dose of 1mg/kg infusion at the start of the surgical procedure and if required repeated during surgery[10,11] along with inj.
Ondansetron. Local anaesthetic nerve blocks like Infraorbital, Posterior superior Nasopalatine and Greater palatine were given bilaterally as per the requirement with Inj. Articain.

For general anaesthesia preinduction sedation given as inj.midazolam 0.03 mg /kg, and inj. Fentanyl1mcg/kg after obtaining wide bore IV access and attaching multipara monitors. After adequate preoxygenation patients were induced with inj propofol 2mg/kg and inj succinyl choline 1.5 mg/kg. nasal intubation is done and anaesthesia maintained with oxygen:nitrous oxide mixture 40:60, sevoflurane, vecuronium and positive pressure ventilation.

In both groups intraoral circumvestibular incision in maxillary arch was given to expose the fracture site. After reducing the fracture, IMF was done. Fractures fixation was done using 1.5mm titanium mini plates and titanium screws with head diameter of 1.5mm and 6mm length. IMF was released. Closure of surgical site was done with 3-0 vicryl. Surgical procedure including incision, fracture reduction and closure of surgical site remained the same for all patients in both the group.

Method of Assessment:

Patients were evaluated using following parameters-

1. Time required for the procedure from the administration of respective anaesthesia to the completion of procedure.
2. Patient's assessment was done for –

a. Vital parameters like heart rate, blood pressure and SpO_2 atpreoperatively, during surgery at 15 mins interval and post operatively up to 6 hours[5].
b. Behavioural assessment scoring during surgery was done with criteria like facial muscles relaxation, restlessness, muscle tone, vocalization, consolability[12,13,14]

3. Immediate post operative complications like Nausea & Vomiting, Hiccup, Aspiration pneumonia and other complications like Oedema, infection, dehiscence etc[15].
4. Intra operative and post operative Occlusion stabilization.

5. Preoperative and post operative Radiographic evaluation.
6. Duration of hospital stay measured in hours.

Patients were followed up for three months.

Data analysis (statistics): SPSS version 16.0 was used for statistical analysis. Independent t'test was used to compare quantitative variables and chi square test was used to compare qualitative variables. P-value ≤ 0.05 was considered as statistically significant.

OBSERVATIONS AND RESULT

Table 1

Criteria	Group I (RA)	Group II (GA)
Mean age	26.7	28.9
male	16	16
female	4	4
Duration of stay	2.4 HRS	56.4 HRS
Duration of surgery	85.25 min	115.07min

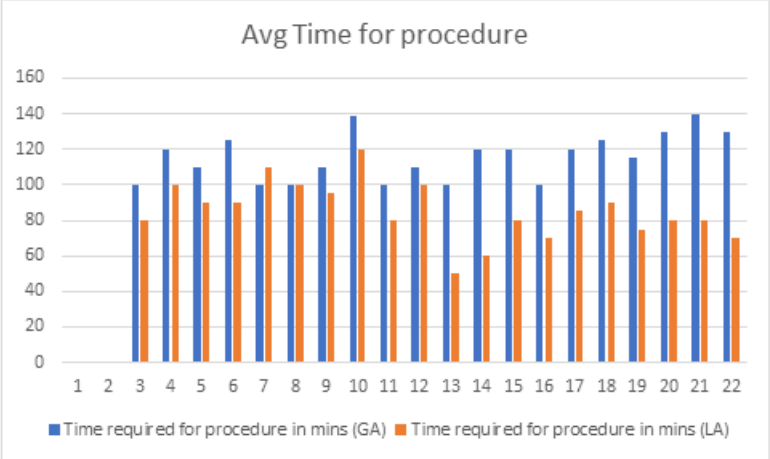

Chart 1: Average time for completion of procedure

Y axis- Time in minutes

X axis- Patient

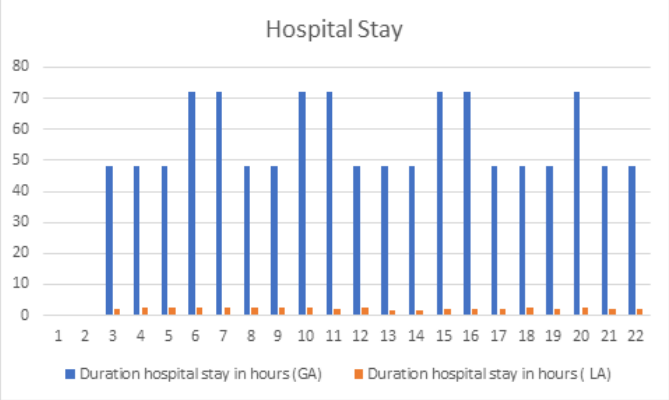

Chart 2: Hospital stay in hours.

