Original Article - Evaluative Study

A Randomized Control Trial of Awake Oral to Submental Conversion versus Asleep Technique in Maxillofacial Trauma

Shahna Ali, Manazir Athar, Syed Moied Ahmed, Obaid Ahmad Siddiqi, Amrin Badar

Department of Anaesthesiology and Critical Care, Jawaharlal Nehru Medical College, Aligarh Muslim University, Aligarh, Uttar Pradesh, India

Abstract

Aim: This study was designed to evaluate the efficacy of awake oral to submental conversion over asleep technique. **Materials and Methods:** This randomized clinical study was conducted in maxillofacial department of a tertiary care hospital in patients who had panfacial or mandibular fractures requiring elective surgical correction. The patients were randomly divided into two groups of 12 patients each, asleep fiberoptic-assisted submental intubation (SMI) (Group G; n = 12) and awake fiberoptic-assisted SMI (Group A; n = 12). The primary predictor was mean conversion time of oral to SMI while other predictors were overall success rate, ease of conversion, and complications. Data are presented as mean (±standard deviation) and frequencies (%) as appropriate. Statistical analysis done using unpaired t-test or Chi-square test was performed and $P < 0.05$ was considered statistically significant. **Results:** Twenty-four patients (19:5;Male:Female) aged 18–55 years (Group G = 35.96; Group A = 32.43 years) were included in the study. SMI was successful in all except two patients in group G. Overall success rate was similar in both groups. Time to convert orotracheal intubation to SMI was significantly less in group A (Group G = 9.55 ± 1.42, Group A = 5.67 ± 1.73; $P < 0.001$). Ease of SMI was found Grade I in 30% and 83% of the patients of group G and A, respectively. No serious complications were observed except 2 cases of bleeding, and 1 case of tube damage. **Conclusion:** Awake oral to submental conversion requires lesser time in comparison to asleep technique besides improving the ease (Δ = 53%) of the procedure.

Keywords: Airway management, anesthesia, awake, panfacial fracture, submental intubation

Introduction

Panfacial fractures, apart from posing surgical challenges, also leads to specific problems in airway management that require modifications in the standard anesthesia technique. These patients may have nasal or oral intubation, but, nasotracheal intubation (NTI) should be avoided in patients with the fracture of base of skull and comminuted midfacial fractures as there is always a risk of complications such as cerebrospinal fluid (CSF) rhinorrhea, meningitis, and communication of nasal cavity with cranial fossa.[1-3] In addition, the surgical reconstruction of nasoorbitalethmoid (NOE) complex is hampered with the presence of nasotracheal tube.[4] On the other hand, orotracheal tube interferes with maxillomandibular fixation (MMF), compromising the reduction, and stabilization in these fractures.[5]

Another technique for airway control is the tracheotomy, which is considered by many as the preferred route for airway management in patients with complex maxillofacial fractures.[6-9] However, it is generally associated with a significant number of intraoperative and postoperative complications, including tracheal stenosis, subcutaneous emphysema, pneumothorax, damage to laryngeal nerves, tracheomalacia, tracheoesophageal fistula, and scarring.[10-14]

Submental endotracheal intubation (SMI) is an alternative form of intubation through the submental route. Altemir first described this procedure as an alternative technique of airway management in patients with maxillofacial injuries.[15] It is usually carried out under general anesthesia with or without fiberoptic assistance.

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Address for correspondence: Dr. Manazir Athar, Department of Anaesthesiology and Critical Care, Jawaharlal Nehru Medical College, Aligarh Muslim University, Aligarh - 202 002, Uttar Pradesh, India.
E-mail: drmanazirathar@gmail.com

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However, holding the mask firmly over the face during induction of general anesthesia is often responsible for the displacement of comminuted fracture segments of maxilla and nasal bones. Furthermore, posteroinferior displacement of maxilla parallel to inclined plane of skull base can block the nasopharyngeal airway and cause fresh bleeding.[16] Patient's cooperation during awake fiberoptic orotracheal intubation may avoid these potential problems besides making the conversion to SMI easier. Despite being an easy to learn technique, SMI may be troublesome in children, obese and those with thyroid swelling.[17]

Till date, there is no study where the comparison has been done between awake and asleep SMI. Most of the studies have either not mentioned the status of the patients at the time of SMI or conversion has been done subsequent to full induction and relaxation of the patient, later to the awake oral intubation.[18-22]

Hence, the purpose of this study was to compare the efficacy of awake versus asleep conversion of oral to SMI. The investigators hypothesized that awake SMI may ease the process and avoid the complications associated with asleep SMI. The specific aims of the study were: (1) time taken for conversion, (2) overall success rate, (3) ease of conversion, and (4) complications (if any).

