

A Randomized Prospective Study to Compare Truflex Articulating Stylet (TAS) versus Rapid Position Intubating Stylet (RPIS) by using D - Blade Video Laryngoscopy with Manual Inline Stabilization During Cervical Spine Surgeries

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Abstract

Background: Intubation is an optimal method for opening the airway and effective ventilation to the patient. There are some problems during intubation. It is important to identify devices like videolaryngoscopes and guides for shorten the procedure. This study addresses the use of a Truflex Articulating Stylet (TAS) versus Rapid position intubating Stylet (RPIS) using D-blade video laryngoscopy with manual inline stabilization during cervical spine surgeries. **Subjects and Methods:** It was single blinded, prospective, randomized, interventional study. Sixty patients between 18 and 60 years of age belonging to either sex undergoing tracheal intubation under uniform general anesthetic technique will be randomly divided into Rapid position intubating Stylet (RPIS) group and Truflex articulating stylet group during cervical spine surgeries. For comparison of intubation times and the Intubation Difficulty Score, ANOVA will be used. Mallampati grading (MPG), mouth opening (MO), thyromental distance (TMD), sternomental distance (SMD), Cormack Lehane's grading (CLG) were recorded. Student t test, Fisher's exact test, Mann-Whitney U test and Chi square test were used where appropriate. A p value of less than 0.05 was considered statistically significant. **Results:** Intubation using a video laryngoscope with a Truflex articulating stylet was more effective than that using a standard intubation stylet with the same laryngoscope. There were no complications observed during the procedure with either of the stylets. There was no significant difference between the two groups with respect to total intubation time. **Conclusion:** The results suggest that the patients intubated using Truflex articulating stylet and RPIS stylet has no difference in terms of successful or failed intubation. The patients intubated using Truflex articulating stylet has lesser endotracheal tube negotiation time compared to the patients intubated with RPIS and without much significant difference in number of attempts, total intubation time, glottoscopy time and any complications in any stylets.

Keywords: Tracheal intubation, Truflex articulating stylet, laryngoscope

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Introduction

Tracheal intubation is a resuscitative procedure and is regarded as the optimal means of securing the airway. For patients, it provides effective ventilation and also protects them from regurgitation.^[4,5] Tracheal intubation is most commonly performed, and is considered as a gold standard in securing the airway and is considered mandatory in a variety of patient populations and operations. For intubation, a variety of methods are available, direct laryngoscopy, intubating LMA, fiberoptic endoscopic intubation, retrograde intubation and awake intubation. The Direct Laryngoscopy (DL) technique is universally used for tracheal intubation in emergency. Videolaryngoscopes now play an important role as an alternative to conventional rigid laryngoscopy. A major advantage of the videolaryngoscope is better visualization of the larynx.^[1,2] Videolaryngoscopes serve as a valuable

teaching aid as they display the laryngeal structure on a video screen.^[3-6] The Macintosh laryngoscope has been the most widely used device for intubation to visualize laryngeal structures and there by the endotracheal tube is inserted and advanced into the trachea. Despite several advantages offered by the videolaryngoscopes, their major handicap is their enhanced anterior angulation of the blades, such as that of the Glide-Scope™ (Verathon Medical, Bothell WA, USA), the McGrath series 5 (Aircraft Medical, Edinburgh, UK), and the TruView™ PCD devices (Truphatek International Limited, Netanya, Israel), which makes viewing of the laryngeal structure easier,^[1,2] but negotiation of the endotracheal tube (ETT) towards the glottis difficult, and at times a failure.^[7,8] An-unstyleted ETT is unable to do this as its inherent radius of curvature of nearly 14 cm cannot align with the acute radius of curvature of the D-blade of the C-Mac™ or other videolaryngoscopes, which is 7 to 8 cm.^[9] This may result in a longer intubation time.^[10] Unfortunately,

these malleable rigid stylets permit only a fixed shape to the advancing endotracheal tube. This may increase total intubation time and may cause soft tissue injury and hemodynamic disturbance.