Y Axis- Time in hours.

X Axis- Patients.

Table 2

Post operative nausea and vomiting(grading)	Group II	Group I
0	4	15
I	8	5
II	2	
III	3	
IV	2	
V	1	

Gradation for Immediate post operative complications like Nausea & Vomiting, Hiccups.

1. No complications-0
2. Nausea-1
3. Nausea & Vomiting-2
4. Nausea & Hiccup-3
5. Vomiting-4
6. Hiccup-5

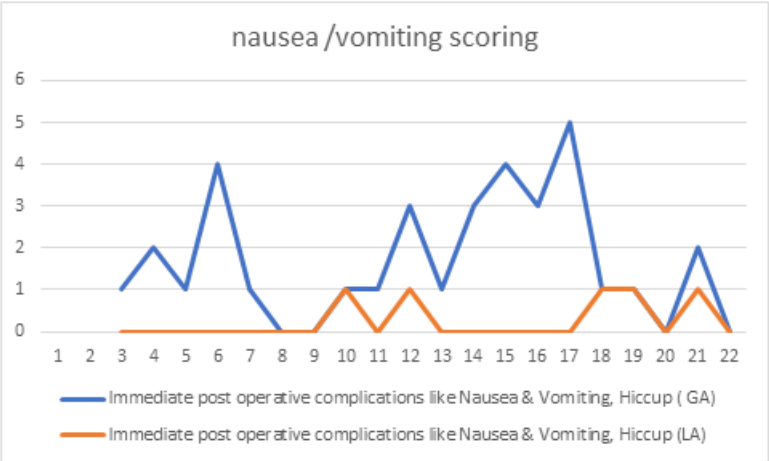

Chart 3: Nausea /vomiting in two groups.

x Axis-Patient. y Axis-Nausea/Vomiting scoring.

Table 3:Postoperative oedema.

Postoperative edema	Group II	Group I
Mild	8	14
moderate	7	4
severe	5	2

Gradation for Immediate post operative oedema-

1. Mild
2. Moderate
3. Severe

Table 4: Postoperative occlusion.

Postoperative occlusion	Group II	Group I
Grade I	15	18
Grade II	5	2
Grade III	0	0

Gradation for Immediate post operative Occlusion--

1. Stable-1
2. Slightly Deranged -2
3. Deranged- 3

Table 5: Behavioural Pain Scale for Patients operated under Regional Anesthesia

BAS	0	I upto 2	II upto 4	III upto 6	IV upto8	V upto 10
Group I	0	9	7	2	1	1

1. Facial muscles during the procedure -

(a) Relaxed (0)

(b) Tension, frown, grimace (1)

(c) Frequent to constant frown, clenched jaw (2

2. Restlessness –

(a) Quiet, relaxed appearance, normal movement (0)

(b) Occasional restless movement, shifting position (1)

(c) Frequent restless movement may include extremities or head (2)

3. **Muscle tone –**

(a) Normal muscle tone(0)

(b) Increased tone, flexion of fingers and toes(1)

(c) Rigid tone (2)

4. **Vocalization –**

(a) No abnormal sounds (0)

(b) Occasional moans, cries, whimpers and grunts(1)

(c) Frequent or continuous moans, cries, whimpers or grunts (2)

5. **Consolability –**

(a) Content, relaxed(0)

(b) Reassured by touch, distractible (1)

(c) Difficult to comfort by touch or talk (2)

(Scoring is done from 0-2 for each parameter. Total score is calculated 0-10)

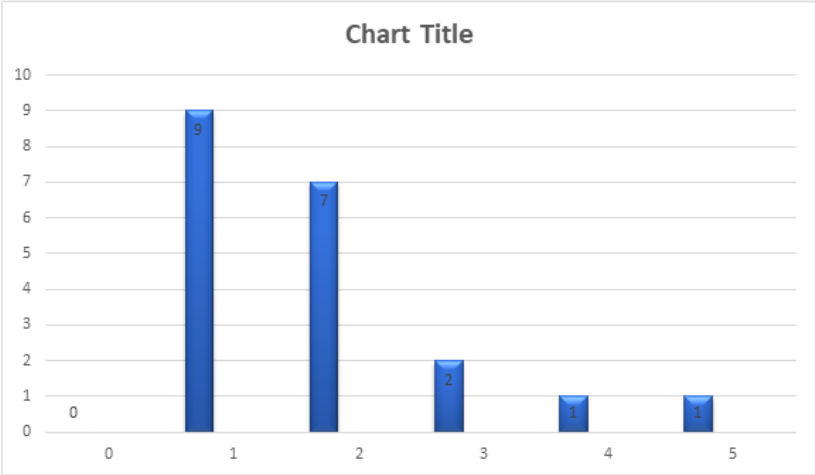

Chart 4: behavioural pain scale in group I
X axis- Scoring scale
Y axis- Number of patients.