Materials and Methods

To address the research purpose, the investigators designed and implemented this prospective randomized clinical study following institutional ethical clearance. The study population was composed of all the patients presenting for elective surgical correction of facial fractures in the maxillofacial department of a tertiary care hospital over a period of 2 years (2013–2015). To be included in the study sample, patients had to be aged between 18 and 55 years, mid facial fractures including Le fort I, II, III along with NOE, and mandibular fractures. Patients were excluded as study subjects if they have neurological damage, subnormal intelligence, thoracic trauma, mouth opening <2 cm, and local anesthetic allergy [Figure 1].

Twenty-four patients included in the study were randomly divided into two groups of 12 patients each, asleep fiberoptic-assisted SMI (Group G; n = 12) and awake fiberoptic-assisted SMI (Group A; n = 12) by computer generated random numbers (www.randomization.com) with allocations concealed in sealed envelopes. The primary outcome variable was time taken for conversion, while secondary variables were overall success rate, ease of conversion, and complications (If any). Patient's demographic characteristics such as age, sex, weight, ASA grading, thyromental distance, and interincisor distance were also measured.

Emergency Airway Kit including surgical tracheostomy was kept ready as the backup in case of failure which was then analyzed according to intention to treat to basis. Patients were premedicated with ranitidine 50 mg, glycopyrrolate 0.2 mg, and dexmedetomidine 1 μg/kg loading over 15 min followed by 0.3 μg/kg/h intravenously in both groups until conversion to SMI. During the procedure, the Anesthesiologist used the Ramsay Sedation Scale (RSS) to assess the level of sedation. If the RSS was <2, rescue doses of up to 20 mg propofol were administered.

Technique of asleep (General Anaesthesia) fiberoptic-assisted submental intubation

The procedure was explained to the patient. The patient was preoxygenated for 3 min followed by anesthetic induction with propofol 2 mg/kg/iv. After confirming bag-mask ventilation, relaxation was achieved with succinylcholine 1.5 mg/kg to facilitate oral fiberoptic endotracheal intubation.

Technique of awake fiberoptic-assisted submental intubation

The procedure was explained followed by psychological preparation of the patient in the preanesthetic clinic initially and then on the day of surgery. Anesthesia of the airway was achieved using nebulization with 4% lignocaine, superior laryngeal nerve block, and transtracheal instillation of 2 ml of 2% lignocaine. The total dose was calculated and kept well below the threshold to avoid any kind of toxicity. The oxygenation was continued at a flow rate of 5 L/min through nasal prongs. The fibreoptic bronchoscope, adequately lubricated with 2% lignocaine gel was mounted with size 8.0 mm ID flexometallic endotracheal tube (ETT) subsequent to confirmation of the easy removal of ETT connector. Oral fibreoptic bronchoscopy was attempted with Berman airway held between the incisors followed by intubation and confirmation with end tidal CO_2.

Technique of submental intubation

Using an aseptic technique, skin infiltrated with local anesthetic followed by 1.5–2 cm skin crease incision in the submental region at a distance one-third way from symphysis just medial to the lower border of the mandible. The side opposite to the fracture was preferred. The mouth was kept open using dental prop to expose the floor of the mouth. A curved artery forceps was then utilized for blunt dissection toward the floor of mouth till there is sufficient space for the placement of the tube. Dissection of the tissue layers such as subcutaneous fat, platysma, investing layer of deep cervical fascia and mylohyoid muscle was kept close the lingual surface of mandible to avoid any injury to lingual nerve, submandibular gland and its duct. After a thorough dissection, tube connector was removed, pilot balloon deflated, grasped with the artery forceps and pulled out of the floor of mouth in the submental region. Then quickly, artery forceps was once again inserted through the submental incision and the tracheal tube pulled out. The connector was then re-attached, the cuff reinflated and the tracheal tube reconnected to the breathing circuit. The position of the tube was confirmed and noted using capnography and auscultation. The time from incision to capnographic tracing was taken as "time to conversion," and it was taken as the primary objective for the purpose of sample size calculation. Tube was fixed using silk (2/0) suture and a circumferential adhesive tape [Figure 2]. The ease of conversion of oral to SMI was graded as; Grade 1: Pilot balloon assembly easily grabbed and pulled, ETT end pulled out easily with dental prop but without manipulation,

Grade 2: Pilot balloon assembly easily grabbed and pulled, ETT end pulled out with dental prop but after manipulation in the form of tongue retraction, and Grade 3: ETT end cannot be pulled out. All SMI were done by the same anesthesiologist.

