Original Article

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Comparison of Videolaryngoscopy-guided and Blinded Paramedian Techniques for Ambu AuraGain Insertion in Elective Surgeries: A Randomised Controlled Trial

Anaesthesia Section

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ABSTRACT

Introduction: Blind insertion of Supraglottic Airway Devices (SAD) often results in suboptimal positioning in the oropharynx or hypopharynx. On the other hand, laryngoscopy-guided insertion will give a better One-Lung Ventilation (OLV) and prevention of aspiration. A limited number of studies have been done to compare this blind and videolaryngoscopic positioning of a new device, Ambu® AuraGain™, which is a single-use, anatomically curved device with intubation capabilities.

Aim: To compare videolaryngoscopy-guided insertion with the blind paramedian insertion technique of Ambu® AuraGain™ for the efficacy of ventilation.

Materials and Methods: This Randomised Controlled Trial (RCT) was conducted at Vardhaman Mahavir Medical College and Safdarjung Hospital, New Delhi, over a period of 18 months (July 2022 – December 2023) in 100 patients in a tertiary care centre of a tier one city. At the end of 5 minutes and 30 minutes after device insertion, oropharyngeal leak pressure was measured as the primary outcome of the study. Randomisation was done into two groups (B and V). Group B was taken as the control group and group V was the test group, where the videolaryngoscopic-guided insertion of the device was done. Other parameters studied were successful attempts, ease of insertion and passage of the gastric catheter. Independent t-test, Chi-Square test, Fisher's-exact test and Statistical Package for Social Sciences (SPSS) 25.0 were used to analyse data. For statistical significance, a p-value of less than 0.05 was considered statistically significant.

Results: The demographic profile of all 100 patients was comparable in both groups, based on age, gender, American Society of Anaesthesiologists Physical Status (ASA) classification, and Body Mass Index (BMI). C-MAC® videolaryngoscopy-guided technique of insertion of Ambu Aura Gain provides better efficacy of ventilation in terms of higher Oropharyngeal Leak Pressure (OLP) as compared to the blind paramedian insertion technique in adult patients undergoing elective surgery under General Anaesthesia (GA). The mean oropharyngeal leak pressure (cm of H_2O) at 5 minutes and 30 minutes post device insertion in group V and group B was 37.14±1.77 vs. 34.20±1.68 and 37.9±1.61 vs. 35.2±1.54, respectively. Time taken for effective ventilation was more in the C-MAC® group (34.64±0.98 sec vs. 27.18±1.35 sec, respectively).

Conclusion: C-MAC® videolaryngoscopy-guided technique of insertion of Ambu® AuraGain™ provides better efficacy of ventilation in terms of higher oropharyngeal leak pressure as compared to the blind paramedian insertion technique in adult patients undergoing elective surgery under GA.

Keywords: Ambu® AuraGain™, C-MAC®, Oropharyngeal seal pressure

INTRODUCTION

Ensuring and supervising airway integrity are pivotal tenets in both anaesthesia and emergency care. Inadequate airway management can substantially elevate the risks of patient morbidity and mortality [1]. Supraglottic Airway Devices (SADs) have gained considerable traction in recent times, offering versatility, serving both as a means of ventilation and intubation, while also causing minimal disruption to cardiovascular and respiratory parameters [2]. There are multiple known methods of inserting a SAD, such as blind insertion, laryngoscopic-guided insertion, bougie-guided insertion, etc. Blind paramedian insertion requires SAD insertion with the tip of the cuff in the mouth, pressing upwards against the hard palate and flattening the cuff against the hard palate, followed by advancement of the SAD into the hypopharynx in a smooth circular motion, pressing the contours of the soft and hard palate until a definite resistance is felt. C-MAC® guided insertion of SAD uses a Mcintosh blade that is inserted in the oral cavity, and a good glottic view is achieved. The SAD is then inserted in the oral cavity and placed at the glottic opening under vision, avoiding any epiglottic downfolding and misalignments. In both methods, after placing the device, without holding the tube, the cuff should be inflated with just enough air to obtain a seal with a maximum intracuff pressure of 60 cm of H_2O [3].