From the study it is observed that mean time required for complete procedure under RA was significantly less (85.25 min) than that under GA (115.07 min) with p value-0.01. Also the mean hospital stay for the group I patients was 2.4 hrs which was significantly less than group II (54.8 hrs) with p value-0.001. Post operative complications like nausea, vomiting, hiccups were significantly more in group of patients treated under GA. While insignificant difference was present in criteria like intraoperative blood pressure and heart rate, post operative oedema and occlusion in both the groups. In case of behavioural assessment scale, 9 patients treated under RA had score 1 while 7 patients had score 2 and 2 patient had score 3. Only 1 patient had severe pain with score 5. That means more than 90% of the patients could tolerate the procedure well.

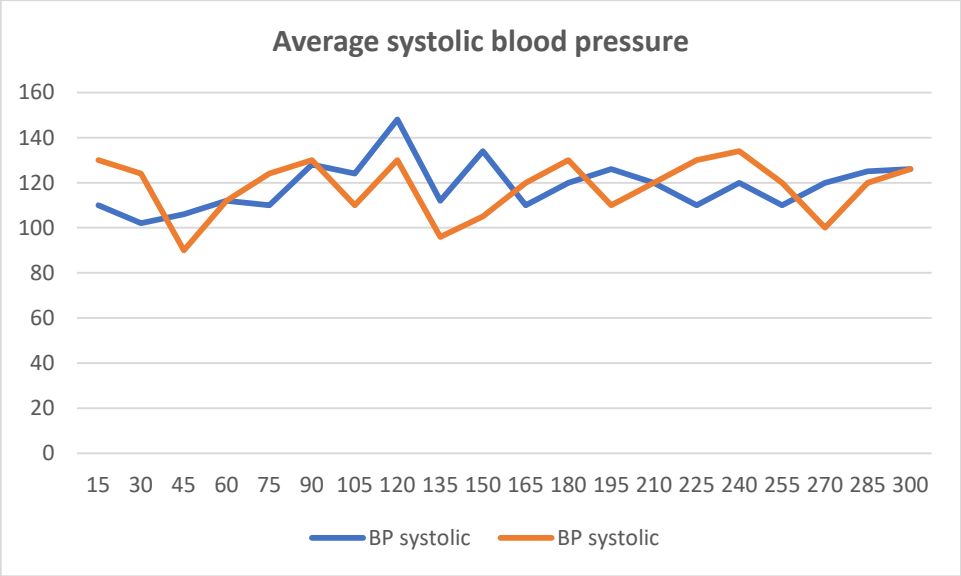

Chart 5
X axis-time in minute.
Y axis-Average systolic blood pressure during surgery.

