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Jason W Nickerson

ORIGINAL ARTICLES

Can an interprofessional tracheostomy team improve weaning to decannulation times?
A quality improvement evaluation
Cynthia Welton, Melissa Morrison, Marifel Catalig, Juliana Chris, Janos Pataki
There are several indications for percutaneous tracheostomy and, although it is a common bedside procedure performed by a surgeon in intensive care units, gaps exist in follow-up after transfer to the ward. Given that deficiencies in specialized tracheostomy management may lead to serious complications – some of which may be life threatening – it is important to address these knowledge gaps in particular management strategies. Prompted, in part, by the lack of formalized processes at the author’s institution and the scarcity of high-quality literature evidence supporting the value of interprofessional tracheostomy teams, this article describes the implementation of such a team and its impact on several metrics.

Southmedic OxyMask™ compared with the Hudson RCI® Non-Rebreather Mask™:
Safety and performance comparison
Keith Lamb, David Piper
The non-rebreather mask is an oxygen delivery system with many applications and has been a valuable tool in specific patient care scenarios. Under certain low-flow conditions, however, a lack of washout of exhaled gases and rebreathing of carbon dioxide may occur – a situation scarcely addressed in the literature. This bench study compared two commercially available products in an attempt to shed more light on this important issue.

Evidence regarding patient compliance with incentive spirometry interventions after cardiac, thoracic and abdominal surgeries: A systematic literature review
Aqilah Leela T Narayanan, Syed Rasul G Syed Hamid, Eko Supriyanto
Reducing postoperative pulmonary complications by improving postoperative lung expansion and ventilation is a primary goal after major thoracic surgeries, and can directly impact morbidity and downstream health care costs. Although deep breathing exercises, with or without devices, have demonstrated efficacy, the evidence regarding the utility of incentive spirometry has been inconclusive. Accordingly, this comprehensive literature search and review examined selected randomized controlled trials investigating several aspects of incentive spirometry interventions.

Early versus late tracheostomy for critically ill patients: A clinical evidence synopsis of a recent Cochrane Review
Allison Keeping
Although a general range has been recognized, evidence-based practice has yet to determine the optimal timing for tracheostomy during intubation. This article provides a synopsis of eight randomized controlled trials, including almost 2000 patients, highlighted in a recent publication, and examined several salient parameters such as mortality with regard to early versus late tracheostomy and length of follow-up, days spent in the intensive care unit and complications.

DEPARTMENTS

Advertisers’ Index

Health Careers & Classified Advertising

Calendar of Events
Respiratory therapists have long been known as keen innovators in clinical practice, and many of us consider this to be central to our professional identity. Many of us regard ourselves as a ‘go-to’ resource for other health professionals encountering challenging or unusual clinical cases, bringing a critical care perspective to all aspects of patient care, improvising new and needed modifications to medical equipment, and improving the processes of care to benefit our patients. Examples of this innovation emerge frequently in discussion and in presentation at conferences but, unfortunately, are rarely disseminated broadly and often are not systematically evaluated.

Publishing case studies is one mechanism for identifying promising practices, sharing challenging clinical cases and highlighting potentially effective approaches to rare events. Case studies are an opportunity to flag an issue of importance and to share a clinical experience with other professionals, and have particular importance for rare, or high-risk, low-probability events, as well as for new innovations that are not fully formed. They highlight challenges faced in delivering care and provide a mechanism for frontline clinicians to engage with others who may have had similar experiences.

Case studies are, however, often limited in their scope and, therefore, we need to be cautious of the weight assigned to their conclusions. The purpose of case studies is not to imply that their findings can or should be applied to entire patient populations, but rather to highlight unique and challenging situations encountered in the delivery of patient care. The value of reporting on small numbers of patients, however, needs to be viewed in the proper context, with a proper recognition of how case studies fit into a hierarchy of evidence for decision making.

Medical research is too-often guided by novelty more than reliability, and quantity more than quality, and many reward systems reinforce these problems across medicine as a whole (1). There is an obvious need to balance the need for innovation and novelty with quality and reliability, although it is also important to note that these are not mutually exclusive. In a discipline such as respiratory therapy, in which research driven by the profession is still in its early stages of developing, we need to be open to providing opportunities to highlight innovative and promising practices as a starting point for driving a more ambitious and rigorous program of research, and this is what we are aiming to achieve.

Many journals have moved away from publishing case studies for many of these reasons. We believe, however, that when properly contextualized and examined with their limitations in mind, case studies present a useful entry point for building a body of research in innovative respiratory therapy practices that, in Canada, too-often remain unreported, leaving good ideas behind closed doors. It is, therefore, our decision to continue to publish case studies and to encourage their submission from frontline clinicians whose experiences should drive or should be applied to entire patient populations, but rather to highlight unique and challenging situations encountered in the delivery of patient care. The value of reporting on small numbers of patients, however, needs to be viewed in the proper context, with a proper recognition of how case studies fit into a hierarchy of evidence for decision making.

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Case studies in respiratory therapy

Les études de cas en inhalothérapie

Depuis longtemps, l’innovation en milieu clinique est une force chez les inhalothérapeutes et nous sommes nombreux à la considérer comme un élément central à notre identité professionnelle. Souvent, divers professionnels en milieu de santé se tournent vers nous lorsqu’ils sont aux prises avec des cas cliniques inhabituels ou difficiles, preuve que les inhalothérapeutes abordent les divers aspects des soins en milieu intensifs, que nous improvisions de nouvelles modifications selon les besoins et toujours dans le but d’améliorer les processus de soins pour le bien de nos patients. Divers exemples de telles innovations font fréquemment l’objet des discussions et présentations lors de colloques et congrès. Malheureusement, ces innovations sont rarement diffusées et ne font souvent pas l’objet d’une évaluation systématique.

Grâce à la publication d’études de cas, on peut énoncer certaines pratiques prometteuses, partager des cas cliniques difficiles et présenter des approches possiblement efficaces lors d’événements rares. Les études de cas sont des occasions de souligner un enjeu d’importance et de partager une expérience clinique avec d’autres professionnels. Elles sont particulièrement importantes dans le cas d’événements rares ou à haut risque, mais à faible fréquence, ainsi que dans le cas d’innovations qui ne sont pas pleinement établies. Elles font ressortir les difficultés dans la prestation des soins et permettent aux cliniciens de première ligne d’échanger sur des expériences comparables.

Cependant, les études de cas sont souvent de portée limitée. Il faut donc mesurer avec prudence la valeur accordée à leurs conclusions. Les études de cas ne visent pas nécessairement à être utilisées pour l’ensemble des populations entières de patients, mais à faire ressortir des situations uniques et difficiles pour la prestation des soins. Comme elles portent sur un petit nombre de patients, il faut toutefois les percevoir dans le bon contexte, selon leur place dans la hiérarchie des données de prise de décision.

Les recherches en médecine sont trop souvent orientées par la nouveauté plutôt que par la fiabilité, par la quantité plutôt que par la qualité. En médecine, de nombreux plans de récompenses renforcent ces problèmes (1). Il est manifestement nécessaire de concilier la nécessité d’innover avec la qualité et la fiabilité, même si ces critères ne s’excluent pas mutuellement. Dans une discipline telle que l’inhalothérapie, où la recherche menée par la profession est en encore à ses balbutiements, il faut être ouvert aux occasions de souligner les pratiques novatrices et prometteuses pour encourager des programmes de recherche plus ambitieux et plus rigoureux. C’est ce que nous cherchons à réaliser.

Plusieurs revues ont cessé de publier des études de cas pour bon nombre de ces raisons. Nous sommes toutefois d’avis que, bien contextualisées et examinées en tenant compte de leurs limites, les études de cas représentent un point d’entrée fort utile pour monter un corpus de recherche sur les pratiques novatrices en inhalothérapie qui, au
more in-depth exploration and collaboration to understand new approaches to respiratory therapy and respiratory care for our patients.

A core component of the Journal’s mandate is to educate respiratory therapists on how to present their work in a peer-reviewed journal. Recognizing this, the Journal’s managing editor will be hosting a workshop on how to write a case study for publication at this year’s CSRT Annual Education Conference, specifically aimed at helping clinicians develop and refine this skill. Beyond this, we are working with our international editorial board to ensure that the Journal is viewed as a resource for publishing these kinds of reports not only for Canadian authors, but for respiratory practitioners around the world. We recognize the limitations of these reports, but also recognize that we need to provide a mechanism for respiratory therapists to share their successes and challenges in dealing with complex cases, and to leverage this as a starting point for building a more robust research agenda for the profession. This is why we will continue to publish these reports and provide a mechanism for clinicians to share their experiences.

Jason W Nickerson RRT FCSRT PhD, Editor-in-Chief

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1. Ioannidis JPA, Greenland S, Hlatky MA, et al. Increasing value and reducing waste in research design, conduct, and analysis. Lancet 2014;383:166-75.

Canada, ne sont souvent pas déclarées et occasionnent la perte des bonnes idées. Nous avons donc décidé de continuer de publier les études de cas et d’inciter leur soumission par les cliniciens de première ligne dont les expériences devraient susciter une exploration et une collaboration plus approfondies, dans le but de mieux comprendre les nouvelles approches en inhalothérapie et en soins respiratoires.

Au cœur du mandat de la Revue ont découvre l’éducation des inhalothérapeutes à titre de présenter leurs expériences en milieu de travail dans des publications révisées par des pairs. C’est pourquoi l’éditeur en chef de la Revue animera un atelier sur la rédaction d’une étude de cas en vue de sa publication lors du prochain congrès annuel de la SCTR, afin d’aider les cliniciens à améliorer et peaufiner cette compétence. Par ailleurs, nous collaborons avec le comité de rédaction international pour que la Revue soit envisagée pour publier ce type de rapports, non seulement par des auteurs canadiens, mais aussi par des inhalothérapeutes sur le plan international. Nous concédons la présence de limites face aux études de cas, mais constatons également la nécessité de fournir aux inhalothérapeutes des occasions de partager leurs réussites et leurs difficultés à l’égard de cas complexes. Nous souhaitons également nous en servir comme d’une rampe de lancement pour construire un programme de recherche plus solide au sein de la profession. C’est pourquoi nous continuerons de publier les études de cas et de permettre aux cliniciens de partager leurs expériences.

