

Comparison of Two Different Shapes of Stylets for Intubation with the McGrath MAC®: A Randomized Controlled Trial

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Research Article

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Abstract

Background: Adequate shapes for videolaryngoscopes are important for safer, faster, and successful intubation. The aim of this study was to compare two different shapes of stylets, the 60° and J-shape stylets, for intubation with the McGrath MAC®.

Methods: In this multicenter, prospective, randomized controlled study, patients undergoing elective surgery under general anesthesia were randomly assigned into the 60° group or the J group. After anesthetic induction, subjects in both groups were intubated with an endotracheal tube bent into a specific shape according to the group allocation. Time to intubation, difficulty of intubation, glottic view grade, use of external manipulation, and number of intubation attempts were recorded.

Results: One hundred and eight patients in the J group and 110 patients in the 60° group were enrolled. Time to intubation in the J group [23.1 (20.6-28.0)] was not different from the 60° group [24.8 (20.5-28.3), $P = 0.623$]. There were no differences in difficulty of intubation, glottic view grade, use of external manipulation, and number of intubation attempts between the two groups.

Conclusions: Adding extra curvature to the tube to resemble the shape of the blade did not improve the intubation conditions of the McGrath MAC®.

Background

Difficult tracheal intubation is critical for healthcare practitioners managing airways. Videolaryngoscopes, which are novel intubating devices, were introduced to facilitate intubation in normal as well as difficult airways. They are superior in glottic visualization compared to the direct laryngoscope by indirectly displaying the airway through a monitor [1]. Various types of videolaryngoscopes are now available and have been adopted as alternative tools in cases of failed intubation with the direct laryngoscope [2].

The McGrath MAC® (Aircraft Medical, Edinburgh, UK), a commonly employed videolaryngoscope, has a similar structure to that of the conventional Macintosh laryngoscope, making it easily used by novices [3]. The efficacy of the McGrath MAC® has been well described in previous studies in both normal and difficult airways and is characterized by faster and successful intubation [4,5]. However, an improved laryngeal view with the McGrath MAC® does not always guarantee successful intubation. Because oral-pharyngeal-laryngeal axes are not straightly aligned and the tip of the blade is not visualized on the screen, it can be challenging to direct the endotracheal tube into the tracheal lumen [1,6,7]. Therefore, manufacturers recommend the routine use of stylets to angle and guide the passage of the endotracheal tube [4,8].

Several studies have investigated various angulations and shapes of stylets suitable for intubation with videolaryngoscopes [8-11]. For the McGrath MAC®, a previous study has shown that bending the stylet

60° was preferable to 90° [8]. However, bending the tip might not be sufficient to overcome the oral-pharyngeal-laryngeal curvature during intubation. Therefore, we hypothesized that adding extra curvature at the proximal part forming the J-shape, similar to the curvature of the McGrath MAC® blade, might compensate for the non-aligned axes, and facilitate the passage of the endotracheal tube. The aim of the present study was to compare the effect of the 60° shaped stylet and the J-shaped stylet on intubation conditions when using the McGrath MAC®, including time to intubation, use of external manipulation, difficulty of intubation, and number of intubation attempts.

Methods

Study design

This study was a multicenter, prospective, randomized controlled trial and was approved by two Institutional Ethics Committees (Kangbuk Samsung Hospital Institutional Review Board, Seoul, Republic of Korea; Approval number: KBSMC 2018-01-033, and Hanyang University Hospital Institutional Review Board, Seoul, Republic of Korea; Approval number: HYUH 2018-01-016) and registered at ClinicalTrials.gov (NCT03524547). The present study was conducted in two hospitals in Seoul, Korea (Kangbuk Samsung hospital and Hanyang University Hospital). After screening for eligibility, written informed consent was obtained from all participants. We included patients aged 19 to 65 years with an ASA I through III who required tracheal intubation for general anaesthesia during elective surgery. Exclusion criteria were as follows: previously diagnosed for difficult intubation, pregnancy, and severe obesity, defined by a BMI of 40 kg/m² or higher. Airway assessments were performed, including thyromental distance (from the mental protuberance to the thyroid cartilage at the extension of the neck), Mallampati score, mouth opening (maximum distance between the lips with the mouth opened), neck mobility (normal, reduced, fixed flexion), and upper incisors dentation status (none, normal, prominent).

