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Contents

Introduction

Welcome to the 2012 journal of the Association of Chartered Physiotherapists in Respiratory Care (ACPRC). The aim of the ACPRC is to promote best practice in respiratory physiotherapy for the benefit of patients and the journal achieves this by providing a medium for the dissemination of findings of research which can be discussed within your workplace.

The articles in this year's journal cover the four champion areas: chronic disease, paediatrics, surgery and critical care and also a range of research methodologies from both qualitative and quantitative domains. These studies highlight the diversity of work within respiratory care and also the dedication of physiotherapists to provide the best possible care for their patients.

Looking forward to next year, the ACPRC conference will be held in Leicester 19th-20th April 2013. This is a great opportunity for us to meet, discuss hot topics and develop the ACPRC as a professional network of the Chartered Society of Physiotherapy.

We hope you enjoy this issue of the ACPRC journal and remind you that author guidelines with detailed instructions are available on the ACPRC website www.acprc.org.uk. The deadline for submission to the next journal is 31st January 2013. The editorial team are more than happy to discuss any potential article – so get writing!

With best wishes

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A study to investigate the clinical use and outcomes of EZPAP positive pressure device to determine its effectiveness as an adjunct to respiratory physiotherapy.

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Summary

Few clinical studies relate to the EZPAP positive pressure device leading to a small investigation to analyse physiological outcomes, allowing for an informed evidence based decision prior to purchasing the units. Results demonstrated improvements in all physiological parameters and the study concluded that EZPAP has the potential to be an additional and viable adjunct to respiratory physiotherapy.

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Introduction

The EZPAP was first introduced to the UK in 2003 after its launch in the USA in 1999. It is marketed as an adjunct to respiratory physiotherapy as a technique to increase lung volume and reduce atelectasis by amplifying an input flow of either air or oxygen approximately four times using the coanda effect. This augmentation provides a larger flow and volume with less effort than an unsupported inspiration and positive expiratory pressure (PEP) is provided on expiration. Studies regarding reliability of the positive pressure during the respiratory cycle prove it is consistent on both the inspiratory and expiratory phase of respiration if flow is set at >5 litres, (CITECH, 1999) and Ogrinc et al (2002) advocates that the pressure achieved is within a clinically useful range for lung expansion. Black et al, (2006) clarify that positive pressure is maintained throughout the patients breathing cycle at predictable airways pressures at delivered flows.

However, there are few clinical trials and a literature search only yielded seven results which are summarised in table 1.

Paper	Study Design	Method	Main Findings	Limitations	Conclusions	Recommendations
Tarnow & Daniel (2002)	Observational Study	EZPAP used as alternative to IPPB and prescribed 2-4 hourly for patients ordered for lung expansion therapy. Small scale study (5 patients)	SaO_2 - mean increase of 2%. 4 patients did not require intubation and ventilation	Not randomised No comparison to IPPB Limited quantifiable results/physiological observations measured Doesn't state time frame/number of interventions	EZPAP may offer safe alternative treatment of atelectasis.	Further randomised studies required.
Daniel & Tarnow (2001)	Observational Study	EZPAP used as alternative to IPPB to treat patients with atelectasis as diagnosed by CXR. SaO_2 and RR used as baseline measurement before and after 20 min treatment session with EZPAP. Small scale study (8 patients)	Statistically significant increase in SaO_2 ($p<0.05$) post EZPAP when compared to oxygen therapy only. Reduced RR post EZPAP compared to no therapy ($p<0.05$).	Not randomised No comparison to IPPB.	Preliminary findings only. EZPAP offers effective alternative treatment to improve SaO_2 and decrease RR in patients with atelectasis.	Further study required to truly establish role of EZPAP in reversing atelectasis.
Wiersgalla (2002)	RCT	50 patients randomised to have either incentive spirometry or EZPAP post CABG to improve post op atelectasis. CXR used as measure and reviewed before/ after by radiologists.	Incentive spirometergroup (n=20) showed 25% improvement of atelectasis compared to 100% of EZPAP group (n=30), statistically significant ($p<0.001$)	Only used one outcome measure of CXR. Not clear if had control group.	EZPAP demonstrated measurable improvements in atelectasis post CABG.	Shoudl be considered as option for polmonary management post CABG.

Table 1 – A table to show findings of literature review of 'EZPAP'

Paper	Study Design	Method	Main Findings	Limitations	Conclusions	Recommendations
Synder et al (2001)	Experimental	Purpose of study: to examine inspiratory / expiratory pressure during normal breathing at different flow settings. Tested on 3 volunteers with normal lungs, flow adjusted from 1-15 litres.		Small test group Only tested on healthy lungs	Pressures achieved are within a clinically useful range and constant throughout breathing cycle. Addition of nebuliser doesn't affect operation of device.	May cause fatigue at higher pressures and patients may need to rest between cycles.
Smiths Medical (nd)	Clinical Testimonials	Subjective reviews by respiratory therapists across USA who had used EZPAP in practice.	Varying comments including: • Easy to use • Imprved atelectasis • Effectively clears secretions.	Subjective Single patient case studies Lack of quantitive data	Respiratory therapists who use EZPAP in clinical practice report positive outcomes following interventions	Personal testimonials
Kopp (2009)	Observational study in own workplace	Review of EZPAP in authors workplace in post operative patients	Easy to use Good patient compliance Improvement of gas exchange	Perceptions of staff and patients Lack of quantifiable data, no objective measures	EZPAP has high level of patient compliance	No sufficient clinical studies to prove positive clinical experiences
Harland (2003)	Testimonial	Review of products available Development of hyperinflation protocol	Identified EZPAP as possible adjunct to respiratory therapy	Proposed hyperinflation protocol - not yet tested	Identifies that EZPAP could be more effective than incentive spirometer if patient unable to inhale 10ml/kg	Not tested

Table 1 – Summary of Studies

Referring to table 1, it can be seen that most of the evidence in respect EZPAP is mainly observational or personal testimonials, with only the result of a single clinical trial published. However, this limited research does suggest that in clinical practise EZPAP is effective in treating atelectasis, sputum load and decreased gas exchange. Other benefits identified by these studies included the simplicity of the set up, for both the patient and those administering (Daniel & Tarnow 2002). Additionally, patients have also perceived the system more comfortable and demonstrate a high level of compliance with the treatment (Kopp 2009 & Harland 2003).

Due to a lack of clinical studies it was necessary to investigate the outcomes of EZPAP prior to purchasing this device, ensuring it was effective an adjunct to respiratory physiotherapy.

The aim, through a small scale, department based clinical study was to measure clinical outcomes of the EZPAP in relation to increasing lung volume, sputum clearance and gaseous exchange. The results would then determine if the EZPAP device was purchased.

Methods

Physiotherapists carried out comprehensive respiratory assessments on all patients referred to the physiotherapy service during the study which lasted six months, and on analysis of the patient's problems the physiotherapist had the professional autonomy to select the treatment technique. If EZPAP was selected, the patient then entered the study and data collection was completed on the specifically designed measurement tool. Twenty EZPAP units were provided for the study by Henley's Medical Ltd. Physiotherapists were asked to document all physiological parameters, completed as part of a normal respiratory assessment before and after treatment, and their analysis of the intervention and the reason for their treatment choice. Additionally, as part of the subjective assessment patients were asked to comment about the treatment technique in respect to effectiveness and ease / difficulty of use. A pragmatic approach of using several outcome measures was utilised within this study because it has to be acknowledged that there may be subjective bias in completion of physiological observations, therefore multiple outcome measures may improve validity and also aid in drawing conclusions in relation to risks and benefits.

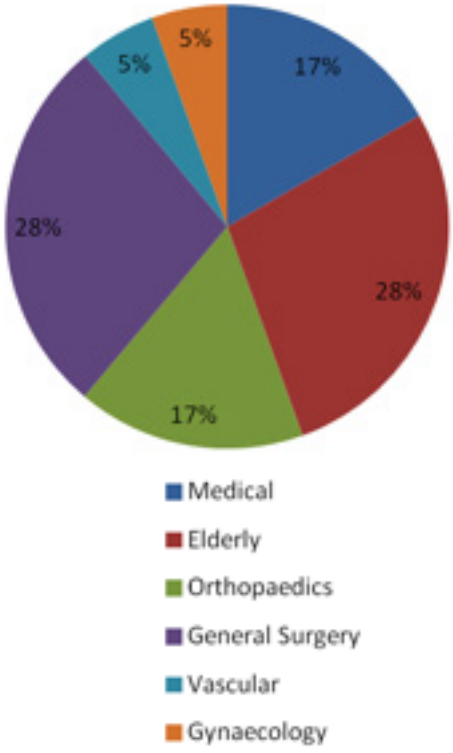
Physiotherapists involved in data collection all received theoretical and practical workshops on EZPAP, as well as being up to date with their on call competency programme. Other respiratory physiotherapy adjuncts remained available throughout the duration of the study. The physiotherapist chose the treatment adjunct based on clinical reasoning.

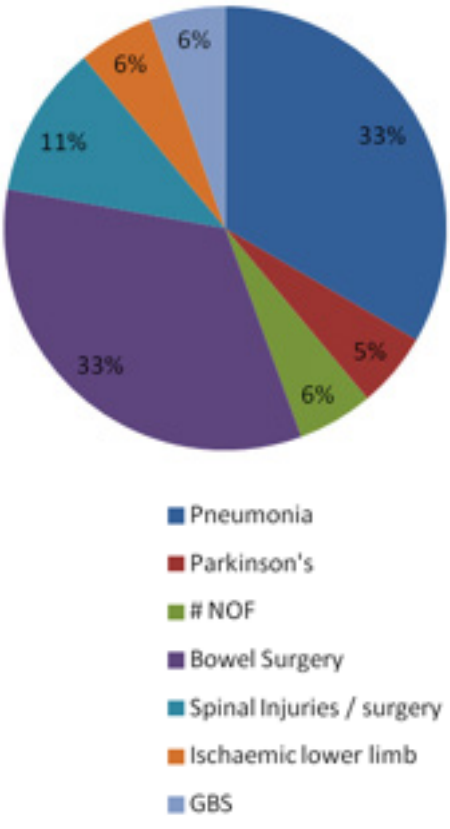
Results

In respect to data analysis, the free text questions, patient and physiotherapists perceptions were analysed by content analysis, and quantitative data was analysed by simple percentages with percentage differences documented where applicable for changes in physiological measurements so comparisons could be made pre and post treatment.

Eighteen sets of data were returned giving a return rate of 90%. There was a wide variety of patients with differing medical diagnosis across the whole spectrum of clinical specialities where EZPAP had been utilised and this is shown in figure 1.

Figure 1 - Pie Charts to demonstrate the clinical speciality and admitting diagnosis of patients who were selected for EZPAP





When selecting EZPAP as the treatment technique, physiotherapists chose to use it instead of other modalities in 42% of the cases to increase lung volume, 36% to clear secretions, 14% to increase gas exchange and 8% to prevent atelectasis. Comments to justify treatment choice included; required positive pressure intervention, ease of use for both patient and practitioner and neurological deterioration. In 24% of occasions it was used as an additional adjunct to respiratory physiotherapy. On average patients required 2.8 treatment sessions over a mean of 1.2 days,

when in 72% of cases alternative treatment modalities, namely mobilisation were then practised, only a small minority ceased due to complications; too drowsy (11%), pain (5.5%) and non compliance (5.5%).

Table 2 summarises the outcomes of EZPAP in relation to physiological observations, physiotherapist's analysis of treatment and patient perceptions. For ease of comparison, the results have been grouped into outcomes for increasing lung volume, sputum clearance, gas exchange, decreasing work of breathing and any other comments. Included in this table is the physiotherapist's analysis of their treatment intervention, plus subjective comments from the patient. Dawes et al (2005) advocates that those delivering and receiving the treatment should be involved in the process.