Truflex articulating stylet has an articulating tip which can be manually controlled. Therefore a preloaded endotracheal tube with the Truflex articulating stylet will not only shorten the intubation time but also attenuate the possibility of soft tissue trauma in patients whose anatomy makes access more difficult; compared to endotracheal tube preloaded with RPIS.

The aim of this study is to compare the RPIS with the TAS as an intubation guide during laryngoscopy in elective tracheal intubation.

Subjects and Methods

It was a single blind, prospective, randomized interventional controlled study conducted in patients undergoing elective tracheal intubation. Sixty patients between 18 and 60 years of age belonging to either sex undergoing tracheal intubation under uniform general anesthetic technique randomly divided into Rapid position intubating Stylet (RPIS) group and Truflex articulating stylet group.

The study protocol has been approved by the Institutional Ethics Committee, Narayana medical college, Nellore. Patients between 18 and 60 years of age, of either sex, graded I or II according to the criteria of the American Society of Anesthesiologists, undergoing spine surgery under general anesthesia and tracheal intubation, and who give written informed consent were included. 30 patients were maintained by Rapid position intubating Stylet and another 30 patients were maintained by Truflex articulating stylet.

For patients in group RPIS, a well-lubricated PIS was used to shape the ETT according to the curvature of the videolaryngoscope D-blade. This pre-shaped ETT will be guided into the trachea after obtaining an adequate view of the glottis of an anesthetized and fully relaxed patient using the D-blade videolaryngoscope. For patients in group TAS, a well-lubricated TAS was used in place of the rigid stylet to change the curvature of the ETT as per need to negotiate into the glottis, using the same videolaryngoscope. In both groups, videolaryngoscopy and tracheal intubation was done by an experienced anesthesiologist.

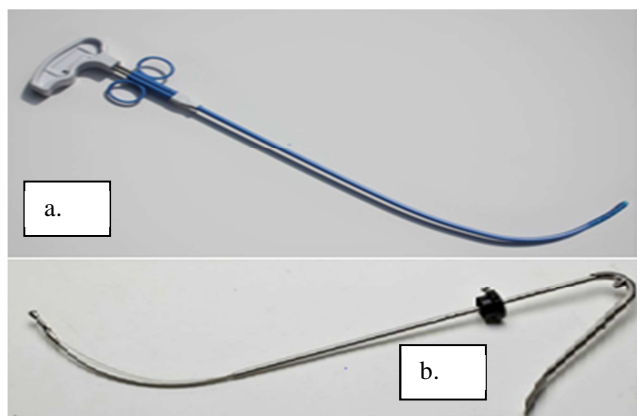


Figure 1. Rapid position intubating Stylet and Truflex articulating stylet

Statistics:

Mallampati grading (MPG), mouth opening (MO), thyromental distance (TMD), sternomental distance (SMD), Cormack Lehane's grading (CLG) were recorded. Student t test, Fisher's exact test, Mann-Whitney U test and Chi square test were used where appropriate. A two-sided, 95% confidence interval will be calculated for the mean difference between the treatment groups. For evaluation of intubation times and the intubation difficulty score, analysis of variance (ANOVA) will be used for comparison between both treatment groups. A p value of less than 0.05 was considered as statistically significant.

Results

The mean age 40.64 ± 12.38 and 39.85 ± 12.79 years in RPIS and TRUFLEX groups. 14, 16 males & females in RPIS group and 16, 14 male and female subjects were observed in TRUFLEX groups. There was no statistical significance observed.