The day before surgery, one investigator (M.S.L) randomly allocated subjects into the group 60° or group J by 1:1 proportion according to the preformed randomization list generated by the computer-generated randomization sequence with an internet-based response system (www.randomization.com).

Patients were premedicated with intramuscular glycopyrrolate (0.005 mg/kg) one hour before surgery. Blood pressure, electrocardiograph, and pulse oximetry (SpO₂) were applied and monitored in the operating room. The depth of anesthesia was monitored by state entropy with the Entropy EasyFit Sensor (GE Healthcare, Helsinki, Finland) and muscle relaxation was monitored at the adductor pollicis muscle by a train of four count with a neuromuscular monitor device (M-NMT MechanoSensor, GE Healthcare, Finland). The subjects lied in the supine position, with the head arranged in the sniffing position by placing a donut gel pillow under it. Preoxygenation was performed with 100% oxygen over three minutes to achieve SpO₂ 100%. Anesthetic induction was conducted with propofol 1.5-2.0 mg/kg IV and remifentanyl 1 mg/kg IV. After loss of consciousness, rocuronium 0.8 mg/kg IV was administered and the subjects were ventilated with 100% oxygen and sevoflurane 5-8% vol. When the train of four count reached zero, tracheal intubation was conducted with the McGrath MAC® after dropping the anti-fog in

front of the lens. Intubation was performed by one of two anesthesiologists with more than 20 years of experience with McGrath MAC® (E.A.C and H.Y.L). After lubricating the stylet (KoMAC stylet, KoMAC, Seoul, Korea), it was inserted into the endotracheal tube (Shiley™, Covidien, Mansfield, USA) of sizes 7.0 mm I.D. for females and 7.5 mm I.D. for males, and bent to a specific angle according to the group allocation. The angulation in the present study is based on previous studies [8,10]. For the group 60°, the stylet was bent 60° at 6.5 cm above the endotracheal tube tip [8]. For the group J, the stylet was angled using the blade of the McGrath MAC® as a template [10]. (Figure 1)

The primary outcome of this study was time to intubation (TTI). TTI was calculated as the time the tip of the blade passed through the incisor teeth to the first end tidal CO₂ wave appearance. TTI was assessed by the assistant investigators. After obtaining an optimal view from the McGrath MAC® monitor, modified Cormack-Lehane (C-L) grade [12], percentage of glottic opening (POGO) score [13], and vocal cord status, whether it was abducted or adducted, were recorded. In cases of poor laryngeal view, the airway was facilitated with external manipulation such as external laryngeal pressure, additional lifting force, or chin lift. After successful intubation, difficulty of intubation was assessed by the investigator performing the endotracheal intubation. If TTI was greater than 60 sec or SpO₂ dropped under 95%, the intubation was stopped and the patient was ventilated with 100% O₂ via a mask. Intubation was attempted up to three times; further attempts were performed with different tools based on the anesthesiologists' preferences, and were excluded from analysis. In cases of multiple attempts, the number of attempts was recorded and TTI was defined by the summing the times of each intubation attempt. After successful intubation, oropharyngeal bleeding was assessed by observing blood tinged at the blade tip.

Statistical analysis

The primary outcome of the present study was TTI. The sample size was calculated based on a previous study [8]: TTI (mean ± SD) was 29.3 ± 6.4 sec for the 60° stylet and 32.5 ± 9.4 sec for the 90° stylet, 101 patients in each group were needed for 80% power, and the type I error was set at 0.05. Predicting a dropout rate of 10%, a total of 222 patients (111 in each group) were deemed sufficient to detect significant differences between groups.

Data are presented as mean (SD) or median (IQR) for continuous variables or as numbers (%) as appropriate. For continuous variables, the independent *t*-test and Mann-Whitney U test were used. Categorical variables were analyzed with the chi-square test or Fisher exact test. Subgroup analysis between the low modified C-L group (modified C-L grade 1 and 2a) and the high modified C-L group (modified C-L grade equal or more than 2b) for TTI was compared in the group J and group 60° using the one-way analysis of variance test. A *P*-value of < 0.05 was considered statistically significant. Statistical analyses were performed with SPSS software 20.0 (SPSS, Inc., Chicago, IL, USA).