Clinical Outcome	Physiological Observation	Phsiotherapist Analysis	Patient Perception
Lung Volume	72% patients who demonstrated decreased breath sounds bi basally pre treatment had an improvement post treatment 100% increase in patients who initially demonstrated decreased unilateral expansion to achieve noraml expansion	Improved lung volume (40%)	Feels like I've done exercise to open my lungs Chest feels more mobile Increased air going into my lungs Feels like I am taking deep breaths
Sputum Retention	45% reduction of crepitations on auscultation 83% reduction of tactile fremitus	Cleared secretions (16%) Stimulated cough (12%)	Feels something has moved Feels something has shifted Feels less sputum after treatment
Gas Exchange	33% of patients of demonstrated an improvement in SaO_2	Increased SaO2 (33%) of patients Decreased oxygen demand (12%) 2 patients weaned off oxygen	
Prevent Atelectasis	Physiological observations maintained	Maintained respiratory status in neurological patients (4%)	
Work of Breathing	Mean decrease of 3.5 breaths per minute Greatest reduction of 10 breaths per minute	Reduced work of breathing (4%)	Improved breathing pattern Easier to breath (2) Decreased my breathing rate
Other Comments	No changes in heart rate post EZPAP intervention	Non complian Unable to achieve seal Drosy patient	Tiring (5) Discomfort on inspiration due to surgical wound Feels much better after treatment (4)
Ease of Use		Ease of use (12) Quick to set up Can teach Nursing Staff and patient to use between physiotherapy sessions	Comfortable (2) Easy to use (6) Visual Aid with manometer

Table 2 – Table to show outcomes of EZPAP intervention

Discussion

The aim of this study was to measure changes in physiological observations pre and post EZPAP intervention so to establish clinical outcomes for EZPAP in relation to lung volume, sputum clearance and gaseous exchange which in turn would lead to an informed decision whether to purchase EZPAP as an adjunct to respiratory physiotherapy care. This decision was also supported by the comments and opinions gained from the practising physiotherapists and patients. It is acknowledged that the reliability and validity of this research would have been improved by using radiological studies and arterial blood gas analysis; however, this wasn't feasible at this time. The small scale of this study utilised the outcome measures of physiological observation which are normally conducted as part of a respiratory physiotherapy assessment, thus not creating extra pressure on staff to complete data collection. The physiological observations of auscultation, lung expansion, respiratory rate and SpO_2 all showed an improvement after EZPAP and this is recorded in table two. The results therefore support existing research. Daniel & Tarnow (2002) identified EZPAP as a technique to increased lung volume, as did Wiersgalla (2002). Whereas Harland (2003) suggested EZPAP as an effective method to clear secretions and Kopp (2009) to improve gas exchange. Regarding work of breathing, there is little evidence available; Daniel & Tarnow (2001) found it decreased respiratory rate in a small number of patients with atelectasis. The results of this study demonstrated improvements in respiratory rate, physiotherapist analysis identifying the work of breathing to be reduced and patient perception of improved respiratory status. Except for the identified study, the literature search only yielded circumstantial case studies, DHD Healthcare, (n.d) to support EZPAP as a treatment modality, so it could be concluded that this study enhances the evidence base by utilising physiological outcome measures, even at this small scale and also involves those receiving the treatment as advocated by Dawes et al (2005).

Daniel & Tarnow (2002) and Kopp (2009) revealed that the simplicity and ease of use of the EZPAP, comfort for the patient and compliance were additional benefits to this treatment modality when considering effectiveness and efficiency. This study confirms that both physiotherapists and patients highlighted these factors. Further research needs to be undertaken in relation to financial costs. As highlighted in this study and supported by Kopp (2009), EZPAP can be used by the nursing staff or independently by the patient, thus reducing physiotherapy contact time and possible on call visits.

Conclusion

It can be seen from this study that there was a wide variety of clinical conditions and specialities that the physiotherapists identified suitable for the use of EZPAP. Effectiveness of the device has been proved on a small scale by the improvements of physiological observations for increasing lung volume, preventing atelectasis, clearing secretions and improving gas exchange as identified in existing research. However, where much of this literature was circumstantial this study used objective markers to clarify the successful outcome of EZPAP interventions, however it is acknowledged additional outcome measures such as arterial blood gas analysis and chest x rays would have improved the validity and reliability of this study. This study also identified that EZPAP may also be used as a physiotherapy technique to reduce the work of breathing and this requires further investigation.

Alongside clinical improvements, both patients and clinicians found the device easy and comfortable to use, quick to set up with rapid results, utilising only one clinician therefore is a cost effective adjunct, and it was the physiotherapist's perceptions that EZPAP is potentially an alternative adjunct to respiratory physiotherapy and EZPAP has subsequently been purchased for use at our hospital.

Recommendations

This study was small scale at a local level and further randomised trials utilising ABG's, radiological evidence and amount of sputum cleared should be carried out. EZPAP should also be compared to devices such as the cough assist mechanical insufflators – exsufflator, flutter, acepella and PEP masks.

Key Points

- EZPAP is a versatile tool for physiotherapists in respiratory care
- EZPAP is easy to use with a high level of patient compliance

Acknowledgments

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Validity and reliability validation of a questionnaire to explore physiotherapy practice into the use and delivery of nebulised isotonic saline in the UK

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Summary

Nebulised isotonic saline (0.9%) as a method of enhancing airway clearance has become a clinically accepted adjunct to physiotherapy in the treatment of many chronic lung conditions despite little scientific evidence for its use. The aim of this research study was to develop and validate a data collection tool to explore current physiotherapy practice in the United Kingdom on the use of nebulised isotonic saline.

Introduction

Nebulised isotonic saline (0.9%), as a method of enhancing airway clearance, has become a clinically accepted adjunct to physiotherapy in the treatment of many chronic lung conditions, but there is little scientific evidence on which to base its use (Kellet et al., 2005). In current clinical practice, the use of nebulised isotonic saline to aid the clearance of sputum appears to be based mainly on anecdotal evidence. No studies were found that investigated the use of nebulised isotonic saline within physiotherapy clinical practice, although there have been those exploring humidification (Conway et al, 1992).

The value of a questionnaire depends on the validity and reliability of the information it gathers. Validity is how well the questionnaire measures what it is intended to measure (Meadows, 2003). The validity of the questionnaire was measured by face and content validity. Face validity is based on whether the items look appropriate and content validity is assessed on the extent to which the questionnaire's content includes everything it should and does not include anything it should not (Meadows, 2003).

Reliability refers to how well the data collected by using the questionnaire can be reproduced.

This is part of a larger study, which used the questionnaire to gather data from respiratory physiotherapists in the UK.

Aim

The aim of this study was to develop and assess the reliability and validity of a questionnaire exploring physiotherapy practice on the use of nebulised isotonic saline.

Method

This methodological study assessed the face and content validity and reliability of a questionnaire, designed in order to collect data from a large geographical area, containing mainly closed questions. This method of data collection minimises the risk of interviewer bias. As there were no funds available for printing and posting, the aim was to distribute the questionnaire electronically.

To promote the response rate in this study, the questionnaire was developed to be short and simple with minimal jargon and acronyms (Houser and Bokovoy, 2006). Careful attention was paid to design and layout of the questionnaire, reducing the risk of errors in posing and interpreting questions and in recording and coding of responses (McColl et al., 2001). This also helped to minimise the potential for inter-rater variability. The content of the questions were informed by current literature and the lead author's experiences of working in the respiratory physiotherapy field. The studies found concerning nebulised isotonic saline revealed numerous models of nebuliser and many different protocols used. For example, the protocols varied in the gas choice and gas flow rate to drive the nebuliser and some papers did not state these at all.

The questions were grouped together in six sections, including demographic background of participants, prescription of nebulised isotonic saline, clinical indications, the setup of the nebuliser, participants' clinical views and in the closing part of the questionnaire an opportunity for the participant to add qualitative comments (see, Appendix 1). This design approach ensured that specific questions followed on from general questions (Meadows, 2003) and that there was a consistency to the presentation of visual information (McColl et al., 2001).

Face and content validity were assessed on two occasions; firstly by using an expert panel and secondly by carrying out directive interviews (Oppenheim, 1992). The expert panel was comprised of a clinical respiratory specialist physiotherapist, a professor in aerosol medicine and a consultant respiratory physiotherapist. The questionnaire was considered by the panel in terms of content, flow and terminology used. The changes made from this stage were fed forward to the second stage of face and content validity, directive interviews with two respiratory physiotherapists, from a local clinical interest group, who were also members of the Association of Chartered Physiotherapists in Respiratory Care (A.C.P.R.C). The purpose of these two stages was to ensure the questionnaire did not contain inappropriate material and that the contents were suitable to fulfil the larger study research objectives. Again the changes made in the second stage were carried forward to stage three, which assessed reliability.

Stage Three involved the questionnaire being pre-piloted on five different volunteers, from the local clinical interest group, on two occasions, one week apart, to ensure reliability of the data collecting tool, with a test-retest reliability method (Knapp, 1998). The five volunteers completed the electronic questionnaire and followed the protocol for the main study to return the questionnaire to the lead author.

The expert panel and directive interviews were recorded, with consent, to assist the lead author in engaging with the panel and volunteers. The lead author kept a research

diary in order to reflect upon the process and to ensure that all comments were included. Ethical approval was granted from the Faculty of Health Sciences Ethics Committee at The University of Southampton and permission was granted for product photography inclusion in this research study from the various nebuliser equipment manufacturers.

Results

Face and content validity were judged by the expert panel and directive interviewees, on the relevance of the questions and the themed sections. Recommendations were made for amendments to the questionnaire. It was decided after discussion that Question 11 regarding the clinical indications and diagnoses should include surgical and paediatric options. Suggestions were also put forward regarding the terminology used in the questionnaire and the consistency of the terminology throughout the questionnaire. For example, advice was given to change isotonic saline nebuliser to nebulised isotonic saline. The expert panel were also able to highlight to the lead author that permissions needed to be sought regarding the inclusion of pictures of the nebulisers in the questionnaire. Some ideas that arose during the two stages were deemed too far removed from the topic of nebulised isotonic saline. An example of this was a question about using saline in Intermittent Positive Pressure Breathing equipment, to which it was decided against including, as the lead author and her supervisors felt that is was outside of the scope of this study.

Directive interviews were completed, individually, with two volunteers during completion of the questionnaire, with verbalisation of their thoughts and subsequent questions. This was to ensure the practicalities of completing the questionnaire were not overlooked. Examples of this were to ensure the question was understood as intended by the lead author and that the questionnaire could be completed in approximately 10 minutes.

The usability of the questionnaire was assessed in both Stage One and Two, when further alterations were made to the questionnaire, including the addition of coherent instructions for more complex questions in bold type to ensure clarity for participants; an increase in the size of the text boxes to enable a longer answer to be typed; and the addition of question options were changed to text boxes to allow specific answers rather than a range being chosen.

Reliability was via test-retest analysis at Stage Three. The five participants had the same demographic data answers when completing the questionnaires on the two different occasions. One of the five participants gave the same answer for the closed questions on each occasion and recorded similar answers to the open questions. For Question 12, on the reasons for using nebulised isotonic saline, three participants answered one part differently and one participant made an error by checking two boxes in one part of the question. This equated to 84% of the questions being answered consistently on the two occasions. The three differing answers differed by one point, one moving from disagree to uncertain; one changing from Strongly Agree to Agree and the final one from Agree to Strongly Agree.

The four participants that put a different answer on the first semantic differential scale, in Question 17a, all moved their answer to a more extreme point on the scale, agreeing that nebulised isotonic saline is effective as short-term humidification. One participant answered Question 17f responded at opposite ends of the scale on each occasion. Three parts of Question 17 had an error in one of the answers, when the participant had given two

answers to one question. These answers were excluded from the analysis, as it could not be determined which answer was chosen.

Overall, there was 81.1% agreement on answers over the two tests, and the questionnaire was considered reliable. Due to low numbers of volunteers, statistical analysis of internal consistency, for example Cronbach's coefficient alpha, was not carried out.

The final version of the questionnaire is presented in Appendix 1.

Discussion

The aim of this study was to test the reliability and validity of the designed questionnaire, prior to the main study. After each stage of the testing changes were made to develop and improve the questionnaire, before the next stage was started, ensuring rigour. Meadows (2003) described this process in order to focus on testing the whole administrative procedure of using the questionnaire in a smaller sample of participants before the main study.

Stage One, the expert panel of three key experts in respiratory care gave their consent to take part in the study and assisted by critiquing the questionnaire and ensured that the questions were not biased towards the lead author's area of respiratory care, considering all aspects. The experts also were able to suggest ideas to develop the questionnaire further. Some of these were carried forward, for example, to change the terminology used for nebulised saline. As experts in the field of respiratory care, these professionals ensured that the content of the questionnaire was appropriate to the research question.

The directive interviews in stage Two ensured the practicalities of completing the questionnaire were not overlooked. This was to ensure the question was understood as intended by the lead author and thus limiting error-variance in the final result. It also enabled the length of time needed to complete the questionnaire to be reviewed to ensure it was not too long. This in turn would help to encourage participants to take part in the main study, enhancing the response rate (Oppenheim, 1992).

