Original Article

A randomized controlled trial to evaluate the efficacy of inferior alveolar nerve block as an adjunct to general anaesthesia in mandibulectomy: a pilot study

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Background: Mandibulectomy is considered as the initial definitive treatment for oral cancer. Inferior alveolar nerve block (IANB) is the commonly used nerve block procedure for mandibular anaesthesia. Hence, we evaluate the efficacy of IANB for intraoperative analgesia to block consumption of opioids and propofol in intraoperative period and to note hemodynamic stability by monitoring pulse rate, systolic, diastolic, and mean arterial pressure (MAP) during the intraoperative period.

Methods: This randomized pilot study comprised of 25 patients with American Society of Anaesthesiologists (ASA) grade 1 or 2 were scheduled for mandibulectomy. The study was conducted at a tertiary care centre in south India between November 2017 and December 2018. The patients were then randomly assigned using computer-generated random number tables into two groups: A and B, Group A received only general anaesthesia and group B received general anaesthesia with IANB. The group allocation was done using concealed envelopes by the principal investigator and hemodynamic variables were noted by an independent observer who was not part of group allocation or administration of block. The group allocation was revealed to the surgical team only on the day of surgery. The primary outcome measured was consumption of fentanyl and propofol boluses in intraoperative period. The hemodynamic variability was also measured. Secondary outcomes were vascular and neurological complications if any. Statistical significance was accepted as $P<0.05$.

Results: A total of 13 patients were randomized to Group A and 12 to Group B. Mean fentanyl consumption [Group A: n=8 (66.67%), μ=67.5±24.35 mcg/kg *vs.* Group B: n=6 (60%), μ=41.67±14.72 mcg/kg, $P>0.99$] and bolus propofol required (Group A n=5, 24±20.74 mg/kg *vs.* Group B n=3, 23.33±5.77 mg/kg, $P=0.69$) were not significantly different in both the groups. The mean time of onset of action was observed at 8.35±4.5 minutes after nerve block, where all twelve patients in Group B reported numbness of teeth and nine of them reported numbness in the tongue and two of them also were positive for aspiration test. The mean pulse rate, systolic and diastolic blood pressures were also comparable between both the groups, however, the mean MAP was significantly less in Group B than Group A during dental extraction and at 30 minutes during intraoperative period ($P=0.009$).

Conclusions: Based on primary outcome, the efficacy of IANB with general anaesthesia was comparable to that of general anaesthesia alone. Consumption of opioids and propofol in intraoperative period and hemodynamic stability during the intraoperative period was not significantly altered after administration of IANB.

Trial Registration: The study was prospectively registered with the clinical trial registry of India CTRI/2017/09/009837 (19/09/2017). The status of the trial is now closed.

Keywords: Inferior alveolar nerve block (IANB); mandibulectomy; general anaesthesia; ropivacaine; analgesia

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Introduction

Globally, oral cancer is the sixth most prevalent type of cancer. India contributes to almost one-third of the total burden and is the second country having the highest number of oral cancer cases (1).

While there are multiple methods available for treatment of oral cancer, surgery is known to be the established mode of definitive treatment for the majority of oral cancers in the initial phase (2). Mandibulectomy is a procedure followed to treat oral cavity cancers. Depending on the extent of invasion, either segmental or marginal mandibulectomy is performed (2).

Mandibulectomy and other similar procedures under general anaesthesia induce postoperative complications such as pain, nausea, and vomiting (3). A multimodal approach to alleviate intraoperative pain during mandibular surgery has been suggested by few recent studies. Use of inferior alveolar nerve block (IANB) was suggested to significantly lower post-operative nausea and vomiting, as well as decrease dependency on post-operative analgesia (3,4).

IANB is known to provide adequate anaesthesia to the hemi-mandible region which includes ipsilateral mandibular teeth and gingivae, body and inferior ramus of mandible, anterior two-thirds of the tongue and floor of the mouth (5). Hence, we hypothesize that nerve block can provide excellent intra-operative analgesia.