Jason W Nickerson RRT FCSRT Ph. D., rédacteur en chef

RÉFÉRENCES
1. Ioannidis JPA, Greenland S, Hlatky MA et coll. Increasing value and reducing waste in research design, conduct, and analysis. Lancet 2014;383:166-75.
BACKGROUND: Percutaneous tracheostomy is a common procedure in the intensive care unit and, on patient transfer to the wards, there is a gap in ongoing tracheostomy management. There is some evidence that tracheostomy teams can shorten weaning to decannulation times. In response to lengthy weaning to decannulation times at Trillium Health Partners – Credit Valley Hospital site (Mississauga, Ontario), an interprofessional tracheostomy team, led by respiratory therapists and consisting of speech-language pathologists and intensive care physicians, was implemented.

OBJECTIVE: To evaluate the interprofessional tracheostomy team and its impact on time from weaning off mechanical ventilation to decannulation; and time from weaning to speech-language pathology referral.

METHODS: Performance metrics were collected retrospectively through chart review pre- and post-team implementation. The primary metrics evaluated were the time from weaning off mechanical ventilation to decannulation, and time to referral to speech-language pathology.

RESULTS: Following implementation of the interprofessional tracheostomy team, there was no improvement in decannulation times or time from weaning to speech-language pathology referral. A significant improvement was noted in the average time to first tracheostomy change (36.2 days to 22.9 days; P=0.01) and average time to speech-language pathology referral following initial tracheostomy insertion (31.8 days to 26.3 days; P=0.01).

CONCLUSION: An interprofessional tracheostomy team can improve the quality of tracheostomy care through earlier tracheostomy tube changes and swallowing assessment referrals. The lack of improved weaning to decannulation time was potentially due to poor adherence with established protocols as well as a change in mechanical ventilation practices. To validate the findings from this particular institution, a more rigorous quality improvement methodology should be considered in addition to strategies to improve protocol compliance.

Key Words: Decannulation; Intensive care; Interprofessional; Quality improvement; Respiratory therapy; Tracheostomy

Can an interprofessional tracheostomy team improve weaning to decannulation times? A quality improvement evaluation

C Welton, M Morrison, M Catalig, J Chris, J Pataki. Can an interprofessional tracheostomy team improve weaning to decannulation times? A quality improvement evaluation. Can J Respir Ther 2016;52(1):7-11.
provided to patients with tracheostomies on the wards, an interprofessional tracheostomy team was implemented in 2011 at Trillium Health Partners – Credit Valley Hospital site. The interprofessional team was led by RTs who liaised with intensive care physicians, speech-language pathologists and nurses to advocate for quality patient care and timely decannulation.

The primary objective of the present quality improvement study was to evaluate the impact of an interprofessional tracheostomy team on time from weaning off mechanical ventilation to decannulation; and time from weaning to speech-language pathology (S-LP) referral. Secondary measures included time from tracheostomy insertion to first tracheostomy tube change, time from corking to decannulation and time from tracheostomy insertion to S-LP referral. Tertiary measures evaluated were time from tracheostomy insertion to weaning, time from weaning to corking and time from weaning to initial swallowing assessment.

METHODS

Design
The present study was a retrospective analysis in which performance metrics were collected through manual chart review pre- and postintervention.

Setting
The present quality improvement initiative was conducted in the ICU at the Credit Valley Hospital, a 19-bed medical surgical unit that provides continuous monitoring and invasive therapy including mechanical ventilation. Trillium Health Partners is an academic community hospital that consists of three main sites, Credit Valley Hospital, Mississauga Hospital and Queensway Health Centre. A full range of acute health care services, as well as specialized community-based programs, are offered. In 2014 to 2015, there were 1233 inpatient beds available, 61,844 inpatient admissions and 63,525 surgical procedures completed.

Interprofessional tracheostomy team
A working group consisting of respiratory therapy, S-LP and physician representatives came together to form a model for the interprofessional tracheostomy team and created documents to guide clinical practice. A low-risk decannulation pathway developed by Alberta Health Services (5) was referenced to create the team structure and processes. The interprofessional tracheostomy team started on October 18, 2011. The team, which remains in place, consisted of an intensive care physician, an RT and a speech-language pathologist who met weekly for rounds to discuss all patients with a tracheostomy on the wards. Preprinted orders were developed for tracheostomy tube cuff deflation, downsizing, corking and decannulation, which enabled the RT to perform orders according to an algorithm as opposed to requiring a physician order for each individual procedure. Corking was to be implemented for a maximum of 24 h, if tolerated, then the patient would be decannulated in consultation with the tracheostomy team physician. The preprinted orders were developed by the working group using the low-risk decannulation pathway (5) as a key reference. These orders were approved by several hospital committees before being put into practice. An interprofessional policy and procedure was created for all aspects of tracheostomy care and weaning to guide nursing and RT practice. The hospital policy that defined that the first tracheostomy tube must be changed by a physician after one month was modified to allow the RT to change the tube 10 days postinsertion according to preprinted orders and communication with the team. This change was accomplished in alignment with the respiratory therapy scope of practice legislated by the Regulated Health Professions Act (1991) in Ontario.

Data collection
The primary performance metrics collected were the time from weaning from mechanical ventilation to decannulation, and time from weaning to referral to S-LP. Secondary metrics included time from tracheostomy insertion to first tracheostomy tube change, time from corking to decannulation and time from tracheostomy insertion to S-LP referral. Tertiary measures collected were time from tracheostomy insertion to weaning, time from weaning to corking and time from weaning to initial swallowing assessment. Primary, secondary and tertiary measures are graphically presented in Figure 1.

Pre-intervention data were collected retrospectively between October 1, 2009 and October 17, 2011. Tracking forms for patients with a tracheostomy were not routinely collected in the respiratory therapy department before 2009 and, therefore, were not available. Postintervention data were collected prospectively between October 18, 2011 and May 22, 2014. These data were collected by the RTs using patient-specific tracking forms for the postintervention group. Patients with a tracheostomy were identified through RT record keeping documents utilized for transfer of information between shift changes. Performance metrics were collected by reviewing progress notes, physician consult notes and flowsheets. In some cases, metrics were missing from the tracking forms for the postintervention group; therefore, retrospective chart reviews were performed to collect the missing data. In cases for which the metrics could not be easily located from chart reviews, the patient(s) were excluded. Performance metrics for each patient were tabulated on a computer spreadsheet (Excel, Microsoft
Impact of an interprofessional tracheostomy team

Corporation, USA). Twenty patients were in the pre-intervention group and 24 patients were in the postintervention group. Inclusion criteria included patients who were successfully decannulated. Exclusion criteria included patients who had a permanent tracheostomy, were discharged home and/or patients who died with a tracheostomy in situ.

Data analysis
Calculations were performed using Excel to measure the number of days between performance metrics. Mean days were calculated and compared between the pre- and postintervention groups, in addition to SDs and P values. P values were calculated using a simple independent two-tailed Student’s t test. In addition to the dates of procedures and assessments, patient data were collected to compare patient age, sex and main indication for tracheostomy to determine whether there were any notable differences between the pre- and postintervention groups. Patient age was compared using a simple independent Student’s t test and sex was compared using a χ² test. Differences were considered to be statistically significant at P<0.05. Statistical analysis was performed using StatPlus Professional version 5.8.4.3 (AnalystSoft, USA).

RESULTS

Patient characteristics
Table 1 summarizes the mean patient age and male sex percentage compared pre- and postintervention. There was no statistically significant difference between age and sex in the pre- and postintervention groups. The primary indication for tracheostomy differed across groups; although the majority of tracheostomies in both groups were performed to facilitate weaning from mechanical ventilation, this percentage was higher in the pre-intervention group. In the postintervention group, 37.5% (n=9) of patients had a tracheostomy inserted for airway protection, compared with only 20% (n=4) of patients in the pre-intervention group (Table 2).

Primary performance metrics
As presented in Figure 2 and summarized in Table 3, there was an increase of 4.5 days from weaning to decannulation when comparing pre- and postintervention groups; however, this difference was not statistically significant (P=0.62). The mean number of days between weaning from mechanical ventilation and S-LP swallowing referral improved by 7.8 days; again, this difference was not statistically significant (P=0.27) (Figure 3, Table 3).

Secondary performance metrics
The time between initial tracheostomy insertion and the first tube change was significantly different (13.3 days; P=0.01) when comparing pre- and postintervention groups, as shown in Figure 4. The time to S-LP referral following initial tracheostomy insertion also was significantly different (25.5 days; P=0.01) (Table 3). There was no significant difference in corking to decannulation times (Table 3).

Tertiary performance metrics
The time from tracheostomy insertion to weaning, or the duration of mechanical ventilation post-tracheostomy insertion, was noted to be significantly shorter in the postintervention group (11.3 days versus 28.8 days; P=0.03). Other tertiary metrics, including weaning to corking time and weaning to initial swallowing assessment, were not statistically significantly different (Table 3).

Survey results
The results of the survey completed by staff who used the tracheostomy team (n=10) revealed that 86% of staff believed that the team had improved patient care. Members of the team who completed a survey (n=12) reported that 100% found the team to be beneficial; 83% believed that the team had improved weaning to decannulation time; and 83% believed that communication between the interprofessional team had improved.

DISCUSSION
The interprofessional tracheostomy team was implemented at the Credit Valley Hospital site of Trillium Health Partners to improve the quality of care and experience for patients with a tracheostomy on the wards. The main findings after evaluation of this intervention were that there was no significant change in the primary measures of

| TABLE 1
Patient demographics pre- and post-interprofessional tracheostomy team implementation |
|-----------------|-----------------|-----------------|
| Demographic     | Pre (n=20)      | Post (n=24)     |
| Age, years, mean| 61.6            | 61.0            |
| Male sex, %     | 55.0            | 41.7            |
| P               | 0.90            | 0.38            |

| TABLE 2
Primary indication for tracheostomy pre- and post-interprofessional tracheostomy team implementation |
|---------------------------------|-----------------|-----------------|
| Tracheostomy indication         | Pre (n=20)      | Post (n=24)     |
| Airway obstruction              | 1 (5.0)         | 1 (4.2)         |
| Airway protection               | 4 (20.0)        | 9 (37.5)        |
| Facilitation of weaning         | 15 (75.0)       | 13 (54.2)       |
| Secretion clearance             | 0 (0)           | 1 (4.2)         |
| Data presented n (%)            |                 |                 |
various wards because there is no designated, specialized unit for these patients. At our institution, patients with a tracheostomy are located on the medical-surgical wards. Weaning was lessened once a patient had their endotracheal tube changed and their tracheostomy tube was maintained. It was noted, however, that there was a significant improvement in some secondary and tertiary metrics, including the time to first tracheostomy tube change and time to S-LP swallowing referral following initial tracheostomy.