By involving the expert panel and the clinicians the questionnaire was examined and face and content validity of the questionnaire was supported.

To ensure the reliability of the questionnaire a test-retest method (Knapp, 1998), in Stage Three, allowed data to be produced. Unfortunately, due to the small sample number, the data were not suitable for inferential analysis. A comparison of data from Stage Three evidenced good agreement for the majority of the questionnaire. The main questions for inconsistency were Question 12 and Question 17. Both were scale answers with a greater chance of different answers being documented on the two occasions, than the other questions. Question 12 had 84% agreement of the answers. This may be due to the fact that there were only 5 points on the Likert scale to choose from. Question 17 used a seven point semantic differential scale and this was reflected in the increase in number of different answers. The one participant in Stage Three that answered Question 17f with a five point different answer on the two occasions, may have misread the question on one or both occasions or may have changed their mind in between time one and time two. This may have been due to enquiring or discussing with colleagues during the week in between the two occasions. Overall, the level of agreement between time one and time two questionnaire answers was 81.1%. These results showed that the questionnaire was a reliable tool to collect data.

Conclusions

Research to date does not provide a conclusive rationale, protocol or prevalence data regarding the use of nebulised isotonic saline. This emphasised the need to develop and validate a questionnaire to explore current

physiotherapy practice regarding the use of nebulised isotonic saline in the United Kingdom from the respiratory physiotherapy population. The value of a questionnaire depends on the validity and reliability of the information it gathers; the face and content validity regarding how well the questionnaire measures what it is intended to measure and the reliability to collect reproducible data.

Impact on Clinical Practice

This questionnaire has now been validated and can be used to collect important information on the use and delivery of nebulised isotonic saline in physiotherapy practice in the UK.

This questionnaire has subsequently been sent out to members of the Association of Chartered Physiotherapists in Respiratory Care and the findings will be presented in a separate paper.

Recommendations for Future Research

Further research needs to be carried out, to investigate nebulised isotonic saline, in a range of different ways:

- Exploration of the patient perspective regarding the use of nebulised isotonic saline.
- Interviews or focus groups would provide a more in-depth exploration into the use and prescription of nebulised isotonic saline by physiotherapists.
- Investigation into the financial cost of nebulised isotonic saline.
- Development of protocols and guidelines would provide support for healthcare professionals providing nebulised isotonic saline.

Key Points

A valid and reliable data collection tool is now available to explore the current physiotherapy practice regarding the use of nebulised isotonic saline.

More research is needed into the use and delivery of nebulised isotonic saline.

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Appendix 1

Jo Hobbs, Final Questionnaire v1.1, 23Jun2010 Ethics No:

Questionnaire

My name is Jo Hobbs and I am a respiratory physiotherapist studying at the University of Southampton for my master's degree. The following questionnaire explores the provision and use of nebulised normal (isotonic/0.9%) saline in clinical practice in spontaneously ventilating patients.

Please read the information email with this questionnaire, complete by either: selecting from the drop down box, checking the tick box or typing in the free text box. Please then save the questionnaire as a word document and return by email as an attachment to _____by _____.

1. Are you male or female? Male/Female
2. What Agenda for Change Physiotherapy Banding are you? 5/6/7/8a/8b/8c/8d/9/Other

   If *other*, (please state in text box): Text Box
3. How many years have you been a qualified Physiotherapist? (please state in text box)

   Text Box Years
4. How many years have you specialised in respiratory? (please state in text box)

   Text Box Years
5. What department or speciality of practice do you work in? (please state in text box)

   (E.g. Medicine, Critical Care, Community etc.) Text Box
6. What type of patients do you work with? Adults/Paediatrics/Both
7. How many respiratory patients have you treated in the last 7 days?

   Text Box
8. How many of those respiratory patients, whom you have treated in the last 7 days, were receiving saline nebulisers?

   Text Box
9. Do you personally prescribe normal (isotonic/ 0.9%) saline nebulisers?

   No/ Yes, via Patient Group Directive (P.G.D.)/ Yes, as supplementary prescriber/ Yes, as independent prescriber

   If other, (please state in text box): Text Box
10. How often do you think normal (isotonic/ 0.9%) saline nebulisers should be prescribed?

    Every hour/ 2/ 3/ 4/ 5/ 6/ 7/ 8/ PRN as needed/ Other

    Please explain your answer to this question: (please state in text box)

    Text Box
11. In what circumstances do you think normal (isotonic/ 0.9%) saline nebulisers are indicated?

(Please check **all boxes that apply** below)

Chronic Obstructive Pulmonary Disease (COPD) ☐

Cystic fibrosis ☐

Asthma ☐

Bronchiectasis ☐

Pneumonia ☐

Sputum retention ☐

Increased work of breathing ☐

Decreased lung volumes ☐

Other ☐ (please state in text box): Text Box

12. What do you think of normal (isotonic/ 0.9%) saline nebulisers?

(Please check **one box per statement** below)

	Strongly Agree 5	Agree 4	Uncertain 3	Disagree 2	Strongly Disagree 1
a) I would use nebulised saline to aid secretion clearance.	☐	☐	☐	☐	☐
b) I believe nebulised saline can cause bronchoconstriction.	☐	☐	☐	☐	☐
c) I believe nebulised saline can relieve bronchoconstriction.	☐	☐	☐	☐	☐
d) I would use nebulised saline to reduce sputum viscosity.	☐	☐	☐	☐	☐
e) I would use nebulised saline to reduce work of breathing.	☐	☐	☐	☐	☐

13. Do you have a Standard Operating Procedure (SOP) for the use of nebulisers?

Yes/ No/ Unsure

If *no* or *unsure* go to Question 15.

If *yes* go to Question 14.

14. What is the source of the SOP for the use of nebulisers?

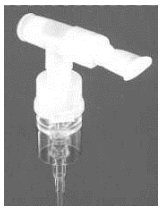
Physiotherapy policy/ Hospital policy/ Other If other, (please state in text box): Text Box

15. What model of nebulisers do you use?

(please check **all boxes that apply** below)







Sidestream ☐ Ventstream ☐ Devilbiss ☐ Whisper jet ☐ Acorn II ☐

Other ☐ (please state in text box): Text Box

16. What is used to drive the nebuliser?

Driver of nebuliser: (please check all boxes that apply below)	Flow rate of gas used litres/min: (please state in text boxes below)	Reason for use? (please state in text boxes below)
Air ☐	Text Box	Text Box
Oxygen ☐	Text Box	Text Box
Nebuliser Box ☐	N/A	Text Box
Other ☐ Please state: Text Box	Text Box	Text Box

17. Please read the statements below regarding nebulised normal (isotonic/ 0.9%) saline:

(Please check **one box per statement** in the box you feel is most appropriate)

a) As short term humidification nebulised saline is:	Effective ☐☐☐☐☐☐☐ Ineffective
b) Nebulised saline is:	Safe ☐☐☐☐☐☐☐ High risk
c) Nebulised saline has a:	Weak evidence base ☐☐☐☐☐☐☐ Strong evidence base
d) Nebulised saline is:	Easy to use ☐☐☐☐☐☐☐ Complicated to use
e) Nebulised saline is:	Misunderstood ☐☐☐☐☐☐☐ Well understood
f) Nebulised saline is:	Difficult to assemble ☐☐☐☐☐☐☐ Easy to assemble
g) Nebulised saline is:	Acceptable to patients ☐☐☐☐☐☐☐ Not acceptable to patients
h) Regarding infection control and nebulised saline, there is:	High infection risk ☐☐☐☐☐☐☐ Low infection risk

18. Have you ever encountered an adverse event regarding the use of a normal (isotonic/ 0.9%) saline nebuliser? Yes/ No/ Unsure

    If *no* or *unsure* go to Question 20.

    If *yes* go to Question 19.

19. Please describe the adverse incident(s) involving normal (isotonic/ 0.9%) saline nebulisers. Text Box

20. From the list below please select which area are you currently working in?

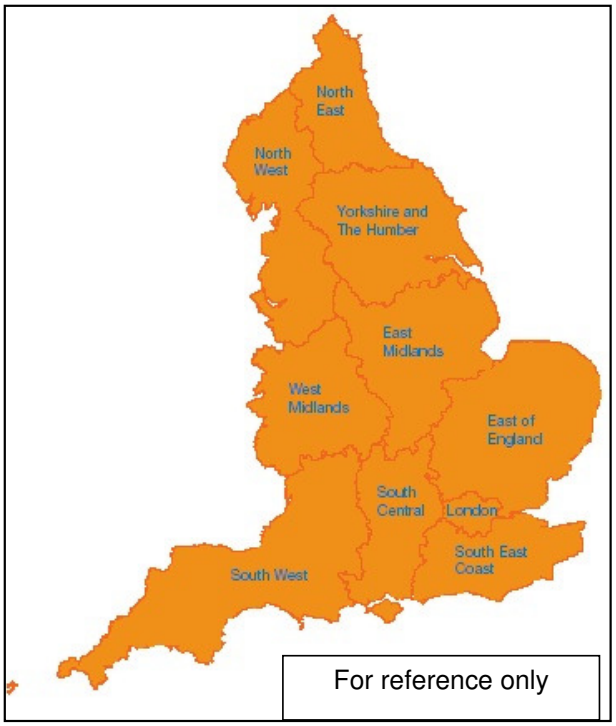
    Northern Ireland/ England/ Scotland/ Wales/ Other

    If *Other* please state: Text Box

    If you answered *England* please go to question 21.

    If you answered *Northern Ireland, Scotland, Wales* or *Other* please go to question 22.

21. Physiotherapists working in England please select which Strategic Health Authority you currently work in geographically:



North East

North West

Yorkshire and Humber

East Midlands

West Midlands

East of England

South West

South Central

London

South East Coast

22. Please use this section to express any comments or suggestions regarding nebulised (isotonic/ 0.9%) saline in physiotherapy practice that you feel has not been addressed.
Text Box

Thank you for completing this questionnaire.

Please save this completed questionnaire and send as an attachment to: _____

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A qualitative study into the experiences of living with long-term oxygen therapy: the perspective of patients with chronic obstructive pulmonary disease

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Keywords:

Long-term oxygen therapy
Self Management
Quality of Life

Summary

Long-term oxygen therapy (LTOT) is proven to improve mortality and reduce the risk of serious complications in patients with hypoxic chronic obstructive pulmonary disease (COPD). This small-scale qualitative study aimed to gain insight into the experiences of COPD patients living with LTOT in order to develop services to support their self-management and improve their quality of life.

Introduction

Chronic obstructive pulmonary disease (COPD) is an incurable long-term condition characterised by chronic systemic inflammation (Gea et al. 2009). Pulmonary manifestations include breathlessness, cough and sputum (NICE 2010). Patients with severe COPD have daily challenges in terms of their physical, social and psychological well-being due to effects of the disease. This often involves complex, multidimensional adaptations by patients in order to manage their condition (McMahon 2002).

Some patients with severe COPD develop chronic hypoxaemia, which if left untreated increases patients' risk of serious compensatory complications such as polycythaemia, pulmonary hypertension, cor pulmonale and increases mortality (Lynes and Kelly 2009).

Long-term oxygen therapy (LTOT) is a proven treatment to improve mortality and reduce risk of complications in COPD patients with chronic hypoxaemia (Nocturnal Oxygen Therapy Trial 1980 and Medical Research Council 1981) which is still valid today (Royal College of

Physicians 1999 and NICE 2010). This life-long treatment involves using supplemental oxygen therapy for a minimum of fifteen hour daily and for mobile patients the use of ambulatory oxygen therapy using portable cylinders for activities outside the home.

Previously scant attention has been paid to the effect that LTOT has on British individuals from a qualitative perspective. Robinson (2005) addressed a qualitative aspect of living with COPD in hypoxic patients requiring LTOT, but with emphasis on COPD rather than LTOT.

This study aimed to identify, explore and gain understanding of the multifactoral experiences of COPD patients using LTOT, in order to develop services to support their self management and improve their quality of life.

Methods

This descriptive phenomenological study sought to gain an understanding of the personal experiences of COPD patients living with LTOT. Taylor (2005) advocates that tape-recorded interviews, which accurately record the participant's words directly, are the most appropriate method of data collection, which was therefore adopted.

