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INTEGRATED SYSTEM FOR AUTOMATIC CARDIOPULMONARY RESUSCITATION

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A single operator, user-friendly system, comprises of a ventilator integrated with automatic external defibrillator (AED) is proposed as a new vision for future automatic CPR system. The system is selfadjusted to the physiological parameters of the patient, allows hands-free operation of the ventilation-mask and intends in the future to assist (or even to replace) manual chest compression by an automatic ventilation induced chest massage (VICM) or other means. The system is designed for single bystander at out-ofhospital - CPR, or for professional use inside the hospital. For the latter, the system is compatible with laryngeal masks and endotracheal tubes.

The system includes: an 'attach and do not touch' (ADNT) hands-free ventilation mask, integrated with a neck-rest module; non-invasive(NIV) ventilator; AED synchronized with the ventilator; simple humanmachine-interface (HMI) and an automatic control system.

Electric-Free Pump/Ventilator (EFPV) system, activated by the high-pressure energy of the oxygen container (or oxygen-enriched air) is designed to perform the VICM. VICM may be generated by continuous cyclic operation of positive end-expiratory pressure (PEEP) and negative end-expiratory pressure (NEEP). Standard ventilation (at the recommended rate of two ventilations for every 15 compressions) will be used for patient oxygenation.

A "proof of concept" of the system, entitled easySAVE, has already been successfully demonstrated in vitro The efficient, automatic hands free mask ventilation module, entitled easyVENT, has also been constructed as stand-alone device for other applications, too. The EFPV device, intended for VICM, was also constructed. The latter module, entitled *easyCARE* will be used for the design of a fully automatic CPR system.

This paper outlines the prospects, vision and the challenges of the new devices, especially in view of the results and lessons learned from past developments, particularly the cough resuscitation, simultaneous chest compression and ventilation (SCV-CPR), active compression-decompression (ACD-CPR) and the inspiratory threshold valve (ITV) approaches.

Introduction:

When 'Early CPR' begins on time, chances of survival are doubled^{i,ii} or even tripledⁱⁱⁱ. Furthermore, when CPR starts immediately and defibrillation is performed within two minutes, chances of survival are 48%^{iv} or even as high as $80\%^{v}$. Thus, the difference between current out-of-hospital survival rate (5-15%) and the potential survival rate is unacceptable.

There is still no solution for shortening the critical time between a sudden cardiac arrest event (in 2/3 of cases occurring at patient's home^{vi}), and the time of the arrival of the professional first aid at the scene. Ornato^{vii} reports that: "To the best of our knowledge, no city has been able to provide defibrillation for the majority of out of hospital cardiac arrest victims within 5 minutes of the recognition of the event". Thus, the bystander's role as the initiator of basic CPR is irreplaceable and advanced means should be developed for automatic, mobile, user friendly, CPR devices.

Nevertheless, mask-ventilation, performed only by professional caregivers, is regarded as one of the most skill-demanding procedures, mostly due to the difficulty at sealing the mask to the face. When professional caregivers use a ventilation mask, they are compelled to hold it with two hands to ensure adequate head tilt and sealing and therefore cannot perform any other life-saving procedures. . Currently, no efficient device exists to allow untrained rescuers to use bag-valve ventilation. Thus, basic CPR is limited to mouth-to-mouth ventilation.

These facts led the authors to design and to construct an independent device includes a hands-free ventilation-mask and neck rest as a stand-alone product.

Ventilation techniques for cardiopulmonary resuscitation: literature review of relevant approaches

(1) Simultaneous Compression Ventilation CPR (SCV-CPR)

The SCV-CPR method, proposed twenty years ago, is based on high airway pressure (60-100 mm Hg) ventilation with simultaneously chest-compressions (achieved by pneumatic vest or by a mechanical "thumper" device) operated at a rate of 40/min. The SCV-CPR may also combine abdominal binding.

Chandra et al^{viii} and Weisfeldt^{ix} et al investigated the method and showed an increase in carotid flow as compared to the conventional CPR. Maneuvers^x that increased intra-thoracic pressure, including ventilation during chest-compressions and abdominal compressions by binding have also been shown to increase carotid blood flow. In various studies, cardiac output at SCV-CPR was about 200%-300% greater than that during standard CPR^{xi}. The SCV-CPR approach was tested on animals^{xii,xiii,xiv,xv} and in large randomize tries ^{xvi,xvii,xviii}. When compared to conventional CPR, SCV-CPR demonstrated survival rate of 22.5% while the conventional CPR achieved 33.5%. As a result, AHA guidelines did not recommended SVC-CPR as an alternative CPR technique^{xix}.

(2) Pneumatic Vest

The concept of pneumatic vest was tested with the SCV-CPR and was used as a stand-alone approach^{xx} with improved aortic and coronary perfusion pressures. Currently, vest CPR has not yet shown to lead to long-term survival. Today, various products are presented in the market^{xxi}.

(3) Active compression-decompression (ACD-CPR)

This approach uses a hand-held suction cup device that is attached to the chest over the sternum^{xxii}. The chest is compressed with the device, as with standard manual CPR, but then actively decompressed after each compression phase, which increases the intra-thoracic vacuum and thereby increases minute ventilation and cardiopulmonary circulation^{xxiii,xxiv}. ACD-CPR is considered an acceptable alternative to standard CPR when rescue personnel adequately trained are using the device (Class IIb).

(4) Inspiratory threshold valve (ITV)

The ITV impedes respiratory gas exchange when thoracic pressure is lower than atmospheric pressure. This creates a negative pressure within the thorax during the decompression phase, which increases blood return to the heart each time the chest wall recoils. The temporary impedance of airflow into the chest during decompression causes the intra-thoracic pressure to remain low, long enough to enhance venous return to the thorax, which increases circulation and primes the heart for the next compression.

This device ⁽²⁵⁻²⁹⁾ was reported to improve ventricular and cerebral blood flow, 24-hour survival, and neurological function.

The ITV device is acceptable as an adjunct to be used with a cardiac compression-decompression device to augment hemodynamic parameters (Class IIb).

(5) Cough resuscitation (CR)

Cough resuscitation in the very early phase of cardiac arrest, while the patient remains conscious, has been included in international resuscitation recommendations. So far, no device is able to use this approach during human resuscitation.

CR generates substantial intrathoracic and intra-abdominal pressures^{xxv}. Animal experiments showed significantly high diastolic coronary perfusion pressures. The CR approach is considered as an example of the "thoracic pump" model of resuscitation because blood flow results entirely from changes in the thoracic and to small extent, abdominal pressure. Rhythmic coughing ensures effective systemic blood flow during VF without direct chest-compression. The main limiting factor is the short time that this measure is effective while the patient is awake, responsive and cooperative.

Discussion: Lessons to be learnt

The techniques best related to the VICM approach are CR, ACD-CPR and SCV-CPR.

It is highly feasible that a typical pressure cycle (or cycles) defined by Criley^{xxvi} for coughing can be simulated and produced by the computerized EFPV to form the same intrathoracic pressures at the patient lungs. Also, the fact that CR was already included formally in resuscitation is also an encouraging factor.

Krischer et al. (16) compared SCV-CPR and conventional CPR in a large-scale study, involving 994 patients. The results were disappointing: survival rate (long term) with the conventional CPR was 14.5%, compared to 7.7% with the SCV-CPR device. Krischer explained the failure of SCV-CPR as follows: Abdominal binding reduced myocardial perfusion.

Compression rate should be higher than the 40/minute used.

The complex nature of the SCV-CPR device.

Krischer also reported that the time until intubation in the SCV-CPR group was longer (median of 4 minutes) than the standard group (median of 3 minutes). Holmberg ⁴ analyzed survival rate (one month) within a population of 2748 cardiac arrest patients, as a function of the time to first defibrillation. Mathematical interpolation of Holmberg's report suggests that a delay of one minute, between the third to the fourth minute (as reported by Krischer) reduces the survival rate in 5%, whereas, a delay from fourth to fifth minute decreases the survival rate in 3%.

As the two above studies were not performed in similar conditions and did not use the same definitions, the only definite conclusion that can be deduced is that any effort should be taken to simplify the operation of any resuscitation device.

Swenson (18) showed that vest compression increases aortic pressure. Adding simultaneous-ventilation can further increase the aortic pressure. On the other hand, coronary perfusion was found to be reduced after adding simultaneous-ventilation to vest compression. Swenson explained the reduction of coronary perfusion as a result of the high end-expiratory pressure (PEEP) used. It may be assumed that if enforced pumping is available during the exhalation phase, benefits of both increased aortic pressure and coronary perfusion may be gained.

The phenomenon of enforced pumping was demonstrated by Chandra et al. (Figure 6 of reference 8). The study described the effect of cyclic positive/negative airway pressures on aortic and right atria pressures. Although coronary perfusion pressure was not directly measured, it can be indirectly assumed by the difference between aortic and the right atrium pressures. It can be seen that when high ventilation pressure (80 Hg mm) and PEEP where used, aortic and the right atrium pressures were at the same level. On the other hand, when negative airway pressure was induced, the difference of the aortic and the right atrium pressures at the diastolic became significant, and could have prompt coronary perfusion.

The same conclusion can also be deduced from the results of ITV studies mentioned earlier.

The vision and challenges:

Our vision for the future CPR system is to design a user-friendly device that combines a ventilator and AED. Such a device will be mobile, and operated by a single bystander, required to attach only the mask and electrodes. All other medical procedures will be done automatically.

Our requirement for a single bystander performing the CPR implies that only non-invasive procedures can be used. Therefore, ventilation will be performed using the hands-free ventilation mask. The artificial

airway can be easily assured by either using a Guedel cannula or by inserting a laryngeal mask airway (LMA), a procedure easy to learn and remember^{xxvii}.

Gastric inflation (GI) may become a potential risk, especially when the airway is unprotected^{xxviii}. GI compresses the lungs, thus decreasing their compliance^{xxix} and forcing a higher airway ventilation pressure. Therefore, ventilation parameters during VICM (i.e., peak inspiratory pressure, negative expiratory pressure, inspiratory time, tidal volume) should be kept within the range of the acceptable limits considered as safe, to ensure minimal risk of GI. Means to ensure this are automatically maintaining the mean airway pressure lower than the lower oesophageal sphincter (LES) pressure, using a high frequency waveform and adjusting the duty-cycle characteristics. The negative airway pressure used at the VICM can have a further role at maintaining a minimal air volume inside the oesophagus. The exact ventilation parameters should be determined upon the results of clinical trials evaluating the effects of VICM.

Conclusion:

Past experimental studies and successful demonstration of the "proof of concept" of the *easyVENT* and *easySAVE* systems inspire us to accomplish the integration of an automatic system. It is also our vision that automatic VICM at moderate PEEP/NEEP ventilation pressures will generate (or to enhance) cardiac flow and maintain some degree of carotid and coronary perfusion.

It is our strong believe that the *easySAVE* system can have a vital role at patient out-of-hospital cardio pulmonary resuscitation until professional team reaches at the scene.

ASSOCIATING ANAESTHETISTS WITH COMPUTER SCIENTISTS FOR SOFTWARE SAFETY CERTIFICATION

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1 The world, the machine [1] and the safety [2]

« The world and the machine » [1], the operating room and the software, the anaesthetist and the computer scientist cannot be dissociated to tackle critical medical software safety.

Together, you will describe the anaesthetics as the software application domain. Together, you will identify the hazards related to the anaesthetic practice to computerize. Together, you will find the causes of these hazards and the potential consequences for the patients.

The severity of the potential harm to the patients with the probability of this harm defines the risk. The higher the risk, the more elaborate the software development has to be and the more important the risk control for this development has to be [3,4].

2 The development life-cycle, the documentation [3,4] and the certification [3]

The software development life-cycle is to the computer scientist what the anaesthesia protocol is to the anaesthetist; the life-cycle documentation is to the computer scientist what the (computerized!) anaesthesia report is to the anaesthetist.

Why is the software development and its documentation so important to establishing the safety and to asking for a certification according to the IEC 60601-1-4 standard [3]? For two reasons: the software failures, not the hardware failures, always result from design faults [3], the tests never discover all the faults [3].

The only efficient solution to reduce the number of residual faults and failures is to apply a complete development life-cycle, for example based on the V-model [3,4]. Furthermore, as the software will never be totally reliable, we must practice a risk analysis (probability and severity of the failures consequences) for the whole life-cycle and conceive the software to follow a path to a fail-safe state in case of failure.

3 The coupling, the complexity [7] and the system approach [5]

Why is it important to have in mind that a software [5], like a patient under anaesthesia [6], is a highly complex and strongly coupled process [7], i.e. with numerous and strong internal links? Because to block the butterfly effect supposes a global, or system or top-down approach [5].

This software high-level approach will produce an architecture [8] safety-oriented and understandable by the anaesthetists and the computer scientists: reducing and simplifying the interfaces will reduce the risk [5], using a standard common language will allow everybody to understand the architecture.

The graphical modelling standard for software systems and in particular for software architecture is nowadays UML 2.0 [9]. It gives, among others, the opportunity to create state diagrams (for example, a patient state diagram) that are an excellent visual formalism of complex systems, recommended for critical

systems [4]. It also provides an opportunity to bring together the mental models of the different stakeholders [5].

[1] Michael Jackson. Software Requirements & Specifications. ACM Press, 1995.

[2] REVEAL, A Keystone of Modern Systems Engineering. Praxis Critical Systems Limited, Bath, UK, 2000.

[3] IEC 60601-1-4 Edition 1.1 Medical electrical equipment – Part 1-4: General requirements for safety – Collateral Standard: Programmable electrical medical systems. IEC, Geneva, 2000. <u>http://www.iec.ch</u>

[4] IEC 61508-3 First edition Functional safety of electrical / electronic / programmable electronic safety-related systems-Part 3: Software requirements. IEC, Geneva, 1998. <u>http://www.iec.ch</u>

[5] Nancy G. Leveson. Safeware: System Safety and Computers. Addison-Wesley, 1995.

[6] David M. Gaba, Kevin J. Fish, Steven K. Howard. *Crisis Management in Anesthesiology*. Churchill Livingstone Inc., Philadelphia, 1994

[7] Charles Perrow. Normal accidents: Living with High-Risk Technologies. Princeton University Press, 1999.

[8] Paul Clements, Felix Bachmann, Len Bass, David Garlan, James Ivers, Reed Little, Robert Nord, and Judith Stafford. *Documenting Software Architectures: Views and Beyond*. Addison-Wesley, 2003.

[9] Martin Fowler, Kendall Scott. UML Distilled Third Edition: A Brief Guide to the Standard Object Modeling Language. Addison-Wesley, 2003.

Associer anesthésistes et informaticiens pour la certification de safety* des logiciels

1 Le monde, la machine [1] et la safety [2]

« Le monde et la machine » [1], le bloc opératoire et le logiciel, l'anesthésiste et l'informaticien sont indissociables pour aborder la safety des logiciels médicaux critiques.

Ensemble, vous décrirez l'anesthésie comme domaine d'application du logiciel. Ensemble, vous identifierez les dangers liés à la pratique anesthésique à informatiser. Ensemble, vous rechercherez les causes de ces dangers et les conséquences potentielles pour les patients.

La gravité des dommages potentiels pour les patients combinée avec la probabilité de ces dommages définit le risque. Plus le risque est élevé et plus le développement du logiciel doit être soigné et un contrôle du risque appliqué durant ce développement [3, 4].

2 Le cycle de vie de développement [3, 4], la documentation et la certification [3]

Le cycle de vie de développement du logiciel est à l'informaticien ce que le protocole d'anesthésie est à l'anesthésiste ; la documentation de ce cycle de vie est à l'informaticien ce que le rapport d'anesthésie (informatisé !) est à l'anesthésiste.

Mais pourquoi se focaliser sur le développement du logiciel et sa documentation pour établir la safety et demander une certification suivant la norme CEI 60601-1-4 ? Pour deux raisons :

les défaillances du logiciel, contrairement aux défaillances de l'électronique, résultent toujours d'erreurs de conception [3],

les tests pratiqués ne suffisent jamais pour découvrir toutes les erreurs [3].

La seule solution efficace pour réduire le nombre d'erreurs résiduelles et de défaillances est de définir un cycle de vie de développement complet, en s'inspirant par exemple du modèle en V [3, 4]. Et comme la fiabilité du logiciel ne sera jamais totale, une analyse des risques (probabilité et gravité des conséquences des défaillances) doit être pratiquée tout au long du cycle de vie et la conception du logiciel adaptée pour que le système évolue dans un état sûr en cas de défaillance.

3 Le couplage, la complexité [7] et l'approche système [5]

Pourquoi est-ce important d'avoir à l'esprit qu'un logiciel [5] comme un patient sous anesthésie [6] sont des processus très complexes et fortement couplés [7], i.e. avec des liaisons internes nombreuses et fortes ? Parce que contrecarrer l'effet papillon suppose une approche globale, ou approche système ou top-down [5].

Cette approche de haut niveau se traduira pour les logiciels par une architecture [8] adaptée à la safety et compréhensible aussi bien par les anesthésistes que par les informaticiens : réduire et simplifier les interfaces réduira le risque [5],

utiliser un langage commun standardisé permettra à tous de comprendre l'architecture.

Le standard de modélisation graphique des systèmes logiciels et de leur architecture en particulier est aujourd'hui UML 2.0 [9]. Il comporte notamment des diagrammes d'état (comme celui du patient), excellent formalisme visuel des systèmes complexes et recommandé pour les systèmes critiques [4]. Il représente une facilité pour rapprocher les modèles mentaux [5].

* La traduction de la CEI « sécurité » est ambiguë en français, « sécurité-innocuité » [10] peu usité, « sauveté » serait un néologisme, nous préférons conserver le mot anglais « safety ».