In addition, use of regional anaesthesia in conjunction with general anaesthesia, controls hemodynamic parameters and the decreases the use of total amount of intraoperative analgesics (6). Since, pre-emptive blockade of mandibular division of trigeminal nerve will prevent the stimulation of nociceptors by surgical stimulus and thereby prevent the activation of sympathetic nervous system and further hypersensitisation of nociceptor. This can translate to stable hemodynamics, lesser consumption of analgesics and lesser incidence of post-operative pain (6).

Literature search reveals that there have been very few human studies that evaluate the efficacy of IANB for intraoperative analgesia and hence is not routinely utilized for pain management in mandibulectomy (7,8). This prospective, pilot study was undertaken to compare the efficacy of IANB as an adjunct to general anaesthesia against general anaesthesia alone, to provide effective intraoperative analgesia. A recent study conducted in Spain shares similar objective, however they used 4% articaine for anaesthesia (9). Ropivacaine, a relatively newer local anesthetic, has a favorable profile like lower toxicity, longer duration of action, and more selective blockade of sensory over motor fibers. Ropivacaine can be an effective alternative for longer duration surgeries without the need of vasoconstrictor (10).

The primary objective of this study was to compare the efficacy of IANB for intraoperative analgesia in terms of consumption of opioids in intraoperative period. The secondary objective was to note hemodynamic stability by monitoring pulse rate, systolic, diastolic, and mean arterial pressure (MAP) during the intraoperative period, along with propofol consumption. We present this article in accordance with the CONSORT reporting checklist (available at https://fomm.amegroups.org/article/view/10.21037/fomm-22-48/rc).

Highlight box

Key findings

- Intraoperative analgesic effect of inferior alveolar nerve block (IANB) as an adjunct to general anaesthesia was equivalent to that of general anaesthesia alone during mandibulectomy.

What is known and what is new?

- IANB is the commonly used nerve block procedure for mandibular anaesthesia.
- There are no significant differences in opioid and propofol consumption between those who received IANB and those with general anaesthesia.

What is the implication and what should change now?

- Alternative IANB methods, role of various adjuncts need to be explored to achieve intra-operative analgesia and to alleviate post-operative vomiting and nausea.

Methods

This single-center, randomized, single-blind, parallel-group trial was conducted in a tertiary care cancer centre after

obtaining Institutional Human Ethics Committee clearance (IHEC No. 15/2017). The trial was conducted in accordance with the Declaration of Helsinki (as revised in 2013).

A total of 25 patients (>18 years) were enrolled for the study between November 2017 and December 2018 and written informed consent was obtained from each of them. The study included adult patients with ASA (American Society of Anaesthesiologists) physical system classification level 1 or 2 posted for mandibulectomy including hemi-, segmental- and marginal mandibulectomy (11), while patients with history of allergy to local anaesthetics, coagulation abnormalities, infection or tumour at the site of block and patients posted for arch mandibulectomy (as it needs bilateral blockade) were excluded.

Since, the primary purpose of pilot studies is not hypothesis testing, but to understand the feasibility of participant recruitment or study design and therefore sample size is often not calculated. Some studies recommend over 30 samples per group while some suggest twelve per group (12-14). An appropriate sample size needs to be determined, not for providing appropriate power for hypothesis testing, but to understand the feasibility of participant recruitment or study design.

Sample size was calculated using the following formula:

$$n = 2\frac{\left(Z_{1-\frac{\alpha}{2}} + Z_{1-\beta}\right)^2}{d^2} \quad [1]$$

where,

$$d = \frac{(\mu_1 - \mu_2)}{\sigma} \quad [2]$$

n is the sample size required per each group, $Z_{1-\frac{\alpha}{2}}$ and $Z_{1-\beta}$ is the standard normal variate corresponding to level of confidence and power, d is effect size, μ_1 and μ_2 are mean in Group A and Group B and σ is the pooled standard deviation.