Tracheostomy weaning

To proceed with tracheostomy removal, a patient must be assessed to determine the likelihood that they will tolerate decannulation. This includes corking trials to assess whether the patient can breathe around the tracheostomy tube and through their upper airway. If corking trials are not initially tolerated, it is common practice at our institution to downsize the tracheostomy tube. As demonstrated in Figure 4, our results revealed that the time to first tracheostomy tube change was significantly improved following tracheostomy team implementation. This is an important step in the weaning to decannulation process. One of the main reasons for this finding was due to the updated hospital policy, which now allowed for RTs to perform the first tracheostomy tube change after 10 days. Allowing RTs to work to their full scope of practice enables immediate data entry and facilitates weaning. The second possible explanation for this difference is that more patients had a tracheostomy inserted for airway protection in the postinterprofessional tracheostomy team implementation group. Improved weaning practices can explain the decrease of 17.5 days in time from tracheostomy insertion to weaning. The second possible explanation for this difference is that more patients had a tracheostomy inserted for airway protection as compared to the pre-intervention group. Although a comparison of performance metrics stratified into subgroups according to indication for tracheostomy would be beneficial, it was not warranted in the present study due to the small sample sizes. This is a potential area for future research.

Improved decannulation times were likely not evident due to poor adherence with established protocols. To improve compliance, regular audits and feedback should be undertaken to encourage the team to strive for continuous improvement. An electronic system that would enable immediate data entry is one possible solution to provide real-time data to staff to improve compliance. An additional reason for this is that corking and weaning to decannulation times did not significantly change, which may indicate a lack of improvement post-interprofessional tracheostomy team implementation.

| Measure | Metric | Days, mean ± SD | Change, days | p |
|---------|--------|-----------------|-------------|---|
| Primary | Weaning to decannulation | 27.3±32.1 (n=20) | 31.8±26.5 (n=24) | 4.5 | 0.62 |
| Secondary | Tracheostomy insertion to first tube change | 36.2±18.4 (n=13) | 22.9±11.8 (n=22) | 13.3 | 0.01 |
| Secondary | Corking to decannulation | 4.8±3.9 (n=16) | 8.5±15.6 (n=22) | 3.7 | 0.35 |
| Secondary | Tracheostomy insertion to speech-language pathology referral | 51.8±37.2 (n=19) | 26.3±26.3 (n=21) | 25.5 | 0.01 |
| Tertiary | Tracheostomy insertion to weaning | 28.8±32.2 (n=20) | 11.3±16.2 (n=24) | 17.5 | 0.03 |
| Tertiary | Weaning to corking | 25.3±35.1 (n=16) | 23.0±17.4 (n=22) | 2.2 | 0.80 |
| Tertiary | Weaning to initial swallowing assessment | 25.4±31.2 (n=19) | 22.0±17.7 (n=21) | 3.4 | 0.68 |

Figure 4) Comparison of time to first tracheostomy tube change pre- and post-interprofessional tracheostomy team implementation

TABLE 3 Summary of primary, secondary and tertiary results pre- and post-interprofessional tracheostomy team implementation

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S-LP referral and assessment
The primary measure of time from weaning to S-LP referral did not reveal a statistically significant change with the implementation of the interprofessional tracheostomy team but did shorten it by 7.8 days, which has clinical implications on the quality of patient care. Our tertiary metric of time from weaning to initial swallowing assessment was also shortened (by 3.4 days); however, this was not statistically significant. Before implementation of the team, S-LP staff members were not informed of all patients who had a tracheostomy and some patients may have been started on oral nutrition without a formal swallowing assessment by a speech-language pathologist, thereby increasing the risk for aspiration and potential complications during the patient’s stay. For a speech-language pathologist to see a patient for swallowing or communication, a physician referral was necessary, putting the onus on the physician to initiate this referral for timely patient care. However, having preprinted orders as part of the process with the tracheostomy team for all tracheostomy patients ensured an automated notification process for S-LP. Also, as evident in the postimplementation survey, having an interprofessional tracheostomy team present meant better communication between S-LP and RTs, enabling the speech-language pathologist to determine candidacy for a swallowing assessment. With timely S-LP services, patients could be placed on the most appropriate diet textures and liquid consistencies to decrease aspiration risk and, ultimately, improve the quality of patient care. Apart from swallowing assessments and management, speech-language pathologists also had the opportunity to work closely with RTs to determine candidacy of speaking valves, which may have improved a patient’s quality of life.

Our secondary metric of tracheostomy insertion to S-LP referral time significantly improved following the tracheostomy team initiative. Duration of mechanical ventilation was noted to be shorter in the postintervention group, which may have confounded the metric of tracheostomy insertion to S-LP referral time. Based on our results, we would expect the time for this metric to decrease, on average, by 17.5 days; however, we witnessed a difference of 25.5 days. An explanation for the significant improvement in this measure was the use of the preprinted orders. Although the orders were designed to be implemented after weaning from mechanical ventilation, some patients were started on the orders sooner, which allowed for an earlier automated S-LP notification while the patient remained in the ICU.

Limitations and challenges
One of the main limitations of the tracheostomy team evaluation was difficulty with data collection. Data collection for the postintervention group was incomplete; therefore, retrospective chart reviews were undertaken. In our institution, the health record is mostly paper based and is scanned electronically postdischarge. Some performance metrics were only captured in narrative notes; therefore, it was challenging to review large volumes of notes to obtain the required information. In some cases, we were unable to find the data required; therefore, approximately seven patient records from the postintervention group were not included in the results. This further limited the sample size for the pre- and postintervention groups. Another limitation we identified in this study was the heterogeneity between pre- and postintervention indications for tracheostomy. The majority of patients in both groups had a primary indication for tracheostomy of facilitation of weaning; however, there was a higher percentage of airway protection as the primary indication in the postintervention group. This difference between groups can be explained by the aforementioned increased use of weaning modes, such as PAV, resulting in less need for percutaneous tracheostomy due to a failure to wean from mechanical ventilation.

CONCLUSION
Before the implementation of the tracheostomy team, patients on the wards with a tracheostomy often did not receive regular follow-up and management with respect to weaning and decannulation. Our evaluation indicates that an interprofessional tracheostomy team can improve the quality of patient care by earlier tracheostomy tube changes and facilitating swallowing referrals in a timelier manner. Our assessment did not demonstrate an improvement in weaning to decannulation times, unlike previous studies (3). Despite the lack of improved weaning to decannulation times, other key processes in the weaning continuum were evident including marked improvement in the initial S-LP referral times following tracheostomy insertion. To validate these findings in other institutions, a more rigorous quality improvement methodology should be used, along with ongoing protocol compliance measurement.

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Southmedic OxyMask™ compared with the Hudson RCI® Non-Rebreather Mask™: Safety and performance comparison

Keith Lamb RRT-ACCS, David Piper PE

BACKGROUND: The non-rebreather mask (NRBM) is used for many applications and in many patient care scenarios in which hypoventilation and resultant hypoxemia are a concern. The NRBM is a low-flow oxygen delivery system that is easily deployed and capable of delivering a relatively high fraction of inspired oxygen (FiO₂). The potential for ineffective carbon dioxide (CO₂) removal at low flow rates is a safety concern.

OBJECTIVE: The authors hypothesized that the use of an OxyMask (Southmedic Inc, Canada) would mitigate these safety concerns while still delivering a relatively high FiO₂.

METHODS: Bench studies were performed in a third-party laboratory by qualified engineers (Piper Medical, USA). A Harvard Respirator Pump (Harvard Apparatus, USA), oxygen source, CO₂ source and a mannequin head were used to simulate various respiratory conditions. End tidal CO₂ (EtCO₂), FiO₂, fraction of inspired CO₂ and percent drop in CO₂ in the first second of exhalation were measured at different mask flow rates and respiratory rates. There were two categories of flow rates: high-flow (15 L/min) and low-flow (2 L/min). In each flow group, the above parameters were measured using a tidal volume of 400 mL, inspiratory/expiratory ratio of 1:2, EtCO₂ of 5% and a breathing frequency of 15, 20 or 24 breaths/min. Mask performance measurements were obtained and compared.

CONCLUSION: The OxyMask outperformed the traditional NRBM in each tested category. There was a higher inspired oxygen level, lower inspired CO₂ level, and more efficient CO₂ clearance at each mask flow level and simulated patient minute volume. This was especially true during conditions in which there were very low mask flow rates.

Key Words: Delivery; Hypercarbia; Hypoxemia; Hypoxia; Non-rebreather mask; Oxygen; OxyMask; Respiratory failure

The patient safety profile of a non-rebreather mask (NRBM) has been a matter of concern for some time; however, there is very little reference to these performance characteristics in the literature (1-3). Low-flow characteristics and a potential lack of effective washout of exhaled gases can lead to rebreathing of carbon dioxide (CO₂) in certain conditions (1-3). This concern has previously led to aftermarket modifications to the NRBM by way of removing one of the one-way valves that are located on either side of the mask. This modification is intended to reduce or attenuate the rebreathing of exhaled gases and potential for hypercarbic respiratory failure and lower fraction of inspired oxygen (FiO₂) leading to hypoxemia. These conditions may exist when the mask flow is set inadvertently low, is accidently disconnected from its fresh gas source or the very small exhalation port is obstructed (2,4). We hypothesized that the open design of the OxyMask™ (Southmedic Inc, Canada) would mitigate these concerns by allowing for less CO₂ rebreathing while delivering inspired oxygen levels that compare favourably with the Hudson RCI® NRBM™ (Teleflex Inc, USA) (5-7).

