Faculty of Medicine and Health Sciences
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Learning Manual Skills in Anaesthesiology and Aspects of Risk Management

Thesis submitted to fulfil the requirements for achievement of the grade of Doctor in Medical Sciences

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Guido Schüpfer
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Chapter 1: Introduction

Designing the problem: Why are learning curves necessary to monitor manual skills?

The assessment of clinical competence is one of the greatest challenges facing medicine today. Training of residents in anaesthesiology according to today’s exacting standards is a complex task. Teaching and mastering practical procedures constitute major challenges in anaesthesiology and are important parts of the process for achieving clinical competence. Common sense suggests that not all trainees will be equally good at learning practical procedures.

It is obvious that manual skills are an important aspect of all complex clinical tasks carried out by an anaesthesiologist. The manual skills of anaesthesiologists are routinely employed in two areas: airway management and regional anaesthesia techniques. A learning curve is always associated with the development of new skills. Trainees need different periods of time for learning. Initial rapid success is not always obvious. A significant number of cases or procedures may need to be completed before sufficient competence has been achieved. Patient satisfaction, a growing demand for cost-effective anaesthesia, and a favourable postoperative recovery profile have resulted in the growing demand for regional anaesthesia. However, it has already been shown that some current forms of teaching of regional anaesthesia may be inefficient.

A structured regional anaesthesia rotation schedule, a dedicated team of mentors with sufficient training in regional anaesthesia and adequate clinical caseload are prerequisites for adequate training. Obviously, many anaesthesia residency-training programs cannot meet these requirements. If the demand for regional anaesthesia continues to increase in coming years, it is imperative to ensure adequate education of graduating residents in order to meet this demand. To establish the minimal caseload necessary for an adequate success rate in performing regional anaesthesia blocks, institutional and individual learning curves are a relevant tool. The mastering of different manual skills will always be an important issue for the anaesthesiologist.

Risks are inherent problems of introducing new techniques into the practice of individual, but also for institutions involved in the teaching process. Therefore not only the gain of a skill or competence has to be monitored, but also possible intrinsic risk for complications has to be addressed by an adequate supervising system. Such a monitoring process has to cover individual and institutional aspects.
In the first part, the thesis tries to answer questions about individual and institutional learning curves. The thesis covers different manual skills important for the practice of anaesthesia such as regional anaesthesia and airway management techniques.

Also the minimal case load necessary to gain competency in the skills assessed is defined. The second part of the thesis focuses on some aspects of risk management, because there is a strong link between learning new skills and the risks for individual or even an institution. Statistical tools to assess and to monitor risks are shown and discussed.
Chapter 2: Methods

The thesis is comprised of two parts: construction of learning curves for manual skills in anaesthesiology and risk assessment associated with such learning processes. Therefore this chapter and the consecutive sections are subdivided into two parts.

2.1. How to generate learning curves in clinical practice

Several methods have been developed to measure competence during training, including assessment of cognitive knowledge, judgement, communicative skills, and adaptability by means of written and oral examinations. However, resident aptitudes for procedural skills are not quantified routinely. As a consequence, it is not clear how and when residents achieve their level of proficiency. Although instructors easily recognise residents who have extreme difficulties as well as those trainees performing the procedures outstandingly, less obvious performance levels may not be recognised. An easily obtainable quantitative measure of performance would help to evaluate the residents’ performance objectively, and thus contribute to better training. Every learning process is a multidimensional function with a wide intra- and inter-individual scatter in performance levels, and is influenced by institutional factors. [1, 3] As previously mentioned, a key consideration when learning a new skill is the concept of the learning curve. Such curves can be constructed by using different techniques (see Table 1 for an overview):


b) 'Cusum' technique e.g. [12]

c) Learning Curves with confidence intervals
Table 1: Comparative table of the three methods for learning curve generation

<table>
<thead>
<tr>
<th></th>
<th>Graphical method</th>
<th>Cumulative Summation technique (‘Cusum’)</th>
<th>Learning Curves with confidence interval</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Advantages</strong></td>
<td>• Simple method</td>
<td>• Easy to interpret</td>
<td>• Confidence intervals are shown</td>
</tr>
<tr>
<td></td>
<td>• Easy to perform</td>
<td>• Didactic graphs</td>
<td>• Definition of minimal case load for given procedure is possible</td>
</tr>
<tr>
<td></td>
<td>• No calculations or statistical assumptions necessary</td>
<td>• Values for the graph are easy to calculate (e.g. spreadsheet program like Excel)</td>
<td>with mean value of necessary attempts and confidence intervals</td>
</tr>
<tr>
<td></td>
<td>• Representation of cumulative failure is simple</td>
<td></td>
<td>• No assumptions for calculations necessary (bootstrapping of data)</td>
</tr>
<tr>
<td><strong>Disadvantages</strong></td>
<td>• Learning phenomena are not evident in a later phase of observation</td>
<td>• Sequential statistical analyses</td>
<td>• Elaborate computing necessary</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Definition of acceptable and unacceptable failure rates in advance necessary</td>
<td></td>
</tr>
<tr>
<td><strong>Remarks</strong></td>
<td>• Old method</td>
<td>• Statistical method developed during World War II</td>
<td>• Contemporary, software provides data immediately</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• For numbers expanding ad infinitum</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Defines the boundaries of the quality envelope (acceptable performance, stopping rule)</td>
<td></td>
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<td></td>
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<td></td>
<td></td>
</tr>
</tbody>
</table>
2.1.1. Graphical Methods: Representation of Cumulative Failure

The performance data is presented in a graph as with the example used by de Leval.[5] The graph shows the number of cumulative failures on the vertical (y) axis versus the number of attempts on the horizontal axis. Thus, a zero failure rate would result in a horizontal line, but a 100% failure rate would result in a 45 degree line through the axis. As the cumulative failure count can never decline, the graph will rise inexorably. This method also provides simple information about approximate success or failure rates at defined procedure numbers such as 10, 50 or 100. But such a graph cannot show the improvement of the performance to an acceptable standard. This is a weakness of this technique for long-term performance monitoring. The method of Lawler et al[9] using a simple graphical method for detecting the number of success and failure on a sequential basis, does not allow further statistical analyses. Kopacz et al. modified the method by using the pooled cumulative success rate at groups of 5 attempts.[13] In summary, all those graphical methods are quite general and rather simple (see also Graph 1).

2.1.2. Cumulative Summation (Cusum) technique (see also Graph 1, Tables 1 - 3)[14, 15]

Cumulative Summation (Cusum) technique is a statistical method that can be transferred from use in industrial or management processes into medicine (and anaesthesiology).[12, 15-18] Cumulative sum (Cusum) analysis is a statistical and graphical tool that examines trends for sequential events over time. It has been used to determine proficiency in technical procedures. Training programs could use Cusum to track the progress of their residents' technical skills in order to guarantee an adequate experience. Cusum analysis can greatly assist instructors in their assessment of the competence of trainees. However, the instructor has to define the parameters on which the Cusum calculations will be based, and ideally this should include valid results from procedures that are the subject of prospective data collection (see table 2 and 3). The instructor has to determine a failure rate that is acceptable or unacceptable for the procedure in question and he also has to determine the probability of false-positive and false-negative errors that is acceptable. The cost of unnecessary retraining efforts (type 1 error) compared with the cost of adverse events (failures) should be calculated with input from actuaries, indemnity organisations and risk managers. A false positive (or type 1) error for failure would lead to the conclusion that the trainee's performance is inadequate when it is not. A false negative (or type 2) error would lead to the conclusion that the trainee successfully completing technical procedures when he is not. The relative cost of either intervention to retrain the trainee or the cost of allowing the trainee to remain technically inadequate will influence the instructor's definition of the limits to activate a stopping rule. There is no interest in detecting performances that are more than acceptable. Acceptable performance should reflect the performance of trained and
experienced operators. The Cusum technique could also be used as a personal self-assessment tool. Some practical issues influence the establishment of unacceptable failure rates for the Cusum method. The probabilities of the type I and II errors and the difference between acceptable and unacceptable failure rates are major determinants of the adequate sample size and the angle of the upward inclination of the Cusum curve at each failure. It has been recommended that for a given size of $\alpha$ and $\beta$, the difference between $p_0$ and $p_1$ should be adjusted to keep the angle of ascent of the Cusum line below 60°. Otherwise, when each failure causes a steep ascent of the Cusum line, it will tend to cross the upper decision limit, even in the presence of an acceptable cumulative failure rate ($\leq p_0$). In contrast, a long run of successful procedures will be required after a few failures for the Cusum line to return to baseline or to cross the lower decision limit ($h_0$), artificially distorting the learning curve. It is also desirable to keep the average number of procedures low to detect failure rates corresponding to $p_0$ and $p_1$ so that corrective measures can be taken at relatively short intervals.

The Cusum method consists of relatively simple calculations that can be easily performed on an electronic spreadsheet (e.g. Microsoft Excel, see also table 2; necessary variables for Cusum calculation, see table 3 for an example of necessary assumptions for the Cusum calculation). Statistical inference can be made from the observed successes and failures. The method also provides both numerical and graphical representation of the learning process (see graph 1; panels I - III). When applying the method for the construction of learning curves, variables of success must be clearly defined and represented by a binary variable.[12, 16, 18]
Table 2: Calculation of Cusum [12, 18]

Symbols used in formulae

- $p_0$: acceptable failure rate
- $p_1$: unacceptable failure rate
- $\alpha$: Type 1 failure rate (The probability of wrongly accusing a trainee of unacceptable performance)
- $\beta$: Type 2 failure rate (The probability of wrongly certifying a trainee’s performance to be acceptable)
- $\ln$: natural log value ($\log_e$)

Cusum graph formulae

- $h_0$: “Nullhypothesis”
  \[ h_0 = -\frac{b}{P+Q} \]
  Defines the spacing between unacceptable boundary lines on a Cusum graph
- $h_1$: Alternative hypothesis
  \[ h_1 = \frac{a}{P+Q} \]
  Defines the spacing between acceptable boundary lines on a Cusum graph

Note: If $\alpha = \beta$ and $h_0 = h_1$, the spacing between both sets of lines is equal.

Intermediate values

- $a = \ln\left(\frac{1-\beta}{\alpha}\right)$
- $b = \ln\left(\frac{1-\alpha}{\beta}\right)$
- $P = \ln\left(\frac{p_1}{p_0}\right)$
- $Q = \ln\left(\frac{1-p_0}{1-p_1}\right)$
- $s = \frac{Q}{P+Q}$

“s” is the decrease with each success on a Cusum plot, while the increase with each failure is $1-s$

(see also graph 1 panel I – III)
Table 3: Assumptions necessary for Calculation of Cusum

<table>
<thead>
<tr>
<th>Assumption</th>
<th>Acceptable failures rates</th>
<th>Unacceptable failure rate</th>
<th>s</th>
<th>h₀, h₁</th>
</tr>
</thead>
<tbody>
<tr>
<td>Obstetric extradurals</td>
<td>5%</td>
<td>10%</td>
<td>0.07</td>
<td>2.94</td>
</tr>
<tr>
<td>Spinal Anesthesia</td>
<td>10%</td>
<td>20%</td>
<td>0.14</td>
<td>2.71</td>
</tr>
<tr>
<td>Central venous Cannulation</td>
<td>5%</td>
<td>15%</td>
<td>0.09</td>
<td>1.81</td>
</tr>
<tr>
<td>Arterial Cannulation</td>
<td>20%</td>
<td>40%</td>
<td>0.29</td>
<td>2.224</td>
</tr>
</tbody>
</table>

Example for necessary assumptions for the calculation of the Cusum statistic (example from the original publication of Kestin)[11]

**Graph 1:** A cumulative failure graph vs. a CUSUM plot for assessment of trainees (Panel I-III)
The differences between the two techniques (cumulative failure graph and CUSUM Plot) are shown (see text for explanation). Adopted from [12, 18]

**Panel I**

**Assessment of trainee competence in new procedures: Cusum technique I**

A cumulative failure graph demonstrating performance of over 200 attempts at a procedure. A set of dotted lines denotes the tendency towards a boundary line, but to a lower standard of proof (alpha and beta set at 0.2 in this example)

Cusum format:
Failed attempts at the procedure are indicated by the upward deviations of the plot. The overall failure rate was 2%. Type 1 and type 2 error rates were set at 0.1 to simplify the graph by making the spacing between acceptable and unacceptable boundaries identical. Competence is demonstrated by the fact that the Cusum plot spans four acceptable boundaries (in the downwards direction) but does not span any boundary lines in the upward directions
Assessment of trainee competence in new procedures: Cusum technique II

Learning Curve in the Cumulative failure format:
Note that the performance improvement to an acceptable standard is by no means obvious in this format, demonstrating the weakness of this technique for long-term performance monitoring.

Learning Curve in the Cusum format:
Initial failure rate of around 20%. From attempt 90 onwards, the Cusum plot spans two acceptable boundaries (from above) and so the performance has improved to an acceptable level during the latter series consistent with effective training.

Assessment of trainee competence in new procedures: Cusum technique III
Early identification of changes in performance

A disastrous learning curve with rescue intervention
0 - 30th attempt: 20% failure rate
30 - 170th attempt 2.0% failure rate

Performance deterioration
0 - 100th attempt 2.0% failure rate
101 - 200th attempt 20% failure rate
2.1.3. Learning Curves

Many conventional statistical methods of analysis make assumptions about normality, including correlation, regression, t-tests, and analysis of variance. When these assumptions are violated, such methods may fail. We used ‘bootstrapped’ estimates of success and failure to construct a convincing graph of institutional or individual learning. The process of bootstrapping seems simple: after completion of the study, the observed attempts with a given realisation of success or failure are randomly drawn from the study population, usually as many as there are participating in the study. Sampling is performed with replacement. This means that each patient can be drawn once, more than once, or not at all until the required number of observations is reached. From this sample the main effect, such as success rate, is calculated. Sampling with replacement is then repeated, and a new effect is calculated. This is done several hundred or even several thousand times. The resulting sample of effects then may be used to calculate the confidence interval. Fifty to 200 repetitions are usually enough for such an estimate of the confidence interval.[19] Alternatively, confidence intervals may be extracted almost directly from the simulated data. In this case, several thousand repetitions may be necessary. Even though this method is a form of simulation, it is based on the observed data. The summary of the estimates of each repetition can then be represented graphically.

Bootstrap methods are not necessarily better than conventional methods, but they do allow a direct appreciation of probable phenomena. Bootstrapping is intended to simplify the calculation of statistical interferences even in situations much more complicated than in the presented studies, - sometimes no analytical answer can be obtained at all. Learning curves in our studies were generated for different typical manual procedures performed in infants, children and adults. The least square fit model and Monte Carlo procedures were used. To establish Cusum plots, the planning process requires the establishment of significant and, at the same time, acceptable failure rates ($p_0$). These may be taken from control groups, actual or estimated institutional rates, previously published studies, or expert consensus (see table 3 for examples).[15, 18, 20-22] However, its feasibility depends on institutional characteristics such as the teaching method, the instructor-to-resident ratio, the time available for training, and the number of procedures performed by residents. The generation of learning curves with reference to our method does not need any assumptions in advance, but the results can be used for the calculations of Cusum analyses.
2.1.4. Manual procedures studied

To investigate their learning process, the performance of inexperienced residents during their initial training was assessed for typical manual procedures in anaesthesiology in the first part of this thesis (see table 4). The trainees were also assessed using a visual analogue scale and selected performance criteria which is described in the first article. Then, the methodology of learning curves using a bootstrap technique was developed (see chapter 2.1.3.) and applied in the following studies. Therefore, the construction of learning curves for some basic manual procedures was possible.

**Table 4: Manual procedures studied**

<table>
<thead>
<tr>
<th>Procedure</th>
</tr>
</thead>
<tbody>
<tr>
<td>Orotracheal intubation using a laryngoscope</td>
</tr>
<tr>
<td>Spinal single shot anaesthesia</td>
</tr>
<tr>
<td>Caudal analgesia (neonates, infants and children)</td>
</tr>
<tr>
<td>Epidural anaesthesia (lumbar approach with catheter placement)</td>
</tr>
<tr>
<td>Penile block (neonates, infants and children)</td>
</tr>
<tr>
<td>Axillary block using a nerve stimulator</td>
</tr>
<tr>
<td>Arterial cannulation (radial artery using the Seldinger technique)</td>
</tr>
<tr>
<td>Central venous cannulation (internal jugular vein using the Seldinger technique)</td>
</tr>
<tr>
<td>Psoas compartment block in children (institutional learning curve)</td>
</tr>
</tbody>
</table>

2.1.5. Implementing a new technique into clinical practice

Previous studies have described learning curves with respect to clinical trials in anaesthesia[23, 24], gaining manual skills in regional anaesthesia techniques[13], new drugs[24], tracheal intubation[25], or the use of new equipment[26], and arterial cannulation. We are not aware of any study that reports on institutional learning when a new regional anaesthesia technique is implemented at a teaching institution. Apart from the presented learning curve studies, another study was designed to investigate whether there is an institutional learning when a new psoas compartment block (PCB) technique is implemented in a residency training program. Modified landmarks for this technique are reported. To evaluate the institutional learning process when implementing this technique, the Cusum technique was used and an institutional learning curve was generated.
2.2. Aspects of risk management: Methodology to assess risks as an inherent consequence of the learning process

A typical risk management approach in medicine is the investigation of the outcome and especially of the relative risk ratios for adverse events (see for example Mueller, Brühwiler, Schüpfer).[27] A learning process is always related to a risk curve. Therefore, besides performance, risks also have to be monitored during the training process. Suitable tools for monitoring the occurrence of rare events are the so-called 'Cusum' technique (already described above) and statistical process control tools (please refer to appendix A for a more detailed explanation of statistical process control).[28] These two tools are well known in the economical community. By applying them to monitor adverse events on a consecutive basis in an institution, they are really working as risk monitoring instruments. The adoption of 'Cusum' and 'statistical process control' to monitor adverse events or risks is proposed as a monitoring tool in anaesthesia departments to assess on an institutional base the risks of teaching and training.

Both can be easily adopted for medical care. Quality aspects of the anaesthetic process are reflected in the rate of perioperative adverse events, which are analysed using statistical process control methods. These analyses can be used for quality improvement. By applying statistical process control methods to the analysis of adverse events, an institution is able to determine whether a process is stable, an intervention is required, and whether quality improvement efforts have achieved the desired effect. These aspects are especially important in a teaching hospital. This is a form of appropriate supervision of anaesthesia residents which is necessary and helps to ensure patient safety.
Chapter 3: Aim of the thesis

Based on the strong link between learning (of a person or an institution) and associated risks, this thesis contains two aims:
- Construction and assessment of learning curves for manual skills
- Aspects of risk management: Assessment of risk as a factor in management policy (at a teaching institution)

3.1. Construction and assessment of learning curves for manual skills

Clinical competence (as far as technical procedures) is achieved through both adequate teaching and mastery through 'hands on' practice. Since all trainees are different, learning practical procedures must occur at different rates.[1, 2]

The following questions need to be answered. Can skills in learning practical procedures be predicted? How many procedures should be carried out to achieve a certain competence? Is a learning curve associated with worse patient outcomes and how should this phenomenon be monitored? Hence, the learning process is a multidimensional function with a wide intra- and inter-individual scattering.[29] As already mentioned, a learning curve is observed when a new skill or competence is learnt.[3, 30] In this first part of the thesis, there is an emphasis on learning curves for manual skills in anaesthesiology for two reasons:

a) Manual skills are important and many techniques have to be learnt during a residency program. Therefore, the determination of the minimal case load for a given task, procedure, technique or skill is required for the planning and designing of teaching/residency programs. An easily obtainable quantitative measure of performance would help objective evaluation of resident performance contributing to better training.

b) With new drugs, equipment, and techniques being introduced each year, it is important for the practising anaesthesiologist to keep up-to-date. Therefore, it is necessary to achieve a better understanding for new concepts, especially in learning new skills. The acquisition of advanced manual skills requires substantial clinical training and time. Learning curves may be used as a tool to monitor, guide and evaluate this learning process.
3.2. Aspects of risk management

How can we monitor adverse events or risks in an institution on a consecutive base, especially with regard to the impact on training residents? The second part of the thesis focuses on risk management aspects in a teaching environment. To demonstrate the concept of learning curve and its consequences, the example of the insertion of a central venous line can be considered.[3, 30] The chosen illustration clearly shows that the risks of this technique as complications - such as pneumothorax or major bleeding - are not uncommon in inexperienced hands. The acquisition of a new skill or competence is also related to new risks. The 'Cusum' method and statistical process control tools are applied to monitor risks in a critical care or an anaesthesia institution.
Chapter 4: Results - Included articles

4.1. Learning curves – individual and institutional learning of manual skills


Psoas compartment block in children: Part I – description of the technique*

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Summary
Background: Until recently only small series of psoas compartment blocks (PCB) in children have been reported. A high incidence of epidural spread as an important side effect was noted. A series of 100 consecutive blocks using new standardized landmarks is reported.
Methods: In 100 consecutive children (5.9–10.6 kg) PCB was performed using a nerve stimulator. In the lateral position, the needle was inserted between the medial 2/3 and the lateral 1/3 on a line from the spinous process of L4 to the posterior superior iliac spine. The blocks were performed by residents in training under supervision of one specific designated pediatric anesthetist.
Results: All blocks were clinically successful. In 64% only one attempt was necessary, in 26 patients two attempts were necessary and in 10 patients more than two attempts were necessary. In 16% a vascular puncture occurred. In one patient with a dense unilateral block a partial epidural spread occurred. No serious complications were observed during the perioperative period.
Conclusions: The described new technique has a very high success rate with no relevant side effects. Although only one case of epidural spread occurred, PCB remains an invasive technique with the potential for serious complications.

Keywords: psoas compartment block; children; regional anesthesia

Introduction
Until recently only small series of psoas compartment blocks (PCB) in children have been reported(1,2). A high incidence of epidural spread as an important side effect was noted(2). We report a series of 100 consecutive blocks using standardized landmarks. All blocks were performed under the supervision of one pediatric anesthetist.

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Methods
The study was undertaken by the Division of Paediatric Anaesthesia of the Department of Anaesthesiology and Intensive Care, Kantonsspital Lucerne, Switzerland, a teaching hospital with 3600 pediatric anesthetic procedures per year (total annual case load 19 000). Regional anesthesia or combined anesthetic techniques are used in 41% of all cases. PCB is one of the established techniques for regional analgesia and/or anesthesia at this institution. However, the technique is rarely used in children. The aim was to standardize the procedure using landmarks adapted to the size of the patient in order to allow successful
teaching to residents. All data were prospectively collected as a part of the institutional quality assurance program as required by Swiss federal law. Informed consent was obtained from all parents and, if appropriate according the age of the patient, from the child. Special ethical committee approval was not necessary as the procedure reflected the standard of care at that time in our institution and randomization did not occur. All quality assurance programs are under the strict supervision and control of the medical director and the hospital directorate.

The data from 100 consecutive children (5.9–106 kg) scheduled for unilateral lower limb surgery, for example interventions involving the hip, the thigh or the knee, are reported. PCB was performed using a nerve stimulator. All blocks were performed by residents during a 2-6-month hospital rotation under the personal supervision of one single staff member. After induction of general anesthesia venous access was obtained and the standard monitors were applied. In the lateral position with the hip joints flexed 90°, the needle was inserted between the medial 2/3 and the lateral 1/3 on a line from the spinous process of L4 to the posterior superior iliac spine (Figure 1). The needle was advanced until muscle twitches in the thigh could be elicited; alternatively, when contact with the transverse process of L5 was reached first, the needle was withdrawn and redirected cranially. The local anesthetic solution, 1 ml kg⁻¹, up to 50 ml of bupivacaine 0.25%, was injected at a point where, using an impulse width of 1.0 ms with a current of 0.3 mA muscle twitches could no longer be elicited.

Clinical failure was assumed if opioid supplementation or rises in concentration of the volatile anesthetic above 0.75 MAC were necessary because of clinical signs of insufficient analgesia such as rises in heart rate and/or blood pressure, movement of the patient or other signs of stress. Recovery characteristics from the block in the PACU were not systematically assessed. Adverse effects of the psoas compartment block such as epidural spread were gathered prospectively.

For statistical analysis Statistics 6.0 (StatSoft Inc., Tulsa, OK, USA) was used for all statistical and graphical analysis.

Results
All blocks were clinically successful; in one patient a bilateral block occurred, probably from partial epidural spread. In one patient the injection was stopped after half the intended volume because of frank aspiration of blood; however, this block was clinically effective. In 84% no vascular puncture occurred. In 61% of the cases clinically successful block was achieved at the first attempt with no bloody tap. The risk of a bloody tap for a successful block with one attempt was 4.7% (three of 64), for two attempts 30.7% (eight of 26) and for three or more attempts, 50% (five of 10). We used a generalized linear model with backwards elimination of variables (gender, height, age, weight) and only the weight was a significant predictor for the depth of needle insertion ($P < 0.01$; Figure 2).

Discussion
This study shows that using a standardized procedure PCB is an effective tool for postoperative pain relief in children. A modified approach based on easily palpable landmarks in children was used. These new landmarks (needle insertion between the medial 2/3 and the lateral 1/3 on a line from the spinous process of L4 to the posterior superior iliac spine; see Figure 1) resemble the classical technique as described by Chayen et al. (3). However, the absolute distances (5 cm lateral and 3 cm inferior

Figure 1
In lateral position, the needle was inserted between the medial 2/3 and the lateral 1/3 on a line from spinal process L4 to the upper posterior iliac spine. A successful attempt was defined as eliciting muscle twitches during the first advancement of the needle without any aspiration of blood.

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to the spinous process of L4 are adapted to the size of the patient.

