

ICU

MANAGEMENT & PRACTICE

THE OFFICIAL MANAGEMENT JOURNAL OF ISICEM

VOLUME 16 - ISSUE 3 - AUTUMN 2016



Visit us
@ESICM
#LIVES2016
#113

Cover Story

The Abdomen

Plus

Point-of-Care Test Devices
in the ED

Redesigning Ambulatory
Emergency Care with
Point-of-Care Testing

Candida Spp. in the
Respiratory Tract

Vasoactive Drugs in Sepsis

Controversies in VAP
Diagnosis

Monitoring Peripheral
Circulation

Touch Creates a Healing
Bond in Healthcare

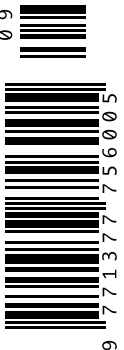
Women in Leadership in
Intensive Care Medicine

Intensive Care Syndrome:
Promoting Independence
and Return to Employment

Burden Caused by
Administrators and Managers

Interview: Prof. Gernot Marx,
University Hospital Aachen

Country Focus: Brazil





TELEMEDICINE IS THE FUTURE

INTERVIEW WITH PROFESSOR GERNOT MARX

Professor Gernot Marx is Director of the Department of Intensive Care Medicine and Intermediate Care, University Hospital Aachen, and Professor of Anaesthesiology and Operative Intensive Care Medicine at RWTH Aachen University, Aachen, Germany. Dr. Marx is a member of the Intensive Care Medicine Scientific Subcommittee of the European Society of Anaesthesiology.



The first tele-ICU service in Germany was set up at the University Hospital Aachen. What were the main challenges?

The first challenge was to install the technology—to ensure secure connection lines between the telemedical centre and the regional hospitals, set up the audiovisual system and provide the electronic case record. All data is assured under data protection rules.

The second challenge was scepticism from colleagues. This is understandable, because with telemedicine you really ‘open up the doors’ and you can look into the heart of the service, which has pros and cons. You may see some suboptimal issues, so overcoming scepticism was an important hurdle. The other point is that the service is not about the ‘big shots’ from the university hospital telling others how to do it. We wanted to create the situation that together we are better and that we learn from each other. This was very important in order to get everyone engaged in the new service.

The telemedicine project has been running for two years, and we have increased coverage from two to five hospitals. It started as a project funded by research money, but now we are in the process of getting the service reimbursed. We have proved that the service is technically possible, is accepted by colleagues, patients and relatives and that it is improving patient outcomes. In our observational study of 1200

patients (Marx et al. 2015) we could show measurable improvement in patients’ outcome. This is why the insurance companies now support this ongoing process.

Now you are on the way to receiving reimbursement, where is telemedicine going in Germany?

The German Society of Anesthesiology and Intensive Care Medicine has a commission for telemedicine and eHealth, which I lead. We published recommendations (in German) on how to structure telemedicine in the ICU and emergency areas (Marx and Koch 2015), and published a guideline on telemedicine in the ICU (AWMF Leitlinie tele-Intensivmedizin). We applied to create a reimbursement code for telemedicine. The process has been started, and we hope that in 3-4 years there will be a national reimbursement code. Several university hospitals are interested in creating a similar service. My vision is that there will be a national roll out. We have more patients because society is ageing, we have fewer experts and we need to share our expertise. In the USA, it has been already proven to be an intervention associated with a survival benefit in a prospective study including more than 100,000 ICU patients (Lilly et al. 2014). Not only in intensive care is this a problem, so I see this as a role model for different areas of medicine.

Is there potential for cross-border tele-medical collaboration?

We have two new projects and we are creating solutions to connect electronic medical systems from different companies (thalea-pcp.eu). We hope to complete this by the end of 2016 so we can then connect intensive care units (ICUs) throughout Europe and the world. From a European perspective, I would like to see the European Society of Anaesthesiology establish a committee on telemedicine. As intensivists we need to take the future in our hands.

How does telemedicine improve patient care?

It is not easy to do randomised controlled trials, but we can use stepped wedge or pre-post designs to test the hypothesis that telemedicine improves patient care. As with our small trial you can see that there is an improvement in measurable outcomes. In a way it is not ‘new medicine’, it is offering access to experts. We have not only the information from the electronic medical record, but we can also see the patient—their eyes, the pupil reaction. We get a very sharp clear clinical picture, and so communication and visualisation is very important. The only thing we cannot do is touch the patient.

Now we have an extra hour at each hospital. If you do this day by day it really creates a

living quality network, because there is a lot of trust when you see and talk to each other every day. You need a large unit, such as we have at University Hospital Aachen. My unit is comprised of 100 beds and I have 15 ICU consultants. You need a large group of experts with many years of experience to provide this extra service 24/7 in a standardised way to support the doctors, anaesthetists and ICUs in the regional hospitals.

