

The Winston Memorial Trust of Australia

Report by - Dr George Ntoumenopoulos – 2002/2 Churchill Fellow

The Bob and June Prickett Churchill Fellowship to study the effects of chest physiotherapy on mucociliary clearance in intubated and mechanically ventilated patients

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Introduction and Acknowledgements

This report details the findings from a 2002 Churchill Fellowship visit to Medical and Research Centers in Sydney Australia, Canada, Denmark, Germany and United Kingdom to investigate the methods used to measure muco-ciliary clearance (MCC). The proposed centers visited used various radio-labelled methods to investigate various pulmonary diseases and therapeutic strategies to enhance MCC.

Centres visited included:

- The Royal Prince Alfred, Department of Respiratory Medicine Sydney, Australia
- Department of Nuclear Medicine, McMaster University Hospital, Hamilton, Canada
- The Department of Clinical Physiology and Nuclear Medicine, Rigshospitalet Copenhagen, Denmark
- Department of Anaesthesia and Intensive Care, Sigmaringen Hospital, Sigmaringen Germany.

Acknowledgements

The invaluable experiences gained through visiting North America, Denmark, Germany and Britain would not have been possible without;

- the financial support and encouragement by The Winston Memorial Trust.
- my family for their love and continued support
- my dear and close friends (extended family) The Hardings, for always being there
- the support and encouragement my valued physiotherapy colleague and Churchill Fellow Henrietta Law.

Executive Summary

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Fellowship objective

To investigate the methods used to measure muco-ciliary clearance as a potential means assess the effect of chest physiotherapy in intubated and mechanically ventilated patients.

Fellowship highlights

1. Visits to The Department of Respiratory Medicine, Royal Prince Alfred Hospital. Additional visits and meetings with researchers in the area of MCC including Bredge McCarren, Lecturer at the School of Physiotherapy at Sydney University, Sydney Australia and Dale Bailey, Head Physicist at the Department of Nuclear Medicine Royal North Shore Hospital.
2. McMaster University, Hamilton Ontario – Meeting with Dr Myrna Dolovich and her team in the Department of Nuclear Medicine and being able to discuss in great detail the complex technical and theoretical issues for the measurement of MCC in intubated and ventilated patients. Dr Dolovich also arranged additional meetings at St Josephs Hospital Critical Care Unit to meet lead Intensive care researcher Dr Deborah Cooke and her team.
3. St Josephs Hospital, Hamilton Ontario – Met with Dr Deborah Cooke world renowned researcher in critical care, and her research team. We were able to discuss research ideas related to outcome based research in intensive care. There is the potential for future collaboration in intensive care research.
4. Rigshospitalet Department of Nuclear Medicine and Physiology – Met with Dr Jann Mortensen who has published prolifically in muco-ciliary clearance in non-intubated patients and was able to discuss the optimal means to measure MCC in the intubated patient group. Dr Mortensen arranged for me to meet the physiotherapist for the Long Term Ventilation weaning unit at Rigshospitalet to discuss clinical issues around optimal means of improving MCC in intubated patients.
5. Professor Franz Konrad, Sigmaringen Hospital Department of Anaesthesia – Professor Konrad through his research in MCC in intubated patients stimulated me to further investigate the role of chest physiotherapy through the Churchill Foundation. Surprisingly, Professor Konrad was unfamiliar with the use of chest physiotherapy to enhance MCC in the intubated patient. Fortuitously I was able to demonstrate the benefits of chest physiotherapy in improving MCC “real time” in a patient in his intensive care unit, who normally required daily fibre-optic bronchoscopy for secretion clearance.