METHODS

The CO₂ source was attached to the inhalation limb of the Harvard Pump (Harvard Apparatus, USA) on the piston side of the inhalation check valve. A 0.125 inch OD sensing oxygen line was attached to the...
head and the sensing end was positioned 1 inch into the 0.875 inch ID simulated oral cavity of the mannequin. Gas sampling was achieved through the line to the oxygen and CO₂ sensor (10 mL/min each) using a vacuum source. End tidal CO₂ (EtCO₂) values were set without the mask in place so as to simulate normal expected breathing. The CO₂ flow was set to the desired settings (Table 1). Once CO₂ flow had been set to the desired EtCO₂ value, the mask was adjusted to the desired oxygen flow rate (2 L/min and 15 L/min, respectively) and placed on the mannequin head as designed. The system was allowed to equilibrate for at least 3 min before obtaining each reading. Each sample was tested three times. The mask was removed from the mannequin head completely and repositioned between each test. Each mask was tested three times. The mask was removed from the mannequin head and after testing. CO₂ measurements were calibrated before testing at laboratory processes met their specifications and requirements before each setting. 3 min to equilibrate a full inhalation and exhalation CO₂ flow settings × 3 respiratory settings = 36 tests total). After allowing There were a total of 36 tests (2 samples × 3 tests per sample × 2 oxygen simulated at both 2 L/min of oxygen flow or 15 L/min of oxygen flow.

Three respiratory settings used for testing

| Parameter                  | Setting | 1   | 2   | 3   |
|----------------------------|---------|-----|-----|-----|
| Respiratory rate, breaths/min |         | 15  | 20  | 24  |
| Tidal volume, mL            |         | 400 | 400 | 400 |
| Inspiratory:expiratory ratio|         | 1:2 | 1:2 | 1:2 |
| End tidal carbon dioxide, % |         | 5   | 5   | 5   |

Table 2 summarizes combined mean data collected while testing both masks with oxygen flow rates of 2 L/min and 15 L/min and respiratory rates of 15, 20 and 24 breaths/min. Table 3 summarizes mean data for each individual test. The OxyMask delivered more or an equivalent amount of oxygen compared with the NRBM at the same conditions. The OxyMask resulted in lower or equivalent EtCO₂ levels compared with the NRBM at the same conditions. CO₂ levels dropped faster during exhalation with the OxyMask than with the NRBM. Performance of the two products tended to be farther apart at lower flow rates of oxygen. Significant differences among the covariates were noted (F=14.56; P<0.001; λ=0.332). When controlling for device flow and respiratory rate, there was a statistically significant effect on End tidal carbon dioxide (F=29.37; P<0.001), O₂ (F=24.17; P<0.001), inhaled O₂ (F=54.60; P<0.001) and percent drop in CO₂ (F=41.72; P<0.001).

DISCUSSION

Patient safety is paramount. It has been historically hypothesized that the use of an NRBM may be unsafe when certain elements exist that create conditions favourable for rebreathing CO₂ (7-10). The literature supporting this notion is virtually nonexistent. Our bench report comparing the Southmedic OxyMask™ and the Hudson RCI® NRBM™ has taken a step toward answering this question. First, we chose parameters that were believed to be appropriate surrogates of common patient conditions. Inhaled and exhaled oxygen levels, as well as CO₂ levels, were measured. Subsequently, varying patient and equipment conditions were introduced by way of changing respiratory rates and oxygen flow rates. Higher oxygen flow rates (15 L/min) were chosen to simulate the standard practice with both masks. Lower oxygen flow rates (2 L/min) were used to simulate an inadvertent decrease from the standard. Increasing respiratory rates were tested to simulate a change in patient condition and minute volume. Our experiments demonstrated, that when the NRBM and OxyMask are used as per the standard (higher flows), they are safe oxygen delivery masks and deliver a relatively high and stable level of inspired oxygen. Additionally, CO₂ appears to be adequately cleared under these conditions. Alternatively, when tested at lower flow rates, the OxyMask appears to outperform the NRBM in terms of CO₂ clearance and at delivering inspired oxygen.
There were limitations to the present study. Although the measurements obtained during these experiments show a statistical significance almost across the board in favour of the OxyMask at lower flow rates, the sample numbers are low and further evaluation may be helpful to suggest a change in safe practice. We believe that our data suggests that the Southmedic OxyMask may be a safer alternative to the Hudson RCI NRBM in which conditions exist that make inadvertent low oxygen delivery flows more likely to occur.

APPENDIX 1: EQUIPMENT LIST

A) Southmedic Adult OxyMask (Southmedic, Barrie, Ontario)
B) Hudson RCI Adult Non-rebreathing Mask with Safety Vent (Morrisville, NC, USA)
C) 0-100 psig Pressure Gauge
D) Gilmont glass float type Rotameter (Barrington, IL, USA)
E) Low Flow Rotameter
F) AccuLAB Standard Electronic Balance TS series (Goettingen, Germany)
G) Vacuum source
H) Compressed gas source
I) Oxygen source
J) CO₂ source
K) Velleman Digital Oscilloscope (Fort Worth, Texas, USA)
L) Ohmeda 5200 CO₂ Monitor (Madison, WI, USA)
M) Data Acquisition System
N) Humidity/Temperature Meter
O) Oxygen Sensor
P) Harvard Respiratory Pump (Harvard Apparatus, Holliston, Massachusetts, USA)
Q) Wright Respirometer
R) Adult Mannequin Head (0.875 inch ID oral cavity, head width = 6.

DISCLOSURES: Keith Lamb has no financial disclosures or conflicts of interest to declare. David Piper is President of Piper Medical, Inc, Carmichael, California (USA) and performed the bench investigation(s). Mr Piper was compensated for conducting these experiments.

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Evidence regarding patient compliance with incentive spirometry interventions after cardiac, thoracic and abdominal surgeries: A systematic literature review

Aqilah Leela T Narayanan MSc PT1, Syed Rasul G Syed Hamid FRCS MD2, Eko Supriyanto PhD1

BACKGROUND: Evidence regarding the effectiveness of incentive spirometry (ISy) on postoperative pulmonary outcomes after thoracic, cardiac and abdominal surgery remains inconclusive. This is attributed to various methodological issues inherent in ISy trials. Patient compliance has also been highlighted as a possible confounding factor; however, the status of evidence regarding patient compliance in these trials is unknown.

OBJECTIVE: To explore the status of evidence on patient compliance with ISy interventions in randomized controlled trials (RCTs) in the above contexts.

METHOD: A systematic search using MEDLINE, EMBASE and CINAHL databases was conducted to obtain relevant RCTs from 1972 to 2015 using the inclusion criteria. These were examined for specific ISy parameters, methods used for determining compliance and reporting on compliance. Main outcome measures were comparison of ISy parameters prescribed and assessed, and reporting on compliance.

RESULTS: Thirty-six relevant RCTs were obtained. Six ISy parameters were identified in ISy prescriptions from these trials. Almost all (97.2%) of the trials had ISy prescriptions with specific parameters. Wilcoxon signed-rank test revealed that the ISy parameters assessed were significantly lower (Z = −5.433; P < 0.001) than those prescribed; 66.7% of the trials indicated use of various methods to assess these parameters. Only six (16.7%) trials included reports on compliance; however, these were also incomprehensive.

CONCLUSIONS: There is a scarcity and inconsistency of evidence regarding ISy compliance. Compliance data should be obtained using reliable and standardized methods to facilitate comparisons between and among trials. These should be reported comprehensively to facilitate valid inferences regarding ISy intervention effectiveness.

Key Words: Abdomen; Heart surgery; Incentive, Respiratory therapy; Spirometry; Thoracic surgery

Les données sur la compliance des patients aux interventions de spirométrie incitative après une chirurgie cardiaque, thoracique ou abdominale : une analyse bibliographique systématique

HISTORIQUE : Les données relatives à l’efficacité de la spirométrie incitative (ISy) sur la capacité pulmonaire après une chirurgie cardiaque, thoracique ou abdominale ne sont pas concluantes. Ce phénomène est attributable à divers problèmes méthodologiques inhérents aux essais d’ISy. La compliance des patients peut également constituer un facteur confondant. Toutefois, on ne connaît pas l’état des données sur la complaisance des patients lors de ces essais.

OBJECTIF : Explorer l’état des données sur la compliance des patients aux interventions d’ISy dans le cadre d’essais aléatoires et contrôlés (EAC) réalisés dans les contextes susmentionnés.

MÉTHODOLOGIE : À l’aide des critères d’inclusion, les chercheurs ont fouillé systématiquement les bases de données MEDLINE, EMBASE et CINAHL pour obtenir les EAC de 1972 à 2015. Ils ont analysé certains paramètres d’ISy, les méthodes utilisées pour déterminer la compliance et les rapports de compliance. Les principales mesures de résultats étaient la comparaison des paramètres d’ISy prescrits et évalués et les rapports de compliance.

RÉSULTATS : Les chercheurs ont extrait 36 EAC pertinents. Ils en ont tiré six paramètres dans les prescriptions d’ISy. Presque tous les essais (97,2 %) comportaient des prescriptions d’ISy aux paramètres précis. Le test de la somme des rangs de Wilcoxon a révélé que les paramètres d’ISy évalués étaient considérablement plus faibles (Z = −5,433; P < 0.001) que ceux prescrits, et 66,7 % des essais indiquaient l’utilisation de diverses méthodes pour évaluer ces paramètres. Seulement six essais (16,7 %) comportaient des rapports de compliance, également incomplets.

CONCLUSIONS : Les données sur la compliance à l’ISy sont rares et contradictoires. Il faudrait obtenir les données de compliance au moyen de méthodes fiables et standardisées afin de faciliter les comparaisons entre les essais. Les rapports devraient être détaillés pour favoriser des inférences valides sur l’efficacité des interventions d’ISy.
METHODS

Literature search
A systematic search was performed using MEDLINE, EMBASE and CINAHL databases to obtain relevant trials from January 1972 to January 2015. Key words used for the search included “heart surgery”, “thoracic surgery”, “abdomen”, “respiratory therapy”, “breathing exercises”, “physical therapy”, “physical therapy”, “coronary artery bypass”, “spirometry” and “incentive”. The search timeline was set to begin from 1972 because the first documented evidence of ISy as a treatment modality appears to be a report by Van de Water (25). References from the selected trials were also searched for any additional relevant articles.

Study selection
The titles and abstracts of articles were screened and read online independently by two reviewers. If they appeared relevant to the study objectives, full-text versions were retrieved. These were assessed for suitability for inclusion using the criteria stated below. Any disagreement was resolved in a consensual manner through discussions with the third reviewer. Inclusion criteria consisted of RCTs that investigated the effectiveness of ISy interventions on postoperative pulmonary outcomes after cardiac, thoracic or abdominal surgeries; clearly stated the use of ISy in their interventions; involved an adult study population; and were English language. Studies were excluded if the RCTs were outside the adult population; in languages other than English; included interventions in which ISy use was not clearly stated; or did not investigate postoperative pulmonary outcomes.

