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Hyper-angulated (Glidescope) versus intermediate-angled (UED-A) videolaryngoscopy for routine tracheal intubation in adults: a prospective randomized controlled trial

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Videolaryngoscopy (VL) has become the gold standard for airway management. However, performance differences among blade geometries—especially between hyper-angulated and intermediate-angled designs—remain underexplored in routine airway management. We conducted a prospective randomized controlled trial comparing a hyper-angulated videolaryngoscope (GlideScope) and a novel intermediate-angled device (UED-A) during elective tracheal intubation of sixty adult patients. Patients were randomized to either device, with total intubation time as the primary outcome. Secondary outcomes included first-pass success, time to glottic visualization, number of attempts, external manipulation, Cormack-Lehane grade, adverse events, and user satisfaction. All patients were successfully intubated. No statistically significant differences were observed between groups in total intubation time (UED-A: 30.9 ± 13.8 s vs. GlideScope: 29.5 ± 13.0 s; $p = 0.73$), time to glottic visualization (UED-A: 12.9 ± 4.7 s vs. GlideScope: 13.5 ± 5.4 s; $p = 0.74$), or first-pass success (UED-A: 93% vs. GlideScope: 97%; $p > 0.99$). Other secondary outcomes were also comparable between devices. In routine adult tracheal intubation, the intermediate-angled UED-A videolaryngoscope demonstrated a non-inferior performance to GlideScope, indicating that both devices offer similarly effective and user-friendly options for standard airway management. This suggests that intermediate-angled UED-A videolaryngoscope may serve as viable alternatives to hyper-angulated GlideScope in clinical practice. Registry: ClinicalTrials.gov, TRN: NCT05721690, Registration date: February 1, 2023.

Keywords Airway management, Hyper-angulated blade, Intermediate-angled blade, Randomized controlled trial, Tracheal intubation, Videolaryngoscopy

Tracheal intubation is a fundamental aspect of anesthetic practice, involving the insertion of a flexible tube through the mouth or nose into the trachea, essential to secure and maintain an open and protected airway in patients undergoing elective surgical procedures or emergency care[1,2]. This procedure enables the delivery of oxygen, anesthesia, and medications, while also facilitating the removal of secretions and protecting the airway from pulmonary aspiration[3].

Despite advances in airway management devices, unanticipated difficult intubation remains a significant challenge, posing life-threatening risks during anesthesia or acute clinical situations[4,5]. Failure to adequately manage the upper airway is associated with significant morbidity and mortality[6]. The incidence of difficult

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科学报告

打开

成人常规气管插管中超角（Glidescope）与中角（UED-A）视频喉镜的前瞻性随机对照试验

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视频喉镜检查（VL）已成为气道管理的金标准。然而，在常规气道管理中，不同刀片几何形状（尤其是超角度与中间角度设计）之间的性能差异仍缺乏深入研究。我们开展了一项前瞻性随机对照试验，比较超角度视频喉镜（GlideScope）与新型中间角度设备（UED-A）在60例成人患者择期气管插管中的应用。患者被随机分配使用任一设备，以总插管时间为主要结局指标。次要结局指标包括首次通过成功率、声门可视化时间、尝试次数、外部操作、Cormack-Lehane分级、不良事件及使用者满意度。所有患者均成功完成插管。两组在总插管时间（UED-A：30.9±13.8秒 vs. GlideScope：29.5±13.0秒；*p*=0.73）、声门可视化时间（UED-A：12.9±4.7秒 vs. GlideScope：13.5±5.4秒；*p*=0.74）或首次通过成功率（UED-A：93% vs. GlideScope：97%；*p*>0.99）方面均未观察到统计学显著差异。其他次要结局指标在不同设备间也具有可比性。在常规成人气管插管操作中，中角度ED-A视频喉镜的性能表现不逊于GlideScope，表明这两种设备为标准气道管理提供了同样高效且用户友好的选择。这表明在临床实践中，中角度ED-A视频喉镜可能成为超角度GlideScope的可行替代方案。注册信息：ClinicalTrials.gov，注册号：NCT05721690，注册日期：2023年2月1日。

关键词气道管理、超角度刀片、中角度刀片、随机对照试验、气管插管、视频喉镜检查

气管插管是麻醉实践中的基础操作，通过口腔或鼻腔将软管插入气管，对于接受择期手术或急诊治疗的患者而言，该操作是确保气道开放和保护的关键[1,2]。该操作既能输送氧气、麻醉剂和药物，又可清除分泌物并防止肺吸入[3]。

尽管气道管理设备取得了进展，但意外的困难插管仍是一个重大挑战，在麻醉或急性临床情况下构成危及生命的危险[4,5]。未能充分管理上呼吸道与显著的发病率和死亡率相关[6]。困难插管的发生率

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tracheal intubation in elective surgeries ranges from approximately 1–2%, increasing to between 11 and 50% in emergency or urgent conditions outside the operating room[7].

Direct laryngoscopy (DL) has always been the traditional technique to perform tracheal intubation, but it has several limitations[8]. In particular, DL often fails to provide an optimal view of the glottis, especially in patients with anatomical variations such as a short neck, micrognathia, or macroglossia[6]. These factors can make intubation not only difficult but also potentially dangerous, increasing the risk of airway trauma and complications during and after airway management[9–11].

In response to these challenges, videolaryngoscopy (VL) has emerged over the past three decades as an advanced technique to facilitate tracheal intubation and is now recommended as the *"gold standard"* for airway management in all recent airway management guidelines[12–15]. This method employs devices equipped with a fiber-optic camera integrated into the blade of the laryngoscope, providing a clear and detailed view of the patient's laryngeal inlet on a monitor[8]. This technology offers numerous advantages, including real-time visualization of the glottis, thereby improving the accuracy and safety of intubation[16,17]. One of the main strengths of VL is its ability to position the operator's eye at the tip of the blade, just 2–3 cm from the laryngeal inlet, effectively allowing them to *"see around the corner"* and better visualize anatomical structures[18]. These features contribute to reducing the number of intubation attempts and increasing *"first-pass success"* rates[19–21], while also decreasing the level of difficulty as assessed by the Cormack-Lehane classification[22]. Consequently, VL reduces the risk of airway trauma and improves the overall experience for both patients and clinicians.

Various studies have widely demonstrated the superiority of VL compared to DL for glottis visualization, especially in cases of difficult intubation[7,23–30].

This has led to a true revolution in the approach to intubation, leading to the development and commercialization of a wide variety of devices in recent years, each with different features[31–33].

Moreover, the blade curvature in a videolaryngoscope has been diversified from a standard Macintosh-type (Macintosh geometry videolaryngoscopy- Mac-VL: ~ 30 degrees) and intermediate-type (between 30 and 60 degrees) to hyper-angulated types (Hyper-angulated or hyper-curved blade videolaryngoscopy- HA-VL: ~ 60 degrees), each differing in thickness and shapes, which result into different practical performances[34,35].

HA-VL have demonstrated superiority over Mac-VL in anticipated difficult airways, although no significant differences have been shown in the context of routine tracheal intubation in adults[36].

Moreover, comparisons between intermediate-angled and hyper-angulated devices have not been sufficiently investigated by existing literature. While HA-VL like the GlideScope and Mac-VL have been extensively studied, intermediate-angled devices such as the UED-A represent a relatively novel category with distinct blade geometry that may impact intubation performance differently.

To address this gap, we conducted a prospective randomized controlled trial to evaluate the effectiveness of a new intermediate-angled videolaryngoscope (UED-A) compared to a HA-VL (Glidescope) during elective tracheal intubation. The main outcome was to compare the performance of these videolaryngoscopes in terms of success rate, total time of tracheal intubation and number of attempts. Our primary hypothesis was that the total time to intubation using UED-A would be not inferior to Glidescope.

Secondary outcomes included the need for external glottic manipulation, Cormack-Lehane grade, operators' satisfaction grade and incidence of adverse events.

Materials and methods

A prospective, randomized controlled clinical study involving patients eligible for General Anesthesia (GA) undergoing tracheal intubation before elective surgery was conducted between February 2023 and May 2023.

This study was approved by the Ethics Committee of the University Hospital Campus Bio-Medico of Rome (protocol number 72/22, date of approval: 21 December 2022) and prospectively registered on ClinicalTrials.gov (TRN: NCT05721690, Registration date: February 1, 2023).

