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Clinical techniques and technologies

Evone® Flow controlled ventilation: a new device for laryngotracheal surgery

Evone® Ventilazione a flusso controllato: un nuovo dispositivo per la chirurgia laringo-tracheale

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SUMMARY

The success of laryngotracheal surgery is mainly related to adequate exposure of the airway lumen. To render airway surgery more efficient, many efforts have been made in recent decades to obtain a safe ventilation system which uses an orotracheal tube that is as small as possible. The first attempt was made by introducing the high frequency jet ventilation (HFJV) technology in clinical practice. Nonetheless, HFJV has some risks related to the high pressure needed for ventilation in the catheter. First, during HFJV, the expiration of air from the lungs is a passive backflow on the trachea wall, potentially causing hypercapnia and air trapping. Second, HFJV creates an open ventilation system that leads to aerosolisation of airborne particles with an increased infectious risk for the surgeon. To overcome these issues, an innovative flow-controlled ventilation (FCV) system with a narrow-cuffed catheter (Evone®; Ventinova, Eindhoven, The Netherlands) was introduced in clinical practice. This paper describes our initial experience with the Evone® FCV system, reporting the first 5 cases ventilated with this technology. In this observational study, we evaluate the feasibility and safety of the Evone® system and deliver a critical appraisal of this novel method of ventilation.

KEY WORDS: laryngotracheal surgery, intubation, stenosis, recurrent respiratory papillomatosis, jet ventilation

RIASSUNTO

Il successo della chirurgia laringotracheale è principalmente correlato a un'adeguata esposizione delle vie aeree, con l'utilizzo di un tubo oro-tracheale più piccolo possibile. Il primo tentativo è stato fatto introducendo la tecnologia della ventilazione a getto ad alta frequenza (VGAF) nella pratica clinica. Tuttavia, la VGAF presenta alcuni rischi legati all'alta pressione necessaria per la ventilazione. Innanzitutto, durante la VGAF, l'espirazione dell'aria dai polmoni è un riflusso passivo sulla parete della trachea, che potenzialmente causa ipercapnia e intrappolamento d'aria. In secondo luogo, la VGAF crea un sistema di ventilazione aperto che aumenta il rischio infettivo per il personale sanitario, a causa dei droplets immessi in circolo tramite aerosol. Per superare questi problemi, è stato introdotto nella pratica clinica un innovativo sistema di ventilazione a flusso controllato con catetere a cuffia stretta (Evone®; Ventinova, Eindhoven, Paesi Bassi). Questo articolo descrive la nostra esperienza iniziale con il sistema Evone®, riportando i primi 5 casi di pazienti ventilati con questa tecnologia. In questo studio osservazionale, valutiamo la fattibilità e la sicurezza del sistema Evone® e forniamo una valutazione critica di questo nuovo metodo di ventilazione.

PAROLE CHIAVI: *chirurgia laringo-tracheale, intubazione, stenosi, papillomatosi respiratoria ricorrente, jet ventilation*

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Introduction

The success of laryngotracheal surgery is positively influenced by adequate exposure of the airway lumen. To render airway surgery more efficient, many efforts have been made in recent decades to obtain a safe ventilation system that reduces, as much as possible, the diameter of the orotracheal tube. Several laryngotracheal diseases cause, in fact, a critical reduction of the airway patency. In these conditions, it is necessary to use a highly narrow orotracheal tube (i.e. inner diameter 4.5 mm) that in most cases, however, does not allow safe ventilation of patients. The first attempt to overcome this crucial issue was made by introducing the high frequency jet ventilation (HFJV) technology in selected patients. This anaesthesiologic technique is based on gas puffs delivered under high pressure through a small catheter placed in the airway, thus creating an open ventilation system [1]. HFJV is useful in situations where access to the airway is potentially hindered by the orotracheal tube, thanks to the small size of the catheter [1]. However, HFJV has some drawbacks due to the high pressure employed for ventilation through a small catheter and the passive backflow of expired air from the lungs, potentially causing hypercapnia and air trapping [1,2]. This phenomenon of air trapping is more likely to occur in case of severe narrowing of the airway and acts as a counterweight to the benefits of a smaller tube [2]. Moreover, creating an open ventilation system leads to aerosolisation of airborne particles with increased infectious risk for the surgical team.