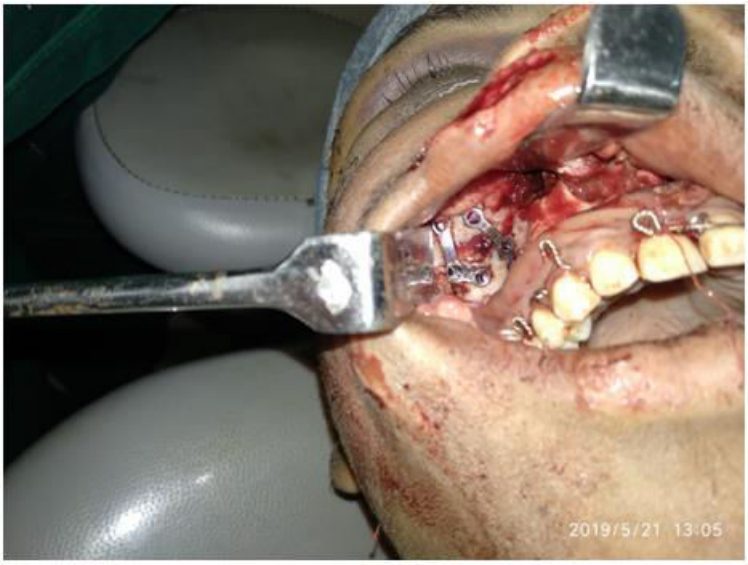

IMAGE I: Open reduction and internal fixation

DISCUSSION

In older days close reduction for maxillo-mandibular fractures was an accepted method for the treatment of fracture maxilla. But with the advent of new technological advances and quench for accuracy for facial dimensions like that of pre trauma status, open reduction and internal fixation (ORIF) has become a standardized procedure. Routinely ORIF for maxillary fracture is performed under general anaesthesia (GA). However, along with obvious advantages of GA, this technique exposes patients to the risks associated with a difficult intubation, polypharmacy and potential postoperative complications as discussed earlier[4]. So also, the anaesthesia related stress may lead to hyperglycemia and other metabolic derangements. Besides, it requires skilled manpower and sophisticated infrastructure leading higher cost[5] which includes prolonged hospital stay for short surgical procedure like maxillary fractures.

There are studies where regional anaesthesia (RA) has been successfully used for various maxillofacial surgical procedures[,6,7,8] like various mandibular fractures[4], reduction of zygoma fractures[5], reduction of nasal bone fractures[6,7], thyroid surgeries, and even gap arthoplasty for ankylosis of TMJ[8].

In this study we used Articaine as a local anaesthetic agent. It differs from the other amide local anaesthetic agent because it contains a thiophene ring which allows greater lipid solubility facilitating diffusion across the lipid-rich nerve membrane to access target receptors. It is an intermediate-potency, short-acting with a fast onset of action in about 3.5 minutes and satisfactory anaesthesia for about 1 hour and fast recovery. Molecular structure of articaine is characterized by having both lipophilic and hydrophilic ends linked together by a hydrocarbon chain[16]. It has got good bone penetration. In most of the cases, we could avoid palatal nerve block as good surgical anaesthesia could be achieved without. Articaine is a safe and effective local anaesthetic drug with maximum dose of 7 mg/kg body weight[17].

Pre-emptive analgesia was given in the form of Injection Tramadol 1mg/kg dose and repeated when required. Pre-emptive analgesia is defined as a treatment that is initiated

before surgery in order to prevent the establishment of central sensitization evoked by the surgical and inflammatory injuries occurring during surgery and in the early postoperative period. Owing to this 'protective' effect on the nociceptive system, pre-emptive analgesia has the potential to be more effective than a similar analgesic treatment initiated after surgery. As a consequence, pre-emptive analgesia can reduce immediate postoperative pain and also prevent the development of chronic pain by decreasing the altered central sensory processing[10],[11].

The advantage of RA over GA is that (1) the patient remained conscious and communicative (2) patient has control over the musculature that maintains the airway and occlusion (3) preservation of protective reflexes (4) decreased requirement of postoperative nursing care (5) have a shorter recovery period and hospital stay. Hence procedure becomes very cost effective.

Besides it may be an option for selected patients who are at high risk to undergo surgery under GA (ASA III/IV) like patients with concurrent chest trauma with underlying pneumonia, component of head injury, COPD, heart disease, severe renal and hepatic dysfunction which precludes general anaesthesia. Regional anesthesia[24] also lowers the incidence of post operative cognitive dysfunction and administration of opioid analgesics and antiemetics.

Despite the safety and reliability of modern GA, it is a highly invasive procedure, causing major physiological disruption in all patients—and particularly in those with compromised or comorbid states[20]. Gulur et al [30] reported that although the superior safety profile of regional anesthesia compared with GA in terms of death, cardiac health, and thromboembolic episodes has been largely nullified by modern perioperative care GA still causes higher intraoperative blood loss and metabolic stress.

With the arrival of COVID-19 pandemic when most of the surgeries couldn't be performed due to various restrictions like fear of spread of infection during intubation and ventilation, shortage of anaesthetist and inpatient facilities, RA is even more indicated.

Nevertheless possible nerve block–related complications include vascular injection, hematoma, syncope, inadequate block, transient facial palsy, accidental deep cervical plexus block, and rarely, diaphragmatic palsy.

Limitation of study is that, only low level, uncomplicated fractures were selected. This study is not to challenge the utility and gold standard of GA. Purpose of this study was to reduce the heavy burden of cases under GA, to make treatment more cost effective with shorter hospital stay. It is also consistent with the current trend in medical fraternity to do surgical procedures on day care basis.

This is also particularly important in providing comprehensive health care to large needy population in developing countries where large number of under privileged people hesitate to seek tertiary health care due to poor economic conditions and unavailability of infrastructural facilities[4] in remote areas.

CONCLUSION

Le Fort I and Le Fort II fracture involving maxilla can be satisfactorily managed using RA. The advantages of RA is , certain selected procedures can be done on day care basis with

minimal post operative complication in resource limiting facilities, hence becomes very cost effective.

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