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Comparison of Intubating Conditions, Efficacy and Safety of Airtraq Laryngoscope and Macintosh Laryngoscope: A Randomized Controlled Trial

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Abstract

Context: Considering the potential difficulties associated with conventional laryngoscopy in difficult incubating conditions, airway devices that increase the ease of performing can have a profound clinical impact. *Aim:* The current study compared the efficacy and safety of AirTraq (AirTraq^R, Prodol Meditec, Vizcaya, Spain)l aryngoscope with Macintosh laryngoscope. *Settings and Design:* The current study was aProspective, Randomized, single-blind controlled trial, conducted in Govt. Mohan Kumaramangalam Medical College Hospital, Salem, between May 2015 and January 2016. Total of 60 subjects requiring endotracheal anesthesia were randomly allocated to AirTraq^R or Macintosh laryngoscope groups. Cormack-Lehane and Intubation Difficulty Score, intubating time, hemodynamic parameters and complication rate were compared. *Statistical methods used:* Independent sample t-test. chi Square test/Fisher's exact test and two way repeated measures ANOVA were used appropriately. *Results:* Both groups were comparable in all the baseline parameters. The intubation difficulty score (1.47 Vs 0.17, p value < 0.001) and duration of intubation (17.2 Vs 11.03, p value < 0.001) were significantly higher in Macintosh group as compared to AirTraq^R. AirTraq^R group had a higher proportion of subjects in CL grade 1 (93% vs 43.3%, P value < 0.001). The proportion of subjects with airway trauma was also higher in Macintosh group (6.67% vs 10%, P value 0.64) as compared to AirTraq^R group. A higher proportion of subjects in AirTraq^R group were in Operator Grade I (93.3% Vs 66.7%). The hemodynamic parameters were comparable between the two groups. *Conclusions:* AirTraq^R laryngoscope shall be considered ahead of Macintosh laryngoscope, where ever feasible.

Keywords: Airtraq Laryngoscope; Macintosh Laryngoscope; Airtraq Vs Macintosh.

Introduction

Unsuccessful or delayed intubation can lead to brain damage and hypoxemic death [1-3] and remains a leading cause of morbidity and mortality in the operative [4] and emergency setups [5,6]. Consequently, airway devices that increase the ease of performing tracheal intubation, particularly in difficult intubating conditions, can have a profound clinical impact. The AirTraq (AirTraq^R, ProdolMeditec, Vizcaya, Spain) is one such device. But there is a scarcity of studies comparing the efficacy and safety of this new device with existing devices. Hence, the current study has been conducted to compare the efficacy and safety of AirTraq^R laryngoscope and Macintosh laryngoscope

Subjects and Methods

The current study was a Prospective, Randomized, single-blind controlled trial, conducted in the Department of Anaesthesiology, Govt. Mohan Kumaramangalam Medical College Hospital, Salem, between May 2015 and January 2016. The study participants included patients posted for elective surgical procedures, requiring endotracheal anesthesia. The study participants were randomly allocated to one of the two interventions.

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- Group A: AirTraq[R]Laryngoscope
- Group B: Macintosh laryngoscope

Inclusion Criteria

- Age 18 years of age and older
- Males and females
- ASA physical status 1,2 & 3

Exclusion Criteria

- Patients requiring special techniques for intubation such as rapid sequence induction
- Intubated prior to surgery
- Severe cardiovascular, hepatic or renal disease, mental illness
- Are unconscious or critically ill
- Need for nasal intubation

Sample Size

The Sample size was calculated assuming mean intubation time in the control group as 19 seconds and in Air Traq[R] group as 14 seconds as per the study by Amor M et al. [7] with a common standard deviation of 6.5. Considering 80% power of study and 5% alpha error, the minimum required sample size as per the above-mentioned parameters was 27 subjects in each group. The sample size was calculated by STATA IC version 13 [8].

Random Allocation

Random allocation of study participants was done by generating an allocation sequence using random number tables, following pre-specification of single digit even and odd numbers to each of the intervention groups, after omitting zero.

Allocation Concealment

Allocation concealment was done by securing the allocation sequence in serial numbered opaque envelopes in the custody of an independent faculty. The allocation sequence was revealed to the investigator, after recruitment and obtaining informed written consent, just before intubation.