[3] CEI 60601-1-4, Edition 1.1, Appareils électromédicaux – Partie 1-4 : Règles générales de sécurité – Norme collatérale : Systèmes électromédicaux programmables, IEC, Genève, 2000. <u>http://www.iec.ch</u>

[4] CEI 61508-3 Première édition, , Sécurité Fonctionnelle des systèmes électriques / électroniques / electroniques programmables relatifs à la sécurité-Partie 3 : Prescriptions concernant les logiciels.CEI, Genève, 1998 <u>http://www.iec.ch</u>

[9] Martin Fowler, UML 2.0, CampusPress, Paris, 2004. (version française d'UML Distilled) [10] J.C. Laprie, Guide de la Sûreté de Fonctionnement, Cépaduès-Editions, Toulouse, 1995

LINKING VENTILATOR AND MONITOR FOR HEMODYNAMIC ASSESSMENT IN VENTILATED PATIENTS

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The clinician who is standing at the bedside in the ICU or operating room is frequently asking him/herself "Will my patient benefit from fluid loading?". Unfortunately, our commonly used monitoring parameters have no, or very limited, predictive ability as to the response of the cardiac output (CO) to fluid load. It is therefore that fluid management of the critically ill is still a challenge, and, most probably, a source of frequent errors. Although fluid loading is one of the most common therapeutic decisions in the ICU, only 50% of the patients do respond to it by increasing their CO. The unnecessary fluid administration in the other half of our patients may be harmful, as positive fluid balance has been repeatedly shown to be associated with increased morbidity and mortality in critically ill patients. On the other hand, it may also be safe to assume that in many instances critically ill patients do not receive enough fluids and remain hypovolemic.

In ventilated patients, however, one can use the mechanical breath as a repetitive challenge of the cardiovascular system, and, by observing and measuring the changes in the left ventricular stroke volume (LVSV), as reflected in the arterial blood pressure curve, learn in an immediate, non-invasive way, whether the patient is fluid-responsive or not. The main hemodynamic effect of the increase in intrathoracic pressure during the mechanical breath is a transient decrease in right ventricular filling, leading eventually to a decrease in LV stroke output and to a decrease in arterial pressure (dDown). The degree by which the LV stroke volume (and the arterial pressure) decrease as a result of the decrease in venous return reflects the fluid-responsiveness of that patient. The absence of such a decrease in pressure is indicative of hypervolemia or congestive heart failure.

The understanding of these heart-lung interactions during mechanical ventilation has led to the development of a number of 'functional' hemodynamic parameters that are based on the analysis of the respiratory induced variations in the arterial pressure waveform. What is common to all these parameters (SPV, PPV, SVV) is that they have been repeatedly shown to be far superior to filling pressures, and even to volumetric parameters of preload, as accurate predictors of fluid responsiveness. For all these parameters, values above 10-13% indicate, with very high sensitivity and specificity, that fluid loading will cause an increase in CO. Besides an immediate estimation of fluid responsiveness, these parameters are extremely sensitive to changes in preload, and therefore are useful in following the response to fluid loading. Of course one has to realize that the presence of fluid responsiveness is not necessarily an indication to administer fluids.

The main limitation of these functional hemodynamic parameters is that their use is limited to patients who are on fully controlled mechanical ventilation. In patients that are breathing spontaneously or are on significant partial ventilatory support, and in the presence of significant cardiac arrhythmias, quantification of the changes in the arterial pressure may be inaccurate and difficult to interpret. In these conditions one has to rely solely on 'preload' parameters, preferably volumetric ones. In addition, variations in the LV stroke output are greatly exagerrated by large tidal volumes (and by air-trapping or reduced chest wall compliance), and are relatively insensitive in the presence of low ones. Another point that may have been underestimated so far is the fact that the SPV, SVV and PPV, include the dUp component as well, a component that is unrelated to fluid-responsiveness. This augmentation in LV stroke volume is quite prevalent in critically ill patients, and may reduce the sensitivity and specificity of these parameters (especially when they are in mid-range).

We have therefore developed the Respiratory Systolic Variation Test (RSVT), which is a measure of the slope of the decrease in the systolic pressure in response to a standardized maneuver consisting of a series of successive incremental pressure-controlled breaths. We hypothesized that in the presence of significant fluid responsiveness, the respective decrease in the venous return and hence in the systolic pressure following each increment in airway pressure will produce a pronounced RSVT slope, while the absence of fluid responsiveness will be associated with lesser changes in the systolic pressure, and hence with a flatter slope. Our preliminary results suggest that the RSVT has a potential to become a useful parameter of fluid responsiveness in mechanically ventilated patients.

In summary, using the tidal volume as a repetitive challenge of the cardiovascular system enables the clinician to easily measure dynamic 'functional' parameters that reflect volume status and predict the response to volume load. Such true linkage of ventilator and monitor should be automated in the future, possibly contributing to a better hemodynamic assessment of ventilated patients, as well as to a reduced use of more invasive and/or expensive monitoring techniques. However, when we use any of these functional hemodynamic parameters we have to remember the following general principles: We are often confronted with a variety of static parameters that do not provide a conclusive picture. Challenging the system with a standardized stimulus may provide new insights about the function of the whole system. The normal effects of this stimulus have to be well-known, so that interpretation of the response to this stimulus is clear and preferably immediate. Confounding factors may decrease the usability of this approach.

PHOTO-TECHNOLOGY IN ANAESTHESIA AND INTENSIVE CARE

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Photons, especially in the visible and near infrared regions, are not harmful to tissues and have the potential to provide physiological information (e.g., noninvasive chemical measurements). However, the use of photo-technology in the anaesthesia and intensive care fields has been limited. I am going to discuss the possibilities and limitations of this technology in our field.

Techniques for identifying and quantifying substances

1) Absorbance: Measuring specific absorption by clinically relevant compounds is the most widely used technique. Absorbance is estimated using one of two methods, transmittance or reflectance.

2) Fluorescence: Some molecules emit light of a specific wavelength, fluorescence, when they are excited by light of higher energy or shorter wavelength. As the fluorescence wavelength is molecule-specific and different from that of the incident light, this technique has several advantages compared to simple absorbance spectroscopy. The emitted light is easily distinguished from the interrogating beam, and allows the analyte to be selected from the majority of non-fluorescent substances.

3) Raman spectroscopy: Raman spectroscopy is based on the detection of scattered light. Radiation may be scattered elastically, that is, without any change in its wavelength, or it may be scattered inelastically, resulting in the Raman effect. There are two types of Raman transition; upon collision with a molecule a photon may lose some of its energy or it may gain some energy. Each compound has its own unique Raman spectrum which can be used as a fingerprint for identification.

Light wavelength

Three wavelength regions are used in the medical field: ultraviolet (< 400 nm), visible light (400-750 nm), and near-infrared (750-2000 nm). Ultraviolet light is widely used for *in vitro* spectroscopy to estimate concentrations of biological substances such as DNA (260 nm) and peptides (280 nm). However, ultraviolet light is not applicable to *in vivo* spectrometry because it damages DNA. Although the wide wavelength spectrum of visible light is potentially available for *in vivo* spectrometry, in practice only red light (650-750 nm) is used because haemoglobin and myoglobin almost totally absorb visible light of a wavelength shorter than 650 nm. The near infrared is the most useful region for *in vivo* spectrometry. However, water strongly absorbs light in the near-infrared region with a wavelength longer than 1200 nm. Therefore, wavelengths between 600 and 1300 nm are the most widely used for *in vivo* spectrometry for clinical monitoring, and might be said to represent the therapeutic window.

The interrogating beam

1) Xenon flash tube: As the xenon lamp serves as a white light source (200-2000 nm), any wavelength can be selected using bandpass filters, interference filters, or monochromators.

2) Light-emitting diode (LED): The advantages of the semiconductor diode are its low cost and compactness. This device does, however, have several limitations in clinical use, in that its low energy, usually in the range 2-10 mW, restricts the depth of tissue penetration. The LED has a rather broad spectral width around 50 nm, and the availability of wavelengths is not abundant.

3) Laser diode: Laser diodes have several advantages as light sources. They have sufficient power up to 10 W and a very narrow spectral bandwidth of 5 nm. Pulsatile operation is possible with a pulse width of between 50 and 200 nsec and a repetition rate between 1.5 and 5.0 kHz. One problem is the limited selection of available wavelengths.

The detector

1) Photomultiplier: The detection of low-energy light has mostly been achieved with photomultipliers. In spite of their high sensitivity, photomultipliers have several weak points and are difficult to use clinically. They require a high-voltage supply, protection from high-intensity light that might damage them, and cooling to make them stable.

2) Photodiode: Although the semiconductor detector is not sensitive enough for some purposes, it does make an instrument more portable and clinically acceptable.

Current noninvasive techniques

1) Transmittance spectrometry: Early *in vivo* spectrometers utilised this technique. The first commercial ear oximeter was developed by Hewlett-Packard, and used eight wavelengths to estimate oxygen saturation, but its ear probe was too large for its acceptance for routine clinical use, and it was displaced by the pulse oximeter. However, multiwave oximeter technology has encouraged the development of *in vivo* spectrometry for monitoring various substances. A haemoglobin concentration monitor, Astrim, is commercially available, which employs wavelengths of 660, 805, and 880 nm.

2) Pulse spectrometry: In addition to the pulse oximeter, the pulse dye densitometer (PDD) is clinically available. The PDD was developed by Aoyagi at Nihon Kohden Ltd., and is designed to allow estimation of the ratio of the concentrations of total haemoglobin and indocyanine green (ICG) in the blood using two wavelengths of infrared light. The PDD provides estimates of cardiac output, blood volume, the ICG elimination constant, and hepatic blood flow.

3) Reflectance or back-scattered absorbance spectrometry: The interrogating beam directed at the skin is scattered backwards as well as forwards in the tissue, and reaches the detector on the skin surface. As the optical path is much longer than the simple physical path, near-infrared light has mainly been used because of its weak absorbance by tissues. Near-infrared spectroscopy is a popular technique for perioperative monitoring. Examples of noninvasive *in vivo* monitoring include the determination of oxyhaemoglobin and deoxyhaemoglobin in the brain, blood glucose, bilirubin, tissue pH, tissue oxygenation, and cytochrome oxidase.

Current invasive techniques

Although non-invasiveness is one of the most important merits of photo-technology, invasive procedures involving central venous catheter placement are common in the fields of anaesthesia and intensive care. Although most manufacturers of photo-technology equipment are developing noninvasive instruments, there have been some attempts to develop invasive techniques. Although an intravenous fibre-optic catheter is clinically available, it is not much used, however, other than for estimating the oxyhaemoglobin fraction.

New techniques under investigation

1) Five-wavelength pulse oximetry: Aoyagi, at Nihon Kohden, who invented pulse oximetry, is now attempting to improve its accuracy using light of five different wavelengths. Conventional pulse oximetry, in contrast, uses two wavelengths to estimate oxyhaemoglobin and deoxyhaemoglobin concentration ratios. The additional three wavelengths are used for the detection of venous pulsation and patient movement, which cause errors in SpO2 values.

2) Oesophageal photoplethysmography: Although pulse oximetry requires adequate peripheral perfusion to operate accurately, conventional sensors must be attached to the most peripheral parts of the body where pulsatile flow is most easily diminished. This drawback is lessened when the sensor is used for monitoring a better perfused central part of the body. The mid-oesophagus is one of the most promising candidates.

3) Fluorescence spectrometry: As the majority of biological tissue constituents do not fluoresce, a fluorescent substance may be selected using this technique. Moreover, fluorescence is usually observed in the ultraviolet or short visible light regions, and compounds fluorescing red or infrared light can therefore be analysed using this method. ICG is one such molecule which emits infrared light with a wavelength of 830 nm when it is excited by incident light with a wavelength of 775 nm.

4) Raman spectrometry: Although there are several issues to be overcome, Raman spectroscopy has distinct advantages. Using infrared spectroscopy, intense water signals interfere with detection of the spectra of targeted substances. As water molecules have relatively weak Raman signals, Raman spectroscopy is a promising technique for *in vivo* spectrometry.

Limitations

The most important issue to be overcome in all these techniques is accurate calibration, and quantifying the absolute concentration of a substance requires complicated techniques. The relative concentrations of two substances, however, are very much more readily estimated. Almost all clinically available instruments are designed to provide a ratio of two components; the pulse oximeter, for example, provides an estimate of the ratio of oxyhaemoglobin and deoxyhaemoglobin concentrations, and the PDD analyser can be used to estimate the relative concentration of ICG against a known haemoglobin concentration.

Future vision

Advanced photo-technology devices will become as small, portable, and low-cost as the pulse oximeter has become. Biochemical analyses and pharmacokinetic studies will be accomplished without the need for blood sampling.

PUPIL SIZE AND IV ANAESTHETICS IN CLINICAL PRACTICE

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Introduction

Estimation of the μ -agonist opioid effect during anaesthesia is often based upon different imprecise clinical measurements such as arterial pressure and heart rate variations, tear formation, sweating and movement. The sympathetic response can be obscured by β -adrenergic blocking agents and EEG derived data such as the BIS index is not affected by low opioid concentrations (1). Moreover, movement is abolished in paralysed patients. During general anaesthesia, pupillary changes to light or to a painful stimulus are rarely explored because of the lack of a convenient and accurate method to record pupillary activity in the operating room. Recently, new accurate and easy to use pupillometers have been marketed which allow measurement of the pupils size without any influence to the light reflex. So the interest of pupil size and reactivity has to be revisited.

Pupil innervation

Pupil size is determined by smooth muscles in the iris that are innervated by the two divisions of the autonomic system (2) and is determined by the equilibrium between the sympathetic and parasympathetic divisions of the autonomic system.

The parasympathetic system (cholinergic innervation) of the iris originates exclusively in the midbrain (Edinger Westphall nucleus), innervates the circular fibers of the iris and has a pupil constrictive action.

Sympathetic outflow begins in the posterolateral area of the hypothalamus. First-order preganglionic neurons descend uncrossed through the tegmentum of the midbrain and pons and terminate in the intermediolateral cell column at the C8 to T2 cord level. Second-order preganglionic fibers exit the cord primarily with the first ventral thoracic root and enter the paravertebral sympathetic chain. The second-order neuron takes a circuitous course through the posterosuperior aspect of the chest and ascends in the neck in relationship to the carotid system. The fibers ascend without synapsing through the inferior and middle cervical ganglia, and terminate in the superior cervical ganglion at the base of the skull. Third-order neurons originate in the superior cervical ganglion and are distributed to the face with branches of the external carotid artery and to the orbit via the ophthalmic artery and ophthalmic division of the trigeminal nerve. This polysynaptic sympathetic system, mediated by alpha-1 adrenergic receptors, innervates the radicular fibers of the iris muscles and dilates the pupil.

Noxious stimulation dilates the pupil in both unanaesthetized and anaesthetised humans and is mediated primarily by the sympathetic system in the awake state. However, during desflurane anaesthesia, pupil dilation to a noxious stimulus appears to involve either inhibition of the pupilloconstrictor nucleus located in the central pathway as high as the rostral mesencephalon, or a previously undescribed noncholinergic, nonadrenergic synapse at neuromuscular junctions within the iris (3).

General anaesthetics and IV drugs used during anaesthesia

The halogenated agents (halothane, isoflurane, sevoflurane, desflurane), the catecholamines and atropine provoke mydriasis (4, 5). Propofol, thiopentone, lidocaine and the muscle relaxants do not alter pupil reactivity (6, 7). The neuroleptic and opioid drugs have a pupilloconstriction effect. During isoflurane anaesthesia, alfentanil did not diminish the light reflex but produced a substantial dose-dependant depression of pupil dilation after a noxious stimulus. Larson and colleagues have demonstrated that alfentanil does not diminish the light reflex but blocks the reflex pupil dilation in response to noxious stimulation and reported a good correlation between plasma alfentanil concentration and magnitude of pupil dilation (8). Dilation was reduced to 50% of control values at alfentanil concentrations around 20 ng.ml⁻¹, and was almost abolished at concentrations approaching 100 ng.ml⁻¹ (8). Larson and colleagues

have also demonstrated that pupil dilation is a more sensitive measure of noxious stimulation than the commonly used variables of arterial pressure and heart rate during isoflurane and propofol anaesthesia (4). The relationship between the effect site concentration (Ce) of remifentanil and the pupil diameter and reactivity in response to a standard noxious stimulation has been evaluated (9). Pupil dilation to a tetanic stimulus of 100 Hz during 10 seconds (T100) decreased progressively and a correlation between pupil dilation to T100 and remifentanil Ce from 0 to 5 ng.ml⁻¹ was found (R₂ = 0.68). The authors concluded that during propofol TCI in healthy patients, the decrease of pupil dilation to a painful stimulus was a better measurement of the progressive increase of remifentanil Ce up to 5 ng.ml⁻¹ than haemodynamic or BIS measurements.

The effect of dopamine D2 receptor antagonists, such as chlorpromazine and haloperidol, on pupil size in awake subjects suggests that these drugs might also alter pupillary reflex dilation and pupil size during general anesthesia. Metoclopramide produced a small decrease in pupil diameter and transiently depressed reflex dilation, whereas droperidol decreased pupil size and depressed reflex dilation throughout the study period (10). Ondansetron had no effect on pupil diameter or reflex dilation (10). The authors concluded that when pupillary diameter measurements are used to gauge opioid levels during experimental conditions or during surgical anesthesia, antiemetic medication acting on the dopamine D2 receptor should be avoided. Moreover, miosis is often considered as an effect of opioid administration during general anesthesia, but other drugs, such as antiemetics might produce a similar effect on the pupil (10).

The effects of intravenous lidocaine on the magnitude and duration of reflex pupillary dilation had also been evaluated in six volunteers anesthetized with desflurane 3.5-6.0% (11). Intravenous lidocaine was administered to a plasma concentration of 5.3 +/- 1.5 micrograms/ml. When the plasma concentrations were stable, a 5-second tetanic electrical stimulus was applied. Lidocaine did not significantly alter the pupillary response to electrical stimulation.