In 1988 Dalens et al. (2) compared, in groups of 25 children each, the technique according to Winnie et al. (4) and what they called a modified approach according to Chayen et al. (3). Here the injection was made at the midpoint of a line between the spinous process of L5 and posterior superior iliac spine. Significantly, this medial and caudal injection resulted in epidural spread in 23 of 25 children. This technique was considered by many workers to be invasive and potentially dangerous. On the contrary, after injections at the level of the inguinal ligament, local anesthetic solution does not reliably reach all three nerves, the femoral, the lateral cutaneous and the obturator nerve. This has been shown in cadavers (5) and by electromyographic (6), radiographic (7) and ultrasonographic (8) studies. The so-called three-in-one-block (9) does not exist. Only injections at the lumbar level can reliably lead to a real lumbar plexus block. Therefore adapted landmarks at lumbar level were evaluated in this study.

Other approaches to improve the technique have been made: Kirchmair et al. (10) applying ultrasonography in adult volunteers and comparing the results with transactions in cadavers. Undoubtedly, ultrasonography is a very promising tool for PCB, especially in small children where the depth of penetration is smaller. Capdevila et al. (11) suggested for adults a modified Winnie’s approach, situating the point of needle insertion at the junction of the medial two-thirds and lateral third of the line between the spinous process of L4 and the line through the posterior superior iliac spine parallel to the spinal column. This results in a slightly more cranial puncture compared with our technique.

In this study, the depth of needle insertion correlated well with the body weight of the children. Up to a body weight of 40 kg a needle-length of 7 cm was sufficient in all cases, above 40 kg a 10–12 cm needle is needed (see Figure 2). In the series of Capdevila et al. (11) a correlation with the body mass index was also found in adults. Dadure et al. (1) demonstrated a correlation for the depth of needle insertion with age in children. The distance between the lumbar plexus and the transverse process is remarkably constant in adults, approximately 18 mm, despite a large variation of the depth of needle insertion from the skin to the lumbar plexus. Data confirming this relation are missing in children. However, practical wisdom suggests not to advance the needle more than 20 mm after loss of contact with the transverse process of L5. Contact with the transverse process gives a strong indication for the position of the lumbar plexus; but, we found contact with this landmark in only half of the patients, in the other half the needle was advanced directly to the lumbar plexus.

Theoretically, PCB is an invasive and deep block with a potential for serious complications (12), although this is not supported by our series of 100 cases. Convulsions (13), retroperitoneal hematomas (14), total spinal anesthesia (12), epidural (15) and even intrathecal catheter placement (16) have been reported. Catastrophic outcomes were usually related to total spinal anesthesia; because of the cardiovascular stability even with high spinal blockade, this is probably not a major issue in infants and children. However, a careful risk–benefit analysis is mandatory in all patients before performing the block, especially in view of the fact that for many indications, for example femoral fractures, effective and less invasive alternatives exist (17,18).

In summary, the described technique using adapted landmarks to the child’s body size allows successful blockade of the lumbar plexus with very few side effects.

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artment blocks after major orthopedic surgery in children: a

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Psoas compartment block (PCB) in children: Part II – generation of an institutional learning curve with a new technique

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Summary

Background: Literature concerning institutional learning processes for anesthesia procedures in pediatric anesthesia is rare. Until recently only small series of psoas compartment blocks (PCB) in children have been reported. We report on a series of 100 consecutive blocks using new landmarks and the institutional learning process.

Methods: In 100 consecutive children (5.9–10.6 kg) PCB was performed using a nerve stimulator. In the lateral position, the needle was inserted between the medial 2/3 and the lateral 1/3 on a line from the spinous process of L4 to the posterior superior iliac spine. Residents unfamiliar with PCB were instructed by one single staff member without manual intervention. Failure was defined as a bloody tap, more than one skin perforation with the needle or relinquishing the procedure to senior staff. To evaluate the institutional learning process the cumulative sum (CUSUM) statistical technique was used. CUSUM analysis was performed using an acceptable failure rate of 10%. A learning curve using a bootstrap technique and a least square fit model was also used.

Results: Although all blocks were clinically successful, only in 64% was a single attempt sufficient. In 16% vascular puncture occurred. Surprisingly the CUSUM analysis showed a clear institutional learning phenomenon. Applying a strict definition for a successful block, more than 100 PCB in an institution may be necessary. Using the generated learning curve, for a success rate of 70% a case load of at least 55 attempts is required.

Conclusions: Although the described new technique had a very high success rate with a low complication rate, PCB in children is not easily implemented into clinical practice when strict criteria of success were used, despite a well-controlled environment. Training programs could use CUSUM to track the progress of their institutional learning in order to guarantee adequate experience.

Keywords: psoas compartment block; anesthesia; learning curve; regional anesthesia; manual skill

*Presented in part at the Annual Meeting of the European Society of Anaesthesiology, May 2002, Nice, France

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Introduction

Few published data are available concerning institutional learning processes for adopting a new regional technique, especially in pediatric anesthesia (1, 2). This study was designed to investigate whether there was a learning curve associated with the implementation of psoas compartment block (PCB) in children using a new technique with modified landmarks (the technical details are outlined in part I). We report a series of 100 consecutive blocks and the use of the cumulative sums (CUSUM) technique.

To evaluate the institutional learning process the CUSUM statistical technique was used. Cumulative sum (CUSUM) analysis is a statistical and graphical tool that examines trends for sequential events over time (3–6). It has been used to determine proficiency in technical procedures. CUSUM technique was used to determine the number of attempts necessary for proficiency in our training program.

Methods

The study was undertaken by the Division of Paediatric Anaesthesia of the Department of Anaesthesiology and Intensive Care, Kantonsspital Lucerne, Switzerland, a teaching hospital with 3600 pediatric anesthetic procedures per year (total annual case load 19,000). Regional anesthesia or combined anesthetic techniques are used in 41% of all cases. Data were collected as a part of our quality assurance program. Psoas compartment block is an established technique in our institution. However, the technique is rarely used in children. The aim was to standardize the procedure using landmarks adapted to the size of the patient allowing the successful teaching to residents. All data were prospectively collected as a part of the institutional quality assurance program as required by Swiss federal law. Informed consent was obtained from all parents and if appropriate according to the age of the patient, from the child. Special ethical committee approval was not necessary as the procedure reflected the standard of care at that time in our institution and randomization did not occur. All quality assurance programs are under the strict supervision and control of the medical director and the hospital directorate.

In 100 consecutive children (5.9–10.6 kg) scheduled for surgery involving the lower limb PCB was performed using a nerve stimulator. All blocks were performed by residents during a 2–6-month hospital rotation under the supervision of one single staff member. The technical details are described in part I. The residents performed the blocks without manual intervention of the supervisor, verbal comments were allowed. The landmarks chosen by the resident were controlled.

The CUSUM technique is a valuable tool for sequential analyses of processes. Therefore this method was applied to study whether there is an institutional learning curve when implementing this new technique into clinical teaching practice. It defines the boundaries of the quality envelope and an acceptable performance (for calculation of CUSUM values per attempt see Table 1, a concise explanation is given by Bolkin and Cosmon (4)).

For the calculation of the CUSUM statistics a binary definition of success and failure is necessary. A successful attempt was defined as eliciting muscle twitches during the first advancement of the needle without any aspiration of blood. Furthermore the block had to be clinically successful. Clinical failure was assumed if opioid supplementation or rises in concentration of the volatile anesthetic above 0.75 MAC were necessary because of clinical signs of insufficient analgesia such as rises in heart rate and/or blood pressure, movement of the patient or other signs of stress. Relevant side effects such as epidural spread were also rated as a failure. Verbal comments

Table 1

<table>
<thead>
<tr>
<th>Calculation of CUSUM value</th>
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<tbody>
<tr>
<td>$p_0$, acceptable failure rate</td>
</tr>
<tr>
<td>$p_1$, unacceptable failure rate</td>
</tr>
<tr>
<td>$\alpha$, type I error</td>
</tr>
<tr>
<td>$\beta$, type II error</td>
</tr>
<tr>
<td>$\ln = \ln(1-\alpha)$</td>
</tr>
<tr>
<td>$\ln = \ln(1-\beta)$</td>
</tr>
<tr>
<td>$I_{11} = s/(P + Q)$</td>
</tr>
</tbody>
</table>

Intermediate values

$s = \ln(1-\beta)/\alpha$

$b = \ln(1-\alpha)/\beta$

$P = \ln(q_0/r_0)$

$Q = \ln((1-p_0)/(1-p_1))$

$s = Q/(P + Q)$

$s$ is the value of decline of the graph for success, $(1-s)$ is the increase of $y$ for each attempt ($s$) for failure.
by the supervisor were not rated as failure, but any manual intervention was.

For comparison an institutional learning curve was generated using the same set of data with bootstrapping technique to mimic a statistical population and a least square fit model.

For statistical analysis Statistics 6.0 (StatSoft Inc., Tulsa, OK, USA) was used for all statistical and graphical analysis.

Results

All blocks were clinically successful, in one patient a bilateral block occurred, probably from epidural spread. In 64 blocks only one attempt was necessary, in 26 patients two attempts were necessary, and in 10 patients more than two attempts. In 84% no vascular puncture occurred. In one patient the injection was stopped after half the intended volume because of frank aspiration of blood; however, this block was clinically effective. In 61% of the cases clinically successful block was achieved at the first attempt and no bloody tap. The risk for a bloody tap for a successful block with one attempt was 4.7% (three of 64), for two attempts 30.7% (eight of 26) and for three or more attempts 50% (five of 10). Surprisingly the CUSUM analysis showed a clear institutional learning phenomenon (Figure 1). From attempt 10 onwards, the CUSUM plot spans two acceptable boundaries (from above) and so the performance has improved to an acceptable level. During the latter series consistent with effective training, a performance improvement can be seen after attempt 17 until 28. Afterwards only a lateral movement of the CUSUM line is seen, indicating no clear trend of improvement or deterioration. According to the applied criteria for the CUSUM analysis from patient 75 until 88 a performance deterioration is seen, thereafter a new stable process improvement phase occurs. Alternatively, the learning process of the institution can be shown as a classical learning curve (Figure 2).

Discussion

This study shows that using a standardized procedure, PCB is an effective tool for postoperative pain relief in children. However, introduction of a new technique in an institution results in a learning curve; as assessed by the CUSUM method, to reach a consistent performance, even with strict supervision by one single instructor an institutional case load of at least 30 cases was necessary.

Although previous studies have described learning curves with respect to clinical trials (9, 10), gaining manual skills in regional anesthesia techniques (1, 2, 7, 11–13), new drugs (9), tracheal intubation (14), arterial cannulation (7, 13), or the use of new equipment (15), few studies have investigated the effects of implementation of a regional anesthesia technique at a teaching institution. This study was designed to prospectively investigate whether there was a learning curve associated with the translation of a standardized PCB technique into a residents training program.

The introduction of a new technique in anesthesia practice, has three common results. The first is the
direct benefit and the second is the cost. (Cost may be documented not solely in financial terms, but there may be undesirable clinical effects or iatrogenic sequelae.) The third, much more subtle consequence of the introduction of anything new is the learning of how to use what is new to obtain maximum benefit. Conceptually, with anything new, over infinite time, cumulative knowledge about the innovation ultimately should become 100%.

The learning curve represents the assimilation of this new knowledge. The shape of the learning curves (sigmoidal, bimodal, exponential, etc.) and the time over which optimal learning occurs are the important factors concerning learning curves (16, 17). The shapes of these learning curves are dependent on two fundamental factors, the amount of knowledge and the ease of learning. It is understood and accepted that the degree of knowledge of any innovation at the time of introduction will change (increase) over time, meaning an expanded knowledge base exists the longer a new drug, device, or concept is applied. This expanded knowledge might be described as a moving target of learning that is inevitable and inherent in the learning process. Therefore a learning curve for the institution using a previously described technique (bootstrapping and least square fit model) was also generated (Figure 2) (1,2,7,13).

If a learning curve is to be described, there are some essential features required to properly do this. The most important is to decide what is to be learned. In the case of a new block technique, one would focus learning on the safety and efficacy. Importantly, it is critical to design the study to span a time sufficiently long to actually measure the learning. Obviously, it is impractical to measure at the beginning and again after infinite experience, but it is crucial that the study time be sufficiently long to encompass a significant portion of the learning. Another factor in the study design is to have an adequate sample size to extrapolate the results to a larger universe of clinicians. Finally, as with any study design, the fewer the confounding variables the better. For these reasons the implementation of the new PCB technique was monitored with clear-cut criteria for success and clinical safety. The first difficulty is in the selection of endpoints of learning. Although all blocks worked clinically, CUSUM analyses showed a clear institutional learning phenomenon even under the supervision of one single senior staff member. This effect may be explained by the chosen features for the definition of proper success: (i) eliciting muscle twitches with the first cutaneous needle perforation, (ii) absence of a bloody tap, and (iii) absence of epidural spread. Another limitation of this study setting is the strict control of landmarks by one single experienced pediatric anesthetist. Accurate identification of surface landmarks is essential for the successful performance of peripheral nerve blocks (18). This modality was chosen to guarantee patient safety in this teaching setting.

Despite these deficiencies, valid conclusions are possible. Using a strict protocol of education with a new technique permits very rapid adaptation and uniform clinical results. What can be learnt from this study, however, is that in future studies a better understanding of how to describe a learning curve must contain measuring the important knowledge domains of learning, sampling over a long enough time to adequately describe the curve, and ideally, sampling multiple times to accurately fit a curve. With properly designed studies, we can determine just how close to ideal the learning curve of an anesthesia innovation is, a fact that will influence its safe, effective and timely adoption.
In summary, an institution acquires the ability to perform a new PCB technique in children with a reasonable numbers of patients when strict criteria are used. In accordance with previous experience, there is however a learning curve with this new technique for our institution.

References

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Generating a learning curve for penile block in neonates, infants and children: an empirical evaluation of technical skills in novice and experienced anaesthetists

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Summary

Background: Literature concerning learning curves for anaesthesiological procedures in paediatric anaesthesia is rare. The aim of this study was to assess the number of penile blocks needed to guarantee a high success rate in children.

Methods: At a teaching hospital, the technical skills of 29 residents in anaesthesiology who performed penile blocks under the supervision of two staff anaesthesiologists were evaluated during a 12-month period using a standardized self-evaluation questionnaire. At the start of the study period, the residents had no prior experience in paediatric anaesthesia or in performing penile block. All residents entered the paediatric rotation after a minimum of 1-year training in adult general and regional anaesthesia. The blocks were rated using a binary score. For comparison, the success rates of the two supervising staff anaesthesiologists were collected during the same period using the same self-evaluation questionnaire. Statistical analyses were performed by generating individual and institutional learning curves by using the pooled data. The learning curves were calculated with the aid of a least square fit model. A 95% CI were estimated by a Monte Carlo procedure with a bootstrap technique.

Results: In a total number of 392 blocks performed, the overall success rate was 92.1%. There was no statistical difference between the success rate of the two staff members (success rate: 96.3%) and the overall success rate of the 29 residents performing a total of 339 blocks. The total success rate for this group was 91.5%. The failure rate for the first 10 blocks performed by the residents was 8.82% (95% CI: 5.0–14.14%), it was 4.12% (95% CI: 1.13–10.22%) for the next 10 blocks and from blocks 21 to 40 it was 6.5% (95% CI: 2.65–12.9%). For blocks 41–60, the failure rate was 4.4% (95% CI 0.54–15.15%).

Conclusions: Penile block in children is easily learned by residents. A steep learning curve was found. The success rate was over 93.5% after more than 40 blocks.

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Introduction
Penile block is a widely accepted procedure for analgesia after penile surgery in neonates, infants and children. Learning curves for manual procedures in anaesthesiology have been generated and recently published (1–6). The development of a rational training programme for manual procedures requires knowledge about the number of procedures necessary to achieve a high success rate. However, only a few studies have been performed to investigate this topic in anaesthesia and no data are available for penile block in paediatric patients. Therefore, the aim of this study was to determine the learning curve for penile blocks and to compare the results of residents in training with data obtained from staff anaesthesiologists.

Method
The study was undertaken by the Division of Paediatric Anaesthesia of the Department of Anaesthesiology and Intensive Care, Kantonsspital, Lucerne, Switzerland, a teaching hospital with 3600 paediatric anaesthetic procedures per year (total annual case load 19,000). Regional anaesthesia or combined anaesthetic techniques are used in 41% of all cases. Informed parental consent was obtained and data were collected as a part of our quality assurance programme.

After premedication with rectal midazolam (1 mg·kg⁻¹ up to 15 mg), anaesthesia was induced by inhaling 8% sevofothane and 60% nitrous oxide in oxygen. The standard monitors were applied, the airway was secured using a laryngeal mask (LMA™) and venous access was obtained. For the subpubic penile block, the penis was fixed using tape between the thighs. The symphysis pubis was palpated with the index finger of the left hand and two paramedian injections by using 25 G 2.54 cm, neonatal spinal needles (Becton Dickinson) were performed. The needles were inserted 0.5–1.5 cm lateral to the midline, immediately below the pubic bone, and directed slightly medially (10–20°) and slightly distally (10–20°), until a marked ‘give’ was felt when Scarpa’s fascia was penetrated and the tip of the needle entered the subpubic space (Figure 1, panels a and b). After careful aspiration, 0.1 ml·kg⁻¹ (up to 4 ml) bupivacaine 0.75% without epinephrine was injected on each side, resulting in a total dose of 1.5 mg·kg⁻¹ bupivacaine. The attending paediatric anaesthesiologist took over after three attempts or at any time if blood was aspirated. These procedures were classified as failures and rated ‘zero’. Clinical failure was assumed if opioid supplementation or rises in concentration of the volatile anaesthetic above 0.75 MAC were necessary because of clinical signs of insufficient analgesia such as rises in heart rate and/or blood pressure, movement of the patient or other signs of stress. Recovery characteristics from

Figure 1
The technique of penile block in children is illustrated in a and b (for details see text).
the block in the PACU were not systematically assessed. A block was considered successful and rated 'one' if the resident performed it without help from the staff anaesthesiologist and the block was clinically effective. Prospectively adverse effects of the penile block such as haematomas were gathered.

The data were assessed by using a bootstrap technique in combination with a Monte Carlo simulation procedure to estimate confidence intervals and to reach consistent results.

Statistical analysis generated individual and institutional learning curves. Consecutive sums were calculated as a modified cumulative summation (CUSUM) analysis and divided by the number of performed procedures. Individual success rates were calculated. The success rates were pooled and compared between both groups of participants. A learning curve for residents was generated using a least square fit model. The institutional learning curve was calculated using a bootstrapping technique, a resampling method, to mimic a large statistical population. The overall success rate of the staff anaesthesiologists was calculated by pooling group data. The 95% CI of the cumulative success rates were calculated by bootstrapping all data (7). The confidence interval of the overall success rate of the staff anaesthesiologists was estimated by the same method. For comparison of success rates between groups, non-parametric procedures were used. \( P < 0.05 \) was considered to be statistically significant.

Results

A total number of 392 blocks were performed and the overall success rate was 92.1%. There was no statistical difference between the success rate of the two staff members (success rate: 96.3%) and the overall success rate of the 29 residents performing a total of 339 blocks. The total success rate for this group was 91.5%. The failure rate for the first 10 blocks performed by the residents was 8.82% (95% CI: 5.0-14.14%), for the next 10 blocks it was 4.12% (95% CI: 1.13-10.22%) and from blocks 21 to 40 it was 6.5% (95% CI: 2.65-12.9%). For blocks 41 to 60, the failure rate was 4.4% (95% CI: 0.54-15.15%). The learning curve of the residents generated is shown in Figure 2. During the study period, no adverse events because of the penile block were observed.

Discussion

Penile blockade is a simple and effective technique (8). The technique is widely accepted and does not require any special skill. It is successful in almost all patients (9). Despite the widespread use of this technique, no data on learning processes or on the number of procedures necessary to maintain technical proficiency are available for this block to date. In this investigation, the learning process of residents in anaesthesiology and the proficiency characteristics of staff anaesthesiologists were studied. We found a steep learning curve for this block. The mean case load for a 90% success rate is 15. No statistical difference in the success rates of staff anaesthesiologists and residents were observed. Penile block in children is easily learned. Only limited training is necessary for residents to achieve high success rates. After more than 40 blocks, the success rate exceeds 93.5%. The learning curve for penile block follows a different pattern in comparison with the learning curves for other manual techniques. Caudal block may be an alternative modality of analgesia in children scheduled for penile surgery. Compared with our recently published data on caudal block in children, learning processes in performing penile blockade in paediatric patients require a lower number of procedures to achieve high success rates. Figure 3 compares the two procedures (5,9). However, teaching and continuous supervision of novices is necessary even in procedures commonly thought to be easily performed.

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The technique used in this study was penile block by two paramedian subpubic injections. The blocks were all performed before surgery under general anaesthesia and the goal was to provide intra- and postoperative analgesia using a long acting local anaesthetic. The duration of postoperative analgesia was not systematically recorded, however the majority of the patients needed no additional pain medication at all, based on our routine postoperative quality survey.

In studying institutional or individual learning behaviour, not only generation of learning curves is of special interest, but also the risk curves deserve special attention. As no adverse events were observed in this study, we were not able to calculate any risk curves.

This study has several limitations. First, our definition of failure does not necessarily mean that analgesia for the individual patient was insufficient. The end-point of success was defined by judging both technical performance and clinical efficacy. This form of evaluation could not differentiate between complete and partial failures. Complete success excluded any physical help by the attending anaesthesiologist and was meant to indicate a technically perfect procedure with clinical functionality. Failure included manual assistance by the attending anaesthesiologist or the necessity of changing the anaesthetic technique. The specific reasons for failure were not collected. The overall success rate of residents and more experienced staff anaesthesiologists are comparable, but lower for residents. This may be the result of the fact that manual intervention by the supervisor was rated as a failure for the resident, although the block was clinically successful from the viewpoint of the patient.

Secondly, other techniques for analgesia after penile surgery have been described, such as a median subpubic injection, penile ring block or topical application of local anaesthetic agents. Our results may not be representative for these techniques.

Thirdly, our results may be product of a special teaching situation, defined by factors such as the staff to resident ratio, the type of patient and the caseload during training, etc. Our institutional setting provides only a limited number of residents and staff members. The staff members and their results in performing penile blocks were used as a benchmark to reflect the cultural, social and environmental circumstances at our institution. Anonymous reporting by the participants increases the reliability of the self-evaluation questionnaires and individual performance was not under discussion. Furthermore, clinical efficacy was scored by an independent investigator not otherwise involved in the study.
Fourthly, we used bootstrapping as a resampling technique to mimic a statistical population to generate valid confidence intervals of the learning curves. There are other techniques published to generate learning curves. In this study, relative success rates, including confidence intervals, were calculated with the success of each procedure performed, depending on the previous experience. This approach provides typical learning curves with 95% CI for easy comparison (3,5,6). Simple graphical methods as published by Lawler et al. for detecting the number of successes and failures on a sequential basis, might be appropriate for a single anaesthetic (4,10). However, this approach does not provide confidence intervals. Continuous quality assurance in health care has necessitated the adoption of statistical methods developed for industrial process monitoring techniques. One such statistical technique is the CUSUM methodology, which can continuously monitor production process and detect subtle deviations from a preset defined level of achievement. The method is practical, simple to apply, easy to introduce and has proved popular with trainees in some specialities. But consensus on acceptable and unacceptable failure rates is necessary when using the CUSUM method. As with our method, CUSUM requires a binary specification of the targeted value for outcome measure (2,5,6). A clear disadvantage of the CUSUM method is that a great number of attempts may be necessary to prove statistical significance (11,12).

In summary, penile block for postoperative analgesia in a paediatric population is easily learned. The minimal caseload for a mean 90% success rate is 15. However, our data also show that teaching and continuous supervision of novices is necessary for all manual skills, even for apparently easy techniques such as penile block.

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Background and Objectives: Learning curves for anesthesia procedures in adult patients have been determined, but no data are available on procedures in pediatric anesthesia. The aim of this study was to assess the number of caudal blocks needed to guarantee a high success rate in performing caudal epidural analgesia in children.

Methods: At a teaching hospital, the technical skills of 7 residents in anesthesiology who performed caudal blocks were evaluated during 4 months using a standardized self-evaluation questionnaire. At the start of the study period, the residents had no prior experience in pediatric anesthesia or in performing caudal epidural blocks. All residents entered the pediatric rotation after a minimum of 1 year of training in adult general and regional anesthesia. The blocks were rated using a binary score. For comparison, the success rates of 8 experienced staff anesthesiologists were collected during the same period using the same self-evaluation questionnaire. Statistical analyses were performed by generating individual and institutional learning curves using the pooled data. The learning curves were calculated with the aid of a least square fit model and 95% confidence intervals estimated by a Monte Carlo procedure with a bootstrap technique.

Results: The success rate of residents was 80% after 32 procedures (95% confidence interval of 0.59 to 1.00). The pooled success rate of the staff anesthesiologists was 0.73 (mean) with a standard deviation of 0.45, which was not statistically different from the success rate of the residents.

Conclusion: High success rates in performing caudal analgesia in pediatric patients can be acquired after a limited number of cases. Success rates of residents learning this procedure are comparable to the results of staff anesthesiologists.

Key Words: Caudal analgesia, Pediatric anesthesia, Learning curve, Regional anesthesia.

In recent years, caudal analgesia has gained widespread popularity in pediatric surgery, in particular, for procedures below the umbilicus. Single-shot epidural analgesia with a local anesthetic using the caudal approach combines clinical efficacy with a high success rate. Caudal analgesia for pediatric surgery was first described in 1930 and was found to be a reliable and safe technique in young children and can be used even in ambulatory surgical patients. Therefore, nowadays, single-shot caudal epidural block is one of the most popular regional anesthetic techniques used in pediatric surgery.

