No. 15

MAQUET

Critical Care News

Theme:

Clinical evaluation of NAVA in a series of pediatric ICU patients

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Dr Brendan O'Hare, with NAVA patient, parents and staff in Dublin.

This issue of Critical Care News features articles from ICU departments from a wide range of geographical locations: Sao Paulo, Brazil; Coimbatore, India; Novara, Italy; Dublin, Ireland and a regional hospital serving patients from southern Sweden. What do these institutions in such contrasting areas of the world have in common, in addition to the worldwide ICU nursing shortage?

One common denominator for all of these intensive care units is a continuing focus on lung protective, patient friendly ventilation therapies. Their mutual belief seems to be to strive for such gentle, synchronized and lung protective therapies as possible for the mechanically ventilated patient, and to get the patient off the ventilator at the earliest opportunity.

Global intensive caring – by means of lung protective ventilation strategies

This issue of Critical Care News highlights a wide range of ventilation strategies used at various ICU departments around the world, in their continuing efforts to achieve lung protection and patient comfort.

Neurally Adjusted Ventilatory Assist – NAVA in a series of neonatal and pediatric patients in Dublin

The continuing global interest of the intensive care community in NAVA as a means to provide improved patient ventilator synchrony has led to a clinical evaluation of NAVA at Our Lady's Children's Hospital Crumlin in Dublin, Ireland.

The clinical evaluation has engaged and involved many ICU staff members, including physicians, nurses and clinical engineers, and parents as well. The staff members share their experiences, observations and excitement in connection with the clinical evaluation, as well as some of their thoughts on the possible future cultural shift from pneumatically driven ventilation therapies to ventilation that is neurally based.

Clinical implementation of non-invasive ventilation protocols

The first Intensive Care Unit in Brazil at Hospital Sirio-Libanes in Sao Paulo, Brazil, has implemented strategies and protocols for weaning patients mechanically ventilated for over 48 hours,

Hospital Sirio-Libanes, Sao Paulo

Mobile ICU patient and nurses at Kristianstad Regional Hospital, Sweden.

to extubation or to non-invasive ventilation with a protocol developed according to current guidelines in research and literature. Dr Guilherme Schettino, who is internationally known for his research in mechanical ventilation and non-invasive ventilation therapy, shares his experiences in regard to the utilization and implementation of these protocols.

NAVA from a historical perspective and current clinical observations

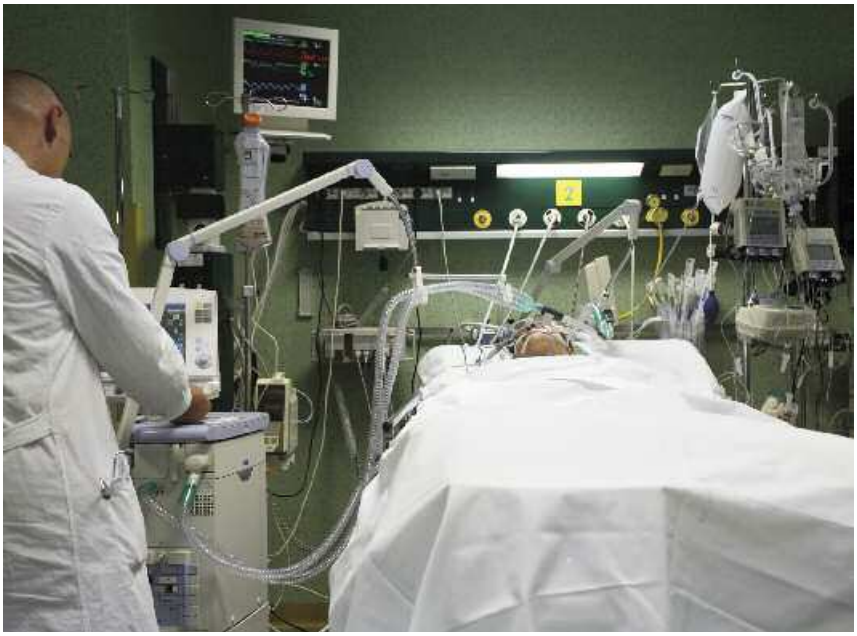
Neurally Adjusted Ventilatory Assist, as a new approach to improve patient-ventilator interaction, was first reported by Christer Sinderby and published in Nature Medicine in 1999. Dr Paolo Navalesi participated in this initial research, and is currently involved in an ongoing clinical evaluation of NAVA in adult patients together with his ICU colleagues at the Ospedale Maggiore della Carità in Novara, Italy.

Experiences with lung recruitment in ARDS patients

The medical ICU of the Kovai Medical Center and Hospital in Coimbatore, India has been investigating and utilizing lung protective strategies in ARDS patients for many years. For the past two years, the staff have been gaining experience with a lung recruitment tool with a protocol for titration of physiological endpoints.

Lung protective ventilation and patient comfort in a mobile ICU

Regional transport of critical care patients between hospitals is becoming a common situation in densely populated metropolitan regions, where availability of ICU specialty care and procedures is being optimized among hospital institutions. The Kristianstad Regional Hospital in the south of Sweden has been creating solutions within this area for the past 30 years. The ICU staff and project team members share their experiences and data in the creation of a customized mobile ICU solution to maintain ventilatory care and comfort during ICU patient transports.



Dr Paolo Navalesi, Novara, Italy

Dr Gopalakrishnan Raman, Coimbatore, India.

Dr Brendan O´Hare with 2 week old NAVA patient and parents.

Clinical evaluation of NAVA in a series of pediatric ICU patients

Our Lady's Children's Hospital Crumlin in Dublin is the largest pediatric hospital in Ireland, and is responsible for providing the majority of tertiary care services for children. The hospital is also a leading research and educational institution in Ireland, and provides training to undergraduate students from University College and Trinity College in Dublin as well as The Royal College of Surgeons in Ireland. The Children's Research Center, based in the hospital, generates many scientific publications and has an international reputation in pediatric medicine.

The most recent research at the pediatric ICU at Our Lady's Children's Hospital Crumlin has been an evaluation study of Neurally Adjusted Ventilatory Assist – NAVA. Critical Care News met with the key investigative physicians and other staff members involved in the study.

Dr Brendan O'Hare is Director of Intensive Care at Our Lady´s Children´s Hospital Crumlin in Dublin.

Critical Care News spoke with Dr Brendan O'Hare, who is a Consultant Paediatric Anaesthetist and Director of Intensive Care at Our Lady's Children's Hospital Crumlin. He reported his experiences and perceptions of NAVA in the series of patients in the evaluation study, as well as his thoughts for potential opportunities with NAVA in the future.

Can you give us some background about your institution and how your organisation became involved in the NAVA evaluation study?

To give a sense of our department and what we do, we are a multidisciplinary unit encompassing 26 beds, 850-900 patients per annum, including pediatric ICU, high dependency care and transitional care unit, with intensive care facilities located on three levels in the hospital. We have a high infant patient population, of which 25% are neonates, and up to 70% need some sort of ventilatory assistance. About 40% of our workload is cardiac, as we are the National Center for the Congenital Heart Disease Program in Ireland, with approximately 350 surgical cases per annum.

We have a dynamic relationship with our MAQUET representative, and we have standardized our ventilation platform with SERVO-i ventilators in recent years, as we have wanted a platform that was robust and reliable for the broad spectrum of patients we treat here. We first learned about NAVA from the same representative, and the concept of neurally adjusted ventilatory assist as a new, exciting dimension in ventilatory management. After that, we attended an international NAVA workshop in The Netherlands earlier this year, and that was our background before agreeing to collaborate in the clinical evaluation study.

We are delighted to be part of what is quite an exciting time in ventilation research and development.

After 30 minutes of Pressure Support as per the clinical evaluation protocol, a marked decease in pressures was noted after switching over to NAVA in this infant patient.

How is the NAVA evaluation study progressing, and can you tell us about your current experiences?

We have enrolled nine patients thus far, all of whom completed the trial protocol without any specific problems and all tolerated the mode extremely well. Indeed one brittle infant with pulmonary hypertension became very agitated and difficult to settle upon completion of the trial protocol when attempting to re-establish the ventilatory strategy that was in place pre NAVA.

Which types of patient categories are you treating at this point?

The predominant patient category where we have used NAVA so far are cardiac post-op patients who have progressed through their initial post op course and are on the weaning phase.

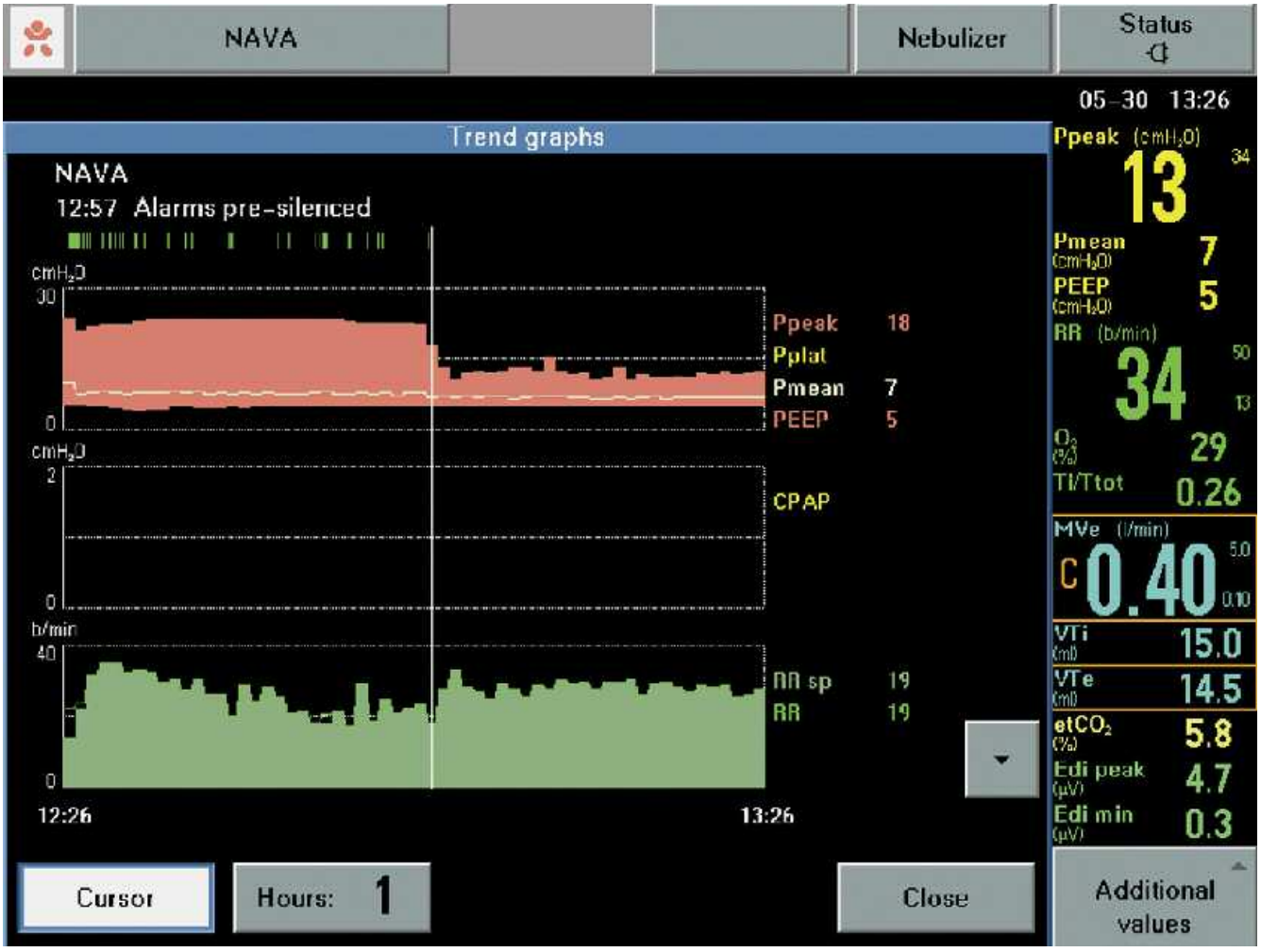
We have also evaluated a two week old neonate with an arrhythmia-induced cardiomyopathy with severely compromised pulmonary compliance. My consistent observation is that to generate effective minute ventilation based on the parameters that we have, we are consistently achieving this using NAVA with lower peak inspiratory pressures than would be required on Pressure Support.

Upon observing the patients in our study a potential very attractive feature of NAVA is hinted at, namely that the Edi signal provides us with the opportunity of an objective, parametric measurement of the patient's effort of breathing, which could be trended.

In the neonatal pediatric population, in considering the work of breathing and the oxygen consumption and metabolic cost of that in terms of asynchrony, I think we perceive the very valuable potential of NAVA, where we might better marry the effort to the machine. Better synchrony must potentially provide many benefits in this respect.

What do you think will be of interest regarding NAVA in future research?

In terms of future research, there are other aspects of NAVA that potentially are of interest as well. The ready availability of atrial electrocardiograms will open new horizons for arrhythmia diagnosis and management. Allowing for improved synchrony, the lower mean intrathoracic pressures that you are generating as a consequence of the effect of tidal ventilation at consistently lower mean airway pressure, NAVA presents us with



In another neonate, even more contrast in decrease in pressures was noted when switching from Pressure Support to NAVA, without significant changes in frequency.

a scenario that may guarantee an effective tidal ventilation with another further drop in our intrathoracic pressure from ventilation, which I think would be a major area for research in future, in terms of hemodynamic performance in patients. These subtle differences may even be more important in the sicker categories of patients. I think this is a ripe area for further research and investigation, looking beyond the respiratory mechanics.