The leading causes of critical narrowing of the airway lumen are malignant and benign diseases, the most frequent of which are selected glottic carcinomas, recurrent respiratory papillomatosis (RRP) and laryngototracheal stenosis. In such situations, HFJV is not the ideal device for ventilation. In the case of patients affected by RRP, the risk of aerosolisation of viral particles would expose health care workers to an extremely high risk of contagion. On the other hand, in the case of severe airway stenosis, the phenomenon of air trapping would not allow for adequate ventilation of the patient.

To overcome these limitations, an innovative flow-controlled ventilation (FCV) system with a narrow-cuffed catheter (Evone®; Ventinova, Eindhoven, The Netherlands) can actively expel air out of the lungs through negative pressure. The negative pressure is generated using jet-flow (Bernoulli's principle) and was devised to be automatised. It is normally used with a cuffed small lumen tube, which streamlines the ventilation while allowing airway protection, with allegedly less hypercapnia and hypoxia. In case of unintentional cuff breaking, the ventilation system shifts automatically to the HFJV, thereby avoiding the need for a sudden new orotracheal tube insertion. This new device seems very encouraging since it could conceivably unite all benefits of different ventilation techniques, as it could offer similar secure, steady, and easy-to-follow ventilation as a normal bore tube [2]. This paper describes our initial experience with the Evone® FCV system, reporting the first 5 cases ventilated using this technology. In this observational study, we evaluate the feasibility and safety of the Evone® system and deliver a critical appraisal of this novel method of ventilation.

Description of clinical techniques and technology

We prospectively collected data on the first 5 patients treated from May 2021 to July 2021 at the Unit of Otorhinolaryngology, Head and Neck surgery of IRCCS Policlinico San Martino, Genoa, Italy. All patients were female. Two were affected by idiopathic subglottic stenosis (ISS) and 3 by RRP with subglottic and tracheal extension. During the 5 procedures, Evone® FCV was employed as an alternative to standard endotracheal intubation or HFJV. The decision to use Evone® was based on the pathology and planned surgical procedure (endoscopic radial incisions and dilation of severe subglottic stenosis, and endoscopic removal and photocoagulation of subglottic and/or tracheal papilloma) (Fig. 1).

Anaesthesia material and technical data on working mechanism of Evone®

Evone® is a flow-controlled ventilation system that uses a tube with three lumens: one for the inflation and deflation of the cuff, one for the measurement of the pressure in the trachea, and one for the patient ventilation. As a flow-controlled ventilator, the machine does not rely on the passive elasticity of the lung, but produces a negative pressure thanks to the Bernoulli principle, actively recalling air out of the lung during the expiratory phase (Figs. 2, 3). As reported by other authors in the literature [3], the attending anaesthesiologist set the following ventilator parameters: FiO_2, inspiratory flow rate, Inspiratory:Expiratory (I:E) ratio, PIP and EEP. Conventional capnography was used for evaluation of end-tidal carbon dioxide partial pressure (PetCO2). Further measured values were minute volume, respiratory rate, inspiratory tidal volume (VT), peripheral blood oxygen saturation (SpO_2), noninvasively measured blood pressure (NIBP) and heart rate (HR). The intratidal tracheal pressure amplitude (Dp), defined as the difference between PIP and EEP, was calculated offline.