Since there was no previous study, by assuming a medium effect size d=0.5 mcg/kg and with 90% confidence level and 80% power, the sample size will be,

$$n = \frac{2(1.65 + 0.84)^2}{(0.5)^2} \quad [3]$$

By assuming, non-response rate of 5%, the final sample size will be 53 cases in each group. However, our study was a pilot trial hence, a minimum sample of 25–30 is considered ideal. This study is conducted with a sample size of 25.

A detailed pre anaesthetic check-up (PAC) was carried out in all the cases. A routine PAC to evaluate fitness for surgery and anesthesia was done for all the cases. The patients fulfilling the eligibility criterion and consenting for study were also enrolled at this stage. Patients were randomly assigned to Groups A and B, using computer generated random number tables, with an allocation ratio of 1:1, into two groups, with thirteen patients in group A (general anaesthesia only) and twelve patients in group B (general anaesthesia with IANB).

Computer generated random numbers generated the randomization sequence. After the enrolment of the patient by the principal investigator, sequentially numbered, stapled and opaque envelopes used for concealing the group allocations was handed over to the anaesthesiologist, who performed the block if the patient was in group B only on the day of surgery. The stapling ensured that the concealment has not been compromised and there is no selection bias. The group allocation was done using concealed envelopes by the principal investigator and revealed to the anaesthesia and surgical team only on the day of surgery. The block was administered in the pre induction room under standard ASA monitoring and the patient was shifted inside the operation theatre subsequently.

Conventional IANB was administered to the operated side in group B.

IANB technique

The technique involved application of local anaesthetic, after which the nerve was approached from the opposite side of the mouth by angling the syringe from the premolars on that side. The point of insertion was along an imaginary line bisecting the fingernail with the finger resting on the deepest point of ascending ramus. Tissues were kept taut for atraumatic insertion of needle. The penetration depth was 20–25 mm until bone was hit, when the needle was withdrawn slightly and 2.5 mL of 0.75% Ropivacaine was injected slowly over 1 minute after negative aspiration.

After the administration of the block, sensory loss was checked and the time of onset of sensory loss was also noted in the lower lip/chin and tongue. Incidence of negative aspiration test was also recorded to detect inadvertent intravascular injection. Using a Luer syringe with a 32 mm long 24 G needle, that was directed towards the mandibular foramen, was withdrawn 2–3 mm, followed by withdrawal of piston of syringe to check for entry of blood into the syringe (15). If sensory loss was not achieved in 15 minutes the block was labelled as failure and the patient was

excluded from the study. Patients were then taken to the operative room and standard monitoring was initiated.

Before the surgery, premedication was provided with injection of fentanyl 2 mcg/kg. Standard intravenous induction was done with propofol and vecuronium 0.1 mg/kg and anaesthesia maintained with O_2/air/sevoflurane. Airway was secured with a nasotracheal tube. $EtcO_2$ was kept at a standard range of 30–35 mmHg and Bispectral Index (BIS) maintained between 40–60. Fluid administration was standardized at 2 mL/kg/hour of crystalloid. Injection fentanyl infusion 0.5 mcg/kg/hour was also administered. Ventilator was set at TV 6–8 mL/kg to maintain normocapnia with respiratory rate of 12–16, and PEEP 5, FiO_2 titrated to 95% saturation.

Hemodynamic variability (blood pressure, heart rate, etc.) was particularly noted at crucial events like tongue stitch, dental extraction, osteotomy, condylotomy and marginal resection, along with the usual vital charting at 15 minutes intervals within one hour for all patients, until mandibulectomy was completed The vital signs were noted by an independent observer who was blinded to whether the block has been performed in the patient or not. The observer was introduced into the study only after the block was completed in the pre induction room.

Any raise in blood pressure or heart rate more than 20% of baseline was managed with a bolus of fentanyl 1 mcg/kg. This dose was repeated after 5 minutes if there was no adequate response and the number of doses required were noted.

In case there was no adequate response even with a second dose, propofol boluses/rate controlling agents/antihypertensives were administered and the drug and dose used were noted. Bolus medication required more than the background infusion and premedication was noted for statistical analysis. The study ended after completion of mandibulectomy which was completed in an hour for most patients and no further readings were recorded. Any complications encountered during the study were also noted.