Results

Two hundred and twenty-eight patients were assessed for eligibility between May 2018 and July 2018. After excluding four patients who did not meet the inclusion criteria and two patients who declined participation, 222 patients consented to participate in the present study. From the 111 subjects in each group, one subject from each group was withdrawn due to unavailable staff, and one subject from the group J was withdrawn due to cancellation of the operation. Therefore, 109 subjects in the J group and 110 subjects in the group 60° were included in the analyses. (Figure 2)

Table 1 shows demographic data and baseline characteristics of the study population. There were no significant differences between the two groups except for BMI: BMI was higher in the group J than in the group 60° [24.8 (3.5) vs. 23.7 (3.6), $P = 0.033$].

Intubation profiles were compared between groups. TTI in the group J was 23.1 sec (20.6-28.0) and was comparable to that in the group 60° [24.8 sec (20.5-28.3)] ($P = 0.623$). Other intubation variables, including modified C-L grade, POGO score, external manipulation, difficulty of intubation, and number of intubation attempts were not different between groups. (Table 3)

In the subgroup analysis, TTI was higher in subjects with the high modified C-L grade than in those with the low modified C-L grade. However, there was no difference between the two groups. (Figure 3)

Discussion

In this multicenter, prospective, randomized controlled trial, we compared intubation conditions of the McGrath MAC® videolaryngoscope using different shapes of stylets, namely, the J shape and the 60° angled shape. We hypothesized that adding extra curvature to the stylet forming the J shape might facilitate tracheal intubation with McGrath MAC® by overcoming the oral-pharyngeal-laryngeal curvature. However, contrary to our expectations, intubation conditions, including TTI, use of external manipulation, difficulty of intubation, and number of intubation attempts were not different between the two groups.

Videolaryngoscopes facilitate tracheal intubations in various situations, including normal and difficult airways, and are commonly used in various medical fields [1,2]. To overcome the non-straightened alignment of the oral-pharyngeal-laryngeal axes with videolaryngoscopes, stylets are routinely used. However, although rare, stylets may cause airway complications when used with videolaryngoscopes. Therefore, stylets must be used with care [14-20].

Previous studies have shown that because of differences in blade design, different angulation and shapes of stylets should be used according to type of videolaryngoscope used. For example, the 90° angled stylet facilitated endotracheal intubation with GlideScope® compared to the 60° stylet [10]. For the C-MAC® videolaryngoscope, D-shaped and hockey stick configured stylets showed better performance, with shorter TTI [21]. There was one randomized controlled trial studying intubation using the McGrath MAC®. In this study, the authors compared 60° and 90° stylets in tracheal intubation using the McGrath MAC®, and found that the 60° was more acceptable for intubation [8].

The J shape stylet or the shape which resembles that of blade was previously investigated in studies that used various types of videolaryngoscopes [9,10,21]. For the GlideScope®, TTI was longer in the J shape than the 90° stylet [10]. However, another study demonstrated faster intubation with the J shape for GlideScope®, as well as for the C-MAC [9,21]. In our study, the J-shape showed comparable intubation quality with the 60° stylet for intubation with the McGrath MAC®. We assume that this is because the rigidity of the stylet compensates for the non-aligned anatomy and facilitates handling of the endotracheal tube under the guide of visualization of the McGrath MAC®[1].

Most studies of stylet angulations have included patients with lower C-L grade (1 or 2) under videolaryngoscope and demonstrated easier intubation [8,10]. Because the vocal cord in the higher C-L grade is located more anteriorly, the J shape, which has more curvature, might be preferable than bending the tip of the 60° shape. However, in our study, TTI was not different in the higher C-L grade according to the stylet angulation. Expert anesthesiologists with sufficient experience performed the intubations in this study; further studies incorporating those with less experience may show different outcomes.

There is a limitation in our study. The anesthesiologists (E.A.C and H.Y.L) performing the tracheal intubation could not be blinded to the group allocation. However, neither anesthesiologist was aware of the primary outcomes and assessments, and the assessments, including the TTI, were performed by assistant anesthesiologists blinded to the group allocation. Thus, the results were unlikely affected by this limitation.

