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Use of a Silicon Stoma Stent as an Interim Step in High-Risk Tracheostomy Decannulation

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Abstract

Objective. To describe use of a stoma stent to facilitate high-risk decannulation.

Methods. Retrospective chart review of 14 consecutive patients who received a stent from March 2013 to December 2016 at a quaternary health care service. Primary outcome measures were decannulation outcome and adverse events.

Results. Decannulation outcome: 12 of 14 patients had their tracheostomy tube (TT) removal facilitated by stent use. Patients had the stent for a median of 6 days (interquartile range, 49). Reasons for use included medical instability, risk of sputum retention, uncertain airway patency, and the need for ongoing airway access. All patients survived to discharge. One patient residing in the community has retained a stoma stent. Adverse events: One patient removed the stent on the day of insertion, necessitating reinsertion of the TT. Granulation tissue at the stoma site was seen in 2 patients.

Discussion. A tracheostoma will normally close within 48 hours following decannulation, which is problematic if TT reinsertion is required. By using the stent, reversal of decannulation becomes a simple ward-based procedure. In comparison to a TT, which is secured with ties, the stoma stent proved unsuitable for use in an agitated patient.

Implications for Practice. Decreasing total cannulation time is of benefit as patients with tracheostomy are subject to high rates of complications and adverse events. A stoma stent poses little risk and a low morbidity burden to the patient in comparison to alternative management.

Keywords

tracheostomy, decannulation, Montgomery cannula, patient safety/quality initiative (PS/QI)

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Most patients with tracheostomy insertion follow a straightforward path to either decannulation or discharge home with a permanent tracheostomy tube (TT). However, in some cases, the need for an ongoing artificial airway is less clear. Given that surgically and percutaneously created tracheostoma will close rapidly (<48 hours after decannulation), a device to maintain a patent stoma after removal of the TT allows clinicians to evaluate decannulation tolerance without the risk of stoma closure. Another feature of the Montgomery cannula (MC), which makes it desirable to patients and caregivers, is the reduction in care required in comparison to a TT. As the patient is able to breathe normally through his or her mouth and nose with an MC, there is no requirement for additional humidification as with a tracheostomy. It may be easier to cough pulmonary secretions to the mouth as there is no tracheal obstruction and most patients will no longer require invasive suctioning with an MC. It is possible to voice normally at all times with an MC, whereas enabling speech with a TT requires the use of a 1-way valve or capping. Tracheal stoma dressings are also no longer needed and simple cleaning of the stoma site in the shower is generally sufficient. This reduction in care may facilitate discharge out of the acute care environment to subacute care or the community.

Prompt, nontraumatic reinsertion of a TT can be performed if required when a stoma stent is in use. There have

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Figure 1. Montgomery long-term cannula. © Boston Medical Products.

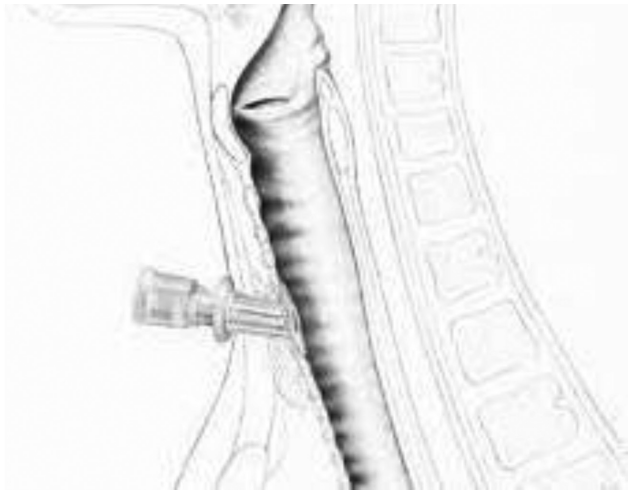

Figure 2. Transverse view of the Montgomery cannula shown in situ. © Boston Medical Products.

been some recent descriptions of the use of devices to maintain the tracheostoma to evaluate decannulation tolerance[1,2] or as a long-term alternative to TT.[3,4] Our multidisciplinary Tracheostomy Review and Management Service (TRAMS) completed this audit to evaluate the potential role of such a device at our health service.