Inclusion criteria involved age over 18 years and American Society of Anesthesiologists (ASA) physical status classification I-III. Exclusion criteria included patients requiring an awake fiberoptic intubation[13], ASA class IV, age < 18 years, patients with predictors of difficult laryngoscopy (inter-incisor distance < 3 cm, severe limitation of cervical mobility, lingual deformities, anatomical neck abnormalities) and patients undergoing cardiac or otorhinolaryngologic surgery[37,38].

Eligible patients were randomly allocated into two groups to receive tracheal intubation with UED-A videolaryngoscope (UED-A group) or with GlideScope videolaryngoscope (GlideScope group).

Randomization was achieved using computer-generated lists in blocks of five with a 1:1 ratio, and treatment allocation was concealed using consecutively numbered, sealed, opaque envelopes.

To minimize the risk of operator-related bias during the procedure, the described techniques were always performed by the same anesthesiological team, consisting of four anesthesiologists experienced in airway management and tracheal intubation using videolaryngoscopes. Written informed consent was obtained by each patient before enrolment.

Collected data included age, gender, weight, height, Body Mass Index (BMI) (kg/m^2), inter-incisor distance (cm), neck extension (°), thyromental distance (cm), Mallampati score (I–III) and El-Ganzouri Risk Index (EGRI).

After a pre-oxygenation phase for 3 min using a face mask (FiO_2 100%), GA was induced through the administration of Propofol 2.5 mg/kg to obtain a Bispectral Index (BIS) between 40 and 60, Fentanyl 200 mcg and Rocuronium 0.6 mg/kg to obtain a deep neuromuscular block as showed by neuromuscular monitoring (TOF 0, PTC < 2). At this point, VL was performed using either the UED-A or GlideScope, depending on the patient's group assignment. Once the glottis was successfully visualized, tracheal intubation was carried out by inserting a size 7 endotracheal tube for women or size 7.5 for men. Each tube was equipped with a flexible stylet shaped to match the curvature of the blade (60° for Glidescope and 42° for UED-A).

择期手术中的气管插管发生率约为1%-2%，而在手术室外的急诊或紧急情况下，该比例可升至11%-50%[7]。

直接喉镜检查（DL）一直是气管插管的传统技术，但存在若干局限性[8]。特别是对于存在解剖变异（如短颈、小颌或巨舌）的患者，DL常无法提供最佳声门视野[6]。这些因素不仅会使插管操作困难，还可能带来潜在危险，增加气道创伤及气道管理期间和之后并发症的风险[9–11]。

为应对这些挑战，视频喉镜（VL）在过去三十年间发展成为一种促进气管插管的先进技术，现已被所有最新气道管理指南推荐为*“金标准”*[12–15]。该方法采用配备光纤摄像头的喉镜叶片装置，可在监视器上清晰详细地显示患者喉入口[8]。这项技术具有诸多优势，包括实时显示声门，从而提高插管的准确性和安全性[16,17]。VL的主要优势之一是能将操作者视线定位在叶片尖端，距离喉入口仅2-3厘米，从而有效实现*“窥视角落”*并更清晰地观察解剖结构[18]。这些特征有助于减少插管尝试次数并提高*“首次通过成功率”*[19–21]，同时根据Cormack-Lehane分级评估，也降低了操作难度[22]。因此，VL降低了气道创伤风险，并改善了患者和临床医生的整体体验。

多项研究已广泛证实，与DL相比，VL在声门可视化方面具有优势，特别是在困难插管的情况下[7,23–30]。

这导致了插管方法的真正革命，导致近年来各种不同特征的装置的开发和商业化[31–33]。

此外，视频喉镜的刀片曲率已从标准麦金塔型（麦金塔几何视频喉镜-Mac-VL：约30度）和中间型（30至60度之间）发展到超角度型（超角度或超曲率刀片视频喉镜-HA-VL：约60度），每种类型在厚度和形状上均有所不同，从而导致不同的实际性能[34,35]。

HA-VL在预期困难气道中已显示出优于Mac-VL的优势，尽管在成人常规气管插管背景下尚未显示出显著差异[36]。

此外，现有文献对中角型与超角型器械的比较研究尚不充分。虽然GlideScope和Mac-VL等HA-VL器械已得到广泛研究，但像UED-A这样的中角型器械属于相对较新的类别，其独特的叶片几何结构可能对插管性能产生不同的影响。

为填补这一空白，我们开展了一项前瞻性随机对照试验，旨在评估新型中角度视频喉镜（UED-A）与HA-VL（Glidescope）在择期气管插管术中的有效性。主要结局指标为比较这两种视频喉镜在成功率、气管插管总时长及尝试次数方面的性能。我们的主要假设是：使用UED-A完成气管插管的总时长不会劣于Glidescope。

次要结局指标包括外部声门操作需求、Cormack-Lehane分级、操作者满意度评分及不良事件发生率。

材料与方法

2023年2月至5月期间，开展了一项前瞻性、随机对照临床研究，研究对象为符合全身麻醉（GA）条件且拟在择期手术前接受气管插管的患者。

本研究经罗马大学医院Campus Bio-Medico伦理委员会批准（方案编号72/22，批准日期：2022年12月21日），并在ClinicalTrials.gov前瞻性注册（TRN：NCT05721690，注册日期：2023年2月1日）。

纳入标准包括年龄超过18岁且美国麻醉医师协会（ASA）体格状态分级为I-III级。排除标准包括需要清醒纤维支气管镜插管[13]、ASA IV级、年龄<18岁、存在喉镜检查困难预测因素（切牙间距离<3厘米、颈部活动度严重受限、舌部畸形、解剖颈部异常）以及接受心脏或耳鼻喉科手术的患者。[37,38]

符合入组标准的患者被随机分配至两组，分别接受使用UED-A视频喉镜（UED-A组）或GlideScope视频喉镜（GlideScope组）进行气管插管。

采用计算机生成的五联列表以1:1比例实现随机化，治疗分配通过连续编号、密封、不透明的信封进行隐匿。

为最大限度降低操作过程中操作者相关偏倚的风险，所述技术始终由同一麻醉团队执行，该团队由四名具有气道管理及视频喉镜气管插管经验的麻醉医师组成。所有患者在入组前均签署了书面知情同意书。

收集的数据包括年龄、性别、体重、身高、体重指数（BMI）（kg/m^2）、切牙间距离（cm）、颈部伸展度（°）、颏舌距离（cm）、Mallampati评分（I–III）和El-Ganzouri风险指数（EGRI）。

在使用面罩进行3分钟预氧合（FiO_2 100%）后，通过给予丙泊酚2.5毫克/千克（使双频指数BIS达到40-60）、芬太尼200微克及罗库溴铵0.6毫克/千克（经神经肌肉监测确认深度神经肌肉阻滞， TOF 0，PTC<2）诱导全身麻醉。此时根据患者分组情况，采用UED-A或GlideScope进行喉镜检查。成功确认声门后，为女性患者插入7号气管导管，男性患者则使用7.5号导管进行气管插管。所有导管均配备与刀片弧度匹配的柔性探条（GlideScope为60°，UED-A为42°）。

Additionally, a preliminary training phase was conducted for the investigators involved in the study on the use of the new UED-A videolaryngoscope. This included a theoretical lesson followed by practical tests on a SimMan simulation mannequin (Laerdal Medical). On the other hand, the GlideScope videolaryngoscope has been routinely used for several years in our hospital by the entire anesthesiological team, including the investigators participating to this study. Thus, each team member had prior clinical experience with both the hyperangulated GlideScope and the intermediate-angled UED-A devices, ensuring familiarity with the techniques and minimizing operator-related bias.

The main outcome of our study was to compare the performance of two videolaryngoscopes in terms of success rate and total time of tracheal intubation, number of attempts, time to glottic visualization. Secondary outcomes included the need for external glottic manipulation—BURP (Backward-Upward-Rightward-Pressure) and the evaluation of quality of glottic visualization assessed by recording the Cormack-Lehane grade, the ease of use of the videolaryngoscopes, evaluated through an operator satisfaction score on a numerical scale from 0 to 10 (0 represents the worst experience ever with a video laryngoscope and 10 represents the best experience ever with a video laryngoscope) and lastly the safety of the videolaryngoscopes, including documentation of any episodes of desaturation and/or bleeding during the intubation.

Videolaryngoscopes

The UED-A videolaryngoscope (UE Medical Corp, Zhejiang, China- Fig. 1) is a new multifunctional device equipped with a single-use blade featuring a 42° angled tip with fiber optics. The images captured by the camera positioned at the tip of the blade are displayed in real-time and high definition on an external portable screen measuring 8 inches. It is designed to help during indirect laryngoscopies for both routine and difficult airway intubations and can therefore be used to facilitate tracheal intubation in GA during elective surgery, as well as for cardiopulmonary resuscitation during cardiac arrest.