Findings

There is very limited published evidence investigating the effects of chest physiotherapy on MCC in the intubated and mechanically ventilated patient. Chest physiotherapy is commonly used for the treatment of the critically ill patient and therefore research is warranted to investigate its effects on MCC to improve patient care and outcomes. The findings from this scholarship are that:

- The radio-labelled aerosol measurement of MCC is used widely to evaluate the effects of chest physiotherapy and drug therapy in various groups of non-intubated patients around the world
- The effects of chest physiotherapy on MCC in the intubated and mechanically ventilated patient are at present unknown
- The optimal method to investigate MCC in the intubated patient is unknown but we may base some of the initial work on the non-intubated patient research
- Whether impaired MCC in the intubated and ventilated patient is related to increased patient morbidity or mortality is unknown

The potential benefits of measuring the effect of chest physiotherapy on MCC include:

- More effective physiotherapy treatment for MCC
- Reduced complications associated with intubation and mechanical ventilation
- Reduced time on mechanical ventilation
- Reduced time in the intensive care unit
- Reduced need for more invasive and costly forms of intervention including but not limited to fibre-optic bronchoscopy and antibiotics
- Reduced rates of VAP (Ntoumenopoulos et al 2002)

Seminars

Invited speaker to discuss the optimal means of measuring MCC in the intubated and mechanically ventilated patient:

- 2003 Physiotherapy Department St Thomas' Hospital, London UK
- 2003 Intensive Care Unit, St Thomas' Hospital, London UK

Pending Publications

One refereed article describing the need for and the complexities of investigating MCC in intubated and mechanically ventilated patient.

Planned Research

Submitted grant to The Charitable Trust of Guys and St Thomas' to provide backfill for my clinical position at St Thomas' Hospital for 3 months to allow me to be the primary investigator to research MCC in the long term intubated and mechanically ventilated

patient at St Thomas' Lane Fox Unit. Funding available via Lane Fox Unit and Intensive Care Unit at St Thomas' Hospital.

Introduction

Background

Excessive airway secretions and respiratory muscle weakness often combine to both precipitate episodes of acute respiratory failure in patients with chest wall and or neuromuscular disease and prolong the process of weaning from mechanical ventilation (Bach et al 1993). Prolonged intubation and mechanical ventilation also predisposes the patients to increased risk of additional complications such as secretion retention and ventilator-associated pneumonia (Konrad et al 1994). The development of these pulmonary complications is associated with increased mortality, cost of care, time on mechanical ventilation and time in the intensive care unit.

Physiotherapists in intensive care utilize various methods to assist in airway secretion clearance such as postural drainage, airway suctioning, assisted cough, manual lung hyperinflation and chest wall vibrations. These interventions have been demonstrated to improve lung/chest wall compliance and increase the volume of airway secretions cleared (Hodgson et al 2000) and assist in the prevention of ventilator-associated pneumonia (Ntoumenopoulos et al 2002). However, we are unclear as to how these interventions affect mucociliary clearance in the intubated and mechanically ventilated patient and which of these are most efficacious (Bach et al 1993, Ntoumenopoulos et al 2002).

There has not been any published research to date from an Australian center investigating mucociliary clearance in intubated and ventilated patients. The gold standard to investigate muco-ciliary clearance is the radiolabelled aerosol method, with the deposition of nebulised inhaled radio-labelled particles followed by scintillation camera scanning of the chest to monitor the effects of various interventions. Research centers in Germany, Canada and Denmark have investigated MCC via these methods predominantly in the non-intubated patient but some centre have included intubated patients. There are many important unanswered questions concerning the clinical importance of impaired MCC in intubated and mechanically ventilated patients and whether the normalization of MCC is beneficial (Mortensen 1998).

The aim of this Fellowship is to gather the necessary knowledge and skill base to understand the issues of the measurement of MCC in the intubated and mechanically ventilated patient.