Epidural anaesthesia

The hypothesis that pupillary dilation in response to noxious stimulation would predict the level of sensory block achieved during combined epidural/general anesthesia has also been tested in volunteers and patients (12). A twofold increase in pupil size following electrical stimulation in volunteers and an increase in pupil size exceeding 50% in patients were considered the predicted block level. After general anesthesia was discontinued, observers blinded to the pupillary measurements independently determined the actual epidural block level using pain in response to a pinprick as the criterion. The level predicted by pupillary responses was within two dermatomal segments of the actual level and never differed by more than four dermatomes. The authors conclude that dilation of the pupil in response to electrical stimulation is an accurate test of the sensory block level during combined epidural/general anesthesia (12). The influence of typical plasma lidocaine concentrations observed during epidural anesthesia are unlikely to prevent the use of pupillary responses to evaluate sensory block level (11).

Conclusions

If pupil size cannot help the anaesthesiologist to evaluate the depth of analgesia, the pupil reflex dilation in response to a standard noxious stimulus could help the anaesthesiologist to quantify the level of epidural or opioid analgesia during general anaesthesia. However, the relation between pupil reflex dilation to a noxious stimulus and the opioid concentration is limited because no pupil dilation is observed at very high opioid concentrations. Consequently, pupil dilation to a noxious stimulus could only be a sensitive measure of low or moderate opioid analgesia in the daily clinical practice. In the future, the relationship between pupil reactivity and adequacy of preoperative and postoperative analgesia must be studied on a larger scale. Moreover, other studies are required to evaluate the relationship between pupil reflex dilation analgesia in some particular clinical conditions such as in elderly patients or patients tolerant to opioids.

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PATIENT COMPUTER INTERVIEWING: QUESTIONS AND TENTATIVE ANSWERS.

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In 1972, Warner Slack wrote, "Doctors as interviewers are busy, expensive, and sometimes hard to find. It seems reasonable, therefore, to look for substitutes that will serve at least some of the purposes of medical interviewing in widespread and inexpensive ways. One possible substitute is the computer, programmed as an interviewer." Now, more than a generation later (thirty-two years), the wisdom of Warner's observation has been confirmed countless times in numerous studies, but it is fair to say that patient-computer interviewing has not been widely adopted and is in daily use in only a few isolated settings.

On the other hand, it is no longer simply the elusive and expensive nature of the physician that motivates adoption of computer interviewing. Numerous recent studies have also shown that widespread adoption of computerized record keeping will make health care safer and permit more effective health care cost management. Patient computer interviewing is inevitably a part of automated record keeping in medicine. And finally, whereas in 1972, the Internet was simply a gleam in the eye of researchers at DARPA, it is now on every desktop.

What holds patient computer interviewing back? On the one hand, paper questionnaires. At CHRU Tours, every pre-anesthetic patient fills out a paper questionnaire. These questionnaires are among the most useful and legible part of the record. They benefit from a standard, traditional, and uncontroversial security system. And, they are much less expensive than any computerized system.

On the other hand, patient-computer interviews that tend to mimic paper questionnaires may embark on a losing strategy. The mere fact that data are automatically captured during a patient computer interview is not enough to sell such a system either to a patient or to a physician, particularly if the resemblance to a paper questionnaire is too strong. The computer must add more, much more to the interview experience, both on the patient's side and on the physician's to finally gain widespread acceptance in this arena.

At this crossroads, what are the elements that will permit the computer to fulfill Warner's vision of 30 years ago? We will propose and discuss the most useful strategies for going forward. The computer's interface strengths combined with patient education will be shown to be the essence of any reasonable strategy.

VIRTUAL REALITY AS A TEACHING TOOL FOR FIBEROPTIC INTUBATION

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Any anaesthetist who trained before the last decade would not have had an opportunity to train in the use of fibre-optic intubation. Today, in contrast, fibre-optic skills can be counted in the core skills of anaesthesia and should feature in any initial training program. Those without this skill may be deterred from learning by its association with difficult or impossible airway control, the expensive and sophisticated, but vulnerable equipment involved, and lastly with the potential for transmission of Creutzfeldt-Jakob disease. Training opportunities for those who have missed out are available in many departments, and are evident in workshops and special sessions provided as part of small and large national and international meetings. The teaching of fibre-optic intubation is a particular interest, and this article will comment on a number of teaching points.

Clinical training

Training in the clinical arena has an ethical dimension. It is unacceptable to perform a naso-fiberoscopy as a teaching event, when the clinical need will be satisfied with an oro-tracheal intubation, for example during a gynaecological procedure. On the other hand justification maybe be found in a hypertensive coronary arteriopath in whom direct laryngoscopy might be a hazard. A further concern that does not permit quantification of risk, is prion transmission from the multi use device. The role of the clinical arena in training can be used to best advantage, and all risks minimised, if it is immediately preceded with a period of pre-clinical training.

Anatomy

The first phase of any educational program is to gain a precise knowledge of the regional anatomy. Anaesthesiologists are remarkably familiar with the upper airway configuration as routinely observed during direct laryngoscopy. Conversely, the different axes successively followed by the structures involved during a fiberoscopy, and their reciprocal spatial organisation, are less a matter of emphasis in the classical teaching programs. Moreover, many sketches or drawings in medical textbooks are inaccurate, showing the upper airways as a regularly curved line joining the oro- or naso- pharynx to the carina. This is obviously misleading because three successive directions have to be followed in the supine patient in order to reach the trachea through the nasal or the oral route. These successive directions are:

1. Downward

to the posterior wall of the oropharynx or nasopharynx

2. Upward

to the anterior commissure of the vocal cords

. 3. Downward again

into the laryngeal and tracheal lumen to the carina

Technique

When performing a fiberoscopy via the oral route, it can be difficult to stay in the median sagital plane, During anaesthesia, when obstructive flaccidity of the pharynx is present, this gets worse. The difficulty can be overcome with the use of a special airway, such as the Ovassapian device, for instance, help from an assistant, or fiberoscopy through a Laryngeal Mask Airway. Special airways and masks to aid insertion of the fibrescope, such as the Fibroxy device, should be available on the fibrescope cart, and tongue forceps can also be useful.

During the second phase of the fiberoscope progression, the upward direction to the anterior commissure of the vocal cords, the posterior part of the glottic aperture comes into view. In the absence of anatomical distortions, the temptation to push the fibrescope directly in this direction should be resisted. It may be

better to continue towards the anterior commissure of the cords, keeping the tip of the device in a sharp anterior path (by pushing down with the thumb on the button of the handle). Only when the anterior commissure is approached, should the tip be angled correctly downwards, towards the middle of the lumen of the larynx. This manoeuvre aligns the fibrescope with the anatomical axis of the larynx in its supra and infra glottic segments, avoiding contact damage to the mucosae and arytenoid cartilages. This anatomical approach may be even more important in the awake patient.

Role of virtual reality

The role of virtual reality is to make trainees familiar with the basic approach to airway navigation, but not at the expense of human beings. Not all simulators are the same, but a common strength is that the 3D reconstructed images are based on real patient CT or MRI images. The result is greater accuracy than mannequins or sketches can provide, that can be viewed at home on a personal computer. This is cost effective when compared with a formal simulation session with supporting teams. User-friendly computer models can illustrate progress, simulating a genuine endoscopy by showing internal navigation of the airways on the screen. Some also allow simultaneous adjustment of the position from which the internal view is taken. This virtual progression permits the user, without any constraint linked to ethical or clinical considerations, to accurately capture the various phases of a fiberoscopy, underlining the stepwise approach detailed above. This is in contrast to the intuitive but unguided advancement of the scope that characterises early attempts at intubation in the clinical setting.

A single CD-Rom is sufficient to display several reconstructions covering different age groups (adults and paediatric) and different pathologies ranging from cleft palate to post tracheotomy tracheal stenosis. The upper airway is approachable in most cases both by mouth and nose. A key quality of a virtual fiberoscopy computer program is that free navigation is possible in the airways, without pre-calculated routes. The trainee should be allowed to make virtual errors and will learn, alone or with a mentor, from experience. Conversely, since no particular skill is necessary to manipulate the handle of an intubation fiberoscope (only one button moving only upwards or downwards) the virtual navigation can be performed with the computer mouse.

Note: A virtual fiberoptic intubation (VFI) teaching tool featuring all the above mentioned characteristics has been presented at the 2003 ASA Meeting in San Francisco and was awarded the Ellison C. Pierce Award for the best scientific exhibit. [APSF Newsletter 2003-2004;18 (4):48.].

CHOOSING A NERVE STIMULATOR

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To date, in Europe nerve stimulation is the technique of choice for locating peripheral nerves. While the expansion in regional anaesthesia will depend on the success rate of plexus and peripheral nerve blocks, the benefits need to be constantly balanced against the risks inherent to each technique. For optimal placement of the needle tip and intentional avoidance of paresthesia, nerve stimulation may have the best risk-benefit ratio. For choosing a nerve stimulator, it is essential to be aware of the performance characteristics and limits of each nerve stimulator. The technology in these devices has advanced greatly in recent years. We underline the differences between modern devices and their predecessors and we print out their clinical implications.

Evaluation

To evaluate the electrical characteristics of the nerve stimulators, a digital oscilloscope (Tektronix TDS 3034) and a calibrated resistance of 1000 ohms were used for the measurements. Several nerve stimulators were tested (Table 1). All the devices, except one, which was supplied from the mains, were tested with a new battery.

Waveform

The nerve stimulator needs to deliver repetitive current impulses that are rectangular, monophasic and negative. The signal amplitude corresponds to the current and is expressed in milliamperes (mA). The duration of this signal is measured in milliseconds (ms) or microseconds (μ s). As the rise and decay times decrease the signal becomes more rectangular. For this feature, we evaluated the overall waveform, the constancy of the signal at low intensities, the artefacts, the overshoot of each impulse and also, the signal deformation with increasing impedance of the external electrical circuit.

Current

According to Ohm's law (U = RI), the resistance calibrated at 1 kilohm allows us to calculate the current by measuring the potential difference between the leads of the nerve stimulator, that is to say, U (in volts) = I (in mA). The potentiometer displays the value corresponding to the requested intensity. Not only does each measured current need to correspond to the assigned current, but also the current needs to vary in a linear manner. A digital display and an ergonomic potentiometer dial are essential. Accuracy within the tuning range is indispensable for accurate nerve localization with the possibility of using the device at low values approaching zero. The precision of the current intensity is of the highest importance in the final approach to the nerve, at currents less than 1mA.

Duration of impulse

The duration of impulse needs to remain stable at each assigned current. A point of particular importance is the possibility of having a short duration of impulse equal to or less than 100 μ s, a quality assuring the best discrimination of distance between needle and nerve. The possibility to choose between several predefined durations is well appreciated. The theoretical duration of impulse for each nerve stimulator are shown in table 1. The shortest duration was, according to specification, $40 - 1000 \ \mu$ s. Only four devices did not have a duration $\leq 100 \ \mu$ s. Some devices allowed a choice between two and five predefined durations.

lerve stimulator	Duration			Verall performance	
timuplex S (B Braun)	00				ow
timuplex Dig (B Braun)	00				verage

00					verage
00	00	000			ligh
00	00	000			ligh
00	00	000			ligh
00	00	000			Average
00					ligh
00					ligh
00	00	00	000		ligh
0	00				ligh
0	50	00			ligh
00					verage
0	00	00	00	000	verage
95					ow
0					ow
0					ow
20					ow
00					ow
0					JOW
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Table 1: Nerve stimulators, theoretical durations of impulse (μ s), overall performance

Maximum voltage output under large loads, maximum load output

Currently, all devices have a constant current output. Ohm's law, U=RI explains the principle (U being the potential difference between the poles of the nerve stimulator or the voltage output; R, expressed in Ohm's being the impedance of the body and the circuit or the impedance of an external electrical circuit; I being the current). When the impedance varies the current is maintained constant by modifying the voltage output. Each device has the capacity to a greater or lesser degree to keep the current constant. During testing, as the impedance of the external electrical circuit increased, the rise and decay times were progressively greater than before. Beyond a noted limit (maximum load output measured at 5 mA, if possible) for each device, the current could no longer stay constant and the effective current decreased, no longer corresponding to the displayed current. For some devices, considerable deformations in the waveform lead to disappearance of the plateau. It is of great relevance to have a high, but not excessive, voltage output.

Ergonomics and safety

A nerve stimulator needs to be easy to handle and robust with a weak bulk. The double function, neuromuscular blockade monitor and nerve stimulator, is not desirable. The ergonomics, the reliability of connections, easily identifiable polarities, the quality of cables, the range of alarms (e.g. circuit closure, battery, high impedance...), the audible and visible nature of these alarms, the display of effective current and the display of the selected duration are all considered to be important. The dial needs to be perfectly balanced. A rotating dial is more ergonomic than up and down buttons. Most of the devices offered a choice between at least two output frequencies, 1 Hz or 2 Hz that is one impulse or two impulses per second. The quality of cables was variable. For the polarities, the colour coding was not always easily identifiable with black for the negative pole and red for the positive. The nerve stimulators were all more or less well equipped in terms of safety signals, audio and visual alarms. The possibility to choose from many predefined signal durations should be accompanied by a safety display guaranteeing the selected choice. Only the newest devices displayed the signal duration on the screen.

Overall performance

Three groups of devices were observed with low, average and high performance (Table 1).

Clinical implications

In the last 15 years stimulator technology has progressed greatly. This advance has been reflected in this series of tests detailing the basic principles, the features, the performances, the limits and the practical use of these devices [1-9]. Adjustment of the voltage output is needed to maintain a constant current during an increase in impedance of the external electrical circuit. Nerve stimulators have improved not only in their signal form and precision but also in the linear variation of the current, the maintenance of current stability

during the increase in impedance of the external electrical circuit and the possibility to choose between many predefined durations of signal [8]. However, a recent series of tests outlined imprecisions in current at values ≤ 0.5 mA in the majority of devices. Furthermore, the durations used were different depending on which device was tested. These authors suggested it would be desirable to require standardization of the features when manufacturing nerve stimulators [9]. The results from our test series have allowed us to identify a group of devices with high performance that possess the essential elements to enable us locate nerves in an accurate and safe fashion.

The nerve stimulator can be used akin to radar, a guide in the search for the nerve. According to Coulomb's law, the electric field produced for a current of constant duration is inversely proportional to the square of the distance. Our aim is to bring the needle tip as near as possible to the nerve through the progressive diminution in stimulation intensity. On the other hand, a very high intensity is needed once the needle tip is some distance from the nerve. These facts underscore the importance of devices with a digital display, precision and linear variation in the delivered current. The minimal stimulating current necessary to produce an effective block remains unknown. Many works have addressed the importance of the minimal stimulating current. This was a predictive criterion of failure in brachial canal blocks performed in one series of 1417 patients [10]. In volunteers, undergoing 4 sciatic blocks by the posterior popliteal approach, the motor responses provoked by nerve stimulation correlated with the results of the block [11]. For some authors [12], the qualitative result of a nerve block will depend more on the minimal current than the type of motor response obtained during the search. Certainly, this minimal current plays an important role [13-16]. In studies of morbidity, adherence to a safety threshold of 0.5 mA has been proposed [17, 18]. However, this proposition is not based on objective data, especially as the impulse duration is rarely specified. It seems dangerous to try to associate the risk of neural injury only with a figure of intensity whatever that may be. The nerve stimulators available have a duration of stimulation between 40 and 1000 μ s. Depending on the nerve stimulator used, the charge for a current of 0.5 mA will vary from 20 to 500 nC. In the literature a number of authors have opted for values of 0.1 to 0.5 mA (often forgetting to denote the duration of stimulation). The minimal stimulating current can be defined as the value below which an adapted muscular response is no longer obtained after a search within the three axes of the space [5, 19]. This threshold, insufficient for a 100% success rate, is an essential criterion in giving an estimation of needle position. As a consequence, the systematic search for this value may allow a diminution of the risk of neural lesion [20]. In a review article on the practice of brachial plexus anaesthesia, it was suggested that the final current should be less than 0.5 mA and values of 0.3 mA were proposed to further improve success rates [21]. Although this point of view is not unanimously held [22,23], for patients without polyneuropathy, safety and success seemed to be obtained at a current of about 0.3 mA at a pulse width of 100 µs [24].

The importance of short durations was signalled in 1984 because of a better discrimination in observed responses [1]. The variation in current as a function of distance is more important when the pulse width is short. Experimentally, the shorter the duration, the greater the variations in current observed for the same distance between needle and nerve. The best discrimination of distance between needle and nerve has been shown in practice. For an impulse with a current of 0.3 mA applied for a short duration the needle tip has been shown to be closer to the nerve in comparison to a long duration [24]. In the course of the technology evolution, the standard duration of stimulation has decreased 10-fold from 1000 to 100 μ s. In 1980, a response at 0.5 mA could be compared to an identical response today at 2.0 mA.

The ability to choose between several predetermined durations can be used in certain situations. By locating nerves more easily, the longer impulses $(300\mu s)$ may shorten the performance time for axillary blocks when using a multistimulation technique [25]. For a sensory nerve, a stimulus of long duration can aid the initial search. Aß fibres, afferent skin receptors, have conduction velocities, which can approximate motor fibres. This could explain how low intensities applied for short durations during the final search for a sensory nerve are able to elicit rhythmic paresthesia when using the nerve stimulator [26,27]. This debate between eliciting paresthesia and nerve stimulation is far from closed. Recent studies have attempted again to compare the subjectivity of the search for paresthesia with the objectivity of a motor response obtained with a nerve stimulator [28-30]. The chronology of events at the time of approach to the nerve with the help of a nerve stimulator will be above all the obtaining of a motor response, then the appearance of an electrical paresthesia which disappears with the stopping of the nerve stimulation and finally in the case of direct contact the obtaining of a mechanical paresthesia. Moreover, as part of a systematic approach to the administration of local anaesthetics the reappearance of a muscular contraction is linked to the increase in charge, which in turn depends on its current intensity and duration. For the same charge in nC, the motor response is more intense with the use of a short duration. This is why it is necessary to indicate every time the signal duration for a given current (mA) or charge (nC).

