



Tracheostomised patients in the community have lower rates of tube colonisation

Joseph Freeman¹, Marin Duvnjak², Maria Viola-Moll², Faruque Riffat^{3,4,5}

¹Faculty of Medicine and Health, University of Sydney School of Medicine, New South Wales, Australia; ²Department of ENT Surgery, Westmead Tracheostomy Service, Westmead, Australia; ³Department of ENT Head Neck Surgery, Westmead Hospital, Wentworthville, Australia; ⁴Department of ENT Surgery, Macquarie University, Sydney, Australia; ⁵Department of ENT Surgery, University of Sydney, Sydney, Australia

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Correspondence to: Faruque Riffat, BSc (Med), MBBS (Hons 1), MS, FACS, FRACS. Department of ENT Head Neck Surgery, Westmead Hospital, PO Box 533, Wentworthville, NSW 2145, Australia. Email: Faruque.riffat@sydney.edu.au.

Background: Tracheostomised patients present a challenging inpatient burden in acute hospitals. It has been postulated that pathogenic colonisation rates of tubes may be lower within hospital settings, discouraging early discharge. This study analyses the rate of tracheostomy tube colonisation in those managed as inpatients compared to outpatients. A secondary factor assessed whether colonisation of cuffed tubes, with resultant impaired mucociliary clearance, differed from uncuffed tubes.

Methods: This cohort was collected non-selectively from 65 consecutive adult patients reviewed by the Westmead Hospital, Department of Otolaryngology tracheostomy service in the hospital and community between September 2017 and March 2019. Patients were controlled for medical variables.

Results: Sixty-five patients were analysed for rates of pathogenic microbial colonisation. There were significantly fewer patients with colonised tubes in outpatients compared to inpatients (38.1% vs. 65.9%, $\chi^2=4.485$, $P=0.034$). There was little to no evidence that there was a true difference in colonisation between patients with fenestrated and non-fenestrated tracheostomy tubes (53.8% vs. 59.0%, $\chi^2=0.167$, $P=0.683$).

Conclusions: This study suggests that care of tracheostomised patients in the community when safe should be encouraged and fear of colonisation of tubes should not confound this. This difference was unlikely due to differing rates of fenestrated or non-fenestrated tubes as there was no statistically significant difference between those groups.

Keywords: Tracheostomy; infection; fenestrated; community

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Introduction

Tracheostomy is a common procedure done to form a surgical airway. It is indicated for patients with prolonged upper airway obstruction or prolonged need for mechanical ventilation. The procedure involves creation of a stoma (surgical opening) in the anterior neck and trachea providing an alternate entry point for intubation and ventilation (1). Common aetiologies involve head and

neck cancer, stroke, traumatic brain injury, neurological degeneration, and airway stenosis.

Tracheostomy is generally preferred over prolonged translaryngeal intubation for reasons including ease of tube change (after maturation of stoma) and suctioning, increased speech and swallowing function, patient management in community, and increased patient comfort (2).

Patients commonly require tracheostomies for a long duration of months and years (2). Therefore, questions

Table 1 Participant inclusion and exclusion criteria

Inclusion criteria
Inpatient or outpatient
Pre-existing or new patients
Within or outside usual catchment of Westmead tracheostomy service
Surgical or percutaneous tracheostomy
Exclusion criteria
Patient seen for second time in study period (patients data collected only once on initial appointment)
Paediatric (<16 years)
Emergency tracheostomy change
Requiring active machine ventilation
Active lower respiratory tract infection
Immunosuppressed

of long-term management are highly impactful to patient wellbeing.

Technological advancements and the rising number of tracheostomies performed internationally has led to many of those with long-term tracheostomies being managed as outpatients in the community (3,4). Improved outcomes through the use of dedicated tracheostomy teams also contributes to increased preference for management of tracheostomy in the community (5). The Westmead tracheostomy service provides specialist level input in the community through clinical nurse consultants. Patient preference and hospital economic incentives commonly align with regards to community care (6). Due to the large number of patients and evidence of safety, Westmead tracheostomy service is increasingly utilising community management.

Choice of tracheostomy tube used by patients is critical in optimal management and transition to community. Tubes may utilise an inflatable cuff and be non-fenestrated so that airflow is only via the stoma. Fenestrated, uncuffed tubes allow patients to occlude the stoma with a speaking (one-way) valve or occlusion cap facilitating upper airway flow and phonation. Immediately upon stoma formation, a non-fenestrated cuffed tube is used to maximally protect the airway. Subsequently, after clinical and functional assessment, patients may change to a fenestrated, uncuffed tube.