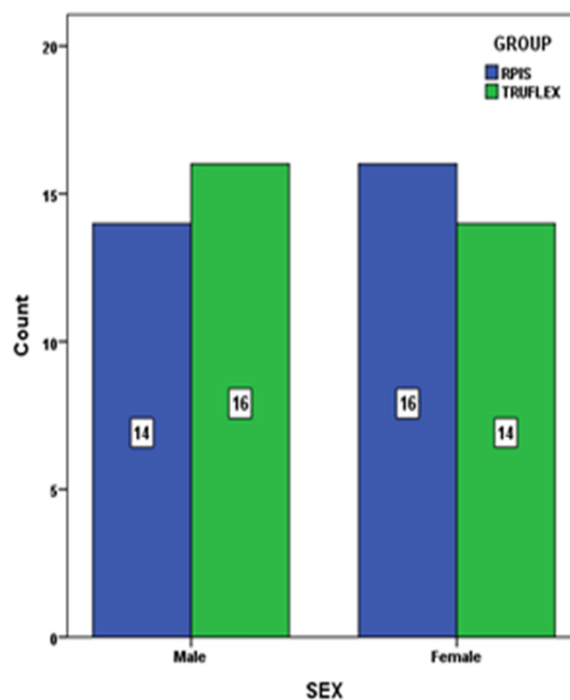


Figure 2: Gender count in RPIS/TRUFLEX GROUP

Table 1: Crosstab between SEX and RPIS/TRUFLEX GROUP

		GROUP		Total	
		RPIS	TRUFLEX		
SEX	Male	Count	14	16	30
		% within SEX	46.7%	53.3%	100.0%
		% within GROUP	46.7%	53.3%	50.0%
	Female	Count	16	14	30
% within SEX		53.3%	46.7%	100.0%	
% within GROUP		53.3%	46.7%	50.0%	
Total		Count	30	30	60
		% within SEX	50.0%	50.0%	100.0%
		% within GROUP	100.0%	100.0%	100.0%

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Table 2: Crosstab between ASA-Grade in RPIS/TRUFLEX GROUP

			GROUP		Total
			RPIS	TRUFLEX	
ASA_Grade	1	Count	21	22	43
		% within ASA_Grade	48.8%	51.2%	100.0%
		% within GROUP	70.0%	73.3%	71.7%
	2	Count	9	8	17
		% within ASA_Grade	52.9%	47.1%	100.0%
		% within GROUP	30.0%	26.7%	28.3%
Total		Count	30	30	60
		% within ASA_Grade	50.0%	50.0%	100.0%
		% within GROUP	100.0%	100.0%	100.0%