In our era, the devices used generate a constant current. For a given current, each time the impedance varies the current needs to be maintained constant by altering the voltage output. Each device has the capacity, to a greater or lesser degree, to maintain the current constant. Beyond a certain limit, the device cannot guarantee a constant current and the effective intensity decreases and no longer corresponds to the intensity displayed. The more the voltage output can be elevated, the better the device performs in critical situations. Some authors have suggested that a high voltage can provoke a sensation of burning through the local production of heat, in particular if one uses a dry electrode at the positive pole [31]. This point remains controversial and has not been observed in practice [32]. The maximal load output can be maintained close to 15 kilohms for the best nerve stimulators. Even in these extreme conditions, the maximal voltage stays five times lower than for a neuromuscular blockade monitor, which can cause burns [33].

In using a nerve stimulator it is essential to check the correct function of the device and the integrity of the circuit. The connections are now more reliable and the polarities more easily identifiable. The cathode is connected to an isolated needle; the anode is linked to an electrode at a distance from the nerve to be stimulated [34]. The gap between this electrode and the needle puncture site is of secondary importance [13,35]. A safe technique also requires the aid of visual and auditory alarms. In this area, some progress may be made. It would be necessary in a perfect device not only to have one digital display of effective current but equally a permanent display of the duration and different alarms to signal every abnormal situation such as a circuit fault, a weak battery or a high impedance.

Every user needs to know the characteristics of the nerve stimulator. It is essential to take account of its precision and weaknesses. The technological evolution in these devices has direct consequence in the way in which we proceed to obtain an accurate and safe search. The main advantages of newer devices concern signal quality, precision and linear variation of the current and several predetermined durations. To enhance the safety and success rate of nerve blocks using nerve stimulation, it seems useful to rely not on a single minimum current value but rather on combination of criteria [19,20]. This should include the minimal current for a defined duration, the sensation of penetrating the relevant fascia, the type of muscular response obtained, the disappearance of a muscular contraction following the injection of 1 mL of agent, the ease of finding again this contraction by increasing once more the current, painless injection without resistance, etc. It is under these conditions that it will be possible on the one hand to improve further the risk-benefit ratio of nerve stimulation, and on the other hand to establish the predictive indicators of success that will enhance our practice.

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ULTRASOUND FOR REGIONAL ANAESTHESIA

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Introduction:

For years, it was commonly claimed that if an anaesthesiologist really knows the anatomy of a peripheral nerves, additional imaging is not required. This advice may contain elements of truth if one focuses only on surgical applications of regional blocks. The introduction of pain medicine into many practices, and the necessity of implanting devices and catheters for prolonged periods in patients, implicates that we further understand normal, as well as potentially altered, anatomy.

Winnie once predicted: "Sooner or later someone will make a sufficiently close examination of the anatomy involved, so that exact techniques will be developed"^{xxx}. Ultrasonography may represent such a method for providing a "sufficiently close examination of the anatomy". The ideal in the practice of regional anaesthesia would be to deliver precisely to the target nerve the local anaesthetic solution without incurring any risk of damage to the nerve or its related structures. We currently, use needles and catheters, guided mostly by the motor response to electrical nerve stimulation or, in the past, by the elicitation of paraesthesia. Unfortunately, this is essentially a blind process, and a modern imaging technique might be used to overcome this. Ultrasound has also been used to visualize the spread of the local anaesthetic solution and to validate currently used landmarks.

History:

Ultrasound guided nerve blocks have been reported in the anaesthetic literature since 1978, with an increased interest from the mid 1990's, probably as a result of improvements in equipment. In 1978, La Grange et al.^{xxxi} reported the used of a Doppler ultrasound to improve identification of the subclavian vessels before brachial plexus block by the supraclavicular approach. Other authors^{xxxii} used Doppler ultrasound device to check for the localisation of the axillary artery when it was not palpable. In 1988, Vaghadia and Jenkins^{xxxiii} described the use of Doppler ultrasound for intercostals nerve block. Ting and Sivagnanaratnam^{xxiv} in 1989, used ultrasound to confirm placement of a cannula in the axillary sheath and to document the spread of local the anaesthetic solution for upper limb surgery. In 1995, Guzeldemir and Ustunsoz^{xxxv} described the placement of a catheter under ultrasound guidance for continuous axillary brachial plexus blockade. Two ultrasound studies of the brachial plexus were published in 1998. It is also worth mentioning that ultrasound has been used to assess the depth of the epidural space^{xxxvi} and to assess the lumbar epidural space during pregnancy^{xxxvii}. In early 80, Cork et al.^{xxxviii} and Currie et al.^{vii} observed a strong relationship between ultrasound location of the epidural space and the depth to the point of the epidural needle. Wallace et al.xxix found that ultrasonography was an useful means to detect the point of skin puncture. In 1995, Bonazzi et al.^{x1} valued ultrasonic measurements of epidural space depth as a useful diagnostic tool with a potential to decrease the complication rate.

Generalities:

How close is close enough with the nerve stimulator? This question revolves around efficacy and safety^{xli}. What about safety?

Ultrasound technique is helpful for regional anesthesia in two ways: first, it allows the systematic, non invasive, in vivo assessment of topographic sonoanatomy and its variations^{xlii}. Performing careful ultrasound measurements enhances our understanding of the anatomy, tests the accuracy of common block techniques, and can even result in suggestions to change them ^{xxx}, as likewise demonstrated with MRI^{xliii}. We still have much to learn from in vivo ultrasound, in as much as anatomy textbooks rely mainly on cadaver dissections. Second, and probably most important, ultrasound helps to individually guide the needle in real time. Advantages of ultrasound guidance include the direct visualization of the nerves, the

entire needle, or the needle tip; identification of adjacent structures to avoid; and, finally, monitoring of local anaesthetic spread.

When performing ultrasound guided infraclavicular block, Greher and al^{xxx} have often observed the optimal puncture site to be different from that predicted by the infraclavicular vertical brachial plexus block technique, indicating that the classical landmark can carries an inherent risk of complications. Knowledge of anatomy takes the needle to the general area of the nerve and helps avoiding other structures. The specific nerve localisation technique allows a close approach, hopefully without the risk of nerve damage. Most commonly, block failures result from imprecise needle placement, and even in skilful hands, the failure rate can be as high as 10-15% xliv. In fact, the key steps in any successful regional anesthetic technique involve: identifying the exact position of the nerve, placing precisely the needle, without damage to any adjacent structures, and finally carefully injecting local anesthetic. Most of the studies of ultrasound in regional anaesthetic practice have looked at one or more of the various approaches to the brachial plexus, some using ultrasound to identify and mark the skin over blood vessels and others using it to guide the needle or catheter to the nerve. Sheppard et al.^{xlv}, while not specially describing ultrasound for nerve blocks, evaluated the ability of this technique to visualize components of the brachial plexus, using MRI as a guide to background anatomy. They described the plexus nerves as having a hypoechoic appearance, with thin hyperechoic rims which were tubular on longitudinal scans and oval to round on traverse scans. They also suggested that colour Doppler was essential to prevent the confusion of nerves with small blood vessels. As with tendons, the connective tissue within the nerves displays an anisotropic behaviour, depending on the angle of the emitted ultrasound wave relative to the long axis of the nerve^{xlvi}. In a study by Silvestri et al^{xlvii}. comparing the histologic structure with ultrasound echotexture of peripheral nerves, the hypoechoic components correspond to neuronal fascicles, and the hyperechoic areas correlate with the connective tissue layers forming the epineurium. Compared to nerves, vessels, tendons and muscles are also hypoechoic, whereas fat and bones are hyperechoic. In the transverse view, small vessels, lymph nodes and muscle fascicles can be mistaken for nerves because they have similar size and echogenicity. For this reason, they advocated the use of color Doppler and electrical stimulation to determine the identity of the hypoechoic shadows, presumably nerves.

Modern ultrasound equipments typically operate in the 2,5-20 MHz frequency range. Higher frequencies, probes (7 to 15 MHz) image resolution. The higher the frequency the better the spatial resolution, but at the expense of reduced depth penetration. Lower frequencies provide deeper penetration but at lower spatial resolution. Additional features, such as pulsed-wave and colour Doppler imaging, allow the identification of vessels and the blood velocities in those vessels. Ultrasound devices are now mobile, providing increased flexibility and applicability. Modern ultrasound equipments are cheaper and produce better quality imaging. Accordingly, the highest frequency is not automatically the best choice at all site of block performance. For example, in Perla's study ^{xx} the 12 MHz probe provided higher resolution compared to lower frequency transducers in superficial plexus locations but failed to identify the nerves in 73% of the cases in the infraclavicular region, where they were easily identified with 5-10 MHz ^{xxx}. Different frequency probes will probably be needed for different purposes. For example, Greher et al. use a 15 MHz probe in experimental laboratory setting but a 4 to 5 MHz probe for an ultrasound guided posterior lumbar plexus block with a target deeper than 5 cm. To visualize the brachial plexus at 1 cm depth at the interscalene, supraclavicular, or axillary level, the 12 MHz transducer is obviously an excellent choice.

Diagnostic ultrasound equipment has multiple probes and software packages, and costs from 50000 to 75000 euros. But a modern portable ultrasound machine, which might be used for regional anaesthesia and peripheral arterial and central venous cannulation, would have a single variable-frequency linear array transducer (5-10 MHz), and costs approximately 7500 euros.

Advantages and drawbacks:

Blinded techniques can cause complications, patient discomfort, and long time procedure. Although infrequent, direct or indirect needle injury may cause serious complications such as nerve damage, spinal cord injury (interscalene block), pneumothorax, vascular puncture and systemic local anesthetic toxic reactions. Ultrasound is non-invasive, mobile and moderately priced. This real time imaging technology is really a plus in brachial plexus blocks and infraclavicular region. Such new image enhancing capability allows clear visualization of nerves. With the ultrasound guided technique, skin pressure exerted by the probe is probably less than manual palpation allowing a greater degree of nerve mobility. Whether ultrasound guided brachial plexus block can decrease the risk of nerve injury associated with needle trauma or intraneural injection is not known at this time. Another interesting finding of the current study is the

inconsistency of nerve stimulated muscle contraction when the needle is in contact with a nerve in some cases.

Conceivably, if ultrasound visualization during local anesthetic injection can identify the extent of circumferential and proximal spread, it is not necessary to block nerves individually, thus avoiding less multiple attempts and potentially, nerve injury.

During pregnancy, however, obesity and oedema frequently obscure anatomical landmarks. The investigation by ultrasound of the epidural space before puncture is fast and free of discomfort and does not present a risk for mother or foetus. When a difficult puncture of the epidural space is expected, ultrasound images facilitate the procedure. With increased information on the individual anatomy, a general quality enhancement of epidural analgesia could be expected.

How to use a ultrasound technique:

With the ultrasound technique, identification of surface landmarks is not important. A preliminary scan prior to needle insertion shows distinct anatomic details of the nerves and their neighbouring structures.

The site for needle puncture is the site with the shortest skin to nerve distance. It is easy to place the nerve seeking needle on the outer end of the ultrasound probe and advanced it in a lateral to medial direction. The most unique feature of this technique is the alignment of the path of needle advancement with that of the ultrasound beam. In this case, one can see the needle shaft and its tip as a hyperechoic linear shadow on the screen and can follow needle movement toward the target nerves. Guided by the ultrasound images, needle movements are controlled and target specific. Instantaneous feedback provided by real time imaging guides the angle, depth, and direction of needle penetration so that any improper shift is recognized and corrected quickly. It is noteworthy that there are other ultrasound beam. In this case, only indistinct needle movement in the subcutaneous tissue can be observed and not the actual needle shaft. Dynamic examination of nerves shows that they are mobile structures and they typically move away or to the side when approached by the insulated needle. Conceivably, nerve movements may protect itself from direct needle injury to some extent.

In performing ultrasonography guided blocks, observing a homogeneous and complete local anesthetic spread around the nerve is the most reliable predictor of block success. This is not necessarily achieved with the needle tip in the closest proximity to the nerve. This means a fundamental difference from the blind, one dimensional nerve stimulator technique in which injections are typically performed after the needle is placed as close to the nerve as possible (as defined by a low stimulating current).

The ultrasound scan head is positioned and oriented at each location to obtain the best possible transverse view of the brachial plexus (the ultrasound beam in a plane approximately 90° to the brachial plexus). Thus, the probe is in the axial oblique plane for the interscalene location, parasagittal for the supraclavicular location, and transverse to the arm for the axillary and midhumeral locations. Ultrasound images^{tlviii} of the brachial plexus and its components showed round to oval shaped nodular hypoechoic structures (dark images on the monitor) often punctuated with small internal hyperechoic (bright) shadows. When in cluster, the nerves appear as grape like structures in the transverse view. With the probe 12-15 MHz, high quality images of the brachial plexus and its components with the exception of the infraclavicular location, in which brachial plexus images were obtained in only 27% of cases.

By using transverse vascular imaging, the plane of the ultrasound beam does not include the advancing needle until the moment it reaches the imaged target. A small gauge needle, especially if not nearly perpendicular to the ultrasound beam, can be very hard to see on the ultrasound screen. Failure to appreciate that the needle's tip has reached the brachial plexus could result in damage to the adjacent structures (pleura) or even nerve trunk.

-Interscalene block: when scanned in the axial oblique plane at this level the most superficial structure consistently encountered is the sternocleidomastoid muscle. It shape like a triangle with the apex pointing laterally. Deep to the sternocleidomastoid muscle are the scalenus anterior and medius muscles. At the level of the cricoid cartilage, the brachial plexus is consistently found between the scalenus anterior and medius muscles in the interscalene groove as expected. Depending on the angle of the probe, it is most common to identify one to the three hypoechoic structures at this level. When scanned above the cricoid cartilage in the axial plane, the original nerve roots can be seen existing next to the transverse process of the cervical vertebra.



Fig. 1. Ultrasound probe position at five anatomical locations. It is directed in the axial oblique plane for the interscalene location (1), coronal oblique for the supraclavicular location (2), parasagittal for the infraclavicular location (3), transverse for the axillary location (4), and transverse for the midhumeral location (5).

The root within the neural foramina can not be seen because of shadowing from bone. When scanned caudal, the original nerve roots now move to a more superficial location. Other structures identified are the carotid artery and internal jugular vein situated anteriorly and medially to the brachial plexus and occasionally the vertebral artery.



Fig. 2. Transverse sonogram in the interscalene region showing brachial plexus as hypoechoic nodules (N with *arrows*) interposed between scalenus anterior (SAM) and medius (SMM) muscles, beneath the posterior margin of the sternocleidomastoid muscle (SCM). CA = carotid artery; IJ = internal jugular vein.

-*Supraclavicular block*: When scanned in the coronal oblique plane at this location, the ultrasound images obtained shows the first rib with the subclavian artery lying immediately above. In this plane with the ultrasound beam at approximately 90°, the subclavian artery appears as a round pulsatile hypoechoic structure and the first rib appears as a curved linear hyperechoic shadow. The brachial plexus is found consistently in clusters lateral, posterior, and often cephalad to the subclavian artery.



Fig. 4. Transverse sonogram in the supraclavicular region shows brachial plexus as a group of hypoechoic nodules (*N* with *arrows*) lateral to subclavian artery (SA) and cephalad to the first rib (R). PL = pleura; SAM = scalenus anterior muscle; SV = subclavian vein.

Scanning more medially shows the subclavian vein and the anterior scalene muscle. Pleura is also hyperechoic and often seen on either side of the first rib. Pleural and lung movement can be observed during respiration.

-Infraclavicular block: the probe 12-15MHz must be positioned 2 cm medial to the coracoid process for this assessment. The brachial plexus in this location is deep to the pectoralis major and minor muscles, in close proximity to the axillary artery and vein.



Fig. 5. Transverse sonogram in the infraclavicular region showing brachial plexus as hypoechoic nodules (N with *arrow*). AA = axillary artery; AV = axillary vein; PMaM = pectoralis major muscle; PMiM = pectoralis minor muscle.

-Axillary block: most previous ultrasound studies examining brachial plexus anatomy used scanning probes with frequency in the range of 5-10 MHz and 12-15MHz. Branches of the brachial plexus can be easily identify in close relationship to the axillary artery (one) and veins (one or two). Veins are differentiated from artery by their ease of compressibility by the ultrasound probe and by colour flow Doppler. The axillary vein(s) are typically found medial and posterior to the artery and can be anterior to the nerves. Ultrasound images show three distinct terminal branches of the brachial plexus (median, ulnar and radial

Ultrasound images show three distinct terminal branches of the brachial plexus (median, ulnar and radial nerves). The location of the three nerves is highly variable, most often lateral or medial to the axillary artery and less often directly anteroposterior to the artery.

-Midhumeral block: the probe is positioning at the junction of the upper and middle third of the outstretched arm. At this level, the ultrasound images consistently identified two nerves (median and ulnar). The musculo-cutaneous and the radial nerve can't be seen.



Fig. 7. Transverse sonogram in the midhumeral region showing two terminal branches of the brachial plexus as hypoechoic nodules (N with *arrows*). BA = brachial artery; BM = biceps muscle; H = humerus; TM = triceps muscle.

-*Popliteal sciatic block:* Sinha A. and al.^{xlix} use a linear 5cm, 4 to 7 MHz probe inside a sterile cover was applied onto the posterior thigh approximately 8cm proximal to the popliteal crease of the operative leg. The probe positioned horizontally at this level captures a transverse view of the sciatic nerve (the ultrasound beam is at 90° to the nerve) and shows the sciatic nerve as a single oval, well circumscribed, hyperechoic structure. The nerve is consistently superficial and within 1 to 2 cm lateral to the pulsatile hyperechoic popliteal artery, which is commonly 3 to 4 cm deep to the skin. Inserted below the mid point of the probe perpendicular to the ultrasound beam, the needle is seen in cross section on ultrasound as a hyperechoic without full image of the needle shaft. Only needle and thigh tissue movement are observed in real time. The transverse view allows to check for local anesthetic spreading.