PROGRAMME

Sydney - Australia

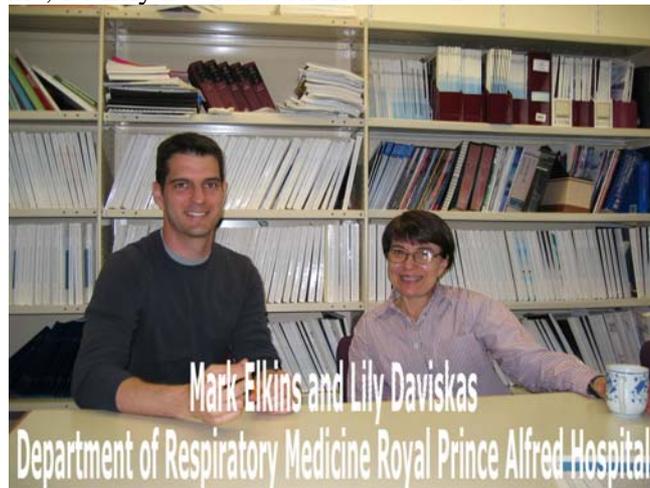


The Department of Respiratory Medicine at RPA has published many research papers investigating MCC in patients with chronic respiratory diseases such as cystic fibrosis, asthma and bronchiectasis. Mr Mark Elkins is a PhD candidate in the Department. Mark is at present the National coordinator of an Australian trial investigating the effect of hypertonic saline on MCC in patients with cystic fibrosis. Discussions with Mark Elkins assisted to me to conceptualize and distinguish the differences between bronchial mucous velocity as measured by Konrad et al (1994) versus MCC as measured by others such as Mortensen et al. There is the issue that BMV as measured by Konrad et al (1994) may not detect an increased rate of mucus clearance especially where there is an increased depth of mucus versus increased ciliary beat frequency and how the first scenario may not be detectable by BMV. The alternatives to these invasive techniques includes the measurement of the volume of secretions labelled with radioactive substance removed with conventional airway suctioning and has been investigated by other authors (Mortensen 1998). MCC will be looked at in a proposed study at the LFU in St Thomas' Hospital, London, to determine the effectiveness of the various chest physiotherapy interventions on the rate of MCC i.e., postural drainage, chest wall vibrations, MHI, cough/suction, through repeated measures study design. Other options used by several previous investigators (Hodgson et al 2000) includes the measuring of sputum volume removed by endotracheal suctioning instead of radio-labelled clearance, but this technique is potentially unreliable and is not the optimal means to assess the effect of physiotherapy.

There is the unresolved issue of whether increased sputum volume or sputum retention is related to pulmonary complications, and whether it leads to increased morbidity and or mortality. The un-answered questions relate to the potential detrimental effects of the volume of sputum, the tenacity/viscosity, location of the secretions i.e. bronchial tree as opposed to more peripheral, the bacterial load, the method of ventilatory support, drug

therapy, presence or absence of cough and ability to generate expiratory flow. There is also the potentially controversial issue for physiotherapists that mucus may in effect protect the lung and that treatment aimed at enhancing MCC may be detrimental to lung function.

Mark then organized for me to meet a fellow researcher within the Department of Respiratory Medicine, Dr Lily Daviskas on the 16/09/2003.

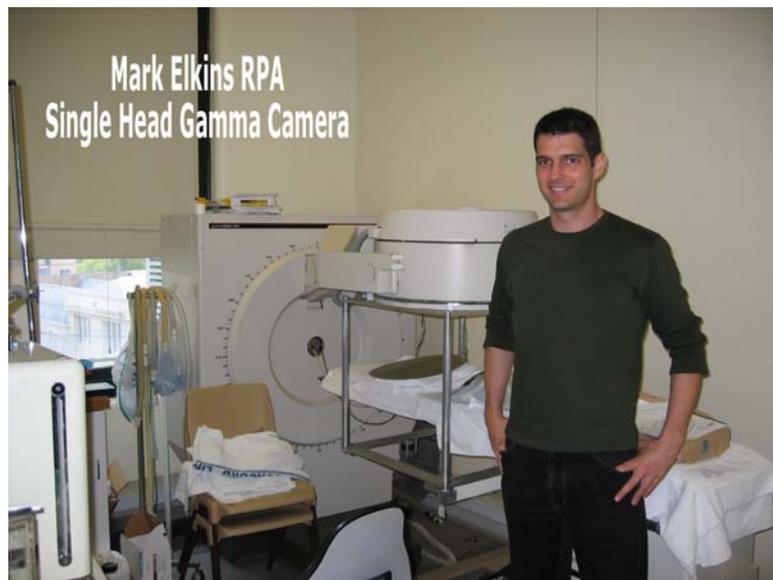


Dr Daviskas has published many papers on the optimal delivery of medications in various disease states using the radiolabelled aerosol method. She made some excellent suggestions to assist with my planned research. This includes meeting up with other researchers in London such as Dr Hasani at the Royal Free Hospital. Dr Daviskas also emphasized that hydration of the airways is very important for adequate MCC and that chest physiotherapy may not be as effective without adequate hydration.