Data extraction
The selected studies were examined by two of the authors (ALTN and SRSH). ISy prescriptions were identified and details regarding ISy performance and usage based on parameters stated in the ISy clinical practice guidelines 2011 (6) were extracted and tabulated. Other information extracted included details regarding assessment of compliance with these prescriptions, methods used for determining compliance and reporting on compliance. The studies were then re-examined by another author (ES) to verify the extracted data.

Data analysis
Data were analyzed using SPSS version 16.0 (IBM Corporation, USA) (26). Descriptive data were expressed as frequencies and percentages. Because data were not normally distributed, ISy parameters prescribed and assessed were compared using the nonparametric Wilcoxon signed-rank test. Any ISy parameter identified in each study was accounted for and included in the analysis. The number of ISy parameters assessed was expressed as a percentage of the number of parameters prescribed for each included study before conducting the Wilcoxon signed-rank test. Level of significance was set at α=0.05 to test the null hypothesis that there was no difference between prescribed and assessed parameters; the null hypothesis would be rejected if P<0.05.

RESULTS
The search strategy yielded 527 records. Fifty-four relevant RCTs were identified and reviewed for inclusion. Eighteen did not meet the inclusion criteria and were excluded. Figure I depicts the selection process of studies included for analysis and reasons for exclusion of the 18 studies.

Study characteristics
Thirty-six RCTs (25,27-61) that fulfilled the inclusion criteria were obtained. These were published over a span of 42 years (1972 to 2014). Of a total 3753 patients involved in these studies, 1957 (52.1%) had received ISy interventions. Table I presents details of the extracted data from each selected trial.

ISy prescriptions
ISy prescriptions were not given in one trial (52), while the remainder (97.2%) had prescribed various ISy parameters. Six different ISy usage parameters were identified from these prescriptions:

1. Session duration – specifying the duration (in units of time) patients were to perform ISy.
2. Session frequency – specifying the frequency of ISy sessions per day.
3. Inspiration frequency – specifying the number of times inspiratory manoeuvres should be performed.
4. Volume targets – the inspiratory volume goal the patient should achieve.
5. Breath hold – the duration which the patient was to hold their breath at maximal inspiration.
6. Flow rate – how quickly, or the speed at which each inspiration should be performed.

Of these, only ‘session duration’ was not stipulated in the current ISy guidelines (6).
TABLE 1
Brief summary of reviewed articles with details regarding incentive spirometry (ISy)

| Study, year; | Total patients/patients using ISy, n/n | Type and method of IS | Parameters prescribed | Parameters assessed | Method used to determine compliance | Reporting on compliance |
|--------------|----------------------------------------|-----------------------|-----------------------|---------------------|-------------------------------------|-------------------------|
| Van De Water et al (25), 1972; 30/15 | Bartlett-Edwards: 4× daily; As many inspirations as possible; Hold breath as long as possible with each maximal inspiration; Inhalate at rate >100 mL/s leak rate in IS | Session frequency Inspiration frequency (frequency not specified) Breath hold (duration not specified) Flow rate | Record of cumulative time of breath hold Flow rate | Bartlett-Edwards IS that records breath hold time | Data regarding total breath hold time (in seconds) for each postoperative day for 2 patients (one with and one without PPCs) |
| Craven et al (27), 1974; 70/35 | Bartlett-Edwards: 10 maximal inspirations/h; Breathe to volume target based on patient’s inspiratory effort each POD; Hold breath as long as possible with each maximal inspiration; Inhalate at rate >100 mL/s leak rate to keep IS light on | Session frequency Inspiration frequency Volume target Breath hold (duration not specified) Flow rate | Inspiration frequency Volume achievements Flow rate | Bartlett-Edwards IS | General observation on possible association between inspiration frequency and volume achievements with development of PPCs |
| Dohi and Gold (28), 1978; 64/34 | Triflo: 5 maximal inspirations every waking hour, 8× daily | Session frequency Inspiration frequency | Not stated | Not stated | None |
| Iverson et al (29), 1978; 145/58 | Not specified: 3 to 5 maximal inspirations every 3 h; Hold breath as long as possible with each maximal inspiration | Session frequency Inspiration frequency Breath hold (duration not specified) | Not stated | Not stated | None |
| Lyager et al (30), 1979; 94/43 | Bartlett-Edwards: 4 maximal inspirations every waking hour; Hold breath as long as possible with each maximal inspiration; Inhalate at rate faster than 100 mL/s leak rate to keep IS light on | Session frequency Inspiration frequency Breath hold (no specific duration) Flow rate | Inspiration frequency Flow rate | Bartlett-Edwards IS | Average inspiration frequency for whole postoperative period |
| Gale and Sanders (31), 1980; 109/51 | Bartlett-Edwards: 20 min sessions, 4× daily; Minimum 10 maximal inspirations per session; Hold breath as long as possible with each maximal inspiration; Inhalate at rate faster than 100 mL/s leak rate to keep IS light on | Session duration Session frequency Inspiration frequency Breath hold (duration not specified) Flow rate | Not stated | Supervision by respiratory therapist | None |
| Jung et al (32), 1980; 126/45 | Spirocare: 15 to 20 min sessions, 4× daily; As many inspirations as possible; Breathe to preset volume target set arbitrarily between 1400 to 1750 mL; Hold breath 3 s with each maximal inspiration | Session frequency Session duration Inspiration frequency (frequency not specified) Volume target Breath hold | Not stated | Supervision by staff | None |
| Lederer et al (33), 1980; 79/79 | Triflo; Spirocare; Bartlett-Edwards: 10 maximal inspirations every waking hour; Progressively attempt to breathe to preset volume target set at preoperative maximal inspiratory volume; Hold breath 2 to 3 s with each maximal inspiration | Session frequency Inspiration frequency Volume target Breath hold | Session frequency | Daily feedback from patients on frequency of use | No specific data on any ISy parameters Data available – percentage of patients using the 3 different types of IS from POD 1 to POD 5 |
| Minschaert et al (34), 1982; 20/11 | Respirex: 6 maximal inspirations every waking hour; Hold breath 3 s with each maximal inspiration | Session frequency Inspiration frequency Breath hold | Not stated | Not stated | None |

Continued on next page
| Study, year; | Total patients/patients using IS, n/n | Type and method of IS | Parameters prescribed | Parameters assessed | Method used to determine compliance | Reporting on compliance |
|-------------|--------------------------------------|----------------------|----------------------|-------------------|-----------------------------------|-------------------------|
| Stock et al (35), 1982; 65/22 | Bartlett-Edwards: 15 min sessions every 2 h when awake | Session duration | Not stated | Supervision by physicians and therapists | None |
| Dull and Dull (36), 1983; 49/16 | Spirocare: 10 maximal inspirations 4× a day | Session frequency | Not stated | Supervision by physiotherapists | None |
| Celli et al (37), 1984; 172/45 | Not specified: Minimum of 10 maximal inspirations, 4× daily; Breathe to preset volume targets ranging from 100–800 mL starting from at least 50% of preoperative vital capacity until 70% vital capacity; Hold breath 3 s with each maximal inspiration | Session frequency | Not stated | Supervision by respiratory personnel | None |
| Stock et al (38), 1984; 38/12 | Bartlett-Edwards: 15 min every 2 h when awake; Volume achievement each session target for subsequent sessions; Hold breath 3 s with each maximal inspiration; Inhale at rate faster than 100 mL/s leak rate to keep IS light on | Session duration | Inspiration frequency | Barlett-Edwards IS Data on mean number of times 3 s breath hold achieved and mean maximal volume achieved for the 15 min sessions from POD 1 to POD 3 | None |
| Stock et al (39), 1985; 65/22 | Bartlett-Edwards: 15 min every 2 h when awake; Volume achievement each session target for subsequent sessions; Hold breath 3 s with each maximal inspiration; Inhale at rate faster than 100 mL/s leak rate to keep IS light on | Session duration | Inspiration frequency | Barlett-Edwards IS Data on mean number of times 3 s breath hold achieved and mean maximal volume achieved for the 15 min sessions from POD 1 to POD 3 | None |
| Ricksten et al (40), 1986; 43/15 | Triflo: 30 maximal inspirations every waking hour | Session frequency | Session frequency | Each hourly session noted on record sheet by nurse or patient | None |
| Schwieger et al (41), 1986; 40/20 | Inspiron: 5 min/h at least 12× daily | Session duration | Not stated | Supervision by respiratory personnel | None |
| O'Connor et al (42), 1988; 40/20 | Inspiron: 3 maximal inspirations every waking hour; Progressively increase inspiration volume to achieve preoperative volume; Hold breath 3 s with each maximal inspiration; Inhale at rate sufficient to keep ball at tip of IS chamber for 3 s | Session duration | Not stated | Not stated | None |
| Rau et al (43), 1988; 60/60 | Spirocare; Voldyne: 4 sessions daily; then continue as many inspirations as possible every waking hour | Session frequency | Not stated | Group 1 and 2 – 4 daily sessions supervised by therapist | None |
| Jenkins et al (44), 1989; 110/38 | Triflo: 10 maximal inspirations every waking hour | Session frequency | Not stated | Patients' self-reports (instructed to report frequency of sessions – 10 inspirations equals one session) | None |