The study commenced after ethical approval was granted which included methods to ensure confidentiality and anonymity. 'Purposeful sampling' was used to select that specific group of patients via the respiratory department's LTOT database (Carter and Henderson 2005). Eleven patients were forwarded Welsh and English invitation letters, information sheets and consent forms in accordance with the Department of Health's Research Governance Framework for Health and Social Care (DOH 2005). Nine consent forms were returned. Two participants were selected for piloting, to assess and refine the novice researcher's interviewing skills but were not included in the analysis. Seven participants were interviewed in their home, the interviews tape-recorded and transcribed by the researcher. One participant sadly passed away, therefore their data was removed from analysis. The sixth interview was the point of 'theoretical saturation', since no new data was being generated, although importantly, previous findings were being confirmed (Holloway 2005). Each transcribed interview was forwarded to the participants to validate the data. The researcher utilised a phenomenological attitude to analyse the data following Giorgi's five manageable steps (Giorgi 2008).

Results

The participants described breathlessness as the main symptom which was an unpleasant sensation and affected their every move. This resulted in reduced activity, increased dependence on others and avoidance strategies.

Two groups of patients emerged; non-oxygen dependant (NOD) i.e. those using oxygen fifteen hours daily, and those who were oxygen dependant (OD) i.e. constant oxygen therapy.

Analysis of the six interviews identified four main categories which most affect these COPD patients living with LTOT:

- increased work to live;
- loss of spontaneity;
- significant others;
- struggle to live with it/can't live without it.

The participants describe how living with COPD required increased effort, but also how the extra burden of the oxygen therapy required constant planning, and organisation in order to avoid running out of oxygen, which limited activities outside the home:

"I have to plan to make sure I have enough to get home, and then have to order some for when I'm back in two days and it gets very

complicated …"

Two patients in the NOD group described difficulties achieving the minimum daily hours:

"My biggest difficulty I suppose is trying to maintain fifteen hours a day."

Due to the extra effort, some participants developed strategies to avoid its use in situations which it would be beneficial:

"Oh I can walk further with it … but it's a fine line between helping me and being a blinking nuisance …"

There is a sense of loss about not being able to just 'get-up-and-go', especially when it comes to travel and all reflected on how they rely on 'significant others':

"Because of the oxygen you have to stay in this country, and then you can't just go for a weekend"

"I have to admit it, I couldn't manage without XX. Either washing or doing most of the things I do"

However, despite the frustrations of living with home oxygen:

"I feel like yanking this off and throwing it through the window, you know it can be a nuisance and I get all worked up and everything as I can't do what I want to do";

All the participants said they couldn't, and wouldn't, want to envisage life without it:

" … I don't know what it would be like without oxygen now. I just wouldn't do anything. I suppose I'd probably die in my sleep …"

"Well without it I wouldn't be here would I?"

Discussion

The literature recognises that patients with COPD have to expend more energy undertaking routine, everyday activities, which translates into increased work (McMahon 2002). Analysis of this study's interviews reinforces this issue and revealed two groups of oxygen use; i.e. NOD and OD groups. The NOD group avoided using their prescribed ambulatory supply. This reluctance was due to; being embarrassed by it; wanting some 'normality' in their life or; the effort of using it was deemed too great. This trend was seen by Lacasse et al. (2005) in their randomised trial of ambulatory oxygen and compressed air usage in LTOT patients. Despite a carefully chosen group where a benefit was anticipated, early analysis revealed minimum use of ambulatory equipment, (either oxygen or air), therefore the study was stopped. Interestingly, participants in this study left their home three times more often without cylinders than with cylinders.

The lack of spontaneity described by the participants in this study can be seen in the literature, together with the constant planning required to assess oxygen requirements outside the home. Ring and Danielson (1997) identified the restrictions of COPD and LTOT in their Swedish interviews, together with the constant planning, and the restriction of outings despite the availability of oxygen supply. Robinson (2005) had a more positive view from her interviewees regarding LTOT, but the sense of freedom described by one of her participants was due to the their ability to fund a more portable system. Robinson's study (2005) emphasised the effects of living with COPD as opposed to LTOT, whereas this study focuses primarily on experiences relating to oxygen therapy as opposed to COPD. However the two elements are difficult to separate, as endorsed by a number of the participants of this study.

The majority of participants described restriction of domestic travel, and the loss of travel abroad. Despite the availability of domestic holiday oxygen supply, some participants had not tried it. For those that had, it had generally been a very positive experience, but again an element of restriction

due to the need for frequent portable cylinder deliveries. There does not appear to be any literature to either support or refute this finding.

Living with COPD and LTOT requires the support of family and friends for a reasonable quality of life to be attained (McMahon 1992). This was evident from the experiences of the participants of this study, and all bar one volunteered this information, without prompting. Kanervisto and colleagues (2007) studied thirty-five Finnish patients with severe COPD with and without LTOT. Their quantitative study identified dimensions of family dynamics. They concluded that families living with COPD patients with LTOT were significantly better in the dimensions of individuation, mutuality, flexibility, and stability compared to families living with COPD patients without LTOT. Whilst this may be a surprising finding, these families and patients may have had longer to adapt to the effects of COPD. According to the experiences of the participants of this study, other than helping them use the oxygen therapy, friends and family did not seem to be affected by it, once they were familiar with its use. They described how they were dependant on their partners for varying degrees of personal care, mobility and household chores, but perhaps were either not aware of the impact of their illness and oxygen therapy had on others, or preferred not to discuss it, possibly not wanting to tell the researcher, as their clinician. Cornwell (1984) suggests that patient narratives facilitate the 'private' account of their experiences, as opposed to the 'public' account which is conveyed at a clinical level which may be the case in this study.

Whilst all the participants described varying degrees of burden of living with LTOT, none could envisage living without it. For both oxygen usage groups there was an understanding of the body's need for oxygen therapy, and a sense of relief in the knowledge that the body would be getting some oxygen when the nasal cannulae were in situ. Knowledge that the body needs oxygen, rather than just a modality for the relief of breathlessness, is supported by Ring and Danielson's study (1997).

The purpose of this study was to gain insight into the experiences of COPD patients living with LTOT in order to improve services. Wilcock et al. (2003) advises that first you have to identify the individuals' needs and concerns. Whilst they recognised that interviews are time-consuming and costly, they deem them an extremely effective method of exploring and discovering an individual's experiences, leading to improved health care services. This proved to be the case for this study as well.

Wilcock et al. (2003) continue by postulating that an improvement in service quality is achieved when the service matches the needs of those who utilise the service. This study identified minor immediate changes to improve spontaneity for two patients with the provision of liquid oxygen to facilitate more freedom. However further assessment of the present service, support and oxygen equipment is required to match the service to the patient's needs i.e. more freedom.

Conclusion

Long-term oxygen therapy (LTOT) is proven to improve mortality and reduce the risk of serious complications in patients with hypoxic chronic obstructive pulmonary disease (COPD).This small-scale phenomenological study into the experiences of a group of COPD patients who live with LTOT has highlighted areas that affect their daily lives. This includes: increased work required to live, loss of spontaneity, reliance on significant others and a struggle to live with it yet can't live without it. They describe life overshadowed by the constant need to plan their every move due to their dependence on oxygen. Being a novice, the researcher had not envisaged the depth and richness of data that would be gained from the interviews, and the impact this experience would have on her personally.

A system of assessing patient's satisfaction with

home oxygen services should be developed to facilitate feedback in a more structured way, with the inclusion of interviews as part of that system, so that the true experiences of the individuals may be captured. This should be augmented by the increased availability of devices and equipment provided by the home oxygen service suppliers, allowing patients greater freedom to leave their homes and enjoy travel.

The researcher believes that these findings should be disseminated and further research into the effects of living with LTOT should be undertaken to identify the needs of COPD patients in larger numbers and in different locations. In addition qualitative research should be undertaken with patients with other pathologies causing chronic hypoxaemia, such as pulmonary fibrosis, to identify their specific experiences and needs.

Key Points

LTOT improves mortality in hypoxic COPD patients.

COPD patients struggle to live with LTOT, lack spontaneity and are dependant on others.

Further assessment of equipment and support services are required to improve patient's quality of life.

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Effects of high frequency chest wall oscillation on global ventilation in children with cystic fibrosis: A pilot study

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Keywords:

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Paediatrics
High Frequency Chest Wall Oscillation (HFCWO)
Electrical Impedance Tomography (EIT)

Summary

The effects of high frequency chest wall oscillation (HFCWO) airway clearance therapy in children with cystic fibrosis (CF) were investigated in terms of global lung ventilation, oxygen saturations (SaO_2) and comfort levels. Electrical impedance tomography (EIT) was used as a surrogate measure of global lung ventilation. Results from this pilot study indicated changes in regional ventilation, SaO_2 and comfort levels during and following HFCWO.

Introduction

Cystic fibrosis (CF) is a multi-system disease characterised by airway obstruction, chronic infection and airway inflammation. Airway clearance techniques (ACTs) are an essential component of the physiotherapy management of CF. There are many forms of ACTs available including high frequency chest wall oscillation (HFCWO). HFCWO therapy is administered through an inflatable jacket linked to an air-

pulse generator, worn around a patient's chest. The generator delivers an intermittent flow of air into the jacket which, on inflation, generates pressure on the chest wall (Chatburn, 2007). Rapid compression pulses, which compress and release the chest wall externally, are then applied at a variety of oscillation frequencies, selected from a possible range between 2-25 Hz (Selsby and Jones, 1990). These compression pulses generate changes in trans-respiratory pressure whereby the body surface pressure increases relative to the pressure at the airway opening (Oermann et al., 2001, Chatburn, 2007, Hansen et al., 1994). This theoretically creates a transient expiratory flow bias in the airways, which assists in the movement of mucus from the periphery towards the mouth (Stites et al., 2006, Dasgupta et al., 1995, Tomkiewicz et al., 1994, King et al., 1983, Osman et al., 2009). These have been referred to as "mini-coughs" (Dosman and Jones, 2005, Chatburn, 2007). HFCWO therapy has been shown to be as effective as 'standard' chest physiotherapy in terms of volume of mucus cleared and lung function measurements. Standard chest physiotherapy included postural drainage (PD) and positive expiratory pressure (PEP) in these studies (Kluft et al., 1996, Braggion et al., 1995). More recently Sontag et al (2010) reported, in a long term study of ACTs at 20 centres in America, that the rate of decline in the lung function measurement FEF_{25-75} was faster in the HFCWO group compared with the oscillating PEP and PD and percussion groups.

Electrical Impedance Tomography (EIT) is a relatively novel, non-invasive method of lung ventilation imaging that can be used at the bedside. EIT measures real time changes in ventilation (Bodenstein et al., 2009) and has the potential to be used by physiotherapists as an outcome measure for monitoring the effectiveness of ACTs. EIT has been validated against standard methods of regional ventilation measurement such as CT and MRI scanning (Bodenstein et al., 2009, Wrigge et al., 2008, Hinz et al., 2003). EIT has also been shown to be a reliable measurement in terms of test-retest (Frerichs et al., 2007) and inter- and intra-tester reliability (Smit et al., 2003). In brief, EIT provides a measure of the magnitude of bio-impedance when a harmless electrical current is passed through the body tissues. This measure can be used as a surrogate measure of ventilation as low air content regions do not impede electrical current, while high air content regions offer significant impedance (Brown, 2003). Changes in ventilation during the breath cycle can therefore be identified.

The purpose of this pilot study was to investigate the effects of HFCWO on lung ventilation, measured by EIT, in children with CF. Secondary objectives were to assess the effects of HFCWO therapy on oxygen saturations (SaO_2) and to investigate children's comfort levels during the treatment.

Method

Ethical approval was granted by the London Bloomsbury Regional Ethics Committee (reference number 10/H0713/34). Children (aged 6-16 years), with a confirmed diagnosis of CF, were recruited to the study from Great Ormond Street Hospital for Children NHS Foundation Trust either whilst they were inpatients or during outpatient clinic visits. Patients who were hospitalised were receiving routine intravenous (IV) antibiotics or treatment for an infective exacerbation. These patients were only studied once they had returned to their baseline physiological health status (defined by lung function (FEV_1), SaO_2 and subjective sputum volume expectorated during ACT). Written parental/guardian consent and assent from the children was gained for all participants. Children were excluded from the study if skin allergies or conditions precluded the application of electrodes for EIT monitoring, if they had a cardiac pacemaker, frank haemoptysis in the last 48 hours, rib fractures or if written consent could not be gained.