Are there any other patient categories that you find to be potentially interesting in future?

Most of the patients in our validation study have been extubated twelve hours post NAVA. Sometimes these patients could benefit from an extra period of "non invasive" ventilatory assistance following their initial extubation and it would be very attractive to be able to withdraw the endotracheal tube to above the vocal cords and still provide some ventilatory support via this supraglottic airway.

It would be attractive to see NAVA in this regard, since triggering in NAVA is independent of leaks and the whole problem of leakage, since triggering depends upon the electrical activity of the diaphragm in these children. Other specific populations that I would consider that may benefit include infants with congenital diaphragmatic hernia and the preemie group with IRDS.

Have you had any particular patient cases where you have made interesting observations?

We have had an interesting scenario, where we had one patient generating an impressive Edi potential which was greater than expected, who seemed to be doing reasonably well otherwise. This Edi profile was similar to earlier case reports of a partially paralyzed diaphragm, where the phrenic nerve was an issue. We pursued and screened to determine that the phrenic nerve was fine, but interestingly there was a substantial subpulmonary effusion; the base of the lung was remote from the diaphragm and there was a sequestered subpulmonic effusion. The Edi signal gave us a clue as to the presence of this abnormality.

Phrenic nerve injury is a subtle clinical diagnosis, diagnosed radiologically, but simpler means of detecting this earlier could be useful. NAVA may contribute to this more prompt appreciation of a significant abnormality.

Dr Martina Healy is Consultant in Paediatric Anaesthesia and Intensive Care at Our Lady´s Children´s Hospital Crumlin in Dublin.

Dr Martina Healy, Consultant Anaesthetist at Our Lady's Hospital for Sick Children, has also been involved in the NAVA evaluation and shared her thoughts in regard to her experiences.

In the evaluation study, there have been about 9 patients in total so far, how many of these have you had experience with?

I have had experience with about 4 so far. Selecting the patients is not a problem; we pick out the cardiac patients, and run 3 hours of NAVA as a weaning program.

What are your perceptions so far?

The first patient was a 16 year old, a quite large patient who had a restrictive lung problem. The positive impressions were not as obvious in this patient as compared to the neonates we later treated. The neonates have a high respiratory rate and often require a great deal of sedation just to keep their tube in, so my impression of NAVA in these patients is that it seems to be quite useful in this group.

Have you noticed a contrast switching over from Pressure Support to NAVA?

Yes, I think that in the patients I have seen that they seem to be incredibly comfortable when switching them over. As a point of interest, we tend to use PRVC with Automode as a very comfortable mode of weaning, in this patient category for straightforward

post-op situations, so it was interesting to observe that NAVA seems to provide even more comfort and require less sedation in these patients. It also seems as though the smaller they are, the easier it is for the patients to do well on NAVA.

These specific patient experiences have been primarily smaller children. Are the Edi signals of value in this patient group?

In the group of patients we have seen so far, Edi seems to have been of value for diagnostic purposes. Based on the Edi signals of one particular patient, we were wondering whether the patient had a paralyzed diaphragm or not. It is early days yet, but I can certainly see where it could be useful in the future.

From your experience at this point, what is the most important thing to know about NAVA?

Based on the current experience in weaning, it is important to have a group of patients who are ready to be weaned, where you want to require less sedation, less invasive weaning, you would use it. That is where I see the usefulness at present, based on my experience this far. Cardiothoracic post-op patients, to be weaned after surgery, seem to do very well on NAVA.

Which types of patients are you most interested in gaining more experience with NAVA?

The group of neonates I see for potential for NAVA are the chronic lung disease group. If they are on morphine, they will be on it for longer periods of time, and sometimes the weaning period takes weeks rather than days in this group. If NAVA can provide better patient comfort and less sedation in this group, I think it would be great.

We have not yet had any bronchial pulmonary dysplasia patients, usually we seem to get them in groups of three or four, but of course we are curious how NAVA will work in these BPD patients. They also have a fast respiratory rate, and are on morphine and can become agitated when you try to wean them, so I think we are curious to see how NAVA will work in these patients as well.

In general, I think we all find a group of patients who are difficult to wean, and everybody is looking for a way to treat those patients. These can include asthmatics, pneumonia patients and those with diaphragmatic hernias. There are general questions as to how to measure peak pressures, and other values that we have seen, such as PEEP, in pneumatic ventilatory modes. NAVA is a totally different concept, what you set on the ventilator traditionally is not necessarily what the patient will set himself in NAVA.

You can see the difference in compliance – what NAVA has done is not only to help us to look at what we set for the patients, and how the patient requirement might differ, but it also makes us think about how we are using the other modes and settings on the ventilator, in terms of lung compliance.

Have there been any practical considerations or concerns at this point in the evaluation?

There really have been no issues in connection with the Edi catheter placement, or from parents of patients in regard to the nasalgastric tubes. The main concern from the parents has been if their child will be disturbed in any way, and there is no disturbance, as once the nasogastric tubes are in, they can be left there for a few days anyway.

Dr Healy shared her thoughts in regard to her experiences with NAVA in the evaluation study.

Clinical Nurse Facilitator Linda O´Donnell.

Linda O'Donnell, RN, has been working as a nurse for 20 years and is a Clinical Nurse Facilitator at Our Lady's Hospital for Sick Children. She shared her first impressions and thoughts about NAVA.

What were your first impressions of NAVA?

I heard about the concept of NAVA from the clinical engineers, and then I learned more about it by means of the internet.

I have seen it on two or three patients. My initial impression was a somewhat disappointed reaction, since I perceived it as an answer to be used to ventilate in all patient groups, in different physiological and anatomical needs. At present, the evaluation study might pose some limitations. It appears that it might be limited in some groups such as phrenic nerve damage or muscular dystrophy, which are patient categories that need long term ventilation, and that I hope to see a solution for. But I think that these limitations that I perceive at the present time might be due to our limited experience and knowledge of NAVA in these patient categories, due in turn to the limitations of the evaluation study protocol.

Do you see any potential with NAVA in future?

Absolutely, but we are in very early days. Until it gets into regular clinical practice, we won't know the full potential. At present, it appears that it works very well as a means for weaning specific patient categories, and I think that this is a safe and effective process of development, to use it on these specific groups to begin with.

Which patient groups do you think are the most interesting in the future?

In terms of patients needing lung protection, such as very small neonates or lung diseased patients who are physiologically compromised already, such as BPD, this is the group we most need to help find solutions for, where it will be interesting to see how NAVA will help.

Tony Fitzgerald, Principal Clinical Engineer, and Jim Davenport, Chief Clinical Engineer have been involved in the NAVA evaluation from the beginning.

Members of the Clinical Engineering Department at Our Lady's Hospital for Sick Children have been intensively involved in the NAVA clinical evaluation study from the onset. The staff has extensive experience of different ventilation treatment modes and modalities that have been introduced over the span of many years. Critical Care News spoke with Jim Davenport, Chief Clinical Engineer, and Tony Fitzgerald, Principal Clinical Engineer about their latest experiences.

What are your observations from the NAVA evaluation study at this point?

Jim Davenport: In general, it seems to be working excellently, and the synchrony with the patient is quite remarkable. The children are so comfortable on it. NAVA seems to coincide well with the natural progression as we have associated with the SERVO ventilators for many years. It is very interesting to see the diaphragm signals activating the ventilator.

Basically we were surprised with NAVA to see all the additional information coming from the nasal gastric tube, which you have been putting down in many of these patients anyway.

Has it been difficult to learn NAVA?

Tony Fitzgerald: No, not at all, but it can be more user friendly in time. At this point in time, you need to have a great deal of understanding of what you are doing in NAVA in order to be able to use it effectively. From a patient perspective and a triggering perspective, it looks fantastic so far, but from a user-perspective we simply have a lot more to learn about the neural method in terms of interpreting Edi signals and understanding the background of switches from NAVA to Pressure Support, and/or Pressure Control, and back to NAVA again. It is a new way of thinking, and a lot of new terminology, which people do not as yet have reference to. We have all been living in the Pressure/Volume world for such a long time, so that this is a clinical cultural change for many of us.

Jim Davenport: I agree, we have been educated and experienced in the pneumatic ventilatory mode environment, and now it seems that we are moving into the patient-neurally controlled future. At the moment we do not have many definitive answers on NAVA, since we are participating in the evaluation study.

But we observe that it has worked very well, and the children are comfortable on it, and even the parents have noticed the difference. The parents are a little bit anxious about their children participating in the study, but they seem to quickly notice that their children are more comfortable.

In fact, we had one father who couldn't make up his mind if his child should participate in the study, and he came over to see NAVA in use on another child, and he simply said, "Oh, yes, we will go for that!"

In future, I think it will make a huge difference, especially with small babies, to make use of their diaphragmatic muscle electrical activity.

Tony Fitzgerald: We have seen a lot of excitement among the other physicians here, pediatricians and neonatologists, who are looking forward to seeing and using it. In our experience this far, there have been no real difficulties with it, compared to other new modalities we have learned. These patients are intubated, and already have the nasogastric tube in place, so it is very simple.

Most of the children we see are extubated within the first 24 hours; it would be interesting to see how NAVA will be useful in the long term patients. The most fascinating experience so far was to learn that one of our patients had a partial paralysis and phrenic nerve damage, just from doing the NAVA evaluation study.

Tony Fitzgerald and Jim Davenport have over 30 years experience with different ventilation modes.

Biography

Brendan O´Hare completed his medical training and graduated with honours from The Medical Faculty, University College Dublin, Ireland in 1984. His surgical and medical internships took place at Mater Hospital in 1984-1985, followed by a two-year medical rotation at Mater Hospital, Wexford General Hospital and Louth County Hospital. His anaesthesia general professional training took place at a number of Dublin hospitals during the years 1987-1990, followed by anaesthesia/ICU higher professional training during 1991-1992.

Brendan O`Hare was Clinical Fellow at the Department of Anesthesia and the Department of Critical Care of the Hospital for Sick Children in Toronto, Canada during the years of 1993-1994, and Research/Clinical fellowship in the same hospital in Toronto in 1995. He was Senior Clinical Fellow during 1995-1996 at the Cardiac Intensive Care Unit of The Children's Hospital and Harvard Medical School in Boston.

He is currently Consultant in Anaesthesia and Intensive Care, Our Lady's Hospital for Sick Children, Crumlin, Dublin, and Consultant Anaesthetist, Royal Victoria Eye and Ear Hospital, Dublin. He has won numerous distinctions, including the Hynek Rothbart Award, Shields Research Day, University of Toronto in 1995.

Brendan O´Hare has conducted and published research for a number of years, and is a frequent speaker at national conferences. He is a member of many associations, including the Royal College of Physicians of Ireland, European Society of Paediatric and Neonatal Intensive Care, Irish Paediatric Anaesthesia and Critical Care Society (convenor) and the Association of Paediatric Anaesthetists of Great Britain and Ireland.

Biography

Dr Martina Healy received her initial degrees as MB, BCh, and BAO at the National University of Ireland in 1984, followed by Fellowship of the Faculty of Anaesthetists of the Royal College of Surgeons in Ireland (FFARCSI) in 1991. She obtained her Certificate of Completion of Higher Professional Training in 1995. Her continued professional training in anaesthesia began at the Liverpool Central Rotational training scheme in Anaesthesia in Liverpool, U.K. during 1986-1992, followed by Research Registrar in Anaesthesia, Mater Misericordiae Hospital in Dublin 1992-1993. Her Higher Professional training scheme in Anaesthesia in Ireland occurred from 1993 to 1996.

Her paediatric intensive care training was initiated as Registrar in Intensive Care, Royal Children's Hospital, Parkville in Melbourne, Australia from 1998 to 1999, followed by a position as Trust Fellow in Paediatric Intensive Care at Great Ormond Street Hospital for Sick Children from 1999 to 2001.

Dr Martina Healy is currently Consultant in Anaesthesia and Paediatric Intensive Care at Our Lady's Children's Hospital, Crumlin, Dublin, Ireland where she has been appointed since 2001.

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Guilherme Schettino, MD, PhD, is internationally known for his research and lectures. He has conducted research for many years in the areas of mechanical ventilation and non-invasive ventilation.

ICU implementation and clinical application of non-invasive ventilation protocols

The very first intensive care unit in Brazil was opened at Hospital Sirio-Libanes in 1971. The principles of humanism, pioneering and excellence are still prevalent in the current ICU environment of 22 beds, scheduled to expand to forty beds in the next year. For many years, the ICU at Sirio-Libanes has focused on less invasive and more patient friendly therapies, and this unit is internationally recognized as a center of excellence.

Critical Care News spoke with Guilherme Schettino, MD, PhD, Director of the ICU at Sirio-Libanes, São Paulo, Brazil, regarding their utilization of non-invasive ventilation and weaning protocols on a routine basis.

Dr Schettino in conference with other ICU staff members at Sirio-Libanes.

As an internationally-known profile in research and on the lecture circuit, could you tell us briefly about your background?