How has patient and family acceptance of the telemedicine service been in regional hospitals?

Feedback has been excellent. They feel that they are already part of the university hospital medical service. Previously relatives quite often approached colleagues to ask why we could not transfer patients to the university hospital. That does not happen now because they are already part of the centre. This is an advantage for families and patients, because we provide this top-quality service close to home. It is easier for them to visit their relatives locally, so it really has many advantages.

Clinical Trials

Your intensive care unit is participating in the Gelatin in ICU and Sepsis (GENIUS) trial. What is the rationale for this trial?

Gelatin in ICU and Sepsis (GENIUS) (clinicaltrials.gov/ct2/show/NCT02715466 or clinicaltrialsregister.eu/ctr-search/trial/2015-000057-20/AT) is the first large trial on gelatin. It is a trial to compare balanced crystalloids against balanced gelatin plus balanced crystalloids. It is scheduled to recruit 600 patients from 10 centres in Germany, Austria, France and Hungary.

There are some differences with previous trials. Instead of central venous pressure (CVP), we're using the passive leg raising test and advanced monitoring stroke volume measurement in the patients. The evidence in guidelines is that that you cannot assess indication for fluid replacement with CVP nor can you assess the success of the therapy on CVP. This is an important difference.

In addition we decided not to have 28-day mortality as a primary outcome. Many people feel that this is not the right outcome parameter for research in the intensive care area, especially in sepsis (Mebazaa et al. 2016). 28-day mortality is more a measure of safety rather than the outcome parameter. In terms of efficacy

we need other outcomes and priorities, for example organ dysfunction or reduction of organ dysfunction. The GENIUS trial has the time to achieve haemodynamic stabilisation as the primary outcome.

Is the large randomised controlled trial in intensive care still a good model?

My vision is to have smaller trials using a complex protocol. We have to stratify patients to move more towards personalised medicine. One example is response to inflammatory response, measured by who has immune competence. Like our oncology colleagues we need to see that not every patient is the same in location of infection and response to infection. We need to have more detailed information and then put those patients in certain trials and investigate. When we have this information and we can connect our databases, we have big data research availability and we can confirm our data and make smaller trials. I expect to see more pattern recognition type research in the future.

■ ■ We wanted to create the situation that together we are better and that we learn from each other ■ ■

What is the situation in Germany with sepsis?

We just conducted a trial about sepsis epidemiology in Germany (German Sepnet Critical Care Trial Group, in press). We prospectively put twelve thousand patients into this trial all over Germany in more than 100 units. Mortality is still very high. It is different to examining mortality in randomised trials, where you have protocols and obviously you look at a very defined group. In this trial we included all septic patients. As we performed the trial at the end of 2013 we were using the old sepsis definition. The lesson is that it is still a very common disease, mortality is still very high and we have to tackle it. The most important point is what we have learnt from the Surviving Sepsis Campaign bundles, that the first hours are very determinant for outcome. It requires standard therapy,

recognition, antibiotics, and haemodynamic stabilisation.

Intravascular Volume Therapy Guidelines

You were involved in producing the German guidelines on intravascular volume therapy. How were these developed?

The German Society of Anesthesiology and Intensive Care Medicine initiated this guideline and coordinated the process. I was the coordinator from the German Society of Anaesthesiology and Intensive Care Medicine, and we included fourteen medical societies, who all sent an independent expert. We developed the guidelines according to the rules and regulations of the Association of the Scientific Medical Societies in Germany (Arbeitsgemeinschaft der Wissenschaftlichen Medizinischen Fachgesellschaften 2014). We engaged a top expert in methodology with his team. When we screened the publications there was always one physician and one expert in methods and there was always a cross check. That is why it took more than two years to develop the guidelines. The evidence was thoroughly analysed and condensed, and the experts received a very detailed analysis of each paper. Based on that we made our recommendations and suggestions, always after long discussions, with at least 75% consensus between all 14 societies. Afterwards each society's board had to approve the recommendations, with the Association of the Scientific Medical Societies in Germany having the final say. It was a very robust process. We have now a thorough evidence-based recommendation in this very important field. The guidelines are published open access in both German (awmf.org/leitlinien/detail/ll/001-020.html) and English in the *European Journal of Anaesthesiology* (Marx et al. 2016).

In Germany how will you evaluate use of the guidelines and measure process?

We had a pre-questionnaire and will have a post-questionnaire and then we will see whether practice has changed or not. This will be our measurement of the process change after introduction of the guidelines.