At the conclusion of surgery, extubation through oral or submental route was dictated by the presence of MMF. In oral route, tracheal tube followed by pilot balloon was pulled intraorally. The submental incision was then closed with the interrupted sutures. Moreover, neuromuscular blockade was reversed with injection glycopyrrolate 0.02 mg/kg and injection neostigmine 0.05 mg/kg intravenously. The patient was allowed to regain consciousness and trachea was extubated after the return of protective reflexes and train of four of 0.9.

Statistics

Sample size calculation on the basis that 50% change in mean conversion time would be a clinically relevant difference required the inclusion of 10 patients in each group (PS Power and Sample Size Calculator-Version 3.0.43; Dupont WD, Plummer WD, Department of Statistics of the Vanderbilt University, Nashville, TN, USA). Considering 10% dropout or failure, we included 12 patients in each group. The Type I error probability associated with this test, for the null hypothesis that there is no difference in conversion time of SMI between two groups was $\alpha = 0.05$, while Type II error $\beta = 0.8$. Statistical analysis was performed using Excel 2013 (Microsoft, Redmond, VA, USA), and Graph Pad Prism 5.00 (Graph Pad Software, San Diego, CA, USA). Data are presented as mean (±standard deviation), and frequencies (%) as appropriate. Group demographic data and adverse events were compared using unpaired *t*-test or Chi-square test, whichever applicable. Success rate and ease of conversion were compared using Chi-square test, while conversion time was compared using unpaired *t*-test. A $P < 0.05$ was considered statistically significant.

Results

No significant difference was observed in patient characteristics such as age, sex, weight, ASA grade, thyromental distance, or interincisor distance [Table 1]. The most frequent etiology of the trauma was traffic accidents ($n = 18$) while the most common fracture type was Le Fort II with nasal fracture ($n = 10$). SMI was successful in all except two patients in group G, which ultimately required preoperative tracheostomy due to bleeding

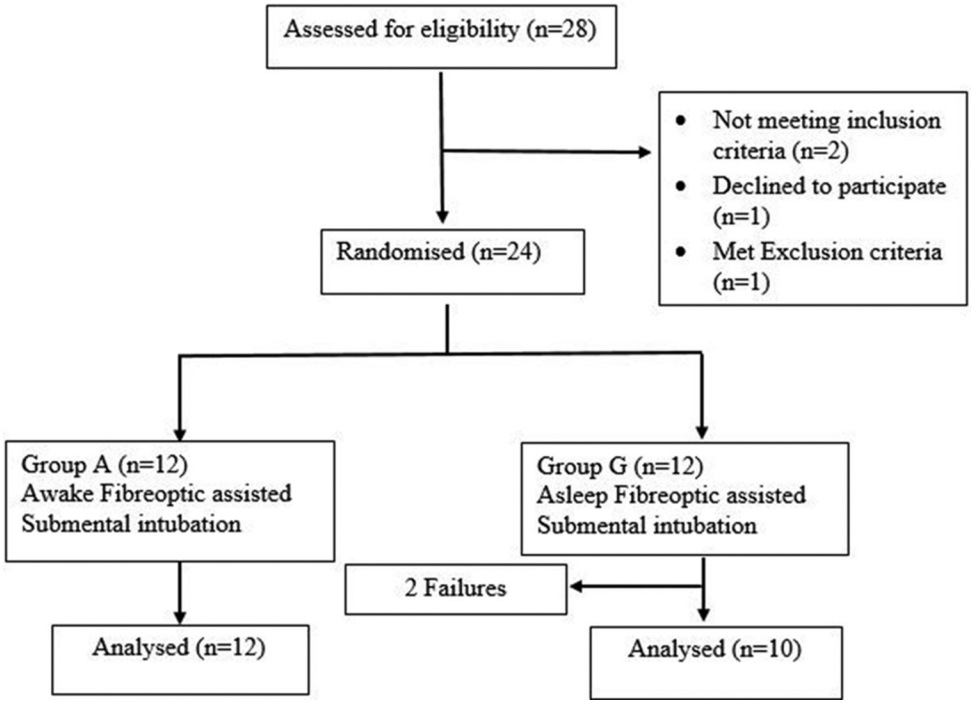

Figure 1: CONSORT flow diagram showing the allocation and analysis of the participants (Source: Original)