When used appropriately, fenestrated tubes can improve phonation and speech, swallowing, and quality

of life. These benefits of fenestrated tubes are weighed against risks including granulation tissue formation and potential for increased risk of colonisation and infection. Possible mechanisms of increased risk include the area of fenestrations providing space for accumulation of debris, and connection of the lower airways to the nasal and oral spaces.

This study provides evidence regarding microbial colonisation of tracheostomised patients in the community versus formal health settings and considers as a secondary outcome, the effect of choice of fenestrated versus non-fenestrated tube. This secondary outcome aims to capture a possible confounding factor as outpatients are more likely to use fenestrated tubes than inpatients.

The authors hypothesise that the lower density of pathologic microorganisms in the home environment, in concert with multidisciplinary support and training, may produce a lower rate of tracheostomy tube colonisation. This may lead to less clinical infection as several studies support that indwelling device colonisation leads to infection (7,8).

We present the following article in accordance with the STROBE reporting checklist (available at <http://dx.doi.org/10.21037/ajo-20-84>).

Methods

Ethical approval

This study was approved by the Westmead Hospital Ethics Committee (QA-5426) and was performed in accordance with the ethical standards laid down in the Declaration of Helsinki (as revised in Brazil 2013). All patients provided informed consent.

Population

This dataset was collected prospectively and non-selectively. It includes 65 consecutive adult patients reviewed by the Westmead Hospital, Department of Otolaryngology tracheostomy service between September 2017 and March 2019. These patients therefore represent a sample of all patients in the Westmead Tracheostomy Service, though restricted by inclusion and exclusion criteria, defined in *Table 1*. The first analysis of the data showed that there was no association between timing of tracheostomy tube changes on microbial colonisation rates (9). This study will re-analyse this existing population.

Patients with both surgical and percutaneous tracheostomies were included. Ongoing follow up and review were provided to all study participants including those managed in the home however tracheostomy tube changes were carried out exclusively in the hospital for patient safety.

Patients were excluded from the study if under 16 years, underwent emergency tracheostomy change due to dislodgement or obstruction, required active machine ventilation, active lower respiratory tract infection, or were immunosuppressed. This is shown in *Table 1*.

Study procedure and data collection

Participants provided informed consent and were provided with a participant information sheet. All participants were followed to ensure ongoing coordinated care. Tube changes were at an interval of 2–4 weeks after stoma formation then usually 4–6 weekly and up to 3-monthly at the discretion of the head of the tracheostomy service. At each tube change a detailed history and clinical examination was performed. This included examination of the external stoma site and flexible nasendoscopy attempting to visualise the proximal and distal extent of the tracheostomy tube to confirm positioning, identify current and potential complications including stenosis, erosion and granulation, and to analyse for reversibility of the factors leading to tracheostomy.

Routine tracheostomy tube changes were undertaken with aseptic technique as per local health district protocol. At the time of tube change signs of clinical infection were sought and microbiological swab specimens were taken separately from the cuff/outer-cannula and tip/inner-cannula. Specimens were then provided to a pathological laboratory for microscopy, culture, and sensitivity (MCS). Bacterial culture result was used as a primary variable in subsequent analysis. It was also considered a surrogate for biofilm formation. Electronic medical records were accessed for further information. There were no records with missing data.

All collected data was entered into a password-protected spreadsheet. Medical data collected were history of smoking, hypertension (defined as prescribed regular antihypertensives), chronic obstructive pulmonary disease (defined as an FEV1/FVC <0.7 post bronchodilator), obstructive sleep apnoea (defined as apnoea-hypopnea Index >5), gastroesophageal disease, asthma, diabetes, and cardiovascular disease. Variables collected about tracheostomy tube were time since insertion, indication,

time since last change, number of times inner cannula changed per day, tube make, tube inner diameter, fenestrated/non-fenestrated, cuffed/uncuffed, fixed/adjustable flange, MCS of cuff/outer-cannula, MCS of tip/inner-cannula, and mechanical ventilator use.

A tracheostomy tube was considered positive for colonisation with a given organism only if both swabs (from inner and outer) grew that microorganism. A tube was considered negative for pathogenic colonisation if the organism grew on only one swab or if the organism was deemed 'normal skin flora'.