I have been working in critical care medicine for the last 15 years as a pneumologist and intensivist, and I have published some studies on mechanical ventilation. I also work together with Carlos Carvalho and Marcelo Amato at Hospital das Clinicas at Sao Paulo University where I did my PhD thesis on mechanical ventilation. I did my research fellowship for two years with Bob Kacmarek in Boston at Massachusetts General Hospital, where I also conducted some research on non-invasive ventilation. When I returned to Brazil, I assumed the position of ICU Director here at Hospital Sirio-Libanes.

Can you describe your current ICU operations and capacity?

Yes, we are operating with two adult medical-surgical ICUs, one on the first floor with 12 beds, and the other one on the eighth floor with an additional 10 beds. We also have an intermediate care unit with 24 beds for adult patients, where we do a lot of non-invasive ventilation and invasive ventilation for chronically ventilated patients with tracheostomies.

We are now completing a project for a new ICU with forty beds to consolidate the ICU operations. It will be quite large, but we are expanding the hospital and need more beds for critically ill patients. I think it will be up and operating in the beginning of 2008.

When did you start utilizing non-invasive ventilation therapy?

I used non-invasive ventilation for the first time more than 14 years ago at Hospital das Clínicas, after reading the Meduri´s paper on non-invasive ventilation for COPD patients. We started by using an ICU ventilator with a mask. I think we were the first group to start using non-invasive ventilation here in Brazil.

Was there a particular patient category at that time?

At that time it was patients with COPD exacerbations. We were using ICU ventilators with Pressure Control and a mask to deliver non-invasive ventilation. Since that time, non-invasive as a ventilation therapy has changed a lot, with different interfaces and different ventilators that are more tailored for non-invasive treatment, with leakage compensation, and so on.

Currently, when we use non-invasive ventilation, we use either BIPAP machines or ICU ventilators that have software to compensate leakage, such as SERVO-i.

You mentioned that you are using masks, have you had experience of the helmet in non-invasive ventilation?

I received a few helmets from Paolo Pelosi in Italy, so I have used the helmet a few times, and it worked well. I think however, that the helmet works better on patients who need non-invasive ventilation for a short period of time, for instance patients with cardiogenic pulmonary edema. The cost of the helmets is a factor here in Brazil.

You started out by gaining experience of non-invasive ventilation with COPD patients, which patient categories do you use non-invasive ventilation most frequently on today?

Now I think we are using non-invasive in almost all COPD patients in the ICU. I really think the best way to take care of patients with COPD exacerbation is to use non-invasive very early in the treatment. We also use non-invasive ventilation in most patients with

Dr Guilherme Schettino.

cardiogenic pulmonary edema and in patients weaning from invasive ventilation, and also in patients with hypoxemic respiratory failure. In patients with COPD exacerbation or patients with cardiopulmonary edema, we use non-invasive in the emergency room or in the step down unit, but for patients with hypoxemic respiratory failure, we only use non-invasive here in the ICU, since we have all the facilities for monitoring and intubating the patient, if necessary. All of the ICU staff members are trained in non-invasive ventilation, and we have a good team of nurses and physiotherapists. Our situation here differs a bit from the United States, where they have respiratory therapists; here in Brazil it is similar to Europe in that we have no respiratory therapists but a team consisting of physical therapists, and nurses specialized on respiratory support and mechanical ventilation, working closely together with physicians.

We are using a lot of partial facial masks, and total face masks. But I am waiting for the helmet to become commercially available in Brazil, which I think will be useful for patients with cardiogenic pulmonary edema and some patients with post-operative respiratory failure, because most of these patients are using nasogastric tubes, and it may be easier to provide non-invasive ventilation with a helmet than a mask in these patients.

What is your ratio of patients, roughly, in terms of invasive and non-invasive?

I think that for patients with respiratory failure in the step down unit, most of them use non-invasive ventilation. Here in the ICU I have at least three to four patients using non-invasive ventilation each day, which means roughly 25-30% of patients in the ICU receive non-invasive, or at least we try to administer it before intubation. This has grown in recent years. We have now 12 BIPAP ventilators at Sirio-Libanes, and sometimes all twelve are in use.

We talked about CPAP for patients with lung edema and non-invasive ventilation may be controversial in this setting. Could you tell us more about your use of non-invasive ventilation in patients with cardiogenic pulmonary edema?

We use non-invasive ventilation in patients with cardiogenic pulmonary edema, and one question posed in the medical research is which mode is best to treat these patients; CPAP, BIPAP, Pressure Support and PEEP? I think that for most patients if you use CPAP, it is okay to treat cardiogenic pulmonary edema. But for some patients, especially those with hypercapnia, I think it is better to use BIPAP or Pressure Support with PEEP to increase the alveolar ventilation. In a paper that was published some years ago, there was a report of a few patients with myocardial infarction treated with BIPAP, which was subsequently followed by a lot of papers published to show that BIPAP or Pressure Support with PEEP is safe in this patient category. There was a meta-analysis in JAMA 2006 showing that you can use both modes; both are safe and work similarly. One very nice study that has been published about using non-invasive ventilation for patients with cardiogenic pulmonary edema; comparing BIPAP with CPAP, was done by a Brazilian colleague named Marcel Parker at Hospital Clinicas a few years ago and published in Critical Care Medicine.

When you encounter a patient in any category with leakage problems, how do you address this situation?

I think that the first action is to try to adjust the mask and avoid leakage. But this may be difficult at times, and if you have to use high pressures, you can change the face mask to a total face mask that will work better with high pressures. If you use a non-invasive ventilator, like the BIPAP, it works very well even in the presence of high leakage. Non-invasive ventilation with SERVO-i with leakage compensation works also very well in these situations. You can also adjust the cycling off criteria for Pressure Support that is good in non-invasive ventilation. If you are using an ICU ventilator where you cannot adjust the cycling off criteria for Pressure Support, then one option is to change the mode to Pressure Control – which works well and is an alternative – but in this case it is not so comfortable for the patient.

Since facial morphology can differ from one patient to another, this must be a challenge?

Yes – it is always a challenge for the patient interfaces – sometimes we need to try a number of different masks and

adjust them in a variety of different ways on different patients. It is an individual process in each patient.

Can you tell us more about using non-invasive ventilation as a step in the weaning process?

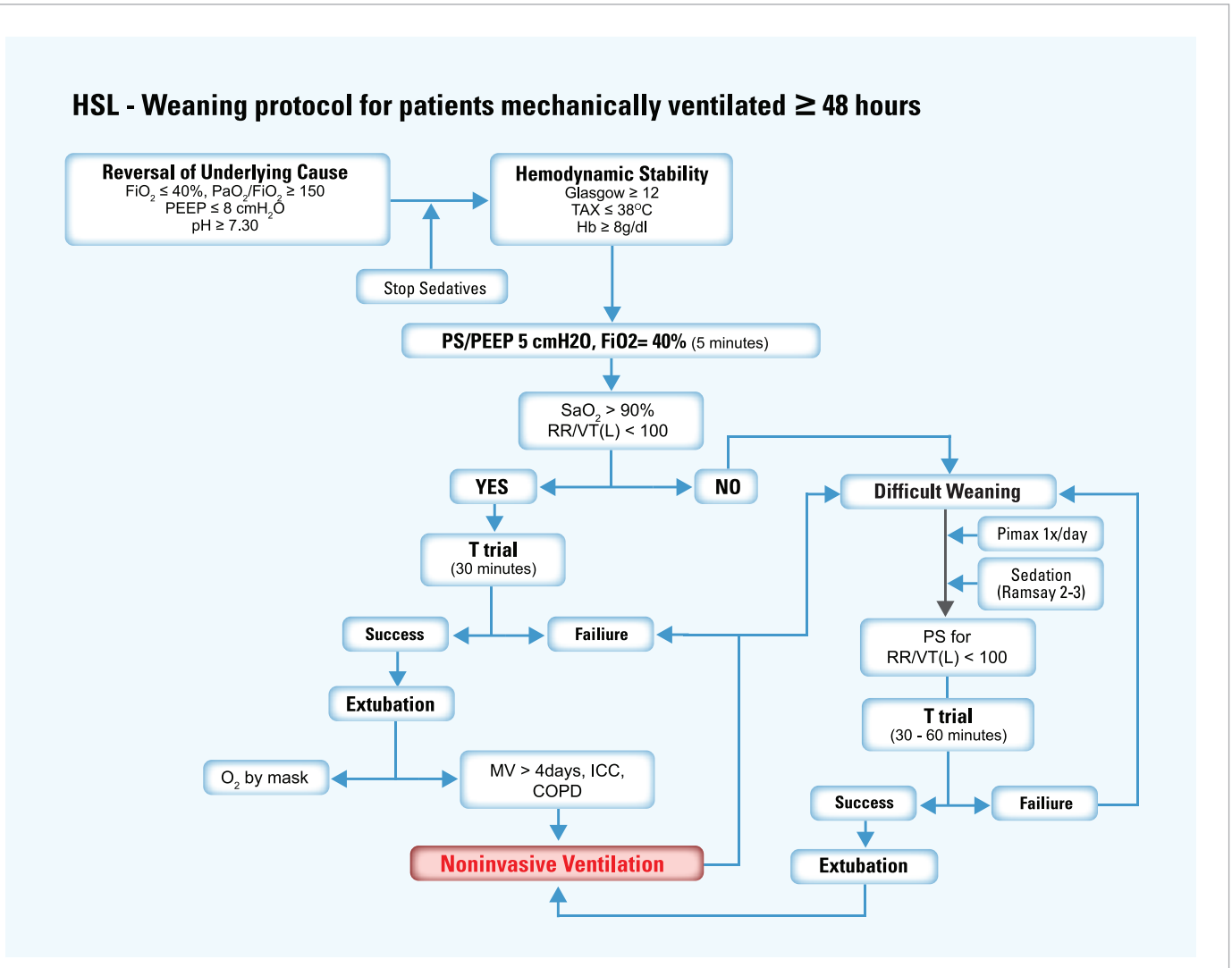
Yes, we use it in the step down unit, but also in the ICU, as a method for weaning. We developed a very nice weaning protocol for patients who we believe are at high risk to develop post-extubation respiratory failure. For that group of patients, immediately after extubation, even if the patient is ok, I use non-invasive ventilation for 4-6 hours. Patients receiving non-invasive ventilation after extubation include patients with COPD, all patients with cardiological problems, and patients that have been invasively ventilated more than 4 days, as well as patients who failed spontaneous breathing trials the day before. Our team utilizes the protocols every day: the physical therapists check for criteria for weaning against the protocol, and the therapists and nurses follow the protocol. We use non-invasive ventilation to avoid reintubation, whenever possible.

There seems to be a trend in some countries, where non-invasive ventilation is not recommended in patients with gastric problems?

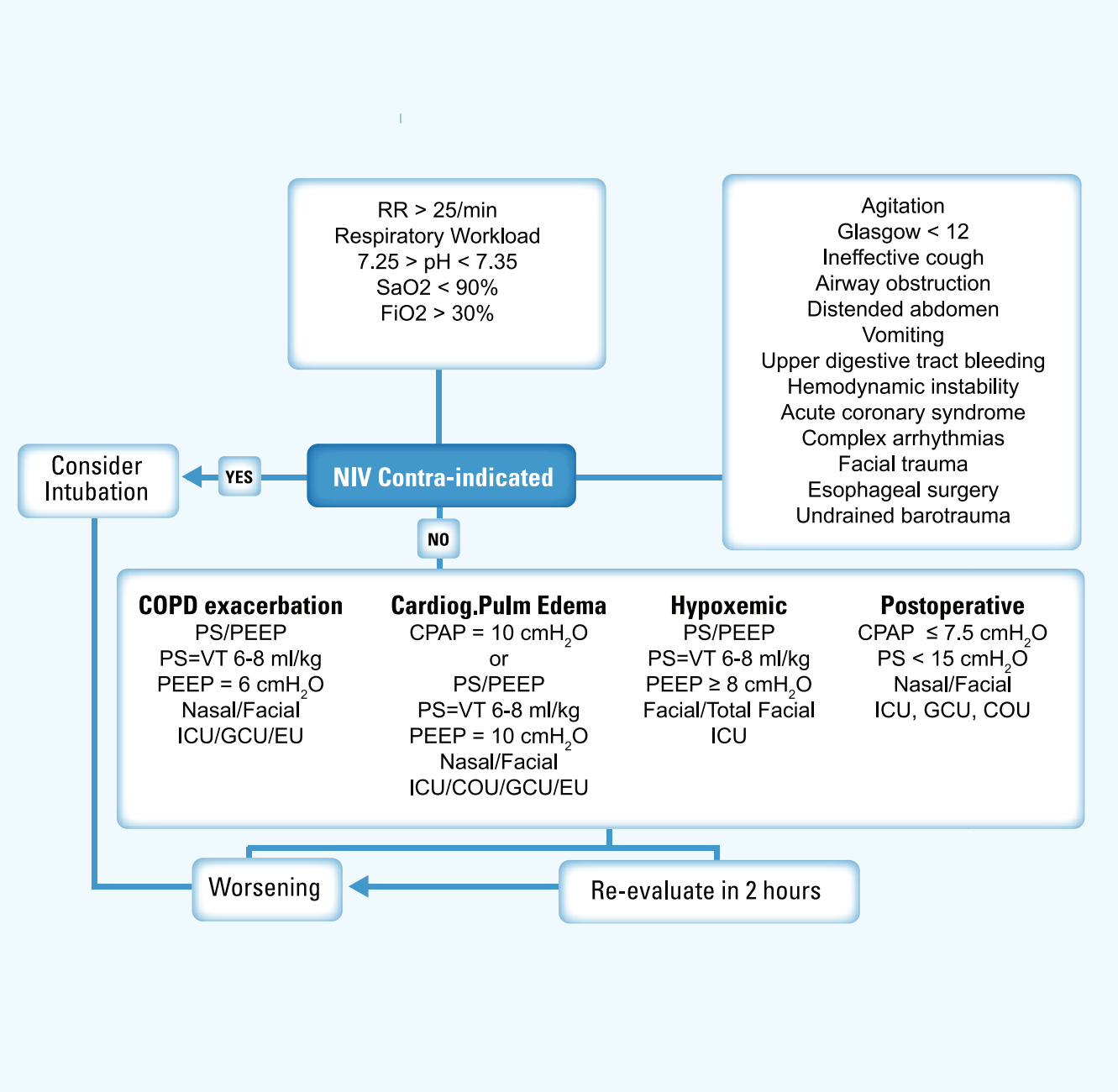
In my opinion, non-invasive ventilation is contra-indicated in patients with esophageal surgery. For patients with gastric surgery, we do use non-invasive ventilation in some cases. I discuss the case with the surgeon, and we decide together if the patient is a good candidate for non-invasive. Some obesity patients having gastric surgery receive non-invasive ventilation before the surgery, because of issues like sleep apnea. There are some papers published in the literature saying it is safe to use non-invasive ventilation in this category, and I think that this patient category benefits from the use of non-invasive ventilation, to avoid post-op atelectasis. But again, with patients with esophageal surgery, non-invasive ventilation is contra-indicated in my opinion. Non-invasive ventilation is obviously also contra-indicated in patients with gastric distention, or vomiting.