The GlideScope videolaryngoscope[37] with LoPro blade (Verathon Medical, France- Fig. 2) has similar features to the aforementioned UED-A in terms of components, functionality, and applications but is distinguished by blades with a hyper-angulation of approximately 60°. Its use is widespread, making it one of the most studied and cited videolaryngoscopes in scientific literature[39].

Statistical analysis

Regarding primary outcome, we predefined a non-inferiority margin of 10 s, based on our clinical experience and in line with previous trials[40,41].

To calculate sample size using G*Power software, we considered our primary hypothesis, that total time to intubation with UED-A is not inferior to Glidescope. Based on previously published data regarding VL with Glidescope, we estimated the total time to intubation as mean 22.2 and SD 9[42,43]

Based on this information and assuming a two-sided significance level of 5%, we conducted 10,000 simulations, each with a sample size of 30 per group. According to this analysis, a total sample size of at least 60 patients was associated with 90% statistical power to detect group disparities in total time to intubation as minimal as 8 s. This value was chosen as a conservative assumption to ensure that the study was adequately powered even for smaller differences than the predefined margin.

A per-protocol technique was used for the statistical analysis. Continuous quantitative variables are presented as Mean ± Standard Deviation (SD), while discrete variables are expressed as the median and interquartile range (IQR). Qualitative variables are represented by the number of observations and the percentage distribution. The parametric distribution of numerical variables was assessed using the Shapiro–Wilk normality test. Group differences for continuous parametric variables were evaluated using Student's t-test, while the Wilcoxon–

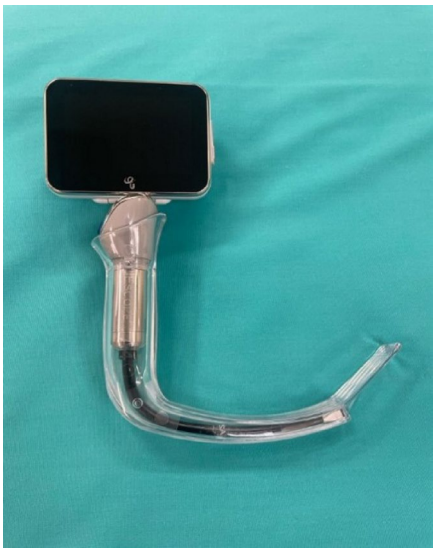

Fig. 1. UED-A videolaryngoscope.

此外，本研究还为参与人员开展了新型UED-A视频喉镜的初步培训。培训内容包括理论讲解及在SimMan模拟人体模型（Laerdal Medical）上的实操测试。另一方面，GlideScope视频喉镜已在本院麻醉团队（含本研究参与者）中常规使用多年。因此，每位团队成员均具备使用超角度GlideScope和中角度UED-A设备的临床经验，确保熟悉操作技术并最大限度减少操作者相关偏倚。

本研究的主要目的是比较两种视频喉镜在气管插管成功率、总插管时间、尝试次数及声门显露时间方面的性能。次要结局指标包括：是否需要进行外部声门操作（BURP，即后仰-上抬-右压操作），以及通过记录Cormack-Lehane分级评估的声门显露质量；视频喉镜的操作便捷性（通过操作者满意度评分进行评估，评分范围为0至10分，其中0分代表使用视频喉镜最差体验，10分代表最佳体验）；最后是视频喉镜的安全性，包括记录插管过程中出现的任何脱氧和/或出血事件。

视频喉镜

UED-A视频喉镜（中国浙江UE医疗公司生产，见图1）是一款新型多功能设备，配备一次性使用刀片，刀尖呈42°角度并带有光纤。安装在刀片尖端的摄像头实时高清显示图像，画面通过8英寸便携式外接屏幕呈现。该设备专为辅助间接喉镜检查设计，适用于常规及困难气道插管操作，既可用于择期手术中全身麻醉下的气管插管，也可用于心脏骤停时的心肺复苏。

GlideScope视频喉镜[37]（配备LoPro刀片，法国Verathon Medical公司生产，见图2）在组件、功能及应用方面与前述UED-A具有相似特性，但其显著区别在于刀片具有约60°的超角度设计。该设备应用广泛，成为科学文献中研究最多、引用率最高的视频喉镜之一[39]。

统计分析

关于主要结局指标，我们根据临床经验并参照既往试验[40,41]，预先设定了10秒的非劣效界值。

为使用G*Power软件计算样本量，我们考虑了主要假设，即使用UED-A的插管总时间不劣于Glidescope。基于先前发表的关于Glidescope的VL数据，我们估计插管总时间为均值22.2秒和标准差9 [42,43]。

基于上述信息并假设双侧显著性水平为5%，我们进行了10,000次模拟，每次模拟每组样本量为30例。根据该分析，至少60例患者的总样本量可确保90%的统计功效，以检测总插管时间差异（最小8秒）的组间差异。选择该数值作为保守假设，以确保即使对于预设差异范围之外的较小差异，研究仍具有足够的统计功效。

统计分析采用符合方案集（per-protocol）方法。连续定量变量以均值±标准差（SD）表示，离散变量以中位数和四分位距（IQR）呈现。定性变量通过观察次数和百分比分布展示。数值变量的参数分布采用Shapiro-Wilk正态性检验评估。连续参数变量的组间差异采用Student ′s t检验进行评估，而Wilcoxon–