The stoma stent used at our health service is the MC (Boston Medical Products, Boston, Massachusetts). It is a hollow silicon tube that sits securely in the tracheostoma, maintaining its patency without impinging within the tracheal lumen (**Figures 1** and **2**). It became available for clinical use in 1978 as an alternative airway in the presence of intermittent or permanent upper airway insufficiency in conditions including obstructive sleep apnea (OSA),[5-7] bilateral vocal fold paralysis, subglottic edema, laryngeal insufficiency, and other pathologies.[8,9]

While the MC can be used as an airway, it can also be occluded using the external plug-ring set and is secured anteriorly either by a faceplate or ring washer.[8,9] In this configuration, the MC allows evaluation of decannulation tolerance and maintenance of stoma patency, as well as permitting prompt and nontraumatic TT reinsertion if required.

In 2002, our institution established a multidisciplinary tracheostomy team (TRAMS) to manage patients with tracheostomy across 3 campuses and into the community.[10] This service model has been implemented at numerous centers worldwide.[11,12] The team consists of respiratory physicians, intensive care unit (ICU) doctors, clinical nurse specialists, physiotherapists, and speech pathologists. Other specialist services consulted as required include ear, nose, and throat (ENT) surgeons; thoracic surgeons; and medical specialists from the treating or parent unit.

This case series reviews MC use to describe and evaluate the safety and effectiveness of this tool as an interim step in high-risk decannulation. We hypothesize that use of the MC allows clinicians to simulate decannulation in high-risk patients while maintaining the tracheostoma to decrease the risks associated with reintubation or stoma dilatation in case of decannulation failure. This reduction of risk allows for earlier tracheostomy decannulation,[1] and although the patient still has a device in the tracheostoma, the MC has been described as more comfortable than a TT and associated with less tracheal secretions and improved vocalization.[3] We also report our experience with adverse events occurring during MC use.

Methods

An audit was conducted to identify all patients who received an MC during the period from March 2013 to December 2016. Inclusion criterion was any patient who had an MC inserted to facilitate decannulation during the study period.

Detailed medical record review of the identified cases was conducted, and the following information was retrieved; age, sex, primary diagnosis, tracheostomy insertion technique, length of the time the tracheostomy was in place, reason for insertion of an MC, location at time of MC insertion, duration of use of the MC, decannulation outcome, survival to hospital discharge, discharge destination, and adverse events. Ethical approval for the study was obtained from the Austin Health, Human Research Ethics Committee HREC no. LNR/16/Austin/357.

Accuracy of data collection was maximized by review of the data by 3 TRAMS clinicians who were familiar with the cases identified. Crosschecking of the medical record was conducted in any cases lacking consensus. Adverse events were defined as respiratory distress directly related to the presence of the MC, formation of granulation tissue, bleeding at the tracheostoma, and dislodgement of the MC.

The diameter of the MC chosen for insertion was matched to the external diameter of the patient's existing TT. The lower airway of all subjects was inspected prior to insertion with a tracheoscopy to assess airway anatomy and integrity and also to assess the depth of the pretracheal

tissues to enable accurate measurement of the length of cannula required.

Prior to the removal of the TT and MC insertion, a detailed entry was made into the patient's history as per our center-wide decannulation protocol. This document outlines the requirements for tracheostomy removal, by whom the procedure has been authorized, and actions to be taken in case of patient deterioration. The criteria used to indicate decannulation readiness were the presence of adequate airway protection against aspiration, adequate airway patency above the level of the tracheostomy tube, the ability to clear secretions from the airway, a stable respiratory status indicated by no new chest x-ray changes, minimal FiO_2 requirements, no need for invasive ventilation, and minimal to moderate sputum production only. Other considerations such as the initial reason for tracheostomy insertion being resolved, no further surgical procedures being planned in the short term, an adequate level of consciousness and cooperation, and the presence of medical stability were all discussed by the multidisciplinary team. As all of the cases were high-risk decannulations, intensive postprocedure protocols were in place, including half-hourly observations for the first 2 hours and constant pulse oximetry for the first 48 hours. All mandatory equipment necessary for reinsertion of the tracheostomy was left by the patient's bedside for 48 hours as per local decannulation protocol. In addition, the senior ICU medical staff on call for ward patients were informed of the procedure when the patients were not located in the ICU.