In regards to ICU colleagues around the world who are considering implementing non-invasive ventilation, what are your most important recommendations in starting up?

I think that first you have to train your team in non-invasive ventilation. Just like



MV weaning protocol used at Sirio-Libanes Hospital, Sao Paulo.



Non-invasive protocol developed and used by Dr Schettino and staff at Sirio-Libanes Hospital.

other interventions in the ICU, you need to train the physicians, nurses, physical therapists or respiratory therapists. I think that one good recommendation is to develop your own protocol for using non-invasive ventilation. It makes it easier to utilize in terms of patient categories and situations, based on literature and local experience. Define clearly what kind of contra-indications should be made for non-invasive ventilation. You can use non-invasive in a lot of patients with respiratory failure, but define the conditions that are not safe for the patients, like patients with shock, in patients with esophageal surgery or gastric distention. Together with the team, define the criteria for failure of non-invasive ventilation: when you would need to intubate the patient, to avoid using non-invasive ventilation for too long and needing to intubate in a worsening clinical situation. In my opinion, if the patient condition does not improve in the first two hours of non-invasive ventilation, I think it is better to intubate.

Are there any research developments that you see that might have an impact on non-invasive therapy in future?

I believe that NAVA (Neurally Adjusted Ventilatory Assist) will play a significant role in non-invasive ventilation, where you can solve the problems of synchrony, leakage and patient comfort. ■

Sirio-Libanes Hospital.

Biography

Guilherme Schettino, MD, PhD is Director of Intensive Care at Hospital Sirio-Libanes, Sao Paulo, Brazil, as well as a staff member of the Respiratory ICU at Hospital das Clinicas in Sao Paulo.

He obtained his medical degree at the Universidade Federal do Rio de Janeiro in 1988, and was resident at the Faculdade de Medicina da Universidade de Sao Paulo where he received his degrees in Pneumology and Intensive Care in 1992. He attained the degree of PhD at the Faculdade de Medicina da Universidade de Sao Paulo in 1998, and completed his Research Fellowship at Massachusetts General Hospital, Harvard Medical School in Boston 2002.

Guilherme Schettino, MD, PhD is an internationally-known profile who has lectured at many international meetings and congresses, and has conducted research for many years within the areas of mechanical ventilation and non-invasive ventilation.

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Department Director Professor Francesco Della Corte, MD and staff members within the Department of Anesthesia, Critical Care and Critical Emergency Medicine.

NAVA – past, present and future perceptions

The centuries-old "Ospedale Maggiore della Carità" associated with the Università del Piemonte Orientale in Novara, Italy, has a long history of clinical activity and a shorter institutional research and education life, stemming as an independent branch of the University of Turin since 1998. The General Intensive Care Unit within the Department of Anesthesia, Critical Care and Critical Emergency Medicine is presently evaluating the clinical application of NAVA – Neurally Adjusted Ventilatory Assist, for future research. NAVA, in contrast to conventional mechanical ventilation, triggers the ventilator by means of electrical diaphragm activation from signals originating in the patient's brain.

Critical Care News spoke with Department Director Professor Francesco Della Corte, MD about the hospital history and department background, and with Dr Paolo Navalesi, who presently works at the Department directed by Professor Della Corte as Head of the Intensive Care Unit and has contributed to some of the early research on NAVA and is involved with the current NAVA evaluation.

In addition to his responsibilities at the Ospedale Maggiore della Carità, Professor Francesco Della Corte, MD is also Course Director and co-founder of the European Master in Disaster Medicine.

Department Director, Professor Francesco Della Corte is an internationally known profile within the Critical Care, Emergency and Disaster lecture circuit and has conducted extensive research within the areas of anesthesia, critical care and emergency care. We talked with him about the hospital and the general operations of the Department of Anesthesia, Critical Care and Critical Emergency Medicine.

Can you describe the size of your department, average number of patients and staff?

We are a level 1 hospital for the Piemonte region in Italy, which means that we have a patient uptake area of over 860,000 inhabitants. Our department embodies three units – anesthesia, ICU and emergency care.

Can you tell us about this hospital?

Historically, it is a very old hospital, and has been located here for centuries, with the oldest part of the institution dated from the 17th century. We are a university research hospital, and our special research areas include mechanical ventilation, sepsis and trauma as well as education and training, emergency and disaster management. We are currently in the process of rebuilding and extending the hospital, which should be completed in a few years time.

We are the regional referral hospital for all emergencies and level 1 trauma, and transplantation. We provide 750 beds and offer day surgery as well as ambulatory care. All hospital specialities are represented here, with the exception of a burn unit.

Which types of ICU patient situations do you most frequently encounter?

We provide a general ICU with 14 beds, and treat an average of 800 patients per year. Our patient ratios are roughly a mix of 40-50% medical ICU patients, 25% - 30 % major trauma patients, while the rest is comprised of complex post-op patients including cardiothoracic and neurological surgical patients.

Our daytime staff usually comprises 5 physicians, 3 residents and 2 staff members, and our nurse to patient ratio is generally 1 nurse to every 2 patients.

Dr Navalesi was a co-author in the original study by Christer Sinderby "Neural control of mechanical ventilation in respiratory failure" published in Nature Medicine 1999.

Dr Paolo Navalesi has conducted extensive research within mechanical ventilation, and was an early contributor to the original research about NAVA. He is currently involved in the ongoing clinical evaluation, and he shared his past experiences, his current perceptions, and some of his ideas in regard to the future of NAVA.

You were a co-author with Christer Sinderby on the initial research for the landmark study "Neural control of mechanical ventilation in respiratory failure" published in Nature Medicine in 1999. Can you tell us some of the background of how you came to be involved in researching the method for acquisition and processing of diaphragmatic electrical signals?

It began very simply, with humble origins. I was doing research in Montreal, at the Meakins Christie Laboratories, with a prototype for a new mode of mechanical ventilation called proportional assist ventilation when I met Christer Sinderby, who was working with diaphragmatic EMG research. We developed a close friendship, and in the course of our relationship, I urged him to research the opportunity of the EMG signal to drive the ventilator. Naturally, as Christer Sinderby is a physiologist, he was not all that interested in this subject, in the beginning. About two years later, when he was my guest in Italy, late one evening over a bottle of Grappa and a Cuban cigar, we theorized more about this opportunity, and decided to do some tests and to make a simulation.

Later that summer we met at an ERS meeting in Stockholm, and he presented the simulation that was exciting and extremely promising. He started to do work on the algorithm, and the first version of NAVA was very rough – on a homemade ventilator. But in time, a SERVO 900C ventilator was used to trigger on a neural signal. Finally, Christer Sinderby decided that we had enough research to provide a paper, and he contacted the editor of Nature Medicine, who thought the research was interesting and asked for a submission. The original article is simple yet very communicative, but it took us some time to complete it. Ultimately, the paper was published and received very good reviews. It is important to point out that I have never had any commercial interest in the subject, in the past or otherwise.

What were your perceptions at that time, in regard to the concept of NAVA and what you possibly saw as the future of the method of Neurally Adjusted Ventilatory Assist?

In Montreal, the reason why I urged Christer to develop the EMG trigger opportunity was my interest at that time

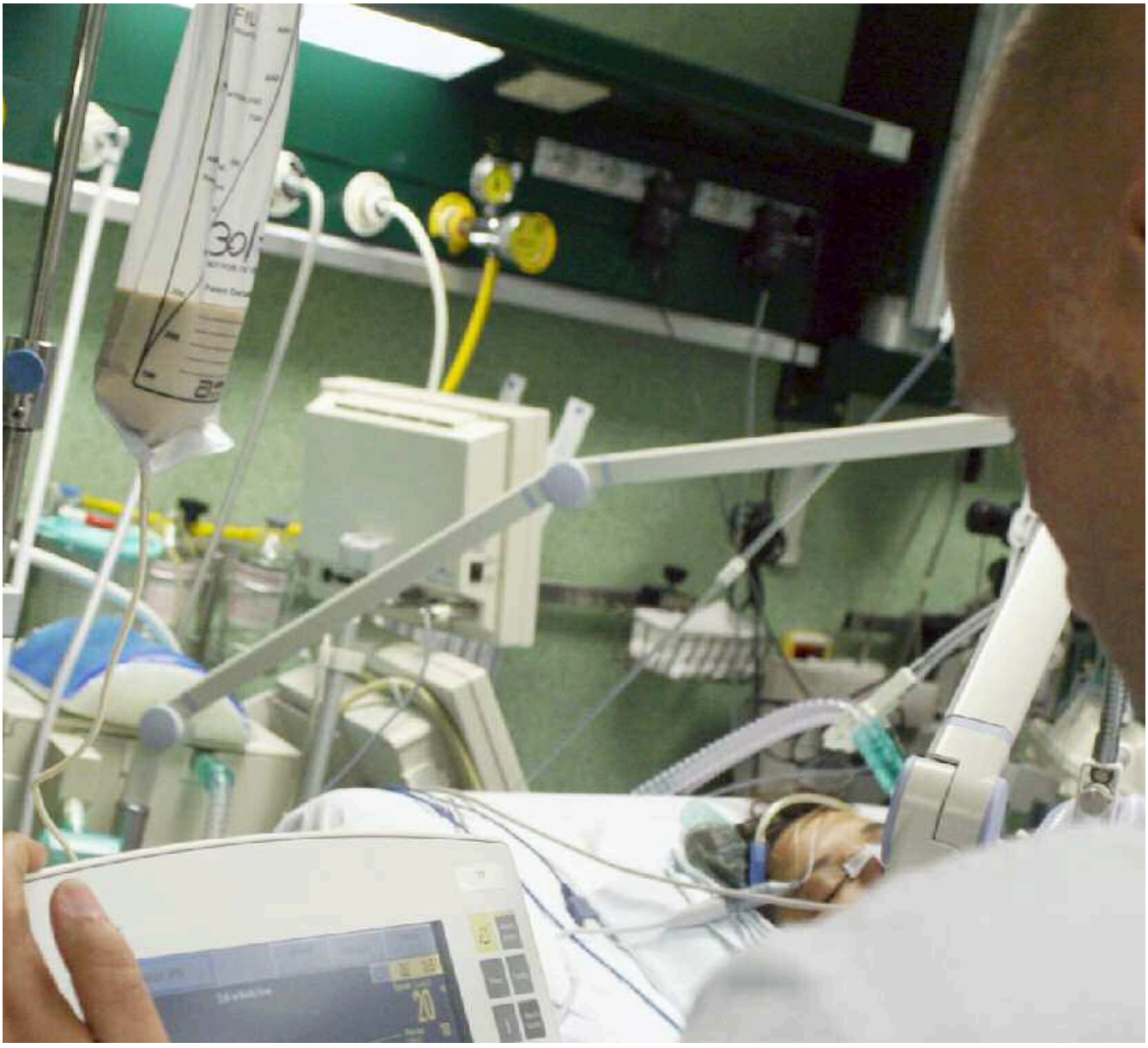
that stemmed from my work with COPD patients with acute exacerbation requiring mechanical ventilation, and the method we used of applying external PEEP to counterbalance intrinsic PEEP, which was not an easy task. Because of the difficulties in setting up the right ventilator settings in the COPD patient, it became apparent to me that the best approach in these patients would be to use the effort of a major respiratory muscle in order to avoid any other products in between the patient and the ventilator. So the idea with NAVA was born to treat COPD patients with acute exacerbations in the ICU - I still believe this is one of the most potentially important areas for the application, although in recent years the COPD patients who require endotracheal intubation is largely reduced secondary to the use of non-invasive ventilation, which has been shown to be very effective in this patient population. That was the beginning, in this disease category.