Learning curves for manual procedures in anesthesia have been generated and recently published. The development of a rational training program for manual procedures requires knowledge about the number of procedures necessary to achieve a high success rate. Only a few studies have been performed to investigate this topic in anesthesia and no data are available for caudal blocks in adult or pediatric patients. Therefore, the aim of this study was to determine the learning curve for caudal
blocks and to compare the results of residents in training with data obtained from staff anesthesiologists.

Methods

The study was undertaken by the Division of Pediatric Anesthesia of the Department of Anesthesiology and Intensive Care, Kantonsspital, Lucerne, Switzerland, a teaching hospital with 3,600 pediatric anesthetics per year (total case load, 18,000). Regional anesthesia or combined techniques are used in 41% of all pediatric cases. The residents participating in this study had more than 1 year of training in adult anesthesia, including regional anesthetic procedures, but not caudal epidural blocks. They had no previous experience in performing anesthesia for pediatric surgery. All residents were supervised by 1 of 2 specialty-trained pediatric anesthesiologists. The 8 staff members participating in the study protocol rotate to the pediatric anesthetic service. Data were gathered prospectively by a standardized evaluation form, which was collected anonymously. This form has been evaluated in a previous investigation. Caudal block was combined with a general anesthetic technique (Sevoflurane; Abbott Co, Cham, Switzerland and nitrous oxide) for minor surgical procedures, such as hernia repair or urological surgery. Exclusion criteria included: age above 6 years, body weight above 30 kg, and American Society of Anesthesiologists (ASA) Status higher than II. After induction of anesthesia with Sevoflurane, a laryngeal mask was introduced, and a peripheral venous catheter was established. The spontaneously breathing patients were then turned into the left lateral decubitus position. A single-shot caudal epidural block was performed with a 23-gauge butterfly needle. Bupivacaine, 0.125%, with epinephrine 1:200,000 was administered incrementally to a total of 1 ml per kg body weight. During injection, electrocardiogram (ECG), peripheral oxygen saturation, expired gas concentrations, and acoustic control of breathing and heart sounds using a precordial stethoscope were monitored.

Caudal analgesia was rated as successful, if 2 conditions were fulfilled: (1) the procedure was performed without assistance by a supervisor (verbal comments or suggestions were allowed) and no more than 3 attempts, which means 3 passes with the needle through the skin were needed, and (2) clinical success of the block was achieved. Failure of the block was assessed by a nurse trained in anesthesia not involved in the study. Clinical failure was assumed if opioid supplementation or increases in concentration of the volatile anesthetic above 0.75 minimal alveolar concentration (MAC) were necessary due to clinical signs of insufficient analgesia, such as increases in heart rate and/or blood pressure, movement of the patient, or other signs of stress. A successful procedure was rated with a score of 1. The attending pediatric anesthesiologist took over after 3 attempts or at any time if blood was aspirated. These procedures were classified as failures and rated with a 0. Prospectively adverse effects of the caudal block were gathered. Recovery characteristics from the caudal blocks in the postanesthesia care unit (PACU) were not assessed.

Statistical analysis generated individual and institutional learning curves. Consecutive sums were calculated as a modified cusan analysis and divided by the number of performed procedures. Individual success rates were calculated. The success rates were pooled and compared between both groups of participants. A learning curve for residents was generated using a least-square fit model. The institutional learning curve was calculated using a bootstrapping technique, a resampling method, to mimic a large statistical population. The overall success rate of the staff anesthesiologists was calculated by pooling group data. The 95% confidence interval of the cumulative success rates were calculated by bootstrapping all data. The confidence interval of the overall success rate of the staff anesthesiologists was estimated by the same method. For comparison of success rates between groups, nonparametric procedures were used. A P value below .05 was considered statistically significant.

Results

Seven residents performed a total of 126 procedures. The 8 staff anesthesiologists performed 167 caudal blocks. All caudal blocks were scored using the binary rating system (see Methods). The response rate to the evaluation forms was 100%. No adverse events of caudal epidural blocks were observed in the study population.

The learning curve of the residents is shown in Fig 1. After a steep increase in performance during the first attempts, the improvement slope decreases after 15 procedures. After 32 attempts, the mean success rate was 80% for residents with a 95% confidence interval between 0.59 and 1.00. The overall success rate of the residents was 0.64 with a standard deviation of 0.48. The overall pooled success rate of the staff members was 0.73 (standard deviation, 0.43). There was no statistical difference between the 2 groups.

Discussion

Caudal epidural block for lower abdominal and urological surgery in pediatric patients has gained
widely popular. Caudal epidural block is a simple and effective technique, particularly in younger children. Despite the widespread use of this technique, no data on learning processes or on the number of procedures necessary to maintain technical proficiency are available.

In this investigation, the learning process of residents in anesthesia and the proficiency characteristics of staff anesthesiologists were studied. Compared with our recently published data on adult anesthetic procedures, learning processes in performing caudal epidural block in pediatric patients requires a lower number of procedures to achieve high success rates.

Reasons for this steeper learning curve may be the distinct anatomical landmarks of the sacral hiatus in children, our institutional teaching setting, or the preexisting experience in performing regional anesthesia in adults. In comparison to other regional anesthetic techniques, our data show that high success rates in performing caudal epidural blocks in children are achieved after a lower caseload than for other regional anesthetic procedures, even if the success rate of experienced anesthesiologists is used as a benchmark.

In the present investigation, the endpoint of success was defined by judging both technical performance and clinical efficacy. This form of evaluation cannot differentiate between complete and partial failures and the intraoperative management. The specific reasons for failure were not collected. This might also be the explanation for the wide range of confidence intervals. The overall success rate of residents and more experienced staff anesthesiologists is comparable to data published in the literature. In a series of 750 patients, Doleni and Hasnawi reported an overall success rate of 96%. However, difficulties were encountered in 25% of patients, and the sacral hiatus could not be punctured in 4% of cases. Taking these factors into consideration and due to our restrictive definition of success, we believe there is no relevant difference with our results.

No statistical difference in the success rates of staff anesthesiologists and residents was observed. This could lead to the following conclusions: (1) epidural analgesia using the caudal route in small children is easy to perform, and only limited training is necessary for residents to achieve high success rates; (2) in experienced anesthesiologists, limited numbers of procedures are sufficient to maintain high success rates in performing caudal epidural blocks in children.

Our learning curves should be validated by further studies. Our results may be the product of a special teaching situation defined by factors such as the staff to resident ratio, the type of patients, and the caseload during training, etc. There are also some other limitations of our study. (1) Our institutional setting provides only a limited number of residents and staff members. In prolonging the study period, we would have influenced our institutional system. Therefore, bootstrapping as a resampling technique to mimic statistical population was chosen to generate valid confidence intervals. (2) Failures due to regression of the blocks at the end of surgery were avoided, as only patients scheduled for minor elective surgery lasting less than 1 hour were
studied, and bupivacaine was used. The staff members and their results in performing caudal blocks were used as a benchmark to reflect the cultural, social, and environmental circumstances at our institution. (3) Anonymous reporting by the participants increases the reliability of the self-evaluation questionnaires, and individual performance was not under discussion. Furthermore, clinical efficacy was scored by an independent investigator not part of the study.

In studying institutional or individual learning behavior, not only the generation of learning curves are of special interest, but also risk curves during the learning process. Because no adverse events were observed in this study, we were not able to produce any risk curves.

In conclusion, our learning curves help to define the average number of cases needed to adequately train residents in successfully performing caudal epidural blocks in pediatric patients. A mean success rate of 80% is achieved at our institution after 32 cases. This is very low in comparison to other procedures taught at our institution (Table I).

Acknowledgment

We thank Dr. Stefan Zbinden, Head of the Department of Anesthesiology, Kantonales Spital Wolhusen, Switzerland, for editorial assistance and all participants for their honesty in completing the questionnaires.

References


Manual skills in anaesthesiology

Abstract

Assessment in anaesthesia traditionally takes the form of written papers and oral examinations. These are important for assessing trainee's knowledge and judgement, but do not test for competency in practical skills, which is essential for successful clinical practice. The presence of learning curves for practical skills in anaesthesia is now well recognized and they are useful tools to monitor a learning process. From these, estimates of the number of procedures that must be performed by trainees in order to reach an acceptable success rate can be produced. It is clear that these figures give some help for the rational design of training programs, however, numbers alone do not provide a sufficient basis to declare a trainee competent for a given procedure. Not only technical skills need to be taught, but also decision-making and even more important behavioral skills. In clinical practice there are often problems in providing all the necessary training on patients and by this reorganization of residency programs may be necessary. However, the role of medical simulation in the assessment of anaesthetists in training is still unclear, and the introduction of simulator-based tests may be premature.

Keywords

Manual skills · Learning · Anaesthesia · Learning curves · Education


Lernkurven helfen, die durchschnittlich erforderliche Fallzahl für ein adäquates Training in einer Institution zu generieren. Die Abb. 1 und 2 erläutern die Bedeutung von Lernkurven für das Monitoring einer Ausbildung. Tabelle 1 gibt die so gewonnenen Daten über minimale Fallzahlen wieder und vergleicht sie mit der Literatur. Für Lernkurven können folgende Feststellungen gemacht werden:

1. Es gibt einen raschen initialen Anstieg.


Lernkurven mit der Kumulativen Summen-Methode (Kumsum-V erfahren)

Die kumulative Summen-Methode (Kumsum-Technik genannt) ist eine statistische Methode, die aus der industriellen Qualitätssicherung in die Medizin übertragen wurde [5]. Sie ist besonders zur Performance- oder Ausbildungsmonitorierung geeignet [5, 7, 8]. Die Kumsum-Technik wurde während des 2. Weltkriegs entwickelt, um die Qualität der Produktion von Munition zu überwachen [63]. Diese Technik der Sequen
tialanalyse wurde von Wald als Erstes beschrieben (zit. nach Böslin u. Duy [9]).

<table>
<thead>
<tr>
<th>Verfahren</th>
<th>Erfolgsrate (Mittelwert ± 95% Konfidenzintervall)</th>
<th>Case load (Mittelwert ± 95% Konfidenzintervall)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Kaualanalyse (Kinder)</td>
<td>0,80 (0,59–1,00)</td>
<td>32</td>
</tr>
<tr>
<td>Intubation</td>
<td>0,90</td>
<td>57–80</td>
</tr>
<tr>
<td>Spinalästhesie</td>
<td>0,95 (0,72–1,00)</td>
<td>43±28</td>
</tr>
<tr>
<td>Regionalästhesie</td>
<td>0,99 (0,75–1,00)</td>
<td>71</td>
</tr>
<tr>
<td>Coagulation</td>
<td>0,99 (0,53–1,00)</td>
<td>&gt;45</td>
</tr>
<tr>
<td>Epiduralästhesie</td>
<td>0,85</td>
<td>36±20</td>
</tr>
<tr>
<td>Axillarblock (Technik mit Stimulator)</td>
<td>0,80 (0,71–1,00)</td>
<td>&gt;90</td>
</tr>
<tr>
<td>Arterieller Katheter (A. radialis)</td>
<td>0,95 (0,85–1,00)</td>
<td>83–110</td>
</tr>
<tr>
<td>Zentralvenöser Katheter (V. jugularis interna)</td>
<td>0,80</td>
<td>21±11</td>
</tr>
<tr>
<td>Venenpunktion (peripher)</td>
<td>0,95</td>
<td>79±47</td>
</tr>
<tr>
<td>Platzerfahren einer Pyrexmaske [45]</td>
<td>0,80</td>
<td>50</td>
</tr>
<tr>
<td>Gesamteine</td>
<td>0,50</td>
<td>10</td>
</tr>
</tbody>
</table>

Die minimalen Case load für ein gezieltes Verfahren und eine entsprechende Erfolgsrate ist dargestellt (sofern nicht anders vermerkt, handelt es sich um Daten der Gruppe aus Lazen [34, 46, 62]). Abhängig vom gewählten graphisch-statistischen Verfahren zur Darstellung der Lernkurven lässt sich der minimale Case load bestimmen.

* Basiert sich auf Angaben von Rapoport et al. [63].


<table>
<thead>
<tr>
<th>Tabelle 3</th>
<th>Airway Management: Trainingsbedingungen für verschiedene Fertigkeiten. (Steinger et al.[73])</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Unter klinischen Bedingungen zu erlernde Fertigkeiten</strong></td>
<td><strong>Mit Erfahrung unter nichtklinischen Bedingungen zu erlernde Fertigkeiten</strong></td>
</tr>
<tr>
<td>Maskenbeatmung, Gede und Wendel</td>
<td>Intubation durch eine Larynxmaske (blind oder fiberoptisch)</td>
</tr>
<tr>
<td>Larynxmaske</td>
<td>Fiberoptische Intubation durch Nase oder Mund</td>
</tr>
<tr>
<td>Direkte Laryngoskopie und tracheale Intubation</td>
<td>Wache Intubation</td>
</tr>
<tr>
<td>„Rapid-sequence-Induction“</td>
<td>Verschiedene Hilfsmittel wie Combithére®</td>
</tr>
<tr>
<td>Gebrauch von verschiedenen Spaten und Boigies</td>
<td>Retrograde Intubation</td>
</tr>
<tr>
<td>„Failed intubation drill“</td>
<td>Notfallklinische Erstversorgung</td>
</tr>
</tbody>
</table>


**Beispiele von Lernkurven**

**Regionalanästhesieverfahren**

Der Erwerb von komplexen manuellen Fähigkeiten, wie das Anlegen einer Regionalanästhesie, hängt von vielen Faktoren ab. So werden ungefähr 50 spezifische Grundtypen von perzeptiv-motorischen Fähigkeiten beim Menschen genetisch bedingt postuliert. Als Programme werden angeführt: Räumliche Orientierung, Informationsverständnis, Rechts- oder Linkshänder etc. [35]. Inwieweit die Fähigkeit zur Entwicklung von neuen psychomotorischen Fertigkeiten ein Prädiktor für die Steilheit der Lernkurve oder das Fällen des Kusum-Plots ist, lässt sich nicht beantworten. Für das Erlernen der Epiduralanästhesie in der Geburtshilfe gelang der Nachweis nicht für den Fortschritt beim Erlernen der fiberoptischen Intubation wird er vermutet [15, 16]. Das Erlernen typischer manueller Fähigkeiten im Bereich der Anästhesie ist durch eine raumliche Zunahme der Erfolgsrate für die ersten 30 Versuche charakterisiert (Abb. 1). Dennoch sind einige Verfahren schwieriger zu erlernen als andere. Eine detaillierte Analyse lehnt sich in jedem Fall. So weisen die Lernkurven für die Spinal- und die axilläre Plexusanästhesie 2 Schultern auf. Nach dem oben erwähnten Peak bei 30 Versuchen kann nach 120-130 Versuchen nochmals eine Steigerung der Erfolgsrate beobachtet werden. Von verschiedenen Autoren wurden beispielsweise für die Spinalanästhesie mehr als 45 Versuche für eine durchschnittliche Erfolgsquote von 90% und für die Epiduralanästhesie mehr als 85 Prozeduren gefordert [34, 36]. Um eine verbesserte Exposition zur Durchführung peripherer Blockaden zu erreichen, sind Restrukturierungen der Ausbildungsprogramme nötig und erfolgreich [46], um eine als ungenügend angesehene Fallzahl von 34-45 peripheren Nervenblockaden zu überschreiten [23, 38, 70]. Bei der Etablierung von Ausbildungsprogrammen ist neben der Definitive der notwendigen Fallzahlen auch die Überprüfung der tatsächlichen Effektivität erforderlich. In diesem Zusammenhang wurde schon gefordert, dass angehende Fachärzte strukturiert anhand von festgelegten Protokollen oder mit Video bei der Durchführung von Regionalanästhesien beobachtet sind [6, 46]. In einem ersten Schritt sind sicherheitsebezogene Aspekte eines Ausbildungsprogramms wichtig, in einem weiteren sicherlich auch die qualitati-

der Umgang mit regionalanästhesie muss vertraut sein, und die Verfahren müssen kompetent angewandt werden. Entsprechende Bestrebungen Trau

**Airway Management**


Die Lerngeschwindigkeit hängt auch von Anforderungen an die manuelle Kompetenz ab. Die LMA z. B. wird auch von erfahrenen Praktikern rasch in das eigene Repertoire aufgenommen, da sie relevante klinische Bedürfnisse abdeckt. Betrachtet man die Lernkurve für das Platzieren einer LMA, so zeigt sich ein steiler Anstieg [45]. Schon für den
ersten Versuch gibt es Berichte über Erfolgsraten von 94% und für den zweiten bzw. dritten Versuch von mehr als 90% [4, 41, 42, 43, 44]. Im Gegensatz dazu ist die Beatmung mit Atembeutel und Maske bedeutend schwieriger: Die Erfolgsrate für den ersten 10 Versuche liegt hier unter 50% [2].


Formale Lernkurven wurden auch für die fiberoptische trancheale Intubation erzeugt. Abhängig von den Bedingungen (z. B. Zeitdauer), die an die Erfolgsdefinition geknüpft werden, sind für eine 90%-Erfolgsquote 10 Versuche und für das Erlernen des experienti- veaust eines der mindestens 45 Versuche erforder- lich [47, 49] (Tabelle 4).

Verschiedentlich wurden auch sog. objektive, strukturierte Beurteilungen von technischen Fertigkeiten (OSATS, „objective structured assessment of technical skill“) vorgeschlagen, die die Informationsqualität von Logbüchern unterschiedlicher Güte ist [51]. Dabei wird ein Vorgang nach genau vorgegebenen Kriterien beobachtet und bewertet. Dieses Verfahren zeigt minimale Schranken zwischen verschiedenen Beobachtern. Für den Anästhesiebereich wurden Assessments nach dem OSATS-Prinzip für die Spinalanästhesie [52], die

### Allgemeinanästhesie

<table>
<thead>
<tr>
<th>Erfolgsrate</th>
<th>Case Load</th>
<th>Rahmenbedingungen</th>
</tr>
</thead>
<tbody>
<tr>
<td>0.90</td>
<td>10°</td>
<td>Im ersten Versuch innerhalb 2 min</td>
</tr>
<tr>
<td>0.70-0.80</td>
<td>&lt;18°</td>
<td>Innerhalb 60 s</td>
</tr>
<tr>
<td>Experteinw.</td>
<td>45°</td>
<td>Monophasen-estes Fix-Modell</td>
</tr>
</tbody>
</table>

### Kanülierung einer zentralen Vene


### Einflussfaktoren in der Andragogik

Lernkurven werden durch die Institutionen beeinflusst, die mit der Ausbildungsmethode, dem Verhältnis zwischen Fachärzten und Facharztanwärtern, den zur Verfügung stehenden Patientengut, dem Zeitdruck und der Auswahl an Prozeduren das Lernen prägen. Zum einen können Hilfsmittel, wie Vi-}


Generell erweitern Erwachsene ihr Können und ihre Kompetenz auf einer anderen Basis als Kinder, wenn auch die Unterscheidung zwischen Pädagogik und Andragogik vor dem Hintergrund der Theorie nicht immer zwingend.
Fazit für die Praxis


Das formale Erstellen von Lernkurven trägt dazu bei, den Erwerb von Fähigkeiten und auch die Aufrechterhaltung einer klinisch genügenden Kompetenz zu überwachen. Die so gewonnenen Daten können helfen, Ausbildungsprogramme zu optimieren und die Anforderungen in Bezug auf die notwendigen Fallzahlen auf eine rationale Basis zu stellen.

Diskussion Die Autoren danken Dr. M. Jöhr, Luzern, für die freundliche Unterstützung und die Durchsicht des Manuskripts.

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Learning Manual Skills in Anesthesiology: Is There a Recommended Number of Cases for Anesthetic Procedures?

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Institute of Anesthesiology, Kantonsspital, Lucerne, Switzerland

The learning process is a multidimensional function with a wide intra- and interindividual scattering. To determine the learning process in anesthesia, we evaluated 11 first-year residents according to their rate of success or failure when applying manual anesthesiological skills, such as performance of spinal, epidural, or brachial plexus anesthesia and tracheal intubation or insertion of an arterial line. Epidural anesthesia was the most difficult procedure ($P < 0.05$). Significant differences were found between epidural anesthesia and tracheal intubation ($P < 0.05$), insertion of an arterial line ($P < 0.05$), and brachial plexus block ($P < 0.05$), as well as between spinal anesthesia and otorrhaphy intubation ($P < 0.05$). Learning curves are a valid tool for monitoring institutional and individual success. Implications: To investigate the learning process in anesthesia, typical anesthetic procedures were performed by inexperienced residents during their first year. Learning curves were generated for each procedure performed. Epidural anesthesia was the most difficult procedure to perform ($P < 0.05$). (Anesth Analg 1998;86:635-49)

Individual and institutional learning processes are complex and depend on a wide variety of factors, such as institutional preferences, the learning and teaching situation, and the number of cases over time. Data on the acquisition of manual proficiency in anesthesia are scarce (1). To develop rational training programs, the necessary number of cases per anesthetic procedure should be determined to achieve an optimal rate of success. Few studies have been investigated this topic in anesthesia (2,3). Nevertheless, training programs with minimal requirements have been propagated without a clear scientific understanding (4).

The aim of the present study was to describe the learning process during the first year of an anesthesiological residency and to define the minimal number of cases of each procedure required to achieve minimal rates of failure in regional anesthetic procedures, as well as in tracheal intubation and insertion of an arterial line. Furthermore, the interindividual scattering of learning progress was determined.

Method
Eleven first-year residents were evaluated using a standardized self-evaluation questionnaire. The setting was an anesthesia department of a teaching hospital with an annual caseload of more than 18,000 anesthetics, with 41% performed under regional anesthesia. The success or failure of the procedure to be tested was documented each day by the residents over an 1-yr period. To promote good compliance and a high response rate, data collection and analysis were anonymous. The following procedures were assessed: spinal and lumbar epidural anesthesia, axillary brachial plexus block, orotracheal intubation, and insertion of an arterial line in the radial artery for monitoring purposes. The clinical duties of the residents were supervised by a senior staff member (two to three operating rooms per attending anesthesiologist) at all times. For the individual procedure, no preselection of patients with regard to ASA classification and/or anatomical difficulties was performed. Patients in whom a difficult airway was anticipated were excluded from the intubation group.

Spinal anesthesia was performed in the left lateral decubitus position using a 27-gauge Quincke needle with an introducer and a midline approach (Abbott Co., Chicago, IL). Lumbar epidural anesthesia was also performed in left lateral decubitus position using an 18-gauge Tuohy needle with a loss of resistance technique with a 10-ml glass syringe and saline. In
each case, a 20-gauge epidural catheter was used (Braun Co., Melsungen, Germany). Axillary brachial plexus block was performed using an insulated 25-gauge, 1.5-in. stimulating cannula and a peripheral nerve stimulator (1 or 2 Hz, stimulus width 0.1 ms; Fenned Co., Bonn, Germany). Orotracheal intubation was performed with a 3 or 4 Macintosh blade and plastic Magill orotracheal tubes with an outside diameter of 7.5-8.0 mm (Mallinckrodt Co., Athlone, Ireland). Finally, a Selinger technique with a cannula and a 2-French Teflon catheter (Plastimed Co., France) was used for placement of an arterial line.

Success was defined as adequate technical performance. When the procedure was successfully terminated without any physical help from a staff member, it was rated 1; when physical assistance by a staff member was required, it was rated 0. Verbal comments and suggestions were allowed. For a successful regional anesthetic procedure, only small doses of IV analgesics and/or sedatives were allowed with the patient breathing spontaneously. The attending anesthesiologist took over after a maximum of three attempts or an elapsed time period of 10 min for regional anesthesia procedures or for arterial lines. In orotracheal intubation, two attempts were allowed before the staff member took over. Besides success or failure, no other detailed analysis was documented, nor was the type of help given by the attending anesthesiologist recorded.

On average, 90 cases per procedure and resident were available for analysis, with the exception of the axillary brachial plexus block, for which only 70 cases per resident were available for analysis. The procedures were equally distributed among the residents. Statistical analysis was as follows: to generate confidence intervals, consecutive sums were calculated as a modified cusum analysis and divided by the number of performed procedures. Individual rates of success were generated from these numbers. These success rates were pooled among all participants. The institutional learning curve was calculated by applying a fitting model with a Monte Carlo procedure, a random number simulation technique to mimic a statistical population. To calculate the 95% confidence intervals, the data were boot-strapped. Using the confidence intervals, institutional learning curves for each procedure were created. To compare the learning curves for the different procedures, multivariate analysis of variance, nonparametric tests, and Student’s t-tests with Bonferroni’s correction were used as appropriate. A P value <0.05 was considered significant.

Results
The process of learning manual skills in anesthesia is characterized by a rapid improvement of success during the first 20 attempts. Comparing various regional anesthetic procedures, orotracheal intubation, and insertion of a radial arterial line, epidural anesthesia was the most difficult task. It was significantly more difficult than orotracheal intubation (P < 0.05), insertion of an arterial line (P < 0.05), and axillary brachial plexus block (P < 0.05). Even spinal anesthesia was more difficult than orotracheal intubation (P < 0.05) (Table 1).

The learning curves revealed a marked improvement of skill after 20 attempts, with a success rate ranging from 85% (arterial line) to 65% (epidural anesthesia) (Fig. 1). Analysis of the learning curves showed marked differences among the individual procedures.

The intubation learning curve reached a 90% success rate after a mean of 57 attempts. Even after 80 intubations, 18% of the residents needed assistance. However, an improvement could be seen with the interindividual confidence intervals among resident performance, decreasing significantly from 70% at 10 attempts to 18% after 80 attempts (Fig. 2).