Statistical analysis

Data analysis was done using R i386 3.6.3. Categorical variables were represented by frequency tables and continuous variables were represented by mean ± standard deviation. Categorical data was compared using chi-square test/chi-square test with simulation and *t*-test/welch *t*-test/Man-Whitney *U*-test were used to compare the pulse rate, blood pressure, and MAP. Shapiro Wilk test used to test the normality and Levene test for testing the equal Variance assumption. Multiple imputation technique was used for data analysis. Fully conditional specific Markov Chain Monte Carlo (MCMC) method with predictive mean matching was used to fill the missing data. P value <0.05 was considered as statistically significant.

Results

A total of 25 patients were enrolled for the prospective study, among them 13 were randomly allocated to Group A, who received general anaesthesia alone and 12 were allocated to Group B, who received nerve block and general anaesthesia (*Figure 1*). Among the patients the common comorbidities included well controlled diabetes (n=6), hypertension (n=5), past smoking (n=3) and post chemotherapy status (n=5). One patient had bronchial asthma and non-oliguric chronic kidney disease.

During the follow-up, 1 patient from each group was excluded from the study due to change in surgical plan based on intraoperative findings. In the patient from group A, the intraoperative frozen section returned negative and therefore mandibulectomy was not performed and the 1 from group B was excluded as the patient posted for hemi-mandibulectomy was converted to arch mandibulectomy because of extensive disease. Hence, a total of 22 subjects were considered for the analysis.

Mean age of the patients in both groups were 54.5±13.03 and 56.1±8.56 years, respectively and the number of males were higher than females in both groups [11 of 12 patients in Group A (91.67%) and 6 of 10 patients in Group B (60%)]. The mean values have been summarized in *Table 1*. A total of 8 patients had CA buccal mucosa, 6 had CA lower alveolus, 5 had CA tongue, 2 had CA floor of mouth, and o1 CA lip. Segmental mandibulectomy was performed in twelve patients, marginal mandibulectomy in eight, and hemi mandibulectomy in two. Bone graft was not performed in any of the patients.

Comparison of fentanyl and bolus propofol requirement in both groups has been summarized in *Table 2*. Among 12 patients in Group A, 8 (66.7%) required 67.5±24.35 mcg/kg mean dose of fentanyl and in the nerve block group, 6 (60%) out of ten patients required a mean dose of 41.67±14.72 mcg/kg. However, the requirement of both fentanyl (P>0.99) and propofol bolus (P=0.69) was not significantly different between the groups.

Similarly, the mean dose of bolus propofol consumed by 5 (41.67%) and 3 (30%) cases in Group A and Group B was