Conclusions

In conclusion, bending stylets to achieve more curvature to resemble the blade shape and oral-pharyngeal-laryngeal curvature did not decrease TTI nor improve intubation conditions compared to 60° angulation in tracheal intubation with the McGrath MAC®.

Declarations

Ethics approval and consent to participate

This study was approved by the two Institutional Ethics Committees (Kangbuk Samsung Hospital Institutional Review Board, Seoul, Republic of Korea; Approval number: KBSMC 2018-01-033, and Hanyang University Hospital Institutional Review Board, Seoul, Republic of Korea; Approval number: HYUH 2018-01-016). Written informed consent was obtained from all the participants.

Consent for publication

Not applicable

Availability of data and materials

The full study protocol and raw data set can be obtained from Dr. Cho (eunah.cho@hanmail.net).

Competing interests

The authors declare that we have no competing interests

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Authors' contributions

HYL collected, analyzed, interpreted the data, and wrote the manuscript. MSL collected the data and helped to design of the study. KHR designed the study, revised the manuscript. SHL collected the data, helped to design of the study, and revised the manuscript. EAC designed the study, revised the manuscript, and conducted the study. All authors read and confirmed the final version of the manuscript.

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Not applicable

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Tables

Table 1 Demographic data and baseline characteristics of the study population

	Group J	Group 60°	<i>P</i> value
	(n=109)	(n=110)	
Age, years	45 (14)	47 (11)	0.170
Sex, female	59 (54.6%)	58 (52.7%)	0.778
Height, cm	164.5 (8.9)	164.3 (8.4)	0.876
Weight, kg	67.1 (11.4)	64.4 (12.9)	0.103
BMI, kg/m ²	24.8 (3.5)	23.7 (3.6)	0.033*
ASA class			0.468
1	66 (61.1%)	66 (60.0%)	
2	40 (37.0%)	44 (40.0%)	
3	2 (1.9%)	0 (0%)	
Thyromental distance, cm	8.5 (1.4)	8.2 (1.4)	0.106
Mallampati score			0.703
1	52 (48.1%)	46 (41.8%)	
2	35 (32.4%)	44 (40.0%)	
3	15 (13.9%)	14 (12.7%)	
4	6 (5.6%)	6 (5.5%)	
Mouth opening, cm	4.7 (1.1)	4.7 (0.9)	0.697
Neck mobility			0.890
Normal	93 (86.1%)	94 (85.5%)	
Reduced	15 (13.9%)	16 (14.5%)	
Upper incisors			0.894
Absent	2 (1.9%)	1 (0.9%)	
Normal	102 (94.4%)	105 (95.5%)	

Prominent	4 (3.7%)	4 (3.6%)	
Type of surgery			0.432
General	46 (42.6%)	51 (46.4%)	
Orthopedics	23 (21.3%)	31 (28.2%)	
Ear, nose, and throat	21 (19.4%)	15 (13.6%)	
Obstetrics and gynecology	10 (9.3%)	9 (8.2%)	
Others	8 (7.4%)	4 (3.6%)	

Data are presented as mean (SD), numbers (%) for numerical variables.

BMI: Body Mass Index.

ASA: American Society of Anesthesiologists.

* $P < 0.05$, independent t -test

Table 2 Intubation profiles of the study population

	Group J (n=109)	Group 60° (n=110)	<i>P</i> value
TTI, seconds	23.1 (20.6-28.0)	24.8 (20.5-28.3)	0.623
Modified C-L glottic grade			0.959
1	45 (47.7%)	44 (40.0%)	
2a	46 (42.6%)	51 (46.4%)	
2b	14 (13.0%)	13 (11.8%)	
3	2 (1.9%)	2 (1.8%)	
4	1 (0.9%)	0 (0%)	
POGO score	80 (60-100)	80 (60-100)	0.929
External manipulation			0.776
External laryngeal pressure	7 (6.5%)	6 (5.5%)	
Additional lifting force	3 (2.8%)	1 (0.9%)	
Others	1 (0.9%)	1 (0.9%)	
None	97 (89.8%)	102 (92.7%)	
Difficulty of intubation			0.237
Easy	89 (82.4%)	97 (88.2%)	
Moderate	14 (13.0%)	12 (10.9%)	
Difficult	5 (4.6%)	1 (0.9%)	
Multiple attempts to intubation	1 (0.9%)	0 (0%)	0.495
Bleeding	1 (0.9%)	0 (0%)	0.495

Data are presented as mean (SD), or median (IQR) as appropriate for continuous variables, and numbers (%) for numerical variables.