The learning curve of spinal anesthesia rose significantly slower in comparison to the learning curve of orotracheal intubation (Fig. 3). To reach a success rate of 90%, 71 attempts were required, with no clear effect on the confidence intervals.

Epidural anesthesia was the most difficult task, reaching a success rate of barely 80% after 90 attempts. Initial learning was quick, with a 60% success rate after 20 procedures. The interindividual scattering decreased significantly over time, indicating the continuing learning process (Fig. 4).

A steadily increasing learning curve was observed in the performance of axillary brachial plexus block (Fig. 5). After 20 cases, a 70% success rate was achieved, with a continuously narrowing confidence interval.

The learning curve for the insertion of an arterial line followed a different pattern (Fig. 6). After a rapidly increasing success rate to 80% during the initial 20 cases, the learning curve plateaued. Interestingly, the

### Table 1. Success Rate and Recommended Case Load

<table>
<thead>
<tr>
<th>Procedure</th>
<th>Success rate (%)</th>
<th>Recommended case load (Mean)</th>
<th>95% confidence interval for success rate*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intubation</td>
<td>70</td>
<td>57</td>
<td>0.80-0.99</td>
</tr>
<tr>
<td>Spinal anesthetic</td>
<td>90</td>
<td>71</td>
<td>0.75-1.0</td>
</tr>
<tr>
<td>Epidural anesthetic</td>
<td>78</td>
<td>90</td>
<td>0.71-0.85</td>
</tr>
<tr>
<td>Brachial plexus</td>
<td>87</td>
<td>62</td>
<td>0.76-0.97</td>
</tr>
<tr>
<td>Block</td>
<td>84</td>
<td>60</td>
<td>0.60-1.0</td>
</tr>
</tbody>
</table>

*Confidence intervals are given for the mean recommended numbers (values were calculated from all 31 residents).
confidence interval widened after 50 attempts and returned to the initial values after 90 procedures.

Discussion
This study demonstrates that learning manual skills in anesthesia differs greatly among the individual procedures. Regional anesthetic procedures are significantly more difficult to learn than the basic manual skills necessary for a general anesthetic. Epidural anesthesia was the most difficult procedure.

Learning manual skills is a multimodal function that depends on many variables (5). Besides individual variations, the institution and its environment, as well exposure to a sufficient number of cases, influence the learning process. For certification in the specialty of anesthesiology, only written and oral exams are usually performed, but some countries and/or subspecialties require the performance of a certain number of additional anesthetic procedures. Log
books are not very informative in their present form because they only document exposure to the procedure, not the success or failure of the procedure.

In this study, the end points were defined as complete success or failure. Complete success excluded any physical help by the attending anesthesiologist and was meant to indicate a technically perfect procedure with clinical functionality. Failure included manual assistance by the attending anesthesiologist and the necessity to change the anesthetic technique. Relative interval rates, including confidence intervals, were calculated with the success of each procedure performed depending on the previous experience. This approach provided typical learning curves with 95% confidence ranges for easy comparison. For institutional reasons, we did not use cunisim analysis (2,6), which would have required us to include the anesthesiology staff for comparison.

Regional anesthesia techniques seem to be more difficult to learn than the manual skills for general anesthesia. Epidural anesthesia was significantly more difficult to learn than all other procedures tested. Like others (2), we found that epidural anesthesia is also more difficult than spinal anesthesia. Failure rates for epidural and spinal anesthesia resulting in general anesthesia are reported to be 4%-5% (7). A distinction was made between technical failure and management failure, the latter accounting for approximately 75% of the failures (8). Our learning curves examined only the technical part of the anesthetic management.

Most of the learning curves demonstrate a continuous improvement with some increase of the confidence interval after 40 cases for spinal and epidural anesthesia and insertion of an arterial line. A possible explanation could be that the more experienced the residents become, the more difficult the cases assigned to them, thereby increasing the chance of failure. Whether this is a bias caused by patient selection or a demonstration of overconfidence on the part of the residents cannot be determined. The reduction of confidence intervals is a measure of the steadily improving learning process. To avoid stigmatization of slow learners and to acquire honest data, we did not analyze the learning curves of the individual residents. Our data are in agreement with those of Kopacz et al. (9), who reported that 40 attempts to perform regional anesthesia or orotracheal intubation are inadequate to achieve an acceptable success rate.

The training of residents in a specialty such as anesthesia incorporates basic science, clinical science, and manual skills. Basic science and clinical knowledge can be taught and maintained in a number of ways, such as journal study, interactive studies, problem-based case discussions, and self-evaluation programs. Manual skills must be acquired in the operating room, under supervision and/or with simulators. In some subspecialties, a variety of procedures deemed necessary for assessing adequate performance have been suggested (4,10) but never validated. In addition, with the increasing tendency toward recertification, there is a definitive need for more information about the successful learning process and the number of procedures required to maintain manual skills (11). Using learning curves, as we did in this study, training programs can estimate the number of trainees that can be accepted in the program by looking at the institutional case load. Factors such as the staff to resident ratios in teaching manual skills must also be taken into account. In addue, a certain number of cases must be performed by the attending staff so that they can retain their manual skills.

One limitation of this study is that the results may apply only to the local setting and may represent only a specific staff to resident ratio, the type of patients, or physician preferences. Thus, the learning situation can vary greatly among institutions. In addition, the preference of the staff for special procedures, as well as the attraction of the specialty and method of resident recruiting, might be a factor. Another limitation may be the binary evaluation, as we made no distinction between partial and complete failure. Nevertheless, we consider the data valid because the end point—successful technical performance—is clinically relevant.

In conclusion, by using learning curves, it is possible to generate the minimal numbers of each manual procedure required to achieve an adequate success rate. Common regional anesthetic tasks, such as epidural or spinal anesthesia, are more difficult to learn than some techniques used in general anesthesia, such as orotracheal intubation or insertion of an arterial line. Learning curves may be a useful tool for monitoring the learning process of a given institution or individual. In the future, similar studies from different institutions might help to delineate the average number of cases for each procedure required to ensure adequate training and to maintain manual skills.

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References

Lernkurven für manuelle Anästhesieverfahren

Empirische Bestimmungen und Konsequenzen

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Schlüsselwörter: Lernkurven – Anästhesieverfahren – Fallzahl – Facharztausbildung

Einleitung


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Methode


Ergebnisse


<table>
<thead>
<tr>
<th>Erfolgsrate in %</th>
<th>Case Load (Mittelwert)</th>
<th>95%-Vertrauensintervall</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intubation</td>
<td>90</td>
<td>110</td>
</tr>
<tr>
<td>Spinalanästhesie</td>
<td>90</td>
<td>71</td>
</tr>
<tr>
<td>Epiduralanästhesie</td>
<td>80</td>
<td>&gt; 90</td>
</tr>
<tr>
<td>Arteriokatheter</td>
<td>90</td>
<td>110</td>
</tr>
<tr>
<td>Arteriokatheter</td>
<td>90</td>
<td>60</td>
</tr>
<tr>
<td>Zentralvenenkatheter</td>
<td>60</td>
<td>40–60</td>
</tr>
</tbody>
</table>

Eine detaillierte Analyse deckt erhebliche Unterschiede zwischen einzelnen Prozeduren auf. In der Lernkurve der orotrachealen Intubation wird eine 90%ige Erfolgsrate bei durchschnittlich 110 Versuchen erreicht. Trotzdem brauchte nach 80 Intubationsversuchen in rund 18% der Fälle der Assistenzarzt Hilfe oder konnte nicht selber intubieren (Abb. 2). Die Lernkurve für die Spinalanästhesie steigt im Vergleich zur Lernkurve der orotrachealen Intubation langsamer an (Abb. 3). Um eine 90%ige Erfolgsrate zu erreichen, waren 75 Versuche nötig und die Spannweite des Konfidenzintervalls nahm im Vergleich zur Intubationstechnik weniger rasch ab. Ein analoger Trend wurde bei der Epiduralanästhesie beobachtet (Abb. 4). Nach 20 Versuchen betrug die durchschnittliche Erfolgsrate lediglich 60%. Nach den gegebenen 90 Versuchen wurde im Durchschnitt knapp eine 80%ige Erfolgsrate erreicht. Dies illustriert die erhebliche technische Schwierigkeit der Epiduralanästhesie. Bei der Plexusblockade wurde eine gleichmäßiger wachsende Kurve beobachtet (Abb. 5). Nach 20 Versuchen ist eine 70%ige Erfolgsrate mit einer gleichmäßig abnehmenden Spannweite des Konfidenzintervalls kalkulierbar. Nach rund 60 Versuchen flacht die Lernkurve ab und zeigt erst nach über 100 Verfahren einen weiteren Zugewinn. Die Ergebnisse für das Anlegen eines arteriellen Zugangs folgen einem anderen Muster (Abb. 6).


**Diskussion**

Am Ende der Facharztausbildung werden – beispielsweise in der Schweiz und in den USA – vorwiegend kognitive Fähigkeiten und kommunikative Kompetenzen geprüft, nicht aber die erforderlichen manuellen Fertigkeiten der Facharztstandards. Da die Prognosevalidität wissensfokussierter Fachprüfungen für technische und manuelle Fähigkeiten in der Medizin unbestrittenenmaßen gering ist, gewinnt die Monitoring des Erlernens manueller Fertigkeiten im Verlauf der Facharztausbildung zentrale Bedeutung [10, 17]. Die gewonnenen Lernkurven erlauben, die Lernfortschritte der auszubildenden Assistentärzte zu analysieren und zu beurteilen, und sie durch Fachärzte adäquat zu überwachen. Ein subjektiver Bias durch die evaluiierenden Assistenzärzte kann...
ausgeschlossen werden, denn erstens gilt die tatsächliche klinische Effektivität des angewandten Anästhesieverfahrens als Erfolgskriterium und zweitens konnte in einer vorangehenden Studie nachgewiesen werden, daß zwischen Selbst- und Fremdeinschätzung der Assistenzärzte eine sehr hohe Korrelation besteht [16]. Für die Dokumentation des verfahrenspezifischen Erfolges sind allerdings die sogenannten Logbücher in der üblichen Form nicht sehr zweckmäßig, weil die unabhängig von Erfolg oder Misserfolg lediglich die Anzahl der durchgeführten Verfahren erfassen [13].

Für das Erlernen manueller Fähigkeiten ist neben günstigen individuellen und organisatorischen Bedingungen eine bestimmte Anzahl von zur Verfügung stehenden Fällen (caseload) von erheblicher Bedeutung. Am Kantonsspital Luzern kann pro Assistenzarzt in Ausbildung für jedes diskutierte Verfahren mit rund 100 Versuchen gerechnet werden. Tab. 2 faßt die erbrachten Leistungen des Institutes für Anästhesie am Kantonsspital Luzern zusammen. Zur Bestimmung eines kritischen caseloads sind die gewonnenen, einfach interpretierbaren Lernkurven mit 95%igen Konfidenzintervallen sehr nützlich. Dabei bleibt allerdings zu berücksichtigen, daß nicht nur in der initialen Lernphase eine minimale Fallzahl erforderlich ist, sondern auch im Anschluß daran ein kritischer caseload garantiert werden sollte, um die erlernte Fähigkeit zu erhalten [8].

### Tab. 2 Zusammenstellung der Anästhesieverfahren im Jahr 1996 am Kantonsspital Luzern, Schweiz

<table>
<thead>
<tr>
<th>Anästhesieverfahren</th>
<th>1996</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anästhesieverfahren total</td>
<td>18 141</td>
</tr>
<tr>
<td>davon Regionalanästhesietechniken</td>
<td>41%</td>
</tr>
<tr>
<td>Spinalanästhesien</td>
<td>2 005</td>
</tr>
<tr>
<td>Epiduralanästhesien</td>
<td>1 912</td>
</tr>
<tr>
<td>axilläre Plexusanästhesien</td>
<td>1 375</td>
</tr>
<tr>
<td>jugulare interna-Katheter (Zentralvenenkatheter)</td>
<td>1 426</td>
</tr>
<tr>
<td>arterielle Katheter (Arteria radialis)</td>
<td>1 807</td>
</tr>
<tr>
<td>otochordale Intubationen</td>
<td>6 508</td>
</tr>
</tbody>
</table>

Die minimale Fallzahl, um eine Erfolgsrate von minimal 90% zu erreichen, ist für verschiedene zu erlernde manuelle Fähigkeiten im Bereich der Anästhesie unterschiedlich. Die otochordale Intubation kann sehr rasch erlernt werden. Erfolgsraten von 100% nach 21 Intubationen wurden publiziert [15]. Im Gegensatz dazu werden in der Literatur zwischen 1 und 18% schwierige Intubationen erwartet [4,6,14]. Aus unseren Daten kann aber gefolgert werden, daß 21 Intubationen aus statistischer Sicht im Rahmen eines Notfallmedizin- oder Notärzteausbildungsmprogrammes nicht genügen, um eine optimale Erfolgsrate zur Sicherung der Atemwege mittels otochordalem Tubus in Notfallsituationen zu erreichen (vgl. dazu Baden-Württemberg, 1995 [3]). Im geregelter Setting eines Operationsprogramms sahen wir eine mittlere Erfolgsrate von 98% erst nach rund 100 otochordalen Intubationsversuchen. Erst mit zunehmender Erfahrung mit über 120 Intubationsversuchen wird eine 95%-Erfolgswahrscheinlichkeit erreicht. Entsprechend der Literatur ist auch für Erfahrenere mit 1–5% schwierigeren Intubationen zu rechnen [4].

muß, welche Patienten für die auszubildenden Anästhesisten selektiert werden.


In Anbetracht der vorliegenden Daten sind die Anforderungen der amerikanischen Fachgesellschaft an die Anzahl durchzuführender Fälle im Anästhesieverfahren (je 50 epidural- und spinalanästhesien) sowie 40 periphere Nervenblockaden während der ganzen mehrjährigen Ausbildung zum Facharzt kritisch zu beurteilen [2]. Am Kantonsspital Luzern betrugen die möglichen Fallzahlen für die obengenannten Verfahren ungefähr 100 Fälle pro Jahr für jeden Assistenten in Ausbildung. Dies führt zu einer großen Fallzahl innerhalb eines Jahres. Dennoch wird damit erst eine Erfolgsrate von 80% erreicht (Tab. 2).

Zusätzlich kann aus der Darstellung der Lernkurven nicht nur die minimale Fallzahl für eine gegebene Prozedur abgeleitet werden, vielmehr lassen sich aussteigende Lernkurven oder solche mit breiten 95%- Konfidenzintervallen die Forderung nach strengerer Supervision zu.

Schlußfolgerungen


**Literatur**

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Lernkurven bei Anästhesieärzten

Empirische Analyse und Konsequenzen am Beispiel von Assistenzärzten der Anästhesie am Kantonsspital Luzern

Am Institut für Anästhesie und Reanimation des Kantonsspitals Luzern wurden Assistenzärzte1 von Beginn ihrer Tätigkeitsaufnahme an kontinuierlich evaluiert. Unabhängig von der Fremdevaluation durch Fachärzte bewerteten Assistenzärzte ihre Leistungen nach 6 Monaten zusätzlich selbst. Dabei zeigte sich eine sehr hohe Korrelation zwischen Fremd- und Selbstevaluation. Zwischen der Veränderung des Evaluationsscores und dem gleichzeitig erhobenen Sympathiescore für die evaluier-
Lernkurven bei Anästhesieärzten
ten Assistentärzte bei den bewertenden Fachärzten konnte kein Zusammenhang festgestellt werden. Beides dürfte Ausdruck einer verinnerlichten Professionskultur sein. Mit dem validierten kontinuierlichen on-the-job-Evaluationssystem von Assi-
stenzärzten können erstmals institutspezifische Gesamtlernkurven für Assistenz-
arzte erstellt werden. Der betriebliche Nutzen von Assistentärzten in Ausbildung kann aus den gewonnenen Lernkurven abgeschätzt werden, deren höhere Kompli-
kationsraten bleiben aber unberücksichtigt.

1. Problemstellung

Fast alle öffentlichen Spitäler in der Schweiz bilden Ärzte nach Beendigung des Studiums weiter. Diese Mediziner in Assistenzarztfunktion qualifizieren sich entsprechend den Curricula der Ver-
bindung der Schweizer Ärzte (FMH = Foederatio Medicorum Helvetiorum) zu
Fachärzten (FMH) unterschiedlichster Richtungen. Die Ausbildungsstätten brau-
chen diese Mediziner, um ihr Dienst-
leistungsniveau (Notfallpräsenzdienste usw.) aufrechtzuerhalten. Viele medizini-
sche Fachdisziplinen sind allerdings kom-
plex, und die ärztlichen Tätigkeiten sind
nur schwierig in standardisierte Abläufe zu gliedern. Dennoch ist es von Bedeu-
tung zu evaluieren, wie lange Mediziner nach dem Staatsexamen brauchen, um
selbständig (d.h. ohne ständige Überwa-
chung und Intervention) am Patienten tätig zu sein. Die Fachrichtung Anästhesie ist
für derartige Analysen insofern geeignet,
as Anästhesieverfahren viele standard-
disierte Tätigkeiten (vgl. Tab. 1) aufweisen.

Werden fachunerfahrene Mediziner als
Assistenten in eine grosse Fachabteilung aufgenommen, so müssen diese innert
nützlicher Frist ärztlich-anästhesiologi-
sche Aufgaben unter fachärztlicher Super-
vision vor allem im Rahmen des Nacht-
und Wochenenddienstes wahrnehmen
können. Am Institut für Anästhesie und

Tabelle 1

<table>
<thead>
<tr>
<th>Manuelle Fertigkeiten in der Anästhesie</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Orophreale Intubation</td>
</tr>
<tr>
<td>(Platzieren eines Beatmungsschlauches in der Luftröhre)</td>
</tr>
<tr>
<td>2. Durchführen einer Spinalanästhesie</td>
</tr>
<tr>
<td>(rückenmarksnahes Regionalanästhesieverfahren)</td>
</tr>
<tr>
<td>3. Durchführen einer Periduralanästhesie</td>
</tr>
<tr>
<td>(rückenmarksnahes Regionalanästhesieverfahren)</td>
</tr>
<tr>
<td>4. Durchführen einer Plexusanästhesie</td>
</tr>
<tr>
<td>(medikamentöse Blockade des Nervengeflechtes einer Extremität; Regionalanästhesieverfahren)</td>
</tr>
<tr>
<td>5. Einlegen eines Zentralvenenkatheters</td>
</tr>
<tr>
<td>6. Einlegen eines Arterienkatheters</td>
</tr>
</tbody>
</table>

Reanimation des Kantonsspitals Luzern sind 18 Assistentärzte und 12 Fachärzte beschäftigt, welche sich von verschiedene-
en Universitäten rekrutieren. Jährlich werden rund 18 000 Anästhesien durch-
geführt. In den Dienstzeiten sind je ein Fach- und ein Assistenzarzt zusammen mit zwei Anästhesiepflegepersonen verfügb.
bar. Da die Operationssäle der chirurgisch tätigen Fachrichtungen wie Chirurgie, Kinderchirurgie, Frauenklinik usw. örtlich dezentralisiert sind, ist im Dienstbetrieb eine unmittelbare Supervision des Assi-
stenzarztes durch den Facharzt nicht möglich.
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Einer periodischen Leistungsbeurteilung von Assistentärzten kommt somit eine mehrfache Bedeutung zu:

- Evaluation der erforderlichen Dauer der Einführungsphase, d.h. Überprüfung des Zeitbedarfes bis Assistentärzte nach dem Staatsexamen unter fachärztlicher Überwachung bedingt selbständig nachts und an Wochenenden eingesetzt werden können;
- Grundlage für die Optimierung der Schulungs-, Supervisions- und Einsatzplanung von Assistenz- und Fachärzten;
- Ausgangspunkt für die Analyse von individuellen und organisatorischen Lernbedingungen.

2. Vorgehen

Beim Design eines Beurteilungssystems sind u.a. drei Aspekte zu bestimmen:

- institutionelle die Beurteilungsträger, z.B. Beurteilung durch Vorgesetzte, Unterstellte, Gleichgestellte, Kunden oder Selbstbeurteilung
- inhaltlich die Beurteilungskriterien, z.B. ergebnis- und/oder prozess- und/oder personenbezogene Kriterien
- methodisch das Beurteilungsverfahren: frei oder gebunden (vgl. Liebel/Oechsler 1992, 22)


<table>
<thead>
<tr>
<th>Tabelle 2</th>
</tr>
</thead>
<tbody>
<tr>
<td>Evaluationskriterien</td>
</tr>
<tr>
<td>1. Selbstständiges Durchführen einer Allgemeinanästhesie bei Patienten der Risikoklasse ASA I und II*</td>
</tr>
<tr>
<td>2. Selbstständiges Durchführen einer rückenmarksnahen Anästhesie bei Patienten der Risikoklasse ASA I und II*</td>
</tr>
<tr>
<td>3. Organisation des Notfallteams</td>
</tr>
<tr>
<td>4. Fähigkeit zum Multitasking</td>
</tr>
<tr>
<td>5. Fähigkeit, aufgrund von wenigen Informationen rasch Entscheidungen zu treffen</td>
</tr>
<tr>
<td>6. Befähigung für den Einsatz im Rettungsdienst als Notarzt</td>
</tr>
</tbody>
</table>

* Risikoklassierung der American Society of Anesthesiologists (ASA):
ASA I: tiefste anaesthesiologische Risikostufe
ASA V: höchste anaesthesiologische Risikostufe
Lernkurven bei Anästhesieärzten


Abbildung 1: Individuelle Lernkurven der Assistenzärzte (je Arzt ein graphisches Zeichen). Durchschnittliches Rating nach sechs Monaten: 54.5±12.7 (Standardabweichung). N=27. Durchschnittliche Beobachtungsdauer: 12 Monate ±11 Monate (Standardabweichung). Score = 104.7 * (1/1+6.7/Monat )

3. Ergebnisse

3.1 Befund 1


3.2 Befund 2

Acht Assistenzärzte konnten von Anstellungsbeginn an länger als sechs Monate

Abbildung 2: Korrelation zwischen dem Selbstrating der Assistenzärzte (n=8) und dem gemittelten Rating der drei Fachärzte (Fremdrating) 6 Monate nach Tätigkeitsaufnahme als Assistenzarzt (r=0.91142; y = 7.3351+0.86963x)

beobachtet werden. Wie Abbildung 2 zeigt, korreliert deren Selbstbeurteilung streng mit der Fremdbeurteilung durch die Fachärzte. Der Korrelationskoeffizient r
Lernkurven bei Anästhesieärzten

beträgt 0,91, das Beta in der Regressionsanalyse 0,90.

3.3 Befund 3

Abbildung 3 zeigt einerseits die Zunahme des Facharztratings und andererseits die Sympathieeinschätzung der Fachärzte bezüglich der Assistenzärzte. Dabei kann keine Korrelation zwischen dem gemittelten Sympathiescore sechs Monate nach Anstellungsbeginn und der Zunahme des Facharztratings zwischen dem dritten und sechsten bzw. sechsten und neunten Anstellungsmonat festgestellt werden.

4. Diskussion

4.1 Beurteilungskriterien

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Wie Abbildung 1 zeigt, kommt es in den ersten sechs Monaten zu einem raschen Lernfortschritt, der sich in der Folge aber verlangsamt. Wenn die Assistenzärzte nach sechs Monaten in die Nacht- und Wochenenddienstrotation eintreten, so liegt ihre Tauglichkeit hierfür im Mittel lediglich bei 54 von 100 möglichen Scorepunkten bei einer Standardabweichung von 12,7 Punkten. Erst nach 18 bis 24 Monaten werden Scores zwischen 90 und 100 Punkten erreicht.


4.2 Lernkurve als Zunahme des Facharztratings

Abbildung 1 zeigt, dass das Facharztrating degressiv zunimmt. Die Zunahme wird als Lernkurve interpretiert. Die Gültigkeit dieser Interpretation bedingt, dass Beurteilungsfehler so ausgeschlossen werden können, dass die Zunahme des Facharztratings tatsächlich im Lernfortschritt der Assistenzärzte begründet liegt.

Validität der Beurteilungskriterien vor- ausgesetzt, sind grundsätzlich drei Quellen von Beurteilungsfehlern in Betracht zu ziehen: der Beurteiler, der Beurteilte und das Verfahren. Verfahrensbedingte Fehler sind im vorliegenden Fall insofern unerheblich, als standardisiert bei jeder Beurteilung das gleiche Verfahren angewendet worden ist. Auch beurteilungsbedingte Fehler können ausgeschlossen werden, da die
Lernkurven bei Anästhesieärzten

Assistenzärzte bis zum sechsten Monat nach Anstellungsbeginn vis-à-vis der stattfindenden Evaluation blind waren.


4.3 Hohe Korrelation zwischen Fremd- und Selbstbeurteilung als Ausdruck einer Professionskultur


Im vorliegenden Fall der Assistenzärzte am Institut für Anästhesie und Reanimation des Kantonsspitals Luzern fällt das Steuerungsprinzip Preis ausser Betracht. Auch bürokratische Steuerungsmechanismen liegen nicht vor. Es erfolgt keine formalisierte Überwachung von prozessbezogenen Regeln oder Standards, sondern die Assistenzärzte werden durch alle Fachärzte des Institutes in ihren Tätigkeiten angeleitet. Damit verbleibt der Clanmechanismus (welcher den Medizinern gerne nachgesagt wird) als mögliche Erklärung. Als «Clan» ist dabei die Profession zu verstehen. In diesem Sinne sind es die im Prozess der beruflichen Sozialisierung sich einstellenden gemeinsam geteilten und für die konkrete Profession charakteristischen Werte, Normen, Fertigkeiten und Kenntnisse, welche für die hohe Korrelation zwischen Fremd- (d.h.
Lernkurven bei Anästhesieärzten


4.4 Kosten und Nutzen von Ärzten in Ausbildung


Beider Beschäftigung auszubildender Assistenzärzte der Anaesthesie fallen u.a. folgende Kosten in Betracht:

a) direkte Personalkosten
b) Ausbildungskosten der Unterweisung und Anleitung
c) Kosten der Supervision
d) Kosten der Komplikationsrate.