All patients and their care staff were instructed to keep the MC closed/plugged whenever possible. In the event of respiratory distress, stridor or increased work of breathing the MC could be briefly opened until the issue was resolved. All patients were provided with a personalized booklet, which explained the day-to-day care and emergency management of the MC. The infrequent use of the MC in our center necessitated significant staff education and monitoring of patients using the device. A replacement tracheostomy of a suitable size and one size smaller was available at the bedside in case of the need for emergency recannulation. Community-based patients were instructed to bring the booklet with them whenever they attended a hospital emergency or outpatient service, as this device is not widely used in our health care region.

Results

Fourteen patients were identified as having received an MC to facilitate decannulation during the study period; their characteristics are included in **Table 1**. Twelve of 14 subjects had their tracheostomy removal facilitated by using the MC as an interim step. In 1 case (case 3), the MC was removed by the patient on the day of insertion and was not considered beneficial in facilitation of decannulation. Of the remaining 13, 12 progressed to complete decannulation with only 1 retaining the MC long term (**Table 2**). Our overall success rate for decannulation

Table 1. Patient Characteristics.

Patient No.	Primary Diagnosis	Age, y	Sex	Reason for TT Insertion	Insertion Method	Time with TT	Reason for MC Insertion	Location at Insertion of MC
1	Multiorgan failure	33	F	FV	Percutaneous	52 days	Medically unstable	ICU
2	Muscular dystrophy	24	M	FV	Surgical	35 days	Poor sputum clearance	VWU
3	Refractory epilepsy	23	M	FV	Percutaneous	107 days	Poor sputum clearance	GW
4	Congenital myopathy	40	M	FV	Unknown	18 days	Poor sputum clearance	VWU
5	Bilateral vocal fold palsy	75	F	A	Unknown	44 months	Airway patency	GW
6	Bilateral vocal fold palsy	39	M	A	Surgical	35 months	Airway patency	GW
7	C6 tetraplegia in halo-thoracic vest	44	M	FV	Surgical	15 days	Maintain airway access	GW
8	Guillain-Barré syndrome	69	F	FV	Unknown	8 months + 22 days	Airway patency	VWU
9	Radiotherapy-induced laryngeal edema	60	M	A	Surgical	16 months	Airway patency	GW
10	C4 quadriplegia	45	M	FV	Unknown	27 days	Airway patency	GW
11	Liver/intestinal/pancreatic transplant	23	M	FV	Surgical	24 days	Medically unstable	ICU
12	Paracetamol overdose	20	F	FV	Surgical	33 days	Medically unstable	ICU
13	Medullary thyroid cancer	20	M	A	Unknown	7 years	Airway patency	GW
14	Head and neck cancer	81	F	A	Surgical	17 days	Maintain airway access	GW

Abbreviations: A, loss of upper airway including inability to intubate or concurrent head and neck surgery; F, female; FV, facilitation of ventilation; GW, general ward; ICU, intensive care unit; M, male; MC, Montgomery cannula; TT, tracheostomy tube; VWU, ventilator weaning unit.

Table 2. Patient Outcomes.

Patient No.	Days In Situ	Reinsertion of TT Required	Adverse Events
1	3	N	N
2	6	N	N
3	1	Y	Y (MC dislodged)
4	3	N	N
5	1	N	N
6	Ongoing	N	N
7	17	N	N
8	24 + 150	Y	Y (TT reinsertion + hypergranulation)
9	55	N	Y (hypergranulation)
10	7	N	N
11	4	N	N
12	5	N	N
13	63	N	N
14	49	N	N

Abbreviations: MC, Montgomery cannula; N, no; TT, tracheostomy tube; Y, yes.

using a stoma stent as an interim step in the cohort was 92%. Two patients successfully used noninvasive ventilation as part of their usual care while the MC was in place.

Three patients (cases 6, 9, and 13) were discharged into the community and 2 patients (cases 8 and 14) to our rehabilitation facility with the MC in situ. The TRAMS provided ongoing support to these patients. The 3 community-dwelling patients retained their MCs to monitor their airway patency over time, resulting eventually in safe removal in 2 cases.