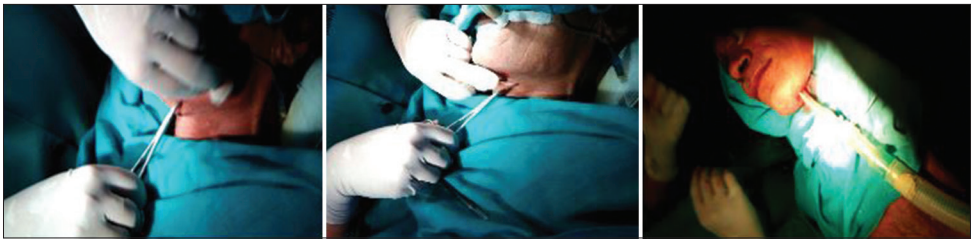

Figure 2: Shows submental intubation with endotracheal tube *in-situ* (Source: Original)

Table 1: Patient characteristics

Variable	Group G (*n*=12)	Group A (*n*=12)	*P*
Age	35.96±10.39	32.43±12.63	0.46
Male:female	10:2	9:3	1.00
Weight (kg)	53.50±5.16	55.07±10.37	0.64
ASA I/II	8/4	10/2	0.63
Thyromental distance (cm)	6.4±0.7	6.6±0.6	0.46
Interincisor distance (cm)	3.8±0.5	3.9±0.6	0.66

Data are expressed as number of patient or mean±SD or percentage; *P*≤0.05 is considered significant. SD=Standard deviation; ASA=American Society of Anesthesiologists; *n*=Number of patients

Table 2: Shows the characteristics of the submental intubation

Variable	Group G (*n*=12)	Group A (*n*=12)	*P*
Conversion time (min)	9.55±1.42	5.67±1.73	<0.001
Overall success rate (%)	10 (84)	12 (100)	0.47
Failure to intubate (%)	2 (16)	0	-
Ease of conversion			
Grade I (easy)	3	10	0.02
Grade II (difficult)	7	2	0.02
Grade III (difficult)	0	0	1.00
Complications			
Desaturation (SpO_2 <90%)	0	0	1.00
Bleeding (%)	2 (17)	0	0.48
Fracture dislocation (%)	4 (33)	0	0.09
Tube damage (pilot balloon)	1	0	0.45
Trauma	0	0	1.00
Orocutaneous fistula	0	0	1.00
Bradycardia	0	0	1.00

Data are expressed as number of patient or mean±SD or percentage; *P*≤0.05 is considered statistically significant. SD=Standard deviation; *n*=Number of patients

in upper airway. Overall success rate was similar in both groups (Group A = 100%, Group G = 84%; $P = 0.47$). Ease of SMI was found Grade I in 30% of the patients of group G, whereas 83% of the patients in group A. There were 70% of the patients in the group G who had difficult SMI in comparison to 17% in group A. Time to convert orotracheal intubation to SMI was significantly less in group A (Group G = 9.55 ± 1.42, Group A = 5.67 ± 1.73; $P < 0.001$). None of the patients required propofol boluses. No serious complications were observed except 2 cases of bleeding, where tracheostomy was performed and 1 case of tube damage which was replaced over the tube exchanger. Both of these complications occurred in Group G [Table 2]. Patients were followed in the postoperative period at 1 week and 1 month. No deficit in the salivation was observed. Normal healing with no signs of infection was found.

Discussion

This prospective study was designed to evaluate the efficacy of awake over asleep conversion of oral to SMI in terms of time to conversion, overall success rate, ease of conversion, and complications (if any), with the hypothesis that awake SMI may ease the process and avoid the complications associated with asleep SMI. In our study, the overall success rate was found to be similar in both groups. However, conversion time and ease of SMI was found to be significantly improved in the awake technique.