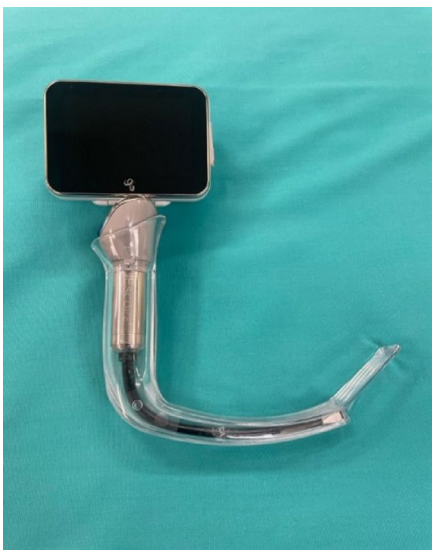

图1。 UED-A视频喉镜

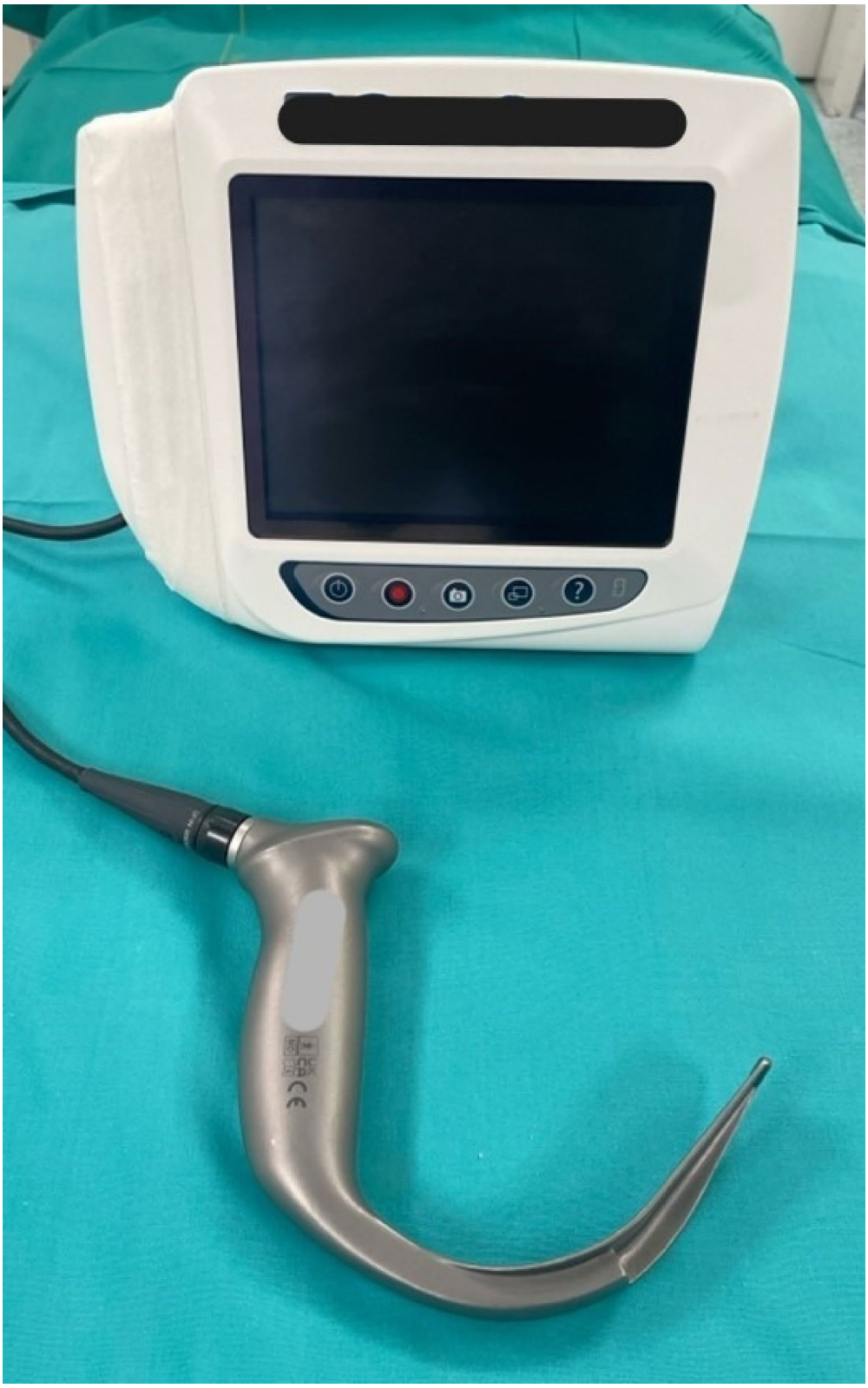

Fig. 2. GlideScope videolaryngoscope.

Mann–Whitney U test was employed when appropriate. Categorical variables were compared using Pearson's chi-squared test. For the primary and secondary continuous outcomes, mean differences between groups were reported together with 95% confidence intervals, calculated using Welch's t-test approximation, to assess non-inferiority against the predefined margin. Statistical significance was defined as a p-value < 0.05. Statistical

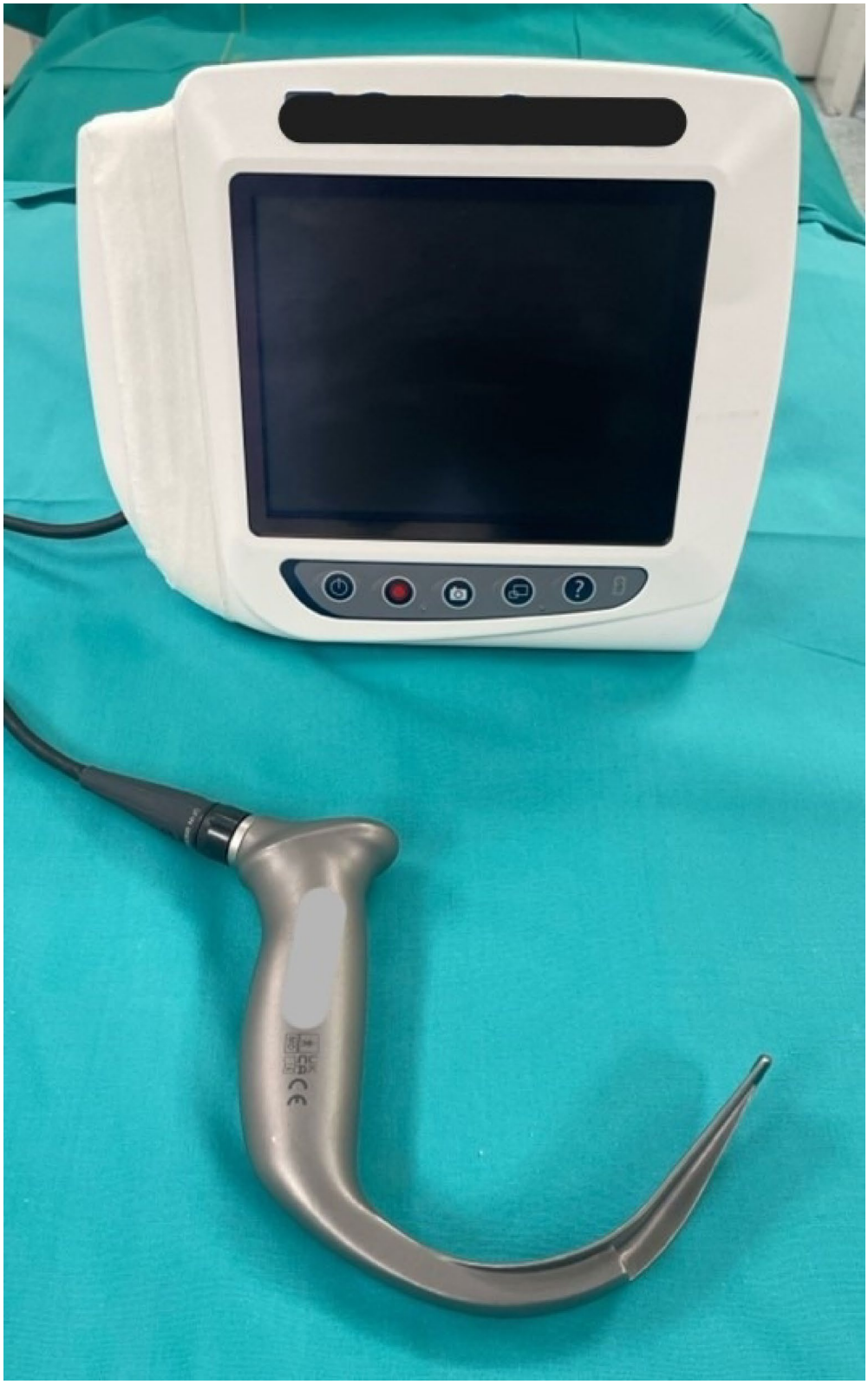

图2。 GlideScope videolaryngoscope.

在适用情况下采用Mann–Whitney U检验。分类变量比较采用Pearson卡方检验。对于主要和次要连续结局指标，报告组间均值差异及95%置信区间（通过Welch t检验近似计算），以评估是否达到预设的非劣效性标准。统计学显著性定义为p值<0.05。

analysis and visual presentation were obtained using GraphPad Prism 8 software (GraphPad Software Inc., La Jolla, CA, USA).

Results

A total of 60 patients were included in the study, with 30 assigned to the UED-A group and 30 to the GlideScope group (Fig. 3). Patient characteristics are summarized in Table 1.

Patient characteristics are summarized in Table 1. TI was successfully performed in all enrolled patients. No significant differences were observed between the groups for the primary outcomes (Table 2).

The time to glottic visualization was similar between the two groups (UED-A: 12.9 ± 4.7 s; GlideScope: 13.5 ± 5.4 s; $p = 0.74$). Likewise, the total time required for TI did not differ significantly (UED-A: 30.9 ± 13.8 s; GlideScope: 29.5 ± 13.0 s; $p = 0.73$). The mean difference in total intubation time (UED-A – GlideScope) was 1.4 s, with a 95% confidence interval of − 5.6 to 8.3. Given the predefined non-inferiority margin of 10 s, the upper bound of the 95% confidence interval remained below the margin, thereby formally demonstrating non-inferiority of UED-A compared with GlideScope. In most cases, endotracheal tube placement was successful on the first attempt (UED-A: 93%; GlideScope: 97%; $p > 0.99$). In the remaining cases, a second attempt was required (UED-A: 7%; GlideScope: 3%; $p > 0.99$). No cases required a third attempt with fiberoptic assistance.