Mr Elkins had then arranged for me to meet with Head Physicist Mr Dale Bailey at Royal North Shore Hospital.



Interestingly Mr Bailey originally worked with Dr Daviskas and Mr Elkins at RPA and then moved to work at St Thomas' Hospital in the Department of Nuclear Medicine. Mr Baily has provided me with additional essential technical information on the optimal procedures using the inhaled radio-labelled method. The use of a suitable nebulisation system is critical to the stability/repeatability of the assessment procedure by ensuring constant tidal volume and inspiratory flow rate consistent with each measurement procedure. Mr Bailey also importantly emphasized the minimal health risks for both patient and staff posed by the use of this radiation procedure as long as strict safety guidelines were followed.



Mark Elkins then organized a visit to his research centre to observe the equipment and testing procedures during a MCC study on a patient with cystic fibrosis. However, the SPECT unit (radiological imaging unit) was not functioning on the day of the visit. Mark discussed some of his recent interesting un-published research findings. In the cystic fibrosis patients' studied to date, they failed to demonstrate a consistent relationship between the severity of the respiratory dysfunction and the rates of MCC. Mark explained how he then proceeded to examine the effect of different chest physiotherapy treatment packages in CF patients on MCC in this same group of patients. The study design they utilized is not that dissimilar to the planned study design I intend on undertaking at St Thomas' Hospital. They failed to demonstrate any significant differences in the rate of MCC clearance either in the central or peripheral airways when compared with the control intervention. This has raised several questions for the research group and they have alluded that there be increased clearance with chest physiotherapy but they have not monitored for long enough after treatment or that there were inadequate number to detect the treatment differences.

Mark then arranged for me to meet with a fellow physiotherapy researcher Ms Bredge M'Carren, a PhD candidate at the University of Sydney School of Physiotherapy



As part of her Doctorate Bredge McCarren is investigating the effects of the chest physiotherapy technique chest wall vibration in non-intubated patients with the debilitating disorder of bronchiectasis. The study design and the treatment and outcome variables to be monitored by Ms McCarren are also similar to our planned investigation and further assisted me in understanding the complex nature of such an investigation.

The visit to Sydney Australia gleaned some very important technical and clinical issues surrounding the measurement of MCC. This includes the data obtainable by the use of static versus continuous scans, the method of radio-labelled aerosol delivery and the use of the repeated measures study design being the most appropriate means to measure the effect of several chest physiotherapy procedures in the same patient.

Hamilton - Ontario

I then traveled to Hamilton Ontario to meet with Dr Myrna Dolovich at McMaster University Hospital.



Picturesque Hess Village in Hamilton

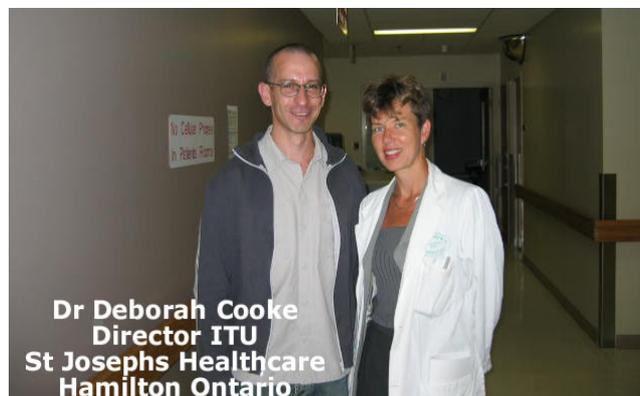


Dr Dolovich and her research group are world experts in the research associated with the optimal methods to investigate the effects of various physical and pharmacological therapy procedures on MCC. With regards to the my planned research to investigate MCC, Dr Dolovich also emphasized as others have on the importance of controlling as many variables known to affect the aerosol deposition within the lungs to standardize the measurement process. Another important study design feature that I was not aware of, is the importance of effective airway suctioning of all patients prior to the radio-labelled aerosol delivery to ensure appropriate central and peripheral airway deposition of the