Blind insertion of SADs often results in suboptimal positioning in the oropharynx or hypopharynx. Suboptimal positions of SADs are mostly caused by: 1) initial downfolding of epiglottis at device insertion; 2) distal cuff folding over backwards or jamming between the two vocal cords; 3) mis-alignment between tip of the epiglottis and rim of the proximal cuff because of incorrect size being used, cuff hyperinflation/hypo inflation, too deeply or too superficially positioned SADs; and 4) relocation of epiglottis in the bowl of the SAD [3]. These suboptimally positioned SADs can cause ventilatory failure (including insufficient tidal volume, air leak, and airway obstruction), airway or tissue trauma and may lead to gastric insufflation and subsequent aspiration [4].

It is a known fact that laryngoscopy-guided placement of SAD gives a better OLP and hence better protection against aspiration [5]. However, there is a paucity of studies comparing the efficacy of direct laryngoscopy and videolaryngoscopy for the insertion with Ambu® AuraGain™, which is a newer single-use anatomically curved second-generation SAD with intubation capability [6]. Therefore, this study was taken up to compare videolaryngoscopy-guided insertion

with the blind paramedian insertion technique of Ambu® AuraGain™ for the efficacy of ventilation in adult patients undergoing elective surgery under GA with controlled ventilation, with oropharyngeal leak pressure as the primary objective. Secondary objectives were the number of attempts taken for successful insertion of the device, time for achieving effective ventilation, ease of insertion of the device and gastric catheter insertion and Fibreoptic Bronchoscopic score (FOB) score regarding anatomical alignment of the device.

MATERIAL AND METHODS

The randomised controlled trial was planned at Vardhaman Mahavir Medical College and Safdarjung Hospital, New Delhi, over a period of 18 months (July 2022 – December 2023). The study was initiated after receiving Institutional Ethics Committee approval (IEC/VMMC/SJH/Thesis/06/2022/CC-02 dated 11/07/2022). Written informed consent was taken from all the patients, and the study was conducted in accordance with the principles of the Declaration of Helsinki (2013).

Sample size calculation: It was calculated using a previous study by Wong DT et al., where it was observed that the mean OLP with the blind insertion technique with Ambu® AuraGain™ was 26.4±2.8 cm of water [7]. Taking these values as reference and assuming a difference of 10% in OLP between blind insertion and videolaryngoscope guided insertion of Ambu® AuraGain™, the minimum required sample size with 99% power of study and 5% level of significance was calculated to be 42 patients in each study group. To reduce the margin of error, the authors decided to recruit 100 patients (50 in each group).

Inclusion criteria: A total of 100 patients (50 in each group), aged 18-60 years, belonging to ASA physical status I and II, undergoing elective surgery under GA, were enrolled for this RCT.

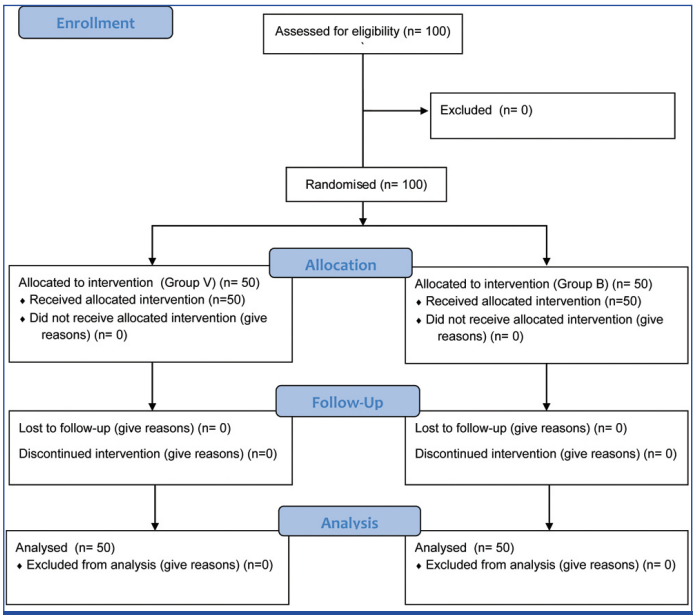
Exclusion criteria: Patients with anticipated difficult airway (mouth opening <3.5 cm, BMI >30 kg/m^2, poor dentition, cervical spine pathology and risk of aspiration), prolonged duration of surgery (>4 hrs), intestinal and oesophageal pathology and risk of postoperative sore throat were excluded from the study.