Regarding the secondary outcomes (Table 3), no statistically significant differences were observed in the need for the BURP maneuver (UED-A: 20%; GlideScope: 13%; $p = 0.73$) or in the Cormack-Lehane grade during tracheal intubation (UED-A: CL I 77%, CL II 20%; GlideScope: CL I 83%, CL II 17%; $p > 0.74$ and $p > 0.99$, respectively). A single case of Cormack-Lehane grade III was reported in the UED-A group, while no cases of grade IV were observed. No statistically significant differences were found in the incidence of adverse events related to videolaryngoscopy. One case of peri-procedural desaturation occurred in the GlideScope

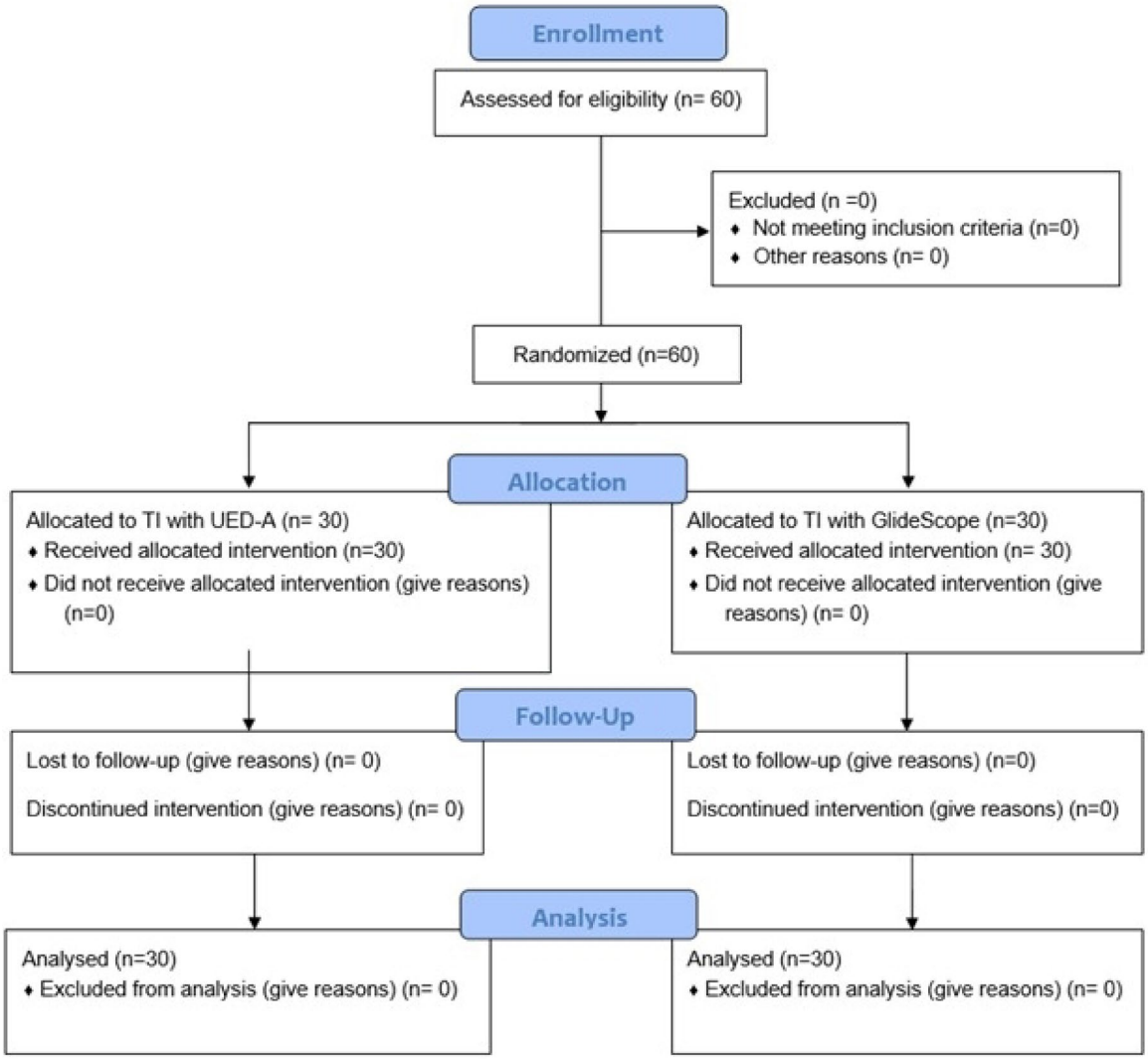

Fig. 3. Consolidated standards for reporting experiments (CONSORT) flowchart.

数据分析与可视化呈现采用GraphPad Prism 8软件（GraphPad Software Inc.，美国加利福尼亚州拉霍亚）完成。

结果

本研究共纳入60例患者，其中30例分配至UED-A组，30例分配至GlideScope组（图3）。患者特征总结见表1。

患者特征总结见表1。所有入组患者均成功完成TI（经颅磁刺激）治疗。各组间主要结局指标无显著差异（表2）。

两组的声门可视化时间相似（UED-A：12.9 ± 4.7 秒；GlideScope：13.5 ± 5.4 秒；p= 0.74）。同样，总插管时间也无显著差异（UED-A：30.9 ± 13.8 秒；GlideScope：29.5 ± 13.0 秒；p= 0.73）。总插管时间的平均差异（UED-A − GlideScope）为 1.4 秒，95% 置信区间为 −5.6 至 8.3。鉴于预设的非劣效性界值为 10 秒，95% 置信区间的上限仍低于该界值，从而正式证明了 UED-A 相对于 GlideScope 的非劣效性。大多数情况下，气管插管在首次尝试中即成功（UED-A：93%；GlideScope：97%；p> 0.99）。其余病例需二次尝试（UED-A：7%；GlideScope：3%；p>0.99）。无病例需要借助纤维支气管镜辅助进行三次尝试。

关于次要结局指标（表3），在需要使用膀胱排空术（BURP）方面未观察到统计学显著差异（UED-A组：20%；GlideScope组：13%；p=0.73），气管插管期间的Cormack-Lehane分级也无显著差异（UED-A组：CL I级77%，CL II级20%；GlideScope组：CL I级83%，CL II级17%；p分别>0.74和p>0.99）。UED-A组报告了1例Cormack-Lehane III级病例，而IV级病例未见。视频喉镜相关不良事件的发生率亦无统计学显著差异。GlideScope组出现1例围手术期血氧饱和度下降。