Analysis

This study retrospectively analysed the prospectively collected cohort for pathogenic colonisation rate under two sets of variables: inpatient versus outpatient and fenestrated tube versus non-fenestrated tube. In describing the data, categorical variables were presented with percentages and raw numbers, and continuous parametric data with means and standard deviations.

Hypothesis testing was conducted on binary categorical variables with chi-square testing with P value less than 0.05 considered statistically significant. All data analyses were performed in Microsoft Excel for Office 365 MSO (16.0.12614.20348).

Results

Sixty-five patients met inclusion criteria and having provided informed consent were enrolled into the study. They were analysed for rates of colonisation between inpatient versus outpatient and fenestrated versus non-fenestrated tubes using two sample χ^2 testing. Mean age of participants was 52.3 years and the majority were female (55.4%). Time with tracheostomy ranged from 6 years to 5 days with a mean of 14.8 months. *Table 2* describes patient demographic characteristics.

Significantly fewer outpatients (38.1%) compared to inpatients (65.9%) were found to have swabs positive for microbial growth ($\chi^2=4.485$, $P=0.03$). *Table 3* describes rate of colonisation in inpatients versus outpatients.

There was little to no evidence that there was a true difference between patients with fenestrated and non-fenestrated tracheostomy tubes (53.8% *vs.* 59.0%, $\chi^2=0.167$, $P=0.68$). *Table 4* describes rate of colonisation in those with fenestrated *vs.* non-fenestrated tubes.

The most cultured microorganism was *Pseudomonas*

Table 2 Patient demographics

Demographics	All patients	Culture +	Culture –
Number of patients	65	37	28
Mean age at presentation (SD), years	52.3 (15.2)	50.2 (15.8)	55 (14.1)
Gender, n (%)			
Male	29 (44.6)	21	8
Female	36 (55.4)	16	20
Smoking	19	12	7
Hypertension	29	13	16
COPD	6	3	3
OSA	2	0	2
GERD	21	9	12
Asthma	6	2	4
History of CVA	14	6	8

Table 3 Rate of pathogenic colonisation in inpatients vs. outpatients

Setting	All patients	Culture +	Culture –	% infected
Inpatient	44	29	15	65.9%
Outpatient	21	8	13	38.1%
Total	65	37	28	56.9%

aeruginosa (n=24). Other gram-negative bacteria found were *Klebsiella pneumoniae* (n=6), *Enterobacter cloacae* (n=2), *Enterobacter kobei* (n=2), and *Citrobacter* (n=1). Methicillin-sensitive *Staphylococcus aureus* was second most common overall (n=10) while only 2 instances of Methicillin-resistant *Staphylococcus aureus* were found. Two bacteria in a culture were found in 9 cases and no atypical bacteria were found. Table 5 describes cultured microorganisms.

Discussion

The results of this study support the initial hypothesis that tracheostomised patients in the community have lower rates of tube colonisation than those managed in the hospital.

Historically, patients have remained in hospital for extended periods to manage their tracheostomy. Hesitance to manage tracheostomised patients in the community has related to perceived higher risk of colonisation. This unfounded fear could lead to a staff perception of increased

Table 4 Rate of pathogenic colonisation in fenestrated vs. non-fenestrated tracheostomy tube

Tube type	All patients	Culture +	Culture –	% infected
Fenestrated	26	14	12	53.8%
Non-fenestrated	39	23	16	59.0%
Total	65	37	28	56.9%

Table 5 Microorganisms

Microorganisms	Number
Positive for 2 bacteria	9
<i>Pseudomonas aeruginosa</i>	24
Methicillin-sensitive <i>Staphylococcus aureus</i>	10
<i>Klebsiella pneumoniae</i>	6
<i>Enterobacter cloacae</i>	2
<i>Enterobacter kobei</i>	2
Methicillin-resistance <i>Staphylococcus aureus</i>	2
<i>Citrobacter</i>	1

risk of stomal site infection and aspiration related lower respiratory tract infections. Staff often have a presumption that carers and patients will be less competent in aseptic and clean techniques, and that a non-clinical environment may be more contaminated. Our previous publications highlight the importance of a tracheostomy MDT in knowledge and skill transfer leading to incremental, objective and assessable competency gain in carers (9).