Der Substitution von Assistenzärzten durch qualifiziertes Pflegepersonal sind enge fachliche und kostenmäßige Grenzen gesetzt. Fachliche Grenzen ergeben sich durch die für die Anaesthesietätigkeit erforderlichen ausbildungsmäßigen Voraussetzungen. Darüber hinaus wäre der Einsatz von qualifiziertem Pflegepersonal bezogen auf die vier oben erwähnten Kostenarten a) bis d) rauchteurer.

Beim Einsatz von Fachärzten an Stelle von auszubildenden Assistenzärzten würden die Kosten b) bis d) entfallen. Eine Substitution von Assistenzärzten durch Fachärzte wäre dann ökonomisch sinnvoll, wenn der damit verbundene Pro-
Lernkurven bei Anästhesieärzten

duktivitätszuwachs höher als die Zunahme der entsprechenden direkten Personalkosten wäre. Analysiert man das bestehende Lohngefüge und die Lernkurve von Abbildung 1, dann kann dieser Fall ausgeschlossen werden.

Somit verbleibt als Ergebnis, dass die Beschäftigung von auszubildenden Assistenzärzten für die Spitälä nicht nur nicht mit zusätzlichen Kosten, sondern mit Einsparungen verbunden ist. Diese Einsparungen werden u.a. durch die Assistenzärzte selbst finanziert, indem sie zu einem tieferen Kosten-je-Anästhesieinstunden-Lohnsatz zu arbeiten bereit sind. Als Kompensation dafür sind sie Nutznieder der später abgeschlossenen Facharztausbildung, die ihnen und nicht dem sie ausbildenden Spital zugute kommt. In humankapitaltheoretischer Sicht ist die Facharztausbildung eine Akkumulation von generellem Humankapital, das durch die Auszubildenden zu finanzieren ist, und nicht ein betriebsspezifisches Humankapital, wofür das jeweilige Spital aufzukommen hätte.

5. Folgefragen

Ausgehend von den in Abbildung 1 dargestellten Lernkurven ergeben sich Folgefragen, die zum Gegenstand gesonderter theoretischer und empirischer Untersuchungen gemacht werden können. Ansatzweise sollen drei kurz genannt werden.


- Synchron zur Lernkurve ist grundsätzlich eine Risikokurve (Komplikationsrate) bestimmbar. Damit können der ausbildungsbedingte Risikoumfang und Kosten-Nutzen-Überlegungen zur Risikobegrenzung präzisiert werden.

- Lernkurven verschiedener Personalgruppen und/oder zwischen unterschiedlichen organisatorischen Einheiten erlauben zwischenbetriebliche Vergleiche und zielgerichtete Dif- ferenzanalysen, sei es z.B. um den Einfluss der Lernumgebung zu bestimmen oder die Ausbildungsproduktivität zu optimieren.

Literaturhinweise


Lernkurven bei Anästhesieärzten


4.2. Aspects of risk management

Konrad C, Schmeck J, Schüpfer G. Statistische Prozesskontrolle zum Qualitätsmanagement in der Anästhesie. Anästhesiologie & Intensivmedizin 2001; 42:946-950


Statistische Prozeßkontrolle zum Qualitätsmanagement in der Anästhesie

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Einleitung


Grundkonzept: Natürliche Variabilität und statistische Kontrolle


* Herrn Prof. Dr. Dr. h.c. Klaus van Ackern zum 60. Geburtstag


In Konsequenz dieser Definitionen gibt es zwei grundsätzlich verschiedene Interventionsstrategien, um die Qualität des jeweiligen Prozeßtyps zu verbessern: Bei gut definierten und stabilen Prozessen mit kontrollierter Variation können die Variationen nur noch durch Reduzierung der Variationen oder durch die Erhöhung der Qualität der Prozesse reduziert werden. Bei Prozessen mit unkontrollierten Variationen müssen die Ursachen für dieses Verhalten gesucht und beseitigt werden, um ihn zu stabilisieren und damit substanzial zu verbessern. Ein Umbau des Produktions systems ist zu diesem Zeitpunkt ökonomisch nicht sinnvoll (14).

**Control Charts: Formatierung, Gebrauch und Interpretation**


Auf diese Weise sind Control Charts zur Verbesserung von Prozessen sehr variable Werkzeuge (7, 12, 14). Veränderungen lassen sich statistisch fassen und absichern. Es gilt einerseits spezifische Variationsursachen zu identifizieren und zu eliminieren und andererseits...
Abbildung 2: Run-Rules als Methode der SPC.

Folgende Run-Tests kommen zur Anwendung:

a) 9 Datendpunkte in Folge auf einer Seite der Mittellinie innerhalb Zone C oder darüber hinaus. Beim Vorliegen dieses Musters ist der Prozess außer Kontrolle.

b) 6 Datendpunkte in ansteigender oder abfallender Reihen. Dieser Test ist ein Indikator für die Verschiebung des Durchschnitts. Einfußgrößen sind in der Industrie Abnutzung des Werkzeuges, nachschichtige Wahrung oder aber auch Lerneffekte und verbesserte manuelle Geschicklichkeit.

c) 14 Datendpunkte abwechselnd ober- bzw. unterhalb der Mittellinie. Dieser Test weist auf eine alternierende systemische Ursache hin.

d) 2 von 3 Punkten in Folge in Zone A oder darüber hinaus. Dies ist ein Warnhinweis für eine Verschiebung des Prozesses.

e) 4 von 5 Punkten in Folge in Zone B oder darüber hinaus. Dies ist ein Warnhinweis für eine Verschiebung des Prozesses.

f) 15 Punkte in Folge in Zone C (über und unterhalb der Mittellinie). Dieser Test legt eine geringere Variabilität des Prozesses nahe verglichen mit den berechneten Kontrollgrenzen.

g) 8 Punkte in Zone A, B oder darüber hinaus abwechselnd auf einer Seite der Mittellinie. Dieser Test weist daraufhin, dass verschiedene Proben von unterschiedlichen Faktoren beeinflußt wurden (bimodale Verteilung).

die natürlichen, allgemeinen Prozeßschwankungen so zu beeinflussen, daß die Kontrollgrenzen sich der Mittellinie nähern. Damit operiert der Prozeß näher am Zielwert. Von großem Vorteil ist dabei die Tatsache, daß die Limiten unabhängig von der Grundverteilung, welche die Daten mathematisch sonst am besten beschreibt, sicher errechnet werden können. Die Daten müssen also z.B. nicht normalverteilt sein.

Control Charts sind also einerseits einfache und effektive Mittel, um klar zwischen Routinevariationen und Ausreißern aufgrund spezifischer Ursachen unterscheiden zu können, andererseits aber auch induktive Instrumente, um mit einer Datenssequenz aus einem kontrollierten Prozeß in der Vergangenheit zukunftsbezogene Aussagen machen zu können. Sie sind stets realitätsbezogene Führungshilfen und keine Wahr scheinlichkeitsmodelle (7).

Control-Charts-Typen

Es gibt unterschiedliche Control Charts. Ihre Anwendung richtet sich nach der Datenstruktur und der Verteilung der Grundgesamtheit, entsprechend variiert das zu Grunde liegende mathematisch-statistische Konzept. Die adäquaten Formalsammlungen sind in Standardwerken referenziert (1, 7, 8, 12). Die statistische Prozeßkontrolle (SPC) stammt als Instrument aus der industriellen Fertigung und wurde zuerst nur bei der Produktionskontrolle angewandt. Sie ist aber auch bei Dienstleistungen jeder Art anwendbar (6).

Neben Variablen aus einer Intervallskala können auch Daten aus einer Nominal- oder Ordinalska (sog. Attributdaten) verwendet werden (14, 15, 16, 17). Der Datentyp bestimmt die zu wählende Control Chart.


Für diskrete Daten werden meist zwei verschiedene Paare von Control Charts verwendet. Für binomial verteilte Daten werden np und p Charts und für poisson verteilte Daten c und u Charts verwendet.


Grundsätzlich ist das Ereignis gleich wahrscheinlich (z.B. Fehler bei der Rechnungsstellung, Anzahl der Patienten mit Relaxanenüberhang und Nachbeatmung pro Woche, Auftreten von Duraperforationen pro Monat; vergl. dazu Abbildung 1). Die auf der Poisson-Verteilung basierenden c und u Charts werden für Zählarten ohne theoretisches Maximum verwendet (z.B. Anzahl aufgenommener Patienten in den Schockraum pro Schicht, Anzahl von Gebirgern mit Epiduralanalgesie etc.). Meist sind Voraussetzungen für die oben erwähnten Charts gegeben. So sind g und h Charts anzuwenden, wenn die zu Grunde liegende statistische Verteilung geometrisch ist (2). Dieser Analysetyp ist zum Monitoring seltener dichotomer Ereignisse geeignet (z.B. Anzahl Zahnzuchäden nach Intubation, Todesfälle bei Allgemeinästhesie).

Hinweise zum Gebrauch von Control Charts

Vor einem zu simplifizierten Anwenden von Control Charts muß trotz des einfachen Konzeptes gewarnt werden. So sollten die Prozeßkontrollgrenzen auf den empfohlenen Formeln beruhen, drei Standardabweichungen betragen und nicht auf der Standardabweichung der Gesamtdaten basieren. Autokorrela-

**SPC zur Qualitäts sicherung in der Anaesthesie**


**Summary:** The management philosophy of continuous quality improvement and the tools of statistical quality control have the potential for advancing quality management in medicine as they have in industry. Statistical process control was adopted as a technique for continuous quality improvement in an anaesthesiological department. We illustrate the use of control charts (p-Charts, X-mR Charts) to identify an opportunity for process improvement, to develop an improvement strategy and to measure the efficacy of the intervention. Statistical process control is able to improve institutional process quality because the major determinant of patient care quality is the system through which services are delivered and not the individual care provider.

**Key-words:**
Anästhesie;
Qualität control;
Process assessment (health care).
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Improving time-sensitive processes in the intensive care unit: the example of ‘door-to-needle time’ in acute myocardial infarction

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Abstract

Objective To assess and reduce delays in coronary thrombolysis in patients with acute myocardial infarction.

Design Prospective, descriptive study using statistical process control.

Setting Interdisciplinary intensive care unit of a 300-bed community hospital.

Subjects Thirty-seven consecutive patients with acute myocardial infarction who were receiving thrombolytic therapy.

Interventions To perform an interdisciplinary formal process analysis aimed at detecting delay-causing factors, review of existing house rules, generation and implementation of new practice guidelines.

Main outcome measures Comparison of ‘door-to-needle times’ of patients admitted before, during and after formal process analysis and implementation of new guidelines.

Results Mean ‘door-to-needle time’ fell significantly from 57 minutes (±25.4) in 16 patients studied before, to 32 minutes (±9.0) in 16 patients studied after the formal process analysis and the implementation of new guidelines (P<0.002). An even more pronounced but transient decrease to 24 minutes (±5.8) was observed in five patients studied during the phase of formal process analysis (P<0.004). Delay-causing factors were identified in the areas ‘communication’, ‘people’ and ‘methods/rules/guidelines’. Equipment failure was never responsible for delays.

Conclusions Formal process analysis, followed by implementation of revised guidelines resulted in a significant reduction of ‘door-to-needle time’. An initial dramatic but transient reduction of ‘door-to-needle time’ was considered observational and must not be mistaken as the definite new level of performance. We conclude that formal process analysis techniques are suited to improve processes in the intensive care unit.

Keywords door-to-needle time, formal process analysis, myocardial infarction, quality assessment in health care, thrombolytic therapy

The main driving forces of today’s medicine are the continuing scientific progress and the increasingly rigid cost constraints. Quality of care has emerged as a third key element. In the quality debate, attention is shifting increasingly towards process quality. Many processes in the hospital, such as the care of patients with acute myocardial infarction (AMI) receiving thrombolytic therapy, are highly time-sensitive. Prognosis of patients with AMI is significantly improved by early thrombolysis [1,2]. Benefit is reported up to 12 hours after onset of symptoms [3,4], the major effect being observed within the first few hours [5]. Apart from precious time losses in the pre-hospital phase [6,10], delays also occur after hospital admission [8,11–13]. The reduction of the time span between hospital admission and the initiation of thrombolytic therapy – commonly known as the ‘door-to-needle time’ (DTNT) – is thus a worthwhile target for improvement. A DTNT of 30 minutes is a generally accepted standard [14–16]. When viewed as a marker of efficiency of the team involved, DTNT can serve as an indicator of process quality. Despite the many time-sensitive tasks in the hospital

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and the manifold opportunities for improvement connected herewith, clinicians are mostly unfamiliar with the practical use of quality management tools. We conducted a clinical study to assess and improve the process of thrombolytic therapy by using formal process analysis techniques. Our work tries to exemplify the successful use of formal quality control measures in the hospital.

Methods

We undertook a prospective, descriptive quality control study over 16 months from January 1996 to April 1997; we recorded DTNT (defined as the interval between hospital arrival and application of the thrombolytic bolus) of all consecutive patients with AMI receiving i.v.-thrombolysis at our 10-bed intensive care unit (ICU). Our institution, a 300-bed community hospital, serves a mountain area with 160,000 inhabitants.

All patients fulfilling the following lysis criteria were included in the study:

- ST-segment elevations > 1 mm in two or more standard limb leads of the electrocardiogram (ECG);
- or > 2 mm in two or more contiguous precordial leads;
- or a newly appeared left bundle branch block on ECG;
- and onset of typical, persisting chest pain less than 6 hours before admission.

Recombinant tissue plasminogen activator and streptokinase were the thrombolytic agents used. The drugs were administered exclusively in the ICU. All patients admitted to the hospital with proven or suspected AMI were transferred directly to the ICU. Patients with non-specific chest pain were initially evaluated in the emergency department (ED). Those, who were found to have AMI and fulfilled the above criteria were consecutively transferred to the ICU for thrombolysis. The unit is adjacent to the ED; therefore transfer related delays were minimal.

We studied three phases. First, we only documented the DTNT of 16 consecutive patients and compared them with the set standard of 30 minutes. In a second phase we conducted a formal process analysis to detect factors causing delays in the in-hospital management. In an interdisciplinary session among involved physicians and nurses of all functional levels the patient's way from hospital arrival to the application of the thrombolytic bolus was analysed step by step. Every participant named causes for delays he had personally experienced. All identified factors were depicted in a 'fishbone diagram' [17]. This was followed by rewriting our previous guidelines, adding an additional section with explicit instructions about optimal timing of these cases. In a third phase implementation of the new guidelines occurred by
formally teaching unit staff about the modified written rules, which were from now on readily available. Target DTNT was explicitly set at 30 minutes or less. By comparing the new DTNTs with those recorded during the preceding phases we assessed the impact of the new guidelines and their implementation.

Data were analysed with non-parametric ANOVA and adequate post hoc methods. In addition, methods of statistical process control [18] were used for longitudinal chronological analysis. Analysis was performed by using the software Statistica 3.1 (StatSoft Inc, Tulsa, OK, USA) and Memory Jogger Version 3.21 Fa (Grol/QPC, Methuen, MA, USA).

The hospital ethics committee waived informed consent for this type of quality control study.

Results

During the study period a total of 116 patients with AMI were admitted. Thirty-seven (32%) qualified for and received thrombolytic therapy. Each diagnosis of AMI was confirmed by elevated CK levels later in the hospital course. The mean DTNT for the first 16 patients (before process analysis) was 57 minutes (±25.4) (Figure 1).

The ‘fishbone diagram’ compiles the findings of our process analysis (Figure 2). Factors causing delays were identified in the fields ‘communications’, ‘people’ and ‘methods/rules/guidelines’. One of the most striking factors involved was an apparent lack of communication. Aside from late or even absent notification about patients to be admitted to the ICU and interaction deficits between different in-hospital services (e.g. ICU laboratory) we perceived a generally underdeveloped communication culture (e.g. nurses not calling for immediate support when venipuncture failed). Often, too many people were present at the bedside, thereby slowing down the coordination of ongoing procedures. Internal medicine staff were notoriously not arriving in time. Often residents in charge were wasting time by not focusing on essentials. Delays also occurred when the involvement of a cardiologist was necessary. Delays in processing urgent laboratory analyses.
were seen, especially during the daytime. An unwritten law that had demanded a chest X-ray before the administration of thrombolytic therapy was also discussed and abandoned. Similarly the practice of awaiting certain lab results was given up, specifically the creatine kinase (CK) levels. Furthermore the list of contraindications for thrombolytic therapy was considered too long and too restrictive.

Areas not found to cause delayed response, equipment, technology and availability of nursing staff.

Our new guidelines including the list of indications and contraindications for thrombolytic therapy – the result of our final interdisciplinary discussion – are shown in Tables 1 and 2.

Mean DTNT for five patients studied during the ongoing analysis but before implementation of new guidelines was significantly shorter: 24 ± 3.8 minutes (P < 0.004). Having finished the process analysis we implemented the new written guidelines. Mean DTNT for the next 16 patients remained significantly lower than in the pre-analytic period (32 ± 9.0 minutes; P < 0.002). Ten (62.5%) patients of the final group were treated within the new set DTNT standard of 30 minutes. In contrast none of the first phase patients but all five patients of the second phase group had received treatment within the targeted 30 minutes.

Analysis by statistical quality control charts (Figure 3) showed that the process of in-hospital patient management in the first 16 patients, apart from being too slow, had also drifted outside of statistical control limits; this is reflected by an unnatural variability of DTNT in this group. After initiating the formal process analysis variability of DTNT was clearly reduced, indicating the presence of a statistically controlled process.

During the study period no major complications of thrombolytic therapy (e.g. intracranial haemorrhage) occurred.

Discussion

Smooth processes will become key issues in the quality of health care debate. Among other factors, good timing will be a main target for improvement. To analyze specific processes it is necessary to quantify them. Overall process quality cannot be measured directly; we must resort to the use of quality indicators as easy to assess surrogate markers reflecting overall quality. DTNT, in our example, is a prototype of such an indicator, because it represents the result of a very complex set of processes but nevertheless is simple to measure.

In our ICU, as in other institutions [7,11,13], DTNT was usually too long. In order to improve, we applied a quality control tool, well known to the industrial world but not to clinicians. This step-by-step analysis of the in-hospital course of patients with AMI receiving thrombolytic therapy was based on the experience of different staff members (physicians and nurses). The results therefore represent the collective expert knowledge about the investigated process. The 'fishbone diagram', a classical quality management tool [17] allowed for a clearly arranged presentation of the entire complex process. The main delay-causing factors could be detected easily in the fields communication, co-ordination and existing guidelines.

Table 1 Indications and contraindications for thrombolysis in AML Adapted from [23]

<table>
<thead>
<tr>
<th>Indications</th>
<th>Contraindications</th>
</tr>
</thead>
<tbody>
<tr>
<td>Typical thoracic pain</td>
<td>Known bleeding diathesis, current use of anticoagulants in therapeutic doses (INR &gt; 2–3)</td>
</tr>
<tr>
<td>ECG alterations</td>
<td>Active peptic ulcer</td>
</tr>
<tr>
<td>ST-segment elevations &gt; 1 mm in two or more standard limb leads or</td>
<td>Recent internal bleeding (within 2–4 weeks)</td>
</tr>
<tr>
<td>ST-segment elevations &gt; 2 mm in two or more contiguous precordial leads or</td>
<td>Recent major trauma or surgery within 6 months</td>
</tr>
<tr>
<td>New left bundle branch block</td>
<td>Recent cerebrovascular stroke within 12 months or intracranial/intraspinal surgery within 6 months</td>
</tr>
<tr>
<td></td>
<td>Previous haemorrhagic stroke at any time</td>
</tr>
<tr>
<td></td>
<td>Known intracranial neoplasm</td>
</tr>
<tr>
<td></td>
<td>Suspected aortic dissection, bacterial endocarditis, pericarditis</td>
</tr>
</tbody>
</table>

Relative contraindications

- Severe uncontrolled hypertension on presentation (blood pressure > 180/110 mm Hg)
- Recent traumatic or prolonged (> 10 minutes) cardiopulmonary resuscitation
- Proliferative haemorrhagic retinopathy (e.g. diabetic)
- Previous intramuscular injection
- Pregnancy

NTR, International normalized ratio; CPR, cardiopulmonary resuscitation.

Reproduced with permission [23]. © 1996 by the American College of Cardiology and American Heart Association, Inc.

Availability of technology and staffing was not a delay-causing factor in our setting. We did not, however, attempt to measure the identified items separately. The very complexity of the process with its major and minor contributing elements did not permit any pin-pointing.
Table 2 Guidelines for management of patients with typical chest pain and suspected AMI

<table>
<thead>
<tr>
<th>Timing</th>
<th>Physicians’ tasks</th>
<th>Nurses’ tasks</th>
</tr>
</thead>
<tbody>
<tr>
<td>10 minutes</td>
<td>Patient’s history</td>
<td>Record admission-time</td>
</tr>
<tr>
<td></td>
<td>Short examination</td>
<td>Obtain 12-lead ECG</td>
</tr>
<tr>
<td></td>
<td>Interpretation of ECG</td>
<td>Aspirin p.o. or i.v.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Placement of first i.v. line</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Draw blood for serum cardiac markers, haematology, chemistry and lipid profile</td>
</tr>
<tr>
<td>10 minutes</td>
<td>Rule out contraindications</td>
<td>Placement of second i.v. line</td>
</tr>
<tr>
<td>10 minutes</td>
<td>Staff physician decides about</td>
<td>Prepare and administer thrombolytics</td>
</tr>
<tr>
<td></td>
<td>thrombolysis</td>
<td>Record ‘door-to-needle time’</td>
</tr>
</tbody>
</table>

Figure 3 Process control chart of ‘door-to-needle times’ of 37 consecutive patients. Centre line denotes target ‘door-to-needle time’ of 30 minutes with a desired 3 SD of 5 minutes (dotted lines). ●, ‘Door-to-needle time’ out of statistical control; ++, ‘Door-to-needle time’ within statistical control.

The exercise was impressively cost-effective. Except for some extra time and effort spent by the ICU team our study consumed no additional resources. We can thus prove that meaningful and significant improvements in ICU care can indeed be achieved with minimal or no additional investment.

Potential for improvement was found mainly on the operational side. This knowledge was turned into management decisions and resulted in the generation and implementation of new guidelines (Tables 1 and 2). Clinical practice guidelines are a helpful tool in a physician’s daily practice. Checklists with indications and contraindications for thrombolysis may shorten the decision making in patients with acute chest pain and suspected AMI. To be of value, guidelines must be clearly formulated and readily available. They have to be reviewed and adapted regularly as shown in our example.

In view of the self-evident results the use of statistics could be debated. We used statistical process control tools, expecting to learn more about monitoring an ongoing process. Post hoc analysis by ANOVA showed that mean DTNT after, and even during, our effort was significantly lower than before the analysis. Any intervention will change a defined process and even merely measuring DTNTs in our unit represents an intervention. Thus, our process was already influenced at the beginning. Because methods of classical statistics require independence of variables, the evaluation of our data with a post hoc analysis was considered insufficient. Furthermore it is appropriate to analyse continuous processes by using methods of statistical process control. So-called control charts [19] allow insight into the investigated process and permit monitoring of consecutive events. In contrast, classical statistical methods control charts provide additional longitudinal information [18].

Evaluation of our data by using control charts showed that in the beginning there was considerable variability of DTNTs signifying that the process of in-hospital management of patients with AMI was out of statistical control. Shortly after the initiation of formal process analysis DTNTs were reduced significantly and remained within a narrow range, now showing a stable and statistically controlled pattern. Thus, process quality was significantly improved by our efforts.

The control charts revealed another interesting phenomenon, namely the changes observed in the beginning of
formal process analysis. We consider this initial improvement of performance to be an observational bias, a consequence of the increased general awareness of all people involved in the analysis. It is important to note that this observational effect was only temporary and did not represent the definitive new level of performance. Such transient improvements must not be mistaken for the real result.

One might also argue that most of the delay in treatment of patients with AMI happens before hospital admission, especially by patient-related variables [9,10] and that assessing insignificant in-hospital delays has little meaning. However, attempts to reduce pre-hospital delays by community education programmes seem to be disappointingly ineffective [20,21]. Even if programmes intending to defer diagnostic procedures and therapy to the pre-hospital period showed benefit in certain studies [11,22], they are not feasible everywhere. As long as hospitals lack influence on the pre-hospital phase, they should at least keep the in-hospital course of these patients as short as possible.

In our study, a simple and straightforward process analysis technique significantly and persistently improved the quality of a time-sensitive process: the in-hospital treatment of patients with AMI receiving thrombolytic therapy. Measuring lower and less variable DTNTs substantiated this result. We conclude that methods of formal process analysis, together with proper implementation of the findings, are most desired to improve complex procedures in the hospital. Not only the result of the analysis but also the analytic process by itself will influence the process in question and therefore observational effects do occur. Observational effects are transient and must not be mistaken for the definitive result. We recommend the use of process management techniques as quality control tools for time-sensitive tasks in the ICU.

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Detection of Fluid Volume Absorption by End-Tidal Alcohol Monitoring in Patients Undergoing Endoscopic Renal Pelvic Surgery

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Study Objective: To determine the risk of relevant fluid absorption (calculated volume above 500 ml) during endoscopic procedures of the renal pelvis.