Do you think there will be difficulties in trying to adapt treatment culture from conventional pneumatic mechanical ventilation to neurally driven ventilation?

Yes. I believe these difficulties come with a sort of medical inertia within the field. Changing our attitudes in regard to procedures, methods and devices that have been used in a certain manner for many, many years can be a long process. We have to consider that this may take some time. However, I think that there might be a general level of curiosity to this new approach that may help very much in this respect.

How many patients have you treated with the clinical application of NAVA at this time? Which types of patient categories are they?

We have been using the current clinical application in the last month in a series of



Dr Paolo Navalesi is involved in evaluation of the current clinical application of NAVA.

Dr Davide Colombo and Dr Gianmaria Cammarota have also been involved in the current clinical evaluation of NAVA in adult patients.

10 adult patients so far, in a broad spectrum of very different types of underlying diseases with no specific pathologies. Our underlying statistical analysis will start, and we will have more discussions with the manufacturer before we proceed further.

Which ventilation therapies would normally have been used in these patients?

Pressure Support is primarily used. That is why we want a head-to-head comparison of Pressure Support and NAVA in this series of patients. We are dealing with forms of partial ventilatory support, so we should compare it to other forms of partial ventilatory support, to assess whether or not we can have advantages. Another interesting future use of NAVA might be in patients with acute lung injury and ARDS. Some believe it might be possible to maintain these patients in assisted spontaneous breathing and the hypothesis is that NAVA might provide protective ventilation while avoiding the level of sedation compared to controlled mechanical ventilation in this patient group. Again, however, at this point, it is still only a hypothesis.

Are there some specific patient experiences that are of special interest?

I think that any patients with altered neuro-mechanical coupling are good candidates for NAVA. Newborns are probably one of the most potentially interesting categories. In some patients with very severe disease, NAVA may help maintain non-invasive ventilation more extensively than other more conventional techniques. I think perhaps three general categories may be of interest in the future: patients with acute or chronic airway disease, children, and patients

using non-invasive ventilation.

What is your perception of patient –ventilator synchrony in regard to NAVA?

In patients with wasted inspiratory efforts, the use of NAVA is absolutely beneficial in my opinion, in helping these patients to avoid wasted inspiratory efforts. In COPD patients, we definitely observed a clear improved synchrony with NAVA, as opposed to other forms of partial support, both at the onset and the end of the inspiration. End inspiration synchrony is improved in most of the cases, in our observation. It is not possible, however, at this time to substantiate a preference for neural triggering over the conventional inspiratory triggers for the large majority of patients.

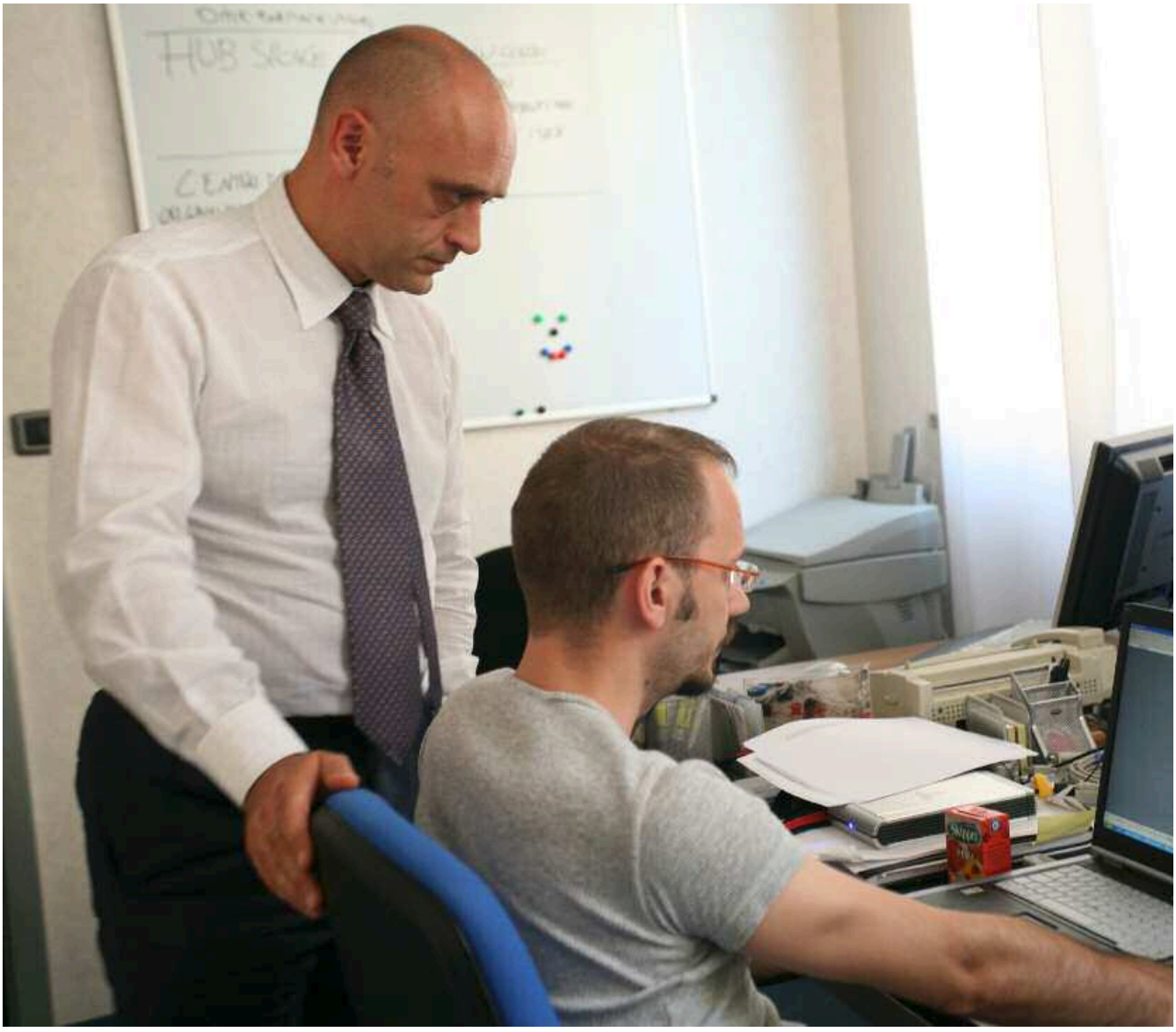
In terms of patient-ventilator asynchrony, what are the most significant risks?

At present, there is an interesting paper published by Professor Laurent Brochard's group in regard to outcome of patients with poor ventilatory synchrony, with much longer duration of mechanical ventilation and longer ICU stay. This research documents that compromised synchrony affects patient outcome.

What is your opinion regarding the advantage of Edi signals as a completely new parameter in ventilation?

I think that the Edi signal, besides NAVA, provides a very interesting new parameter to the ICU physician to help deal with and improve knowledge of the patient undergoing mechanical ventilation.

This is the closest signal to the brainstem respiratory center that we can collect today. In patients with altered neuro-mechanical coupling, the Edi might be really useful, as you might have a poor mechanical output (i.e. a very limited amount of pressure generated by the



Dr Navalesi and Dr Colombo are in the process of studying the clinical data from the first series of patients in the evaluation.

diaphragm) but very strong Edi signal, due to the altered respiratory muscle function. Indeed, Edi signal may provide a new area for research in the field of control of breathing during mechanical ventilation.

Has it been difficult to teach your other staff members in regard to the concept and application of NAVA?

There are two aspects to this issue: the first being education in the knowledge of what this signal means. As we in the ICU are used to the aspect of pressure in discussions, it is easy to misunderstand Edi and confuse it with what pressure the signals results in. This is the primary aspect for learning and teaching. The secondary aspect is the practical one of positioning the catheter, which has been indeed much easier than expected in the clinical application.

What according to your experience so far, are the most important aspects for ICU staff to learn, prior to initiating NAVA ventilation therapy?

As mentioned previously, I think the most important issue is the understanding of the physiological aspect of the Edi signal and learning the significance of it.

Which types of patient categories would you recommend others to start with, in order to gain experience?

I have seen NAVA used in many patient categories: brain damage, quadriplegic, acute lung injury and COPD, to name some. In my experience, COPD patients are those to get the most immediate satisfaction from a user experience. But I really do not see many limitations in general, although it is too early to discuss which groups would benefit the most. I think it might be good for new users to start with tracheotomised patients, as this group generally needs less sedation, and as sedation may alter neural drive, it may be easier here to start to evaluate and experience NAVA. The impact of different types and amounts of sedatives on diaphragm activation and, consequently, on NAVA, is one of the problems that deserves more attention; at the time being we are setting up a study to define this aspect.

Do you believe that a significant number of ICUs around the world will be gaining clinical experience with NAVA in the next few years?

This is a difficult question to address, but should be considered in a general manner. Certainly NAVA will never be the only mode of ventilation used in the ICU and it will never replace entirely conventional mechanical ventilation, however in the coming years it may more generally be seen to be beneficial in improving patient synchrony in the categories we have discussed earlier. It will start out in a niche position in some patient categories, and I am not sure at this time how large that niche will become. But we can say that most modes of mechanical ventilation started out in niche positions at one time or another. If we look at the historical perspective, currently in our ICU, about 80% to 85% of our patients are using Pressure Support, and twenty years ago probably this same ratio of patients were receiving controlled mechanical ventilation. So we have seen a historical shift on a long-term perspective. Incidentally, I think that Pressure Support is still an excellent mode of ventilatory assistance.

Which research opportunities do you see with the clinical application of NAVA in the coming years?

I think that, as we have discussed, in the area of patient-ventilator synchrony, NAVA is a perfect tool for this type of research, and in general I think that we will re-write some pages in regard to control of breathing in mechanical ventilation, as we will probably find things that were never considered before. And as we have also discussed, I think that as NAVA enters into the area of pediatrics and newborns, it might represent a positive revolution for these types of patients.

Biographies

Professor Francesco Della Corte, MD received his medical degree at the Catholic University in Rome in 1979, where he also completed his training in Anesthesia and Intensive Care. Professor Della Corte was also named Associate Professor in Emergency and Disaster Medicine at Catholic University in Rome, and Associate Professor in Intensive Care at the University of Eastern Piedmont, Italy.

Professor Francesco Della Corte is currently Director of the Department of Anesthesiology, Critical Care and Critical Emergency Medicine at Ospedale Maggiore della Carità in Novara, Italy. He is also Full Professor of Anesthesiology and Intensive Care at the University of Piedmont.

Professor Della Corte has a long-standing affiliation with several international associations, including Society of Critical Care Medicine, the European Society of Intensive Care Medicine, the Italian Society for Anesthesia, Analgesia and Intensive Care, as well as the European Society for Emergency Medicine, where he has been Secretary of the Society from 1999 to 2006.

He is Course Director and co-founder of the European Master in Disaster Medicine, a well known international, inter-university academic program. He is reviewer to numerous international journals, including European Journal of Emergency Medicine, Critical Care Medicine, Intensive Care Medicine, Minerva Anesthesiologica, International Journal of Disaster Medicine and the American Journal of Disaster Medicine.

Professor Francesco Della Corte, MD has contributed to 14 chapters in books, and has over 64 papers

published on indexed reviews. He was also Editor for the Manuale di Emergenze Medico-Chirurgiche (McGraw Hill 2002). He has made extensive presentations as invited speaker in over 200 national and international congresses.

Dr Paolo Navalesi received his medical degree in Italy from the University of Genoa with the highest score and completed his training in Pulmonary Medicine and in Critical Care Medicine at the University of Milan. Dr Navalesi also completed a post-graduate research fellowship in Pulmonary Medicine at the McGill University, Montreal, Canada.

Dr Paolo Navalesi works at the Ospedale Maggiore della Carità in Novara Italy, where he is Head of the Intensive Care Unit of the Department of Anesthesia and Intensive Care. He teaches at the School of Anesthesiology and Intensive Care of the University of the Oriental Piedmont.

Dr Paolo Navalesi is the Secretary of the scientific group "Non invasive ventilatory support" of the European Respiratory Society. He collaborates with the Italian Health Minister for Continuous Medical Education in Pulmonary Medicine. He is an independent referee for several international scientific journals including the American Journal of Respiratory and Critical Care Medicine, Critical Care Medicine, Intensive Care Medicine, European Respiratory Journal, Thorax, and Respiratory Medicine. He is author or co-author of several publications mainly focused on mechanical ventilation, and has published in numerous international journals such as Nature Medicine, American Journal of Respiratory and Critical Care Medicine, Journal of Applied Physiology, Critical Care Medicine, Intensive Care Medicine, Chest, Anesthesiology, and Respiratory Medicine. He has been invited as an expert to the International Consensus Conference on Weaning, held in Budapest in April 2005. He has contributed to numerous review articles and book chapters.