Continued on next page
Table 1 – Continued
Brief summary of reviewed articles with details regarding incentive spirometry (ISy)

| Study, year; Total patients/patients using ISy, n/n | Type and method of IS | Parameters prescribed | Parameters assessed | Method used to determine compliance | Reporting on compliance |
|---------------------------------------------------|-----------------------|-----------------------|--------------------|--------------------------------------|------------------------|
| Hall et al (45), 1991; 876/431                      | Airlife:               | Session duration      | General compliance levels – specific ISy parameters not stated | Assessments on compliance made by research nurse on 0–100 mm visual linear analogue scale | No specific data on any ISy parameters – only brief mention on outcomes of ‘poor compliers’ |
|                                                    |                       | Session frequency     |                    |                                      |                        |
|                                                    |                       | Breath hold (duration not specified) |                    |                                      |                        |
|                                                    |                       | Flow rate             |                    |                                      |                        |
| Oikkonen et al (46), 1991; 52/26                   | Coach:                 | • Session frequency   | Not stated         | Not stated                           | None                   |
|                                                    |                       | • Inspiration frequency |                    |                                      |                        |
|                                                    |                       | • Breath hold         |                    |                                      |                        |
|                                                    |                       | • Flow rate           |                    |                                      |                        |
| Hall et al (47), 1996; 456/380                     | Airlife:               | Session frequency     | General compliance levels – specific ISy parameters not stated | Assessments on compliance made by research nurse on 0–100 mm visual linear analogue scale | No specific data on any ISy parameters |
|                                                    |                       | Inspiration frequency |                    |                                      |                        |
|                                                    |                       | Breath hold (duration not specified) |                    |                                      |                        |
|                                                    |                       | Flow rate             |                    |                                      |                        |
| Crowe et al (48), 1997; 185/90                     | Voldyne:               | Session frequency     | Not stated         | No specific data on any ISy parameters – only brief mention on outcomes of ‘poor compliers’ |
|                                                    |                       |                       |                    |                                      |                        |
| Weiner et al (49), 1997; 32/17                     | Coach:                 | Session duration      | Not stated         | Not stated                           | None                   |
|                                                    |                       | Inspiration frequency |                    |                                      |                        |
|                                                    |                       | Breath hold (duration not specified) |                    |                                      |                        |
|                                                    |                       | Flow rate             |                    |                                      |                        |
| Gosselink et al (50), 2000; 67/32                  | Voldyne:               | Session frequency     | Not stated         | No specific data on any ISy parameters – only brief mention on outcomes of ‘poor compliers’ |
|                                                    |                       | Inspiration frequency |                    |                                      |                        |
|                                                    |                       | Volume target         |                    |                                      |                        |
|                                                    |                       | Breath hold (duration not specified) |                    |                                      |                        |
|                                                    |                       | Flow rate             |                    |                                      |                        |
| Matte et al (51), 2000; 96/32                      | Coach:                 | Session frequency     | Not stated         | Not stated                           | None                   |
|                                                    |                       | Inspiration frequency |                    |                                      |                        |
|                                                    |                       | Not specified         |                    |                                      |                        |
| Ebeo et al (52), 2002; 21/12                       | Not specified:        | Session duration      | Not stated         | Not stated                           | None                   |
|                                                    |                       | Session frequency     |                    |                                      |                        |
| Savci et al (53), 2006; 60/30                      | Not specified:        | Session duration      | Not stated         | Not stated                           | None                   |
|                                                    |                       | Session frequency     |                    |                                      |                        |
| Romanini et al (54), 2007; 40/20                   | Voldyne:               | Session duration      | Not stated         | Not stated                           | None                   |
|                                                    |                       |                     |                    |                                      |                        |
| Haefener et al (55), 2008; 34/17                   | Voldyne:               | Session duration      | Not stated         | Not stated                           | None                   |
|                                                    |                       | Session frequency     |                    |                                      |                        |
| Renault et al (56), 2009; 36/18                    | Respiron:              | Session frequency     | Patients record on session frequency in ‘adherence’ log | Mean frequency of ISy sessions as obtained from adherence log |                       |
|                                                    |                       | Inspiration frequency |                    |                                      |                        |
|                                                    |                       | Breath hold (duration not specified) |                    |                                      |                        |
|                                                    |                       | Flow rate             |                    |                                      |                        |

Continued on next page
IS incentive spirometer; POD postoperative day; PPCs postoperative pulmonary complications

TABLE 1 – CONTINUED
Brief summary of reviewed articles with details regarding incentive spirometry (ISy)

| Study, year; | ISy | Parameters prescribed | Parameters assessed | Method used to determine compliance | Reporting on compliance |
|-------------|-----|-----------------------|---------------------|-------------------------------------|-------------------------|
| Narayanan et al (57), 2010; 50/50 | Kundra et al (57), 2010; 50/50 | Not specified: 15 maximal inspirations every 4 h | Session frequency Inspiration frequency | Feedback from patients | None |
| Cattano et al (58), 2010; 37/37 | Dias et al (60), 2011; 35/12 | Airlife: Group 1: 10 maximal inspirations 5× daily Group 2: 3 maximal inspirations once a day; slow sustained maximal inhalations | Session frequency Inspiration frequency Flow rate | Volume achievements | No specific data on any ISy parameters |
| Kulkarni et al (59), 2010; 80/20 | Dias et al (60), 2011; 35/12 | Spiroball: 15 min/session, 2× daily | Session duration Session frequency Inspiration frequency Flow rate | Not stated | Supervision by physiotherapists |
| Agostini et al (61), 2013; 180/92 | | Voldyne: 3–5 maximal inspirations, 2× daily; Slow sustained maximal inhalations | Session frequency Inspiration frequency | Not stated | None |

ISy prescribed versus parameters assessed
Collectively, ISy parameters had been prescribed a total of 112 times. The parameter most frequently prescribed was session frequency (25, 27, 28, 31, 32, 36, 37, 42, 43, 44, 45, 49, 53, 54, 55, 59), followed by inspiration frequency (25, 27, 28, 31, 32, 36, 37, 42, 43, 44, 45, 49, 53, 54, 55, 59), breath hold (25, 27, 28, 31, 32, 36, 37, 39, 42, 43, 44, 45, 49, 50, 53, 54), flow rate (25, 27, 30, 31, 38, 39, 42, 45, 47, 49, 50, 56, 60, 61), followed by inspiration frequency (25, 27, 28–30, 31, 32, 36, 37, 42–43, 44, 45, 49, 53, 54, 55, 59), breath hold (25, 27, 28, 31, 32, 36, 37, 39, 42, 43, 44, 45, 49, 50, 53, 54), flow rate (25, 27, 30, 31, 38, 39, 42, 45, 47, 49, 50, 56, 60, 61) and inspiratory volume target (27, 32, 37–39, 50).

Only 10 (27.8%) of 36 trials that had ISy prescriptions indicated they had assessed any of these parameters. However, none had assessed all of the parameters that were prescribed in their respective prescriptions. Collectively, assessment of parameters had been performed 19 times. Parameters assessed were flow rate (25, 27, 29, 38, 39), inspiration frequency (27, 30, 38, 39), volume achievements (27, 38, 39, 58), session frequency (33, 40, 56) and breath hold (25, 28, 39, 37–39, 42, 45, 47, 49, 50, 53, 56). Some parameters were coalesced in several trials (ie, they were integrated with one another and, as such, occurred simultaneously at a certain target point). For example, breath hold and flow rate were coalesced in one trial (25) in which the duration of breath held at a specific flow rate was recorded by a special timing device. Flow rate and inspiration frequency were coalesced in two trials (27, 30), in which inspirations with specific flow rates to preset volume goals were recorded; while flow rate, breath hold and inspiration frequency were coalesced in two trials (38, 39) in which only inspiration volume targets achieved with a specific flow rate and three-second breath holds were recorded. Session duration was not assessed in any of the trials.

The Wilcoxon signed-rank test to compare mean percentages of prescribed parameters to assessed parameters included only 35 studies. One study (52) was excluded from analysis because it was not possible to discern individual parameters prescribed and assessed in this trial. Figure 2 shows the frequencies of the different ISy parameters that were prescribed and assessed. Results indicated that parameters prescribed were significantly higher than the parameters assessed in which P<0.05 (Z=−5.433; P<0.001) (Table 2).

Prescriptions for ISy usage or performance parameters
Prescriptions for ISy had specified many different goals or ‘dosages’ for each parameter. Specific prescriptions or goals for session frequency, session duration and volume target were specified in all trials that had prescribed these parameters. Session duration ranged from 5 min (41, 45), 10 min (55), 15 min (35, 38, 39, 53, 59), 15 min to 20 min (32, 55), 20 min (31) and 30 min (50). Prescriptions for session frequencies included sessions to be conducted every hour when awake (30, 33, 34, 42, 45, 61), every 2 h when awake (35, 38, 39), every alternate hour when awake (45), every hour (27, 47, 48, 50), twice hourly (51, 56), three times hourly (29), four times hourly (57), and once (53, 58), twice (53, 55, 59, 60), four times (25, 31, 32, 36, 37, 43), five times (59), eight times (28) or 12 times (41) daily.

Volume targets were also prescribed in a variety of ways. Craven et al (27) progressed volume targets based on their patients’ inspiratory efforts each postoperative day, while Jung et al (32) required patients to inspire to preset volumes set arbitrarily between 1400 mL to 1750 mL. Patients in the study by Celli et al (37) had to inspire to preset volume targets ranging from 100 mL to 1800 mL, while the studies by Lederer et al (33) and O’Connor et al (42) sample had to increase inspiratory volumes progressively and aim to achieve preoperative volumes. Stock

TABLE 2
Comparison between mean percentages of incentive spirometry parameters prescribed with parameters assessed

| Parameter assessed | Parameter prescribed | P   |
|-------------------|----------------------|-----|
| 100               | 12.95                | <0.0001 |
et al (38,39) used maximally achieved inspiratory volume for each session, and targets for the subsequent session and target volume goals were increased daily in the study by Gosselink et al (50); however, the basis on which this was done was not stated.

Inspiration frequency was explicitly specified in 22 trials with prescriptions for this parameter. The most prescribed inspiration frequency was 10 maximal breaths for a specified session or duration (27,31,33,36,37,44,47,56,58,61). This was followed, in descending order by: three to five (29,60), five (28,46), 30 (40,49), three (42), four (30), six (34), 10 to 20 (50), 15 (57) and 20 breaths (51). Three trials (25,32,43), however, did not set any specific inspiration frequency because patients were instructed to perform as many inspirations as possible.

Of the 19 trials with ‘breath hold’ prescriptions, nine specified duration of breath hold. Three-second holds were specified in five (32,34,37,42,53) trials, while ranges between 3 s to 4 s (33) or 5 s (38,39,45) were specified in others. The remainder (25,27,29,31,45,47,49,50,56) required breath holds as long as possible at the end of maximal inspirations with no specific duration indicated.

Eight of 15 trials with flow rate prescriptions specified inspiratory ‘speed’ in various ways. Six (25,27,30,31,38,39) used an IS model with a piston in its volume chamber, which activated a light bulb at a specific target volume. Because there was an air leak of 100 mL/s incorporated into the chamber, patients were required to inspire faster than the leak rate to keep the bulb lit. O’Connor et al (42) used another IS model in which the leak in the volume chamber could be preset at different flow rates depending on clinical requirements, while Odkkonken et al (46) required patients to adjust their own flow rates using a flow-rate guide at the side of the volume chamber of their IS model. The remainder of the trials (45,47,49,50,57,58,60) did not define explicit targets; patients were instructed to perform slow maximal inspirations.