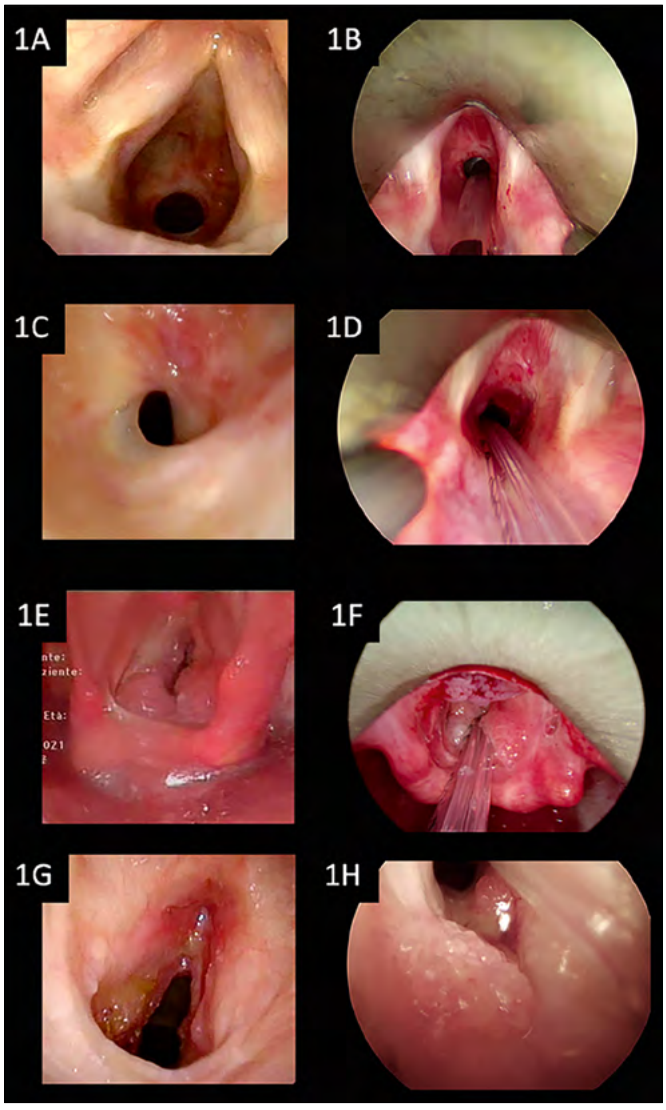

Figure 1. (**A-C**) preoperative office flexible view of idiopathic subglottic stenosis (Cotton-Myer grade III); (**B-D**) the tritube provides minimal traumatic intubation and guarantees an ideal working space and exposure by maintaining stable ventilation; (**E**) an advanced case of RRP (Derkay site score: 12; Derkay clinical score: 7); (**F**) this difficult intubation can be achieved by small-lumen ventilation, such as Evone®. This latter, compared to HFJV, protects against aerosolisation of papillomavirus in the operating theatre; (**G**) the larynx of a patient repeatedly treated for RRP with a posterior glottic stenosis (Bogdasarian II); (**H**) the use of a narrow tube allows the treatment of the posterior compartment of the larynx, despite the presence of the posterior web.

Figure 2. Evone® FVC system.

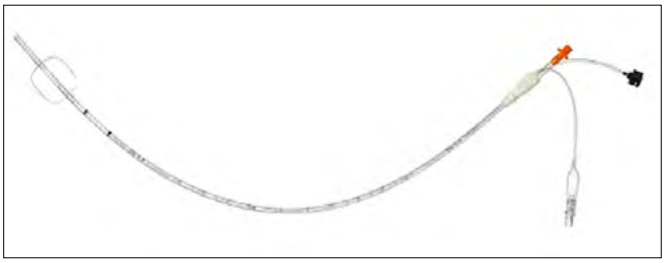

Figure 3. Evone® Tritube. The tritube is a cuffed tube with an external diameter of 4.4 mm allowing a larger surgical field during elective surgery with a lower risk of contamination.

Patient characteristics

C.B., female, 49 years old

C.B. was affected by idiopathic subglottic stenosis (ISS) grade IIIa according to European Laryngological Society (ELS) classification system. She underwent previous endoscopic treatment in 2017. In March 2021, she complained of a new worsening of dyspnoea. At preoperative videolaryngoscopy, an ELS grade IIIa subglottic stenosis was found. Evone® FCV ventilation was employed. Radial incisions with CO2 laser Lumenis Encore Ultrapulse (Tel Aviv, Israel) coupled with a digital Acublade micromanipulator were performed. Endoscopic dilation with Savary bougies was done at the end of the procedure.