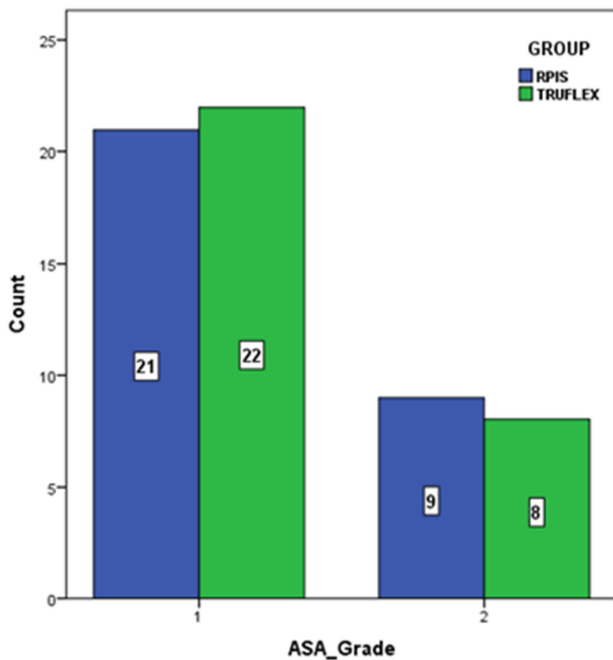


Figure 3: ASA_Grade in RPIS/TRUFLEX GROUP

The mean height 164.25 ± 6.34 and 162.5 ± 5.39 years in RPIS and TRUFLEX groups. Thyromental Distance: The thyromental distance (TMD) is defined as the distance from the chin (mentum) to the top of the notch of the thyroid cartilage with the head fully extended. A TMD measurement of 6.5 cm or greater with no other abnormalities indicates the likelihood of easy intubation. TMD observed as 6.54 ± 0.22 and 6.5 ± 0.25 in RPIS and TRUFLEX groups without statistical difference. A TMD measurement of 6.0 to 6.5 cm indicates that alignment of the pharyngeal and laryngeal axes will be challenging and that difficulty with laryngoscopy may result. However, intubation is possible with the use of adjuncts such as an Eschmann introducer or an optical stylet. A TMD measurement of less than 6 cm indicates difficult laryngoscopy; specifically, intubation may be impossible. Sterno-mental distance: Estimated the distance from the suprasternal notch to the mentum and investigated its possible correlation with Mallampati class, jaw protrusion,

interincisor gap and thyromental distance. It was measured with the head fully extended on the neck with the mouth closed. A value of less than 12 cm is found to predict a difficult intubation. SMG observed as 12.6 ± 0.32 and 12.61 ± 0.28 in RPIS and TRUFLEX groups.

Mouth opening (MO): Regarding the normal mouth opening in males and females various research work has been mentioned in literature and it ranges from 40–74 mm in males and 35–70 mm in females. Mouth opening observed as 4.89 ± 0.46 cms and 5 ± 0.62 cms in RPIS and TRUFLEX group.

Mallampati grading (MPG): In RPIS group, 19 subjects in MPG 1, 8 subjects in MPG 2, 2 subjects in MPG 3, and 3 subjects in MPG 4 were enrolled. Whereas, In TRUFLEX group, 17 subjects in MPG 1, 4 subjects in MPG 2, 3 subjects in MPG 3, and 6 subjects in MPG 4 subjects were enrolled. There was no statistical difference observed between these two groups.

Table 3: Crosstab between MPG_Grade and RPIS/TRUFLEX GROUP

			GROUP		Total
			RPIS	TRUFLEX	
MPG_Grade	1	Count	19	17	36
		% within MPG_Grade	52.8%	47.2%	100.0%
		% within GROUP	63.3%	56.7%	60.0%
	2	Count	6	5	11
		% within MPG_Grade	54.5%	45.5%	100.0%
		% within GROUP	20.0%	16.7%	18.3%
	3	Count	2	2	4
		% within MPG_Grade	50.0%	50.0%	100.0%
		% within GROUP	6.7%	6.7%	6.7%
	4	Count	3	6	9
		% within MPG_Grade	33.3%	66.7%	100.0%
		% within GROUP	10.0%	20.0%	15.0%
Total		Count	30	30	60
		% within MPG_Grade	50.0%	50.0%	100.0%
		% within GROUP	100.0%	100.0%	100.0%

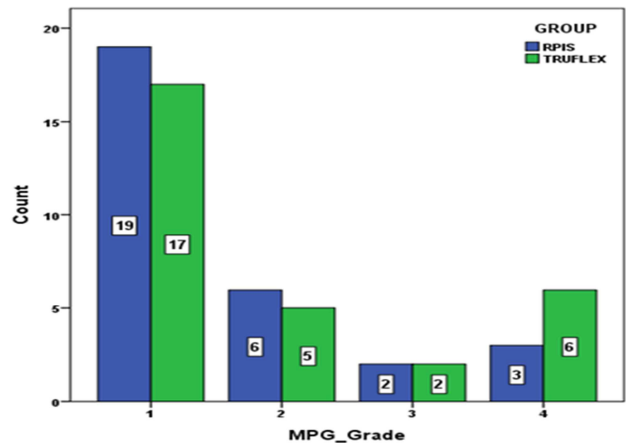


Figure 4: MPG_Grade and RPIS/TRUFLEX GROUP

Table 4: Descriptives (T-Test)