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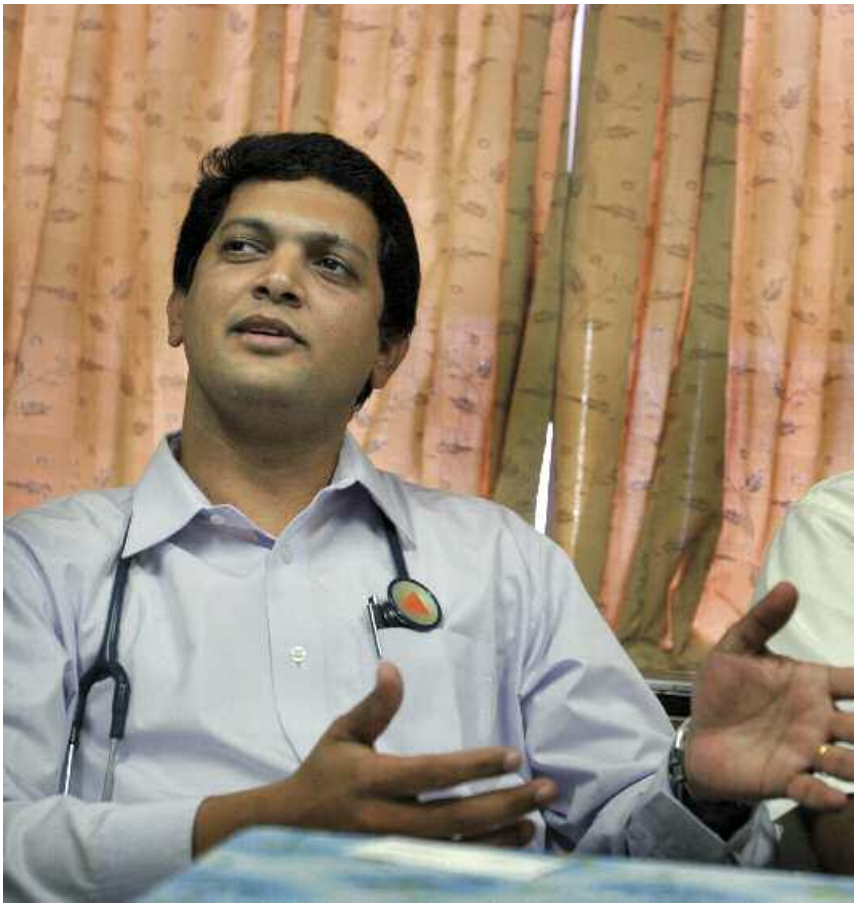
Chief Consultant Dr Gopalakrishnan Raman assessing an ICU patient after lung recruitment maneuver.

Open Lung methodology in ARDS patients

The Kovai Medical Center and Hospital of Coimbatore, India, established in 1990, is a private, super-speciality hospital offering multi-disciplinary care in over 40 medical disciplines. In addition to 10 surgical theaters, the center is also a site for research and education, through the Kovai Medical Research Center and Educational Trust.

The medical ICU of Kovai Medical Center has been utilizing lung recruitment procedures in the interest of lung protection for many years. For the past two years, the ICU has been gaining experience in the use of a tool with a protocol for titration of physiological endpoints and breath-to-breath graphics for lung recruitment in specific patient categories.

Critical Care News spoke with Dr Gopalakrishnan Raman, Chief Consultant of the medical ICU at Kovai Medical Center, and Dr V R Pattabhi Raman, Pulmonologist, about their experiences with the lung recruitment tool.



Dr V R Pattabhi Raman is Consultant in Pulmonology at the Kovai Medical Center and Hospital.

How and when did you come to use Open Lung methodology in connection with ARDS patients in the hospital?

Dr Gopalakrishnan Raman: We heard about the methodology and tool from the manufacturer, and decided to try it out about two years ago. We had very good results on the first series of 4 patient cases, and continued to use the Open Lung Tool, primarily in ARDS patients.

Which types of procedures were you using for ARDS prior to the Open Lung Tool?

Dr Pattabhi Raman: Prior to that we had read about a procedure with 180 seconds of inspiratory pressure with Pressure Control but we were not brave enough to try that. We then heard about the procedure of recruitment of 40 cm at 40 seconds, and we tried this and saw some dramatic results in some patients. Based on this recruitment experience, we heard about the Open Lung Tool and were interested in trying it out. So our lung recruitment measures have been concentrated primarily in this group.

Have you defined any specific inclusion/exclusion criteria for lung recruitment in ARDS?

Dr Gopalakrishnan Raman: In terms of exclusion criteria, basically we would not recruit any patient with embolisms, as there is too much risk in this patient category. Another exclusion group is hemodynamically compromised patients, which is a category where we would not risk recruitment.

In your experience are parameters such as dynamic compliance and $VTCO_2$ useful in evaluation of the recruitment maneuver?

Dr Pattabhi Raman: Yes, it is very helpful in setting the PEEP to always use dynamic compliance as a tool. In the past we were looking at tidal volumes and pressures, so dynamic compliance is giving us more specific information in order to set PEEP, or adjust PEEP in selected patients. We have found that patients with extrapulmonary ARDS have a much better outcome with the recruitment maneuver using dynamic compliance and the Open Lung Tool, probably since we can follow the patients' progress more closely and monitor the respiratory situation in more detail.

What are your opinions of the ARDSnet guidelines and recommendations?

Dr Gopalakrishnan Raman: We have followed the 6 ml/kg tidal volume recommendation, but perhaps deviate somewhat in regard to recommendations for PEEP. We have tried to follow the PEEP recommendations in the ARDSnet protocol, but we felt we had the need to increase it sometimes. Sometimes we will adjust the PEEP according to the blood gas oxygenation, if it would be too low. So we increase the PEEP individually, as each patient needs it.

Dr Pattabhi Raman: We have found that there are some groups that don't respond. Basically extrapulmonary ARDS and septic patients respond well in our experience, but with more complex pulmonary patients we do not increase the PEEP to high levels, but more moderate levels. At present, you could say that we generally follow ARDSnet, but with variations, we don't usually go to a respiratory rate of 35, so there are certain deviations we have from ARDSnet.

Dr Gopalakrishnan Raman:
To summarize, you could say that we follow ARDSnet recommendations, with some deviations at the present. At least until we get something better, in terms of guidelines.

Dr Pattabhi Raman: Yes – part of the problem today is that we are lumping the whole thing together; in looking at the population of patients, the distinction between pulmonary and extrapulmonary really cannot be made. In general, the intensive care community probably needs more data about etiology, and about certain factors, for example the use of

Dr Pattabhi Raman performing a lung recruitment maneuver in an ARDS patient.

surfactant therapy in ARDS patients. I think that once we have data in a more homogenous population, instead of lumping data together, and a more precise global consensus of the definition of ARDS, we will have the possibility to adjust and adapt the guidelines more precisely.

What is your experience and opinion in regard to PEEP levels in connection to lung recruitment?

Dr Pattabhi Raman: Once we have recruited, we generally maintain PEEP levels between 15 and 19; we rarely go over these levels.

What sort of outcomes are you experiencing with use of Open Lung Tool in ARDS patients? How is the situation compared to the previous procedures you were using in this patient group?

Dr Gopalakrishnan Raman: We initially started using the Open Lung Tool two years ago in lung recruitment in a series of 4 or 5 patients, with very positive results. These first positive experiences were the reason why we have continued to use the recruitment tool.

Dr Pattabhi Raman: We do not have any data or studies at this point, but on an observational level we have definitely experienced a distinct difference, and we know more about what is happening in this recruitment process as you get more information by means of using this tool. Our perception is that outcome is definitely better in terms of inflection point and getting down to the levels of PEEP where we want to be, with more confidence than we had before.

Dr Gopalakrishnan Raman: It is a more objective way of applying the procedure, in a more scientific manner than in the past, in terms of recruiting the patient and adjusting the PEEP level, by means of adjusting PEEP according to lung mechanics rather than gas exchange. And it also allows us to track the changes that have been made or occurred during the course of recruitment, which provides us with more information in order to further tailor the treatment.

Are you using any protocol for weaning when patients are improving after lung recruitment procedures? What is the average weaning time for ARDS patients who have been undergoing Open Lung recruitment maneuvers?

Dr Pattabhi Raman: We follow a standard weaning procedure, where we use CPAP or Pressure Support on a spontaneous breathing trial, and checking them, prior to extubation. The average weaning time for ARDS patients from

start of Pressure Support to extubation usually ranges between 2 to 5 days.

Which types of staff members are involved in applying or monitoring the recruitment maneuvers with the Open Lung Tool?

Dr Gopalakrishnan Raman:
The physicians are in charge, but the respiratory therapists are conducting the recruitment maneuvers. There is no hard and fast training, but we teach them by doing the procedure, and monitoring their recruitment maneuvers as they learn and become more experienced. We have dedicated respiratory therapists who look after the ventilators, under direction of the physicians.

Is there delegation for re-recruiting after suctioning/disconnection?

Dr Pattabhi Raman: As a rule for ARDS patients, suctioning is not a routine process. We try to avoid suctioning and only conduct it when it is absolutely required. Following suctioning, we repeat the recruitment maneuver to re-establish the values accordingly. If the requirement of PEEP is heavy, we use closed suctioning systems, which are more expensive here.

Will you be expanding or modifying the procedure in future, or modifying it for other patient categories or outcome endpoints? If so, which endpoints are of interest and which changes will be made?

Dr Pattabhi Raman: Based on the two-year experience we have, we have seen some patients do well, and some do extremely well. Since we cannot be really dogmatic about anything, we would like to continue concentrating on the subgroups, and identifying which of the subgroups that are responding most positively, and examining how the recruitment procedure is benefitting these patients. We have a lot of findings and observations at this point, but it would be nice to conduct a controlled clinical trial to postulate on why some of the subgroups, such as extrapulmonary ARDS and sepsis, do so well with the procedure.

Biographies

Dr Gopalakrishnan Raman attended Calicut Medical College, receiving his degree in 1991. He obtained his MD in Anesthesiology from King Edward VII Memorial Hospital in Bombay in 1995 and passed his National Board Examination the same year.

He worked as a lecturer at King Edward VII Memorial Hospital during 1994-1995, and was Senior Resident in Cardiac and Anesthesiology at the prestigious Sree Chitra Tirunal Institute for Medical Sciences and Technology in 1996. In 1997 he worked in various training posts in the United Kingdom, becoming Staff Anaesthetist and Intensivist at the University Hospitals of Hartlepool and North Tees. After working for several years in the U.K, Dr Gopalakrishnan Raman returned to India to assume the position of Chief Consultant Intensive Care Medicine at the Kovai Medical Center and Hospital in Coimbatore.

Dr V R Pattabhi Raman received his MBBS degree from Tirunelveli Medical College and obtained his MD and Diploma in National Board in Respiratory Medicine from Madras Medical College. He was awarded 3 gold medals in MD for academic excellence in pulmonology. He has presented papers in national and international congresses, and is a member of the Indian Chest Society, the American College of Chest Physicians – Indian Chapter, the Indian Medical Association and the Indian Society of Critical Care Medicine.

After gaining experience in respiratory and critical care medicine in Chennai, and sleep medicine in Sydney, Australia, Dr Pattabhi Raman returned to India to assume the position of Consultant in Pulmonology, critical care and sleep medicine at the Kovai Medical Center and Hospital in Coimbatore.

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Ronny Knutsson, RN and Anne Magnusson, RN prepare an ICU patient for mobile transport.

Evaluation of a ventilator solution in a mobile ICU

Kristianstad Regional Hospital has been creating solutions and generating experience in transporting ventilated patients in the southern region of Sweden since 1978. In recent years, they have cooperated with partners and authorities to create a customized transport carriage for a mobile ICU to facilitate transport of critical care patients within the region. All inter-hospital patient transports in the mobile ICU were documented on protocol during the year 2006.

Critical Care News met with the project team members representing key functions; project director, anesthesiologist, ICU physicians, ICU nurse and clinical engineering, to discuss their impressive results.

You have a long tradition of transporting ventilated ICU patients in this region of Sweden. Can you tell us a little about the historical background?

Lennart Ohlsson, MD, Department of Anesthesiology and Intensive Care: We started back in 1978 or 1979 when we equipped an ambulance with a SERVO 900A ventilator with gas cylinders and an electrical converter that was quite advanced for the time, with 220 voltage that was approved and validated for the first time in an ambulance. In 1990 we implemented a SERVO 900 C ventilator on an integrated stretcher-trolley, which worked well as a transport solution for 13 years. During these years, we have gained experience and have developed practical solutions during the course of this experience. Our goal has always been to provide continuous ventilation therapy to the patient during transport, while minimizing interruptions as much as possible. But one of the difficulties with the older ventilator models was the need to interrupt ventilation while transferring the patient from the ICU down to the ambulance, and interrupting again when arriving at the receiving hospital.

When the SERVO-i ventilator was launched in 2001, we saw the possibility of developing a mobile ICU with a bedside adaptation to provide uninterrupted ventilation to the patient for the entire transport chain, from ICU bedside, during inter-hospital transport to the ICU bedside at the receiving hospital. The project group received approval during 2002, and started to customize and develop the new solution, based on our previous years of experience.

This new mobile ICU solution has also been used for transport of small neonatal patients between university hospitals in the region.

Many people in different groups have been involved in the various stages of the process, but we are the primary project team that has been involved in the development and implementation of this latest solution, and many of us have been actively involved in the transport experiences of the past. Our project team has had the resources, some luck, but we have also had enough determination to finalize the project, and implement this latest solution. This means that we have found the evaluation results to be especially rewarding to us within the group.

Loading ICU patient on transport trolley into the mobile ICU.