Blinding

Considering the nature of the intervention, it was not possible to blind the investigator. The participant was blinded to the nature of the inter-vention and the statistician analyzing the data was also blinded.

Ethical Considerations

Ethical approval was obtained for the study from the institutional human ethics committee. Informed written consent was obtained from all the study participants, after explaining the risks and benefits involved in the study and voluntary nature of participation. The confidentiality of the participants was maintained throughout the study.

Study Procedure

After obtaining the informed written consent, for each participant, history was obtained regarding previous anesthesia, snoring, voice change, previous surgery, trauma, burns, and tumor in and around the oral cavity, neck or cervical spine. History of systemic illness like Diabetes, Hypertension, Ankylosing spondylitis, and Rheumatoid arthritis were asked and recorded.

General examination included an examination of facial anomalies, Temporomandibular joint pathology, anomalies of the mouth and tongue, pathology of the nose, pathology of the palate. Height in centimeters and weight in kilograms were recorded and Body Mass Index was calculated.

Individual airway indices were measured, including A-O joint movement, neck flexion, and temporomandibular joint function. Upper lip bite test, assessment of Thyromental distance, sternomental distance and neck circumference was also done. Examination of dentition was done to rule out cracking, buck tooth, loose, artificial and absence of incisors. Participant's airway was assessed by Samson and Young modification of Mallampatti grading. After assessment patient shifted to the operating room. i.v line started and monitors connected. Patient allotted to either AirTraq[R] or Macintosh group by way of sealed envelopes. AirTraq[R] and Macintosh laryngoscope checked for battery power. Appropriate size endotracheal tube for the patient selected. Heart rate, blood pressure and SpO_2 measured (preinduction) Inj. Glycopyrrolate 0.2mg and Inj. Fentanyl 2mcg/kg given as premedication. Then preoxygenated with 100% Oxygen at 6ltr/min for 3 min. Induction did with Inj.Thiopentone 5mg/kg + NDP neuromuscular blocker. Ventilated with a face mask for 3 min. Heart rate, blood pressure and SpO2 measured (preintubation). Intubation attempted with AirTraq[R]/Macintosh laryngoscope. Observation of Cook's modification of Cormack and Lehane grading and Intubation Difficulty Score were noted.

If intubation with AirTraq[R] failed and saturation maintained, Macintosh blade was used for

intubation and if the saturation decreased, mask ventilation with 100% oxygen followed by intubation with Macintosh laryngoscope.

Apart from Cormack-Lehane and Intubation Difficulty Score, the following factors were also noted.

- *Intubation time*: Measured from the entry of the device into the oral cavity until confirmation of proper placement of the tracheal tube.
- Heart rate, blood pressure, and SpO_2 were measured 1,3 and 5 minutes post intubation.
- *Complication rate*: All complications will be recorded, with special attention to common complications such as upper airway and dental trauma.

Statistical Methods

All the quantitative variables were checked for a normal distribution within each of the study groups. All the baseline variables were compared between the two study groups. The quantitative outcome variables were compared between the two groups using independent sample t-test. The categorical outcome variables were tested between the two groups using chi Square test/Fisher's exact test. The time changing variables were compared between two groups, using two way repeated measures ANOVA.P Value < 0.005 was considered as statistically significant. IBM SPSS statistical software version 21 was used for statistical analysis [9].

Results

A total of 60 subjects were included in the final analysis, with 30 subjects in each group. No statistically significant differences were found between the two groups in mean age, sex distribution and Body Mass Index of the patients (Table 1).

The proportion of subjects with various airway measurements above desired measurement levels were comparable across the study groups. Though the proportion of subjects with Mallampatti class 1 in group B was slightly higher, the differences between the two groups were statistically not significant. Also, no statistically significant differences were observed in neck circumference between the two groups (Table 2).