TTI: time to intubation.

C-L: Cormack-Lehane.

POGO: percentage of glottic opening.

Figures

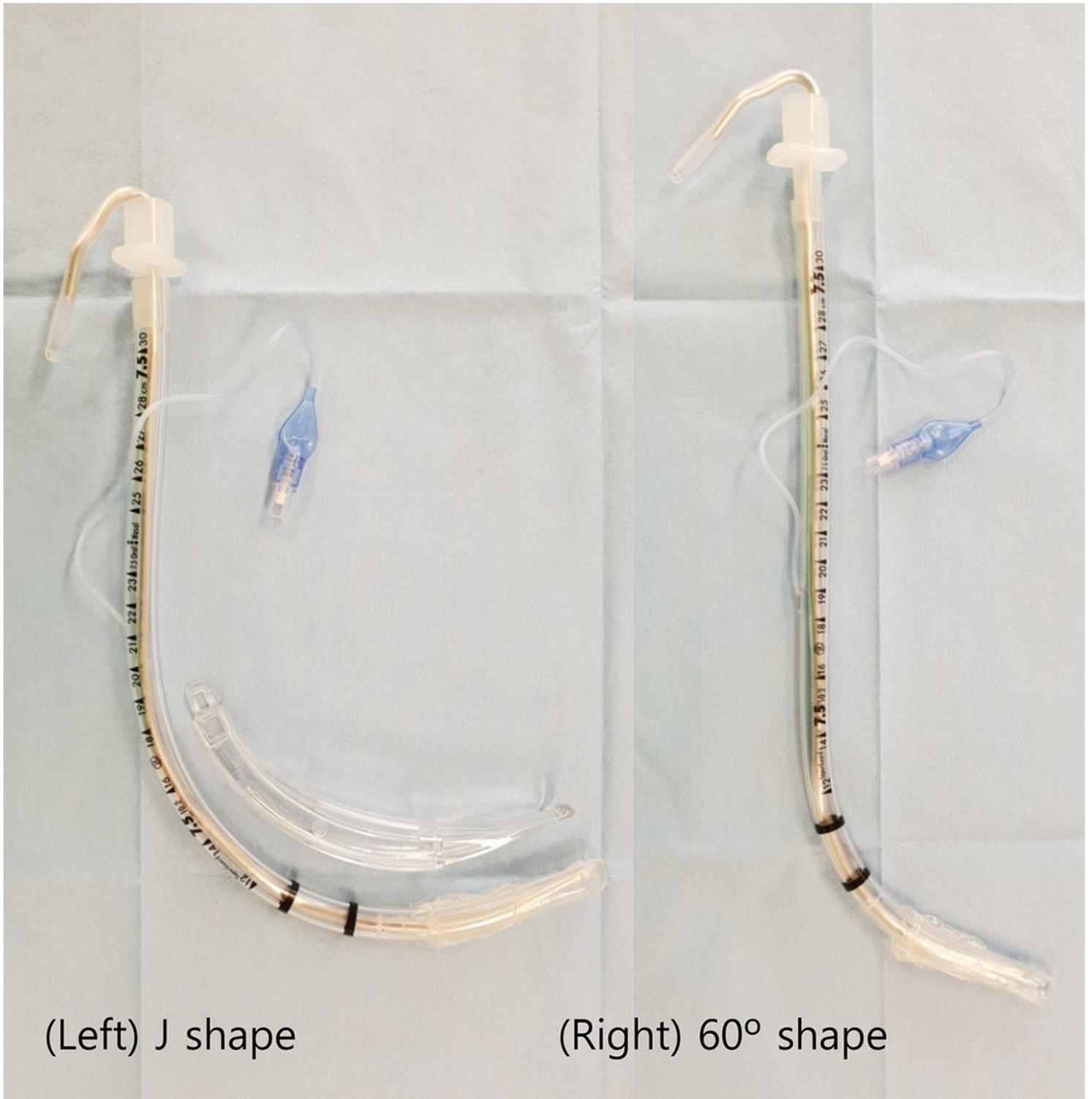


Figure 1