How do the recommendations differ from current practice?

The guidelines have a lot of evidence on the indications for when to use fluids. Therefore

there is a lot about monitoring. As I indicated before central venous pressure (CVP) has a grade A recommendation not to be used for indication or monitoring of fluids therapy. We have to use dynamic parameters, we have to use flow parameters, and we have to use passive leg raising and ultrasound but not CVP. That is not to say: "never use CVP", just not for this indication. This is new.

There is a strong recommendation to use balanced fluids and not to use saline. This is in contrast to the previous recommendations. Also there is no evidence that use of colloids has any negative side effect or benefit in terms of outcomes perioperatively; thus colloids may be used in the operating room. This is a weak recommendation, because there is not a lot of evidence there. First-line treatment choice in the ICU is crystalloids. But also colloids can be used, gelatin or albumin, if necessary in shock patients. We made an important statement on these issues because all the trials so far had severe methodology problems, e.g. using CVP or recruitment of patients being performed after haemodynamic stabilisation was already done. In contrast, in the GENIUS trial we include patients within 90 minutes while they are still in shock and need fluid therapy. We use passive leg raising not CVP as an evidence-based parameter for indication and monitoring of volume therapy.

You have been involved in a pilot project in Germany on voluntary peer review. How does this work?

We have two processes in Germany. One is peer review, which is voluntary. Colleagues visit colleagues to have a look at the unit and its processes and give feedback. This is organised by the German Interdisciplinary Association of Intensive Care Medicine (DIVI), and results in specific recommendations for each particular ICU.

The second established process for quality control is a quality certificate, which has been established by the German Society of Anaesthesiology and Intensive Care Medicine. ICUs apply and will be audited by two externally trained experts. Certification means that your unit is performing intensive care medicine at a high quality level. We published the standards in 2014 (Bingold et al. 2014), and have started the certification process. Fifteen ICUs have now passed this quality certification. It may take anything from four months up to a year for units to prepare to apply for this process.

I am involved in both receiving and giving peer review and certification. It is very important that we have critical feedback, and it's important that our specialty defines what is quality, because we know best. Obviously, we have to be in discussions with the authorities. I am sure this will come in Germany and

in Europe that there will be certain quality measures that need to be in place to assure that there is a quality ICU service. It would be good to have this in place across Europe.

This interview will appear in *ICU Management & Practice's* issue with a cover story on the abdomen. How do you see the role of haemodynamic monitoring in relation to intra-abdominal pressure?

The whole area of advanced haemodynamic monitoring in the operating room for anaesthetists needs to be explored further; we need more data and randomised trials to see whether it is a valuable tool with advantages for the patients. So far the 'noise' is towards that direction, but as this is a costly investment for the area of anaesthesia then it is important to get more evidence to convince the management at different sites to invest. In patients with increased intra-abdominal pressure it is a valuable tool to identify haemodynamic disturbances as early as possible. ■

References

AWMF Leitlinie tele-Intensivmedizin. [Accessed: 17 September 2016] Available from awmf.org/leitlinien/detail/II/001-034.html Registernummer 001 - 034

Bingold TM, Bickenbach J, Coburn M et al. [2014] Modulares Zertifikat Intensivmedizin der DGAI. "Anästh Intensivmedizin, 55: 316-29.

German Sepnet Critical Care Trial Group (In press) Incidence of severe sepsis and septic

shock in German intensive care units: the prospective, multicentre INSEP study. DOI: 10.1007/s00134-016-4504-3.

Lilly CM, McLaughlin JM, H Zhao J et al. [2014] A multicenter study of ICU telemedicine reengineering of adult critical care. CHEST, 145(3): 500-7.

Marx G, Beckers R, Brokmann JC et al. [2015] [Tele-cooperation for innovative care using the example of the University Hospital Aachen.

Telematics in intensive care medicine, emergency medicine, and telemedical intersectoral rehabilitation planning in geriatric trauma] Article in German]. Bundesgesundheitsblatt Gesundheitsforschung Gesundheitsschutz, 58 (10): 1056-61.

Marx G, Koch T [2015] Telemedizin in der Intensivmedizin: Strukturempfehlungen der DGAI. Anästh Intensivmed, 56: 257-61.

Marx G, Schindler AW, Mosch C et al. [2016]

Intravascular volume therapy in adults: Guidelines from the Association of the Scientific Medical Societies in Germany. Eur J Anaesthesiol, 33(7): 488-521.

Mebazaa A, Laterre PF, Russell JA et al. [2016] Designing phase 3 sepsis trials: application of learned experiences from critical care trials in acute heart failure. J Intensive Care, 4: 24.