Removal of the MC and definitive closure of the tracheostoma were not achieved in patient 6 who had bilateral vocal fold paresis, vocal tremor, and dysarthria after brain injury. At times during exercise/exertion or upper respiratory tract infection, this patient experienced stridor and the MC could be intermittently opened to ease shortness of breath. Trials of MC removal were discussed at length with the patient, family, and members of the multidisciplinary team. Consensus opinion held that the risk of airway loss was potentially catastrophic, and continued use was indicated. Prior to insertion of the MC, the client had lived in the community with a TT for 22 months. Three previous attempts at TT removal were unsuccessful. This patient and his family report that they greatly prefer the MC to the TT for comfort and ease of care.

Temporary recannulation with a TT was required in 1 patient (case 8). This subject transferred to our rehabilitation facility with the MC in situ for airway patency but after 24 days developed aspiration pneumonia necessitating emergency readmission to the acute care hospital, recannulation, and invasive ventilation. In this situation, recannulation of the patient could be easily and rapidly performed via the retained tracheostoma, facilitating a timely return to the invasive ventilation required. After resolution of the pneumonia, the MC was reinserted and the patient transferred back to rehabilitation for a further 150 days before definitive closure of the tracheostoma.

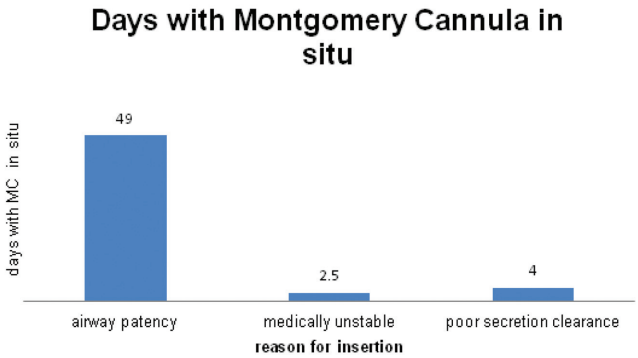

Figure 3. Mean number of days the Montgomery cannula remained in situ by reason for insertion.

We observed a relationship between the reason for MC use and duration of use. Those who had the MC inserted for monitoring airway patency retained it for a mean of 49 days in comparison to those who had the cannula introduced for risk of sputum retention (4 days) or medical instability (2.5 days) (**Figure 3**).

Subject 14 had an unusual indication for MC use. This patient required a TT briefly after head and neck surgery for airway patency while waiting for postoperative edema to resolve. Further surgical procedures to revise a microvascular flap were planned over a period of weeks to months, and the friable nature of the surrounding tissues made reintubation with an endotracheal tube unsuitable. Retention of the tracheostoma was therefore required, but the TT was not. The anesthetic team requested an MC for the interim period to enable TT reinsertion when required during sedation. The patient was able to transfer to a rehabilitation center between the surgeries with the MC in situ.

All patients survived to hospital discharge and returned home.

Adverse Events

We experienced 1 case where use of the MC was unsuccessful (case 3). The patient was acutely agitated and, despite close supervision, removed the MC after 10 hours. A TT was reinserted by our hospital's medical emergency team as per instructions in the medical record, leading to eventual decannulation without further use of the MC.

Two patients developed hypergranulation tissue (cases 8 and 9), resulting in irritation and pain at the stoma site. Treatment included topical application of silver nitrate to the hypergranulation tissue and increased frequency of stoma cleaning.[13] Resolution of the granulation tissue was only fully achieved after MC removal.

One patient required reinsertion of the TT after developing pneumonia during inpatient rehabilitation. Following resolution of the pneumonia in the acute hospital, the MC was reintroduced and the patient returned to rehabilitation.

Discussion

Literature on the topic of tracheostomy decannulation consists mainly of expert opinion[14-18] with a recent notable exception of the development of an as yet unvalidated predictive clinical score.[19] The most frequently cited indicators that decannulation can proceed are that the original reason for tracheostomy insertion has resolved, tolerance of capping or speaking valve use indicating upper airway patency is proven, and that the patient has the ability to protect the airway from aspiration as well as having an effective cough.[14-19] There is, however, a high level of practice variability in decannulation observed in the literature.[19] Use of a cannula that can maintain the patency of the stoma without obstructing the tracheal lumen offers an important adjunct to clinicians seeking to progress patients with an uncertain tolerance of decannulation.