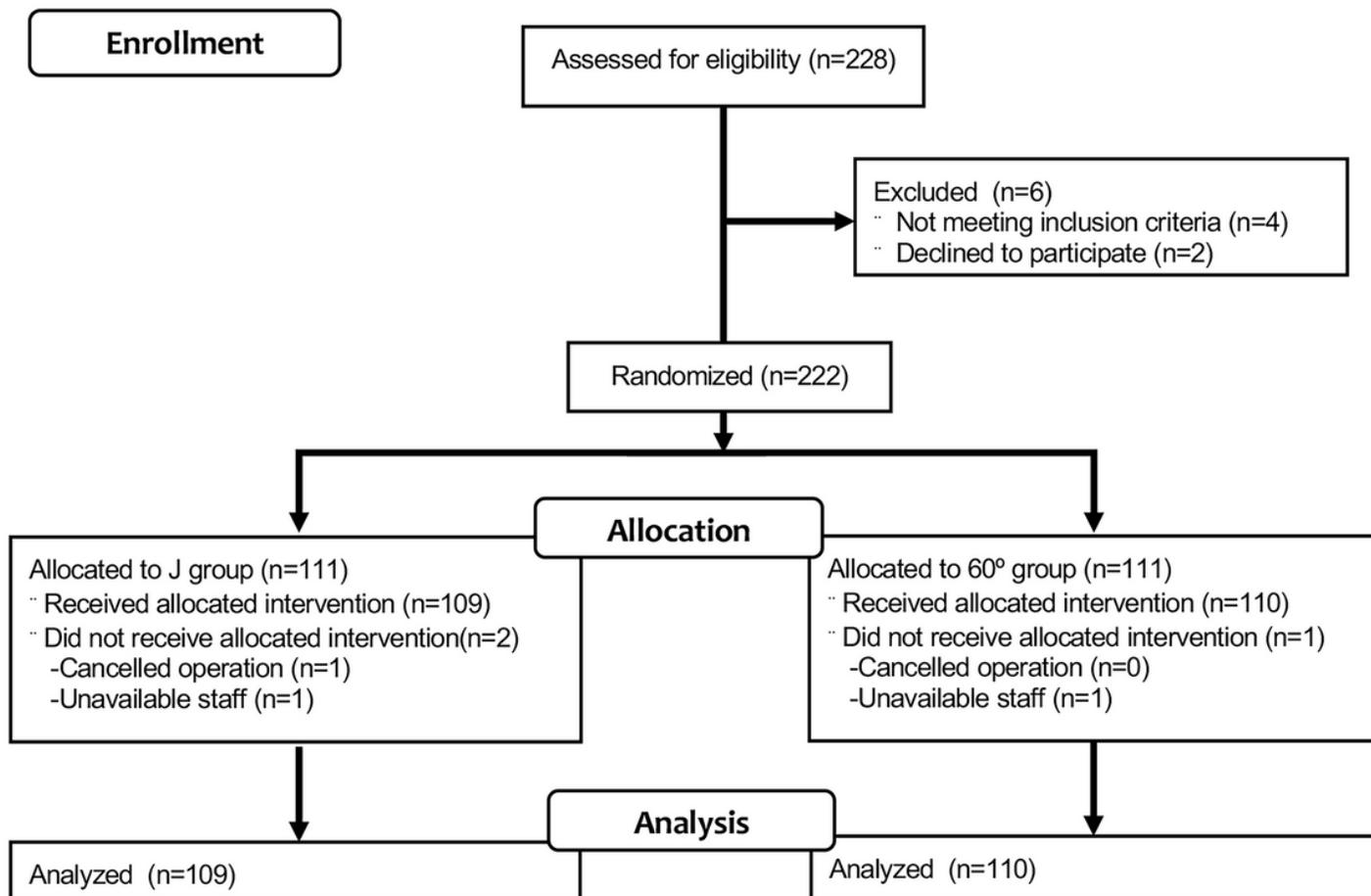


Figure 2

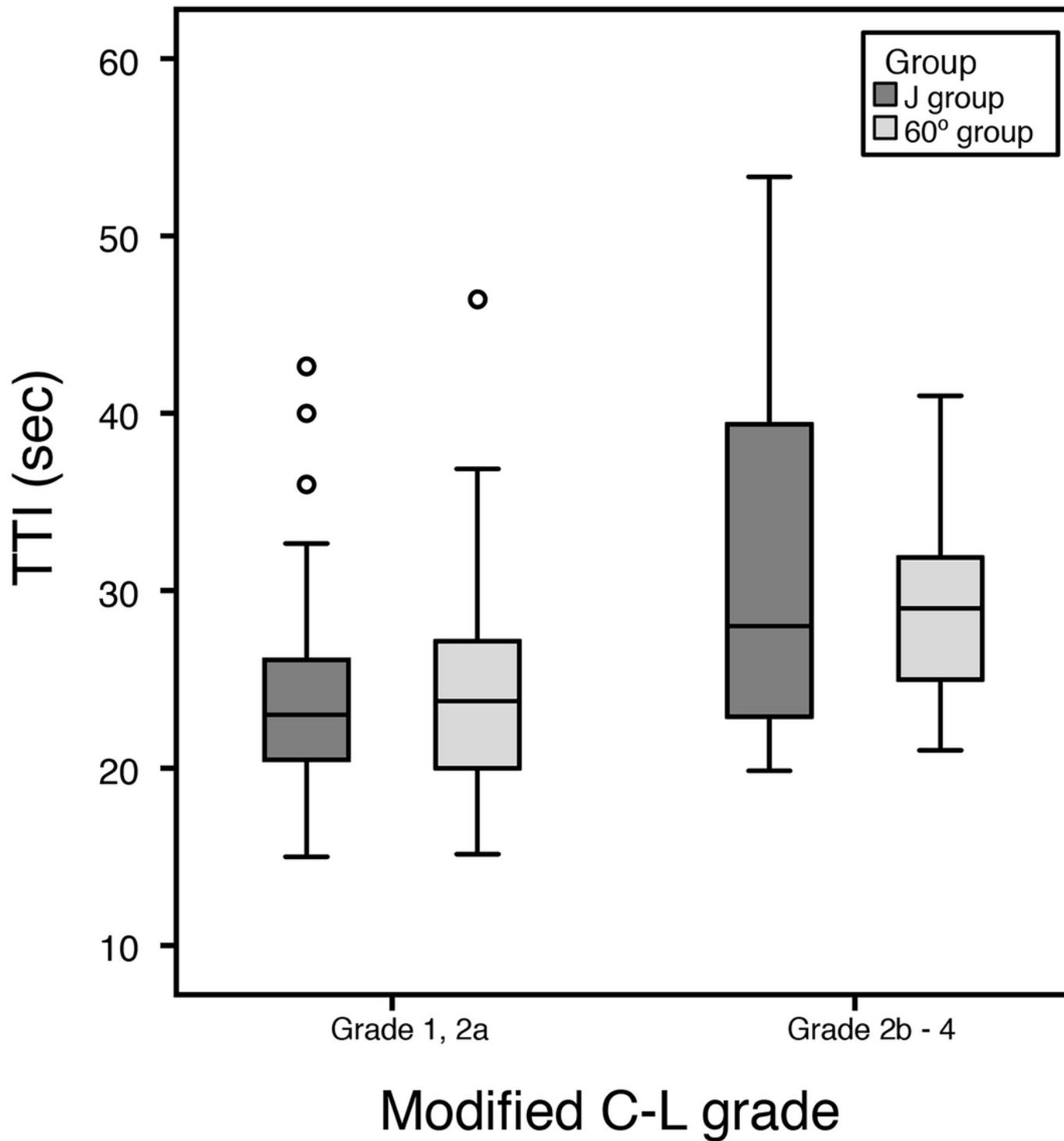


Figure 3