A familiarisation session was undertaken prior

to the day of testing with all participants so that they could become accustomed to the equipment and testing procedure. On the day of testing, the child was connected to the EIT equipment for baseline monitoring. This involved placing 16 electrodes around the chest to form a ring, ensuring equal spacing between each electrode (Figure 1). The electrodes were then connected to the EIT device. Baseline EIT measurements and SaO_2 were measured continuously during the 1 hour prior to treatment, while patients participated in calm activities (eg watching TV) while seated. Age appropriate comfort scores (the 6 point Wong-Baker Faces Pain Rating Scale (Belville and Seupaul, 2005) for children aged 6-10 years and a 10-point 10cm visual analogue scale (VAS) for children aged 11-16 years) were used to measure perceived comfort before the treatment.

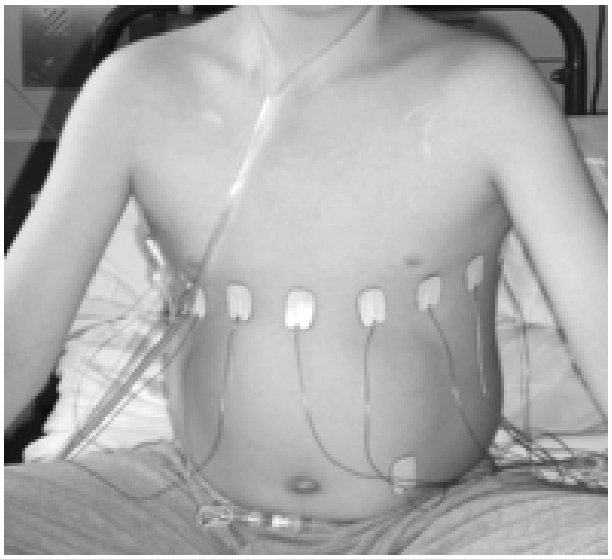

Figure 1 - 16 EIT electrodes placed around the circumference of the chest and 1 earth electrode on the abdomen

During treatment, HFCWO (The Vest®, Hill-Rom®) was applied to the child for a total of 20 minutes (4x5 minute sessions). Forced expiratory techniques (FET) and coughing were undertaken at the end of each 5-minute session in accordance with common clinical practice. Normal cilia beat frequency is in the range 8-15Hz and tracheal mucus clearance has been shown to be frequency dependent with the most striking effect in the 11-15z pulse range (Knowles and Boucher, 2002, King et al., 1983). HFCWO settings were standardised throughout the study with all patients receiving frequency settings of 14 Hz with pressure of 4 (on the Vest® this is an arbitrary unit scale of 1- 10) according to manufacturer recommendations and accepted clinical guidelines (Kempainen et al., 2010). Comfort scores were repeated in the intervals between the HFCWO treatments.

At the end of the treatment, the HFCWO device was removed but EIT electrodes remained in place and recordings, together with SaO_2 and comfort scores, were measured continuously in the hour following treatment.

Descriptive analyses of the baseline characteristics and demographics of the population sample were performed. Data were presented as mean and standard deviation [SD] and total number and percentage (%) where appropriate. Outcome measures were compared before and after the intervention using paired-samples t-tests (within subject for lung impedance measurements and between subjects for SaO_2 measurements).

Results

During the study period (May to August 2010), 11 children with CF were eligible for recruitment to the study. 9 were approached to take part as one participant was too unwell due to non-CF complications and one was assessed for eligibility during a day procedure which did not allow sufficient time. Of these, 7 children consented to participate. Consent was declined by 2 potential participants, the first due to unwillingness to re-attend the hospital for the testing session and the second reported that the study testing procedure was too long. Full data collection was achieved in 6 patients as one participant (6 years) withdrew consent following the initial familiarisation session due to reported discomfort from the Vest®.

The 6 recruited patients were aged between 6 and 16 years (mean [SD] age 12.4 [3.7] years),

4 were female and the mean [SD] predicted FEV_1 for the group was 58% [19.15]. Three participants had severe CF lung disease with an FEV_1 <40%.

Four of the six participants (67%) showed a reduction in mean global impedance following HFCWO treatment (suggesting a reduction in ventilation following treatment), and this reached statistical significance in 3 participants ($p<0.05$). The remaining 2 children showed a non-significant increase in global impedance following HFCWO treatment (Figure 2).

Two male participants (both 16 years) reported no discomfort throughout the duration of the study. Four participants (3 female), aged 9-14 years reported an increase in discomfort (mean increase from 0cm to 3.3cm on VAS, and a mean increase of 1 face on Wong Baker Faces Pain Scale) during HFCWO. Reasons for discomfort included an initial sensation of breathlessness, abdominal pain, central sternal pain, pain at the Portacath site, increased skin temperature, skin irritation and mild nose itchiness. Comfort levels returned to baseline on cessation of the treatment.

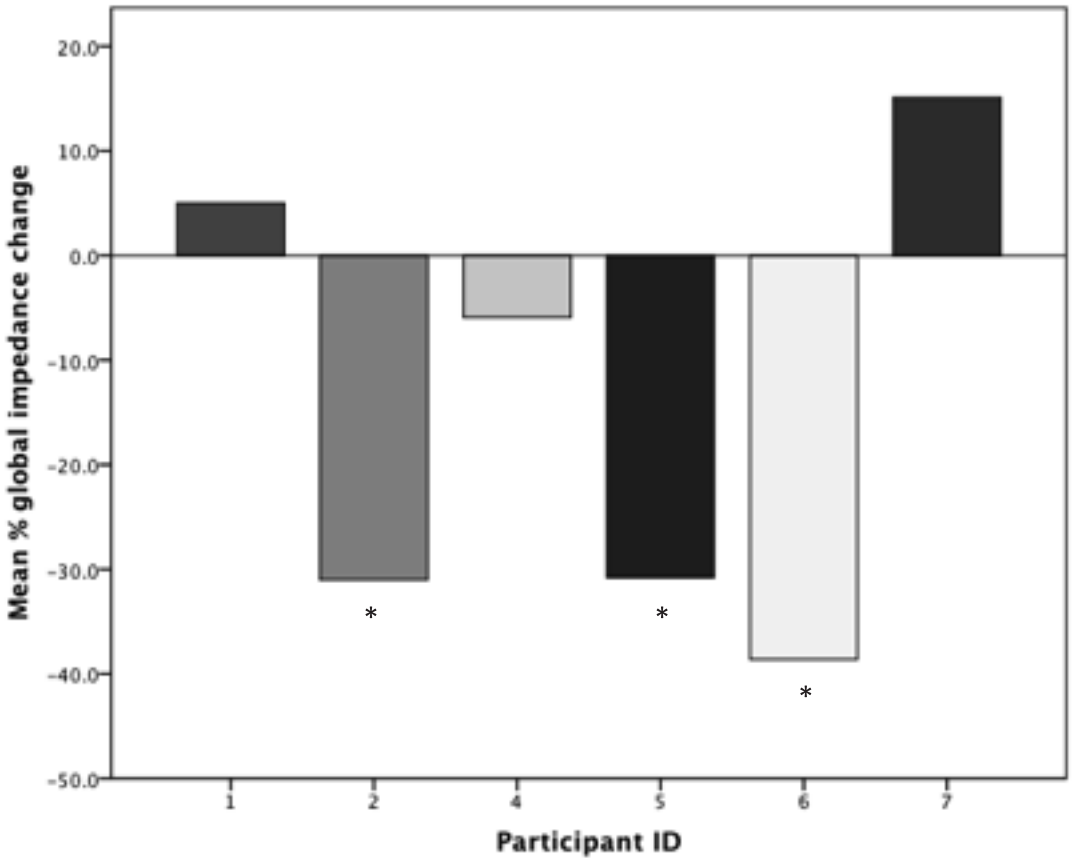

Figure 2 - Mean global relative impedance change (%) following the HFCWO therapy
* denotes statistical significance $p<0.05$

There was a statistically significant group reduction in SaO_2 following HFCWO from mean (SD) 94.8 (3.14)% to 94.2 (3.13)% ($p=0.03$), although the clinical importance of this change remains unclear. There was no significant correlation between change in SaO_2 and relative impedance change, (Pearson's product-moment correlation coefficient: $r=0.03$, $p=0.88$).

Discussion

This study suggested a reduction in global ventilation following HFCWO for 4 participants, which reached statistical significance in 3 out of the 6 participants. This study also demonstrated a small mean reduction in SaO_2 for the group and an increase in perceived discomfort in 67% of the participants during HFCWO therapy.

Previous studies in individuals with CF reported that, after HFCWO treatment, gas mixing and ventilation homogeneity increased when measured by single-breath inert gas washout test (Darbee et al., 2005, Arens et al., 1994). By contrast EIT is a measure of air distribution in the lungs. The complex relationship between air distribution and gas exchange in chronic lung disease remains poorly understood.

Both previous studies had larger sample sizes, used a longer HFCWO intervention period (30 minutes per patient) and different HFCWO settings, which further limit the comparisons between these studies.

Kempainen et al (2010) also reported greater homogeneity in ventilation (measured using single-breath inert gas washout test) following HFCWO in adults with CF. However, the exclusion criteria included patients with an FEV_1 <40%. In this current study 3 participants had an FEV_1 of 40% or below, of whom 2 showed statistically significant reductions in impedance after HFCWO. Further studies which simultaneously measure gas mixing and global ventilation may begin to shed some light on this relationship.

Although this current study was not powered to identify subgroup differences, a trend towards greater decreases in impedance and therefore lung ventilation, was shown in those with lower FEV_1 and therefore more severe airways disease. This may suggest that HFCWO is more appropriate for use in children who have mild-moderate, rather than severe, airway disease.

A group mean reduction in SaO_2 was shown in this study. This is consistent with the findings of Darbee et al (2005) but in contrast to that of Arens et al (1994) who reported a significant improvement in SaO_2 both during and up to one hour after HFCWO in an adult CF population. It is unlikely that the reduction shown in this study was of clinical significance but the importance of monitoring SaO_2 during HFCWO therapy is highlighted.

Discomfort either during or immediately after HFCWO was reported by 67% of the participants in this study. This was despite every effort being made to ensure that the Vest® was comfortable prior to each treatment period. The minimal clinically significant difference (MCSD) in VAS score has been reported to be in the range 0.9-1.3cm (Kelly, 2001) and the MCSD for the Wong Baker Faces Pain Scale has been reported as a change of 1 face (Belville and Seupaul, 2005). The results of this current study showed that 67% of the individuals, aged 11-16 years, showed a clinically significant change in comfort during or immediately after HFCWO. The increase in discomfort with HFCWO reported in this study highlights the importance of this consideration when offering this treatment option to paediatric CF patients, particularly for young (<6 years) children and developing adolescent females. If patients feel substantial discomfort while undergoing an ACT, it is unlikely that the resultant breathing pattern will optimise outcome. The EIT electrodes (similar in size to standard ECG electrodes (see Figure 1), which were in place directly on the participants skin under the HFCWO jacket may have contributed slightly to the discomfort reported, but these produced no discomfort when measured independently of the HFCWO therapy.

This study has shown that it is feasible, albeit time consuming, and technically cumbersome, to assess the effects of HFCWO on lung ventilation measured using EIT. The sample size (n=7) obtained for this pilot study was limited primarily by pragmatic attendance reasons. Most of the children approached were keen to participate in the study, particularly those who were in-patients in hospital. This result demonstrated that over a longer time period a larger sample size should be achievable.

An element of selection bias may have occurred as children with more severe airways disease were more likely to be admitted and therefore more likely to be approached. If, as suggested above, there is a severity linked response, this may explain differences between the findings

of this and other studies. However, the small sample size in this pilot study precludes any definitive conclusions.

A future larger study would provide more confidence in results, but the following recommendations could cautiously be considered as a result of this study. As this study and other studies have shown, SaO_2 decreased during HFCWO. SaO_2 should therefore be monitored during therapy and supplemental oxygen considered if necessary. Clinicians should be aware of the potential discomfort to children, which may be caused during HFCWO treatment. EIT could also be considered as a potential outcome measure for assessing the effects of alternative ACTs on ventilation.

Conclusion

This pilot study is the first of its kind to measure changes in regional lung ventilation as a result of HFCWO therapy in children with CF. The study was able to demonstrate the feasibility of EIT measurement in this population, which suggested a reduction in global ventilation, reaching significance in half of the participants. While this study was not powered to support any firm conclusions, the attendant reductions in SaO_2 noted and the discomfort reported by more than half the participants, suggest that this is a clinical area that would benefit from further larger scale studies. SaO_2 monitoring should be undertaken during HFCWO therapy, as well as close observation of patient comfort.