Use of such a device, to specifically evaluate decannulation tolerance, has previously been described.[1] In a cohort of 384 weaning patients, Budweiser et al[1] used a tracheostomy retainer (TR) similar to an MC to facilitate decannulation, the TR being a silicon tube reinforced in sections with a metal coil with a flexible oval disc at the tracheal end, which seals the trachea proximally rather than distally. In contrast to the MC, the TR requires the use of tapes around the neck to secure the device, and its recommended duration of use is not more than 7 days. The authors report that almost half of their cohort used a TR, with 81% of these progressing to decannulation.

In the study by Budweiser et al,[1] the TR was used much earlier in the decannulation process than in our group. The TR was placed in patients who had as little as 6 to 8 hours free from invasive ventilation. In our cohort, all patients had been liberated from invasive ventilation for at least 72 hours or were successfully transitioned to noninvasive ventilation for a period of 48 hours. Very early MC insertion in the TR group may account for the failure to decannulate rate of 19.4% not seen in our cohort where only 1 patient failed to progress to eventual decannulation due to insufficient airway patency. Comparison between Budweiser et al[1] and our study is difficult as our cohort consisted mainly of patients with neuromuscular weakness and head and neck surgery complications, none of which are represented in Budweiser et al,[1] which was a mix of cardiopulmonary failure with some postsurgical and trauma patients. The benefit of changing much earlier in the decannulation process to a stoma retainer remains an area for further investigation.

The Hood stoma stent (Hood Laboratories, Pembroke, Massachusetts), which is another silicon cannula used to maintain the tracheostoma, was used in a group of 9 patients with high spinal cord injuries, mainly as a long-term device to allow access for positive pressure ventilation in patients using full-time diaphragm pacing and for the prevention of obstructive sleep apnea, with only 1 patient proceeding to decannulation.[4] The Hood stent as described by Hall and Watt[4] was mainly used as an alternative to long-term TT and not as a tool to facilitate decannulation.

This current case series most closely resembles the work of Bayan and Hoffman,[2] with 4 of their cohort of 20 being successfully decannulated (20%), 5 had the TT reinserted, and 11 retained the MC long term. The 4 patients in their group who proceeded to decannulation had the MC inserted for airway patency, but their mean duration of use was substantially longer at 30.8 months. A further 15 patients in their study had airway patency as at least one of the indications for MC insertion but were unable to either tolerate the MC or proceed to decannulation. Our successful decannulation rate of 93% could be attributed to a highly selective process when initially choosing candidates for the MC. We were consciously identifying patients in the acute setting who were planned for decannulation but were considered high risk. In the airway patency group, we followed patients closely after discharge, reevaluating their airway patency over time to assess for improvements, indicating suitability for decannulation.

Our choice of the Montgomery long-term cannula system is based on some characteristics that distinguish it from the 2 other stoma stents identified in this discussion. The TR as used by Budweiser et al[1] is also silicon but has a metal flap that occludes the tube proximally as opposed to the distal occlusion of the MC plug/ring set. The distal occlusion of the MC allows for easy opening of the stent if required in cases of compromised upper airway patency. The internal placement of the TR flap does not allow for this function. The metal flap and metal coil reinforcement of the TR may also render it incompatible with magnetic resonance imaging studies. The TR was also not recommended for use for more than 7 days, and many patients may require their stoma stent for much longer time periods to facilitate eventual decannulation.

The Hood stoma stent used by Hall and Watt[4] is also silicon but somewhat stiffer than the MC. It has a larger fixed faceplate and a fixed length and comes in curved or straight configurations. It is also available in different diameters and lengths as is the MC. The MC can be cut to length to suit before or after insertion, which makes it very easy to fit to patients, whereas the Hood requires more expertise on the part of the clinician to identify the appropriate fit prior to insertion. The Hood may be better suited for use in the restless patient, as it would appear to be more firmly held in place in comparison to the MC.

Our finding that patients requiring the MC to evaluate airway patency used it for longer periods in comparison to other uses may be related to the dynamic nature of airway patency. Airway patency, including vocal fold dysfunction, can fluctuate over time and can be influenced by numerous factors, including fatigue, tension, inflammation, and infection. Speech pathology treatment for this patient group can be effective and includes education on basic physiology and vocal hygiene. Previously, the patients in our cohort who required assessment of airway patency over time may have been managed with a permanent tracheostomy. By simulating decannulation using the MC in these patients, the sufficiency of their airway could be assessed during exertion or

infection over a period of time ranging from weeks to months.