Tracheostomy remains the option of choice when neither nasal nor orotracheal intubation is feasible.[5] However, it is associated with significant morbidity and rarely mortality. Complications such as hemorrhage, subcutaneous emphysema, injury to the recurrent laryngeal nerve, tracheal stenosis, and postsurgical scar are sometimes associated with the procedure.[23] In the past few decades, a number of alternatives to tracheostomy have been proposed. In maxillofacial trauma which requires surgical reduction of nasal fracture or MMF, nasal tube switch to oral route can be done within few minutes without requiring extubation.[24,25] Contrary to this, attempting nasal intubation in patients with frontobasilar fractures can lead to life-threatening complications such as intracranial introduction of tube, CSF leak, meningitis, or sepsis. Retromolar and SMI are another simple way to avoid NTI and interference with dental occlusion.[1,26] The SMI seems to be very suitable technique; apart from securing airway provides an unobstructed intraoral surgical field, avoids intra- and post-operative complications of tracheostomy, and overcomes disadvantages of NTI. Schütz and Hamed[27] in their comparative study, between SMI and tracheostomy concluded that the SMI is associated with low morbidity and can replace tracheostomy in selected cases of maxillofacial trauma.

In this study, we compared the overall success rate which was similar in both groups, except two cases where tracheostomy has to be performed due to nasal bleed as a result of pressure by face mask during the process of general anesthesia. Fiberoptic intubation was not attempted in these two cases due to the presence of blood in the airway.

Ease of conversion from oral to SMI was easy in awake patients as compared to the patients under GA. This was probably because they followed the anesthetists command to pull the tongue in the mouth that allowed the easy manipulation of the ETT. None of the patients complained of any discomfort in the awake group or required additional sedation, which further suggest that the above-used doses of dexmedetomidine are sufficient for conscious sedation. In the GA group, even the dental prop and tongue retraction posed difficulty in grabbing the end of the ETT and pulling it out.

Similarly, conversion time to SMI was significantly shorter in awake patients. This again could be due to the cooperation of the patients during the conversion. Apart from this, inducing general anesthesia before securing the airway may cause displacement of comminuted fracture and may induce a fresh nasal bleed. To prevent such complications, one case report documents use of awake fiberoptic orotracheal intubation. However, they also converted oral to SMI under anesthesia.[28]

Literature shows that the complications of SMI are relatively rare and generally in the form of injuries to salivary gland, nerves such as lingual and marginal mandibular, infection, and unesthetic scars.[8,13,27,29] However, accidental extubation, obstruction, and cuff damage are much more difficult to manage in cases of SMI. In this study, the pilot balloon assembly got damaged in one patient of the general anesthesia group during conversion to SMI, which was successfully replaced with the help of tube exchanger. Drolet *et al*. have successfully used ETT exchanger to facilitate SMI.[23] There was no episode of desaturation (spO2 <90%) in any of the patients. The patients were followed up for 1 week and 1 month postoperatively. Postoperative salivary fistula, as reported in the literature regarding the cases of prolonged ventilation was not seen in the present study.[6] The risk of sepsis or an abscess in the submental tunnel related to the passage of the possibly contaminated balloon and ETT during extubation is an important and dreaded complication, none of the patients in either group had such problem.[30,31] The scar remains healthy and not noticeable in any of the patients. Most of the patients were discharged in 2–3 days postsurgery. However, the two patients with tracheostomy had a prolonged stay.

Despite these facts, our study has certain limitations, most of our patients had Le-Fort II fractures that does not involve the floor of mouth. All the patients were taken up on elective basis so the problem of edema of the airway and floor of the mouth associated with lower jaw fractures were not encountered. However, it can be a concern in patients of pan facial trauma posted as an emergent case.

Conclusion

Awake conversion of oral to submental endotracheal intubation improves the ease ($\Delta = 53\%$) and decreases the procedure time. However, considering the smaller sample size of our study, further larger trials are needed to confirm these preliminary findings.

Declaration of patient consent

The authors certify that they have obtained all appropriate patient consent forms. In the form the patient(s) has/have given his/her/their consent for his/her/their images and other clinical information to be reported in the journal. The patients understand that their names and initials will not be published and due efforts will be made to conceal their identity, but anonymity cannot be guaranteed.

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Nil.

Conflicts of interest

There are no conflicts of interest.

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