Ronny Knutsson, RN, ICU nurse: Many of us who accompany the patients in the mobile ICU today have had experience of patient transports with the older systems and vehicles. This means that we have experienced details from practical and care giving aspects that were areas for improvement in the past. We took these experiences with us into the development process for the new solution in this most recent project group for the new mobile ICU.

Christer Karlsson, KAMBER, Project Director: The mobile ICU consists of the TRANSMOBIL stretcher-base combination, which is secured to the trolley and allows transfer of the patient without changing position. The transfer trolley houses the SERVO-i ventilator, up to six jet infusion pumps, patient monitor and suction equipment, with fixed connections and couplings as well as locking mechanisms for the equipment and trolley. This means that the trolley is completely self-sufficient with an operational capacity of 3-4 hours for air, oxygen and power.

The specially designed vehicle contains both a 12 V DC and a 230 V AC power supply. Double air and oxygen tanks are available with 5000 liters each of air and oxygen, and switching between them is easy. Strength, durability and stability were key parameters in designing the mobile ICU, which required special customized frames and braces to hold the equipment. These have been developed to twice the strength and durability required, and will function even after a collision.

What practical and clinical aspects led to the development of your current mobile ICU solution? Can you tell us about the project group behind the solution?

Lennart Ohlsson, MD: It is important to point out that this has been a cooperative project between KAMBER, the Regional Health Ambulance provider, and the Regional Hospital here in Kristianstad, where we have team members from key functions within the hospital; physicians and nurses from the Department of Anesthesia and Intensive Care, and our Clinical Engineering Department.

Mattias Svensson, Clinical Engineer: The entire mobile ICU is composed of

Nurses Ronny Knutsson and Anne Magnusson accompany ICU transport patient from ward to mobile ICU.

many components, but must be regarded as one system. There are a lot of regulations to follow when developing and customizing components and the entire system. The initial risk analysis process is the key basis for initiating a project of this scale. It is a long thorough process of identifying every possible risk for the system, components and transport process, and adjustments and modifying details to avoid each risk.

Ronny Knutsson, RN: We planned and anticipated anything that could possibly happen with the patient and treatment during the transport process: traffic jams, vehicle breakdown, the need to intubate or reintubate during transport; we considered every possible risk scenario and came up with solutions to how we would handle these.

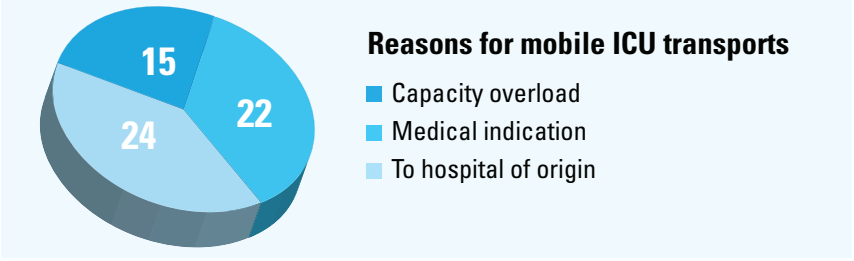
In regard to your past experience of transports of intensive care patients, what proportion of patients are acute/emergency as opposed to secondary planned ICU transports?

Tomas Åhlund, MD, Anesthesiology and Intensive Care: The mobile ICU is not often used in acute cases – accidents, bleeding, trauma – these cases are most frequently transported in conventional ambulances.

The mobile ICU is mainly used for transporting intensive care patients who need the clinical performance of an ICU ventilator during transport. Historically, we have transported ICU patients back to Kristianstad ICU from the University Hospital of Lund, where the patients have been sent for specialist care, for example thorax, neurological or plasma phoresis treatment, ICU patients who are returning home here to Kristianstad for continuing ICU care. This inter-hospital transfer of ICU patients within the region started to grow during the 1990's, and is continuing to expand, due to temporary lack of ICU patient bed capacity within hospitals in the region.

Our hospital here in Kristianstad is about an hour away from the big metropolitan areas and larger hospitals, so we have become a "buffer" hospital within the region, when ICU patient capacity is overloaded at the other hospitals. In this respect, we also cooperate with the region of Själland in Denmark, primarily with neonatal patients. As the cooperation between hospitals in the region increases, we have seen an increase in our receiving patients from the hospitals in Malmö, Lund and Helsingborg, while maintaining the same amount of patients we have transferred out of Kristianstad for care in those centers. We understand that this increasing trend of transferring ICU patients between hospitals is at an even higher level in other parts of Europe, for example Germany and Great Britain.

During the course of our one year evaluation of the mobile ICU in 2006, we collected data showing the transfer of a total of 84 ICU patients from 12 ICU departments in the different hospitals within the region. A total of 68 of these patients were mechanically ventilated, of which 15 of these were transported due to capacity overload at the transferring intensive care department.



ICU patient transport protocol data, 2006

Which types of patient categories are seen most frequently in these planned ICU transports?

Ronny Knutsson, RN: Basically, you could say that the patients transported in the mobile ICU are the same mix of patient categories in the ICU ward: general ICU patients with pneumonia, COPD, sepsis, post-op, you name it. The ICU patients we treat in the department are the same categories transported in the mobile ICU to other hospitals.

Lennart Ohlsson, MD: We can transport patients in the mobile ICU that otherwise would have been regarded as not suitable for transport in the past. Our objective is to give the patients the same level of care in the mobile ICU as they receive in the ICU departments. This means the same level of patient monitoring, the same treatment medications, the same quality of ventilatory care, without interruption. In order to monitor and ensure that the level of care is the same quality, we document everything that happens, prior to transport, during transport, and after transfer to the new ICU, in order to follow the patients as closely as possible.

Christer Karlsson, Project Director: We are also in the process of including blood gas analyzers in the mobile ICU. We have started to include these in the neonatal patient population, and they will be available for all patient categories by this summer.

Lennart Ohlsson, MD: Much has happened in regard to development and experience during the past decades we have been involved in patient transports. Today, we have syringe infusion pumps, which facilitate the process and are easier to place. In general, most of the equipment has become much smaller and lighter, with increased battery time.

Ronny Knutsson, RN: Another big difference is that in the past the nurse was alone with the patient during transport. Now, depending on the status of the patient, an anesthesia nurse and an intensive care nurse may accompany the patient. We also have better communication with mobile phones, and can be in contact with the responsible physician for consultancy during the transport process, if necessary. The quality of care is much improved; in fact, it is as if the entire care team is accompanying the patient, some of us physically and the rest electronically. Nowadays, we also have room for a third staff member in special situations, and we can also accommodate an aortic balloon pump if needed.

In these general ICU patient categories, which type of clinical performance is required from the mobile ICU ventilator that is delivering therapy?

Lennart Ohlsson, MD: In general, the mobile ICU ventilator should provide the same clinical performance that the patient requires of the ventilator bedside in the ICU. This is a great benefit to the patient, to be able to use the ICU ventilator with the same settings bedside, and continue with the same ventilator and settings throughout the entire transport process, bedside to bedside at the receiving ICU. This is without a doubt best for the patient, it is safer and more comfortable than interrupting therapy, and it is also beneficial to the staff since it requires fewer staff members and less time.

Tomas Åhlund, MD: I agree that it is important to maintain the same clinical performance in ventilation throughout the entire process. Transporting ICU patients is a risk factor per se, and the idea that the intensive care patient should receive a lower level of care or become more

Mobile ICU Project Director Christer Karlsson is employed by KAMBER-Skåne, the regional ambulance transport service.

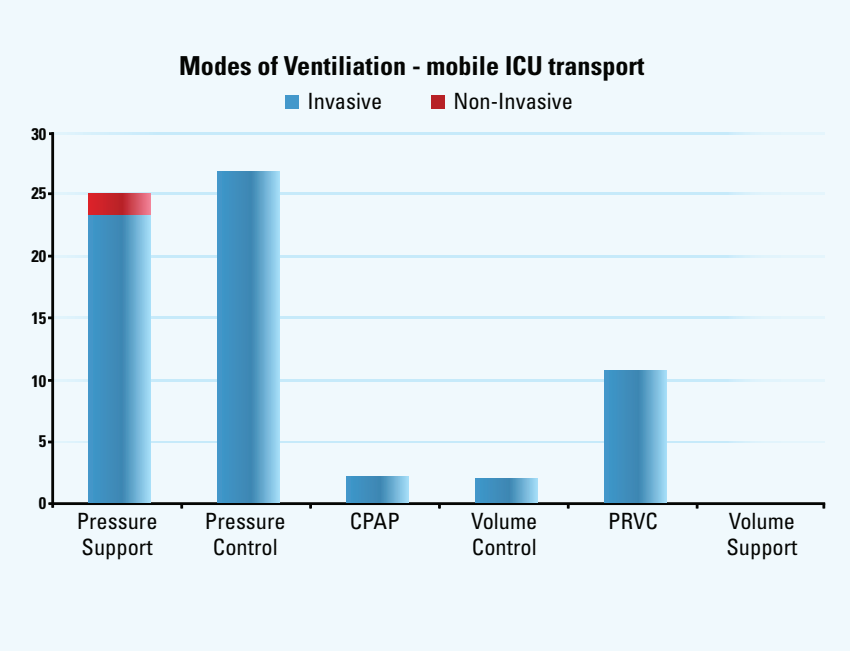
uncomfortable due to a suboptimal ventilator during the transport process is very negative indeed. The other factor is that we see a continued increasing focus on non-invasive and supported ventilation in recent years. This means that the mobile ICU must have a ventilator to accommodate these modes, just as at bedside, and the other modes as well: for intubated patients with controlled or supported ventilation modes as well as patients with non-invasive ventilation. When we purchased the SERVO-i in 2002, it was clear to us that it would suit all of these treatment requirements in transport, as well as the battery back-up time and the other practical features.

Ronny Knutsson, RN: It can be of interest to note how we came to the optimal arrangement of the equipment. We knew what supplies we wanted on the trolley, but we were not sure how to fit each item optimally in proportion to each other, so we were continually sketching and drawing up drafts. At the same time, we had construction going on in the Department of Anesthesiology and Intensive Care, and the floor was covered in sheets of protective paper, so we took some of them and cut them to the size and dimension of the lower level of the trolley. We arranged the gas cylinders, ventilator and other equipment on the paper "trolley", so that everything would be placed compactly and proportionately. We called this starting at "ground level".

Christer Karlsson, Project Director: Another issue we were struggling with was how to ensure an uninterrupted gas supply to the ventilator. We were looking at all kinds of elaborate vents, and valves, and ended up with a very simple and easy solution in the final version: a valve on every hose that could be opened or closed, to let us run gas from the cylinders, or from the vehicle supply.

Mattias Svensson, Clinical Engineer: Everything had a challenge, especially how to ensure that all procedures were free from interruption during the entire process. It all stemmed from the risk analysis, right down to extra hoses, tubes and suctioning devices.

Lennart Ohlsson, MD: We strived for optimal simplicity, with one connection for the entire trolley that supplied and conveyed everything; electrical power, oxygen and air. At the same time we wanted to make sure that if anything happened when the patient trolley was enroute in the corridors between the ICU and the mobile ICU, we could simply plug into a wall outlet.



ICU patient transport protocol data, 2006

Mattias Svensson, Clinical Engineer: The more cords, tubes and hoses you have, the greater the risk of forgetting something, or something becoming damaged.

What are the types of ventilation strategies or modes that are most commonly used during mobile ICU transports, and why? How often do you transfer the identical settings from the patient's ventilator in the ICU to the SERVO-i in the mobile ICU?