-Thoracic epidural space: in thoracic epidural anesthesia, the loss of resistance technique is the standard but the feed back is often solely tactile. In Grau et al.¹ study, the capacity of ultrasound imaging to depict epidural space was limited. Due to the better overview , MR images were easier to interpret. However ultrasound proved to be better value than MRI in the depiction of the dura mater. Patients was placed in sitting position and a 7 MHz linear transducer or a 5 MHZ curved array is necessary.

-Epidural block: For the ultrasound scan of the spinal column at L3-L4 interspace in transverse and longitudinal planes, most of studies used a ultrasonography equipped with a 5 MHz curved array probe. Ultrasound scanning gives an accurate reading of structures up to a depth of 12 cm under the skin surface. As the epidural space is located at a depth of 20-90 mm^{li}, pre-puncture ultrasound examination is theoretically possible.



Fig. 8. Landmarks and transverse sonogram in the epidural region.

The epidural space itself does not reflect ultrasound waves. The ultrasound image provides three important pieces of information that may account for the significant reduction of puncture attempts:

the distance from the skin to epidural space

the optimal skin puncture site

the ideal direction of needle advancement

Vertebral bones surrounding the spinal and epidural space make it more difficult for ultrasonic guided epidural block. Depending on the ultrasound frequency being used, 92% to 100% of the beam's energy is reflected by, and therefore lost on, the calcified structure in front of the epidural space.^{lii} The epidural space is filled with soft tissue, mostly collagen fibers, vessels and fat. The ligamentum flavum and dura mater are similar in density and their acoustic pattern can be nearly iso-echoic. The ultrasound beam enters the spinal column through an acoustic window between the spinous process. The ligamentum flavum is the first echogenic structure encountered beyond which lies the dura mater and, in between, the nonechogenic epidural space.

Compared to the median ultrasonic approach, the paramedian access improves overall visibility of all examined structures^{liii}.

Results:

In 1989, Ting and Sivagnanaratnam^{*} 'study the cannula were placed without ultrasound guidance by palpation of the artery and feeling for a click on entering the sheath. In this study, the block was successful in all the subjects and no paraesthesiae or vascular punctures occurred. A larger study, including 40 patients, was performed by Kapral et al.^{liv}, who used ultrasound to guide the placement of cannula within the brachial plexus sheath and to confirm the spread of local anaesthetic in both axillary and supraclavicular approaches. All the blocks were performed without damage to vessels or nerves and pleura. The authors commented that the advantages of ultrasound guidance were that it showed directly the effect of over abduction of the humerus, which compresses the axillary vessels and could interfere with the proximal spread of the anaesthetic, and that it allowed relatively small volumes of local anaesthetic to be administred.

Studies comparing ultrasound guidance with nerve stimulator guidance have documented significantly higher success rates, shorter onset times ^{xxxi}, and a decrease in local anesthetic requirement and complications with the former method. Ootaki et al.^{1v} reported ultrasound guidance for infraclavicular block in 60 patients. Their success rate was 95%, meaning that all but 3 patients underwent surgery with no further anaesthetic or analgesic. None of the patients required general anaesthesia. The success rate was similar to that reported in larger studies by Raj et al.^{1vi} and Kilka et al.^{1vii}, and there as no complication other than paraesthesiae in 3 patients. The advantage of ultrasound in avoiding pneumothorax was apparent, because Ootaki et al. were able to see the needle, pleura and lung, to place the needle accurately on each side of the subclavian artery for local anaesthetic injection. The brachial plexus was not stated as having been identified in this study. Greher et al.^{1viii} used ultrasound to identify the brachial plexus in the infraclavicular region in order to assess the accuracy of existing landmarks for infraclavicular vertical plexus block. Interestingly their study indicates that these landmarks are not ideal in all sizes of patient, and

may decrease the margin of safety by allowing the close approach of a needle to the pleura and vessels. Their recommendation was that ultrasound guidance be used when performing this block or that modification of the cutaneous landmarks be used if ultrasound was not available.

In his study, the authors contribute further to our knowledge with a volunteer study, using the newesttechnology high-frequency probes (12 MHz) to identify the brachial plexus in five typical localisations and to guide a needle and verify its position with nerve stimulation. The brachial plexus components were successfully identified in the transverse view as round to oval hypoechoic structures with small internal punctuate echoes in all regions examined except the infraclavicular area (visualized in 27% of the cases). The authors' technique of advancing the needle in line with the ultrasound beam allowed moment by moment observation of the needle shaft and tip movement at time of nerve localization. Hypoechoic structures were stimulated electrically and confirmed to be nerves. These preliminary data show that the high resolution 5 to 12 MHz probe provides good quality brachial plexus ultrasound images in the superficial localisations (interscalene, supraclavicular, axillary and mid humeral regions). The needle technique described for ultrasound assisted nerve localization provides real time guidance and is potentially valuable for brachial plexus blocks.

Perlas^{xx} shows that nerve images are particularly distinct in the interscalene and supraclavicular locations but not the infraclavicular locations. Sheppard and al.^{xvii} recommends linear transducers of 7,5 MHz or higher for scanning at the supraclavicular and infraclavicular locations.

Lower limb nerve blocks were investigated by Marhofer et al. in 1997 and 1998 in two studies on the 3-in1 technique. In the first one^{lix}, ultrasound guidance was compared with nerve stimulator guidance in 20 patients in each group. The onset time of the 3-in-1 block was significantly shorter (16+/-14 vs 27+/-16 min, p<00,5) and the quality, on a percentage scale (100% representing uncompromised sensation), was significantly better in the ultrasound group (14+/-10% of initial value vs 17+/-14% of initial value, p<0,05). The ultrasound group achieved a complete 3-in-1 block in 95% of the cases compared with 85% in the nerve stimulator group. In the second of their 2 studies^{lx}, the authors investigated whether ultrasound guidance in the 3-in-1 block affected the dose of local anaesthetic required. They compared 3 groups of 20 patients each. One ultrasound guided group using 0,5% bupivacaïne 20ml, and two nerve stimulator groups using 0,5% bupivacaïne, 20ml and 30ml respectively. The study was identical in other aspects to the previous one, and the overall success rate, as defined by loss sensation to 30% of the baseline response, was 95% in the ultrasound guided patients and 80% in each of the other groups.

Grau et al.^{ki} identified the epidural space in all cases and both guiding structures (ligamentum flavum and dura mater) could be identified in 88% of cases.

Sutton et Litter^{kii} examined the skin to epidural space distance range in a large obstetric population. They found only 76% of the 3011 epidural space examined within a "normal" range (4-6cm). In 16% of parturients, the epidural space was located at a "shallow" depth (2-4 cm). As the skin to epidural space distance ranges from 2 to 9 cm, the flaval ligament can be anywhere in this 7 cm span. Pre puncture ultrasound examination reduces this probable depth to midline epidural entry" to 7,9mm span in 95% of all cases. However, first, the blunt Tuohy needle by a high pressure can cause a tissue deformation which account for a difference in the skin to epidural depths measured. Second, the Tuohy needle must be inserted beyond the flaval ligament to allow the passage of the catheter. So the skin to flaval ligament distance measured by ultrasound is a priori shorter than the depth of needle insertion at entry of the epidural space. Third, if the angle at which the epidural needle inserted differs from the angle used at scanning, the required depth of needle insertion will be greater than the distance measured by ultrasonography. Should anaesthetists use ultrasound to guide needle insertion in nerve blockade?

The simple answer is "yes", on the basis of the result of the studies mentioned and, to a certain degree, on common sense. It can be argued that it is better to use the best equipment available to actually identify structures rather than to infer their position from surface anatomy and older nerve localisation methods. However, the complicated answer is "it depends". It depends on what type of nerve block is planned, on what the complications are and on the individual's personal experience. Thus it may be used in certain blocks for which the complication rate is high or the complications are more serious, such as brachial plexus blocks. It might be considered particularly appropriate when performing nerve blocks in anaesthetized patients, such as the 3-in-1, for which it has been demonstrated that the success rate is higher using ultrasound and that the dose of local anaesthetic required is lower.

Could any anaesthetist, with minimal training, use ultrasound to visualize the needle during a nerve block? Teaching and training is obvious important application of ultrasound in regional anaesthesia. In all studies, only in one, one person performed all the block, but in the others there was no mention of different researchers performing the blocks.

Is the combination of ultrasound and nerve stimulation the "dream solution" for those who practice regional anaesthesia?

It appears that the use of ultrasound can help prevent accidental puncture of blood vessels and the pleura, but that it does not prevent paraesthesiae^{lxiii}. The use of a nerve stimulator avoids the need to elicit paraesthesiae and has been claimed to reduce nerve damage, although this is contentious^{kiv}. Certainly, the use of a nerve stimulator does not eliminated the risk of nerve damage. Using ultrasound might help prevent nerve damage, but this hypothesis remains to be tested.

Conclusion:

The use of ultrasound guidance in regional anesthesia and interventional pain management is growing. From all these studies, it appears that ultrasound can be a useful aid whether it is used to locate arteries, to mark the skin for unguided blocks or as a real-time guide of needle or catheter position relative to the nerve or related blood vessels, and can be used to define the spread of local anaesthetic. However, it is interesting to note that, even with the ability to establish that the needle or catheter is close to the nerve, or within its sheath, and then to observe the spread of local anaesthetic, there is no guarantee of an adequate nerve block. In summary, we have a technique for peripheral nerve identification which is being used increasingly in research and appears to offer better accuracy and safety, but is technology-dependent and expensive. The high cost will limit its immediate general availability, but continued technical development and cost reduction will change this ultimately. Any method that offers even the possibility of improved accuracy in identifying the positions of nerves we wish to block and structures we do not wish to damage must continue to be evaluated.

The statement that nobody has an eye on the needle now can be revised.

Ultrasound imaging brings light into regional anesthesia.

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PATIENT SAFETY THROUGH INTEGRATED SOLUTIONS - ERGONOMIC APPROACHES...

- From the Industrial Perspective

A shift from stand-alone products via ergonomic systems towards integrated processes.

THIJS TEELING

Dräger Medical

At Dräger ergonomic approaches have always played an important role in the design and development of new equipment. This has led to optimized and intuitive human interfaces with self-explanatory design concepts to operate the equipment and preventing failures.

The primary object has always been to support the human physiology in as natural a way as possible. Supply units and smart accessories allow an ergonomic setup for process-oriented workflow.

If the diagnostic and the therapeutic devices are optimized, then the next logic step is,

to combine the information of the devices.

But the data management should not only collect the data, but should also provide powerful assistance in evident based medicine.

Having the monitoring systems via a gateway, connected to the network, the comprehensive patient information is available at any acute point of care, at the bedside or at a PC located anywhere in the hospital. IT solutions at the Acute-Point –of-Care guarantee seamless data transfer throughout the care areas.

This will reduce needed manpower, decrease possible human errors and improve the quality of care.

The leading motive has always been to design safety into health care systems at all levels, and that barriers to safety improvement must be broken down.

Another important aspect in the total workflow process is education and training. The industry realizes that also in this aspect, they can provide crucial contributions: Device training, application training and management skills.

Total integrated solutions improve the quality of care, i.e. Patient Safety.

PATIENT SAFETY THROUGH AN INTEGRATED DESIGN OF CLINICAL SYSTEMS

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Situation

Ergonomic design of clinical systems takes patient, staff, machine and organization into account. The goal "patient safety" is a resulting variable which is influenced by a lot of other system variables. Clinical management has to consider all interdependencies of relevant variables to distinguish carefully between variables useful for steering or useful for monitoring.

Methods

"Thinking in networks" offers a method to analyse the interdependencies between variables in complex systems [1]. When applying this method to clinical working systems we get an integrated three dimensional model, which serves as a frame for establishing and controlling patient safety.

Results

Our analysis shows a) four resulting variables [quality of care (including patient safety), quality of innovation, quality of changes, and quality of competition] and b) four steering variables [medical competence (including human and technical resources), management competence, information & communication competence, and innovation competence]. The steering variables could be placed in the corners of a tetrahedron (see figure). The edges are abilities (e.g. the edge between medicine and information & communication represents the treatment ability, the edge between management and information & communication the controlling ability and the edge between management and medicine the process management ability). The edges span areas. For instance the three basis edges span an area representing the quality of care. The four areas enclose a volume which represents the overall success.

Using a fractal approach this model can be used on all symanagement, team-coordination etc. Similar to a Balanced sessing the variables.

Discussion

Our approach rises a lot of questions for hospitals, that have t quality of care (including patient safety) on the different leve Management and which strategies should be used to improve them?

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Innovation

HUMAN FACTORS IN THE DESIGN AND IMPLEMENTATION OF PATIENT SAFETY TECHNOLOGIES

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Introduction

Medication errors are common, occurring in nearly 20% of inpatient medication doses (Barker, Mikeal, Pearson, Illig, & Morse, 1982) and accounting for 7,000 deaths annually (Kohn, Corrigan, & Donaldson, 1999). Our study examines the implementation of Smart IV pumps and its integration with a bar code medication administration (BCMA) system. "Smart IV pumps" have a predefined drug library with built-in drug dose limits to avoid under- and over-dosing of IV medications. Integration of these pumps with BCMA provides ultimate accuracy in patient identification during medication administration. Adding technology to the medication administration process, like bar code systems that match patients with the right medications and IV pumps with the ability to set drug dosing limits, is seen as a solution to medication administration of new technologies in health care has not been without troubles or workaround (Battles & Keyes, 2002; Patterson, Cook, & Render, 2002). Technologies can change the way work is being performed and, because healthcare work and processes are complex, negative consequences of new technologies are possible (Cook, 2002). In our study, we use different human factors engineering methods to assess the positive and negative characteristics of the design and implementation of technologies on patient safety, as well as on end users (nurses and anesthesiologists).

Methods

Our human factors engineering methods include: (1) human factors prospective error analysis (Failure Mode Effects and Analysis-FMEA) of the medication administration process with the technologies (Smart IV pump and BCMA), (2) usability testing of redesigns of the Smart IV pump, (3) five focus groups of end users (medical/surgical nurses, intensive care nurses, anesthesiologists), and (4) questionnaire survey of end users.

Results

The FMEA analyses allowed for the identification of potential problems related to the implementation of the technologies, such as complexity of the pump usage. FMEA helped us understand that the pump use was not as "intuitive" as the other pumps the institution previously used. One outcome of the prospective analysis was to make training "mandatory" for all users before pump use. Users were trained on specific items, such as programming basic infusions, and picking the correct drug profile and medication in the drug profile. The FMEA process identified other problems, such as the possibility of pole clamps breaking (users were told not to hang the IV pump above patient head) and the importance of correctly loading the tubing. In addition, the FMEA heightened the awareness of a large group of people in the institution for the need to seek out problems that the pumps could introduce into the systems. The institution, therefore, was better 'equipped' at identifying problems early and dealing with them on a timely basis. Another organizational impact of the FMEA was to obtain buy-in from all disciplines using the pump, in particular anesthesia. A plan was worked out for the transfer of patients from the OR to the ICU or general care units post-op and included having the anesthesiologist select the correct profile based on where the patient was being transferred. As a result the pump did not have to be turned off and re-programmed upon the patient's arrival to the respective unit. From our experience, a number of challenges to the application of the FMEA process have been identified (Wetterneck, Skibinski, Schroeder, Roberts, & Carayon, 2004).

Usability testing allowed the evaluation of redesigns of the Smart IV pump technology proposed by the manufacturer. As part of the usability tests we evaluated three different pump designs to determine which design was the most user-friendly as well as which one proved most difficult to create infusion errors. We also took the opportunity to re-educate the participants regarding the consequences of misloading IV tubing.

We conducted focus groups to gain insight concerning issues related to the pumps from several groups of like users. Our results clearly demonstrate that the technologies had different impact on different groups of end users. For instance, data obtained in the focus groups showed that intensive care nurses and unit nurses responded to pumps alerts differently based on the frequency with which they exceed pre-assigned upper and lower dose limits. Likewise, because pediatric nurses used less features of the pumps (primarily due to the fact that syringe pumps, in conjunction with the Smart pumps, were the primary means of medication administration for children), they raised different issues such as how children and parents respond to alarms.

The questionnaire data provided useful information on the end users' perceptions of technology characteristics that were in need of changes. For instance, questionnaire data showed a problem with pump alarm messages and noise levels. This led to a greater understanding of the pump design related to the loading of tubing that in turn greatly reduced the incidence of the air-in-line alarm.

Discussion

Some problems related to healthcare technology design and implementation can be anticipated; others cannot. We learned the importance of being on the 'look-out' for problems, especially in the early phases of technology implementation. We learned the importance of utilizing multiple methods of analysis to address human factors issues in the design and implementation of technologies. Technologies are not, per se, the panacea for patient safety: they can create their own problems depending on their design and implementation and the organizational context in which they are implemented.

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MEMORY PROCESSING UNDER PROPOFOL-REMIFENTANIL BASED ANAESTHESIA AND BIS MONITORING FOR CARDIAC SURGERY WITH CARDIOPULMONARY BYPASS.

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Introduction: Many studies have investigated memory processing under general anaesthesia (GA) (1,2). The incidence of awareness inducing explicit memory during cardiac surgery (CS) is high (3). Implicit memory which is unconscious recall of intraoperative events could also be at higher risk during CS. From the six published studies during CS to assess memory processing, divergent results were obtained: four of them showed evidence of the presence of implict memory and sometimes explicit memory, while the two others failed to demonstrate any kind of memory processing. To further investigate memory processing during GA for CS we studied patients exposed to an auditory stimulus under BIS monitoring and anaesthesia maintained with a target controlled infusion (TCI) of propofol and remifentanil.