Study Procedure

All 100 patients enrolled in the study completed the protocol and were accounted for. After a preanaesthetic check-up and confirmation of nil per oral status, patients were made to understand the protocol, and written informed consent was taken. Randomisation was done using computer-generated tables into two groups (B and V) [Table/Fig-1]. Group B was taken as the control group with conventional blind insertion of the device, and group V was the test group where the videolaryngoscopic-guided insertion of the device was done. The random allocation sequence and enrollment of participants were done by the primary investigator. The participants were then made to select one of the two opaque envelopes shown to them, and the group was allocated according to the envelope chosen. In group B, Ambu® AuraGain™ was placed using a blind paramedian approach, and in group V, C-MAC® videolaryngoscope from Karl Storz, Tuttlingen, was used to place the airway device. The airway intervention was done by a trained anaesthesiologist who had experience of at least 50 insertions of the device by both methods. Blinding could not be done due to obvious reasons. To reduce bias, only one trained anaesthesiologist was chosen to do the intervention in all the patients.

The GA was induced using standard Institutional protocols. After induction of anaesthesia, the SDA device was introduced as per the group allotted during randomisation. The size of the SDA device was chosen according to the manufacturer's recommendations and clinical judgement.

The OLP was measured within 5 minutes after device insertion and then at 30 minutes post-device insertion by closing the circle system's expiratory valve at a fixed gas flow of 3 L/min, at bag mode of ventilation and noting the airway pressure (max 40 cm of H_2O allowed) at which equilibrium was reached. Audible air leak at the mouth and the presence or absence of gastric insufflation by epigastric auscultation were also checked during leak pressure testing.



[Table/Fig-1]: Consolidated Standards of Reporting Trials (CONSORT) 2010 flow diagram.

Other parameters measured were number of attempts taken for successful insertion of device, time for achieving effective ventilation (time from holding the supraglottic device or videolaryngoscope at mouth to the first square waveform on the monitor), ease of insertion of device (subjective grading by the operator on a scale of 1-4, 1 being easy insertion, 2 slightly difficult, 3 difficult and 4 being impossible to insert) and passage of gastric catheter (easy or difficult). Anatomical alignment of the supraglottic device was assessed by passing a fiberoptic bronchoscope through the airway port [8-11]. Glottic view was noted and graded (score of 4-1, 4 being full view of cords and 1 being no cord view), keeping the tip of the fibreoptic bronchoscope just inside the distal end of the airway port [12].

Any intra- or postoperative adverse event was noted, like desaturation, aspiration, partial or complete obstruction, device failure (ineffective ventilation even after manipulation and need for device change) and any visible trauma to oropharyngeal structures. Postoperative pharyngolaryngeal morbidity was evaluated by interviewing the patient at 1 hour and 24 hours, and any problems encountered, such as sore throat, dysphagia and hoarseness of voice, was noted.

STATISTICAL ANALYSIS

The data was analysed using SPSS software version 25.0 (IBM manufacturer, Chicago, USA). Categorical variables were presented as numbers and percentages (%), and the quantitative data were presented as the means±SD and as the median with 25th and 75th percentiles (interquartile range). The data normality was checked by using the Shapiro-Wilk test. Quantitative data were analysed using an Independent t test. Chi-square test was used to analyse qualitative data. If any cell had an expected value of less than 5 then Fisher's exact test was used. A p-value of less than 0.05 was considered statistically significant.

RESULTS

A total of 100 patients were assessed and selected according to the study protocol and randomised into the two groups [Table/Fig-1]. The group B (blind paramedian approach) and group V (videolaryngoscopic-assisted approach), were comparable in regard to demographic characteristics, preoperative airway assessment and size of device used [Table/Fig-2].