Key points

HFCWO therapy may cause a reduction in comfort and SaO_2 in some children and should be taken into account when using HFCWO in clinical practice.

EIT is a feasible bedside measure of ventilation, and the results of this study suggested ventilation changes do occur following HFCWO, but the clinical consequences of these changes remain unclear.

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An evidence and consensus opinion based approach to support the selective use of incentive spirometry following elective cardiac surgery; consideration for practice.

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Summary

The aim of this paper is to explain the processes that were involved in adopting an evidence based and expert opinion approach to the selective use of incentive spirometry following cardiac surgery. It also provides considerations for the selective provision of incentive spirometry post cardiac surgery.

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Introduction

In 2010 more than 30,000 patients underwent cardiac surgery in the UK (http://heartsurgerycqc.org.uk/). Cardiac surgery can incur a high incidence of post operative pulmonary complications (PPC) especially in the presence of particular risk factors such as age, smoking history, diabetes and respiratory co morbidity (Brooks-Brunn 1995, Hulzebos et al 2003).This can have a negative impact on length of stay, cost, morbidity and mortality (Ferguson 1999). Incentive spirometry (IS) is a technique that involves the use of a simple mechanical device to encourage deep breathing through visual feedback (Bartlett 1973) and can be used as a treatment adjunct in patients undergoing cardiac surgery. A Cochrane review published in 2007 (Freitas et al) specifically looking at the use of incentive spirometry for preventing PPC post Coronary Artery Bypass Grafts (CABG) found little evidence to support its use based

on a population of low surgical risk. The aim of this service development project was to explore the possibility of adopting a more selective approach to provision of IS to specific patient groups deemed most likely to benefit.

Aim

The aim of the project was to identify which patient groups following cardiac surgery, according to published evidence and expert opinion, are most likely to benefit from IS.

Methods

A literature review was conducted to examine the evidence for the effectiveness of IS in the post operative period following cardiac surgery. The NHS Evidence Health Information Resources website was accessed to identify papers published between January 2005 and December 2011.The databases Amed, Embase, Medline and Cinahl were used. The reference lists of articles were also hand searched for any potentially relevant articles. Inclusion criteria were cardiothoracic surgery, IS and papers where IS was being evaluated on patient groups known to be at high risk of PPC. Papers were excluded if the main focus was on a general surgical population.

Methodological quality was assessed by two independent reviewers using the Critical Appraisal Skills Programme (CASP) tools for review articles and randomised controlled trials (Public Health Resource Unit, England 2006).

To assist with the construction of considerations for practise in the use of IS post cardiac surgery, a questionnaire was designed and sent to lead physiotherapists in 38 cardiothoracic centres across the UK as identified on the care quality commission website (http://heartsurgery.cqc.org.uk/Survival.aspx) to explore current practice. Whilst the questionnaire consisted of largely closed questions, a section was included to permit respondents to comment generally on the use of incentive spirometry post cardiac surgery. Using these two methods of enquiry it was hoped recommendations for the more selective use of IS post cardiac surgery could be developed.

Results

Nine articles were identified, including four reviews, three comparative trials and two randomised controlled trials. Agostini et al (2008) reviewed studies involving both thoracic and CABG patients. Seven papers, scoring highest on methodological rigour using a range of selection criteria were selected as 'best evidence'. The literature review highlighted the variability in selection of outcome measures, making comparison between studies more difficult. One article, a literature review for the Cochrane Collaboration (Frietas et al 2007) concentrated exclusively on patients undergoing CABG and found no evidence of a reduction of atelectasis or pneumonia following the use of IS with patients following CABG in the low risk surgical population. They concluded there was no clear evidence for the routine use of IS in patients undergoing cardiac surgery.

Renault et al (2008), in their literature review of 11 randomised trials investigated the effect of respiratory physiotherapy on pulmonary dysfunction after cardiac surgery. Only three trials included IS specifically, hence there is limited evidence that can be gained for the benefits of this specific modality. They concluded that Bi-level positive airways pressure (BiPAP), or continuous positive airways pressure (CPAP) are superior modalities to IS. They found no consensus in the literature on the most appropriate physiotherapy technique in this early post-operative period and therefore gave no recommendations for practice.

Another literature review by Agostini et al (2009) including systematic reviews and randomised controlled trials (RCT), concluded that some form of respiratory physiotherapy with or without the use of IS is the superior treatment option. From this they were unable to define which physiotherapy regime would

be the 'gold standard' and whether IS should be routinely included within this due to the variety of outcome measures used, varying study designs and low powered studies. However, Agostini et al concluded that there was evidence to support a change from a flow to volume device, encouraging improved diaphragmatic activity and decreased work of breathing.

Basoglu et al (2005), in an RCT, found that IS improved arterial blood gases and quality of life for patients with an acute exacerbation of Chronic Obstructive Pulmonary Disease (COPD), a co-morbidity that patients undergoing cardiac surgery may present with. Unfortunately numbers were small, with no evidence of a power calculation. Characteristics were not well-matched at baseline, with patients in the medical treatment only group being both significantly older and with a greater smoking history. Not all patients completed the study, five patients were excluded (1 from the IS group and 4 from the medical treatment group) due to developing a second new acute exacerbation during the study period. These were not accounted for following the intervention.

Dias et al (2011) in their randomised controlled trial found that the technique of breath-stacking using a one way valve attached to a face mask was superior to IS. The power of the study was small, but did contain a control group who underwent mobilisation alone and all three groups were well matched in baseline characteristics.

Romanini et al (2007) in a non randomised comparative trial demonstrated that IS was beneficial at increasing inspiratory muscle strength. IS was not used in isolation but incorporated into a regime where mobility played a significant role. Results suggested use of IS increased inspiratory muscle strength compared to intermittent positive pressure breathing (IPPB) when combined with mobilisation. These results could have been strengthened by the use of a control group not receiving either adjunct. The papers of Renault et al (2009) and Savci et al (2006) were comparative trials, also with no control groups, comparing deep breathing exercises against IS and ACBT against IS respectively. The relative benefit of IS compared to no lung volume recruitment technique could not be assessed. Renault et al (2009) included the use of non invasive ventilation (NIV) prior to deep breathing or IS. Current studies included multiple interventions so the true effect of IS remains to be determined.

Consensus opinion using questionnaire

Twenty eight (74%) questionnaires were returned completed by physiotherapy clinical leads and clinical specialists.

Routine use of Incentive Spirometry

Only five centres (18%) routinely used IS post operatively. Figure1 explains the reasons given.

Figure 1 – Routine vs Non-routine Incentive Spirometry

Three centres (11%) always issued IS devices. In two of these centres the clinical lead physiotherapists had reviewed the evidence, tried to change practice but met with resistance from consultants. The remaining centre used IS routinely with all heart transplant patients, stating they felt these patients were at high risk of developing pulmonary complications due to immunosuppressive medication. In two of the centres (7%) incentive spirometers were issued by nursing staff and physiotherapists were not involved in the process.

Non routine use of IS

Twenty three (82%) centres did not routinely issue IS. The reasons supplied can be found in Table 1.

Discussion

There is no clear evidence supporting the routine use of IS following cardiac surgery.

This statement concurs with the findings of Frietas et al (2007), who highlighted the lack of supporting evidence for the routine use of IS on patients undergoing CABG surgery in a low risk population. Numbers of studies in the review were small, low powered and with only a modest number of patients. Clinicians currently are not able to make consistent and uniform judgements on the use of IS based on empirical evidence alone. Variability of practise in the use of IS post cardiac surgery was clearly demonstrated in the questionnaire responses supporting this theory.

Smoking history, age and diabetes are recognised as risk factors for PPC (Hulzebos et al 2003).There is still no significant evidence however to suggest if patients present with these risk factors specifically, that inclusion of IS to treatment regimes would provide any superior benefit than promotion of early mobilisation alone. This appears to concur with current UK practise as mobilisation was the most often quoted preferred treatment option in place of IS from respondents who completed the questionnaire.

The findings by Romanini et al (2007) concerning combined therapy of IS and mobilisation demonstrated benefits on patients with reduced inspiratory muscle strength.

Occasionally post operative cardiac surgery patients experience a prolonged ICU stay following complications. These patients can develop significant inspiratory muscle weakness and general deconditioning, which will require considerable respiratory rehabilitation. These positive findings suggest that a regime of respiratory rehabilitation considering the use of IS and mobilisation may benefit this patient sub group.

Inclusion of the Basoglu et al (2005) article was felt to be valid in this investigation. Patients undergoing cardiac surgery may present with a co-morbidity of COPD. Respiratory co-morbidity is a recognised risk factor for PPC following cardiac surgery (Hulzebos et al 2003).

Reason for Non Routine Use of IS	Number of Cardiothoracic Centres
Mobilisation Preferred	9
No Response Given	6
No Supporting Evidence	4
IPPB Preferred	3
PEP Preferred	1
ACBT Preferred	1
"Waste of Time and Money"	1

Table 1 – Replies from UK Cardiothoracic centres; reasons stated for the non-routine use of IS post Cardiac Surgery

Bearing in mind the positive effects using IS that have been demonstrated for patients with COPD, it would appear wise to consider IS in post operative regimes for patients undergoing cardiac surgery presenting with a co-morbidity of COPD. Future research should assess the effect of using IS on pulmonary function and the subsequent effect on rate of PPC in patients with COPD or smokers undergoing cardiac surgery.

In order to fully evaluate the exclusive benefit of IS, future study designs should take into account the effect of multiple treatment interventions. It is difficult to ascertain which intervention has greatest effect. There is a need for studies which have a clear control to determine the efficacy of IS in addition to other treatment modalities.

The questionnaire revealed an overwhelming majority (82%) of centres do not routinely issue IS devices following routine cardiac surgery. The most commonly used response for the non routine use of IS was "clinical indication" suggesting the value of clinical experience and reasoning of clinical lead staff working within this speciality. Specific clinical indicators were not supplied by respondents which made forming recommendations difficult. It is acknowledged that the respondents were not asked to name specific clinical indications. The authors accept this would have been a useful inclusion in the questionnaire design. It appears the use of IS is variable, sometimes even due to historical practice, evidenced in the questionnaire responses. Some clinical leads tried to introduce a more selective approach to IS use, but met with opposition from consultants who still wished their supply to be routine.

As experienced respiratory physiotherapy practitioners we should consider clinical indications to include atelectatic changes on CXR supported by auscultation changes, reduction in thoracic expansion and evidence of retained secretions. A full respiratory assessment, ideally including arterial blood gas analysis should be performed to identify the root cause of the problem.

Active mobilisation was the most often quoted preferred treatment method from respondents to the questionnaire; this is also well evidenced in the literature (Dull et al 1989, Reeve et al 2005, Stiller et al 1994). This appears to be a well established inclusion to post operative regimes in many centres.

These findings challenge the practice of routine provision of IS to post operative cardiac surgery patients. By adopting a more selective approach, organisational costs could be reduced, enabling physiotherapy staff to devote more time to enhancing patient mobility and rehabilitation of patients with complex needs. This assumption requires further investigation and the author is currently evaluating the effect of the more selective use of IS on the cardiac surgery population.

Conclusion

Following appraisal of the literature and the questionnaire responses received, it has been possible to suggest considerations for practice concerning the selective use of IS in patients post cardiac surgery. This includes patients with a co-morbidity of COPD, inspiratory muscle weakness and clinical indications for its use (atelectatic changes on CXR supported by auscultation changes, reduction in thoracic expansion and evidence of retained secretions).

Further research is recommended to determine whether IS and mobilisation are more effective than mobilisation alone as a means of reducing the likelihood of developing PPC. It would also be useful to establish whether IS has a role to play in patients who are not mobile post cardiac surgery.

Key points

This service development project has introduced considerations for the more selective use of IS post cardiac surgery.

Appraisal of current evidence and expert opinion has assisted in identifying specific patient groups deemed most likely to benefit from the routine provision of Incentive spirometry post cardiac surgery.

The evidence based considerations are there to facilitate appropriate use of incentive spirometry but are not exhaustive and clinical reasoning should always be used.

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Early rehabilitation of critical care patients: A review of the literature since 2009

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Summary

This review looks at the literature concerning early rehabilitation of critical care patients that has been published since the NICE Guideline on this subject in 2009. It summarises recent research in this field and highlights key questions for consideration in taking forward early rehabiliation in critical care in the UK.