Design: Prospective clinical investigation with implementation of statistical process control tools (SPC).

Setting: Nonuniversity teaching hospital.

Patients: 62 consecutive ASA physical status I and II patients scheduled for endoscopic renal pelvic surgery with general anesthesia.

Interventions: Intraoperative measurement of breath alcohol for detection of fluid absorption. Irrigation fluid (0.9% saline) with 1% alcohol for tracer the irrigation fluid.

Measurements and Main Results: Calculation of the amount of fluid absorbed using breath alcohol values. Process variability (number of patients with relevant fluid absorption) defined by SPC. The prevalence of fluid absorption in endoscopic renal pelvic surgery was 6%. Peak fluid absorption during a vascular route was detected by the monitoring. Monitoring was easily introduced into routine clinical practice. No relevant side effects due to the monitoring were seen in patients with relevant fluid absorption. There was no mortality, but two patients with detected severe fluid overload were admitted to the intensive care unit for treatment.

Conclusion: Breath alcohol levels during general anesthesia for endoscopic renal pelvic surgery were technically simple to measure. Our results show the predictive value of alcohol monitoring, which has been previously demonstrated only for transurethral prostatectomy. The prevalence of relevant fluid absorption was 6% compared to 13% during transurethral resection of the prostate. © 1999 by Elsevier Science Inc.

Keywords: Absorption; Fluid absorption; monitoring renal pelvic surgery; statistical process control.

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Introduction

Endoscopic techniques for surgical procedures are increasing steadily. At the same time, new side effects of these techniques are on the rise. Therefore, awareness of potential harm is essential in treating patients with new techniques. The fluid absorption of hypotonic irrigation solution is a well-known complication during transurethral resection of the prostate (TURP). Such a syndrome can occur during any procedure in which large amounts of irrigation fluids are used. Excessive absorption may lead to hypervolemia and life-threatening complications such as hypokalemia, electrolyte disturbances, and consequent cardiovascular collapse. Cardiovascular morbidity and mortality were shown to increase with fluid absorption. In the past, various methods such as electrolyte monitoring, monitoring of hemoglobin (Hb) concentration, or measuring the weight of the patient, as well as tracing the irrigation fluid with radioactive isotopes, were suggested as ways to detect fluid absorption. Then, measurement of end-tidal breath alcohol levels was successfully introduced into clinical practice. Measuring end-tidal breath alcohol levels became standard in many institutions. This monitoring tool significantly improved the process quality, resulting in a better outcome with fewer complications after TURP.

Endoscopic renal pelvic surgery using large amounts of irrigating fluid also may pose a high risk for fluid absorption. Therefore, we applied the monitoring with tracing the irrigation fluid with alcohol to endoscopic renal pelvic surgery. The aim of this study was to investigate consecutive patients scheduled for elective surgery on the renal pelvis (nephrolitholapaxy, endopyelotomy) regarding practicality and clinical relevance of findings using the described monitoring.

Material and Methods

After institutional approval from the Kantonsmedizin Ethics Committee, 62 consecutive patients scheduled for endoscopic renal pelvic surgery were investigated. This study was a part of a quality control program with special focus on process quality improvement using an interdisciplinary approach. General anesthesia was chosen in all patients because of patient positioning (prone) and the need for repeated tilt maneuvers. After oral premedication with midazolam (7.5 mg), anesthesia was induced with thiopental sodium (5 to 7 mg/kg), atracurium (0.5 mg/kg), and fentanyl (1 to 3 μg/kg). Anesthesia was maintained with a balanced technique using isoflurane (1 minimum alveolar concentration [MAC]) and oxygen in 60% nitrous oxide. At 10-minute intervals, end-tidal breath alcohol levels were obtained with a portable electronic measurement device (Alcomed 3020, Biotec Co., Frankfurt, Germany). A side-port is incorporated into the device, allowing measurements during intermittent positive pressure ventilation (IPPV). The minimal measurable alcohol concentration is 1 mg/dL. The device corrects for an air/liquid coefficient of 1.2108. A standardized commercial available irrigation solution containing 1% alcohol in 0.9% normal saline was used. The amount of absorbed fluid was calculated with the Widmark formula. This formula has been intensively studied and validated in forensic medicine. For estimation of the absorbed volume, end-tidal breath alcohol levels maximum were used. Because of the short period of our study, corrections for enzymatic alcohol degradation were omitted.

For statistical analysis, STATISTICA™ software for Windows (StatSoft, Inc., Tulsa, OK) was used. The following tests were performed as appropriate: analysis of variance (ANOVA) and multiple regression analysis for noncategorical data, statistical process control tools for serial analysis. Analyses were followed with statistical process control tools. These tools include an estimation of the upper and lower process limits of an ongoing process. By definition, significant changes may appear when the process reaches the predefined limits or when the process loses a random pattern. This may be detected by using run rules, also referred to as A1&I (American Telephone & Telegraph Company) run rules. The run rules are based on statistical calculation to distinguish between a process that is in control, with variation due to random (chance) causes only, from a process that is out of control, with variation that is due to some nonchance or special (assignable) factors such as six data points in a row steadily increasing or decreasing, which is an indicator for a drift in the process average.

Relevant fluid absorption was defined as more than 500 ml. This limit was chosen as outcome parameter. p-Values less than 0.05 were considered significant.

Results

Demographic data are summarized in Table 1.

In this series, time to maximum fluid absorption occurred after a minimum of 30 minutes. Less than 300 ml of irrigation fluid was absorbed in 94% of all cases (Figure 1). Maximal calculated fluid absorption was 2,230 ml after a duration of 30 minutes. Two patients showed a calculated fluid absorption above 1,000 ml. One of these patients showed severe clinical signs of volume overload (lung edema, myocardial ischemia) and was successfully treated in the intensive care unit. The other patient showed only minor clinical symptoms of hypervolemia (radiologic findings of volume overload, mild dyspnea) and was successfully treated in the postoperative care unit.

The amount of the absorbed volume and the duration of surgery were statistically independent variables (nonparametric ANOVA). Body weight, ASA physical status, and gender were not determinants for the increased risk of fluid absorption.

Applying statistical process controls on our data, these tools showed a stable process with a randomly scattering of

*Vol = 1000*0.75^Breath Alcohol Level/Concentration of irrigation fluid. For detail please see Konrad et al.


Table 1. Demographic Data

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of patients</td>
<td>62</td>
</tr>
<tr>
<td>Age (yrs)</td>
<td>49 ± 15</td>
</tr>
<tr>
<td>ASA physical status (median)</td>
<td>1</td>
</tr>
<tr>
<td>Weight (kg)</td>
<td>74 ± 15</td>
</tr>
<tr>
<td>Duration of Intervention (min)</td>
<td>50 ± 28</td>
</tr>
<tr>
<td>Volume of irrigation fluid (L)</td>
<td>20 ± 11</td>
</tr>
<tr>
<td>Absorbed volume (mL)</td>
<td>210 ± 231</td>
</tr>
<tr>
<td>Patients without absorption</td>
<td>21 (34%)</td>
</tr>
<tr>
<td>Absorption less than 500 mL</td>
<td>37 (60%)</td>
</tr>
<tr>
<td>Absorption between 500 and 1,000 mL</td>
<td>2 (3%)</td>
</tr>
<tr>
<td>Absorption above 1,000 mL</td>
<td>2 (3%)</td>
</tr>
<tr>
<td>Procedures</td>
<td></td>
</tr>
<tr>
<td>Percutaneous nephrolitholapaxy</td>
<td>45</td>
</tr>
<tr>
<td>Percutaneous nephrolitholapaxy and endopeloplasty</td>
<td>5</td>
</tr>
<tr>
<td>Endopeloplasty</td>
<td>12</td>
</tr>
</tbody>
</table>

Note: Data are means ± standard deviation, except where otherwise indicated.

the absorbed volume (upper process limit 210 mL) except for the previously mentioned outliers (Figure 2). No non-random changes were observed. According to the rules of statistical process control, these two outliers were identified as special cause variations of the process, which means a non-random change with an assignable cause.

Discussion

During any endoscopic procedure using irrigation fluids, significant fluid absorption can occur. To reduce morbidity and mortality, breath alcohol measurement has been verified to be a quality management tool for TURP. Recently published data and our own results also demonstrate the usefulness of this monitoring in endoscopic renal pelvic surgery.

In contrast to TURP, absorption of fluid can occur rapidly by perirenal vessels as well as more gradually by the retroperitoneal route during endoscopic renal pelvic surgery. A reduction of fluid absorption to a minimum is essential in order to reduce perioperative cardiopulmonary morbidity and mortality. A positive correlation between fluid absorption over 500 mL and cardiovascular risk was observed perioperatively in TURP patients.1,13

The risk of fluid absorption was found to be significantly lower during endoscopic renal pelvic surgery in comparison to TURP despite the larger amount of irrigation fluid used (20 L vs. 12 L).

The kinetics of fluid absorption also differed. During TURP surgery, an immediate increase of breath alcohol measurement is often observed after venous fluid uptake after 30 minutes. During endoscopic renal pelvic surgery, a delay in absorption was observed with a maximum amount absorbed after 60 minutes. This finding points to a slow, non-direct vascular uptake by the retroperitoneal route. Despite significantly more irrigation fluid used during endoscopic renal pelvic surgery, the maximum amount of fluid absorption was higher in the TURP group (2,236 mL during endoscopic renal pelvic surgery vs. 1,680

Figure 1. Absorbed volume of irrigation fluid. The maximum of fluid absorption occurred after 60 minutes due to a slow kinetic absorption, except for the two outliers.

Figure 2. Process quality of fluid absorption in consecutive patients (closed circles). Process control revealed two outliers (open boxes). Otherwise the process is stable. A random pattern of absorption is seen around an estimated mean value. No systematic patterns were recognizable. UL = upper limit; MV = mean value; LL = lower limit.
ml during TURP). Different absorption kinetics (vascular and nonvascular) in TURP and endoscopic renal pelvic surgery need to be differentiated regarding the calculation of the true amount of absorbed irrigation fluid, which is indicated by data on peritoneal fluid uptake. To calculate the amount of absorbed volume exactly after a retrograde urine filling, a double-stone maximum of fluid absorption cannot be overlooked. On the other hand, the two presented outcomes showed completely different absorption patterns with an increase of breath alcohol levels, indicating a vascular fluid absorption. For detection of a fast and critical absorption, an approximation of the absorbed volume provided sufficient data for clinical decision making. Another problem with the extravascular absorption was pointed out by other investigators, who found reduced breath alcohol levels after extravascular absorption during gynecologic and urologic procedures compared with calculations. Thus, direct comparison of results obtained from TURP and endoscopic renal pelvic surgery is difficult, as the correction factor for the measured absorbed volume for extravascular absorption remains unclear.

The prevalence of fluid absorption was lower for endoscopic renal pelvic surgery (6%) in comparison to TURP (15%). This finding reflects the nonindirect, nonvascular absorption by the retroperitoneal route. Both outliers showed different absorption kinetics. A sudden increase of breath alcohol measurements in contrast to the slow absorption kinetics of the usual endoscopic renal pelvic surgery patient group with a delayed absorption pattern makes a different absorption pattern visible. The sudden increase and surgical observations at this time were strongly suggestive of direct vascular uptake. Both patients recovered from hypovolemic symptoms within 12 hours of treatment. Consequently, after detection of such a peak increase in end-tidal breath alcohol levels, an immediate investigation is essential, and which may lead to termination of the procedure.

In contrast to the hypotonic solutions used for irrigation during TURP, normal saline was used in this study; therefore, hypovolemia with neurologic symptoms is uncommon. The main symptom of the absorption syndrome in endoscopic renal pelvic surgery is hypovolemia.

Our study has some limitations. To date, only data on breath alcohol levels have been published. The absence of measurements other than breath alcohol levels can be explained by the clinical situation where, intraoperatively, only data on breath alcohol levels are available. Other parameters such as electrolytes or Hb levels were followed postoperatively, but they did not add any clinical information for intraoperative decisions, as has been demonstrated by others. Therefore, it is necessary to compare the results with other urologic procedures to delineate significant differences and common features. To compare our experience with TURP surgery, previously obtained data were used as reference. Because both studies were performed consecutively with little time overlap, no learning curve was observed during the endoscopic renal pelvic surgery investigation. We observed a random variation in the process but no decline, indicating the learning process, which could be a bias. The management of endoscopic procedures after termination of a large series of TURP interventions using an alcohol monitoring tool may have differed due to the surgeon’s interpretation of elevated breath alcohol measurements. Our finding also may reflect the institutional learning and process improvement in endoscopic urologic procedures.

Another limitation of the presented study is the patient selection. Most of the patients were relatively young compared to the TURP patient group. Thus, slow volume absorption, even of amounts higher than 500 ml, were well tolerated. Preexisting cardiovascular disease may limit the ability to cope with slow fluid overload in other patient populations. For this reason, extrapolation of our data to different patient samples may be difficult. Additional studies in patients with a higher prevalence of preexisting cardiovascular diseases are necessary.

In conclusion, fluid absorption monitoring during endoscopic renal pelvic surgery quantifies the rate of fluid absorption and may detect unexpected vascular penetration with rapid absorption kinetics and a high risk of fluid overload.

Acknowledgments

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References


Operative Factors and the Long-Term Incidence of Acute Myocardial Infarction After Transurethral Resection of the Prostate


Department of Anesthesia, Stockholm South Hospital, Stockholm, Sweden

Abstract

We studied the association between the operative course of transurethral resection of the prostate (TURP) and the morbidity of acute myocardial infarction (AMI) in a cohort comprising 846 patients who underwent this operation between 1983 and 1992. Up to the end of 1993, a total of 69 patients had developed AMI, of which 10 patients had a reinfarction. The relative risk associated with absorption of 500 ml or more of the irrigating medium during surgery was 1.6 (95% confidence interval (CI) = 0.9–3.0) for a first-time AMI after TURP, 6.1 (95% CI = 1.8–20.7) for a reinfarction, and 2.2 (95% CI = 1.3–3.9) for a first-time or a reinfarction combined. A blood loss of 275 ml or more was associated with a decreased relative risk (RR = 0.4; 95% CI = 0.2–0.8) of a first-time AMI after TURP. Patients who lost less than 275 ml of blood and absorbed 500 ml or more of irrigating fluid during surgery had 4.4 times the risk of having an acute myocardial infarction (RR = 4.4; 95% CI = 1.7–11.8). These results appear to indicate that the operative course of TURP is important to the development of AMI over an extended period of time.

Original Contribution

Transurethral Resection Syndrome: Effect of the Introduction into Clinical Practice of a New Method for Monitoring Fluid Absorption

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Department of Anesthesiology and Intensive Care and Department of Urology, Kantonsspital, Lucerne, Switzerland

Study Objective: To determine the effects of introduction of a new monitoring system for fluid absorption during transurethral resection of the prostate (TURP) using an irrigating solution containing 0.5% alcohol.

Study design: Prospective clinical investigation, with implementation of statistical process control.

Setting: Inpatients for TURP at a major university teaching hospital.

Patients: 312 male ASA physical status I, II, III, and IV patients scheduled for TURP. Interventions: Intraoperative breath alcohol levels were measured for detection of fluid absorption.

Measurements and Main Results: Calculation of the amount of fluid absorbed using measured breath alcohol values. Process variability (i.e., numbers of patients with significant fluid absorption) was defined by statistical process control tools. No trend change of prevalence of fluid absorption was noted until 150 procedures had been completed. Reduction of prevalence of significant fluid absorption was noted and no patients were treated postoperatively in the intensive care unit. No relevant side effects were seen in patients with significant fluid absorption. No mortality and no severe clinical morbidity was seen after the introduction of the new monitoring.

Conclusion: Using an irrigating fluid marked with 0.5% ethanol resulted in a decreased prevalence of fluid absorption over time. © 1998 by Elsevier Science Inc.

Keywords: Fluid absorption; monitoring; statistical process control; transurethral resection of the prostate.

Introduction

Endoscopic transurethral resection of the prostate (TURP) is a commonly used surgical procedure to treat benign or cancerous enlargements of the prostate. One side effect is known as transurethral resection (TUR) syndrome, a condition caused by excessive absorption of hypotonic bladder irrigating fluid. Excessive absorption of irrigating solution leads to fluid overload and dilution...
## Appendix 1. Formulas for Calculation of Fluid Absorption using Widmark’s Suggestions

<table>
<thead>
<tr>
<th>Formula</th>
<th>Parameter</th>
<th>Dimension</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. ( A_i = \text{Vol} \times \text{Conc.} / 100 )</td>
<td>( A_i ) = alcohol in absorbed irrigating fluid; ( \text{Vol.} ) = absorbed volume; ( \text{Conc.} ) = concentration of alcohol in irrigating fluid</td>
<td>g ml weight-%</td>
</tr>
<tr>
<td>2. Calculation of amount of alcohol in patient</td>
<td>( A_i = A_i - A_e )</td>
<td>g. Elimination can be neglected due to short resection periods and even shorter absorption period.</td>
</tr>
<tr>
<td>3. Breath alcohol</td>
<td>( A_b = A_i / (w \times W) )</td>
<td>mg/dl</td>
</tr>
<tr>
<td>( A_b ) = breath alcohol; ( w ) = weight; ( W ) = Widmark’s factor mean = 0.75</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Vol. = WF \( \times \) weight \( \times \) \( A_e \) / Conc.

Vol.\% = 1.5 \( \times \) weight \( \times \) \( A_e \) |

| Results in ml | Used concentration 0.5% |

| Formulas 1 through 3 |

**Notes:**
- Bold indicates the formula used for calculation of fluid absorption.

of plasma electrolytes and clotting factors. The resulting hypotension and hypovolemia can cause major morbidity and mortality. Several methods have been proposed to quantify the amount of systemic irrigating fluid absorption; these include measuring the inflow and outflow volumes, body weight, measuring serial plasma concentrations of glucose, mannitol, sorbitol, and glycine; and using radioisotopes in the irrigating solution. In 1986, adding alcohol to the irrigating fluid and measuring end-tidal alcohol concentration was proposed as a routine monitoring method. Considering that absorption volumes in excess of 1000 ml are common, irrigating solutions containing 1% and 2% alcohol can have systemic side effects, with sensory disturbances. Alcohol intoxication can make it difficult to recognize the central nervous sign of hypotension. Thus, the aim of this study was to examine: (1) the utility of a 0.5% alcohol-containing irrigating solution to detect small amounts of fluid absorption and (2) the possible reduction of fluid absorption when monitoring the absorption by an alcohol irrigating solution using statistical methods of process control.

### Materials and Methods

A 0.5% alcohol and 4% glucose containing electrolyte-free irrigating solution was used in 312 consecutive male patients undergoing TURP. The Kantonsspital Ethics Committee approved the change of practice, and each patient gave verbal consent to undergo the procedure.

End-tidal alcohol concentrations were determined at 10-minute intervals during surgery. A portable electrochemical alcohol analyzer (Alcomed 3010, Biotest Co., Frankfurt, Germany) was used to measure ethanol concentrations. The A-mode was used for awake patients, who blew into the alcohol analyzer. In intubated patients, a side stream end-tidal analysis (S-mode) was used. The detection limit is 1 mg/dl. Results for end-tidal ethanol concentrations are expressed as mg/dl. The analyzer corrects for an air/liquid partition coefficient of 1.2100, which was calculated for humidified air with a temperature of 34°C.

After oral premedication with midazolam 7.5 mg, 298 patients received a spinal anesthetic with a 27-gauge Quincke-needle and 15 mg hyperbaric bupivacaine, and 14 patients received a general anesthetic with thioental induction, muscle relaxation with atracurium, and maintenance with fentanyl and isoflurane with nitrous oxide-oxygen. During the preoperative and intraoperative period, saline 0.9% was given intravenously (IV). Surgery was performed by one of three experienced staff urologists using an intermittent irrigating technique of the bladder.

Preoperatively and immediately postoperatively, blood chemistry for electrolytes and glucose, as well as hemoglobin and platelet measurements, were performed. The amount of fluid absorption was calculated from the end-tidal alcohol concentration using the Widmark formula (see Appendix 1). For calculation purposes, maximum values of breath alcohol were taken. When calculations of fluid absorption exceeded 500 ml, the surgeon was notified. At calculated volumes above 1000 ml, the surgeon was asked either to finish the procedure or to use coagulation to stop the bleeding.

For statistical analysis, the software STATISTICA™ for Windows (StatSoft, Inc., Tulsa, OK) was used. The following tests were done for statistical analysis, if appropriate: analysis of variance, multiple regression analysis, and statistical process control (SPC).

The goal of process control is to guarantee and monitor constant quality. Historically, these methods were used to control industrial processes. The entire operative and anesthetic management can be seen as a process with...
Table 1. Basic Demographic Data (means ± SD)

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patients included</td>
<td>312</td>
</tr>
<tr>
<td>Age (yrs)</td>
<td>72.5 ± 7.6</td>
</tr>
<tr>
<td>ASA status</td>
<td>140 (162 II, 108 IV, 2)</td>
</tr>
<tr>
<td>Weight (kg)</td>
<td>77.3 ± 14.5</td>
</tr>
<tr>
<td>Height (cm)</td>
<td>169 ± 7.1</td>
</tr>
<tr>
<td>Duration of TUR (min)</td>
<td>40 ± 23°</td>
</tr>
<tr>
<td>Duration intermediate care (min)</td>
<td>146 ± 52°</td>
</tr>
<tr>
<td>Resected weight of prostate (g)</td>
<td>18/15.5°</td>
</tr>
<tr>
<td>Level of anesthesia (thoracic spinal)</td>
<td>T12 ± T1 levels</td>
</tr>
<tr>
<td>Irrigating volume (L)</td>
<td>12.1 ± 5.7</td>
</tr>
</tbody>
</table>

TUR = transurethral resection.

Data are given in median and quartile ranges.

various interactions. To demonstrate any change in process quality while introducing end-tidal alcohol analysis for TUR surgery of the prostate, the 312 patients were grouped into consecutive subsamples of 50 subjects each. Analyses were done with statistical process tools including an estimation of upper and lower process limits, even when the process is ongoing. We defined the number of patients that we expected randomly to show fluid absorption by using quality control modules. The expected value was compared with the observed number of patients with fluid absorption. Therefore, for in-process changes, the patient population with alcohol monitoring was taken as its own control, as is usually done in industrial process analyses. By definition, significant changes can be seen when the process strays the predetermined limits or when the process loses a scattering pattern. These patterns can be detected using run rules to detect processes that are in control (random changes) or that are out of control (nonrandom changes). The run rules are based on statistical reasoning.13

Intensive care unit (ICU) admission during the study period was taken as a parameter for outcome endpoint. Admission criteria included severe pulmonary, cardiac, and neurologic symptoms, as well as major bleeding. P-values less than 0.05 were considered significant.

Results

Demographic data of the patient population are summarized in Table 1. End-tidal alcohol concentrations were observed in 47.8% of all the patients, indicating fluid absorption. When absorption occurred, maximum values typically were recorded 30 to 40 minutes after the start of surgery (Figure 1). Sudden peak concentrations due to the direct IV route (periportional veins) were observed in single cases. Figure 1 demonstrates the time course of prevalence of absorption. The mean absorbed volume was 233 ml ± 476 (median 0; range 0 to 4689 ml). In 43 patients (13%), an absorption volume of 300 ml or more was calculated from the end-tidal alcohol concentration.

Because the majority of patients received a spinal anesthetic, no meaningful differences could be demonstrated between spinal and general anesthesia. Clinically, no patient had to be treated for signs and symptoms of TUR syndrome. No symptoms of a possible systemic alcohol effect were seen. In the observed period no admission to the ICU was necessary. Previously, 5 to 6 patients per year needed ICU care.

When applying SPC, the introduction of this new monitoring tool brought about a change in the system, as seen in Figure 2. The process mean (central line) of fluid absorption was estimated to be 0.1 cases of significant fluid absorption per 50 procedures, which means that approximately 6 of 50 patients were allowed to show breath alcohol values indicating an absorption above 500 ml of irrigating fluid. After 150 cases were completed, a decline in the process was visible (Figure 2). After 150 cases, all grouped consecutive cases showed a lower prevalence than statistical acceptability by the central line (defined as the mean of the process), which indicates a nonrandom change in the ongoing process. This continuous decline in the prevalence of absorption hants the rule of random scattering of values around the central line and is therefore an early sign of shift of the process.

At our institution, no correlation was found between personal surgical experience and prevalence of absorption.

Discussion

Measurement of the extent of systemic fluid uptake in TURP by marking the irrigating solution with alcohol and measuring end-tidal alcohol concentration was introduced into clinical practice in 1986.4 Initially, we also used 2% alcohol-containing irrigating solution. Because the use of the breath analyzer was somewhat cumbersome, it was not accepted by our staff for routine clinical application. With the advent of a more sensitive analyzer that was easy to use (Alcolmelt 5910, Bioest Co., Germany), we felt that the alcohol content of the irrigating solution could be lowered to 0.5% and we would still be able to detect absorption volumes. The introduction of this new instrumentation and the more dilute solution made this method acceptable in the clinical setting for routine use in all cases of TURP. In analyzing the first 312 consecutive patients, we found that the addition of 0.5% alcohol to the irrigating solution during endoscopic surgery of the prostate was a valuable method for recognizing clinically relevant fluid absorp-
Figure 1. Prevalence of absorption of irrigating fluid during resection as calculated by breath alcohol levels. The maximum ethanol concentration is reached after approximately 30 to 40 minutes of surgery. The maximum absorbed volume seen was in the range of 4.6 liters.