Variables	Group B n (%)	Group V n (%)	p-value
Age (years) (Mean±SD)	35.42±12.17	36.52±11.41	0.642
BMI (kg/m^2) (Mean±SD)	22.35±1.91	22.41±1.79	0.876
Gender			
Male/Female	25/25 (50:50)	23:27 (46:54)	0.689
ASA physical status grading I/II	41/9 (82:18)	39/11 (78:22)	0.617
Duration of anaesthesia (hours) Mean±SD	1.84±0.4	1.93±0.29	0.241
Size of device used 3 or 4	13/37 (26:74)	12/38 (24:76)	0.817
Mallampati Score, 1 or 2	24/26 (48:52)	21/29 (42:58)	0.546
Thyromental distance (cm) (Mean±SD)	7.4±0.36	7.42±0.49	0.817

[Table/Fig-2]: Demographic profile of the patients.
SD: Standard Deviation, BMI ; Body Mass Index, ASA; American Society of Anesthesiology Physical Status, Gender shown in absolute numbers

The OLP measured at 5 and 30 minutes in group V were 37.14±1.77 and 37.9±1.61, respectively, which were significantly higher compared to group B (34.2±1.68, and 35.2±1.54, respectively) (p-value <0.0001) [Table/Fig-3]. The mean time for achieving effective ventilation±standard deviation in group V was 34.64±0.98 seconds, which was significantly higher compared to group B, where it averaged at 27.18±1.35 seconds (p-value=0.0001). Whereas ease of insertion was much better in group V as compared to group B, with 18% patients being labelled in score 2 in group B and all the patients in group V were labelled as score 1 (p-value=0.003). Airway manipulation in the form of the jaw-thrust technique was higher in group B as compared to group V (p-value=0.003) [Table/Fig-3].

Variables	Group B n (%)	Group V n (%)	p-value
Oropharyngeal leak pressure (cm of H_2O) (Mean±SD)*			
T5	34.2±1.68	37.14±1.77	<0.0001
T30	35.2±1.54	37.9±1.61	<0.0001
No. of attempts 1/2/failure of device$	48/2/0 (96/4/0)	50/0/0 (100/0/0)	0.495
Time for achieving effective ventilation (seconds) (Mean±SD)*	27.18±1.35	34.64±0.98	<0.0001
Ease of insertion of device score 1/2/3/4$	41/9/0/0 (82/18/0/0)	50/0/0/0 (100/0/0/0)	0.003
Ease of gastric catheter insertion score Easy/Difficult	50/0 (100/0)	50/0 (100/0)	NA
Anatomical alignment score 4,3,2,1$	26/24/0/0 (52/48/0/0)	46/4/0/0 (92/8/0/0)	<0.001
Airway manipulation$	41/9 (82/18)	50/0 (100/0)	0.003

[Table/Fig-3]: Parameters assessed.
*Independent t test; $Fisher's exact test

In group V, 92% of patients had a bronchoscopic view of score 4 compared to only 52% in group B, however, score 3 was seen more in group B (48%) as compared to group V (8%). Alignment of the device with the glottic opening was better in group V (p-value=0.0001).

Though Peak Airway Pressures (PAP) were comparable in both groups at multiple intervals of time, but the difference of OLP and PAP at 5 and 30 minutes was higher in group V (19.26±3.09 and 19.6±3.08 respectively) as compared to group B (17.16±2.51, p-value=0.0003 and 17.12±2.76, respectively) (p-value <0.0001) [Table/Fig-4].

Postoperative sore throat, dysphagia and hoarseness of voice were studied at 1 hour and 24 hours after surgery; however, no significant results were noted here.

Difference of OLP-PAP (cm of H_2O)*	Group B	Group V	p-value
T5 (5 minutes post device insertion)			
Mean±SD	17.16±2.51	19.26±3.09	0.0003
T30 (30 minutes post device insertion)			
Mean±SD	17.12±2.76	19.6±3.08	<.0001

[Table/Fig-4]: Comparison of difference of OLP and peak airway pressure (OLP-PAP) (cm of H_2O) between group B and V.
*Independent t-test

DISCUSSION

The current study demonstrated that the C-MAC®-guided method of insertion of the SAD was much effective than the blind method in terms of OLP at both 5 mins and 30 mins. The mean OLP was significantly higher in the C-MAC®-guided group both at 5 and 30 mins (5 mins- 37.14±1.77 vs. 34.20±1.68 respectively, p-value <0.0001 and 30 mins -37.9±1.61 vs. 35.2±1.54 respectively, p-value <.0001). This correlates well with previous studies where blind technique was compared with direct laryngoscopy (26.89±3.37 cm of H_2O versus 24.42±3.00 cm of H_2O, respectively; p-value <0.0001) [6,10], another comparing blind with McGrath® videolaryngoscope on insertion of flexible LMA (28.8±8.1 cmH_2O vs 25.2±7.2 cm of H_2O, respectively, p-value=0.024) [11]. Comparison of OLP before extubation was done by Simsek T et al., on 100 patients, where similar results were reported (36.29±7.09 vs. 33.79±8.84 cm of H_2O, respectively, p-value=0.04) [12]. Ozgul U et al., in their RCT comparing results of 119 patients, found that the method of insertion did not affect the OLP (30.28±8.3 cm of H_2O versus 29.86±6.91 cm of H_2O, respectively; p-value=0.764). This result was attributed to the double-cuff design of ProSeal™ LMA, which already provided high OLP [4].