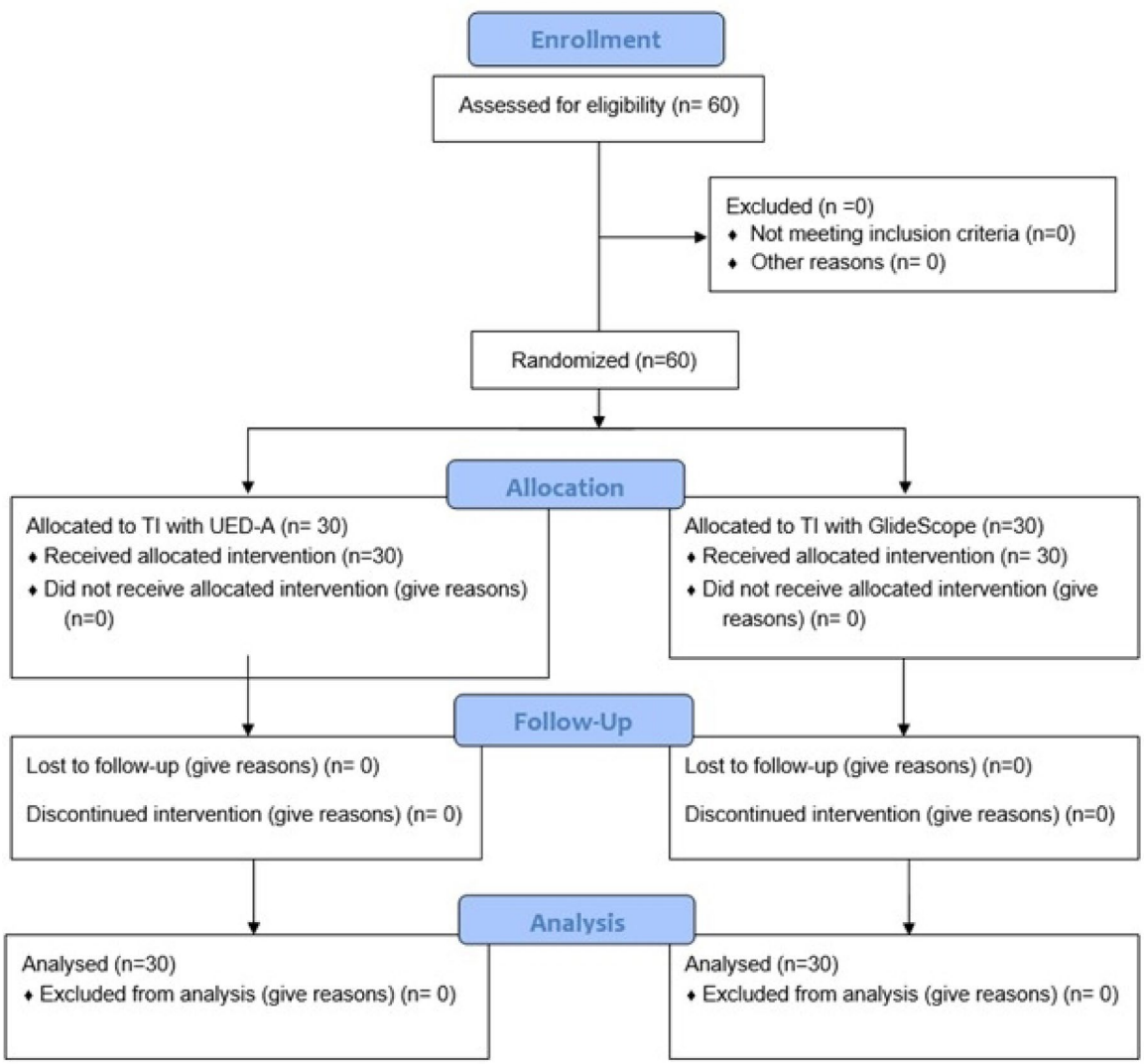

图3。 实验报告统一标准（consort）流程图。

	UED-A ($n=30$)	GlideScope ($n=30$)	p-value
Age (yr)—mean ± SD	59 ± 16	60 ± 18	0.94
Gender (M/F)—%	13/17	16/14	0.6
BMI (kg/m^2)—mean ± SD	28.8 ± 5.9	27.9 ± 6.5	0.56
Inter-incisor distance (cm)—mean ± SD	4.2 ± 0.4	4.4 ± 0.6	0.31
Neck extension (°)—mean ± SD	92 ± 8	93 ± 8	0.45
Thyromental distance (cm)—mean ± SD	6.4 ± 0.3	6.6 ± 0.3	0.1
Mallampati score—%			
I	13 (43%)	13 (43%)	> 0.99
I	10 (33%)	13 (43%)	0.59
III	7 (24%)	3 (10%)	0.29
IV	0	1 (4%)	> 0.99
EGRI—%			
< 4	25 (83%)	28 (93%)	0.42
≥ 4	5 (17%)	2 (7%)	0.42

Table 1. Patients' characteristics and intubation data. *SD* Standard deviation, *BMI* Body mass index, *EGRI* El-Ganzouri risk index.

	UED-A ($n=30$)	GlideScope ($n=30$)	Mean Difference	p-value
TI total time (sec)—mean ± SD	30.9 ± 13.8 (95% CI 25.7–36.1)	29.5 ± 13 (95% CI 24.6–34.4)	+ 1.4 (95% CI − 5.6 to 8.3)	0.73
Time to Glottic Visualization (sec)—mean ± SD	12.9 ± 4.7 (95% CI 11.1–14.7)	13.5 ± 5.4 (95% CI 11.5–15.5)	− 0.6 (95% CI − 3.2 to 2.0)	0.74
TI success rate—%				
1° Attempt	28 (93%)	29 (97%)		> 0.99
2° Attempt	2 (7%)	1 (3%)		> 0.99

Table 2. Primary outcomes. *SD* Standard deviation, *TI* Tracheal Intubation.

	UED-A ($n=30$)	GlideScope ($n=30$)	p-value
Need for BURP—n. (%)			
Yes	6 (20%)	4 (13%)	0.73
No	24 (80%)	26 (87%)	0.73
Cormack-Lehane—n. (%)			
I	23 (77%)	25 (83%)	
II	6 (20%)	5 (17%)	0.74
III	1 (3%)	0	> 0.99
IV	0	0	> 0.99
Complications (n.):			
Post-laringoscopy bleeding (YES/NO)	0/30	0/30	–
Peri-procedural desaturation (YES/NO)	0/30	1/29	> 0.99
Operator satisfaction (NRS 0–10)—median (IQR)	9 (7.3–10)	8 (8–10)	0.59

Table 3. Secondary outcomes. *BURP* Backward-Upward-Rightward-Pressure.

group. Finally, operator satisfaction scores were comparable between the two groups [UED-A: 9 (IQR 7.3–10); GlideScope: 8 (IQR 8–10); $p=0.59$].

Discussion

Our study found no differences in routine tracheal intubation performance between a hyper-angulated (Glidescope) and intermediate-angled (UED-A) videolaryngoscope.

Since the development of tracheal intubation, DL has traditionally been regarded as the *gold standard* for most patients. However, over time, negative outcomes in airway management have been reported, often associated with increased patient morbidity and mortality[44].

	UEDA (*n* = 30)	GlideScope (*n* = 30)	*p*值
年龄（岁）——均值±标准差	59 ± 16	60 ± 18	0.94
性别（男/女）—%	13/17	16/14	0.6
BMI（kg/m2）—均值±标准差	28.8 ± 5.9	27.9 ± 6.5	0.56
切牙间距离（cm）——均值±标准差	4.2 ± 0.4	4.4 ± 0.6	0.31
颈伸展角度（°）——均值±标准差	92 ± 8	93 ± 8	0.45
甲状腺-颏间距（cm）——均值±标准差	6.4 ± 0.3	6.6 ± 0.3	0.1
Mallampati评分			
I	13 (43%)	13 (43%)	> 0.99
I	10 (33%)	13 (43%)	0.59
罗马数字 3	7 (24%)	3 (10%)	0.29
增值	0	1 (4%)	> 0.99
EGRI—百分比			
<4	25 (83%)	28 (93%)	0.42
≥ 4	5 (17%)	2 (7%)	0.42

表1。患者特征与插管数据。*SD*标准差，*BMI*体重指数，*EGRI* El-Ganzouri风险指数。

	UEDA (*n* = 30)	GlideScope (*n* = 30)	平均差	*p*值
TI总时间（秒）—均值±标准差	30.9 ±13.8（95% CI 25.7–36.1）	29.5 ± 13（95% CI 24.6–34.4）	+ 1.4（95% CI −5.6 至 8.3）	0.73
声门可视化时间（秒）——均值±标准差	12.9 ±4.7（95% 置信区间 11.1–14.7）	13.5 ±5.4（95% 置信区间 11.5–15.5）	− 0.6（95% CI −3.2 至 2.0）	0.74
TI成功率—%				
1次尝试	28 (93%)	29 (97%)		> 0.99
第2次尝试	2 (7%)	1 (3%)		> 0.99

表2。主要结局指标。*SD*标准差，*TI*气管插管。

	UEDA (*n* = 30)	GlideScope (*n* = 30)	*p*值
需要使用催吐剂（n.）（%）			
是	6 (20%)	4 (13%)	0.73
不	24 (80%)	26 (87%)	0.73
Cormack-Lehane（n.）（%）			
I	23 (77%)	25 (83%)	
微光	6 (20%)	5 (17%)	0.74
罗马数字 3	1 (3%)	0	> 0.99
增值	0	0	> 0.99
并发症（例数）：			
喉镜检查后出血（是/否）	0/30	0/30	–
围手术期血氧饱和度下降（是/否）	0/30	1/29	> 0.99
操作员满意度（NRS 0-10）——中位数（IQR）	9 (7.3–10)	8 (8–10)	0.59

表3. 次要结局指标。*BURP*向后-向上-向右-压力。

最终，两组操作者的满意度评分具有可比性[UED-A：9（IQR 7.3-10）；GlideScope：8（IQR 8-10）；*p*=0.59]。

讨论

本研究发现，超角度（Glidescope）与中角度（UED-A）视频喉镜在常规气管插管操作中的表现无显著差异。

自气管插管技术发展以来，DL传统上被视为大多数患者的*金标准*。然而，随着时间的推移，气道管理的不良结局已被报道，通常与患者发病率和死亡率的增加相关[44]。

In recent years, the evolution of VL has marked a significant advancement in anesthesiology practice[45]. Current airway management guidelines recognize the VL as the *gold standard* for performing tracheal intubation, both in elective settings and in challenging or emergencies situations where rapid sequence intubation (RSI) is crucial[12–15]. A statistical analysis over the past two decades (1993–1999 and 2000–2012) revealed that approximately 30% of adverse events related to anesthesiological management involve airway control[46]. Furthermore, unanticipated difficult airways are more common than generally assumed. A retrospective analysis of a 2015 Danish database with 188.064 tracheal intubation cases found that airway management difficulties occurred in 1.86% (3391 cases), of which 93% (3154 cases) were unanticipated[47]. However, an analysis of the Difficult Airway Society (DAS) database reported that difficult airway management was anticipated in 58% (391 cases) and unanticipated in 42% (284 cases)[48]. This findings highlight the significant likelihood of encountering a difficult airway, even in the absence of predictors or prior history.

Failure to successfully perform tracheal intubation in any context can lead to serious complications, including hypoxemia, pulmonary aspiration, arrhythmias, and critical situations of CICO (Cannot Intubate-Cannot Oxygenate)[14,49,50]. In the worst cases, these complications may lead to catastrophic outcomes such as death or permanent brain damage[51].