		N	Mean	Std. Deviation	Std. Error	95% Confidence Interval for Mean		Minimum	Maximum
						Lower Bound	Upper Bound		
AGE	RPIS	30	40.64	12.38	2.26	36.02	45.26	17.17	68.04
	TRUFLEX	30	39.85	12.79	2.34	35.07	44.63	14.51	68.64
	Total	60	40.25	12.49	1.61	37.02	43.47	14.51	68.64
Height	RPIS	30	161.25	6.34	1.16	158.88	163.62	148.74	175.23
	TRUFLEX	30	162.50	5.39	.98	160.49	164.51	153.42	175.91
	Total	60	161.88	5.87	.76	160.36	163.39	148.74	175.91
Weight	RPIS	30	64.09	8.70	1.59	60.84	67.34	44.68	83.77
	TRUFLEX	30	64.65	7.66	1.40	61.79	67.51	44.51	77.03
	Total	60	64.37	8.13	1.05	62.27	66.47	44.51	83.77
MO	RPIS	30	4.89	.46	.08	4.72	5.06	4.05	5.67
	TRUFLEX	30	5.00	.62	.11	4.77	5.23	3.60	5.99
	Total	60	4.95	.54	.07	4.80	5.09	3.60	5.99
TMD	RPIS	30	6.54	.22	.04	6.46	6.62	6.10	7.00
	TRUFLEX	30	6.54	.25	.05	6.45	6.63	6.04	6.93
	Total	60	6.54	.23	.03	6.48	6.60	6.04	7.00
SMD	RPIS	30	12.64	.32	.06	12.52	12.76	12.00	13.16
	TRUFLEX	30	12.61	.28	.05	12.51	12.71	12.18	13.27
	Total	60	12.63	.30	.04	12.55	12.70	12.00	13.27

Table 5. Independent Samples Test

		Levene's Test for Equality of Variances		t-test for Equality of Means						
		F	Sig.	t	df	P Value	Mean Difference	Std. Error Difference	95% Confidence Interval of the Difference	
									Lower	Upper
AGE	Equal variances assumed	.013	.910	.243	58	.809 NOT SIG	.790	3.250	-5.715	7.295
	Equal variances not assumed			.243	57.939	.809	.790	3.250	-5.715	7.295
Height	Equal variances assumed	2.010	.162	-.823	58	.414 NOT SIG	-1.250	1.519	-4.291	1.791
	Equal variances not assumed			-.823	56.536	.414	-1.250	1.519	-4.293	1.793
Weight	Equal variances assumed	.108	.743	-.265	58	.792 NOT SIG	-.560	2.116	-4.796	3.676
	Equal variances not assumed			-.265	57.085	.792	-.560	2.116	-4.798	3.678
MO	Equal variances assumed	3.598	.063	-.780	58	.438 NOT SIG	-.110	.141	-.392	.172
	Equal variances not assumed			-.780	53.503	.439	-.110	.141	-.393	.173
TMD	Equal variances assumed	1.351	.250	.000	58	1.000 NOT SIG	.000	.061	-.122	.122
	Equal variances not assumed			.000	57.077	1.000	.000	.061	-.122	.122
SMD	Equal variances assumed	.606	.439	.386	58	.701 NOT SIG	.030	.078	-.125	.185
	Equal variances not assumed			.386	56.996	.701	.030	.078	-.125	.185

Table 6. Mann-Whitney Test

	N	Mean	Std. Deviation	Minimum	Maximum
ASA_Grade	60	1.28	.454	1	2
MPG_Grade	60	1.77	1.110	1	4

Table 7. Test Statistics between ASA grade and MPG grade.