Introduction

The past 25 years have seen improved management of critically ill patients with associated improvement in survival (Morris 2007). The long-term health effects of critical care can be extensive and prolonged: Van der Schaaf et al. (2009) found that one year after intensive care unit (ICU) discharge 69% of patients were still restricted in activities of daily living, and only 50% had resumed work. Exercise intervention in critically unwell patients can slow the deterioration in function (Chiang et al. 2006), can reduce the incidence of pulmonary complications, hasten recovery, decrease length of ventilator time and decrease ICU stay (Thomas 2011).

In 2009 the National Institute for Health and Clinical Excellence (NICE) published a clinical guideline (CG83) for the rehabilitation of adults after a period of critical illness (NICE, 2009). They established guidelines regarding assessment of patients, delivery of rehabilitation and post-discharge follow-up for critical care patients. They anticipate that the consensus based guideline will "stimulate, rather than stifle, research, and the impact of the introduction of the recommendations, along with alternative approaches, should be thoroughly evaluated" (NICE, 2009, pg. 7). The purpose of this paper is to review research that has been carried out in early rehabilitation since the publication of CG83.

Objectives

1. To search for evidence of studies into early rehabilitation of critical care patients subsequent to the publication of the NICE guidelines (CG83) in 2009

2. To review the studies and analyse the evidence presented

3. To draw conclusions and make recommendations for future research

Methods

Database searches of CINAHL and PUBMED were carried out in March 2011. The search included data from the beginning of 2008 to allow for overlap with the publication of CG83. Search terms included critical illness, intensive care, early, rehabilitation, mobilisation and exercise. Other searches included a review of PEDro and Cochrane databases, plus follow up of article citations and searches for key authors to identify further articles for inclusion. Screening to determine inclusion was carried out on title, abstract and where necessary on full content.

Studies concerning early exercise rehabilitation (that which takes place before the patient leaves the critical care department) of adult intensive care patients were included. Foreign language papers, reviews and commentaries were excluded, as were studies of patients suffering head injury or stroke as their primary injury, since these are excluded from CG83.

Results

An overview of the search and the number of articles identified at each stage is shown in Figure 1.

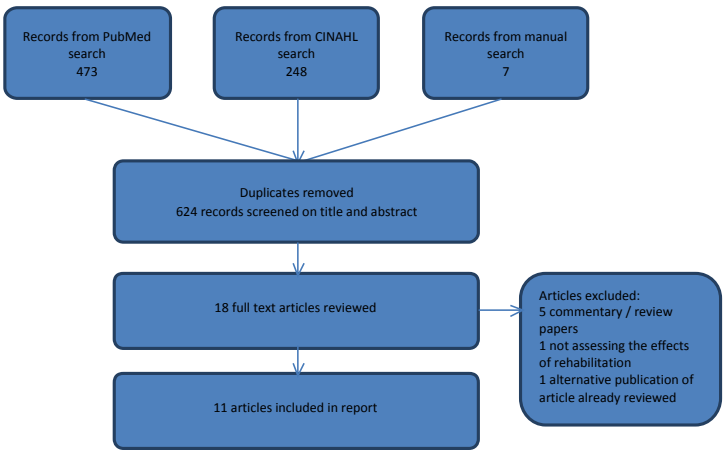

Figure 1 – Search Results

Due to the restrictive timescales of the literature search conducted (2008 to 2012), the number of studies retrieved was small and included a variety of study types (Table 1). For the purposes of discussion the studies are grouped by method.

Study Type	Frequency	Authors
Observational	2	Bahadur et al. 2008; Bourdin et al. 2012
Cohort	3	Morris et al. 2008; Needham et al. 2010; Thomsen et al. 2008
RCT	2	Burtin et al. 2009; Schweickert et al. 2009
Qualitative	1	Hanekom et al. 2011
Protocols of research currently in progress	2	Kayambu et al. 2011; Geneen et al. 2010

Table 1 – Summary of Studies

Observational Studies

Two observational studies were identified and are summarised in Table 2. Bahadur et al. (2008) conducted an observational study to measure mobilisation of tracheostomised patients in their ICU. They found that patients who mobilised had significantly improved survival and discharge rates from ICU. As is common practice in UK ICUs patients were mobilised based on need, as identified by the nursing or therapy staff. The study reports a very high number (65%) of "attempted" mobilisations, where the staff intended to mobilise the patient but did not because the patient was "too unwell". The parameters for "too unwell" were not recorded in the study, but may have included cardiovascular instability or infusion of inatropes. The authors acknowledge that lack of detail on this point is a flaw in their study, but suggest that the high number of patients in this category may be due to a conservative culture around rehabilitation in their ICU. The lack of

control in this study means their findings need to be carefully interpreted: it is possible that patients not mobilised were the most unwell, and therefore the least likely to survive.

Bourdin et al. (2010) conducted a small sample observational study to describe the feasibility and safety of an ICU rehabilitation protocol. They describe the changes in physiological values during rehabilitation events that include hoisting to chair, tilting up in standing and walking. The changes in physiological values show statistical significance in some instances and the authors describe some results as clinically important, without giving a framework for this indicator. Interpretation of these values is difficult, as change in some of these parameters e.g. heart rate is a sought after effect of exercise and rehabilitation. The authors offer no explanation of the implication of these changes for the patients or how prolonged the effects were. They conclude that their intervention is feasible and safe.

Cohort Studies

Three prospective cohort studies were identified in the literature search as summarised in Table 3. They each report the comparison of patient outcomes before and after a described intervention.

Morris et al. (2008) use a specially recruited mobility team to deliver rehabilitation to a number of ICU units. The team is allocated to one unit at any point in time and remain there until 50 patients have been enrolled, and then rotate to the next unit. The patients in units without the mobility team act as controls. The intervention group receive additional therapy from the mobility team, progressing from passive stretches to mobilising, according to patient mobility. They demonstrate a reduced ICU length of stay (LOS) for the intervention and a reduction in hospital LOS.

The study by Needham et al. (2010) measures the effect of a culture change in ICU: policy changes around sedation and bed rest; raising the importance and awareness of rehabilitation; increases in rehabilitation staffing. Patients in the ICU before the change was implemented are used as controls, which limits the ability of the study to attribute the findings to the intervention. They show a decrease in ICU LOS of 2.1 days and hospital LOS of 3.1 days.

The study by Thomsen et al. (2008) looks at the impact of transfer from a general ICU, to a specialised respiratory ICU with a pro-rehabilitation culture. Activity levels before transfer were compared to activity after transfer. They find transfer to an ICU with a pro-rehabilitation culture is a significant predictor of ability to ambulate. However as the patients act as their own controls, the improvements may have occurred without the intervention taking place, and so a causal relationship cannot be established.

Authors	Study	Participants	Intervention	Adverse Events	Results
Bahadur et al. 2008 (UK)	A study of normal care of tracheostomy patients to identify the frequency of mobilisation defined as actively sitting on the edge of the bedm sitting out of bed with any level of assistance, standing, walking. To identify any realtionshiop between level of mobility and patient outcomes.	19 patients mobilised during their ICU stay, mean age 66 (IQR 61 to 77), 12 were female. 11 patients did not mobilise, mean age 70 (IQR 54 to 74), 8 were female	Rehabilitation based on patient need and ability as identified by the physiotherapist. Rehabilitation treatments included sitting on the edge of the bed, sitting out of bed, walking	Not documented	Medain of 2 (IQR 0 to 11) mobilisations per patient during ICU stay. Median of 14 (IQR 7 to 21) intended mobilisations during the same period, with the difference accounted for by the patient being too unwell to treat. Significantly better survival rates ($p<0.01$) between those who were mobilised (5% morality) and those who did not (73% mortality)
Bourdin et al. 2010 (France)	An observational study of usual care in an ICU setting, measuring levels of patient activity and physiological effects of rehabilitation	20 patients, mean age 68 (IQR 32 to 85), 6 were female	Chair sitting, tilting up with tilt table of standing hoist, or walking with assistance. Patients were screened daily by doctors for ability to participate in rehabilitation	3% including drop in muscle tone (without falls), lowered oxygen levels, hypotension and 1 unschedule extubation	Contraindications for rehabilitation occurred on 43% of patient-days in ICU. Chair sitting represented 56% of interventions, walking 11%. Chair sitting significantly decreased heart rate ($p=0.03$) and respiratory rate ($p=0.03$). Waliing significantly increased heart rate ($p=0.002$) respiratory rate ($p<0.001$) and oxygen saturation ($p=0.001$). Tilting up with arms unsupported significantly increased heart rate ($p<0.001$), respiratory rate ($P<0.001$) and oxygen saturation ($p=0.001$). Tilting up with arms supported significantly increased heart rate ($p<0.001$) and mean arterial pressure ($p=0.01$)

Table 2 – Summary of Observational Studies

Authors	Study	Participants	Intervention	Adverse Events	Results
Morris et al. 2008 (USA)	A study to look at the effectiveness of a mobility team delivering rehabilitation to mechanically ventilated patients. The mobility team moved at periods from one ICU in the study to another. The ICUs not currently served by the mobility team were used as controls for the study.	Intervention group - 165 patients, mean age 54 (+/- 16.8) Control group - 165 patients mean age 55.4 (+/- 16.8)	Intervention - the mobility team followed a clear screening protocol to identify the level of activity for each patients, ranging from passive movements through to sitting, active transfers to chairs and mobility. Control - daily stretching by nursing staff, rehabilitation as staffing allowed and as directed by physicians	None	ICU length of stay (LOS) for the control vs. intervention group was 6.9 days vs. 5.5 days, p = 0.027. The hospital LOS was 14.5 days for the control group vs. 11.2 days (p = 0.006). The average cost per patient (including the cost of the mobility team) was $44,302 for the control group and $41,142 for the intervention group, p = 0.262.
Needham et al. 2012 (USA)	A quality improvement study to look at the combined effects of reducing sedation and increasing rehabilitation in mechanically ventilated patients. Patient data from 3 months prior to the study were used as controls for the study	Intervention group – 30 patients, age 53 (IQR 43-69) Control group – 27 patients (IQR 43-59)	Intervention - Default status for patients changed from “bed rest” to “activity as tolerated; sedation policy changed from continuous infusions to delivery as needed , increased PT/OT staffing, guidelines for referral and intervention of OT/PT	4 displaced rectal or feeding tubes	Reduced sedation rates – 73% vs. 96%, p=0.03 Reduced delirium – 21% vs. 53%, p=0.003 Decrease in ICU LOS by 2.1 days (95% CI 0.4-3.8), decrease in hospital LOS by 3.1 days (95% CI 0.3-5.9)
Thomsen et al. 2008 (USA)	A pre-post cohort study to look at the effect on mobility of patients who transfer from an ICU unit to one which has a culture in which early activity is considered a priority. Patient data pre-transfer was used as a comparator to outcomes post-transfer	104, mean age 57.9 (+/- 18.1)	Rehabilitation activity as patient ability allowed including sitting on edge of bed, active transfer to chair and mobilising. Similar activities took place in the units pre-transfer, but within a culture with less emphasis on rehabilitation	Not documented	Regression analysis show the following as predictors of increased ambulation: ICU transfer (odds ratio [OR] 2.47; 95% confidence interval [CI] 1.85–3.4, p <.0001), absence of sedatives (OR 1.90; 95% CI 1.19–3.15; p =.009), female gender (OR 1.88; 95% CI 1.11–3.22; p = 0.019), and lower APACHE II scores (OR 1.06; 95% CI 1.01– 1.12; p = 0.017)

Table 3 – Summary of Cohort Studies

Authors	Study	Participants	Intervention	Adverse Events	Results
Burtin et al. 2009 (Belgium)	A randomised control trial to investigate the effects of using a cycle ergometer as an early intervention in critical care patients No blinding took place	Intervention – 31 patients, mean age 56 (+/-16) Control - 36 patients, mean age 57 (+/- 17)	Intervention – standard care plus 20 minutes of cycle ergometer 5 days per week. The ergometer could be used as passive exercise if the patients were sedated. In awake patients resistance was altered according to their ability Control – standard care, which included passive movements, active exercises and ambulation when considered appropriate by the medical staff	None	Increased 6 minute walking distance (6MWD) on hospital discharge – intervention 196m (126-329) vs. 143 (37-226) p <0.05. Improved SF36 (physical) – intervention 21 (18-23) vs. 15 (14-23) p< 0.01 Improved gains in quadriceps strength during ward stay p < 0.01 No significant difference in Berg Balance scores, Functional Ambulation Measure, weaning time, ICU stay or hospital stay.
Schweickert et al. 2009 (USA)	A randomised control trial to investigate the effects of early therapy interventions (OT and PT) during sedation breaks. Therapists under taking treatment and reviewers were blinded	Intervention – 49 patients median age 57.7 (IQR 36.3-69.1) Control - 55 patients median age 54.4 (IQR 46.5 – 66.4)	Intervention – daily passive movements for sedation patients. Rehabilitation during sedation holds including active exercises, sitting, transfer to chair, pre-gait exercises and walking Control – no routine PT or OT	1 de-saturation, 1 removal of catheter	Functional independence at hospital discharge was increased in the intervention group odds ratio 2.7 p= 0.02 (95% CI 1.2-6.1) Improved Barthel Index in intervention 75 (IQR7.5-95) vs. control 55 (IQR 0-85) p=0.05 Length of ICU stay intervention 5.9 (IQR 4.5-13.2) vs. control 7.9 (IQR 6.1-12.9) p=0.08 No change in hospital LOS

Table 4 – Summary of Randomised Control Trial

Randomised Control Trials

Two randomised control trials were identified and are summarised in Table 4. Schweickert et al. (2009) carried out a high quality randomised controlled trial (RCT) of 104 mechanically ventilated patients. The intervention group received daily physiotherapy and occupational therapy during sedation holds throughout their ICU stay, and continuing progressive rehabilitation until hospital discharge. Therapy progressed from passive movements to active exercise, sitting and walking as patient ability allowed. The control group underwent standard care, which included sedation holds but did not routinely include therapy.