G.M.E., female, 74 years old

G.M.E. was affected by recurrent ISS grade IIIb according to ELS classification. She underwent several endoscopic dilations between 2016 and 2017. From 2017 to early 2021, she did not complain of significant dyspnoea. She arrived at our clinic in May 2021 complaining of worsening dyspnoea.
At preoperative videolaryngoscopy, an ELS grade IIIb subglottic stenosis was diagnosed. Evone® FCV ventilation was employed. Radial incisions with CO2 laser Lumenis Encore Ultrapulse (Tel Aviv, Israel) coupled with a digital Acublade micromanipulator were performed. Endoscopic dilation with Savary bougies was done at the end of the procedure.

P.R., female, 84 years old

P.R. was affected by RRP. She had undergone several mi-

crolaryngoscopic procedures for papilloma excision by microdebrider and CO2 laser. At the last videolaryngoscopy, multiple laryngotracheal papillomas were detected. Derkay's score was used to assess the severity of RRP [4]. The site Derkay score was 17, while the clinical Derkay score was 8. Surgical intervention was carried out in emergency due to the patient's critical dyspnoea. Evon® FCV ventilation was employed due to the airway stricture and subglottic and tracheal extension of papillomas. The debulking of the lesion was carried out by microdebrider with angled-tip 4-mm laryngeal (22.5-cm-long) Skimmer blades (Medtronic-Xomed, Jacksonville, Florida). Suction was applied without irrigation in oscillating mode at speeds of 700 rpm. Laser photocoagulation of papillomas was performed with Wolf 445 nm TruBlue, by A.R.C. laser.

G.L., female, 80 years old

G.L. was affected by RRP. She underwent several microlaryngoscopic procedures for papilloma excision by microdebrider and CO2 laser. At the last videolaryngoscopy, multiple laryngotracheal papillomas were found, in particular at the level of the posterior commissure and subglottic area. The location and extension of papillomas, associated with the presence of iatrogenic posterior glottic stenosis (Bogdasarian grade II), caused mild dyspnoea. Site Derkay score was 7 and clinical Derkay score was 3, for a total Derjay score of 10. Evone® FCV ventilation was employed to ensure adequate exposure of the posterior commissure, subglottic and tracheal areas, allowing complete removal of papillomas. The patient underwent the same surgical approach as case 3.

R.A., female, 42 years old

R.A. was affected by RRP. She underwent several microlaryngoscopic procedures for papilloma excision by microdebrider and CO2 laser. At the last videolaryngoscopy, multiple laryngeal and tracheal papillomas were found. Site Derkay score was 4, with a bulky lesion at the subglottic level. Clinical Derkay score was 7, for a total Derkay score of 11. Evone® FCV ventilation was employed due to critical reduction of the airway lumen and subglottic and tracheal extension of papillomas. The patient underwent the same surgical approach of the case n. 3.

No minor or major complications were reported during anaesthesiologic and surgical procedures. The postoperative course of all patients was regular and all patients were discharged the day after the operation.

Discussion

Ensuring good exposure of the airway is key of successful transoral surgery, although attempting to introduce a conventional orotracheal tube in the presence of conditions that cause critical airway narrowing can be difficult to impossible. Moreover, the use of small orotracheal tubes (i.e. internal diameter 4.5 mm) would not allow safe ventilation or optimal visualisation of the surgical field. HFJV was developed as the first anaesthesiologic technique that allows surgeons to operate with a minute catheter inside the airways. This technique relies on a non-cuffed narrow endotracheal tube with an outside diameter of 4.3 mm and a specialised high frequency ventilator that insufflates small volumes of air at a supraphysiological rate (typically 100-150/min). In the case of neoplastic lesions located at the posterior third of the larynx, HFJV permits ventilating the patient through a narrow catheter that allows complete exposure of the posterior compartment of the larynx, thus reducing the need for orotracheal tube anterior dislodgement or tracheotomy and reducing the rate of positive posterior margins [5]. Nonetheless, the most common HFJV complications are hypoxia, hypercarbia, emphysema and blood aspiration for the absence of the cuff. The need to maintain a FiO2 of 30% during CO_2 laser procedures, together with the risk of hypoxia related to HFJV, requires frequent breaks during the surgery, to ensure proper oxygenation of the patient. In addition, most patients with laryngeal malignancies are heavy smokers and, therefore, have critical pulmonary comorbidities, which places them at greater risk of barotrauma. Moreover, HFJV causes fluttering of vocal cords that makes the procedures potentially less accurate [2]. In addition, any condition that may reduce expiratory flow, such as severe laryngotracheal stenosis, is to be considered an absolute contraindication to the use of HFJV, since it would increase the risk of air trapping and barotrauma. Lastly, the use of HFJV during treatment of obstructive laryngotracheal RRP is debated; HFJV creates an open ventilation system, causing airborne aerosolisation of HPV, leading to an increased infectious risk for healthcare workers.