Figure 2. The prevalence of significant fluid absorption grouped to 50 cases. The x-bar shows the variable prevalence in a series. After 50 cases, a marked decrease was observed. After 150 cases were done, the prevalence declined over the consecutive cases. Mean and sigma (deviation) are calculated. Process limits are defined as mean ± 3× sigma.
tion. Theoretically, the reduction of the concentration of the irrigating fluid would lead to a decreased sensitivity. During this period, no admission to the ICU was necessary for TUR syndrome. Additionally, no clinically significant morbidity such as myocardial ischemia, minor pulmonary symptoms, or neurologic deficits were detected. Therefore, we consider 0.5% ethanol solution a satisfactory alternative for higher concentrations.

It is possible that the irrigating fluid that is necessary to keep the bladder distended can enter the open venous vessels in the prostate tissue and distribute within the vascular, interstitial, and intracellular spaces. This is the rationale to calculate the absorbed fluid volume of the alcohol-containing irrigating fluid by the Widmark formula.12,13 In patients with preexisting pulmonary diseases, studies have shown that end-tidal alcohol concentration measurements correlated well with blood alcohol concentrations,14 even in patients with chronic obstructive pulmonary disease.15

As the volume of distribution of the alcohol is the total body water, abrupt changes in volume uptake need time for equilibration.16 Thus, a 10-minute interval for end-tidal measurements was shown to be adequate to predict accurately the absorbed volume from end-tidal alcohol concentrations, especially after a total of 30 minutes of equilibration.16 Alcohol undergoes enzymatic elimination, probably starting at 1 mg/dl. Approximately 15 mg/dl can be eliminated per hour. Because the duration of the procedure is short and maximum absorption occurs at 30 to 40 minutes, elimination can be neglected in the calculations when using 2% alcohol-containing solutions.15 A limitation of our calculations is that, with the lower concerning TUR syndrome, irrigating solutions that we used, plasma alcohol levels can be in the range of the level of elimination per hour that leads to lower calculated absorbed volume. In spite of this fact, we chose the simplified formula because the significant absorption is seen within 10 to 15 minutes.

In the first reports, alcohol concentration of the irrigating fluid in the range of 1% to 2% were recommended.15 With 2% alcohol, absorption volumes of 100 to 150 ml are detectable by using end-tidal alcohol measurement.15 Volume of 2000 ml and above are thought to be dangerous, leading to the TUR syndrome.10 Absorbed volumes of more than 500 ml are associated with an increased risk of myocardial infarction and neurologic disturbances.10 Thus, we defined 500 ml as significant fluid absorption volume.

Using 0.5% alcohol irrigating fluid we observed a significant (i.e., >500 ml) fluid absorption in 13% of patients. In another series using 1% alcohol solution, 41% of patients had a positive end-tidal alcohol concentration that indicated in 9 patients an absorption volume of more than 1000 ml.10 Others report no TUR syndrome in 52 patients using the same monitoring method.18 Our results indicate that a 0.5% concentration of alcohol in the irrigating fluid is a sensitive marker to avoid high volume fluid absorption. Our irrigating solution theoretically can lead to hyperglycemia, which can be treated easily. Therefore, at our institution, it has also become routine to monitor blood glucose levels. In this series, no hyperglycemic event was seen.

The initial drop after 50 cases, as seen in Figure 2, and the rise after 150 cases were within the normal statistic range and did not reach the upper limits. However, with the application of general run rules (e.g., 9 points at the same side of central line or 6 points in a row steadily increasing or decreasing), there was a continuous decline during the consecutive cases indicating a systematic change within the process. This can be attributed to our new monitoring and intervention protocol. Therefore, we illustrate the effective use of control charts to identify an opportunity for improvement, develop an implementable strategy, and measure the effectiveness of the intervention.

The study is limited by the lack of a control group. Therefore, only data on the treatment group were available. ICU stays during the study period were taken as an endpoint of morbidity. No data were available for direct comparison of ICU admissions for TUR syndrome before the study period, but our personal experience has shown that approximately 1% to 2% of TUR patients were admitted to the ICU.

In conclusion, the addition of 0.5% alcohol to the irrigating solutions in endoscopic surgery of the prostate is a valuable method for recognizing clinically relevant fluid absorption. This method is easy to perform, and it represents an excellent means for both the anesthesiaologist and the surgeon to recognize the absorption of irrigating solutions at an early stage and thus to prevent the potentially life-threatening TUR syndrome from developing.

The introduction of this monitoring and regular intraoperative use lead to improved communication between anesthesiologists and surgeons, resulting in lower rates of fluid absorption. Since this method has become a part of our routine clinical practice, no severe complications due to excessive absorption of irrigating fluid have been observed in this elderly patient population. Statistical process control is able to monitor ongoing processes in a clinical setting and to demonstrate the value of alcohol-containing irrigating solutions in the prevention of TUR syndrome.

Acknowledgment

We would like to thank Beat Kaiser, CRNA, Lacertina, for his enthusiasm and help performing this investigation, and Ron Stevens, MD, Chicago, for editorial assistance.

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Chapter 5: Discussion

The discussion is also separated into two parts. The first part will discuss aspects and consequences of the learning curves found, the second part will focus on risk management issues.

5.1. Value of learning curves for manual skills in anaesthesia

There is only a little published data concerning physicians’ learning processes when adopting anaesthetic procedures.[3, 24, 31] Learning curves have now been documented by our group for anaesthesia trainees when learning a variety of new anaesthesia skills.

The obtained learning curves from our different studies are a graphic representation of the relation between the experience of a trainee and the selected performance indicator. In all except one study[32], the indicator was a binary criterion for clinical success or failure. The following observations regarding these learning curves are important:

1) Success in certain skills improves with repeated practice. However, as success usually improves steadily, it may not reach a flat plateau.

2) Usually, there is a decrease in this plateau of success after having reached initial success. This might be due to the fact that beginners generally start learning new skills dealing with easy, straightforward cases. After a certain training time when the trainees have achieved more confidence they are exposed to more difficult or unusual cases. During this phase performance may decline temporarily. Failed attempts (of a procedure) occur early within the training period, typically during the first one hundred attempts when learning a special manual skill.

3) The skills of different trainees vary according to the number of attempts when a new skill is learnt before first reaching and then maintaining a stable plateau of successful and sustained performance of that skill over a longer period of time.

A learning curve represents the assimilation of some new knowledge, competence or skills. The shape of the learning curves (sigmoidal, bimodal, exponential etc.) and the period of time in which optimal learning takes place are the most important indicators.[3] The shape of such curves depends on two fundamental factors: the amount of knowledge and the ease of learning. It can be assumed that the degree of knowledge is low when a new procedure is introduced and that it is increasing over the course of time. This means that the basic competence expands the more often the new skill (concept or drug) is applied. Four curves are depicted in graph 2 out of the almost infinite range of possible learning curves. An ideal curve (such as A)
has a quick learning phase and no late surprises (as in D) that prolong learning. The last type of curve was developed later during our studies, e.g. for axillary blocks.[32]

**Graph 2: Different types of learning curves**

The different shapes may be explained by complexity of the task, individual and institutional variations.[3]

In the following pages the findings of our studies on different basic manual skills are summarised and discussed.

### 5.1.1. Orotracheal Intubation

Management of the airway is central to the practice of anaesthesia.[33] Good skills in airway management do not only include technical proficiency with an increasingly complex and wide range of equipment, but also judgement and experience to use those skills appropriately. Most experts would agree that after having performed only 30 orotracheal intubations by the end of the residency program, few residents will be adequately trained to perform intubations with an acceptable degree of safety and reliability. Traditionally, skills to place a tracheal tube were gained through on-the-job experiential learning. There was little consensus on which airway skills should be taught to trainees and how to best teach these.[34] Therefore, our work is focused on orotracheal intubation. In our studies we have found a success rate of 95 % after 57-90 attempts (see also table 8).
Intubation Learning Curve

Graph 3
The learning curves for orotracheal intubation performed by residents during their first year of training at Gent University Hospital (black curve) and Kantonsspital Lucerne (grey curve) were compared. Mean and 95% confidence intervals are shown. This study confirms that for a success rate of 95% more than 80 attempts are necessary (shown for comparison)[35].

This fact was also confirmed by a further study that compared Belgian and Swiss residents (see graph 3). In the UK the Calman report has led to a shorter, more structured training[36], because competence in management of the airway requires the mastering of a broader range of skills, from holding an airway and facemask to fibreoptic intubation. When training is provided to acquire all those skills while treating patients (as opposed to simulators), a number of technical and ethical problems will arise. Much work has been done to evaluate alternative teaching methods (e.g. simulator based training; see table 5)[33].

Table 5: Overview of airway management techniques and teaching situation[33]

<table>
<thead>
<tr>
<th>Skills to be learnt in a clinical environment</th>
<th>Skills to be learnt in a non-clinical environment with some clinical experience</th>
</tr>
</thead>
<tbody>
<tr>
<td>Basic airway skills with airway and facemask use of the laryngeal mask airway</td>
<td>Intubation though a laryngeal mask airway (both blind and fibreoptic)</td>
</tr>
<tr>
<td>Direct laryngoscopy and tracheal intubation</td>
<td>Fibreoptic intubation via the nose and mouth</td>
</tr>
<tr>
<td>Rapid sequence induction</td>
<td>Fibreoptic intubation in children[37]</td>
</tr>
<tr>
<td>Use of alternative blades and bougies</td>
<td>Awake intubation</td>
</tr>
<tr>
<td>Failed intubation drill</td>
<td>Use of other airway devices, e.g. Combitube®</td>
</tr>
<tr>
<td>Placement of double lumen tubes</td>
<td>Retrograde intubation</td>
</tr>
</tbody>
</table>

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Placement of double lumen tubes</td>
<td>Emergency cricothyrotomy</td>
</tr>
</tbody>
</table>

Because orotracheal intubation is crucial for the practice of anaesthesia, we focused on this particular skill, although there are many other techniques to learn and to master. Advanced airway techniques such as fibreoptic intubation and use of an intubating laryngeal mask airway are standard techniques, but probably
not the first techniques to be acquired by young residents. Furthermore, many new airway devices have been introduced in the last decade, each claiming perhaps a distinct role in airway management. It has been pointed out correctly that new airway devices have been introduced on the market without trials of their clinical effectiveness.[38]

But it is also clear that the use of a Macintosh laryngoscope alone is not a sufficient core skill to allow safe airway management of all patients!

Our studies clearly show learning curves for orotracheal intubation. The rapidity of learning depends on a particular skill. For instance, studies show that the learning curve for placement of the laryngeal mask airway is very steep. Within the first three attempts a high success rate >90% is possible.[39-44] In contrast, the bag and facemask had a success rate of <50% after 10 attempts.[39] The learning process for tracheal intubation has been studied with a variety of results. Less extensive studies have suggested a rapid improvement of skills after a short training program.[41, 45] However, our more formally generated learning curves suggest a success rate of 90% after 60 attempts, 94% after 100 attempts and a success rate between 97%-99% after 150 attempts (see also graph 2 and graph 3). Interestingly, after 80 attempts 18% of the trainees needed assistance. Cusum was not chosen for analyses of learning orotracheal intubation because very large numbers of sequential attempts are needed to demonstrate statistically acceptable success rates.[16]

5.1.2. Spinal anaesthesia (single shot technique)

Spinal single shot anaesthesia is a venerable and simple technique. Technical competence is achieved early during training (> 90% technical success rate) after only 40–70 supervised attempts. The simplicity and long history of spinal anaesthesia might give the impression that it is an unsophisticated technique. During recent years, our specialty's knowledge has been expanded significantly concerning the anatomy, physiology, pharmacology and applications of spinal anaesthesia. Our data corresponds with the findings published by Kopasz[10], though for a sustained performance more than 120 attempts may be necessary.[32] This is shown by our long-term follow up study.[32]
The results of two studies are compared. The differences of the minimal case load necessary for an 80% success rate are explained by the different definitions of success. The grey learning curve with +/-95% confidence interval is from our group, the black bars are representing the results published by Kopacz.[10] The grey learning curve is based on clinically sufficient anaesthesia whereas Kopacz used a more technical definition of success.

5.1.3 Epidural Anaesthesia and caudal analgesia

In continuous epidural anaesthesia one relies above all on the ‘test dose’ to confirm correct placement of the catheter. This is not always accurate and a number of new techniques have been designed to provide better information about epidural needle and catheter placement. These include electrical stimulation of the catheter, use of ultrasound and the application of simple geometry. Tsui et al.[46-49] recently published a series of articles concerning the use of electrical stimulation via epidural catheter not only to determine, if the catheter is within the epidural space, but also to identify the exact position of the catheter tip in the neuroaxis. One of the most important applications of this electrolocation technique can be found in the field of paediatric anaesthesia. Tsui et al. demonstrated that an epidural catheter may be advanced from the caudal space to any location in the neuraxis.[46] This not only improves the reliability of the epidural anaesthesia and analgesia but may also improve the safety of performing regional anaesthesia in anaesthetised children, where the risk of serious neurological injury is already low. Ultrasound has been used in the past to identify the epidural space and to allow placement of the epidural needle under radiological guidance.[50] However, there have been problems with the quality of the signal and the views obtained, and as a result this technique is not in common use. A recent study of ultrasound assessed different planes to access the lumbar epidural space with a 90% success rate. These authors showed that the visibility of the ligamentum flavum, dura mater, and cauda equina was significantly higher and that
pulsation of epidural vessels could be seen immediately when using median compared to standard transverse planes.[51] As a result, the use of ultrasound may become an option to support correct identification of the epidural space.

However, in our studies ultrasound and nerve stimulators where not used for central blocks. The technique observed for epidural and/or spinal anaesthesia was based on anatomical landmarks and a “loss of resistance” technique. An 80% success rate at epidural anaesthesia was achieved after a mean of 90 attempts. Epidural anaesthesia seems to be the most difficult procedure of those we studied. Our work and other studies suggest that at least 90 attempts may be required before epidural anaesthesia is mastered and a sufficiently high success rate is attained. A study by Kopacz et al. together with our results suggest that 60 attempts for each spinal and epidural anaesthesia are required.[13]

**Graph 5 Epidural anaesthesia learning curve**

The grey learning curve is from our group, with black bars from Kopacz. The difference in the necessary minimal case load is explained by two facts: i) For the construction of the grey learning curve a clinical binary definition of success was used when an epidural catheter was placed. ii) Kopacz used a more technical definition (successful identification of the epidural space).[13]

Similar techniques for epidural anaesthesia are used in children and in adults. Although the various pieces of equipment are adapted to the size of the patient, to some extent, successful technical performance seems to require disproportional large needles and catheters. Since epidural blocks are also performed on very young paediatric patients, the age-dependent pharmacokinetic profile needs to be kept in mind.[52] Therefore our studies focused on the safe procedure of caudal epidural blockade in children, but there was no learning curve generated for lumbar or thoracic epidural catheter placement in paediatric patients. An 80% success rate at caudal epidural anaesthesia was achieved after 32 blocks (see table and Graph 6).
Graph 6: Learning curves for caudal analgesia and penile block in neonates, infants and children

Comparison of two regional analgesia techniques in children is shown. The learning curve for penile block is compared with caudal analgesia. The learning curve for performing penile block and caudal analgesia in paediatric anaesthesia are shown including the 95% confidence interval. The two sets of curves are from the same institution and are calculated by using the same methodology. Both penile block and caudal analgesia technique are not difficult to learn. The two learning curves do not differ statistically.[53, 54]

5.1.4. Axillary block

Technical aspects in the performance of brachial plexus block have been the subject of much interest in the last few years.[32, 55] The debate continues whether a single-stimulation (injection) technique is superior to a multi-stimulation (injection) technique, or vice versa. Recent publications point out both safety aspects and the possibility of introducing a catheter for continuation of the block. In our studies we focused on axillary block by using a nerve stimulator. At least for axillary blocks with a nerve stimulator, a case load of more than 100 attempts is necessary for competency.[32, 55, 56] These findings based on our results are in a clear conflict with official recommendations (Residency Review Committee RRC recommendations,[57, 58] see table 6). Placement of catheters for peripheral blocks was not the focus of our work. During our studies, we have learnt that repetition is important as more than one hundred events may be necessary to achieve reliable success rates. An adequate exposure to peripheral nerve blocks may improve success rates.

The adequacy of resident education in regional anaesthesia is a relevant concern. Inadequate exposure to peripheral nerve blocks might, for instance, represent a problem for teaching programs. In our studies there was a focus on axillary block and the minimal case load necessary for a success rate of 95% is more than 150 blocks at our institution. Others have concluded for example that experience with only 40 unspecified peripheral nerve blocks is not sufficient to reach proficiency in interscalene block technique.[59]
5.1.5. Penile block in children

Penile block in children can be easily learnt.[53] Despite the common use of this technique, no data on learning processes or on the number of procedures necessary to maintain technical proficiency was available for this block before our study had been published. In our investigation, the learning process of residents in anaesthesiology and the proficiency characteristics of staff anaesthesiologists were assessed. The mean case load for a 90% success rate is 15. No statistical difference in the success rates of staff anaesthesiologists and residents was observed. Only limited training is necessary for residents to achieve high success rates. A steep learning curve has been found. After more than 40 blocks, the success rate is over 93.5%. The difference compared to learning curves for other manual techniques is interesting. Caudal block may be an alternative modality for analgesia in children scheduled for penile surgery. Learning processes in performing penile blockade in paediatric patients require a lower number of procedures to achieve high success rates compared to caudal analgesia in paediatric anaesthesia (see graph 6).[53, 54]

5.1.6. Is there a recommended number of cases for anaesthetic procedures?

In the following discussion the recommendations for minimal case loads with regard to regional anaesthesia techniques are examined. The recommendations published by official professional societies are compared with our results for regional anaesthesia procedures.

Although the Residency Review Committee (RRC) clearly specifies the training requirements for spinal and epidural anaesthesia (see table 6), the current recommendations for training in peripheral nerve blocks in the US remain vague.[6, 58, 60]

<table>
<thead>
<tr>
<th>Table 6: Training requirements for peripheral nerve blocks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Residency Review Committee (RRC; USA) in Curr Opin Anaesthesiol 2002; 15:669-673[57]</td>
</tr>
<tr>
<td>50 epidural anaesthetics</td>
</tr>
<tr>
<td>50 spinal anaesthetics</td>
</tr>
<tr>
<td>40 peripheral nerve blocks for surgical anaesthesia</td>
</tr>
<tr>
<td>25 peripheral nerve blocks for pain management</td>
</tr>
</tbody>
</table>

These recommendations suggest that in order to achieve clinical competency, a trainee must perform 40 peripheral nerve blocks for surgical anaesthesia and 25 for pain management. However, as these recommendations do not specify which blocks should be in a core curriculum of training in anaesthesia, it is nearly impossible to ensure that residents graduating from different programs will have comparable degrees of expertise in all nerve block procedures. One suggestion to solve this problem is to categorise regional anaesthesia procedures into three types: basic nerve block procedures, intermediate regional procedures and advanced peripheral nerve block procedures (see table 7).
Table 7: Categorisation of regional anaesthesia procedures

Suggested classification of regional anaesthesia procedures: [http://www.NYSORA.com](http://www.NYSORA.com)

<table>
<thead>
<tr>
<th>Basic</th>
<th>Intermediate</th>
<th>Advanced</th>
</tr>
</thead>
<tbody>
<tr>
<td>Superficial cervical plexus block</td>
<td>Deep cervical plexus block</td>
<td>Continuous interscalene brachial plexus block</td>
</tr>
<tr>
<td>Axillary brachial plexus block*</td>
<td>Interscalene block</td>
<td>Continuous infraclavicular brachial plexus block</td>
</tr>
<tr>
<td>Bier block</td>
<td>Supraclavicular interscalene block</td>
<td>Thoraco-lumbar paravertebral block</td>
</tr>
<tr>
<td>Wrist block</td>
<td>Infraclavicular interscalene block</td>
<td>Epidural anaesthesia (cervical)</td>
</tr>
<tr>
<td>Digital nerve block</td>
<td>Sciatic nerve block: posterior approach</td>
<td>Continuous sciatic nerve block: posterior approach</td>
</tr>
<tr>
<td>Genitofemoral block</td>
<td>Femoral nerve block</td>
<td>Continuous popliteal block: intertendinous and lateral approaches</td>
</tr>
<tr>
<td>Saphenous block</td>
<td>Popliteal block: intertendinous, lateral and lithotomy approaches</td>
<td>Sciatic nerve block: anterior approach</td>
</tr>
<tr>
<td>Ankle block</td>
<td>Epidural anaesthesia (thoracic)</td>
<td>Obturator block</td>
</tr>
<tr>
<td>Spinal anaesthesia (lumbar)*</td>
<td>Continuous femoral nerve block</td>
<td>Paravertebral blocks (thoracal, thoracolumbar)</td>
</tr>
<tr>
<td>Epidural anaesthesia (lumbar)*</td>
<td>Continuous femoral nerve block</td>
<td></td>
</tr>
<tr>
<td>Combined spinal/epidural anaesthesia</td>
<td>Continuous lumbar plexus/sciatic blocks</td>
<td></td>
</tr>
</tbody>
</table>

* covered by our studies

According to these categories, teaching of residents should be organised as follows: Basic nerve block procedures are technically easy to perform, have a low risk of complications and have a wide clinical applicability. These procedures should be a part of the skills of every practising anaesthesiologist. The current requirements of the RRC (residency review committee) for training in nerve blocks consists of 40 nerve block procedures, and this is believed to be sufficient to allow competent practice of these techniques.[57]

While some of the intermediate regional anaesthesia procedures are relatively simple to perform and teach, their complexity and the potential risk of complications is greater than those of the basic block techniques. In addition, far fewer residents graduate with sufficient expertise that these blocks can be successfully implemented in their clinical practice. These techniques are best mastered by spending 1-2 months in a well-structured and mentored elective peripheral nerve block rotation during residency training or fellowship in regional anaesthesia. Alternatively, and provided that adequate proficiency in the basic nerve block techniques is achieved, expertise in these procedures can be attained by additional self-study and participating in various regional anaesthesia workshops.

Advanced peripheral nerve block procedures are highly specialised procedures most of which require significant expertise in the basic and intermediate nerve block procedures for their implementation. Advanced nerve block procedures are either deeper nerve blocks, or blocks that require special equipment.
and insertion of indwelling catheters for continuous infusion of local anaesthetic. There are only a few trainees that are able to master advanced nerve blocks by spending a 1 to 2 month dedicated training period in a mentored nerve block rotation during the later years of anaesthesia residency training. However, most trainees need a 6-12 month fellowship in order to acquire respectable expertise.

Our results regarding regional anaesthesia procedures lead to the following conclusion, independent of our above mentioned suggestions:

It is thus quite clear that the current training recommendations for peripheral nerve blocks do not guarantee that anaesthesiology graduates have acquired sufficient expertise in nerve block procedures. Based on our findings, some skills can be easily learnt, but the recommended minimal case loads for spinal, epidural and axillary blocks are definitively too low!

With regard to the RRC recommendations, our studies focus on the basic techniques (spinal, epidural anaesthesia, axillary block). We have also designed studies in the paediatric population (caudal analgesia, penile block and psoas compartment block) which are not covered by the RRC definitions.

5.1.7. Critical notes

Some critical reflections on the above mentioned results can be made. One may argue that binary criteria for success or failure are too narrow a definition of outcome. Another critical issue may be that the results have been generated in a single centre. Furthermore, it has to be discussed if the presented findings are unique for the discipline of anaesthesiology or if the spectrum can also be extended to other disciplines.

5.1.7.1. Binary criteria for success

In all but one[61] of our studies we used binary criteria for the results for success or failure of a procedure. [32, 35, 53-56, 61-63] This type of endpoint does not differentiate between complete and partial failures. Complete success excluded any physical help by the attending anaesthesiologist and was meant to indicate a technically perfect procedure with clinical functionality. Failure included manual assistance by the attending anaesthesiologist or the need for change of anaesthetic technique. The specific reasons for failure were not recorded. In other studies, time was used as a variable to define learning. Having considered elapsed time as a result, for instance, meant that trainees had to complete nasotracheal fibreoptic intubation successfully within a mean time of 149 seconds at the first attempt decreasing to 49 seconds at the 18th repetition.[64] The half-life time of this learning curve was nine procedures. [64] Time was not a relevant variable in all our
studies because in our view it is important to allow sufficient time for teaching and learning. Nevertheless, we are aware of the fact that teaching practical procedures slows down the work of the surgical team.

5.1.7.2. Single Centre studies

Another limitation in the methods is that some of our studies were conducted in a single centre. At least, we have compared the results of two different learning cultures, those of Swiss and of Belgian first year residents.[35] Using the same methodology as in our previous studies, learning curves of Belgian first year residents were generated for orotracheal intubation and single shot spinal anaesthesia. Those results were compared with the results of Swiss first year anaesthesia residents for the same kind of anaesthesia. No differences in the learning curves of these two procedures were found between Belgian and Swiss first year anaesthesia residents, although cultural differences between the two institutions were likely. It can be concluded that the case load (comparable in both institutions) may be the key factor for an adequate competence (see graph 3 and graph 7).