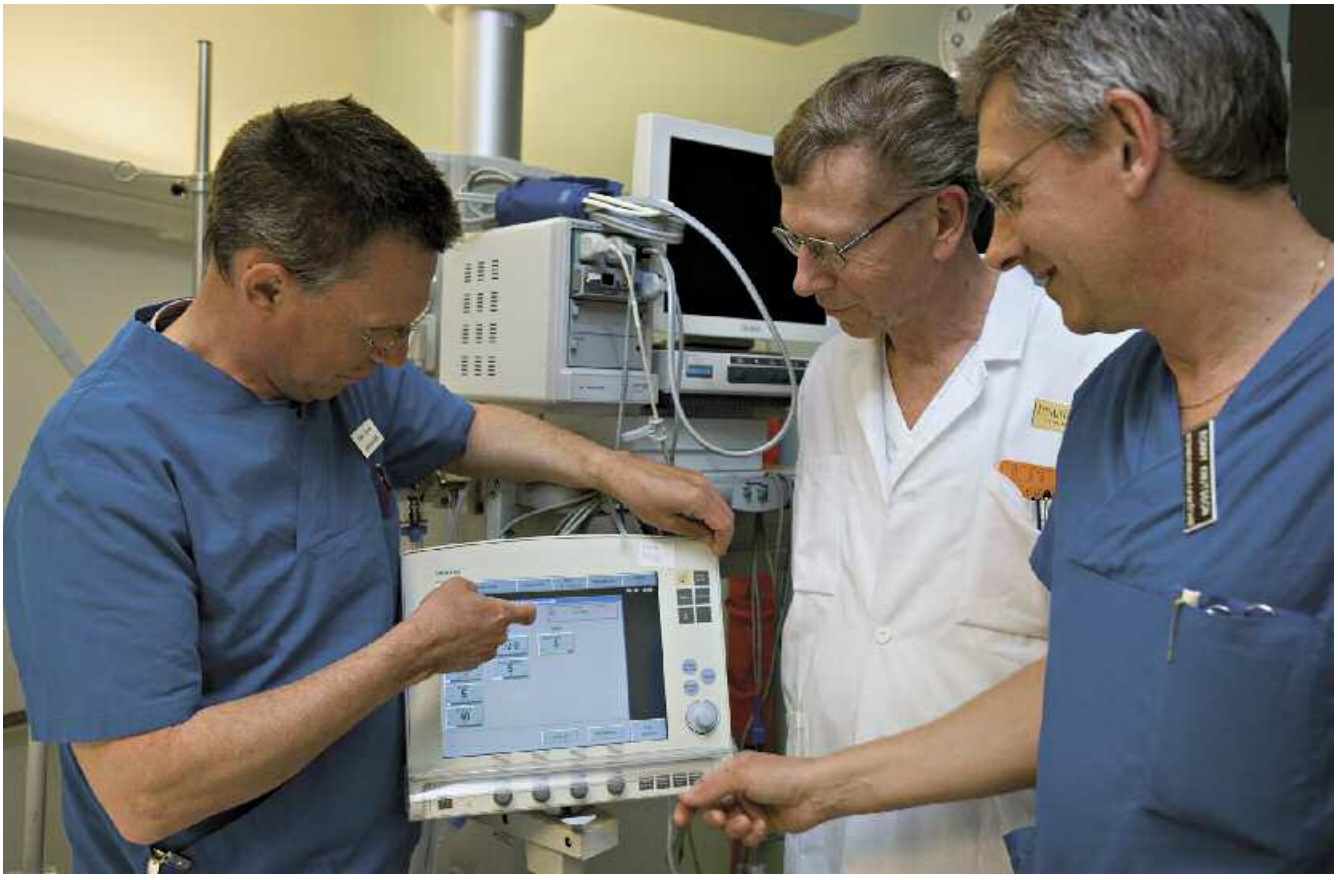
Ronny Knutsson, RN: A total of 84 patients were transported in the mobile ICU during the year of evaluation in 2006. Of these, 68 patients were mechanically ventilated, with 66 receiving invasive ventilation and 2 patients receiving non-invasive ventilation, with CPAP and masks, which worked very well. A variety of ventilation modes have been utilized during the evaluation.

What is the normal range of trigger settings used during transport?

Ronny Knutsson, RN: Of the 68 patients who were mechanically ventilated during the evaluation period, 47 patients had flow triggering and 21 patients had pressure triggering. The trigger function worked optimally in 67 of 68 cases. In one instance, in the very beginning, we experienced auto-triggering, where we believe that the ventilator sensed some vibrations in the tubes. This was solved by switching from flow triggering to pressure triggering instead. Apart from this instance, we had no problems with auto-triggering.

The objective of the project team was for the mobile ICU process to provide uninterrupted delivery of ventilation and care during the transportation process. What results did you record in your evaluation after one year?

Ronny Knutsson, RN: There was no recorded instance of interruption of gas delivery during the transport process, and there were no recorded instances of interruption of power from the ventilator. In one case, there was loss of power from the vehicle to the ventilator when a fuse went out in the mobile ICU, but the ventilator battery provided back-up power supply in this case, with no interruption in ventilation.



Ronny Knutsson, RN, Lennart Ohlsson, MD and Tomas Åhlund, MD have collaborated together at Kristianstad regional hospital for many years.

What is the average ventilation time for intensive care transport patients that you have documented in your evaluation?

Ronny Knutsson, RN: Overall, the evaluation revealed an average mean time of ventilation to be 72 minutes per patient. The shortest case was ventilated for 45 minutes, and the longest case was a patient who was ventilated for 300 minutes.

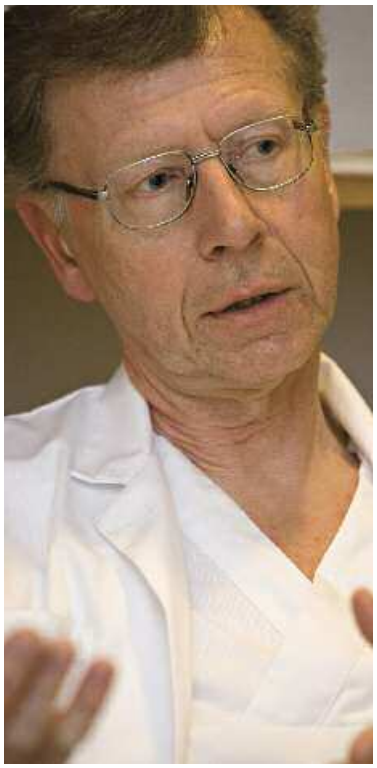
Did you document your experience in regard to CO_2 monitoring with ventilated patients in the mobile ICU?

We monitored four patients with end tidal CO_2 during the evaluation period, and had no difficulties at all from a technical or clinical perspective, it worked excellently.

Can you describe the process of preparing a ventilated intensive care patient for planned transport: at the remitting hospital and at the receiving hospital?

Ronny Knutsson, RN: Preparing the patient in the ICU prior to departure is the most important part of the process. We fasten the tubes and cords, and make sure that everything is stable and in good order, before leaving the ward. If you miss a step here, you will most likely encounter difficulties of some nature later on during the transport period. In the mobile ICU, we are seated to the left of the patient, so if all of the tubing is fastened on the opposite side of the patient, this makes access extremely difficult, for example if you need to administer pharmaceuticals or adjust infusion tubing. It is also important that the staff who are preparing the patient for transport at bedside are the ones who accompany patients in the mobile ICU, which provides experience and continuity in the process. Preparing the patient prior to transport is key to the success of the entire procedure.

Lennart Ohlsson, MD: There are many challenges with these procedures, but now we are at a point where the equipment is so optimal and advanced,



Lennart Ohlsson, MD

Tomas Åhlund, MD

that if you do have problems or if the patient's condition should become worse, you can be confident that the equipment you have can be relied upon. Down the years, there have been a few instances where a patient has almost lost a tube, which is probably the worst scenario. But we are even prepared for this risk, and can reintubate the patient if necessary. We have a case with all kinds of pharmaceuticals and support items, to handle almost any kind of situation.

Ronny Knutsson, RN: A part of the preparation process includes having the appropriate pharmaceuticals with us. We have standard drugs in a case for all transports, and each individual patient, depending on his condition, will require specific pharmaceuticals, that we bring with us from the ICU prior to departure.

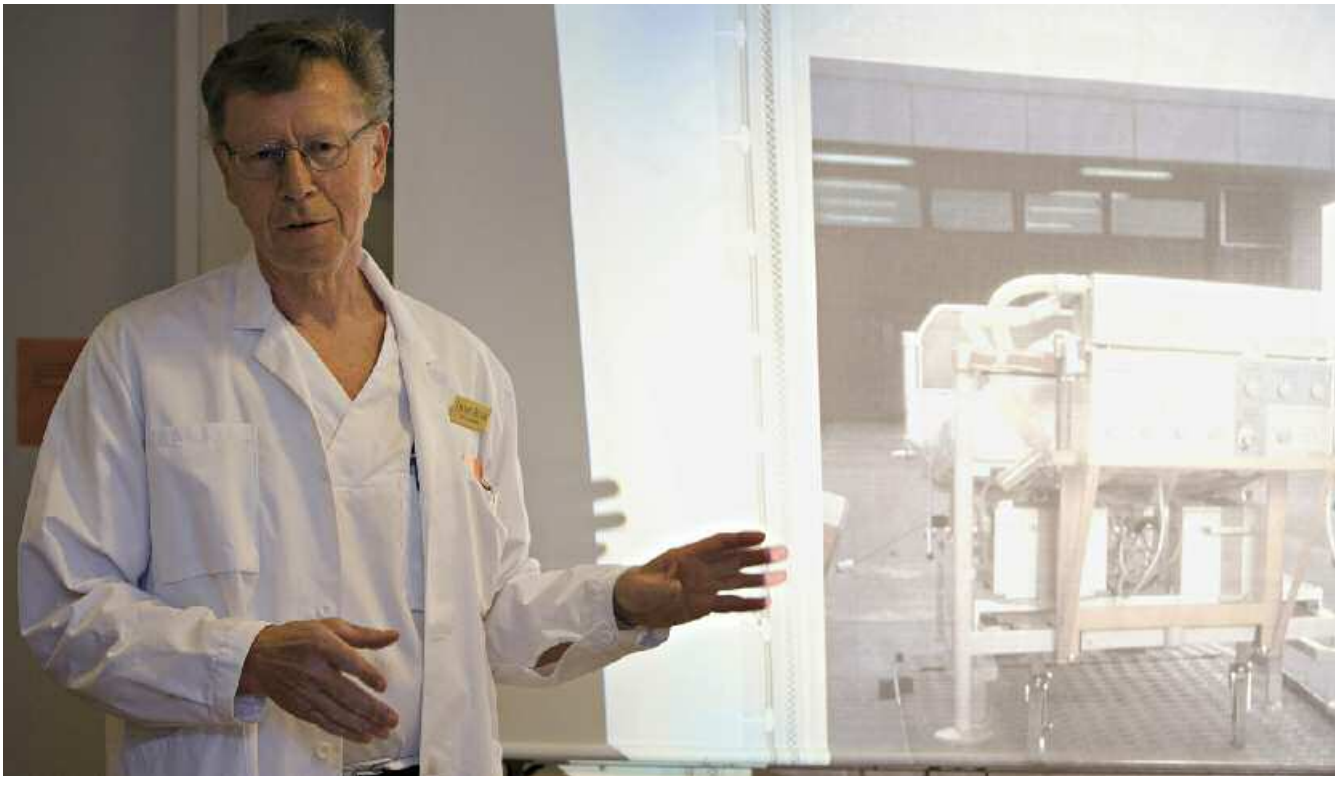
Tomas Åhlund, MD: We have to state that we have almost never had any serious difficulties. Almost all of the transports have been very successful and without any problems. But the fact that most transports are so uneventful is due to the detailed preparation process prior to departure. The key for each successful patient transport is in the preparation. It is a procedure similar to a pilot prior to take-off, with control of equipment and check-lists for every step of the way in the ICU. The staff involved in each individual case is also part of the preparation, to provide the proper competence to the patient need.

What are the contrasts in ventilation treatment in transport with an intensive care ventilator compared to traditional transport ventilators, such as Oxylog?

Lennart Ohlsson, MD: In the beginning in 1978, there were no reliable transport ventilators, which is why we used the SERVO 900. Some years later when the transport ventilators started to show up on the market, we used these in the ambulance as well, but we noticed that the patients were generally in a much worse condition upon arrival at the hospital. ICU patients many times already have lung complications, which is why an ICU ventilator is to be preferred in a mobile ICU.

How do you handle sedation? For ICU patients who are not sedated: how do they generally experience the transport process? Do you need to regularly change the sedation level before transporting the patients?

Ronny Knutsson, RN: The relationship between sedated and non-sedated patients in the mobile ICU is generally identical to the relationship to sedated and non-sedated patients in the ICU department. In a few specific cases, we have increased the level of sedation if the patient has required a higher level of



Lennart Ohlsson, MD, lecturing on the first generation ventilator-equipped ambulances at the hospital in 1978. He was involved in the process, and in all subsequent developments ever since in Kristianstad.

Project director Christer Karlsson, and Mattias Svensson, clinical engineer, have worked closely together in regard to the design and validations of the transport solutions.

comfort during transport. However, our tradition in the ICU is to avoid sedation if it is not necessary, in order to help the patients wean and recover more quickly.

What do you think are the future trends in regard to transport of intensive care patients? Will there be increasing numbers, requirements or special demands in future?

Christer Karlsson, Project Director: In regard to ambulance care, our current solution is very unique. We did a great deal of research prior to starting the project in 2002, but we could not identify any optimal solutions from our perspective, most of what is being used seems to require equipment that is anchored to the vehicle, which disturbs and complicates the transport process from the ICU to the vehicle. Our concept of securing the customized stretcher-trolley as an integral part of the transport solution means that we now have a bedside-to-bedside solution in transport, from beginning to end.

Lennart Ohlsson, MD: Other hospitals in other regions have shown interest in our mobile ICU solution. We are certain that the need to transport ICU patients will continue to increase, as the trend to transfer patients between hospitals grows. And the increasing population density in cities and overcrowded hospitals will influence the need to transfer ICU patients between hospitals. ■

Mobile ICU project members, Kristianstad:

Lennart Ohlsson, MD, has worked as an anesthesiologist since 1972. He has been developing and working with mobile ICU transport since 1976.

Tomas Åhlund, MD, has worked as an anesthesiologist since 1991 and has a special interest in intensive care medicine. He has developed medical routines for the mobile ICU.

Anne Magnusson, RN, has been an anesthesia nurse since 1987 and is a member of the design group for the mobile ICU.

Ronny Knutsson, RN, has been an intensive care nurse since 1984, and is a member of the design group as well as transport coordinator.

Mattias Svensson is a Clinical Engineer at the Department of Clinical Engineering and Physics, and is a member of the design group.

KAMBER-Skåne, Regional Ambulance Transport Service:

Christer Karlsson is project director for the mobile ICU and has been working for KAMBER-Skåne since 2002. He became an anesthesia nurse in 1974, and has devoted 25 years to training nurses at the University of Lund, Sweden.

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