Methods: After approval of the Local Ethics Committee and obtaining patients' written and informed consent, thirty eight adults undergoing CS under cardiopulmonary bypass (CPB) were enrolled and randomised in a double-blind procedure to hear discs A or B where 20 different words were recorded as described in a previous study (4). They were premedicated with alprazolam and anaesthetised under BIS monitoring with an effect site TCI of propofol and remifentanil, using Schnider and Minto's models, respectively. At induction, propofol target effect site concentration was increased by steps beginning at 0,5_g/ml until loss of consciousness (LOC). The disc was played continuously from LOC until the end of surgery. Lowest propofol effect site concentration (LPEC), lowest remifentanil effect site concentration (LREC) and highest BIS value were recorded. Implicit and explicit memories were tested on the first postoperative day with a word stem completion test (WSCT) and a free recall test (FRT). Patients responded to both tests for the two lists of words. We compared two groups within each list: the correct answers from patients who heard the list and their control beeing the correct answers given by the patients who didn't hear the list, as shown in table 1. For data analysis, we used the Student t-test for baseline and demographic characteristics and the Mann-Whitney U test for memory results.

Fable 1: Study design and results from memory tests. CD = Compact Disc. Results are given as median bercentage of correct answers with interquartile range in brackets. A Mann Whitney U test was used for non barametric data. P<0,05 was considered statistically significant.

Group 1 heard list A on CD A	Results of memory tests for group1	on list Results of memory tests for
i = 19.	A. Median 5 % (0-5)	roup1 on list B, used as
		control for beneath.
		Median 15% (10-20)
Group 2 heard list B on CD B	Results of memory tests for group2	on list Results of memory tests for
i = 19.	A, used as control for above.	group2 on list B.
	Median 5% (0-5)	Aedian 10% (5-20)
Statistics	$\mathbf{b} = 0,974$ between above.	$\mathbf{r} = 0,309$ between above.

Results: After randomisation, patients' demographic data and baseline characteristics were comparable. No explicit or implicit memory was evidenced. FRT results were 0 for both groups. In the WSCT, patients who heard disc A and those who heard disc B completed a median of 5% and 10% of correct words respectively on list A and B. The percentage of correct answers given by patients for the disc that was not heard was a median of 5% and 15% respectively for list A and list B. For each list, the difference between the rate of correct answers whether the patients heard the disc or not is not statistically significant (p=0,974 for list A and p=0,309 for list B). No correlation was found between memory tests and BIS values or LPEC or LREC.

Conclusion: In CS with CPB, explicit and implicit memory were not evidenced in patients anaesthetised with a TCI of propofol and remifentanil, premedicated with a benzodiazepine, and under BIS monitoring

for depth of anaesthesia even when concentration of propofol went under LOC values (range 0,7 to 2,5

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BRAIN ACTIVITY AND THE HAEMODYNAMIC REGULATION IN THE COMATOSE PATIENTS.

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Introduction. One of the big problem in the neurological ICU is the estimation of cerebral blood flow efficacy. Only indirect methods have been using. Moreover, the mechanisms of regulation of cerebral, central and peripheral haemodynamic stay unrecognizable usually, especially in the comatose patients (1). Whether the brain activity is connected with the haemodynamic regulation we planed to find out in this work.

Methods. For this aim we used our monitoring system that synchronously registers main haemodynamic parameters (HP) in beat to beat regime. The heart rate (HR) (ECG), blood pressure (BP), stroke volume (SV), cardiac output (CO), aorta pulsation (AP), ejector fraction (EF) and pulsatory amplitude of peripheral vessels (PAPV) were tested by noninvasive bioimpedans method. For estimation the haemodynamic regulation mechanisms we investigated the variability of all parameters. By means of Fourier analysis we determined the fluctuation power (FP) of HP in diapason of 0-0.5 Hz and its four ranges- UVLF (0 - 0,025 Hz – metabolic influences), VLF (0,025 - 0,075 Hz – humoral activity), LF (0,075 - 0,15 Hz – baroregulation), HF (0,15 - 0,5 Hz – parasympathetic or volume regulation). In addition to this analysis, we created the new method of brain activity estimation. Two needles were placed in the two points as a biparietal channel. This zone is considered to be the most sensible because of critical circulation as a result of three vessels systems connection. Then by proprietary software we fixed the middle EEG amplitude between two cardiac beats during the synchronously registration with HP. The trend of EEG amplitude for 500 cardiac beats was analyzed by Fourier method only in diapason of 0-0.5 Hz and the results were compared with the same of HP variability estimation.

Results. In healthy patients the EEG amplitude variability was characterized by specific distribution in diapasons: approximately 40% of FP was in LF, 25 - 30 % - in HF, 20-25% - in VLF and 5-10% - in UVLF diapason. Almost all of patients had a baroregulation dominant in BP regulation, parasympathetic regulation of SV, CO, AP, EF and HR, and maximum of metabolic and humoral activity in PAPV. After that we examined 260 patients with severe brain damage (trauma, stroke and hypoxia). The variability of EEG amplitude and HP in the comatose patients was different, but it was possible to mark out four types of regulation. The increasing of FP in UVLF and VLF in EEG amplitude spectrum and in all HP was observed in patients with hemispheric processes (contusion, hemorrhage or infarction) as rule in case of moderate mass-effect. This type was associated with the good outcome and we appreciated it as an adaptive hypothalamic reaction. The second type was characterized by very high FP in VLF ("splash activity") in BP, SV, AP and CO spectrums. But this time the very low FP was revealed in HR and PAPV, especially in UVLF diapason. In EEG amplitude variability there were significant increasing of FP in HF and moderate decreasing of FP in UVLF, VLF, LF. This type was also observed in hemispheric damage, but the poor outcome, expressive catabolism and multiorgan failure were often in such cases. That is why we supposed that it might be an appearance of disadaptive hypothalamic reaction. In case of brain stem damage the substantial reduction of FP of all HP were revealed. In EEG amplitude spectrum the similar effect were observed but it was marked that the FP in LF diapason was decreased considerably. If the reducing of FP in all parameters turned out to be permanent it would result in poor outcome. In diffuse brain damage resulted of hypoxia we noticed the preference decreasing of FP in UVLF of HR, EF, PAPV and in EEG amplitude, also FP in all diapasons were reduced.

Conclusion. Thus, we didn't reveal the correlations between the alterations of EEG amplitude variability and the variability of one of HP. But we consider that the discovered regularities reflect the pronounced connection of the brain activity and haemodynamic regulation, including cerebral, central and peripheral circulation and the causal relationships in their disturbances. This method of estimation of regulatory brain activity in comatose patients gives valuable information about brain function and may be used for control of treatment efficacy and the outcome prediction.

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Core competence- monitoring tech., signal processing. The aim is to improve efficiency.

THE NARCOTREND INDEX : A COMPARISON WITH BISPECTRAL INDEX, SPECTRAL PARAMETERS, AND ENTROPY PARAMETERS DURING PROPOFOL-REMIFENTANIL INDUCTION OF ANAESTHESIA

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Introduction: The electroencephalogram (EEG) shows characteristic changes under the influence of anaesthetic agents and thus may be used to assess the patients' hypnotic state during anaesthesia. With the Narcotrend Index the EEG monitor Narcotrend (MT MonitorTechnik, Bad Bramstedt, Germany) provides an automatic classification of the EEG on a scale from 100 (awake) to 0 (very deep hypnosis) (Narcotrend version 4.0) [1]. The Narcotrend Index is a further development of the EEG stages A (awake) to F (very deep hypnosis) (Narcotrend version 2.0); automatic classification using these stages has been validated for intravenous and volatile anaesthetics [2,3]. The aim of the present study was to investigate the suitability of various EEG parameters to describe anaesthetic drug effects in propofol-remifentanil anaesthesia. The investigated parameters were the Narcotrend Index, the bispectral index (BIS, version 3.0) [4], 95% spectral edge frequency (SEF95), burst-corrected SEF95 [5], spectral entropy [6], approximate entropy [7], and amplitude entropy [8].

Methods: After institutional review board approval standardized inductions of anaesthesia in 10 male and 10 female patients were analysed. The 20 patients with ASA status I or II were between 15 and 75 years of age (mean 44.7, std dev 15.3 years) and underwent general or plastic surgery. 7.5 mg midazolam was given as oral premedication one hour before anaesthesia. For induction, all patients received 4 mg propofol/kg over 6 min followed by 4 mg/kg/h. For analgesia patients received 0.3 μ g/kg/min remifentanil starting 2 min before propofol application. 0.1–0.15 mg cisatracurium/kg were administered to facilitate tracheal intubation. The EEG was recorded simultanously with the Narcotrend and the Aspect A-2000 EEG monitor. Data from start of propofol injection until 1 min after the end of the induction period, i.e. a time interval of 420 s, were used for statistical analysis. EEG parameters were evaluated every 10 s. All patients were intubated after the study period. Propofol effect-site concentrations were calculated using STANPUMP (Shafer SL, http://pkpd.icon.palo-alto.med.va.gov). Spearman rank correlation was used to quantify the correlation between the investigated EEG parameters and the propofol effect-site concentration.

Results: The table summarizes the average correlation of the investigated EEG parameters with the calculated propofol effect-site concentration. Narcotrend Index and BIS had the highest mean correlation with the Narcotrend showing the lowest variability of the individual correlation values.

arameter	/lean	td Dev	<i>I</i> inimum	<i>I</i> aximum
Jarcotrend Index	0.95	.04	0.98	0.84
Bispectral Index	0.94	.05	0.99	0.78
EF95	0.41	.33	0.98	0.27
Burst-corrected SEF95	0.66	.27	0.98	0.04
pectral Entropy	0.22	.39	0.94	0.50
Approximate Entropy	0.77	.17	0.98	0.39
Amplitude Entropy	0.35	.52	0.93	0.76

Conclusions: The Narcotrend Index showed a high correlation with the calculated propofol effect-site concentration during induction of propofol-remifentanil anaesthesia. Similar results were found in other studies investigating the ability of the Narcotrend Index to describe changes in drug concentration during propofol [9] and isoflurane anaesthesia [10].

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FIRST TELETHERAPY IN TOTAL INTRAVENOUS ANAESTHESIA BY AUTOMATED INFUSION OF PROPOFOL

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Introduction: Whereas remote control of robot-assisted surgery (telesurgery) has been realized some years ago¹, teletherapy has not yet been performed in anaesthesia. We present the first case of an EEG-controlled closed-loop administration of propofol which was realized over a distance of about 200 kilometers.

Methods: After written informed consent, we performed a teletherapeutic propofol infusion during total intravenous anaesthesia with propofol and sufentanil for gastrectomy of a male patient (77 kg, 47 years). The teletherapeutic system consisted of two computer subsystems at the 'patient-site' in Munich and the 'control-site' in Erlangen. Both computer systems were connected through a virtual private network (VPN) with a high speed terrestrial optical-fibre connection of 100 to 1000 megabits per second. Data were transmitted using the UDP protocol. At the 'patient-site' the patient's EEG (one channel: Fp1-Fz) was recorded with an Aspect A1000 monitor. The raw digitized EEG signal (sampling rate: 128 Hz, resolution: 16 bit) and the processed EEG variables were transferred to the 'patient-site' computer. Every second, a package of 1664 bytes containing the EEG data was sent to the 'control-site' computer, where the EEG was analyzed and the median frequency (MEF) of the EEG power spectrum was calculated from epochs of 8 seconds length. The propofol infusion rate was determined by a model-based adaptive feedback algorithm to achieve and maintain a defined MEF. If the EEG was disturbed by artefacts, propofol was administered as target-controlled infusion (TCI). Every 8 seconds, the propofol delivery rate of the infusion pump was updated by the 'control-site' computer and the actual infusion rate was checked. Additional information e.g. the dosing of the analgesic drug, hemodynamic parameters, the status of the surgery and comments were transferred between the computers as free text in a message box. At any time, the anaesthetist at the 'patient site' was able to stop the remote control of propofol and continue the propofol administration by manual dosing.

Results: The surgery had a duration of 3 h, control of propofol lasted 230 min, and the total amount of propofol was 2362 mg. During induction of anaesthesia and during skin incision, propofol was administered as TCI with target concentrations of 2.0 to 4.5 μ g/ml, subsequently the propofol infusion was EEG-controlled for 100 min with a set point of MEF=2±0.5 Hz. At the end of anaesthesia, propofol was again administered as TCI with decreasing target concentrations. During EEG-controlled closed-loop dosing, the measured MEF was 1.9±0.7 Hz with a median deviation of -10% from the set point. From a total number of 2035 transmitted EEG epochs (16280 packages) there were only 3 epochs with transmission errors. Throughout the entire duration of anaesthesia it was not necessary to switch from automated infusion control to manual dosing.

Conclusions: Monitoring of the EEG effect and teletherapeutic drug administration by online processing of the EEG seems to be possible even over longer distances. Further studies have to investigate the practicability and safety of teletherapeutic drug control in anaesthesia and other fields of drug treatment.

SIMULTANEOUS RECORDING OF AEP, SSEP AND EEG PARAMETERS DURING ANAESTHESIA – A FACTOR ANALYSIS

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Introduction: Spontaneous EEG, mid latency auditory evoked potentials (AEP) and somatosensory evoked potentials (SSEP) have been used for the monitoring of anaesthesia. This poses the question whether EEG, AEP and SSEP are independent signals and whether the addition of AEP and SSEP adds substantial information to EEG monitoring alone.

Methods: After informed written consent and institutional approval 18 surgical patients were included in the study. During the anaesthesia a total of 81 variables (31 EEG, 22 SSEP, 28 AEP) were 'simultaneously' recorded, whereby simultaneous means adjacent in time under stable anaesthetics conditions as defined by a set of further conditions. For signal acquisition a specially adapted four channel electrophysiologic recording system was used (Neuroscreen, Viasys Healthcare, Hoechberg, Germany; EEG "Infinity POD", Siemens, Erlangen, Germany)¹. Each AEP epoch consisted of 1000, each SSEP epoch of 306 stimuli. EEG (i.e. no stimulus), AEP and SSEP stimuli were sequentially applied and evenly distributed. Each modality was measured for 1.7 min. In each patient the order of stimulus modalities was randomly chosen for 9 intervals, these intervals were constantly repeated during anaesthesia. A total of 201 cases of the 81 variables at stable anaesthetic states were recorded. For this data set a factor analysis was performed.

Results: Seventeen variables were excluded because of multicollinearity. For the remaining 64 times 172 matrix we extracted 11 factors with eigenvalues >1 and representing 79.4% of total variance. The first 3 factors represented 13.5%, 13.2% and 13.1% of total variance. Factor 1 had only significant loadings from AEP variables, factor 2 only significant loadings from EEG variables and factor 3 significant loadings from SSEP variables.

Conclusions: EEG, AEP and SSEP measure different aspects of neural processing during anaesthesia. This gives rise to the hypothesis that the simultaneous monitoring of these quantities may add information compared to the monitoring of each quantity alone.

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MAKING EEG SIMULATOR

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1. Introduction

With increasing the requirement to evaluate the hypnotic level of the patient, EEG has become an important vital. We have developed numerical model based EEG simulator which can generate numerical data sets of EEG or analogue voltage EEG waveforms through the digital to analogue converter. Recently developed EEG processing algorithm for derivation of the hypnotic level of anesthesia such as bi-spectral, approximate entropy, spectral and amplitude Shannon entropy, and Lempel-Ziv complexity analysis can be tested in this EEG simulator and their achievement scores in response linearity and sensitivity can be evaluated in model based exact same conditions.

2. Methods

We had used two numerical models, an deterministic model and a stochastic one. In the deterministic one, simple trigonometric values was added as the complete autoregressive data into a random generated noise, and with varying their composition ratio we had different level of randomness. In the stochastic model, the logistic function which bifurcates several times and finally become in a chaotic state was used and each level of bifurcation was used as the complexity level. Bi-spectral, approximate entropy, spectral or amplitude Shannon entropy, and Lempel-Ziv complexity were tested in these models. These EEG indexes were plotted on the percent scale of the control value.

3. Results

In the deterministic autoregressive model, the spectral and amplitude entropy have linear response. The Lempel-Ziv also expressed a linear response under the range of less than 60% of randomness. However, BIS was not responsive in the this model. In the stochastic model, the amplitude entropy and BIS showed better response than others.



Fig. 1 Response profiles in the deterministic model



Fig. 2 Response in the stochastic model.

5. Conclusions

It is concluded that our developed two type of EEG models can be used for the evaluation of various analytical EEG algorithms.

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MYOGENIC REFLEX BASED AUTOREGULATION IN BRAIN ARTERIAL NETWORK. INTEREST OF MODELING.

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Cerebral arterial net models could be schematically classified into two groups :

1. Intracranial hydrodynamic model lead to a study of dynamic interactions between several intracranial compartments, including dynamic feed back controls.

2. Mecanical arterial net model, in order to study flow distribution regarding to vessel compliance. Most of these last models do not include "active"changes of vessel resistance. Auto-regulation is defined as the artery network ability to adapt resistance to blood pressure variations, in order to keep the blood flow constant. A part of this regulation is supported by the myogenic reflex. This basic reflex is an autonomous feedback loop leading arteries to develop their resistance as wall tension increases, using vaso-activity.

The aim of this study is to simulate the behaviour of a vasoreactive arterial tree, and to test its ability to regulate flow distribution.

We used a "finite difference" type of model. For each vessel of a binary tree, intraluminal pressure variations led to volume variations, and to resistance variations. Thus, pressure and resistance evolved in the same way. The model allows to test the behaviour of the net for varying blood pressure and for varying "neuron consumption".

Such a model highlights two main phenomena :

- The modelized myogenic reflex, when applied to each branch of an arterial binary tree, can assume auto regulation and flux distribution.

 A spontaneous feedback loop synchronisation is observed in the arterial net during simulation. This last characteristic of the net behaviour could lead to a better understanding of slow cyclic arterial volume variations.