The study shows a significant increase in the number of patients who were functionally independent on hospital discharge in the intervention group, reduced ICU LOS, but no difference in hospital LOS. This study demonstrates that increased therapy input can improve patient ability on hospital discharge. The authors also note that only 39% of the intervention group, compared to 51% of the control group, needed inpatient rehabilitation on discharge. The study also demonstrates that rehabilitation is feasible and safe during sedation holds, a treatment which has not previously been reported in studies of ICU rehabilitation and is not yet common practice in the UK.

The study by Burtin et al. (2009) considers the effect of 20 minutes of ergometer cycling (passive or active, according to patient ability) in addition to usual care, given to critically ill patients starting after 5 days in ICU and continuing until ICU discharge. Patients were included if they were expected to stay on ICU for a further 7 days, which may have led to bias in the selection of patients.

The study finds increased 6 minute walking distance (6MWD) on hospital discharge and an improved SF36 physical score (a patient reported measure of functional health and well-being), but no change in weaning time, ICU LOS or hospital LOS. There is no discussion of the clinical significance of the findings, and the study does not identify whether the improvements made by patients were due the intervention or the additional therapy that patients received. There is no cost analysis of the additional care provided.

Qualitative Research

Hanekom et al. (2011) identify variability in practice in the field of ICU rehabilitation and use a Delphi study of expert opinion to develop a clinical management algorithm. They identify three different groups of patients (unconscious, able to participate, de-conditioned) and use the data collected to draw up a clinical management algorithm for each of the groups. The algorithm suggests evaluations that should be carried out for patients in each category to determine appropriateness for treatment. They also include suggestions for rehabilitation activities and progression of treatment, as well as goal setting and consideration for inter-disciplinary discussions. They suggest that the clinical utility of the tool should be tested in future research.

Study Protocols

Two protocols for research currently taking place were identified, which may further inform this field when completed: a Cochrane review to investigate the evidence for exercise rehabilitation programs initiated after ICU discharge (Geneen et al. 2010) and a prospective randomised controlled trial comparing early targeted rehabilitation to normal care in mechanically ventilated patients diagnosed with sepsis syndrome (Kayambu et al. 2011).

Discussion

The importance of ICU rehabilitation was established in CG83 (NICE 2009). This review of the literature published since those guidelines can be summarised by three key questions.

What rehabilitation should be done?

With the exception of the study by Burtin et al.

(2009) who consider a specific cycle ergometer intervention, there appears to be a consensus around the general nature of rehabilitation for ICU patients. Passive movements are given to sedated patients, active/resisted exercises are used once patients can participate, progressing to sitting on the edge of the bed, chair sitting, standing and mobilising as patient ability allows.

CG83 (NICE 2009) indicates that rehabilitation should start "as early as clinically possible" (pg. 11), yet significant variation exists in the studies regarding timing of intervention. Morris et al. (2008) commence rehabilitation on patients who have been ventilated for less than 3 days, while Bourdin et al. (2010) include patients who have been on ICU for more than 7 days. Unlike other studies, Schweickert et al. (2009) begin active rehabilitation during sedation holds.

Significant variation in practice occurs in different countries. In studies from the UK and Europe (Bahadur et al. 2008; Bourdin et al. 2010; Burtin et al. 2009) "usual care" is to deliver some rehabilitation by therapists based in the ICU, while studies from the USA (Morris et al., 2008; Needham et al., 2010; Schweickert et al., 2009) describe "usual care" as only minimal therapy. Caution is required therefore in assuming that the improvements identified in these studies would be replicated if applied to a European setting.

In keeping with the recommendations of the NICE guideline (NICE 2009), Hanekom et al. (2011) attempt to address this variability by use of an algorithm for managing ICU rehabilitation. The practical application of such algorithms may however be limited (Stiller, Phillips, & Lambert 2004).

Should more rehabilitation be done?

The studies show that ICU rehabilitation can deliver functional benefits to patients (Burtin et al. 2009; Schweickert et al. 2009) as well as economic benefits in reducing costs or length of stay (Morris et al., 2008; Needham et al., 2010). However, increasing the provision of rehabilitation requires an increase in resource, and therefore cost.

Thomsen et al. (2008) suggest that clinical culture plays an important part in increasing the amount of rehabilitation received by patients. The changes undertaken by Needham et al. (2010) include an adjustment in approach to early activity to improve outcomes. Hopkins, Spuhler, & Thomsen (2007) describe an intervention to create an ICU with a culture aimed at early activity, which succeeded in reducing length of stay and daily cost per patients. It may be therefore possible to increase rehabilitation without a large increase in resource and cost.

What should be measured?

CG83 (NICE 2009) calls for comprehensive assessment and rehabilitation goal setting for ICU patients, however there remains a lack of consensus on suitable outcome measures. The studies generally used physiological features to screen patients for suitability for rehabilitation and to monitor their status during treatment. Functional measures used include Functional Independence Measure (Schweickert et al. 2009), Barthel Index (Schweickert et al. 2009), 6 minute walking distance (Burtin et al. 2009), ambulation distance (Thomsen et al. 2008) and SF36 (Burtin et al. 2009). Hospital or ICU length of stay are also used (Burtin et al., 2009; Morris et al., 2008; Needham et al., 2010; Schweickert et al., 2009), but it can be difficult to link changes in these measures to early rehabilitation interventions.

Thomas (2009) points out the need for validation of functional outcome measures in critically ill patients, as they may not be sufficiently sensitive to detect change in patients with low level of function. It is also important to identify clinically significant levels of change in this group of patients. Skinner et al. (2009) propose a new outcome measure (PFIT) specifically designed for use in clinical exercise in ICU, although it has not been used in any of the studies identified here.

Review Limitations

Due to the limited timescale for database selection, the review identified only a small number of studies.

Conclusion

The studies support CG83 (NICE 2009) in identifying the benefits of rehabilitation for critical care patients, but highlight the challenges in delivering it. Research effort now needs to focus on standardising ICU rehabilitation: timing, patient inclusion, type of treatment, amount of treatment. Approaches to changing ICU culture to include greater rehabilitation whilst minimising resource increments also need to be investigated. In particular, owing to the differing nature of rehabilitation across countries, UK based research is required.

To facilitate the goal setting and assessment called for in CG83 (NICE 2009), consensus needs to be reached on the use of outcomes measures. Physiological variables are useful for monitoring patients, but functional measures give a clearer indication of the benefit to patients and carers of interventions. Measures such as hospital or ICU length of stay are useful in indicating the economic effect of interventions.

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Book Review – Sarah Keilty

'Respiratory Care Principles and Practice' 2nd edition. 2012

Editors:

Dean R Hess, Neil R MacIntire, Shelley C Mishoe, William F Galvin and Alexander B Adams

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Price £49.99, Hard back.

This detailed North American Text book is described as a 'Classic and authoritative text for Respiratory Therapy students who need up to date coverage of the technical and professional aspects of respiratory care'. It would also be an excellent resource for post graduate professionals such as respiratory physiotherapists.

It is a large text book with 1372 pages, divided in to 5 major sections.

Like most medical text books on respiratory care, these sections include detailed aspects of respiratory assessment, patho-physiology of respiratory disease, respiratory theraputics, applied sciences in diagnostics, imaging, pharmacology and research. The final section, however covers professional issues in respiratory care including communication, ethics, critical thinking and evidence based practice. Of course being a North American text book it is slanted to aspects practiced in the US but these can be extrapolated to being relevant to respiratory professionals in the EU.

The five core sections mentioned above are further divided in 62 chapters. Each chapter sets learning objectives for the reader at the beginning, with key learning points summarised at the end. Each chapter is extensively referenced.

As this text book is aimed at Respiratory Therapists rather than Medical Students it has a large section on Respiratory Therapeutics, which in its self is over 400 pages long. Because of this, the focus of this book review will concentrate on this section.

The Respiratory Theraputics section is an in-depth practical guide to all aspects of respiratory care, well illustrated with diagrams, tables and photographs. It is extremely relevant to respiratory physiotherapists covering all aspects of care from acute to home care. Largely aimed at adult care, most chapters also consider paediatric and neonatal care.

The chapters in this one section are: Theraputic gases: management and administration; Humidity and aerosol therapy; Sputum collection, airway clearance and lung expansion therapy; Airway management and Cardio-pulmonary resuscitation; Mechanical ventilators - classification and principles of operation; Non Invasive Ventilation (NIV) and Continuous Positive Airways Pressure (CPAP); Neonatal and Paediatric respiratory care; Pulmonary rehabilitation; Home respiratory care; Respiratory care of the elderly; Disaster Management and managing medical information and patient safety.

The chapter on airway clearance is extensive and explores manual techniques, lung expansion therapy and suction. It also covers adjuncts such as in-exsufflation, oscillatory Positive Expiratory pressure (PEP), high frequency chest wall compression and intermittent positive pressure breathing (IPPB).

There are detailed chapters on oxygen therapy describing all aspects of Oxygen delivery devices including High Flow nasal O2. Humidification, aerosol therapy and inhaled drug delivery is also covered here

There is an extensive chapter on invasive

ventilation covering all aspects which would be a great resource for all Physiotherapists working in the Intensive care environment; this is accompanied with chapters on airway management, different types of endo-tracheal and tracheostomy tubes etc...

The chapter on invasive ventilation is complemented by one on non-invasive respiratory support. Both NIV and CPAP are covered from both an acute and home care point of view. There are photographs of all the available interfaces including helmet NIV and CPAP.

Recent history has taught that natural disasters, mass terrorism attacks and pandemic respiratory infection are no longer strangers to us. From this point of view, the chapter on Disaster Management is interesting and focuses on managing a mass casualty of respiratory failure both within the hospital and the community setting.

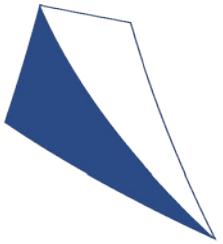
The last chapters in this section cover more chronic issues such as pulmonary rehabilitation, home management of respiratory disease and long term oxygen therapy. A chapter on Paediatric and Neonatal respiratory care is contrasted with one for the care of elderly patients.

Obviously being an American text it has its drawbacks. The Americans do not use metric / SI units (Systems International). The most noticeable are with blood gas and haemo-dynamic monitoring which are expressed in mmHg instead of kPa and cmH2O.

For the price, considering the information packed in to this huge volume, I think it is excellent value – not particularly for an individual to purchase but an ideal resource for any physiotherapy department in any acute Trust. A copy would also be an extremely useful reference resource in universities for students and lecturers alike.

Finally - it weighs approximately 4 - 5 Kg and measures 28 x 22 x 5cm so not one for the back-pack but I do believe it is available in down-loadable (e.g Kindle) formats!

Promoting best practice in respiratory physiotherapy for the benefit of patients



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