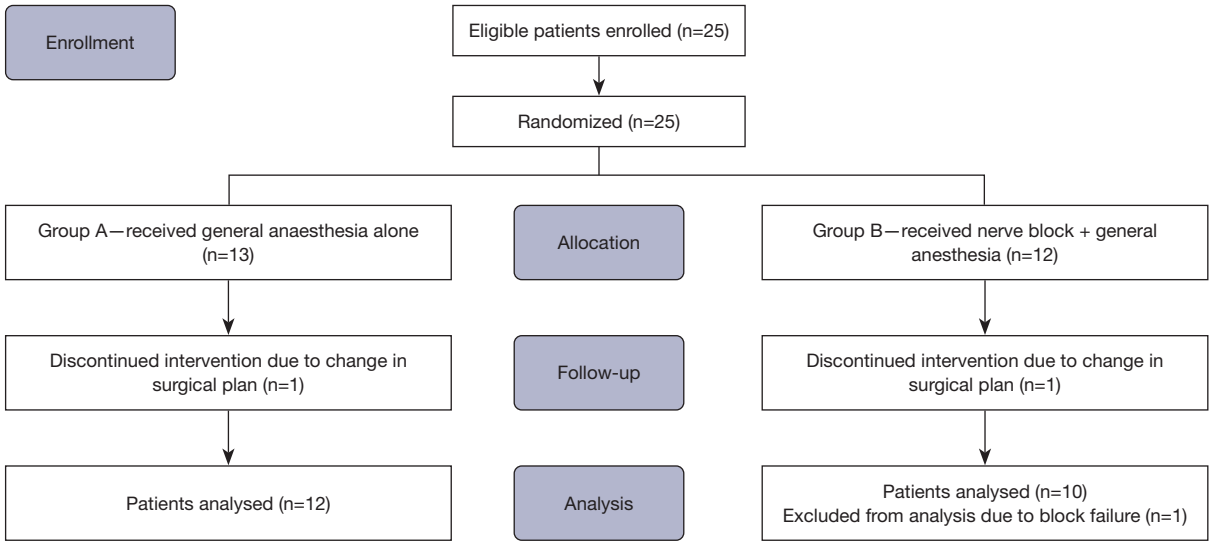

Figure 1 CONSORT 2010 flow diagram.

Table 1 Demographic summary

Factor	Group A	Group B	P value
Age (years)	54.5±13.03	56.1±8.56	0.73[T]
Gender			
Male	11 (91.67%)	6 (60%)	0.14[CS]
Female	1 (8.33%)	4 (40%)	
BMI (kg/m^2)	23.03±2.24	22.04±4.08	0.50[T]

Age and BMI is expressed as mean ± standard deviation. [T], indicates independent *t*-test; [CS], indicates chi-square test with simulation. Group A received general anaesthesia; Group B received general anaesthesia with inferior alveolar nerve block. BMI, body mass index.

Table 2 Distribution of patients based on opioid and anaesthetic requirement

Drug required	Group A	Group B	P value
Fentanyl consumption			
Yes	8 (66.67%)	6 (60%)	>0.99[CS]
No	4 (33.33%)	4 (40%)	
Mean ± SD (mcg/kg)	67.5±24.35	41.67±14.72	–
Bolus propofol requirement			
Yes	5 (41.67%)	3 (30%)	0.69[CS]
No	7 (58.33%)	7 (70%)	
Mean ± SD (mg/kg)	24±20.74	23.33±5.77	–

Mean ± SD was calculated based on subjects who require fentanyl and Bolus propofol consumption. [CS], indicates chi-square test with simulation. Group A received general anaesthesia; Group B received general anaesthesia with inferior alveolar nerve block. SD, standard deviation.

24±20.74 and 23.33±5.77 mg/kg, respectively. There was no significant difference observed in the consumption of Fentanyl and bolus propofol between both groups (P>0.05).

Rapid onset of anaesthetic activity was observed (mean 8.35±4.5 minutes) after nerve block, where all patients in Group B reported numbness of teeth and nine of them reported numbness in the tongue and two of them also were positive for aspiration test. Numbness in the tongue and buccal mucosa was self-reported by the patients and confirmed by loss of sensation to pinprick.

Among the various intraoperative hemodynamic parameters investigated (*Table 3*), there was no significant difference in the mean pulse rate, Systolic and diastolic blood pressure at any time points between the two groups. However, the mean of MAP was significantly less in Group B than Group A at the time of dental extraction and at 30 minutes during intraoperative period.

Discussion

Based on the primary outcome measure of this study, that is the consumption of fentanyl and bolus propofol, the efficacy of IANB with general anaesthesia was comparable to that

Table 3 Comparison of hemodynamic variables between two groups at different time points