Methods used to determine ISy compliance

Twenty-four (66.7%) trials indicated that ISy compliance had been monitored or measured. Six of these (25,27,30,38,39,43) had used IS devices with counter features that could record frequency of volume goal achievements, with one trial adding a special timing device to capture cumulative breath hold time to their IS (25). All of these trials were from the early 1970s to 1980s. Eleven trials (31,32,35-37,41,43,49,55,60,61) indicated direct observation methods by health care personnel to monitor ISy usage. However, patients in two trials (43,61) were subject to unsupervised sessions as well. Seven other trials (33,40,44,48,56,57,58) used various other approaches, such as the use of logs, self-reports or questionnaires, while two (45,47) used a 100 mm visual linear analogue scale to gauge level of compliance. The remaining 12 (33.3%) did not indicate if or how they had determined compliance with prescribed therapy. Figure 3 shows the methods used to determine compliance in the primary studies across the 1972 to 2014 timeline.

DISCUSSION

Findings indicate inconsistency and scarcity of evidence regarding ISy compliance in RCTs gauging the effectiveness of ISy on postoperative outcomes after cardiac, thoracic and abdominal surgeries. Only six trials had some reporting on compliance; however, these, too, were inconsistent and incomprehensive. Nevertheless, several did elicit insights into some compliance-related issues. Two trials (27,30) drew
Electronic technologies have been used in some areas of health care involving the use of medical devices (65-67), and four earlier trials (25,30,38,39) have used IS counters to collect compliance data. Although the BE IS is deemed less suitable for current respiratory therapy practice (15), some of its features, such as the incidence counter, may be an indispensable component. In fact, the IS was conceived not only to facilitate active maximal lung expansion, but also to keep record of the manoeuvres by its inventors (68). As such, innovative methods for reinventing suitable versions of counter devices capable of monitoring and collecting compliance data could be contemplated. However, the implication of cost should also be duly considered, given that current IS models are mainly disposable, single-use units.

Although strategies, such as electronic technology, questionnaires and self-reports, can be used for determining compliance, each method has its own strengths and weaknesses (69). Nonetheless, ideal methods for collecting ISy compliance data can only be ascertained if methods used are evaluated rigorously for reliability and feasibility through appropriately designed trials. This can further facilitate standardization of compliance data collection and comparisons between trials.

Compliance involves human behaviour and can be rather unpredictable, with marked intra- and intersubject variability (20). Furthermore, it is not a dichotomous entity because it can fluctuate and change (70). Complications, such as pain (71) and cognitive dysfunction (72), are common after major surgeries. These experiences are unique to individual patients (71,72) and may affect activities, such as ISy performance, to varying degrees in the postoperative period. Personal beliefs and perceptions also appear to have some effect on patients’ resolve to adhere to ISy prescriptions (73). As such, it is imperative that methods used to ascertain compliance are not only reliable, but also possess the ability to track degrees of compliance accurately throughout the course of interventions.

Methods used for determining compliance should also be stated clearly in published trials so that valid inferences can be made on the quality of data collected (69). Unfortunately, nearly one-half of the trials had no reporting on methods. This, coupled with the lack of uniformity of methods used in the remaining trials, calls for more attention to this aspect in future trials. More than one-half of the trials’ total participants underwent ISy interventions, but there was little information included regarding their compliance levels. Even low rates of poor compliance can subtly underpower trials and affect outcomes (74,75). As such, it must be measured and reported accurately and reliably; not only to facilitate more valid interpretations of intervention effects, but also to inform statistical analysis (64,74,75).

The lack of standardization and inconsistency in prescription of ISy parameters suggests uncertainties on optimal dosages for this intervention. Although inspiration frequency and volume have been cited as important for therapy efficacy (68), supportive evidence regarding optimal dosages is lacking (6). The role and effects of the other parameters are also unclear. This uncertainty can only be addressed if compliance data encompassing the various ISy parameters are systematically collected and compared so that the role of each parameter on therapy efficacy can be ascertained.

The ongoing interest and debate regarding the efficacy of postoperative ISy in addressing PPCs after cardiac, thoracic and abdominal surgery reflects the quest for more conclusive evidence on this routinely used intervention. In fact, the need for more attention to compliance perspectives in IS trials has been highlighted many times in the literature (9,10,14,15,25,27,31-33,46,48,50,56,60,61). Although ISy has been compared with several device-based respiratory therapies (25,28,29,31,32,35,37-40,46,51,52,54), these operate in different ways to achieve lung expansion (76). ISy most closely relates to spontaneous DBEs in physiological principles of lung expansion (57,77), and its carryover effects on respiration may be better than other respiratory interventions (54). Although DBEs should suffice for most postoperative patients in preventing PPCs (78), the challenge would be to determine how well a given ISy prescription is adhered to, even in the absence of

**Figure 4** Frequency of use of incentive spirometers with and without counter features in primary trials between 1972 and 2015

Attention to the degree of noncompliance that may be existent in trials, while one (56) highlighted the possible drawbacks of certain data collection methods. Additionally, two trials (38,39) provided some insights into the possible role of ISy parameters on the effectiveness of therapy. One, which found no significant differences between continuous positive airway pressure therapy and ISy on pulmonary function after cardiac surgery, indicated that frequency of IS use and target volume achievements remained low and did not increase significantly for the duration of their trial (38). The other, in which increases in frequencies and significant increases in volume achievements were evident in the ISy group, found ISy more effective than continuous positive airway pressure therapy on functional residual capacity and atelectasis after upper abdominal surgery (39). It is difficult to draw any valid inferences as to the effects of ISy performance on outcomes because these trials had inherent methodological issues (10,13,15,17); nonetheless, this highlights the need for compliance data to facilitate critical evaluation of research findings.

Despite a majority of trials having prescribed specific ISy parameters, only a small percentage had been assessed. This suggests either a lack of emphasis on compliance data collection, or difficulties in successfully tracking and collecting such data. Of five trials that assessed ISy parameters, four (25,33,38,39) were from the 1970s and 1980s and had used the Bartlett-Edwards (BE) IS, which had incidence-counting features (31). However, the BE IS and Spirocare models, which also have counter features (62), have since given way to single-use, disposable, less-expensive models without counter features. This change is reflected by the IS models used in trials conducted from the 1980s onward. The techniques used to determine compliance also appear to coincide somewhat with the evolution of IS devices, with trials from the 1980s onward using various other strategies. However, direct monitoring or supervision appears to be a fairly consistent choice throughout the four-decade span.

The variety of compliance monitoring and data collection methods in the included IS trials also reflect the lack of standardization and consensus for such efforts. The degree of compliance cannot be ascertained unless effective monitoring is in place (63). Although there are no ‘gold standards’ for determining compliance, direct observation or measurement and electronic monitoring have been suggested as more accurate and reliable techniques (63). However, for ISy interventions, direct methods, such as supervision by staff, may not be viable options in terms of cost, time and manpower resource availability. The proposed advantage of ISy is the reduction of burden on health care resources by facilitating patients’ independent efforts in treatment regimens, and this is bound to be nullified if such strategies were to be used (10). Furthermore, administration of interventions can be influenced by those providing these interventions and pose a threat to the validity of the data collected (64). This should be considered when deciding on techniques for compliance data collection.

The ongoing interest and debate regarding the efficacy of postoperative ISy in addressing PPCs after cardiac, thoracic and abdominal surgery reflects the quest for more conclusive evidence on this routinely used intervention. In fact, the need for more attention to compliance perspectives in IS trials has been highlighted many times in the literature (9,10,14,15,25,27,31-33,46,48,50,56,60,61). Although ISy has been compared with several device-based respiratory therapies (25,28,29,31,32,35,37-40,46,51,52,54), these operate in different ways to achieve lung expansion (76). ISy most closely relates to spontaneous DBEs in physiological principles of lung expansion (57,77), and its carryover effects on respiration may be better than other respiratory interventions (54). Although DBEs should suffice for most postoperative patients in preventing PPCs (78), the challenge would be to determine how well a given ISy prescription is adhered to, even in the absence of
Evidence regarding patient compliance with ISy

The present study reveals a scarcity and inconsistency of evidence regarding ISy compliance. Compliance perspectives need to be incorporated into future trials to build a stronger evidence base for ISy interventions after cardiac, thoracic and abdominal surgery. Compliance should be determined using reliable methods capable of collecting data from various ISy parameters throughout the intervention period so that valid inferences can be made. Data collection methods should be standardized to enable comparisons between trials and reporting should be comprehensive to facilitate valid trial interpretation.

CONCLUSION

The present study reveals a scarcity and inconsistency of evidence regarding ISy compliance. Compliance perspectives need to be incorporated into future trials to build a stronger evidence base for ISy interventions after cardiac, thoracic and abdominal surgery. Compliance should be determined using reliable methods capable of collecting data from various ISy parameters throughout the intervention period so that valid inferences can be made. Data collection methods should be standardized to enable comparisons between trials and reporting should be comprehensive to facilitate valid trial interpretation.

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Early versus late tracheostomy for critically ill patients: A clinical evidence synopsis of a recent Cochrane Review

Allison Keeping BSc

Tracheostomies are used for patients who require long-term mechanical ventilation to help prevent complications from tracheal intubation including ventilator-associated pneumonia, sinusitis and tracheal stenosis. The optimal timing of a tracheostomy has not yet been determined through evidence-based practice, although it is generally performed between day 10 and day 14 of intubation (1). To address the uncertainty in the timing of tracheostomy, a recent Cochrane Review of randomized and quasi-randomized control trials (RCTs) compared early (<10 days postintubation) with late (>10 days postintubation) tracheostomies with regard to mortality, length of mechanical ventilation and other secondary outcomes (1). Table 1 provides an overview of the studies included in the review.

The review included eight RCTs with 1977 patients. Evidence of moderate quality from seven of these trials revealed that the mortality rate in the early tracheostomy patients was lower at the time of the longest follow-up compared with the late tracheostomy patients (47.1% versus 53.2%) (1). The time of longest follow-up varied from study to study and ranged from 30 days (2,3) to two years (4). This comparison demonstrated a statistically significant risk ratio of 0.83 (95% CI 0.70 to 0.98). Three studies assessed the impact of early versus late tracheostomy on patient mortality at 30 days follow-up, with one study (3) demonstrating a statistically significant difference between the groups (0.51 [95% CI 0.34 to 0.78]). The two other studies (Young et al [4] and Zheng et al [5]) showed no significant difference between mortality in the two groups at 30 days follow-up. Two of the studies assessed mortality between the two groups at 180 days. Bösel et al (6) demonstrated a lower mortality in the early tracheostomy group while Young et al (4) observed no significant difference between the two groups. A meta-analysis of the length of mechanical ventilation in the studies by Trouillet et al (7) and Zheng et al (5) reported no significant difference between the early and late tracheostomy groups. These same two studies measured ventilator-free days at 28 days follow-up, with a mean difference between groups of 1.62 days (95% CI -0.01 to 3.25). Both Rumbak et al (3) and Terragni et al (8) reported statistically significant reductions in the length of mechanical ventilation in the early tracheostomy groups while no other studies found a significant difference between the groups (1).