radio-labelled aerosol. Dr Dolovich explained that in the patient with copious mucus airway secretions the aerosol will only lodge as far as the airway secretions, and as such the radio-labelled aerosol clearance data will be skewed and somewhat meaningless. This is unless you wanted to observe the movement of large boluses of mucus. Further technical issues were clarified including the advantages and disadvantages of dynamic versus static mode gamma scanning, as highlighted by Elkins and his group in Sydney Australia. With dynamic scanning we would be able to detect retrograde movement of mucus in the airways, which may be expected to occur in patients with obstructive airway disease or with significant expiratory muscle weakness. Dr Dolovich also emphasized that the inspiratory flow rate used to deliver the radio-labelled aerosol will affect the pattern of aerosol deposition. There will be improved central airway deposition when using high inspiratory flow rates and starting aerosol delivery at the end of inspiration and is the method recommended by Dr Dolovich and others. From the perspective of safety Dr Dolovich emphasized the importance of covering the nebulizer and the expiratory limb of the ventilator circuit with in lead shielding to protect the patient and the staff during aers.

The very important difficult to control factor of the patient coughing during the scanning procedure is the variable that will be most difficult to control and may complicate the interpretation of the data. The mucus clearance that occurs during coughing, huffing and other procedures that enhance expiratory flow are not technically considered to be MCC. This is the secretion clearance that is due to the shearing forces generated due to increased expiratory flow and is considered to occur during most physiotherapy procedures such as MHI, vibrations and airway suctioning. It remains to be elucidated whether the radio-labelled method is the optimal means to measure MCC.

Dr Dolovich had organized for me to meet with Dr Deborah Cook Director of Intensive Care and her research team at St Josephs Hospital. Dr Cook has published prolifically on evidence based practice in Intensive care including the optimal management and prevention strategies for ventilator-associated pneumonia. I was fortunate to be able to discuss with Dr Cooke my previous research paper of the use of chest physiotherapy for the prevention of ventilator-associated pneumonia (VAP). The means by which chest physiotherapy may assist in the prevention of VAP must be further explored.



Denmark

I then traveled to Denmark to meet with Dr J. Mortensen, Chief Physician, MD, MSc
In The Department of Clinical Physiology & Nuclear Medicine 4011, Rigshospitalet,
Copenhagen.



Dr Mortensen has authored many peer-reviewed papers on MCC including a key monograph (Mortensen 1998) detailing the issues surrounding MCC, lung disease and the optimal means to measure MCC via the radio-labelled aerosol method. His research has also involved close collaboration with physiotherapists investigating the role of chest physiotherapy for MCC in various chronic respiratory diseases including cystic fibrosis. As part of my planned research at St Thomas' to measure the effects of various different forms of chest physiotherapy, the patient will often act as they're own control and receive repeated interventions. With this study design we gain greater control of the patient related variables but with repeated measures on the same patient we must ensure consistency of patient positioning with each MCC measurement. I discussed with Dr Mortensen the issues of the movement of patients in between testing and treatment, especially repeated measures of MCC. Dr Mortensen uses cobalt markers taped and

applied to the patients' thorax (T1 and T12 spinous process) whilst imaging, to improve the accuracy of re-locating the patient to the exact same position for each testing procedure. We will use a similar procedure in our planned investigation.

Patients who are prescribed chest physiotherapy are also characterized by being productive of excessive airway secretions and have to cough to clear these secretions. The cough however necessary it may be for the clearance of airway secretion proves to cause problems for the accuracy of measurement of MCC. The difficult issue of coughing during testing was also discussed, as it may be expected to occur during an acute chest infection or the as a result of the disease process. Dr Mortensen and his research group tends to exclude patients' with an acute chest infection due to the excessive coughing, as the coughing makes it very difficult to interpret MCC as there is the movement of large boluses of mucus with radio-labelled particles making it very difficult to interpret the MCC curves. This is especially difficult if you are only imaging with snapshot views i.e., every 5 minutes. However, Dr Mortensen stated that if more frequent imaging is taken i.e., every 30-40 seconds to provide more reliable data enabling the interpretation of the effect of coughing or other clearance procedures on MCC. The other means of determining the effect of cough alone is to include in the control treatment a comparison with the same number of coughs as used during the other treatment interventions.