Investigation	Time points	Group A	Group B	P value
Pulse rate (bpm)	Baseline	77.5±18.82	79.4±10.67	0.78[T]
	Tongue stitch	85.17±7.12	86.1±9.92	0.80[T]
	Dental extraction	76.5±9.51	78.6±14.11	0.68[T]
	Osteotomy 1	79.17±17.64	80.1±14.75	0.90[T]
	Osteotomy 2	74.92±14.8	79.2±16.46	0.53[T]
	15 min	78±11.66	82.4±16.61	0.48[T]
	30 min	74.42±13.71	78.8±19.92	0.55[T]
	45 min	72.42±11.21	79.2±11.39	0.18[T]
	60 min	75.92±11.42	77.6±13.84	0.76[T]
Systolic blood pressure (mmHg)	Baseline	128.33±17.09	130.5±15.42	0.76[T]
	Tongue stich	125.67±10.66	128.8±26.25	0.71[T]
	Dental extraction	128.25±25.01	117.3±12.58	0.20[WT]
	Osteotomy 1	131.5 (35.75)	112 (19.5)	–
		13.21	10.45	0.19[M]
	Osteotomy 2	92.08±17.95	85.8±11.28	0.35[T]
	15 min	127±26.8	113.7±20.2	0.21[T]
	30 min	128.33±18.02	114.7±18.06	0.09[T]
	45 min	127.92±23.27	115.1±15.26	0.15[T]
	60 min	135 (28.0)	116 (28.0)	–
		6.71	4.67	0.23[M]
Diastolic blood pressure (mmHg)	Baseline	80.08±11.11	79.2±10.24	0.85[T]
	Tongue stich	119.5±23.69	121.2±14.66	0.85[T]
	Dental extraction	82±14.08	79.5±7.58	0.62[T]
	Osteotomy 1	82±11.05	79.1±9.81	0.53[T]
	Osteotomy 2	80.08±15.11	78.9±11.96	0.84[T]
	15 min	72.5 (31.25)	72 (28.0)	–
		13.00	9.70	0.25[M]
	30 min	84.33±13.41	74.7±14.67	0.12[T]
	45 min	77.75±14.67	76.3±9.03	0.78[WT]
	60 min	84 (25.0)	83 (25.0)	–
		6.07	4.17	0.22

Table 3 *(continued)*

Table 3 *(continued)*

Investigation	Time points	Group A	Group B	P value
Mean arterial pressure (mmHg)	Baseline	91.83±11.52	88.8±9.55	0.52[T]
	Tongue stich	90.25±9.75	87.1±11.37	0.49[T]
	Dental extraction	92 (21.0)	83 (8.75)	–
		10.14	6.13	0.01[M*]
	Osteotomy 1	91.58±16.16	84.9±11.83	0.29[T]
	Osteotomy 2	88.58±16.29	84.3±14.54	0.53[T]
	15 min	82.5 (31.5)	80.5 (19.5)	–
		13.20	10.45	0.19[M]
	30 min	92.25±10.86	79.5±12.62	0.01[T*]
	45 min	85.5±16.33	83.5±12.83	0.77[T]
	60 min	86 (25.0)	90 (19.5)	–
		5.86	4.67	0.39[M]

Data are expressed as mean ± SD except for the tests done by Mann-Whitney *U*-test, results in median (IQR) and expressed in mean rank in subsequent row. [T], indicates independent *t*-test; [WT], indicates welch *t*-test; [M], indicates Mann-Whitney *U*-test; *, indicates significance at P<0.05. Group A received general anaesthesia; Group B received general anaesthesia with inferior alveolar nerve block. SD, standard deviation; IQR, interquartile range.

with general anaesthesia alone.

Among 25 patients, one of them was excluded from the study due to failure of block which resulted in a transient facial nerve palsy which was resolved by the completion of surgery and no residual weakness was observed on further follow up. Facial nerve palsy is under reported complication of IANB, however it is a rare observation, with a quick recovery usually resolving within 7 hours of onset (16). Overall, the block was performed safely, making the conventional mandibular block the most commonly used injection technique in dentistry (17). None of the patients complained of pain at the injection area, post-operative swelling, syncope or toxication.

We used 0.75% concentration of Ropivacaine for the nerve block, which has shown to induce rapid onset of block within 1.4 minutes and produced a prolonged analgesia for 6 hours (18).