In the present study, vision-guided insertion of Ambu® AuraGain™ prevented the epiglottis from downfolding and blocking the vocal cord during insertion of the device, provided better alignment of the Ambu® AuraGain™ in the periglottic area, prevented suboptimal positioning and provided a better airway seal. An optimally-positioned, correct-sized SAD should sit snugly within the hypopharynx with its distal tip abutting the oesophagus, with the tip of the epiglottis aligned with the rim of the proximal cuff of a correctly inflated mask and epiglottis resting on the outer side of the cuff such that the SAD's airway tube opening opposes the glottic opening and the entrance to the trachea. Van Zundert AAJ et al., in a study, stated that blind insertion of SADs often results in malposition or suboptimal position within the desired segment of oro/hypopharynx [5]. Under vision placement avoids undue cuff hyperinflation/ hypoinflation, too small- or too large-size SAD; and too deeply or superficially-positioned SADs.

Thus, authors conclude that videolaryngoscope-guided insertion of Ambu® AuraGain™ provides better OLPs than the blind paramedian insertion technique of Ambu® AuraGain™, difference of OLP and PAP, which determines safety guaranteed by the device against aspiration, subjective ease of insertion of the device and objective view of the glottis using the fiberoptic bronchoscope through the device. Vyas A et al., reported in their RCT that Macintosh laryngoscopic-guided techniques of insertion of i-gel in 156 adult patients had higher OLP (26.89±3.37 cm of H_2O versus 24.42±3.00 cm of H_2O, respectively; p-value <0.0001) as compared to blind placement of the device [13]. Similar results were also given by Yoo JY et al., in their RCT comparing videolaryngoscope with blind insertion of flexible LMA, where OLP was recorded higher in the former group (28.8±8.1 cm of H_2O vs 25.2±7.2 cm of H_2O, respectively, p-value=0.024) [14]. Kim GW et al., did a similar study with Classic Laryngeal Mask Airway (cLMA) and found the same result with OLP being higher in the McGrath® group (21.4±8.6 cm of H_2O vs 18.1±6.1 cm of H_2O, respectively, p-value=0.031) [8]. However, Ozgul U et al., in their study of 119 patients, compared videolaryngoscope-guided versus standard digital blind insertion technique of ProSeal™ LMA placement and stated that due to the double cuff design of this SAD, which provides a higher OLP, no difference was noted between the two groups [4]. Van Zundert AAJ et al., in a study, stated that blind insertion of SADs often results in

malposition or suboptimal position within the desired segment of oro/hypopharynx [5]. A higher OLP is a marker of safe ventilation in the face of a higher risk of aspiration in cases such as lithotomy position, pneumoperitoneum, obesity, etc. [6].

The rate of successful placement of the device was 100% in present study, though 2 patients (4%) required a second attempt in the blind group, which may be due to the bulky structure and less pliable firm tip of the Ambu® AuraGain™, which prevents it from bending towards the hypopharynx on reaching the paramedian posterior pharyngeal wall. Previous studies have also given similar results with respect to the success rate of insertion [6,9,15].

The total time taken for achieving effective ventilation (calculated from holding the SAD at the mouth to obtaining the first square wave capnograph tracing) was higher in the C-MAC® video-assisted group in current study and was statistically significant (p-value <0.0001). Mean±standard deviation time in group V was 34.64±0.98 seconds, whereas it was 27.18±1.35 seconds in the blind group. This difference in time was due to the extra time consumed in laryngoscopy. Other studies also showed that the videolaryngoscope group took more time for effective ventilation as compared to the blind group (29.0±14.1 seconds vs 44.4±14.8 seconds, p-value <0.001) [6,10,15].