	ASA_Grade	MPG_Grade
Mann-Whitney U	435.000	405.500
Wilcoxon W	900.000	870.500
Z	-.284	-.748
P Value	.776 NOT SIG	.455 NOT SIG

Table 8: FOR RIPS [ASA_Grade * MPG_Grade Crosstabulation]

		MPG_Grade				Total	
		1	2	3	4		
ASA_Grade	1	Count	12	5	2	2	21
		% within ASA_Grade	57.1%	23.8%	9.5%	9.5%	100.0%
		% within MPG_Grade	63.2%	83.3%	100.0%	66.7%	70.0%
	2	Count	7	1	0	1	9
		% within ASA_Grade	77.8%	11.1%	0.0%	11.1%	100.0%
	% within MPG_Grade	36.8%	16.7%	0.0%	33.3%	30.0%	
Total		Count	19	6	2	3	30
		% within ASA_Grade	63.3%	20.0%	6.7%	10.0%	100.0%
		% within MPG_Grade	100.0%	100.0%	100.0%	100.0%	100.0%

Pearson Chi-Square p is 0.614

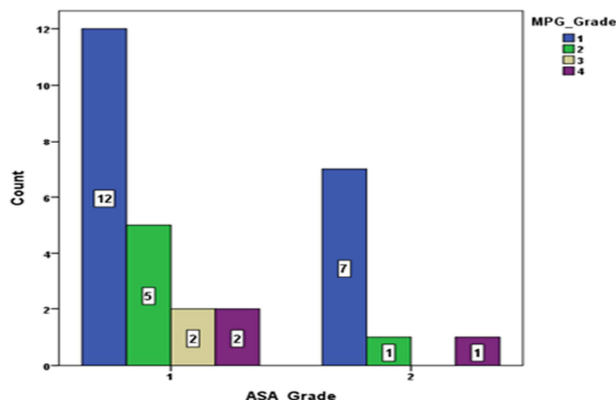


Figure 5. ASA_Grade vs MPG_Grade

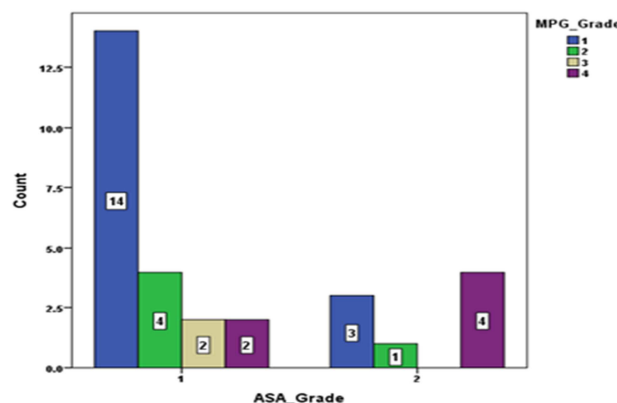


Figure 6. ASA_Grade vs MPG_Grades

Table 9: FOR TRUEFLEX [ASA_Grade vs MPG_Grade Crosstabulation]

		MPG_Grade				Total	
		1	2	3	4		
ASA_Grade	1	Count	14	4	2	2	22
		% within ASA_Grade	63.6%	18.2%	9.1%	9.1%	100.0%
		% within MPG_Grade	82.4%	80.0%	100.0%	33.3%	73.3%
	2	Count	3	1	0	4	8
		% within ASA_Grade	37.5%	12.5%	0.0%	50.0%	100.0%
	% within MPG_Grade	17.6%	20.0%	0.0%	66.7%	26.7%	
Total		Count	17	5	2	6	30
		% within ASA_Grade	56.7%	16.7%	6.7%	20.0%	100.0%
		% within MPG_Grade	100.0%	100.0%	100.0%	100.0%	100.0%

Pearson Chi-Square p is 0.091(Not significant)

Discussion

Successful and quick orotracheal intubation is a key to securing the airway and delivery of anesthesia; especially in the management of difficult airway patients where speed and success is essential. The last decade has seen the emergence of videolaryngoscopes enable us to visualize the laryngeal structures on a high-resolution video screen. These high-resolution video screen. These new aids provide a superior view of the laryngeal structures in normal conditions, and in a plethora of pathological and challenging conditions.

A variety of videolaryngoscopes with angulated blade have been recently introduced into clinical practice. They provide an indirect view of the glottic structures in normal and challenging clinical settings. Despite the very good visualization of the laryngeal structures by these devices, the insertion and advancement of the endotracheal tube may be prolonged and occasionally fail as it does not conform to the enhanced angulation of the blade. To overcome this handicap, it is recommended to use a pre-shaped, styleted tracheal tube during intubation. Unfortunately, these malleable rigid stylets permit only a fixed shape to the

advancing endotracheal tube. This may necessitate withdrawal of endotracheal tube-stylet assembly for reshaping, before undertaking a new attempt. This may cause soft tissue injury and hemodynamic disturbance.

During cervical spine surgeries intubation is usually done following manual in line stabilization (MILS). In such circumstances a cervical collar is usually left in place to restrict cervical spine movement to some degree. laryngoscopy is difficult in such patients due to limited neck extension. D blade of C-MAC with different stylets play an important role as an alternative to conventional rigid laryngoscopy in such cases as it doesn't require neck extension.

This study is aimed to compare Rapid position intubating Stylet (RPIS) with the Truflex Articulating Stylet (TAS) as an intubation guide during laryngoscopy in elective tracheal intubation.

The RPIS is a hand controlled intubating stylet with a tip that can both flex and retroflex to intubate airways with both video and direct Laryngoscopy which improve success when intubating difficult airways.

The TruFlex Articulating Stylet is built with an ergonomic

0 handle that allows for one-handed use of the stylet. It features an easily controllable flexible tip and stopper control to hold endotracheal tube in position.

In this study it was observed that a preloaded endotracheal tube with the Truflex articulating stylet will not only shorten the intubation time but also attenuate the possibility of soft tissue trauma in patients whose anatomy makes access more difficult; compared to endotracheal tube preloaded with RPIS.

The mean age and standard deviation observed as 40.64 ± 12.38 and 39.85 ± 12.79 years in RPIS and TAS groups. There was no statistical difference observed in the age between two groups.

14, 16 males & females in RPIS group and 16, 14 male and female subjects were observed in TAS groups. There was no statistical significance observed.

The mean height 164.25 ± 6.34 and 162.5 ± 5.39 years in RPIS and TAS groups.

In this study, the thyromental distance (TMD) is observed as 6.54 ± 0.22 and 6.5 ± 0.25 in RPIS and TAS groups without statistical difference. A TMD measurement of 6.0 to 6.5 cm indicates that alignment of the pharyngeal and laryngeal axes will be challenging and that difficulty with laryngoscopy may result.

In this study, sterno-mental distance (SMD), value of less than 12 cm is found to predict a difficult intubation. SMD observed as 12.6 ± 0.32 and 12.61 ± 0.28 in RPIS and TAS groups. There was statistical difference observed between the two groups.

In this study, mouth opening observed as 4.89 ± 0.46 cms and 5 ± 0.62 cms in RPIS and TAS group.

Our data support the findings of previous manikin studies of inexperienced practitioners, using other indirect or videolaryngoscopes, such as the Airway Scope.^[11-14]

In this study, in RPIS group, 19 subjects in MPG 1, 8 subjects in MPG 2, 2 subjects in MPG 3, and 3 subjects in MPG 4 were enrolled. Whereas, In TAS group, 17 subjects in MPG 1, 4 subjects in MPG 2, 3 subjects in MPG 3, and 6 subjects in MPG 4 subjects were enrolled. There was no statistical difference observed between these two groups.

Our results showed a significant difference in intubation difficulty between two laryngoscopes while using the different ETT-stylet assembly as used in different studies. This finding holds promise for the future of videolaryngoscopes, as the greater the number of intubation attempts made, the greater is the associated morbidity, specially in patients with an injured cervical spine.^[15,16]

Conclusion

The patients intubated using Truflex articulating stylet has significantly lesser endotracheal tube negotiation time compared to the patients intubated with conventional RPIS.

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