Van Lancker *et al.* has shown that mandibular nerve block reduces intraoperative opioid consumption, however it did not provide better analgesia compared to opioids alone in the postoperative period. They, however, have also used additives such as adrenaline in addition to anaesthetic (19). In contrast, Espitalier *et al.* reports that mandibular nerve block improves intraoperative and post-operative analgesia during mandibular osteotomy under general anaesthesia. However, they performed only split osteotomy (20), in contrast to our study where extensive surgery was done. Overall, our study did not show any significant difference in requirement for opioid consumption among both the groups. Both these studies (19,20) utilized the transcutaneous approach compared to the traditional intraoral approach of IANB done in the present study. Both the techniques block all the sensory branches of the nerve.

In the current study, there were no significant changes observed in both nerve block with ropivacaine as local anaesthetic group and general anaesthesia only group, with respect to intraoperative vital parameters (systolic and diastolic blood pressure, pulse rate), while there was a significant decrease in mean MAP in the nerve block group during dental extraction and at 30 minutes during intraoperative period. A comparison study conducted to evaluate the difference in cardiovascular responses after injection of lidocaine as the local anaesthetic for IANB either with clonidine or adrenaline, showed a significant decrease in systolic pressure and heart rate with clonidine, however there was no significant change observed in MAP (21). While most local anaesthetics used in dentistry have some vasodilating effect, ropivacaine does not lead to any significant change in cardiovascular variables. In the study conducted by Dandriyal *et al.*, 0.5% ropivacaine showed a mild transient

increase in hemodynamic parameters in the second interval during intraoperative period (21), which is contradictory to that observed in our study, where a significant decrease in mean MAP was noted in the nerve block group at 30 minutes during intraoperative period. An effective nerve block is also expected to reduce sympathetic response to surgical stimulus and that can lead to lower MAPs (6).

Studies report that alternative IANB methods offers good postoperative analgesia, and it is not associated with adverse events or hospitalization for prolonged periods. In the present study, we employed the conventional technique of IANB (22). However, further studies must consider the complications related to IANB such as nerve damage due needle induced trauma or neurotoxic effects of anaesthetics used (23). Future areas of research can focus on alternative techniques of nerve block along with imaging methods like ultrasound, fluoroscopy, MRI etc. and use of combination of drugs (like lignocaine, adrenaline, clonidine etc.) (8,22,24,25) which might improve the efficacy of nerve block and, hence providing improved analgesia.

The variables for tongue stitch and dental extraction were not available for all patients, due to factors like surgeon preference and edentulous patient, hence we recommend avoiding use of these steps as point of reference in future studies. One of the limitations of the study was that blood loss was not documented between the two groups as marginal mandibulectomy is expected to have lesser blood loss when compared to segmental mandibulectomy and hemi-mandibulectomy. Hence, for accurate estimation of blood loss, the surgical procedure will have to be standardized. In addition, the classification of tumor status in each patient was not recorded.

Conclusions

The results of the present pilot randomized study revealed that consumption of opioids and propofol in intraoperative period and hemodynamic stability during the intraoperative period was not significantly altered after administration of IANB. IANB is a simple block to perform, easy to learn and has few and mostly only transient potential complications, but further research with a higher sample size is necessary to evaluate its usefulness in mandibulectomy.

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Footnote

Reporting Checklist: The authors have completed the CONSORT reporting checklist. Available at https://fomm.amegroups.org/article/view/10.21037/fomm-22-48/rc

Trial Protocol: Available at https://fomm.amegroups.org/article/view/10.21037/fomm-22-48/tp

Data Sharing Statement: Available at https://fomm.amegroups.org/article/view/10.21037/fomm-22-48/dss

Peer Review File: Available at https://fomm.amegroups.org/article/view/10.21037/fomm-22-48/prf

Conflicts of Interest: All authors have completed the ICMJE uniform disclosure form (available at https://fomm.amegroups.org/article/view/10.21037/fomm-22-48/coif). The authors have no conflicts of interest to declare.

Ethical Statement: The authors are accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved. The trial was conducted in accordance with the Declaration of Helsinki (as revised in 2013). The study was approved by institutional ethics committee of Regional Cancer Center, Thiruvananthapuram (IHEC No. 15/2017). Written Informed consent was obtained from all participants before the study commenced.

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