Ambu® AuraGain™ has been compared with LMA® Supreme™ and ProSeal™ LMA, and the time of insertion of Ambu® AuraGain™ was reported as 32.2±10.5 seconds and 24.32±4.96 seconds, respectively, which is comparable to the time taken in the current study [16,17].The number of patients requiring manipulation for device insertion in group B was significantly higher compared to that in group V (18% versus 0 % respectively, p-value=0.003). Manipulation was required in blind paramedian insertion with Ambu® AuraGain™ due to its non pliable tip, which does not bend easily along the curvature of the oropharynx and hits the posterior pharyngeal wall. Jaw thrust was hence needed to aid the insertion of the Ambu® AuraGain™ in these patients. Paramedian insertion of Ambu® AuraGain™ in our study decreased the number of patients requiring jaw thrust. Studies with blind midline insertion of Ambu® AuraGain™ have shown a higher proportion of patients requiring manipulation for its placement [12,15,18].

Gastric catheter insertion was graded as easy in all the patients in both groups. Easy insertion of a gastric catheter implies proper alignment of the drain tube with the oesophagus. However, Ozgul U et al., stated that orogastric tube insertion with ProSeal™ LMA was easier in C-MAC® videolaryngoscope-guided group than the standard digital group (100% vs. 78%, p-value <0.001), due to the ability of the videolaryngoscope in directing the distal cuff around the back of the mouth and into the hypopharynx, which increases the functional and anatomical optimisation [4].

The glottic view was recorded by inserting the fiberoptic bronchoscope through the airway tube of the SAD and graded using Brimacombe score; Grade 0: Functional failure with the vocal cord invisible, Grade 1: Vocal cords not seen, but function adequate, Grade 2: Vocal cords and anterior epiglottis seen, Grade 3: Vocal cords and posterior epiglottis seen, Grade 4: Only vocal cords visible. A FOB score of ≤2 was considered suboptimal, and a score of 3 or 4 was considered optimal for the anatomical fit of Ambu® AuraGain™. In group B, 52% patients had a score of 4 and 48% had a score of 3, whereas 92% had a score of 4 in group V and only 8% had a score of 3. The better alignment with the glottis in the C-MAC®-guided group is because of visually placing the device in the optimal position and ensuring the correct size of the device, and prevention of epiglottis downfolding during insertion. Similar results were found in other studies [12,19]. Campbell RL et al., did a FOB examination to compare the blind insertion technique and direct laryngoscopy-guided placement. They stated that ideal FOB scores were achieved in 91.5% patients when LMA was inserted under direct laryngoscopy guidance compared to only 42% when it was inserted blindly [18]. OLP should be higher than PAP for sufficient ventilation without much air leak. The higher the difference between OLP and PAP, the safer the ventilation and the less the risk of gastric insufflation [19].

The strength of the study is that in place of using Computed Tomography (CT) imaging to assess the placement of the SAD, which causes a lot of radiation exposure, real-time FOB, which prevented radiation exposure and also the time lag involved in CT reporting.

Limitation(s)

However, the limitation here was that since authors conducted the study in normal airway patients, the results cannot be extrapolated to difficult airways. Observer bias is a possibility here, as blinding during the device insertion was also not possible.

CONCLUSION (S)

The study concludes that both the C-MAC® videolaryngoscopy-guided insertion technique and the blind paramedian insertion technique of Ambu® AuraGain™ are safe and effective techniques for securing an airway for controlled ventilation. C-MAC® videolaryngoscopy-guided technique of insertion of Ambu® AuraGain™ provides better efficacy of ventilation in terms of higher OLP as compared to the blind paramedian insertion technique in adult patients undergoing elective surgery under general anaesthesia. C-MAC® videolaryngoscopy- guided insertion of Ambu® AuraGain™ may be the preferred technique of insertion in patients with reduced thoracic compliance or in those who require ventilation at high peak airway pressures, as with higher OLP of Ambu® AuraGain™ was obtained as compared to that in the blind paramedian insertion technique.

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PLAGIARISM CHECKING METHODS: [Jain H et al.]
- Plagiarism X-checker: Mar 21, 2025
- Manual Googling: Oct 16, 2025
- iThenticate Software: Oct 18, 2025 (12%)

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- Financial or Other Competing Interests: None
- Was Ethics Committee Approval obtained for this study? Yes
- Was informed consent obtained from the subjects involved in the study? Yes
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