Outcome Measures

The intubation difficulty score was significantly higher in Macintosh group as compared to AirTraq^R (1.47 Vs 0.17, p value<0.001). The duration of intubation also was significantly longer in Macintosh group as compared to Air Traq^R (17.2 Vs 11.03, p value<0.001). Air Traq^R group had a higher proportion of subjects in CL grade 1 (93% vs 43.3%), the differences in the proportion of subjects with different CL grading are statistically significant between the two groups (p value < 0.001). Airway trauma was reported in 2 (6.67%) subjects in AirTraq^R group as compared to 3 (10%) subjects in Macintosh group, with no statistically significant difference (p value 0.64). The differences in the

Table 1: Comparison of baseline parameters across the study groups (N=60)

Parameter	Group A (Air Traq^R)	Group B (Macintosh)	P value
Age (years)	36.63 ±13.91	37.4±12.82	0.825
Body Mass Index	25.302±4.375	24.66±3.3787	0.527
Male: Female	3.28:1	1.5:1	0.165

Table 2: Comparison of airway measurements between the two study groups (N=60)

Parameter assessed	Group A (Air Traq^R)	Group B (Macintosh)	P value
Head extension >85°	28(93.3%)	28(93.3%)	1.0
Neck flexion >25°	28(93.3%)	28(93.3%)	1.0
Inter Incisor Distance >3 cm	29(96.7%)	29(96.7%)	1.0
Thyro Mental Distance >6.5cm	28(93.3%)	28(93.3%)	1.0
Mallampatti Class			
1	12 (40%)	20 (66.7%)	0.09
2	17 (56.7%)	10 (33.3%)	
3	1 (3.3%)	0 (0%)	
4	0 (0%)	0 (0%)	
Neck circumference	38.07±3.028	36.83±2.437	0.087

proportion of subjects with different operator grading were statistically significant between both the study groups with a higher proportion of subjects in AirTraq^R group were in Operator Grade I (93.3% Vs 66.7%) (Table 3).

The heart rate was comparable between the two study groups before induction, pre-intubation and at 5-minute post induction, but heart rate was significantly higher in Macintosh group, as compared to AirTraq^R group at 1minute (116.43 Vs 102.07, p value 0.001) and 3 minutes (103 Vs 92.30, p value 0.004) post induction. Systolic Blood pressure was comparable between the two groups at pre-induction and pre-intubation, but during post-intubation at 1 minute, 3 minutes and 5 minutes, it was significantly higher in Macintosh group. Diastolic BP and MAP were also significantly higher in Macintosh group at 1 and 3 minutes post induction. No statistically significant differences were observed between the two groups in oxygen saturation at any point in time (Table 4).

Discussion

Notwithstanding the latest advancements in the tracheal intubation devices, Macintosh's laryngoscope owing to its typical curvature has been the most preferred device [10].

Table 3: Comparison of various outcome measures between the two groups

Parameter assessed	Group A (Air Traq^R)	Group B (Macintosh)	P value
Intubation Difficulty Score	0.17±0.648	1.47±1.676	< 0.001
Duration	11.03±6.071	17.2±5.047	<0.001
Cormack and Lehane grading			
CL1	28(93.33%)	13(43.33%)	<0.001
CL2	2(6.67%)	15(50%)	
CL3	0(0%)	2(6.67%)	
CL4	0(0%)	0(0%)	
Airway Trauma	2(6.67%)	3(10%)	0.64
Operator Grading (Ease of Intubation)			
1	28(93.33%)	20(66.67%)	
2	1(3.33%)	7(23.33%)	
3	1(3.33%)	3(10%)	0.033
4	0(0%)	0(0%)	
5	0(0%)	0(0%)	

Table 4: Comparison of hemodynamic changes across the two study groups (N=60)

Parameter Assessed	Group A (Air Traq^R)	Group B (Macintosh)	P value
Heart rate			
Pre Induction	83.03±12.944	88.73±16.613	0.144
Pre Intubation	86.87±10.734	88.83±14.697	0.556
1 min Post intubation	102.07±17.648	116.43±14.115	0.001
3 min Post intubation	92.30±14.003	103.40±14.483	0.004
5 min Post intubation	84.80±10.506	90.30±13.899	0.089
Systolic BP			
Pre Induction	120.50±15.431	127.20±17.878	0.126
Pre Intubation	111.50±15.136	115.13±18.256	0.405
1 min Post intubation	129.00±18.118	150.80±18.430	<0.001
3 min Post intubation	120.43±16.913	133.57±18.578	0.006
5 min Post intubation	112.73±12.188	120.70±15.825	0.033
Diastolic BP			
Pre Induction	79.20±9.792	83.13±12.889	0.188
Pre Intubation	74.17±11.618	73.87±11.578	0.921
1 min Post intubation	88.67±11.842	100.50±13.354	0.001
3 min Post intubation	80.83±11.546	88.43±12.506	0.018
5 min Post intubation	75.07±10.123	77.20±10.867	0.435
MAP			
Pre Induction	93.00±11.277	97.63±14.129	0.166
Pre Intubation	86.57±12.227	87.63±13.479	0.749
1 min Post intubation	102.03±13.520	117.30±14.707	<0.001
3 min Post intubation	94.07±12.881	103.60±14.036	0.008
5 min Post intubation	87.53±10.644	91.70±12.349	0.167