In contrast to the previous researchers who tightly controlled the inspiratory flow rate during nebulised aerosol delivery, Dr Mortensen uses an ultrasonic nebuliser (see figure below) and tends to not be rigorous about the tidal volume or inspiratory flow rate during the aerosol deposition phase. However, he still did allude to recommending aerosol delivery at the end of inspiration and a rapid expiratory flow to encourage the more proximal airway aerosol deposition in the patient.



There is some controversy in the literature and amongst the researchers visited on the use of either a single view with a single head gamma camera versus the taking of both anterior and posterior views either with a single head camera or double head camera. The main issue relates to the more accurate imaging provided by a two views that provides a geometric mean. A single view from a single head camera is less accurate as it will fail to identify labeled airway secretions that are moving either towards or away from the camera but may still be moving from the more peripheral parts of the lung to the more proximal areas of the lung.

An interesting issue that was discussed with Dr Mortensen and other researchers related to the radioactivity level remaining on the artificial airway and ventilator tubing and the risks posed to the patient, family and staff. The issue of the radioactivity associated with the artificial airway may be minimized if the patient has a double lumen tracheostomy, with the removal of the inner tube after the testing has been completed and changed over for a clean inner tube. Otherwise the tracheostomy may have to be changed over for a new tube. This would have to be tested and to be discussed with the Medical staff including Nuclear medicine specialist and physicist at St Thomas' prior to any interventions proceeding.

I had the pleasure to meet with one of the Senior Respiratory Physiotherapists at Rigshospitalet, Mrs Dorothe Hallund who managed the patients in the neurological long-term intensive care unit. We were able to discuss and compare the chest physiotherapy and ventilatory strategies used in our different hospital centres.



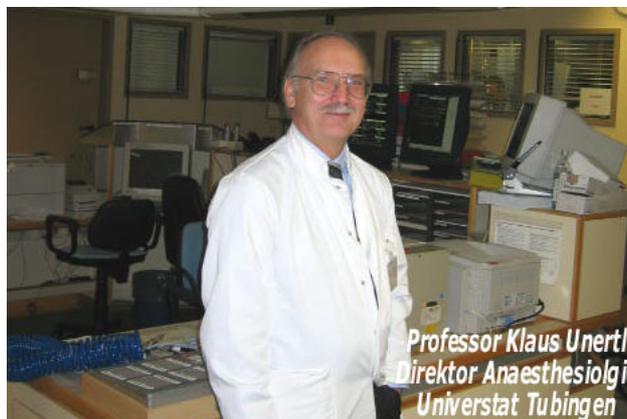
Germany

From Denmark I traveled to Sigmaringen Germany to visit Professor Franz Konrad, The Professor of Anästhesie, Kreis Krankenhaus Sigmaringen. Professor Konrad has published most of the work on MCC in intubated and mechanically ventilated patients. He has investigated the adverse effects of general anesthesia and prolonged airway intubation and his work inspired me to undertake this Churchill Fellowship.

Upon arriving in Stuttgart in Germany, Professor Konrad and his daughter collected me and organized for me to stay in a beautiful town just north of Sigmaringen called Tübingen.



Professor Franz Konrad organized a visit to the ICU at Universitätsklinikum, Tübingen to meet with Professor Klaus E Unertl the Director of Anaesthesiology, to discuss issues related to chest physiotherapy care and prevention and treatment of major pulmonary complications such as VAP.



Professor Unertl identified that micro-aspiration past the endotracheal tube cuff in intensive care patients to be the most common cause of VAP. Interestingly he had designed an investigation almost 20 years ago to demonstrate that ETT cuffs fail to prevent micro-aspiration and are associated with an increased risk of VAP. He investigated a device that could provide the continuous sub-glottis aspiration of secretions pooling above the cuff of the ETT. This form of ETT with the ability to aspirate secretions above the cuff is now used clinically in many intensive care units around the world.

I then travelled to Sigmaringen to meet with Professor Franz Konrad. Professor Konrad very kindly had me stay with his family.