NON INVASIVE VENTILATION (NIV) WITH HELIOX IN PEDIATRIC BRONCHOSPASM.

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<u>Introduction</u>: Acute severe asthma remains a major economic and health burden.. Mortality in medical intensive care units is higher but is less than 3% of hospital admissions, pediatrics patients seemed to be the major target (1).

<u>Methods</u>: We described the case of a 2year old boy (18kg) admitted for acute distress syndrom with hypercapnic acidosis (ph 7.1). Despite nebulisation of adrenaline (0.02 mg/Kg), intravenous perfusions of salbutanol (1 mg/Kg/h) and hydrocortisone (2mg/Kg) the spasticity continued and the patient dropped unconscious. NIV by BIPAP Vision (Respironix) was applied under intravenous anesthesia with clonidine ($2\mu g/kg$ -titrations doses). After 10 minutes, refractory poor ventilatory performances staid unchanged . Heliox (80%-He+/20%-O2) 6litres per minute was connected to the facial mask until spasticity was ruled out totally (3hours long). Ventilatory flow and airways pressures were measured every 5 minutes evolution's times.

<u>Results:</u> Within 30 minutes the ventilatory parameters normalized (Insp vol >10 ml/kg; Thoracic approach comply <25; Resp.Freq.<16/') and the child recovered consciousness. During this period an estimation of 60% of He(+) reached the patient's bronchopulmonary tract through the ventilatory system after what it's concentration was reduced by the gas dilution resulting in ventilatory volume minute recuperation.

<u>Discussion</u>: The use of NIV is still limited but seems promising to threat asthma decompensation on children (2-3). In order to improve the expiratory flow, He+ which modified the Reynolds number, transforms a turbulent flow into a laminar one and therefore improves the respiratory work as well(4). Based on the results heliox at 60% concentration appears to be effective(5).

<u>Conclusion</u>: NIV combined with heliox improved ventilatory performances by a raise of 50% in ventilatory flow and a drop of 35% in airway pressure. This technique seems conservative and suitable for children during asthma crises. Further investigations is required.

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MANAGEMENT OF THE ACUTE POSTOPERATIVE PAIN CAN BE IMPROVED USING A COMPUTER-BASED SYSTEM

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Introduction: Management of postoperative pain is sub-optimal world-wide. A recent survey showed the incidence of moderate or severe pain after surgery is as high as 34% (1). The absence of clinical data to ensure quality improvement in acute postoperative pain management and the limitation of therapeutic strategies available for acute pain control, are factors which may have contributed to it. We developed a method to record and analyze data obtained in the postoperative period to help clinicians in developing new strategies.

Methods: A PC-based system (Pain Control System) to provide anaesthesiologists and surgeons an easy-to-use decision tool for pain control management was developed. According to the type of surgery and physical status of the patient, a list of prioritized pain treatment options were provided to the medical team.

During the five postoperative days, a pain unit nurse visits postoperated patients and records their pain scores (visual analogical scales (VAS)) from clinical chart. Complications according to the European Minimum Standards for the Management of Postoperative Pain recommendations are also checked (2). The pain control system is a PC-based relational-database, written in Microsoft Access[®] that allows the user to analyze complete records: demographic data, specific pain therapy information, VAS for pain and post-operative complications. Data are linked to Microsoft Excel[®] spread sheet allowing different users full interaction with the database. Visual graphics and statistics for the selected patients are also obtained from the system.

Access to post-operative data with Windows PC's in a Novell-network is accessible from any location within the hospital. This system works as a sequential model. Based on pain scores and medical complications, every two months and according to surgical procedures, therapeutic strategies are updated.

Results: The system has been well accepted; it is easy to use and requires little training. Surgeons and anaesthesiologist have found the clinical content to be reliable and helpful for improving the control of acute pain in our hospital. Standardized therapy features and easy access of collected data have been proven to be popular among physicians. The open design of the application allows continuous treatment optimization. Present patients' experiences in front of postoperative pain, helps clinicians to make decisions.

Conclusions: The pain control system provides a frame for post-operative data collection from which information to support evidence-based practice in acute postoperative pain control is generated. The potential for medical errors in drug prescription is also reduced. Data on pain severity and post-operative complications is collected and analyzed. Therapeutic decisions in selection of analgesics agents, the use of invasive analgesic techniques and the identification of procedures that may require special postoperative care, will be make according to empirical data. With a user-friendly design, data evaluation can be concluded easier and faster, and may lead to an increment in patient satisfaction and a reduction in costs.

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WEB ANESTHESIA ASSESSMENT: THE NEW ERA FOR CLINICAL ASSESSMENT?

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Introduction

In the last two decades, in order to reduce hospital costs (1), great emphasis was focused on preoperative length of staying and cancellation of surgery (2). Different studies demonstrated the fundamental role of a correct clinical anaesthesia assessment prior of surgery. In order to identify any potential medical complication for the scheduled surgery, some hospitals have created preoperative anaesthesia assessment clinics (PAACs), an outpatient setting, where patient's medical conditions are optimized, patients feel well-preparated for their surgery, the anaesthesiologist and surgeon are alerted of any potential complications related to surgery and patients' charts are completed prior to the morning of surgery. In our Institution, almost half of patients live far from our preoperative evaluation centre, that is why we found a new method for preop anaesthesia evaluation that we called web anaesthesia assessment.

Methods

After the neurosurgeon visits the patient is invited to visit the web site of our Institution where there is a full and easy guide with instructions and suggestions that will explain to the patient what kind of exams are necessary for a good preoperative evaluation in order to reduce anaesthesia and surgical risks. After the conclusion of the exams required, the patient can complete the anaesthesia assessment form directly from home or with his own general physician in order to have a final assessment directly from the web. For every kind of neurosurgical procedure the patient will be invited to read some general information that will explain the anaesthetic plan and educate the patient on the expected perioperative events. Informed consent will be obtained the day of surgery when the anaesthesiologist will perform the final check of the exams previously required and will speak with the patient in order to reduce preoperative anxiety. Results

The average weight of D.R.G. of our neurosurgical departments is 2.0. The average preoperative length of staying is 2,1 days with a cost of 235 euros a day for the general expenses and 30 euros a day for the physicians cost. In addition to these costs we estimated a 250 euros adjunctive social cost for the patient (transports, loss of work days). We usually perform 2200 neurosurgical procedures a year, after the application of the web anaesthesia assessment we estimate a reduction of 1 day of preoperative length of staying, so the net amount of expenses reduction will be of 583000 euros per year for the hospital and 27500 euros a year for patients expenses.

Conclusions

Web anaesthesia assessment represents a new method for clinical assessment. The patient is guided step to step in order to complete the anaesthesia evaluation form in a correct way. At the end of the form he/she will have a detailed explanation of the procedure for what he/she is scheduled and of the anaesthetic plan and the perioperative setting. The objective evaluation of the patient is completed with some photos that can be inserted in the form. Next step of our research will be to demonstrate not only a reduction of costs for length of staying in the hospital but a similar or reduced incidence of morbility and mortality.

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RISK MONITORING IN CARDIAC SURGERY

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INTRODUCTION: The aim of this work was to evaluate mortality in cardiac surgery -overall mortality, coronary mortality, and valve surgery mortality-, and to assess and to validate the performance of European System for Cardiac Operative Risk Evaluation or Euroscore to predict this mortality:

METHODS: Prospective observational study of 1241 consecutive cardiac surgery patients in a tertiary referral center operated since January 1, 2000 to December 31, 2003. Clinical and physiologic data for several cardiac surgery risk model were prospectively collected applying the criteria and definitions described by the developers Statistical analyses were performed using SPSS (SPSS 11.0 inc. Chicago IL). Predicted hospital mortality was calculated and was compared with the actual mortality. The performance of the system was assessed by evaluating calibration with the Hosmer-Lemeshow goodness-of-fit test, and discrimination with the area under the receiver operating characteristic (ROC) curve.

RESULTS: The sex ratio was 36.9% women (n = 458) vs 60.6% men (n = 783), and the mean age was 60.6 \pm 14 years. The operation performed were 51.1% (n = 635) coronary surgery, 42.8% (n = 532) valve surgery, and 5.9% (n = 74) mixed (coronary & valve surgery) surgery. The overall hospital mortality was 5.4%. The coronary surgery mortality was 3.6%. The valve surgery mortality was 6.7%. The mixed surgery mortality was 10.8%. Lemeshow-Hosmer chi-square was 5.60 for overall cardiac surgery, 5.11 for coronary surgery, and 5.94 for valve surgery. The area under the ROC curve was 0.817 (CI 95%: 0.765-0.869) for overall cardiac surgery, 0.834 (CI 95%: 0.755-0.913) for coronary surgery, and 0.801 (CI 95%: 0.733-0.869) for valve surgery.

CONCLUSION: In our experience, mortality remains adjust to predictions in every group of pathology. Euroscore performs well to predict mortality following cardiac surgery, with high calibration and discrimination, and it is an appropriate tool to assess this mortality. In our experience, Euroscore performs better in coronary surgery than valve cardiac surgery. Predictive models originally developed in another country should be validated in the population to which they are finally applied.

MORTALITY MONITORING IN INTENSIVE CARE AND ABILITY PREDICTION BY GENERAL SEVERITY SYSTEMS

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INTRODUCTION: Critically ill patients are associated with high mortality, and Intensive Care is a major source of health service expenditure. The aim of this work was the monitoring and assessment of the mortality, and the performance of General Severity Systems (APACHE II, SAPS II, MPM II_{0} , and MPM II_{24}) to predict this mortality.

METHODS: Prospective observational study of 2410 consecutive critically ill patients, admitted to an Intensive Care Unit of a tertiary University Hospital, during a period of 42 months, from January 1, 2000 to June 30, 2004. Clinical and physiologic data for several risk models were prospectively collected applying the criteria and definitions described by the developers. Statistical analyses were performed using SPSS (SPSS 11.0 inc. Chicago IL). Predicted hospital mortality was calculated and compared with the actual mortality. The performance of the systems was assessed by evaluating calibration with the Hosmer-Lemeshow goodness-of-fit test, and discrimination with the area under the receiver operating characteristic (ROC) curve.

RESULTS: Medical and surgical patients were 51.7% (n = 1246) and 48.3% (n = 1164) respectively. The sex ratio was 35.9% women (n = 865) vs 64.1% (n = 1545) men. Mean age was 60.4 ± 17 years. Overall hospital mortality was 21.7% (523 deaths / 2410 patients). From the calibration, Lemeshow-Hosmer chi-square was 9.45 for APACHE II, 6.36 for SAPS II, 8.55 for MPM II₀, and 7.43 for MPM II₂₄. The area under the ROC curve was 0.805 (CI 95%: 0.780-0.829) for APACHE II, 0.838 (CI 95%: 0.815-0.861) for SAPS II, 0.823 (CI 95%: 0.799-0.848) for MPM II₀, and 0.832 (CI 95%: 0.808-0.859) for MPM II₂₄.

CONCLUSIONS: In our experience General Severity Systems perform well to predict mortality in critically ill patients, with good calibration and discrimination (in decreasing order: SAPS II, MPM II24, MPM II0, and APACHE II), and they are appropriate tools to assess the mortality. Predictive models may benefit physicians in risk stratification and therefore may be used to optimize resources. Severity Systems developed in another country should by validated in the population to which they are finally applied.

OPTIMIZATION OF WORKFLOW IN ICU WITH GENERALIZED NET

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Introduction. Every ICU admits critically ill patients with disturbed vitally important functions. Time is a critical factor with such patients and the optimum behaviour of the medical team is decisive. Parallel processes of varying complexity, connected with patient care, are taking place at the ICU. They require optimised distribution of the staff and material resources, hence an adequate model of the structure and activities in an ICU is needed. Such a model was built using *generalized nets (GNs)*.

Methods. GNs are extensions of the Petri nets and their other modifications. They, similar to the other Petri nets, have static structure and dynamic elements (tokens), but they have some specific components: (1) matrices associated with the separate transitions, with elements-predicates that determine the directions of the tokens' transfer and representing the logical conditions that determine the development of the modelled process. (2) GN-tokens obtain initial, current and final characteristics containing the analytical description of the information on the real processes. (3) Different time-components representing initial and final moments of the GN-functioning, elementary time-step of the time-scale used; initial moment of the modelled events' realisation and duration of their realisation.

Results. The workflow presented as a GN-model is based on principles and prerequisites typical of ICU. *Principles*: (1) the incoming patients are with different degrees of disorder of one or several vital functions; (2) the principal vital functions are ranked in terms of their weight. From these principles priorities in patient care are identified. *Prerequisites:* (1) the physicians and the nurses in the unit have a certain qualification; (2) at any moment in time they have a certain workload (commitments for the care for concrete patients); (3) there is a fixed capacity of the material facilities at the ICU; (4) there exists a formalised hierarchy in the medical team in the decision-making on patient care. *Structure of the information included in the model*: the updated information on the state of the ICU (occupancy rate of the hospital beds, the state of the patients, the available physicians and nurses, and their distribution for the concrete patients, available material facilities) is supported by specialised databases. There also exists a database of protocols with prescriptions for diagnostic and therapeutic conduct. *The goal attained with GN is*: (1) optimised solution for the admission and servicing of patients at the ICU in a dynamically changing situation at any moment of the night and day; (2) determination of the potential risk to the patient if a compromise is allowed in patient care. A risk may arise at a critical workload for the staff and for the material facilities at the ICU and inability to provide optimum care.

Conclusions. The dynamic workflow model in ICU in the form of a generalized net is an adequate approach for optimum distribution of the resources and optimum conduct in the care for patients with severe disorders of the vital functions.

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10 YEARS WITH PATIENT INFORMATION MANAGEMENT SYSTEM : THE USERS' SURVEY.

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Introduction:

The implementation of the Patient Information Management System (PIMS) seems to be the most radical change to a running intensive care unit. At the ICU of Uddevalla Hospital the PIMS "Deio for Critical Care (TM)" was completely implemented, after two introductory years, in 1994. The system runs supports 18 workstations. The monitoring equipment and pulmonary ventilators are fully interfaced to the system at 10 beds.

The system is interfaced with the hospital's central laboratory and its communication with the X-ray department is under development. The system provides, among other features, the graphical presentation of physiological trends, automatic generation of nursing task lists, and certain extent of decision support.

Method:

The study was performed in the spring of 2003. 60 members of the staff, representing all four staff categories: doctors, nurses, sisters, and medical secretaries, were presented with a questionnaire consisting of 32 questions. The main inclusion criterion was previous experience with traditional, paper-based ICU documentation.

Results:

49 persons returned questionnaires (82% response frequency). 51% of respondents used the PIMS for 10 years, 27% more than 10 years, and 12% less than 5 years. 34 persons (69%) reported no previous computer experience.

94% of respondents reported no undue physical or psychological effects of the work in a computerised environment. 63% and 79%, respectively, expressed the opinion that the admission and discharge of a patient takes longer time with than without PIMS, while 57% stated that the running documentation of patient status was less time consuming than the manual recording. 79% considered PIMS a factor improving patient safety. None of respondents expressed willingness to return to the traditional documentation.

Conclusions:

Staff in general appreciated the automatic collection and display of data from physiological monitors and pulmonary ventilators as labour saving, thus allowing more time for direct patient care. The unequivocal doctors' orders, checked by the system, were perceived as reliable and saving time. Many respondents would like to see better support for admission and discharge routines as well as improved artefact filtering.

USE OF PHYSIOLOGICAL MODELS IN SELECTING VENTILATOR SETTINGS

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Several systems have been developed to aid in the process of selecting appropriate ventilator settings in mechanically ventilated patients. Those finding their way into clinical practice have focused using rules to automate clinical protocols for particular ventilator modes [1], or to keep the patient within a "zone of comfort" during pressure support ventilation [2]. Key to these rule-based systems is that they automate the heuristics of the clinician, controlling patient ventilation without providing a deep physiological picture of the patient's state.

This presentation describes a different approach to computer support for selecting optimal ventilator settings. A decision support system will be presented which is based on physiological models of O_2 transport CO_2 transport and lung mechanics combined with utility functions describing clinical preference toward the outcomes of changing ventilator settings. If the physiological models are tuned to a particular patient, by estimating the parameters, they might be used to simulate "what if" questions predicting the outcomes of ventilation strategies. In addition, when physiological models are combined with the utility functions outcomes can be quantified and ventilator settings selected so as to maximize expected utility.

Currently the system has been tested retrospectively using the data of 19 stable post-operative CABG patients studied at the ICU. Values of ventilation, arterial and mixed venous blood gases, and cardiac output were measured and computer generated settings for FiO2, Vt and f were compared to those used in the clinic by thoracic anaesthesiologist. In general the system suggested ventilator settings similar to those of the clinician.

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APPLICATION OF WEB-BASED TECHNOLOGY FOR REAL-TIME REMOTE MONITORING DURING ANAESTHESIA

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Commercial applications have been developed which enable real-time monitoring of anaesthesia using the Internet for data transmission. One such application, developed by Datex-Ohmeda, has been evaluated in our department. A demonstration is presented, accompanied by a detailed explanation.

The system comprises two components: a server used to transmit the data, and a proprietary Java application that resides on the user's computer and works in conjunction with the user's web browser to display the data in graphical and table form. The server connects to both the Datex anaesthesia network and the local hospital network, and transmits the information available on the anaesthesia monitor across the hospital LAN and the Internet. More than one user can review the monitored locations at one time, depending on licensing and any one of a number of monitors on the local anaesthesia network can be reviewed in detail.

Information available includes alarm information and trend data in either graphical or numerical form. In the patient view, up to 6 waveforms can be displayed at a time. A nice feature is the ability to read numeric data from the graphical display, via the use of a cursor line. The waveforms can be frozen on the remote display in order to review them more closely. Finally, there is provision for printing a copy of the patient view or the numeric trends.

The security model achieves patient confidentiality:

- Java technology is used, providing its own inbuilt sandbox security model for Internet applications.