SPo2			
Pre Induction	100±0	100±0	1.00
Pre Intubation	100±0	100±0	1.00
1 min Post intubation	99.90±.548	99.80±.761	0.561
3 min Post intubation	100.00 ±0.00	99.97±.183	0.321
5 min Post intubation	100±0	100±0	1

Of the total 60 laryngoscopes performed among 60 subjects, the findings show that the intubation difficulty score, which indicates the ease at which the procedure can be performed, was significantly lower ($p<0.001$) in AirTraq^R group compared to the Macintosh group. Consequently, the duration of the procedure was significantly lower ($p<0.001$) in the former group. In their manikin study, Maharaj C H et al. [11], found similar findings. Also, the studies by Dhonneur et al. [12], and Ndoko et al. [13], reported similar findings among morbidly obese patients. Contrastingly, Koh J C et al. [14], reported similar time taken by operators using both devices. For favorable results, AirTraq^R should be inserted into the mouth in the midline with the tip placed in the vallecula, lifting the epiglottis where necessary.

As shown in Table 3 there was a significant reduction ($p<0.001$) in Cormack and Lehane score when the intubation was done using AirTraq^R laryngoscope, which was in accordance with that of Ferranado C et al., in which the procedure was performed by unskillful anaesthesiology residents. Cormack-Lehane scale has been primarily been used to grade direct conventional laryngoscopy, but recently is often used even for AirTraq^R devices [15].

The main advantages of using AirTraq^R are it can be readily used in patients with limited mouth opening or inadequate laryngeal view [16,17]. AirTraq^R seems to induce lesser hemodynamic stimulation, which is the desired advantage in some situations.[13, 16] However, in their study on patients with cervical spine immobilizations and limited mouth opening, Koh J C et al. [14] said that AirTraq^R failed to show any significant alteration in hemodynamic changes.

Regarding the operators' ease of intubation, AirTraq^R administration was significantly ($p< 0.05$) easier than Macintosh laryngoscope. This could be due to AirTraq^R use requires less operator's skill and is easy to teach the beginners [11,15].

The other potential advantage of AirTraq^R is that it is a single-use device, the risk of prion transmission is reduced [18,19]. Such concerns are due to the difficulty of removing the proteinaceous matter from the reusable laryngoscope blades while sterilization [20,21]. In fact 'single-use intubation devices' are recommended by the Association of Anesthetists of Britain and Ireland wherever possible [22].

However, studies have reported that some single-use laryngoscope blades can complicate the intubation conditions compared to Macintosh [23,24]. There are some limitations of our study. The potential for bias exists, as it is impossible to blind the anesthetist to the device used. Also the scoring system of laryngoscopic grading or operators' rating of the ease of intubation, due to their nature can be subjective.

Conclusions

1. The intubation difficulty score was significantly higher and duration of intubation was significantly longer in Macintosh group as compared to AirTraq^R.
2. Higher proportion of subjects in AirTraq^R group were in CL grade I, whereas in Macintosh group higher proportion of subjects were CL grade II and III.
3. A Higher proportion of subjects in Macintosh group had reported Airway trauma than in AirTraq^R group, but the difference was statistically not significant.
4. The differences in the proportion of subjects with different operator grading were statistically significant between both the study groups with a higher proportion of subjects in AirTraq^R group were in Operator Grade I.
5. Subjects in AirTraq^R group had better hemodynamic stability in the post-induction period.

Recommendations

1. Considering the better ease of intubation, lesser intubation time and better operator grading, coupled with superior hemodynamic stability, AirTraq^R laryngoscope shall be considered ahead of Macintosh laryngoscope, where ever feasible.

Limitations

1. Potential bias, its magnitude and direction due to Lack of investigator blinding could not be estimated.

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Conflict of Interest: None declared

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