I spent several days with Professor Konrad at Sigmaringen Hospital visiting the intensive care unit and Department of Anaesthesia. After discussions with Professor Konrad detailing my previous studies, current clinical work and planned research surprisingly it was evident that they did not use chest physiotherapy for secretion clearance in the intensive care unit whilst patients are intubated and ventilated. We had discussed a complex patient being managed in the intensive care unit during my visit and we organized for me to treat this patient, whilst Professor Konrad used a fibre-optic bronchoscope to visualize and assess the effects of chest physiotherapy treatment on MCC (see Figure below).



Professor Konrad initially treated the patient as they normally would with bronchoscopy to right and left main stem bronchi and sub-segmental bronchi of the lungs until he felt that the all the areas of the lung had been adequately cleared of airway secretions. I then treated the patient with chest physiotherapy consisting of postural drainage, chest wall vibrations and manual lung hyperinflation. Copious volumes of airway secretions were removed with chest physiotherapy with a conservative estimate of approximately twice greater volume of secretions compared with bronchoscopy alone. This was an exciting and rewarding experience being able to demonstrate to a multi-disciplinary group of staff (nursing and medical) the benefits of an intervention that would require less cost and potentially greater benefit in terms of volume of airway secretion removal. Hence, this is the purpose of the planned investigation in London to identify the most effective form of chest physiotherapy treatment for the intubated and mechanically ventilated.

London United Kingdom

Returning to London I then met with Dr Craig Davidson, The Director of The Lane Fox Long Term Ventilation Weaning Unit and Dr Michael O'Doherty, Physician in Nuclear Medicine and Mr Chris Page Nuclear Medicine Physicist at St Thomas' Hospital, London.

Several meetings had been organized with these key individuals to discuss my findings from my previous travels on the Churchill Fellowship and to plan and organize the study to investigate MCC at St Thomas' Hospital. It was also here that I was able to further research the optimal study design and plan for the appropriate ethics submission and grant applications to fund the planned investigation.

Discussions with Mr Chris Page centred around the use of cobalt or pen markers as reported by Dr Jann Mortensen, for the more accurate relocation of the patients thorax for the next scan. Mr Chris Page stated that they also used cobalt pens in the department but due to they're size, the patient may not be comfortable lying on them for prolonged periods. He mentioned that they may be able to order sealed sources of cobalt, but there may be a licensing issue on the amount of cobalt the Nuclear Medicine Department is allowed to stock. Chris Page also mentioned that that may be able to create technetium filled markers, which would be similar in effect to the cobalt markers.

On the safety issue of the radio-labelled exposure with any invasive devices i.e., tracheostomy tube, indwelling urinary catheter, if the patient was due to return to the ward and the tracheostomy had to be emergently changed, then as long as that tube or artificial device was stored on the ward in a plastic bin and then disposed of as radioactive waste there would be no issues with radioactive exposure.

I was fortunate enough to be able to meet with Mr Jim Bellinger the radio-pharmacist for the Guys and St Thomas' Trust who manufactures the radio-labelled products to liaise with him further regarding any handling and or licensing issues for radiopharmaceuticals used in the planned study. We discussed the radiation risk the radio-aerosol to be used during the planned study and it is minimal approximately 1/25th the risk of radiation exposure compared with the maximal a person would safely be allowed to receive.

Throughout the month of October and November I have been developing the research protocol for the planned study at St Thomas'. This has included:

1. the detailed research protocol
2. the research and development application
3. the Ethics submission
4. the application for licensing of use of the radio-pharmaceutical for the study.

CONCLUSIONS

There is very little published evidence investigating MCC in intubated and mechanically ventilated patients. This may in part be due to the complex nature of transporting these patients to Nuclear Medicine and the associated costs of the testing procedures. The investigation of the effects of chest physiotherapy on MCC in the intubated and mechanically ventilated patient could have the potential to improve patient outcome. These improvements may be achieved in:

- More effective physiotherapy treatment for MCC
- Reduced complications associated with intubation and mechanical ventilation
- Reduced time on mechanical ventilation
- Reduced time in the intensive care unit
- Reduced need for more invasive and costly forms of intervention including but not limited to fibre-optic bronchoscopy and antibiotics
- Reduced rates of VAP (Ntoumenopoulos et al 2002).

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