The cannula can also be used to maintain tracheostoma patency in patients undergoing surgical procedures, such as laser and tissue debulking aimed at improving the patency of the upper airway. In this situation, patients have a TT reinserted during the surgical procedure to enable mechanical ventilation and then return to MC postoperatively for ongoing assessment of their airway patency. Patients who have the MC in situ without the need to open it and use it as an alternative airway can be considered to have a functionally adequate airway. The correlation between this functional assessment of airway patency and what is seen via direct visualization of the upper airway on tracheoscope presents as an area for further study.

In those patients who received the MC because of poor sputum clearance (cases 2, 3, and 4), it was possible to assess secretion clearance using techniques such as mechanical in/exsufflation and manually assisted coughing over a number of days. It can be argued that this trial could be achieved with a capped TT or use of a 1-way valve. In all 3 cases, this had been trialed and the patients were unable to consistently avoid invasive suctioning on occasion. The advantage of MC use over the capped or valved TT may be that the tracheal lumen is unobstructed, and hence secretion clearance via cough is easier to achieve.

The stoma stent was used in patients with medical instability (cases 1, 11, and 12) to enable trial decannulation without the risk of reintubation in case of deterioration requiring invasive ventilation. These patients had long ICU stays of 52, 24, and 33 days, respectively. All were in intensive care at the time of decannulation, and the potential benefits to the patient of TT removal (improved communication, improved swallow, reduced care needs) were achieved without loss of the tracheostoma.

Another feature of the MC, which makes it desirable to patients and caregivers, is the reduction in care required in comparison to a TT. As the patient is able to breathe normally through his or her mouth and nose with an MC, there is no requirement for additional humidification as with a tracheostomy. It may be easier to cough pulmonary secretions to the mouth as there is no tracheal obstruction, and most patients will no longer require invasive suctioning with a MC. It is possible to voice normally at all times with a MC, whereas enabling speech with a TT requires the use of a 1-way valve or capping. Tracheal stoma dressings are also no longer needed, and simple cleaning of the stoma site in the shower is generally sufficient. This reduction in care may facilitate discharge out of the acute care environment to subacute care or the community.

Adverse events associated with MC use were low in this cohort. The patients who experienced granulation tissue formation had also experienced this same problem with a TT prior to the MC, and it is hypothesized that any prosthesis may have had the same effect. The use of the MC in a restless patient proved to be unsuitable. The stoma stent of choice in this study (the MC) sits in the tracheostoma held in place by 2 small internal flanges and an external plug-ring set or faceplate, both of which are designed to allow for easy removal of the device for cleaning and changing. Restless or delirious patients are more suited to a TT, which can be secured more safely in the tracheostoma with ties to prevent inadvertent removal.

A limitation of our study is the retrospective case series with small numbers, indicating our practice of only using an MC in patients who are high-risk decannulations. Our service sees approximately 110 patients per year with a new or primary tracheostomy insertion. Of the patients who received a tracheostomy during their admission in the period 2015 to 2017, 88% were decannulated. The rest of our patients have a permanent TT most commonly for invasive ventilation secondary to neuromuscular disorders or upper airway insufficiency, generally secondary to malignancy.

Earlier insertion of an MC may be indicated in some patient groups to facilitate decannulation, potentially reducing length of stay. Further investigation of MC use in a larger patient cohort, including investigation of earlier insertion, a qualitative exploration of the patient experience of MC in comparison to TT, and investigation of clinicians' perception of MC usefulness, will further inform our practice in this area.

Implications for Practice

The MC was a useful interim step in cases where there was doubt over a patient's ability to safely tolerate decannulation. Conversely, we acknowledge that there is potential for clinicians to overuse this device where there is the possibility of successful decannulation without the interim step. However, the MC poses little risk and a low morbidity burden to the patient in comparison to complete decannulation with stoma closure.

Decreasing total cannulation time is beneficial as patients with tracheostomy are subject to high rates of complications and adverse events.[16,20]

The MC appeared to be unsuitable for use in patients who are restless or delirious as it is a less secure airway than a standard TT secured with ties around the neck.

Author Contributions

Jacqueline Ross, designed study, collected data, analyzed data, wrote article; **Kristy McMurray**, designed study, collected data, revised article; **Tanis Cameron**, substantial contribution to the concept of the study and interpretation of the work, revised article; **Celia Lanteri**, analyzed data, revised article.

Disclosures

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