- A proprietary application must be loaded on the remote computer before the standard web browsers are able to log in the system remotely.

- Each user is prompted for a username and password before access is enabled.

THE ROLE OF NETWORK ADMINISTRATOR IN ICU

VINCENZO LANZA

A computer network can improve the work flow of an ICU making it easier to share data with colleagues and also with remote partners. The economical investment required is very small: actually every ICU has got personal computers available to get connected to the Internet. It can be easy to install a small server to offer an intranet service to share updated information on-the-fly. More than this, the full project can be realized using Open Source low cost solutions.

Introduction

Since the beginning of the last decade, monitors and ventilators where equipped with a serial port, by which the ICU administrator was able to get an electrical signal and record it or convert it a digital signal to process it, print it and store it. Nowadays monitors, ventilators and other ICU typical equipments are now driven by a Personal Computer; that is, the device itself it is made of a PC that usually loads a common Operative System (OS), like Microsoft Windows or Linux to control it. The PC works as a black-box, the user doesn't have to know how it works, but just switch it on. This methodology is due to the low cost of PC parts on the contrary of proprietary hardware developed especially for just one tool. The developer of the equipment has got only to write the software to drive the whole machine.

The ICU administrator can gain many advantages from this, actually he can connect the equipment to the network and check it or maintain it from a remote console. This way of managing is very common with modern monitors, but it can introduce new menace to system security and privacy.

The availability of a computer network can help in making a simple intranet service to offer advanced services as e-learning and distributed healthcare and medical information system.

The main role of the system administrator of a ICU is to decide the policy of acting inside of the department itself: what kind of services are available to the users inside of the department (e-mail, Web access, FTP, advanced services developed on-site, etc.)? What services are available to users outside of the department? Are there distant formation systems or cooperative tools available to the users?

This policy affects the configuration of the whole computer and network infrastructure. Following, we will discuss how to plan the policy and what are the tools available to the system administrator to improve the security and how to offer advanced network services with a very small economical investment.

Network administration policy

The duty of system administrator starts with the assignation of accounts (login and password) that have to be checked frequently to be sure of their validity and to ensure that the user changes his password often. The system administrator has got to define working groups to share documents in the file system without compromising privacy policy.

Security is an hot topic due to serious pirate attack menace: attacks can be moved in several ways, using other software to steal password and information or causing denial of service attacks (DOS) which are intended to forbid the use of a system or a service. The administrator can use other softwares, like antivirus and spyware-detector to prevent attacks. The installation of a protecting software isn't enough by itself, in fact the administrator has got to keep it updated. An old virus definition list can compromise the protection of a whole network: modern virus knows how to disable anti-viral software, so it is important to be sure of protection since the boot of the PC.

The administrator can use automated tasks to update the files automatically on each computer everyday or every hour.

Antivirus is a local solution to be adopted to avoid DOS attack, but in a network there are more risks to become by yourself the aim on an attack; there are other tools available to protect the network like

"firewalls" and "Intrusion Detection Systems". A firewall is a device (hardware and/or software) that can prevent undesired access from the outside. This task is performed analyzing the datagram stream, that is the stream of data flowing between computers. The administrator must choose services available on the Internet for the LAN users and intranet services available outside of the LAN. It is common to offer the LAN's users Web and e-mail access, forbidding the other services to reduce the risk of attack from the outside.

An IDS is a software that can analyze the data traffic on the network, on this basis, it can discover menace or attack attempts and talk to the firewall to strength the defence.

Computers on the Internet share information using a common protocol (a set of rules that allows the orderly exchange of information) known as TCP/IP. It is very simple and it is based on four layers of abstraction: (1) Network Access, (2) Internet, (3) Transport and (4) Application. Every host has got at least one unique IP address that allows it's recognition on the network. To run different applications (layer 4) that use the network at the same time it as been introduced the concept of logical ports: these are kind of channels that can be used by different software to talk at the same host at the same time.

The system administrator chooses what kind of services to make available the closing and the opening of logical ports. The wise administrator knows that the golden rule is to close every port that isn't necessary, but the real risk is to build a network where no service is available.

Advanced services and Open Source solutions

The administration of a network (whether small or at enterprise level) can be done using Open Source software, that is software developed by the scientific community for the scientific community. The key word is just making the source available to the whole community of developers to share the knowledge: this means more quality (everybody can improve the project), less risk of virus infection or of attack using software unknown bugs (everybody can read the code), less investment in licensees.

The most used solution for building firewall and IDS are IPTABLES, which is part of the "netfilter" project and SNORT. Netfilter is implemented at the kernel level of Linux itself, so if you install this OS with the network extensions, you have got the firewall ready to work too. The setup of IPTABLES may require some more technical skills, but the configuration of every firewall system could require the consultancy of a pro.

More than this, the administrator of a ICU network can offer advanced services to his colleagues, just building a small intranet. The basis can start from implementing a small web server running Apache (the most used web server on the Internet, another Open Source project). It can run whether on Microsoft Windows or on Linux platforms, so the administrator has to choose the one that make him feel more comfortable. The second step could be the implementation of advanced services, like distance learning services, for remote colleagues, or dynamic web sites to use as distributed healthcare and medical information system. The most diffused and simple way to build a dynamic web site or intranet is to use the LAMP platform.

LAMP is the acronym for Linux, Apache, MySQL and PHP: all Open Source solutions. Linux and Apache are the most known Open Source projects, so following we will describe the other two: MySQL is a relational database system (RDBMS: Relational Database Management System) known to be the fastest web oriented database, while PHP is a script language used to interface Apache, the web server, with the RDBMS.

The use of the LAMP platform requires just a few programmer's skill, but if you are not interested in programming you can look for a ready to use Open Source project and look for a professional that will install, make it work and customize for you. That will represent a start-up cost that will not be present anymore, in fact there will be no license fees at all.

Conclusions

The role of a system/network administrator is really tactful, actually it requires a lot of good sense to prevent attacks from the outside and to protect the privacy of ICU patients, but also there is a lot of hard decisions to take to make the network itself works. The use of Open Source solutions can improve the work flow of the whole department and reduce considerably the start-up and the management cost of software used.

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NATIONWIDE DATA COLLECTION USING INTERNET

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Summary:

Background:

Nowadays the Web based data collection systems are using in every day routine. Changing of our previous off-line nationwide data collection program was necessary and the project support from Ministry of Informatics and Communications allowed of it.

Objectives:

Use the resources of previously developed ANESZTINFO Web system and establish the yearly nationwide data collection system.

Methods:

Application and installation of ASP.NET technology background with high security level (SSL). We established a Web page for every department and an analysing surface also. It is mean more than 130 departments. We used the international and national coding systems.

Results:

We achieved and harmonised the system with national representatives of Anaesthesia and Critical Care. Departments accepted the new system. We elevated the digital literacy in Anaesthesiology and Critical Care in our Country.

Conclusions:

We collected the data of 2003rd year with the new and finalised program. After closing the project we organised an evaluation meeting and we accepted all remarks and suggestions from users. Finally we would like to organise an expert group for extending our experiences to European dimension via working on IST EU project.

ISO 9001: 2000 CERTIFICATION IN CARE DOMAIN ; CONTRIBUTION OF A TOTAL PATIENT BEDSIDE COMPUTERIZATION

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The Lagny Marne La Vallée Hospital intensive care unit is certified ISO 9001: 2000 by AFAQ[®], since 2003 October for its quality management system (QMS), which scope is "Provision of services for all technical, relational an hygiene care domain" (1).

To date, it's the one and only care unit certified ISO 9001: 2000 in France for this scope (2), and among a few ones in the world (3,4,5).

Our QMS has demonstrated improvement about quality care and security, notably nosocomial infectious deseases, organization and efficacy with decreased resources consumption, and measured satisfaction of the patients and their family; as, all around the world, certified ISO QMS in industry, trade and services.

The contribution of a total bedside computerization (Philips Carevue[®]) probably has been a determining factor in this success, however our QMS has been designed and was working with "paper".

We have rocked in totality the entire patient documentary in just the once, and since august 2002, without any failure; "the unit don't produce any paper" (AFAQ[®]).

The need of this equipment type has been evaluated and decided according to our organization strategy: -First: the better working environment:

Everywhere everything identical for bedside machines and space organization, available care procedures, drugs concentrations and solutions use.

To restrict the unexpected only to the patient's condition and maximise security.

-Second: saving nurses and physicians time:

With RS 232 connections for every machine, to record any data automatically.

Writing absolutely any act executed but nether the same recording twice.

-Third: total legislation respect in all fields:

Physicians prescriptions, "recording, tracability and follow up of act executed" (AFAQ[®]).

- Fourth: "anything for care and patient".

The result is according to our wishes:

- Total legislation respect

- Improvement of security "with many improvements since the setting up of the system" (AFAQ[®]) in the entire care domain.

- "Better responsibilities control and recording" (AFAQ[®]).

-" Error input decrease" (AFAQ[®]).

- Saved time according to nurses and physicians.

- Quality documentary control.

Since its installation, we have improved our recording data system, so much that now computerization is in dissociable of our QMS, reported by AFAQ[®] as "extraordinary for its wholly integration in the real and daily working of this unit".

AFAQ; Rapport d'audit initial No QUAL/2003/21095.

L'unité de réanimation du Centre Hospitalier de Lagny Marne la Vallée : premier service de soins français certifié ISO 9001 : 2000 ; in Quali Actu Santé, colloque ANAES dpe, « 2 ème accréditation- vers l'évaluation de la qualité du service médical rendu au patient » 11- 12- 2003.

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Workshop sponsored by Philips

SERVEUR D'APPLICATIONS INTELLIVUE PHILIPS

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I. INTRODUCTION

Le but de ce document est de présenter le Serveur d'Application Intellivue Philips. La première partie de ce document montrera l'évolution de l'architecture informatique distribuée depuis les mainframes jusqu'à l'architecture client légers ou clients fins actuelle.

Ensuite, l'architecture clients légers ou serveur centralisé et ses avantages seront clairement présentés. On présentera ensuite l'intégration de cette technologie client léger dans le moniteur Intellivue et ses avantages.

I.1 Contexte informatique général

Les premiers systèmes informatiques étaient volumineux, bruyants et chauffants. Pour gérer ces inconvénients, ils étaient installés dans des pièces dédiées, et les utilisateurs travaillaient sur des consoles. Avec ces systèmes, dit « mini-informatique », les ressources et les données étaient donc centralisées.

Cette première étape s'est achevée à l'avènement de la « micro-informatique » : Grâce à la miniaturisation et la baisse des coûts, la diffusion des ordinateurs de bureau et des portables a véritablement explosé, aboutissant à la démocratisation de l'informatique que nous connaissons aujourd'hui. La conséquence en a été la localisation au niveau de chaque machine de la puissance de calcul, des données et des applications. En complément, la mise en place des réseaux, ressources partagées (imprimantes etc...) et serveurs permet l'échange d'informations et d'applications.

Cette seconde étape atteint aujourd'hui ses limites, en particulier dans le milieu industriel : Les entreprises sont confrontées à des problèmes d'infrastructure majeurs. En effet, elles mettent maintenant en œuvre des parcs importants de micro-ordinateurs, et doivent assumer la gestion de ces parcs, le plus souvent très hétérogènes pour ce qui est de la génération des ordinateurs et des systèmes d'exploitations et pour ce qui est des applications. Les coûts de maintenance ont donc augmenté de façon exponentielle. Par ailleurs, on constate que la capacité des micro-ordinateurs est souvent surdimensionnée pour la plupart des postes, dont la fonction est essentiellement dédiée à la bureautique et à la messagerie.

Concrètement, les responsables informatiques se retrouvent donc face à des difficultés de deux ordres :

- Disposer de suffisamment de ressources pour, par exemple, assurer la mise à jour d'un logiciel sur plusieurs centaines de micro-ordinateurs, l'uniformisation d'une base de données, ou l'installation et la gestion des périphériques. Comme ce n'est le plus souvent pas le cas, ces responsables se heurtent à l'incompréhension et la critique des utilisateurs finaux.
- Assurer l'uniformité de l'outil de travail de l'entreprise, c'est à dire faire en sorte que tout le monde dispose au même instant des mêmes données, du même niveau de performance, des mêmes versions des applications etc..., le tout en adéquation avec les besoins réels des utilisateurs.

On peut donc dire qu'aujourd'hui, les infrastructures informatiques croulent sous leur propre poids.

Pour répondre à ces problèmes, l'informatique aborde une troisième étape de l'histoire : l'ère des clients légers. D'une certaine façon, il s'agit d'un retour à l'architecture des débuts : puissance de calcul, logiciels et données se trouvent sur une machine centralisée (serveur) et l'utilisateur y accède depuis un poste simple (client léger).

L'infrastructure est donc la suivante : On conserve uniquement les clients « lourds » là où c'est justifié, par exemple par un besoin de performance (traitement d'images...) et on travaille pour le reste avec des

clients « légers », c'est à dire des ordinateurs, portables, tablettes ou autres, où se trouve uniquement une configuration simple, dont la fonction essentielle est d'assurer la communication avec le serveur, où se trouvent ressources, applications et données.

Tel M. Jourdain faisant de la prose, tout le monde utilise un client léger sans forcément le savoir. Par exemple lors d'une recherche Medline : la base de données et les outils de recherche se trouvent sur de gros serveurs et le médecin utilise comme client le navigateur Internet de son ordinateur. Il bénéficie ainsi de la performance de cette base de données mondiale, sans installation lourde sur son propre poste. De l'autre coté, les administrateurs de Medline ne se préoccupent que de leurs serveurs et de la base de données, sans avoir à gérer les milliers d'ordinateurs qui l'utilisent chaque jour.

C'est toute la philosophie de l'infrastructure client léger : Mettre à la disposition des utilisateurs ces terminaux peu coûteux et peu ou pas exigeants en termes de maintenance et de mise à jour et se concentrer sur la bonne administration des serveurs.

Pour le responsable informatique, c'est une économie significative de moyens. Pour l'utilisateur final, c'est l'assurance de disposer de ressources adaptées et surtout d'une information mise à jour et uniformisée, puisque on utilise les ressources du même serveur. Tout le monde boit à la même source.

Ces considérations expliquent l'explosion de ces technologies dans l'industrie, les structures de santé ne faisant bien sûr pas exception à la règle.

C'est donc dans ce contexte global et actuel que Philips Systèmes Médicaux offre aujourd'hui d'ajouter au moniteur de surveillance, plate-forme classiquement présente au chevet de chaque patient, les fonctionnalités permettant de l'utiliser comme client léger du système d'informations hospitalier.

I.2 Architecture serveur centralisé et ses avantages

Le modèle serveur centralisé s'appuie sur trois composants essentiels.

Il s'agit tout d'abord du système d'exploitation multi-utilisateurs qui permet aux utilisateurs de se connecter en même temps et d'exécuter des applications sur un serveur dans des sessions indépendantes et protégées. Dans ce modèle , les applications auxquelles accède l'utilisateur final sont donc exécutées sur le serveur et non pas sur le PC de cet utilisateur. C'est Microsoft Windows 2000 Server qui est utilisé sur le serveur d'applications Intellivue Philips.

Le modèle serveur centralisé requiert également un protocole capable de séparer la logique d'une application de son interface utilisateur. Ne transitent alors sur le réseau que les frappes clavier, clics souris et différentiels d'affichage écran. Les performances de l'application ne dépendent donc plus de la bande passante.

ICA de Citrix , RDP de Microsoft sont des exemples de protocoles de présentation à distance d'application.

ICA est le protocole retenu par Philips dans les moniteurs Intellivue pour accéder aux applications servies par le serveur d'applications Intellivue Philips.



Le troisième composant est une gestion centralisée des applications et des clients qui permet aux entreprises d'éviter les problèmes de gestion, d'accès, de performance et de sécurité habituellement liés au déploiement des applications vitales.

Cette gestion est assurée par Citrix Metaframe XP dans le cas du serveur d'applications Intellivue Philips.

Les avantages de cette architecture sont multiples :

- Le protocole ICA étant disponibles pour de multiples plates-formes et de multiples systèmes d'exploitation (PC Windows ou DOS,Unix,Java,Palm, ...), une même application Windows peut être distribuée à travers un ensemble hétérogènes de postes clients (PC,Mac,terminaux Windows, Unix, MS-Dos ...)
- Gestion centralisée des applications : la mise à niveau d'une application nécessite la seule mise à niveau du serveur et non pas de dizaines de postes clients
- Développement d'applications à moindre coûts et rapide
- Gestions des applications et des utilisateurs centralisée
- Coûts de possession prévisible, gestion des licences centralisée

I.3 Intellivue et la technologie client léger

Philips a utilisé cette technologie client léger dans ses moniteurs Intellivue (option Portal) et a développé en collaboration avec Citrix une version embarquée du protocole ICA.

Cette fonctionnalité permet à l'utilisateur , via le serveur d'applications Intellivue , d'ouvrir une fenêtre d'application directement sur le moniteur.

Ces applications peuvent être de divers types (application Windows « classique », navigateur Internet, émulateur de terminal).

Les utilisateurs (médecins, infirmières ...) peuvent donc accéder directement à l'information du patient (résultats de laboratoires, imagerie, bilans ...) et ceci au chevet du patient.



L'accès à cette fenêtre d'application est rendue possible grâce au serveur d'applications Intellivue qui va servir de passerelle entre le réseau de moniteurs Intellivue et les différents serveurs de l'hôpital (laboratoires, web, imagerie ...).



Afin de contrôler le flux de données transmises par les applications sur le réseau clinique Intellivue, le serveur d'applications Intellivue fait appel à la technologie propriétaire TCE (Tunneling Control Engine). La technologie TCE protège ainsi le flux des données de monitorage essentielles et garantit qu'il n'y a pas d'interférence avec le monitorage de vigilance.

Le serveur d'applications Intellivue autorise l'accès simultané de 25 utilisateurs maximum.