Graph 7
The learning curves for single shot spinal anaesthesia performed by residents during their first year of training at Gent (B; University Hospital; black lines) and Lucerne (CH; Kantonsspital; grey lines) were compared. Mean and 95% confidence intervals are shown. No statistical difference between the two institutions compared was seen for both processes, although cultural differences can be postulated between Belgium and Switzerland. This study confirms that success rates of two different institutions are comparable, thus allowing a generalisation of our findings (shown for comparison).[35]
5.1.7.3. Learning curves in other medical disciplines

The learning curve and the number of procedures required before achieving an adequate technical skill have also been the subject of studies in other medical disciplines. Cass et al.[65], for instance, concluded that supervision of the initial 50 and performance of subsequent 100 upper and lower gastrointestinal endoscopies are necessary in order to achieve clinical competence (defined as a 90% success rate). Family practice residents and untrained general practitioners have been shown to require 25 supervised attempts at performing flexible fiberoptic sigmoidoscopy to attain proficiency comparable with that of experienced practitioners.[66] Duong and Havel concluded that 20-30 cases are required to achieve satisfactory skill in managing cardiac anaesthesia patients.[67] Martin and Burton reported on the complications of one senior ophthalmologist familiar with conventional cataract surgery when learning a new phacoemulsification technique. An initial vitreous loss of 4% in the first 300 cases fell to 0.7% subsequently.[68] Some studies have also been published in the surgical field concerning oesophagectomy[69], gastrectomy[70] or neurosurgery.[71] Bridgewater and colleagues have studied the operative results of surgeons in each of their first years of independent practice and report that there is a learning curve for cardiac surgeons in this setting.[72] Laparoscopic Roux-en-Y gastric bypass is a technically difficult operation. Shikoroa published a review and demonstrated that the morbidity and mortality could be reduced by 50% with experience.[73]

5.1.8. Implementing a new regional anaesthesia technique in an institution

Not only the individual learning process is important, but also the institutional learning curve. As there is not very much published data available concerning institutional learning processes in adopting a new regional technique in the (paediatric) anaesthesia department, a study was designed to investigate whether or not there is a learning curve associated with the implementation of a new psoas compartment block technique (PCB) in children.[62, 63] Modified landmarks for this technique are reported. The statistical 'Cusum' technique was used to evaluate the institutional learning process. A block was considered successful and rated “one” (“1” = success; “0” = failure) if the resident performed it without manual help from the staff anaesthesiologist at the first attempt and if the block was clinically effective. Adverse effects of the psoas compartment block such as epidural spread were added up. All blocks were clinically successful, and in one patient a bilateral block occurred, probably due to epidural spread. In 64% of all blocks performed only one attempt was necessary, in 26 patients 2 attempts were necessary and for more then 10 patients more than two attempts were necessary for successful placement of a block. Surprisingly, the ‘Cusum’ analysis showed a clear institutional learning phenomenon. This study has demonstrated that an institution acquires the ability to perform a new PCB technique in children with a reasonable numbers of patients. The described PCB technique can be compared to other suggestions concerning the safe performance of PCB. In accordance
with previous experience, there also exists a learning curve for this new technique regarding a certain institution. This study is the first to assess institutional learning during the implementation of a new regional anaesthesia technique.[62, 63]

5.1.9. Other Aspects

Kestin reported on the use of the statistical method of 'Cusum' analysis to monitor a trainee’s progress.[11] Although he reported on a very small number of trainees, he documented one person who was a very slow learner. Later, similar findings were described by others.[16, 17] These studies demonstrate that competence cannot be guaranteed, even after a large number of attempts. It has also been shown that performance can get worse as well as better (see also graph in the introduction section). Several studies have shown that there is an initial quick improvement in performance, followed by a more gradual improvement during the first 100 cases. But it is unclear whether slow learning of one practical procedure predicts slow learning in another similar procedure. The available studies suggest that there is a rapid improvement in the success rate with at least 20-30 practical procedures, but a significant improvement in the success rate if 80 or more than 110 procedures have been performed. In fact, no certain number of procedures will guarantee a special competence.[11, 13, 16, 17, 32, 53, 54, 56, 61-63, 74] Learning curves like this have not been documented previously within the anaesthesiology literature.

The completion of an approved residency training program is generally equated with the possession of certain skills and knowledge that are required to ensure maintenance of a ‘community standard’ of anaesthesia care. But most professional Board examinations assess the theoretical knowledge of a graduate. Therefore, assessment in anaesthesia traditionally takes the form of written papers and oral examinations. These are important to assess the trainee’s knowledge and judgement but do not test their competence in practical skills which is also essential for successful clinical practice. The objective, to evaluate a candidate's procedural skills, cannot be achieved without some form of generalised formal testing. Learning curves are a valid tool for monitoring institutional and individual success. The importance of learning curves to monitor practical skills in anaesthesia is proven by our studies as well as others. Using those curves, estimations concerning the number of procedures that should be performed by a trainee in order to reach an acceptable success rate can be made. It is clear that these figures support the basis for a rational design for training programs, though numbers alone do not provide evidence on which to declare a trainee competent at performing a certain procedure.

When generating individual and/or institutional learning curves we have shed light on some existing practices in our own institution. A better understanding and application of the training principles should end in a coherent, appropriate context within the learner’s overall curriculum. Expertise in education and technical
matters should go hand in hand. Professional practice in all medical fields is known to include both explicit (formal) and tacit (personal) forms of knowledge. Current anaesthetic training programs appear to favour explicit knowledge.

The attainment of expertise in anaesthesia is based on the ability to reconcile and interpret formal theoretical learning with many sources of knowledge - clinical, social, electronic, and experiential ones. Experts master technical skills but are also able to understand the dynamic and uncertain condition of the anaesthetised patient and can respond to sudden changes. This expertise is acquired by working with colleagues, and, also importantly, by working independently in order to develop personal routines. Routines mark the successful incorporation of new knowledge but also function as a defence against the inherent uncertainty of anaesthetic practice. The experts’ routines are preferred ways of working out of a larger repertoire of techniques and can also be modified when circumstances change. The maintenance of advanced skills may pose a greater problem than their initial acquisition. This important question needs further investigation. The attraction and excitement of practice in anaesthesia may be related to new drugs, techniques and equipment that are continuously being introduced. However, this includes an additional challenge for established practitioners who should keep up-to-date and always be prepared to attain new knowledge and supplementary skills. Our learning curves illustrate some interesting and important aspects of adult learning, in particular how adults acquire new techniques.

Not only technical skills need to be taught, but also decision making and, perhaps even more importantly, behavioural skills. In clinical practice there are often problems in providing all the necessary training on patients and, hence, reorganisation of residency programs may be necessary. However, the role of medical simulation in the assessment of anaesthetists in training is still unclear,[34] and the introduction of simulator-based general testing in the specialty may be premature.[34, 42, 75, 76]

The number and availability of physicians who are in a position to perform a distinct manual procedure (e.g. placement of a laryngeal mask, fiberoptic intubation) and the availability of the necessary equipment form part of the ‘structure quality’ of an anaesthesia department. ‘Process quality’ is directly related to the service provided. It is important to measure not only the outcome, but also the process because a positive outcome (e.g. a successful intubation) does not automatically mean that the underlying processes were conducted correctly. Conversely, an adverse outcome does not necessarily occur when something has been done incorrectly. Manual procedures and techniques in anaesthesia care have to be successful, safe and time-efficient. Learning curves of individuals and institutions are therefore important quality monitoring tools, not only at teaching institutions. Good assistance and profound practical training are an important part in the prevention of incidents in anaesthesia care.
We have now entered an era in medicine in which guidelines for training, certification and revalidation of certificates are important. The development of formal training and certification, especially in regional anaesthesia procedures can improve the quality of the services we offer to our patients. There is no lack of experience or expertise concerning all the different manual techniques of anaesthesia care. But a need for hands-on training and evaluation of competence still remains. Learning curves for different skills are a rational base for such a process. In the evolving pattern of a team approach for perioperative care, anaesthesiologists are expected to implement new techniques and skills such as sonography or echocardiography. Such complex competencies not only have manual skills as a base, but are also based on clinical judgement and experience. The same is also true for every regional or general anaesthesia procedure (see graph 8 and 9).

Graph 8
Template for teaching manual skills in anaesthesiology is shown

5.1.10. Learning Curves – Conclusions

The old saying "see one, do one, teach one" no longer seems to be true (and has probably never been so). Our data suggests that a trainee should practice a new skill at least thirty to sixty times in order to be proficient. Knowledge of learning curves makes clear that caution must be observed when a new skill is to be learned. There will always be a learning curve associated with the development of a new skill.[30] Most studies in the field of anaesthesiology and the investigations in other medical fields support the view that expert supervision should be present during the first 20 or 30 attempts at a new procedure but that expert
performance cannot be expected until the number of cases has reached three times that number, at least. And even a great number of repetitions cannot guarantee a specific competence.[77] [78]

**Graph 9**
Typical summary learning curves (generated by our group) for manual procedures are shown. EDA: epidural catheter placement; SSS: single shot spinal anaesthesia; ITN: intubation; ART: placement of an arterial line in a radial artery; ZVK: central venous line placement (Vena jugularis interna); AX Block: block of the axillary plexus using a nerve stimulator; P Block: penis Block.[56]

Table 8 summarises the results of our studies with reference to the typical learning curves obtained (see also Graph 2). This table may serve as a guideline for the definition of training programs in anaesthesia. Minimal case loads for different important manual procedures are shown.
Table 8: Minimal case load for typical manual procedures

Data are results of our study group[32, 35, 53-56, 61-63]

(items in italics from the literature for comparison)

<table>
<thead>
<tr>
<th>Procedures</th>
<th>Success Rate (mean +/- 95% confidence interval)</th>
<th>Case load (mean +/- 95% confidence interval)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Caudal-epidural analgesia (children)</td>
<td>0.80 (0.59-1.00)</td>
<td>32</td>
</tr>
<tr>
<td>Penile block (children)</td>
<td>0.93 (0.80-1.0)</td>
<td>40</td>
</tr>
<tr>
<td>Orotracheal intubation</td>
<td>0.95 (0.72-1.00)</td>
<td>57–80</td>
</tr>
<tr>
<td>Single shot spinal anaesthesia</td>
<td>0.90 (0.75-1.00)</td>
<td>71</td>
</tr>
<tr>
<td>Epidural catheter anaesthesia</td>
<td>0.80 (0.71-1.00)</td>
<td>&gt;90</td>
</tr>
<tr>
<td>Axillary block (using a nerve stimulator)</td>
<td>0.90 (0.78-1.00)</td>
<td>110</td>
</tr>
<tr>
<td>Arterial line (Arteria radialis)</td>
<td>0.90 (0.60-1.00)</td>
<td>60</td>
</tr>
<tr>
<td>Central venous line (Vena jugularis interna)</td>
<td>0.60</td>
<td>40-60</td>
</tr>
<tr>
<td>Venous canula (peripherally)</td>
<td>0.80</td>
<td>79 +/-47</td>
</tr>
<tr>
<td>Laryngeal mask placement[79]</td>
<td>0.94</td>
<td>no learning curve observed</td>
</tr>
<tr>
<td>Ventilation with mask and bag[80]</td>
<td>0.50</td>
<td>10</td>
</tr>
<tr>
<td>Paediatric Fiberoptic Intubation of the Trachea[37]</td>
<td>0.90</td>
<td>10</td>
</tr>
</tbody>
</table>

5.2. Aspects of Risk Management

5.2.1. Discussion

The second part of this thesis focuses on risk management. Teaching residents may be associated with worse patient outcome or a higher rate of critical incidents[81] Therefore, institutional learning and risk management are also important issues when teaching new skills or educating residents. Anaesthesia management problems are most common during the second year of training and may result in higher costs for the institution, according to a U.S. study.[82] During teaching cases the workload (for the teacher) is also significantly higher than during non-teaching cases.[44] Therefore, the secondary attention of this thesis focuses on institutional learning, risk management and suitable tools for such tasks.

A typical risk management approach in medicine focuses on the outcome and especially on the relative risk ratios of adverse events.[82] Suitable tools for monitoring the occurrence of rare events are the ‘Cusum’ technique (already described before) and statistical process control tools. Both are adopted by our group for anaesthesia in different studies.[62, 63, 83-86]

The management philosophy of continuous quality improvement (CQI) and the tools of statistical quality control can potentially improve quality management in medicine which is comparable with the results in
industry using the same tools. Statistical process control was adopted by our group as a technique to ensure continuous quality in an anaesthesia and critical care department.[62, 63, 83-86] The effective use of control charts (p-Charts, XmR Charts) illustrates their potential to identify opportunities for improvement, to develop improvement strategies and to measure the effectiveness of an intervention. Quality aspects of the anaesthetic process are reflected in the rate of intraoperative adverse events. The purpose of some of our reports is to illustrate how the quality of the anaesthesia (or critical care) process can be analysed using statistical process control methods, and to exemplify how this analysis can be used for quality improvement.

In one of our studies prospectively anaesthesia-related data from all anaesthetics was recorded within a period of five years.[84] We selected the key adverse event of postpunctural headache as an endpoint and analysed the underlying process using ‘p-charts’ for statistical process control. Postpunctural headache is a typical complication of spinal or epidural anaesthesia. We were able to identify a so-called specific cause for process variation due to unusual high rotation of the residents. In our study we have also suggested other adverse events that should be investigated. Later, a similar study was published by a group from Trondheim, Norway.[87]

By applying statistical process control methods to the analysis of adverse events, we also exemplified in urology anaesthesia and critical care the determination of the time when a process is stable, whether an intervention is required, and if quality improvement efforts have the desired effect. Using this tool, we were able to monitor and to control the performance of perioperative care.[83-85]

5.2.2. Conclusion

One of the major determinants of patient care is the system by which services are delivered and not the individual care provider. Therefore, SPC and Cusum analysis are important tools to guarantee the overall quality of care, especially in a teaching institution. We were among the first groups using these tools. Others focused on institutional quality management[28] without expanding their focus on teaching issues. [87, 88]
Chapter 6: Future Perspectives

Learning new skills or competencies is a risky business. Teaching residents has different types of results for the involved institution. The accumulation of new competencies is linked with costs when residents are involved. This is especially true in anaesthesia care, the work load for teachers is higher during an instruction period and residents perform slower than experienced staff members.[81] There is also a risk in being a patient, particularly when being cared for by a less experienced practitioner. Our duty in providing health care is to keep the risk at a minimum while we are learning ourselves and teaching others at the same time. Patients should somehow be protected from the risks of “learning curves”. This can perhaps be achieved in anaesthesia training by adhering to definitions of a minimal case load for certain skills in conjunction with close supervision. But what happens when there is no senior staff member accompanying the resident to take over when there is a risky situation?

Under new reimbursement systems as they are implemented now for example in Germany or Switzerland (e.g. hospital financing by diagnostic related groups = DRG’s) a huge shift towards productivity has been mandated for providers. This is a major challenge for teaching institutions because teaching of residents requires extra staff, time and may create additional risks! [44]

This current climate brings about questions concerning teaching of residents: it is too expensive and probably a competitive disadvantage in the eyes of patients (consumers?) for standard care procedures? A structured risk management for teaching institutions may also be required!

Although learning curves answer some questions about designing training programs, the role which increased practitioner experience plays to achieve and maintain competence requires further investigation. Detailed studies are also necessary to answer the following questions which are still open:

• Which case load is necessary for a sustained performance?
• How should a new method / skill / technique be implemented?
• Do we need sub-specialisation?
• How should a residency program be designed?
Chapter 7: Summary

The assessment of clinical competence is one of the greatest challenges facing medicine today. Training according to today’s exacting standards is a complex business. How should clinicians be trained and how will they maintain their skills? Teaching practical procedures constitutes a major challenge in anaesthesiology and makes up an important part in achieving clinical competence. Common sense suggests that not all trainees will be equally good at learning practical procedures. The following questions need to be answered: can a certain skill in practical procedures be predicted? How many procedures should be carried out to achieve a certain competence? Is a learning curve associated with worse patient outcome and how should this phenomenon be monitored? A key consideration when learning a new skill is the concept of the learning curve. In this thesis there is an emphasis on learning curves for manual skills in anaesthesiology for two reasons. First, the acquisition of (advanced) manual skills requires substantial clinical training and time. Learning curves may be used as a tool to guide this learning process. Second, manual skills are important and many techniques have to be learnt during a residency program. Therefore, the determination of the minimal case load for a given task, procedure, technique or skill is required for the planning and designing of teaching/residency programs. An easily obtainable quantitative measure of performance would support an objective evaluation of resident performance, contributing to a better training.

Concerning generation of learning curves, such curves can be constructed using different techniques including graphical methods, the Cusum technique, and learning curves using the “least square fit” model and Monte Carlo procedures. When analysing learning curves, the observer should be aware of risks. Statistical process control and Cusum are suitable tools to monitor risks, and can easily be transferred from other industries into clinical practice. The generation of learning curves with reference to this method does not require any assumption to be made in advance, but the results can be used for the calculations of Cusum analyses. These techniques can focus on monitoring individual as well as institutional learning. Typical examples are described in this thesis. Currently, only few publications exist concerning this topic and most of them are focused either on graphical or Cusum methods. In this context, our team investigates a new approach.

The benefit of the thesis may be thought of as follows. Written and oral examinations are important to assess the trainees’ knowledge and judgement but do not include the testing of practical skills which are essential for successful clinical practice. There is currently a lack of available published data concerning physicians’ learning processes when adopting anaesthetic procedures. Learning curves have now been documented by our research group for anaesthesia trainees when they have to learn a variety of new anaesthesia skills, such as intubations, spinals, epidurals, arterial lines, brachial plexus blocks, caudal and penile blocks in
children. Repetition and practice of the mentioned procedures are important since from the one hundredth repetition of an intervention onwards it is necessary to achieve reliable success rates, particularly during the learning process of airway interventions. Thus, conclusions drawn by the observation of learning curves are important. The value of using learning curves to evaluate practical skills in anaesthesia should be recognised since they represent a useful tool for monitoring learning processes. Using those curves, estimations of the number of procedures that must be performed by a trainee in order to reach an acceptable success rate can be produced. Furthermore, an individual learning process can be monitored. This illustrates how the use of such graphs may facilitate a rational design of training programs. However, such figures alone do not provide a sufficient basis to declare a trainee to be competent for performing a special procedure.

We have now entered a new era in medicine in which guidelines for training, certificates and credentials are extremely important. The development of formal training and certification, especially in regional anaesthesia procedures can improve the quality of the services we offer to our patients. There is no lack of experience or expertise for all different manual techniques of anaesthesia care. However, there still is a demand for hands-on training and evaluation of competence. Learning curves for different skills are a rational basis for such a process. In the evolving pattern of a team approach for perioperative care, anaesthetists are expected to implement new techniques and skills. Such complex competencies do not only have manual skills as a basis, but are also founded on clinical judgement and experience. The same is true for every regional or general anaesthesia procedure. Although learning curves answer some questions about designing training programs, the role of continuing experience in achieving and maintaining competence is another complex question.
Appendix A

What is statistical process control (SPC)?

Since many institutions now refer to the methodology of SPC and some of our studies are based on this tool as a part of our risk management, a brief overview on this topic is provided in this appendix.

SPC, the data analysis method of quality improvement, has been in use since the 1930s.[89] SPC is the branch of statistics that uses basic statistical techniques to organise data, so that information becomes obvious. In the last 20 years, primarily under the influence of the automotive industry, the use of data to analyse processes and thereby find ways to improve them has undergone standardisation. In all production processes, the extent to which products meet specifications has to be monitored. In the most general terms, there are two "enemies" of product quality.

1) deviations from target specifications
2) excessive variability around target specifications

Every repeated process has some variation. In most processes a degree of variability is inherent due to random effects. These effects vary and produce a random variation in every process output. Shewhart introduced the terminology that a process with only common cause variation is a controlled process and is in a state of statistical control. Such a process is statistically uniform. Such a uniform process has only a random variation, the result of common causes. The data is homogeneous, stable, random and without trends, peaks, steps or cyclical patterns. In a controlled process, the variations are not due to assignable, special or uncontrolled causes, and the data are free from systematic variations, trends, spikes, steps or cyclical patterns. If a trend emerges or if samples come outside from pre-specified limits, the process is declared to be out of control and it should be examined to find the cause of the problem. Every variation outside the limits (3 standard deviations from the mean) are attributed to assignable (Shewart[89, 90]) or special (Deming[91]) causes. When a special cause appears, it is important to investigate it. SPC uses a graphical tool, a control chart. The control chart estimates the limit of the variation due to common causes. Every variation outside the limits is a special cause variation that makes an intervention for correction necessary. If your knowledge is only based on common causes, the process is repeatable within certain limits and only variations by chance are possible. A variation due to common causes may not yield acceptable process results. If no assignable or special causes are present, the process itself should be changed. The variation due to common (random) causes should be decreased. This might be a difficult task because common causes are a part of the usual process whereas special causes are unusual and can therefore be easily identified.[84, 86]
Appendix B

Bedside learning versus formal instruction with the use of animal models, cadavers or mannequins

Teaching residents to perform invasive procedures poses some difficult ethical issues. Patients generally expect the most experienced clinician available to perform the procedure and do not agree that a resident should perform a procedure on them if they are doing it for the first time. But in many cases residents learn on the job. One common approach to procedural training is the impromptu practice of invasive procedures, for instance endotracheal intubation or chest tube drainage. This is a common method of teaching these skills to medical students, residents, attending physicians, and paramedical professionals. Resident curricula mostly lack formal training in these procedures. Mannequins or computer simulators to teach invasive procedures may be a helpful adjunct but actually do not include physical reality of a human patient. Another approach to procedural training involves the use of unembalmed cadavers. Compared with a preserved cadaver, the unembalmed cadaveric tissue is more realistic for practising certain procedures. Several articles report on the use of unembalmed cadavers as a useful educational approach to teach invasive procedural skills. After implementation of cadaveric training, the occurrence of pneumothorax decreased in a statistically significant way from 1.16% (61/5271) prior to cadaveric training to 0.44% (16/3637).[92] PGY-1 surgical residents demonstrated faster performance of chest and endotracheal tube insertion and venous cutdown, with fewer complications compared with outcomes prior to cadaveric training.[93]

Animal models have been used to teach invasive procedures.[94] A major limitation of these studies is a lack of data that compares training with an animal model with the outcomes of training on human subjects. Animals may be less effective than human cadavers as training material for teaching procedures such as cricothyrotomy as an important airway management tool.[94, 95]

Studies are necessary to evaluate and quantify the benefits of the different teaching possibilities such as simulator, cadaver or animal model based training. Evaluation of changes in technical competency and procedural complication rates after instruction via a particular educational model will define the utility of each type of procedural training. The use of randomisation in such studies may enhance their predictive value. It is important to apply an empirical approach in order to determine if the current emphasis on informal bedside instruction is in fact an acceptable strategy for training residents in invasive procedures. The task of accurately correlating procedural training methods with well-defined clinical outcomes is a challenging objective for research that could lead to an improved clinical practice.

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Appendix C

Andragogy

Medical residents belong to the group called adult learners. Therefore, in this appendix some basic ideas of teaching especially adult persons will be outlined. Andragogy is the science and art of adult learning and recognises that the adult learner

a) requires respect
b) is autonomous and self-directed
c) is goal-oriented
d) is relevancy-oriented
e) is practical
f) has accumulated personal life experiences.

Thus, adults tend to be self-initiated, self-directed, self-determined, and self-planned. Adult learners usually find the motivation to learn from within themselves. They determine by themselves the reasons for which they start learning, not only in content but in context as well. Adults are self-determined concerning the topic they wish to learn and self-planned concerning the way how they will learn. [96-99] Adults choose their teaching method, their teacher as well as the time, resources, process and location where the training will take place. Adult learners prefer to keep control of the ‘who, what, where, when, why and how’ of their learning. Adults, even with advancing age, do retain their ability to learn. Furthermore, adults prefer to organise learning new skills in an active way rather than receiving new information in a merely passive way.

A fact to be outlined in adult learning is that it is based on experience of life. However, adult learners may choose quite pedagogical methods for their own learning. This may be true especially when they approach entirely new topics or if they need to acquire important information quickly and efficiently. While the typical characteristics of adult learning processes gain more importance, the difference compared to children’s learning processes becomes more evident.

Experimental and life-centred learning are important to adult learners. Adult learners want to control their own education and decide independently how learning can be facilitated. Some general guidelines are suggested:

1) create a pleasant atmosphere
2) involve learners in mutual planning
3) involve participants in diagnosing their own needs for learning
4) involve learners in formulating their learning objectives
5) involve learners in designing learning plans
6) help learners realise their learning plans
7) involve learners in evaluating their learning

Instructors of adult learners must ensure that the adult learner is involved in all aspects of their learning, including curriculum design, teaching methods and evaluation. Learning curves, too, are an important tool for
this task. However, as mentioned above, probably the most important characteristic of adult learners is that they do maintain the ability to learn for a long period of time.

Anaesthesiologists will always have to experiment with novel techniques as specialisation advances. Reference to the theory of adult learning processes might support – according to our point of view – the understanding of how adult learners learn in our clinical practices. Familiarity with the principles of teaching adult learners will allow more efficient and effective learning. Considering the concept of learning curves will help us to understand its impact on our success when we learn new tricks, and encourage us to include these new approaches into our daily practice.

We still have to recognise that a considerable number of procedures may need to be practised to ensure reliable performance in emergency situations. We have to be aware that only a few successful attempts cannot guarantee persistent success for a longer period of time or a successful outcome in every emergency situation. This might be the reason why residency training takes much time, possibly with an exceedingly high expectation for training accomplishments sometimes in order to ensure persistent, reliable and safe practical skills in the trainees.

Likewise, it has to be realised that the number of successful performances might decrease in the course of time unless kept in continual practice. Being inactive, anaesthesiologists may fall off the learning curve plateau within a longer period of time. Individual skills can vary according to frequency of practice that is needed to maintain a certain capability. While we always remember how to ride a bicycle once been mastered, some other skills, in contrast, may require frequent continuing practice to ensure repeated competent performance. Thus, one question still remains: How might an emergency physician (or any other physician) can sustain qualified performance when using a technique that is only occasionally performed, which means that its routine use is quite infrequent? One possible answer to this question might be to offer special workshops to regularly update certain skills, also including the use of simulators.
References:


