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Assessment of endotracheal intubation procedures following inadvertent esophageal intubation. A randomized crossover manikin trial

Sedat Bilge[1], Yahya Ayhan Acar[2], Attila Aydin[3], Onur Tezel[4], Guclu Aydin[5]

1,2,4 Department of Emergency Medicine, Gulhane School of Medicine, University of Health Sciences, Ankara, Turkey; **3** Miaclinics, Atasehir, Istanbul, Turkey; **5** Department of Emergency Medicine, Gulhane Training and Research Hospital, University of Health Sciences, Ankara, Turkey

Correspondence: Yahya Ayhan Acar. **Email:** yahyaacar@gmail.com

Abstract

Objective: To evaluate the success, degree of difficulty and completion time of endotracheal intubation without removing the endotracheal tube in the event of an oesophageal intubation.

Methods: The prospective, randomised crossover study was conducted at Gulhane Training and Research Hospital, Ankara, Turkey, from July 1, 2018, to August 31, 2018, and used a manikin model. Endotracheal intubation was performed using Miller, Macintosh blades and a video laryngoscope. The procedures were randomised into two groups, with group E+ being subjected to it while an endotracheal tube ETT was placed in the oesophagus (E+) simulating the oesophageal intubation, and control group E- getting the standard procedure without the endotracheal tube in the oesophagus. All methods were evaluated for their success, completion time, and degree of difficulty. Data was analysed using SPSS 22.

Results: There were 120 manikins, with 60(50%) in each of the two groups. The mean completion time with Miller in E+ group was 19.05±9.65 and for E- it was 17.55±11.95 seconds. With Macintosh, E+ had a mean completion time of 19.85±12.66 seconds and E- had 16.75±8.66. With video laryngoscope, E+ group had a mean completion time of 16.75±8.66 seconds, while E- had it 14.60±8.17. No significant difference was found in the paired group comparisons in terms of the degree of task difficulty ($p>0.05$).

Conclusion: In case of inadvertent oesophageal intubation condition, leaving the tube in the oesophagus and performing subsequent endotracheal intubation attempts was not found to decrease the rate of success regardless of the laryngoscope type.

Key Words: Oesophagus, Intubation, Laryngoscopes.

Introduction

Airway management is vital in cases where advanced trauma life support (ATLS) and advanced cardiac life support (ACLS) are provided. Endotracheal intubation (ETI) is the optimum method for preserving the airway and providing ventilation when the patient's score on the Glasgow Coma Scale (GCS) is <8, and is a potentially lifesaving manoeuvre.[1, 2]

ETI is encouraged because of its priority and necessity in definitive airway management and it is recommended that emergency medicine technicians must be trained for this procedure.[3, 4] The success of ETI is considered in airway management algorithms in emergency medical practice, which promote the use of the laryngeal mask airway and other supra-glottic airway device(s) as a rescue tool only after failed intubation attempts and until ETI or surgical airway management is obtained.[5] Unresolved problems persist in pre-hospital airway management related to the management of complications originating from the use of such equipment as oropharyngeal airways, nasopharyngeal airways, laryngeal mask airways, and endotracheal tubes (ETTs).[2, 6, 7] The airway

equipment found in pre-hospital civil and military systems varies according to the economic level of the country and the level of education and experience of the operators. Clear algorithms are needed for the management of complications related to ETT placement, which is available in all healthcare settings and is considered the gold standard approach since no equipment other than ETT is globally available in all care settings.

Oesophageal intubation (EsI) following failed ETI attempts using different equipment has been encountered at varying rates and has been accepted as a complication.[7-11]

It is known that an ETI procedure may result in EsI as a complication if there is a lack of education and experience in the operator, or based on the selected equipment and patient-related factors. New opinions have been presented on a standard approach involving airway management algorithms to be adopted in emergency care.[12, 13] Although such methods fail to explain precisely to operators how to manage a situation in which an ETI attempt results in EsI. In this regard, answers to the following questions need to be established: Should the ETT be removed from the esophagus in the event of EsI for airway management? Should the ETT be left in the oesophagus and the subsequent ETI procedure be repeated with a new ETT? Which type of laryngoscope would be most advantageous in the presence of an EsI? As an important point, an ETT contaminated with gastrointestinal content in the event of EsI should not be used in subsequent ETI attempts, which may be disregarded by some health professionals following the present algorithms. The present airway management algorithms do not provide any definite recommendations for actions that must be taken after an ETI intervention that results in EsI. Thus, novel approaches need data on which tools should be used in EsI and how EsI should be managed as a complication.

The current study was planned to determine the success, degree of difficulty and duration of completion of the ETI procedure in a model simulating EsI using

classical laryngoscopes with Miller (MIL) and Macintosh (MAC) blades and a video laryngoscope (VL). It was also planned to evaluate the benefits of leaving the ETT in the oesophagus when a nasogastric (NG) catheter is needed for gastric decompression.

Materials and Methods

The prospective, randomised crossover study was conducted at Gulhane Training and Research Hospital, Ankara, Turkey, from July 1, 2018, to August 31, 2018, and used a manikin model. Endotracheal intubation was performed using MIL and MAC blades and a VL after approval from the institutional non-interventional research ethics board.

All interventions were made by 20 Ambulance and Emergency Care technicians who had graduated from the Gulhane Military Medical Academy Non-Commissioned Officer Health College. All members had over four years of emergency medical service (EMS) experience and were trained in ACLS and ATLS. After getting written informed consent from all the participants, they were given refresher trainings lasting at least 30 minutes on the ETI procedure by specialists in emergency medicine. These training programmes comprising theoretical and practical aspects, included anatomical landmarks and standard procedural tools on ETI, but EsI procedures were not included.

An airway management manikin (Life/form® Airway Larry Adult A/M Trainer, USA) fitted with a rigid cervical collar (Ambu® Perfit ACE Extrication Collar, USA) was used. An MIL blade laryngoscope (Teutotechnik Inc., Germany, blade no. 4), a MAC blade laryngoscope (Teutotechnik Inc., Germany, blade no. 3), a VL (C-MAC blade, Karl Storz, Germany) and 8-mm internal diameter (ID) cuffed ETTs (Bicakcilar Inc., Turkey) were used for the intubation procedure. A 14-French nasogastric (NG) catheter (Levin, Bicakcilar Inc., Turkey), a lubricant gel, an intubation stylet, and a bag valve mask (BVM) were employed, while a 20-ml syringe was used to inflate the cuff. All devices were used according to

the manufacturers' instructions.

The procedures were randomised into two groups, with group E+ being subjected to ETI with an endotracheal tube ETT placed in the oesophagus (E+) simulating the EsI, and control group E- getting the standard procedure without ETT in the oesophagus.

For the EsI model (E+) setup, the researchers placed an 8-mm ID cuffed ETT in the oesophagus with the aid of a VL and confirmed its location by inflating the cuff. In the control group (E-), the ETT was not placed in the esophagus, and the operators were asked to perform a standard ETI. The E+ and E- models were pre-prepared with a difficult airway status using a cervical collar and presented to the operators. The models were pre-prepared and presented to the operators prior to each intervention. The three different types of equipment were used separately for both groups, meaning there were in all 6 groups: MIL (E+), MAC (E+), VL (E+), MIL (E-), MAC (E-) and VL (E-). The order of the participants starting the trial and the order of the six different applications to be performed by a single participant were randomly determined prior to the study. The procedures were randomised with an online tool.[14] All methods were evaluated for their success, completion time, and degree of ease.

An intervention was considered successful when the operator correctly placed the ETT in the trachea of the model; lung inflation was demonstrated following ventilation by a BVM; and all interventions were completed in 60 seconds. An unsuccessful procedure was defined as one taking more than 60 seconds to secure the airway; absence of manikin lung inflation during BVM ventilation; and recurrent EsI. Only a single attempt was permitted for the insertion of the ETT. The investigators recorded the success of the ETI procedures.

The duration of completion of ETI was defined as the time from the first insertion of the laryngoscope blade into the oral cavity of the manikin to the time of the total removal of the laryngoscope from the oral cavity following the insertion of ETT by the operator. This time period was recorded in terms of

seconds using a chronometer.

In addition, the operators were asked to insert an NG catheter via the oral route following each ETI intervention. These interventions were completed through the oesophageally-placed ETT in the E+ models, and through the oral route in the E- models. The procedures were evaluated as a success or failure, with the criterion of success being that the NG catheter was advanced into the stomach, and the catheter tip was visible to the investigators through the transparent stomach site of the manikin.

The operators graded the ease of their ETI and NG interventions using a numerical rating scale (NRS) with varying scores from 0 = the most difficult intervention to 10 = the easiest intervention.

Based on the reported mean completion time of 14.46±2.31 seconds[14], the sample size related to the operators was calculated assuming a ETI completion time of 17.0 seconds with a 80% power and a two-sided error margin of 0.05.

Data was analysed using SPSS 22. Descriptive data was expressed as mean ± standard deviation (SD). The normality of the data distribution was tested using Kolmogorov-Smirnov test, after which a Student t-test was used to compare normally distributed paired groups. Wilcoxon test was used to compare the degree of difficulty of the procedures. $P<0.05$ was considered statistically significant.

Results

There were 120 manikins, with 60(50%) in each of the two groups. All (100%) ETI interventions were completed successfully by the 20 participants for each group. Mean completion time was 19.53±10.85 seconds for the 3 E+ groups and 16.30±9.65 seconds for the 3 E- groups ($p>0.05$). Also, the degree of difficulty realted to the 3 methods used was no significant (Table 1). (Table 1). Also, there was no significant difference in the ETI completion times using any of the 3 methods ($p>0.05$) (Table 2).

Completion of the procedure was easier when the ETI was performed using a VL compared to the 2 other methods ($p<0.05$). There was significant difference in favour of MAC (E-) group compared to MIL (E-) group in terms of the degree of difficulty ($p<0.05$). The rest of the paired group comparisons revealed no significant differences among the groups ($p>0.05$). A IN terms of the degree of difficulty, the procedure was significantly easier in E+ models than in E- models ($p<0.05$) (Table 3).

Discussion

The current study investigated the success and efficacy of ETI following inadvertent EsI in a simulated manikin model. It is known that an ETI procedure may result in EsI as a complication if there is a lack of education and experience in the operator, or depending on the equipment selected and patient-related factors.[15, 16] The present study obtained unique data on how EsI should be managed as a complication.

Eismann et al. reported the success rates of ETIs performed using a classical MAC blade, a Storz conventional (C)-MAC blade (Karl Storz, Tuttlingen, Germany), and a Storz Volker Doerges (D)-Blade (Karl Storz, Tuttlingen, Germany) as 86.4%, 90.9%, and 95.5%, respectively, with the degree of difficulty found to be significantly increased in procedures using classical MAC blades compared to VLs.[17] The time required for ETI was suggested to be <30 seconds.[18] The findings of the current study are compatible with these results. The completion of subsequent ETI procedures in the event of EsI is expected to be prolonged, or to complicate the procedure, although no difference was noted in the completion times or degree of difficulty in the E- and E+ models in the ETI procedures. This was attributed to the fact that leaving the ETT in the oesophagus following EsI resulted in no lengthening or complicating effect on the subsequent ETI procedure.

Kulkarni et al. reported that ETI using a MAC blade was easier than using a MIL laryngoscope in their prospective randomised controlled study.[19] These findings are similar to the results of the present study regarding the degree of difficulty of the ETI procedure when using MAC and MIL laryngoscopes in the E- model. The study findings of using the MIL, MAC and VL techniques in the E- model are also similar to recent literature in terms of the difficulty degree and completion time.[17, 19-21] The difference between the ease of MAC (E-) and MIL (E-) models was considered to be associated with the fact that operators use predominantly the MAC blade in their daily practice.

The difference noted in the degree of difficulty between the MAC (E-) and MIL (E-) groups was abolished in the (E+) groups. One explanation for that loss of difference is that the operators in this study had not yet conducted the ETI procedure while retaining the ETT in the oesophagus (E+). Further explanations may be that (transverse and vertical diameters of MAC blades are larger than the respective diameters of MIL blades, and that the view obtained while the tube is in the mouth is limited when using a MAC blade. Experience obtained in this study showed that the ETT left in the oesophagus should be deviated to the left in order to obtain an optimal glottic view in ETI.

The similarity between the current literature and the data obtained in this study regarding the E- model, as cited above, favours the generalisability of the data to the E+ model. To the best of our knowledge, there is no data comparing the ETI procedures performed in E+ and E- models. Therefore, one may consider that in EsI cases, educated and experienced operators may perform subsequent ETIs without removing the ETT from the oesophagus. In the case of EsI, the question of how oxygenation and ventilation can be maintained until successful ETI can be achieved is important. The suggestions put forward by Milne et al. may provide the solution to the question of how oxygenation and ventilation can be maintained until successful ETI can be achieved in the case of EsI.[22] They reported that BVM ventilation met the requirements of oxygenation and

ventilation by manipulating the oesophageal ETT to the inferior and posteriorly at the left corner of the mouth.[22] In case of EsI, we observed that the left deviation of the tube in the oesophagus is a necessity for subsequent ETI procedures. When considering the suggestions of Milne et al., pushing the tube to the inferior posterior and left can resolve the problem of bagging between attempts.

The difficulty experienced in the nasal or oral insertion of an NG catheter with the aim of gastric decompression, or in cases of gastric intoxication in emergency units, is well known, and this technique has been reported to fail at varying rates in initial attempts.[23, 24] In the present study, the procedures were found to be easier in the E+ model than in the E- model when using ETT as a rail in NG catheter insertion, similar to Kwon et al.'s findings.[24] In cases when ETT attempts fail and result in EsI, the operators can use the ETT in the oesophagus as a rail when NG tube insertion is required, similar to the E+ model in the present study.

The current study developed a new and useful tool for managing the EsI,and it is proposed that the ETT in shall be left in the oesophagus and before starting the subsequent ETI intervention, left deviation of the tube would be helpful.

The current study has several limitations having being done at a single centre. Additionally, using manikins rather than real patients can be considered a limitation in the translation of the data into clinical effect.

The study, however, may serve as a source for further studies and airway management algorithms, which are expected to become a standard approach in the future.

Conclusion

In case of inadvertent EsI, subsequent ETI attempts without removing the ETT in the oesophagus did not affect the success of subsequent intubation, the

duration of intubation, or the degree of difficulty of the procedure. The finding was independent of laryngoscope type.

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Conflict of interest: None.

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Table 1: Comparison of the duration of completion and degree of difficulty of endotracheal intubation (ETI) procedures in the E+ and E- models according to laryngoscope type.

	Completion Time (seconds)			Numeric Rating Scale	
Group	**ETT Mean±SD**	**P-Value[a]**	**Hazard ratio (95% CI)**	**ETT Mean±SD**	**P-Value[b]**
MIL (E+)	19.05±9.65	0.596	-4.32-7.32	6.65±1.98	0.367
MIL (E-)	17.55±11.95			7.05±1.23	
MAC (E+)	19.85±12.66	0.237	-2.21-8.41	7.05±1.70	0.216
MAC (E-)	16.75±8.66			7.60±1.14	
VL (E+)	19.70±10.56	0.071	-0.49-10.68	8.65±1.56	0.609
VL (E-)	14.60±8.17			8.90±1.17	

CI: confidence interval; MIL (E+): ETI with Miller (MIL) blade with ETT in the oesophagus; MIL (E-): ETI with MIL blade with no ETT in the oesophagus; MAC E(+): ETI with Macintosh (MAC) blade with ETT in the oesophagus; MAC (E-): ETI with MAC blade with no ETT in the oesophagus; SD: Standard deviation; VL (E+): ETI with video laryngoscope (VL) with ETT in the oesophagus; VL (E-): ETI with VL with no ETT in the oesophagus.

[a] p values were calculated using Student's t-test

[b] p values were calculated using Wilcoxon test

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Table 2: Binary comparisons of all laryngoscope types and endotracheal intubation (ETI) models in terms of the duration of completion of the procedure.

Group	MIL E+	MIL E-	MAC E+	MAC E-	VL E+	VL E-
MIL E+	N/A	0.596 (-4.32–7.32)	0.776 (-6.60–5.00)	0.292 (-2.13–6.73)	0.851 (-7.79–6.49)	0.075 (-0.49–9.39)
MIL E-	0.596 (-4.32–7.32)	N/A	0.403 (-7.93–3.33)	0.779 (-5.07–6.67)	0.541 (-9.38–5.08)	0.291 (-2.74–8.64)
MAC E+	0.776 (-6.60–5.00)	0.403 (-7.93–3.33)	N/A	0.237 (-2.21–8.41)	0.968 (-7.55–7.85)	0.104 (-1.17–11.67)
MAC E-	0.292 (-2.13–6.73)	0.779 (-5.07–6.67)	0.237 (-2.21–8.41)	N/A	0.359 (-9.51–3.61)	0.305 (-2.12–6.42)
VL E+	0.851 (-7.79–6.49)	0.541 (-9.38–5.08)	0.968 (-7.55–7.85)	0.359 (-9.51–3.61)	N/A	0.071 (-0.49–10.68)
VL E-	0.075 (-0.49–9.39)	0.291 (-2.74–8.64)	0.104 (-1.17–11.67)	0.305 (-2.12–6.42)	0.071 (-0.49–10.68)	N/A

A *t*-test was used, and *p*-values and confidence interval values (in parentheses) are provided. MIL (E+): ETI with Miller (MIL) blade with ETT in the oesophagus; MIL (E-): ETI with MIL blade with no ETT in the oesophagus; MAC E(+): ETI with Macintosh (MAC) blade with ETT in the esophagus; MAC (E-): ETI with MAC blade with no ETT in the oesophagus; VL (E+): ETI with video laryngoscope (VL) with ETT in the oesophagus; VL (E-): ETI with VL with no ETT in the oesophagus; N/A: not applicable.

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Table 3: Binary comparisons of all laryngoscope types and endotracheal intubation (ETI) models in terms of the degree of difficulty of the procedure in achieving ETI.

Group	MIL E+	MIL E-	MAC E+	MAC E-	VL E+	VL E-
MIL E+	N/A	0.367	0.614	0.063	0.001	0.001
MIL E-	0.367	N/A	0.859	0.022	0.007	0.001
MAC E+	0.614	0.859	N/A	0.216	0.001	0.001
MAC E-	0.063	0.022	0.216	N/A	0.016	0.001
VL E+	0.001	0.007	0.001	0.016	N/A	0.609
VL E-	0.001	0.001	0.001	0.001	0.609	N/A

The *p*-values are given based on a Wilcoxon test; MIL (E+): ETI with Miller (MIL) blade with ETT in the oesophagus; MIL (E-): ETI with MIL blade with no ETT in the oesophagus; MAC E(+): ETI with Macintosh (MAC) blade with ETT in the oesophagus; MAC (E-): ETI with MAC blade with no ETT in the oesophagus; VL (E+): ETI with video laryngoscope (VL) with ETT in the oesophagus; VL (E-): ETI with VL with no ETT in the oesophagus; NRS: numeric rating scale; N/A: not applicable.

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Annexure: Consolidated Standards of Reporting Trials **(CONSORT) 2010 checklist of information to include when reporting a randomised trial***

Section/Topic	Item No	Checklist item	Reported on page-lines No
Title and abstract			
	1a	Identification as a randomised trial in the title	1
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	2
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale	4
	2b	Specific objectives or hypotheses	5 (lines 80-85)
Methods			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	6-7
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	6
Participants	4a	Eligibility criteria for participants	6
	4b	Settings and locations where the data were collected	6 (lines 87-91)
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	6-8
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	5
	6b	Any changes to trial outcomes after the trial commenced, with reasons	Non applicable

Sample size	7a	How sample size was determined	8 (lines 150-154)
	7b	When applicable, explanation of any interim analyses and stopping guidelines	Non applicable
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	7 (lines 124-126)
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	7 (lines 124-126)
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	7 (lines 124-126)
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	7 (lines 124-126)
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	Non applicable
	11b	If relevant, description of the similarity of interventions	Non applicable
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	8 (lines 155-161)
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	8 (lines 155-161)
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	9 (lines 163-166)
	13b	For each group, losses and exclusions after randomisation, together with reasons	No loses
Recruitment	14a	Dates defining the periods of recruitment and follow-up	6 (lines 90-

			91)
	14b	Why the trial ended or was stopped	Non applicable
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	17 (Table 1)
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	18 (Table 2)
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	17-18 (Tables 1 and 2)
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	Non applicable
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	Non applicable
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	Non applicable
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	12 (lines 266-268)
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	11 (line 232-234)
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	10-12
Other information			
Registration	23	Registration number and name of trial registry	None
Protocol	24	Where the full trial protocol can be accessed, if available	Manuscript
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	13 (line 276-278)

*We strongly recommend reading this statement in conjunction with the CONSORT 2010 Explanation and Elaboration for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: for those and for up to date references relevant to this checklist, see www.consort-statement.org.