Of the secondary outcomes measured, four studies found a significant decrease in average days spent in the intensive care unit with early tracheostomies (1). There was no evidence suggesting that either treatment led to a lower likelihood of pneumonia. Laryngotracheal lesions were more commonly observed in patients with early tracheostomies.

La trachéostomie précoce ou tardive chez les patients gravement malades : le synopsis des données cliniques d’une récente analyse Cochrane

L’auteur se demande si une trachéostomie précoce (dans les dix jours suivant l’intubation) s’associe à un plus faible taux de décès qu’une trachéostomie tardive chez les patients sous ventilation mécanique prolongée. La présente brève analyse de huit études à révélé que les personnes qui subissent une trachéostomie précoce présentent un taux de décès légèrement plus faible que celles qui subissent une trachéostomie tardive. Des recherches plus standardisées s’imposent. Cependant, si on envisage de placer un patient sous ventilation mécanique prolongée, il faut effectuer la trachéostomie avant un délai de dix jours.

TABLE 1
Summary of included studies (1–8)

| Study years | 1984 to 2013 |
| Age, years, mean ± SD | 62±4.65 (not specified in one trial) |
| Countries | Global |
| Setting | Surgical, neurosurgical and cardiology departments, shock/trauma centre, medical intensive units, intensive care units, and general and cardiothoracic critical care units |
| Comparison | Tracheostomies performed on or before 10 days tracheal intubation compared with after 10 days intubation |
| Primary outcome | Mortality and duration of mechanical ventilation |
| Secondary outcome | Length of intensive care unit stay, pneumonia rates and laryngotracheal lesions |
The collected studies had substantial heterogeneity among them, which limited the ability to perform a meta-analysis of the data as a whole. For example, there is also a clear inability to blind participants and therapists to the procedure due to its invasive nature. The overall quality of the included studies were considered moderate by the reviewers (1).

There are currently no evidence-based guidelines in Canada on when to perform a tracheostomy for mechanically ventilated patients. The results of the present review, however, suggest that early tracheostomies may be preferential to late tracheostomies and should be performed before 10 days when a patient is expected to require long-term (>21 days) mechanical ventilation (1). The results of this Cochrane Review suggested that the number of critically ill patients necessary to treat with early tracheostomy to prevent one patient death was 11 (1).

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CALENDAR OF EVENTS

2016

March 1-4, Whistler, British Columbia: Canadian Critical Care 13th Annual Conference – Critical Care 2016. Contact the Canadian Critical Care Conference, Conference Coordinator, Zena Davidson, 899 West 12th Avenue, Room 2438, Vancouver General Hospital, Intensive Care Unit, Vancouver, British Columbia V5Z 1M9. Telephone 604-834-9362, e-mail zena.davidson@vch.ca, website www.canadiancriticalcare.ca

March 2-5, Chicago, Illinois: Society for Research on Nicotine and Tobacco (SRNT) 22nd Annual Meeting. Contact the SRNT, 2424 American Lane, Madison, Wisconsin 53794, USA. Telephone 608-443-2462, fax 608-443-2474, e-mail meetings@srnt.org, website www.srnt.org

March 4-7, Los Angeles, California: American Academy of Allergy, Asthma & Immunology (AAAAI) Annual Meeting. Contact the AAAAI Meetings Team, 555 East Wells Street, Suite 100, Milwaukee, Wisconsin 53202-3823, USA. Telephone 414-272-6071, fax 414-272-6070, e-mail annualmeeting@aaaaai.org, website http://annualmeeting.aaaaai.org

April 14-16, Halifax, Nova Scotia: Canadian Respiratory Conference 2016. Contact the Canadian Respiratory Conference, c/o Taylor & Associates, 11-5370 Canotek Road, Gloucester, Ontario K1J 9E7. Telephone 613-747-0262, fax 613-745-1846, e-mail crc@taylorandassociates.ca, website https://cts.lung.ca

April 7-10, Scottsdale, Arizona: Multidisciplinary Update in Pulmonary and Critical Care Medicine 2016. Contact the Mayo School of Continuous Professional Development. Telephone 800-323-2688, e-mail cme@mayo.edu.

April 11-13, Cleveland, Ohio: Wake Up to Sleep Disorders 2016. Contact the Cleveland Clinic Center for Continuing Education, 1950 Richmond Road, TR204, Lyndhurst, Ohio 44124, USA.

April 15-17, Shanghai, China: CHEST World Congress 2016. Contact CHEST Global Headquarters, 2595 Patriot Boulevard, Glenview, Illinois 60026, USA. Telephone 224-521-9800, fax 224-521-9801, website www.chestnet.org

May 24-26, London, United Kingdom: Respiratory Health & Smoking Science Summit. Contact Euroscicon Ltd, Highstone House, 165 High Street, Barnet, England EN5 5SU. Telephone 44-020-7183-8231, e-mail enquiries@euroscicon.com, website http://lifescienceevents.com/Resp2016

May 26-28, Ottawa, Ontario: Canadian Society of Respiratory Therapists (CSRT) Annual Education Conference. Contact the CSRT, 201-2460 Lancaster Road, Ottawa, Ontario K1B 4S5. Telephone 613-731-3164, fax 613-521-4314, website www.csrt.com

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Indications and Clinical Use:
ANORO™ ELLIPTA® (umeclidinium/vilanterol) is a combination of a long-acting muscarinic antagonist (LAMA) and a long-acting beta₂-agonist (LABA) indicated for the long-term once-daily maintenance bronchodilator treatment of airflow obstruction in patients with chronic obstructive pulmonary disease (COPD), including chronic bronchitis and emphysema. ANORO™ ELLIPTA® is not indicated for the relief of acute deterioration of COPD. ANORO™ ELLIPTA® is not indicated for the treatment of asthma. The safety and efficacy of ANORO™ ELLIPTA® in asthma have not been established. ANORO™ ELLIPTA® should not be used in patients under 18 years of age.

Contraindications:
- Patients with severe hypersensitivity to milk proteins.

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- ASThma-Related DEATH: Long-acting beta₂-adrenergic agonists (LABA) increase the risk of asthma-related death. Data from a large placebo-controlled US study that compared the safety of salmeterol (Serevent® Inhalation Aerosol) or placebo added to patients’ usual asthma therapy showed an increase in asthma-related deaths in patients receiving salmeterol. This finding with salmeterol is considered a class effect of LABA, including vilanterol, one of the active ingredients in ANORO™ ELLIPTA®. The safety and efficacy of ANORO™ ELLIPTA® in patients with asthma have not been established.

Other Relevant Warnings and Precautions:
- ANORO™ ELLIPTA® is not indicated for the treatment of acute episodes of bronchospasm (i.e., as rescue therapy), relief of acute deterioration of COPD or for the treatment of asthma.
- ANORO™ ELLIPTA® should not be initiated in patients during rapidly deteriorating or potentially life-threatening episodes of COPD.
- Patients should be instructed to discontinue regular use of short-acting beta₂-agonists and to use them only for acute respiratory symptoms.
- Exacerbations may occur during treatment. Patients should be advised to continue treatment and seek medical advice if COPD symptoms remain uncontrolled or worsen after initiation of therapy.
- ANORO™ ELLIPTA® should not be used more often or at higher doses than recommended. ANORO™ ELLIPTA® should not be used in conjunction with other medicines containing a LABA or LAMA.
- Headache or blurred vision may influence the ability to drive or to use machinery.
- Anticholinergic Effects: Use with caution in patients with narrow-angle glaucoma or urinary retention.
- Cardiovascular effects: ANORO™ ELLIPTA® should be used with caution in patients with cardiovascular disorders, especially coronary insufficiency, acute myocardial infarction, cardiac arrhythmias, and hypertension. Cardiovascular effects such as cardiac arrhythmias, may be seen after administration. Treatment may need to be discontinued. ANORO™ ELLIPTA® was associated with a dose-dependent increase in heart rate and QTc prolongation in healthy subjects receiving steady-state treatment. Caution is recommended in patients with a known history of QTc prolongation, risk factors for torsade de pointes (e.g., hypokalemia), or patients taking medications known to prolong the QTc interval.
A once-daily LAMA/LABA dual bronchodilator for COPD.*

- Endocrine and Metabolism: Use with caution in patients with convulsive disorders, thyrotoxicosis and patients who are unusually responsive to sympathomimetic amines. Use with caution in patients predisposed to low levels of serum potassium or patients with ketoacidosis or diabetes.
- Respiratory: Treatment should be discontinued if paradoxical bronchospasm occurs and alternative therapy instituted if necessary.
- Hypersensitivity: As with all medications, immediate hypersensitivity reactions may occur after administration of ANORO™ ELLIPTA®. Patients with severe milk protein allergy should not take ANORO™ ELLIPTA®.
- Use during pregnancy, labour and in breastfeeding women should only occur if the potential benefit justifies the potential risk.

Adverse Events:
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Recommended Dose:
- The recommended dose is one inhalation of ANORO™ ELLIPTA® 62.5/25 mcg once daily.

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- No dosage adjustment is required in patients over 65 years of age, in patients with renal impairment, or in patients with mild or moderate hepatic impairment. ANORO™ ELLIPTA® has not been studied in patients with severe hepatic impairment.

For More Information:
Please consult the Product Monograph at http://gsk.ca/anoro/en for important information relating to adverse reactions, drug interactions, and dosing information, which have not been discussed in this piece. The Product Monograph is also available by calling 1-800-387-7374.
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*LAMA=Long-acting muscarinic antagonist (also known as a long-acting anticholinergic [LAAC]); LABA=Long-acting beta agonist.
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Reference: 1. ULTIBRO® BREEZHALER® Product Monograph. Novartis Pharmaceuticals Canada Inc., August 18, 2014.

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