The growing body of evidence over the years has established the videolaryngoscope as an essential device in modern anesthesiological practices, leading to a continuously expanding market due to the increasing number of companies investing in the research and development of advanced airway management technologies[45,52].

Video devices have significantly improved the visualization of anatomical structures, particularly but not only in patients with difficult intubation criteria for direct laryngoscopy[17,53]. This has contributed to reduced intubation difficulties and shorter intubation times, increasing the *first-attempt success* rate when used with a flexible stylet, and a decrease in airway-related complications[18]. Among the devices, the McGrath and GlideScope videolaryngoscopes have been the most prominent in the field of indirect laryngoscopy. They are being extensively studied, well-validated by scientific literature, and widely used in clinical practice[54,55]. W.J. Jeon et al.[56] highlighted that the median time to intubation in patients with normal airways using the GlideScope with a hyper-angulated blade and McGrath with an intermediate-angled blade was 40.5 s and 53.3 s, respectively, which is comparable to the times reported in other studies[57–59]. However, unlike our study, the McGrath is considered inferior to the UED-A in terms of screen quality and glottic image resolution. In this regard, Van Zundert et al.[58] reported that using the GlideScope and McGrath associated with a styletted endotracheal tube (ETT) increased first-pass success rates in healthy adult patients, from 53 to 76% and 52 to 74%, respectively. Similarly, Sun et al.[60] reported a 94% first-pass success rate with the GlideScope and a styletted ETT. Rai et al.[57] demonstrated that the GlideScope improved laryngeal visualization and facilitated successful TI. A key advantage of videolaryngoscopy is the ability to display the laryngeal view on a monitor, which not only provides better visual support for the operator but also allows multiple team members to simultaneously observe the laryngeal inlet[61]. This feature enhances teamwork and serves as an effective training and educational tool for healthcare professionals[62]. Additionally, the use of videolaryngoscopes is clearly linked to a reduction in intubation-related complications. Studies bt Lewis et al.[9] and Hansel et al.[8] have highlighted decreased episodes of hypoxia, reduced airway trauma, and better recognition of inadvertent esophageal intubation when using videolaryngoscopes.

The rationale of our study is based on the concept that current literature supports the superiority of the HA-VL versus the Mac-VL for videolaryngoscopes in patients with anticipated difficult airways[34], but no such evidence exists for patients undergoing routine VL without predicted airway difficulties. Similarly, there is a lack of evidence favoring HA-VL over videolaryngoscopes with intermediate blade geometry. Notably, the Canadian Airway Focus Group (CAFG)[14], regarding the management of unanticipated airway difficulties in already unconscious patients, recommends routine primary use of VL with an appropriate blade type for all tracheal intubations without specifying a preferred blade geometry. Moreover, direct comparisons between intermediate-angled and HA-VL remain scarce in the existing literature. Most previous studies have focused on contrasting HA-VL with Mac-VL, leaving a significant gap regarding the clinical performance differences between intermediate-angled and hyperangulated blades. This lack of data limits clear guidance for clinicians on optimal blade selection in routine airway management. Our study aims to address this gap by providing prospective randomized evidence comparing these two blade geometries in patients without anticipated difficult airways.

The HA-VL allows "*around the corner*" visualization of the glottis through indirect videoscopic imaging, providing a view superior to that achieved with DL[8] or Mac-VL[34]. However, directing the endotracheal tube toward the laryngeal inlet can sometimes be challenging with a HA-VL. To address these difficulties during routine tracheal intubation, the CAFG recommends that anesthesiologists consider switching to a non-hyper-angulated blade if attempts with the hyper-angulated blade are unsuccessful.

Furthermore, although HA-VL provide improved glottic visualization, they require the use of a stylet with a greater degree of angulation compared to Mac-VL[63,64]. R. Wakabayashi et al. demonstrated that stylet angulation at the holding position improves the maneuverability of the tracheal tube and enables easy, smooth, and swift tube placement during tracheal intubation with a McGRATH MAC videolaryngoscope[65]. Similarly, J. Lee demonstrated that when intubating patients with the McGrath videolaryngoscope, the 60° angled stylet al.lowed for faster tracheal intubation than the 90° angled stylet[66].

However, this could make tracheal intubation more challenging for operators who lack extensive experience with hyper-angulated devices. In this regard, the need to shape the stylet to match the curvature of the specific hyper-angulated blade adds a layer of operator-dependent variability to clinical practice. This variability may influence both the success rate and time to intubation, as improper stylet shaping can lead to difficulties in advancing the tube through the vocal cords, potentially prolonging the procedure or increasing the number of attempts needed.

近年来，气道控制（VL）的演变标志着麻醉学实践的重大进步[45]。现行气道管理指南将VL视为气管插管的金*标准*，无论是在择期手术中，还是在需要快速顺序插管（RSI）的复杂或紧急情况下[12–15]。对过去二十年（1993–1999年和2000–2012年）的统计分析显示，约30%的麻醉管理相关不良事件涉及气道控制[46]。此外，非预期性困难气道的发生率比普遍认为的更高。对2015年丹麦数据库中188,064例气管插管病例的回顾性分析发现，气道管理困难发生率为1.86%（3,391例），其中93%（3,154例）为非预期性[47]。然而，对困难气道学会（DAS）数据库的分析显示，58%（391例）的困难气道管理是预期性，42%（284例）为非预期性[48]。该研究结果表明，即使缺乏预测因素或既往病史，仍存在遇到困难气道的显著可能性。

在任何情况下，气管插管失败都可能导致严重并发症，包括低氧血症、肺吸入、心律失常以及CICO（无法插管-无法供氧）的危急情况[14,49,50]。在最严重的情况下，这些并发症可能导致灾难性后果，如死亡或永久性脑损伤[51]。

多年来，越来越多的证据表明，可视喉镜已成为现代麻醉实践中的必备设备，由于越来越多的公司投资于先进气道管理技术的研发，导致市场不断扩大[45,52]。

视频设备显著提升了解剖结构的可视化效果，尤其对于喉镜直视困难的患者而言，但不仅限于此[17,53]。这有助于降低插管难度、缩短插管时间，配合柔性探条使用时可提高*首次尝试成功率*，并减少气道相关并发症[18]。在各类设备中，McGrath和GlideScope视频喉镜在间接喉镜领域最为突出。它们正被广泛研究、科学文献充分验证，并在临床实践中广泛应用[54,55]。W.J. Jeon等人[56]指出，使用超角度刀片的GlideScope和中角度刀片的McGrath对正常气道患者的插管中位时间分别为40.5秒和53.3秒，与其他研究报道的时间相当[57–59]。然而，与我们的研究不同，McGrath在屏幕质量和声门图像分辨率方面被认为不如UED-A。在这方面，Van Zundert等人[58]报告称，使用GlideScope和McGrath配合带导丝的气管导管（ETT）可使健康成年患者的首次通过成功率分别从53%提升至76%和52%至74%。类似地，Sun等人[60]报告了使用GlideScope和带导丝 ETT 的94%首次通过成功率。Rai等人[57]证实GlideScope能改善喉部可视化并促进成功气管插管。视频喉镜的关键优势在于能在监视器上显示喉部视野，这不仅为操作者提供更好的视觉支持，还允许多名团队成员同时观察喉入口[61]。这一功能增强了团队协作，并作为医疗专业人员的有效培训和教育工具[62]。此外，使用视频喉镜与减少插管相关并发症有明确关联。Lewis等人[9]和 Hansel 等人[8]指出，使用视频喉镜可减少低氧发作、降低气道创伤，并提高对意外食管插管的识别率。

本研究的理论基础源于以下观点：现有文献支持在预计存在困难气道的患者中，使用HA-VL（高角度喉镜）优于Mac-VL（中角度喉镜）[34]，但针对常规喉镜检查（无气道困难预测）的患者尚无类似证据。同样，目前也缺乏支持HA-VL优于中角度喉镜的证据。值得注意的是，加拿大气道焦点小组（CAFG）[14]在处理已无意识患者突发气道困难时，建议所有气管插管均常规使用合适角度的喉镜，但未指定优选角度类型。此外，现有文献中关于中角度与HA-VL的直接对比研究仍较为匮乏。多数既往研究仅对比HA-VL与Mac-VL，导致中角度与超角度喉镜的临床性能差异研究存在显著空白。这种数据缺失限制了临床医生在常规气道管理中选择最佳喉镜角度的明确指导。本研究旨在通过提供前瞻性随机对照证据，比较这两种刀片几何结构在无预期困难气道患者中的应用效果，以填补这一研究空白。