The findings of this study suggest that there is not an important difference between pathogenic colonisation rates in the hospital versus community environment. Possible reasons for this finding include: healthcare worker related cross infection and breach of hand hygiene; reduced density of people and exposure to immunocompromised patients with higher microbial load in the community (9-11); less opportunity for cross-infection as fewer people responsible for the care of the tracheostomised patient (12); and greater ownership of care of tracheostomy by patients and/or carers.

Quality of tracheostomy care and provider comfort has an important impact on quality of life and safety of tracheostomised patients. This is true of care in both the hospital and the community. However, many centres lack standardised tracheostomy discharge protocols leaving

uncertainty around patient education and responsibility of caregivers (13). This has led to variations in care between inpatients and outpatients (14,15).

The finding of this research of lower rates of colonisation in the community may reflect that the Westmead Tracheostomy Service is multidisciplinary and provides a continuum of care through stoma formation, discharge, and community care. This kind of care has been shown to benefit patients (16,17). For example, multidisciplinary tracheostomy teams are associated with shorter duration of tracheostomy and increased use of speaking valve (18).

Reported benefits of care of tracheostomised patients in the community are wide-ranging. Management in outpatient settings is likely cost saving to the health system (19). In addition, there is reduced exposure to nosocomial infections and improved quality of life (20), propositions which are supported by the results of this study.

Thorough assessment of individual patient factors must take priority in determining appropriateness of managing tracheostomised patients in the community. Where patient factors allow and a specialised tracheostomy home service is available, the authors recommend management in the community due to expected lower rates of tube colonisation and possibly infection.

It was considered that tube type may confound any difference found in inpatients *vs.* outpatients. This is because inpatients are more likely to have non-fenestrated tubes while outpatients have often been weaned to use fenestrated tubes. However, it was found that confounding of the primary outcome of inpatient versus outpatient was unlikely as there was no significant difference in tube colonisation between patients with fenestrated and non-fenestrated tubes.

Additionally, this secondary outcome serves to simplify clinical reasoning in tube selection by diminishing pathogenic colonisation and possible infection risk as a concern. The authors recommend that choice of fenestrated tube be informed by holistic assessment of patient status and goals. Possible benefits of fenestrated tube include improved phonation, swallowing, and quality of life while risks of fenestrated tubes include granulation tissue formation, and aspiration and resultant pneumonia.

Cuffed tubes are indicated after stoma formation and where there is high risk of aspiration (11). Patients who tolerate continual cuff deflation, who do not require positive-pressure ventilation, and who are at low risk of aspiration may transition to fenestrated and cuffless tubes. Fenestrated tubes allow airflow through the upper airways

and phonation, and encourage development of the cough reflex (11). Fenestrations also increase tolerability of speaking or occlusion valves, thus facilitating weaning (21). The advent of fenestrated, cuffless tubes has aided community care of tracheostomised patients as they are more readily reinserted after decannulation due to mishap or at routine tube change. The authors recommend transition to cuffless and fenestrated tubes as early as can safely be achieved.

This study has limitations. Principally, small sample size may mean insufficient power to observe small differences in pathogenic colonisation rates, while observational methodology increases risk of confounding and bias. Randomisation and control are largely not practicable in this patient cohort. Positive bacterial culture of tracheostomy tubes indicates colonisation with potentially pathogenic organisms, but the observational nature of this study can only suggest increased rate of infection. Finally, generalisability is limited beyond a specialised multidisciplinary tracheostomy service.

In summary, significantly fewer outpatients were found to have colonisation of their tracheostomy tube compared to inpatients. This study finds a trend that requires further exploration. A holistic assessment of the patient should be made considering risks, clinical need, and patient preference. Where possible and compatible with overall assessment, management in the community may well be favourable. Such discussions will be aided by further research on factors influencing the safety and wellbeing of patients with tracheostomy tubes. Fear of increased pathogenic colonisation may not be a valid deterrent to care of tracheostomised patients in the community.

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Footnote

Reporting Checklist: The authors have completed the STROBE reporting checklist. Available at <http://dx.doi.org/10.21037/ajo-20-84>

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Ethical Statement: The authors are accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved. This study was performed in accordance with the ethical standards laid down in the Declaration of Helsinki (as revised in Brazil 2013). Ethics approval was obtained from the Westmead Hospital Ethics Committee (QA-5426) and all patients provided informed consent.

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