To overcome these issues, the most recent step in small lumen ventilation is the development of a ventilator that is able to actively remove air from the lungs using negative pressure. Ventilators that use this novel method of active air removal and that do not rely on passive lung emptying are called 'flow-controlled' ventilators (FCVs) such as Evone® (Ventinova, Meerenakkerplein 7, 5652 BJ Eindhoven Netherlands) [2]. The negative pressure is generated using jet-flow (Bernoulli's principle) that is performed automatically. It is used with a cuffed small lumen tube (e.g., Tritube® by Ventinova), which optimises the ventilation and eliminates the risk of blood aspiration, aerosilisation, hypoxia and hypercapnia [2]. The Tritube has three lumens: one for the inflation and deflation of the cuff, one for measurement tracheal

pressure, and one lumen for patient ventilation. The most significant risk is that during the active removal of air from the airways any thick secretions may obstruct the lumen of the Tritube, thus preventing proper ventilation of the patient. For this reason, about an hour before the surgical procedure, it is recommended to perform premedication of the patient with a long-lasting anticholinergic drug to reduce secretions [2]. The Tritube is not certified as a laser-safe tube, and in case of accidental perforation of the cuff by laser the Evone® switches automatically to HFJV mode. Moreover, it is important to note that the Tritube is not made with an inflammable material, so that there is no risk for the patient. However, to avoid any issues, it is mandatory to protect the tube and the cuff with wet gauze and a $FIO_2 \leq 30\%$ should be maintained during laser procedures.

The Evone® system seems very promising: it can potentially overcome all the drawbacks of HFJV, providing stable and safe ventilation, with the benefit of increasing exposure of the working space for the surgeon. For these reasons, in case of high-grade subglottic stenosis and/or diffuse RRP, our choice is the Evone® system to reduce the risk of complications thanks to the presence of the cuff and the possibility to actively manage the expiratory phase, without the risk of air trapping, and with creation of a stable and wide transoral surgical field: the cuff preserves the airways from bleeding and protects the surgical team from viral aerosolisation during RRP surgery.

Finally, an additional field of application of the Evone® is in open surgical procedure for laryngotracheal stenoses, such as cricotracheal resection. The reduced calibre of the Tritube allows the small tube to be kept in place throughout the surgical procedure, avoiding the risk of hypoxia, blood inhalation, and contamination of the sterile surgical field, which is related to the need to remove and insert the tracheal tube several times during the different surgical steps. Evone® FCV allows for safe and ideal surgical transoral and cervicotomic visualisation of the laryngotracheal area in patients treated for critical airway strictures. It also has the advantages of HFJV which permit exposure of critical anatomical sites combined with the safety of traditional ventilation, reducing the need for pre- and postoperative tracheostomy in patients with a critical patency of the airway.

Conflict of interest statement

The authors declare no conflict of interest.

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Authors' contributions

All named authors meet the International Committee of Medical Journal Editors (ICMJE) criteria for authorship for this article, take responsibility for the integrity of the work as a whole, and have given their approval for this version to be published.

Ethical consideration

This study was approved by the Institutional Ethics Committee (Comitato Etico Regionale della Liguria) (protocol number 63/2021 - DB id 11240).

The research was conducted ethically, with all study procedures being performed in accordance with the requirements of the World Medical Association's Declaration of Helsinki.

Written informed consent was obtained from each participant/patient for study participation and data publication.

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