喉镜（HA-VL）通过间接视频成像技术实现了“*近在咫尺*”的声门可视化效果，其观察效果优于DL [8]或Mac-VL [34]。但使用HA-VL时，将气管导管对准喉入口可能颇具挑战。针对常规气管插管中的这些难题，美国麻醉医师协会（CAFG）建议：若使用超角形喉镜刀片仍无法成功，麻醉医师应考虑改用非超角形喉镜刀片。

此外，尽管HA-VL能提供更好的声门可视化，但与Mac-VL相比，它们需要使用角度更大的导丝[63,64]。R. Wakabayashi等人证明，在保持位置时导丝角度的改变可提高气管导管的可操作性，并在使用McGRATH MAC视频喉镜进行气管插管时实现轻松、平稳且快速的导管置入[65]。类似地，J. Lee证实，使用McGRATH视频喉镜插管患者时，60°角度的导丝比90°角度的导丝能实现更快的气管插管[66]。

然而，对于缺乏超角度器械使用经验的操作者而言，这可能使气管插管更具挑战性。具体来说，需要根据特定超角度刀片的曲率对导丝进行塑形，这为临床操作增加了操作者依赖性差异。这种差异性可能同时影响插管成功率和操作耗时，因为不当的导丝塑形可能导致导管通过声带时出现困难，从而延长手术时间或增加尝试次数。

This issue may help explain why, despite the increased global availability of videolaryngoscopes following the surge in purchases during the the Coronavirus disease 2019 pandemic, their use in clinical settings have not yet reached their full potential. Several obstacles to widespread adoption remain, including insufficient training, concerns about de-skilling in DL, equipment and cleaning costs, and environmental impact, among others. It is now evident that in order for patients to fully benefit from the technology and for airway managers to fully understand its role in daily practice, appropriate training and education are essential[67]. In particular, proper training in the correct shaping and handling of stylets is crucial to optimize clinical outcomes and to fully leverage the advantages offered by VL.

In this context, an important consideration in videolaryngoscopy is the potential discrepancy between achieving an optimal glottic view and the actual ease of tracheal tube advancement—the so-called *"can see but can't intubate"* scenario. Although this issue did not occur in our cohort, it represents a well-recognized challenge in clinical practice. Fernández-Vaquero et al.[68] have explored this phenomenon, highlighting that even with high-quality glottic visualization (e.g., elevated POGO scores), intubation may still be technically difficult. Their findings underscore that optimal visualization does not necessarily translate into procedural ease, emphasizing the importance of comprehensive pre-procedural assessment, anticipation of potential difficulties, and appropriate preparation.

However, our study has some limitations. Firstly, we considered a relatively small sample size (60 patients in total), although justified by an "a priori" power analysis. A larger sample size could have included a greater number of patients with anticipated difficult intubation, which would have certainly represented an interesting opportunity for subgroup analysis. Additionally, we assessed glottic visualization using the Cormack–Lehane classification rather than videolaryngoscopy-specific scores such as the Percent Of Glottic Opening (POGO) or Video Classification of Intubation (VCI) scores[69], which may have offered a more precise evaluation tailored to this technique. Incorporating such videolaryngoscopy-specific scores in future studies could enhance the accuracy and clinical relevance of glottic visualization assessment. This limitation further underscores the importance of adopting unified classification and evaluation systems for videolaryngoscopes, as recently emphasized by M. Á. Gómez-Ríos et al.[70], which advocates for the development of standardized frameworks for the assessment and documentation of VL performance.

Bias may have been occurred since it was not possible to blind the anesthesiologist to the device being used. Additionally, all tracheal intubations were performed by experienced anesthesiologists; therefore, the findings may not be generalizable to less experienced operators. We explicitly acknowledge the lack of operator blinding and the resulting performance bias as important limitations of this study. Lastly, the study population was limited to elective surgical patients with normal airways, which restricts the applicability of the results to patients with anticipated difficult airways. Therefore, future studies should focus on larger sample sizes and investigate the use of the UED-A device in patients with predicted difficult airways, such as those with an El-Ganzouri Index greater than 4.

Conclusion

In this randomized controlled trial, the UED-A videolaryngoscope demonstrated performance and safety comparable to Glidescope for routine tracheal intubation in adults with normal airway anatomy undergoing elective surgery. Given its intermediate blade angulation, ease of use, and satisfactory operator feedback, the UED-A represents a valid, safe, and effective alternative to hyperangulated blades for routine videolaryngoscopy in this patient population. However, due to the limited sample size and exclusion of patients with difficult airways, these findings should be interpreted with caution. Further research is needed to evaluate the performance of the UED-A in patients with predicted difficult airways or in emergency settings.

Data availability

The data used and/or analyzed during the study are available from the corresponding author upon reasonable request via email.

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这一问题或许能解释为何尽管2019冠状病毒病大流行期间视频喉镜采购量激增，全球可用性提升，但其在临床环境中的应用仍未充分发挥潜力。阻碍其广泛应用的因素包括培训不足、对视频喉镜操作技能退化的担忧、设备与清洁成本以及环境影响等。现已明确，为使患者充分受益于该技术，且气道管理团队能全面理解其在日常实践中的作用，适当的培训与教育至关重要[67]。特别是，正确培训患者掌握探条的正确塑形与操作方法，对于优化临床效果及充分发挥视频喉镜优势具有关键作用。

在此背景下，视频喉镜检查中的一个重要考量是实现最佳声门视野与实际气管导管推进难易度之间的潜在差异——即所谓的“*可见但不可插管*”情况。尽管这一问题在我们的队列中未出现，但它仍是临床实践中公认的一大挑战。Fernandez-Vaquero等人[68]探讨了这一现象，强调即使声门可视化质量良好（如POGO评分升高），插管仍可能面临技术困难。他们的研究结果表明，最佳可视化效果并不必然转化为操作便捷性，这凸显了术前全面评估、预判潜在困难及充分准备的重要性。

然而，本研究存在若干局限性。首先，尽管通过“先验”功效分析得到了合理解释，但我们采用的样本量相对较小（总计60例患者）。若样本量更大，本研究本可纳入更多预计存在困难插管的患者，这无疑为亚组分析提供了更有价值的研究机会。此外，我们采用Cormack-Lehane分级系统评估声门可视化情况，而非视频喉镜专用评分（如声门开放百分比（POGO）或视频插管分级（VCI）评分[69]），后者可能为该技术提供更精准的评估。未来研究若能纳入此类视频喉镜专用评分，将有助于提升声门可视化评估的准确性与临床相关性。这一局限性进一步凸显了采用统一视频喉镜分级与评估系统的重要性，正如M.A. Gomez-Rios等人[70]近期所强调的，该研究主张建立标准化框架以评估和记录视频喉镜操作表现。

可能存在偏倚，因为无法对麻醉医师实施盲法以避免其知晓所使用设备。此外，所有气管插管均由经验丰富的麻醉医师完成，因此研究结果可能无法推广至经验较少的操作者。我们明确承认操作者盲法缺失及由此产生的操作偏倚是本研究的重要局限性。最后，研究人群仅限于气道正常的择期手术患者，这限制了研究结果对预期存在困难气道患者的适用性。因此，未来研究应扩大样本量，并探讨在预测存在困难气道（如El-Ganzouri指数>4者）患者中使用UED-A设备的可行性。

结论

在这项随机对照试验中，对于接受择期手术且气道解剖结构正常的成人患者，UED-A视频喉镜在常规气管插管中的性能和安全性与Glidescope相当。鉴于其中等角度的刀片、易用性以及操作者反馈良好，UED-A可作为该患者群体常规视频喉镜检查中高角度刀片的有效、安全且有效的替代方案。然而，由于样本量有限且排除了气道困难患者，这些结果应谨慎解读。需要进一步研究评估UED-A在预测气道困难患者或急诊环境中的性能。

数据可用性

本研究中使用和/或分析的数据可通过合理电子邮件请求从通讯作者处获取。

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Author contributions

All authors contributed to the conception and design of the study, analysis of the data, and overall development of the manuscript. SM was primarily responsible for drafting the manuscript and coordinating the writing process. AS and FC significantly contributed to the drafting and critical revision of the text. GP and AR supported manuscript preparation by contributing to the interpretation and presentation of results. LS and AM participated in data handling and contributed content for specific sections of the manuscript. MC and RC provided supervisory input and revised the text for important intellectual content. FEA oversaw the study and contributed to the critical review of the manuscript. GP contributed to the design of the study, interpretation and presentation of results and provided final approval of the version to be submitted.

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Declarations

Competing interests

The authors declare no competing interests.

Ethical approval

All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki Declaration and

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