Clinical impact of the publication of S3 guidelines for intensive care in cardiac surgery patients in Germany: results from a postal survey

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Introduction: The development and implementation of practice guidelines might be an important tool to evaluate the different practices and to consider different local strategies.

Methods: A postal questionnaire with 37 questions was sent to the leading physicians of 80 intensive care units in Germany, treating patients after cardiothoracic surgery. The survey covered the same core questions on current practice of hemodynamic monitoring, volume replacement, inotropic/vasopressor support, and transfusions before and after the publication of an S3 guideline.

Results: A total of 77.5% of the completed questionnaires were returned. Monitoring changed to increased use of central venous oxygen saturation (SvO2) in 55.1% (2005: 20.9%), end-tidal CO2-monitoring 36.2% (2005: 24.3%), and decreased use of the left atrial pressure with 12.3% (2005: 23.3%) and pulmonary artery catheter 47.5% (2005: 58.2%). For volume therapy, there is a decreased use of Hydroxyethyl starch (HES) with 38.7% (2005: 63.4%) and an increased use of crystalloids 41.9% (2005: 22.4%). For inotropes, there is a trend to a decreased use of dopamine with 9.7% (2005: 29.1%, P = 0.074). The clinical relevance of the guidelines was judged ‘high’ by 43.5% and ‘medium’ by 50% of the responding physicians; however, change of treatments was reported by one quarter of respondents.

Conclusion: Despite ongoing variability in the use of monitoring devices, volume replacement and vasopressor/inotrope use in cardiac surgery patients, there have been some changes in the therapy of these patients after publication of the guidelines. Because the guideline has been considered as clinically relevant, further interdisciplinary development and implementation support should be considered.

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Hemodynamic monitoring and adequate volume therapy, as well as the treatment with positive inotropic drugs and vasopressors, are the basic principles of the post-operative intensive care treatment of patients after cardiothoracic surgery. In December 2006, the German Society for Thoracic and Cardiovascular Surgery (DGTHG) and the German Society for Anaesthesiology and Intensive Care Medicine (DGAI) published S3 guidelines to give recommendations on therapeutic goals for monitoring and therapy of patients after cardiac surgery.1 The goal of the guideline was to assess available monitoring methods and their risks, as well as the differentiated therapy of volume replacement, positive inotropic support and vasoactive drugs, the therapy with vasodilators, inodilators and calcium-sensitizers, and the use of intra-aortic balloon pumps. The guideline was developed according to the recommendations for the development of guidelines by the Association of the Scientific Medical Societies in Germany2 and was consented by DGTHG and DGAI after two consensus meetings.

To evaluate the clinical practice in monitoring and treatment of cardiac surgical patients in Germany before the establishment of practice-oriented guidelines, a survey was performed.3 As the results of that survey reflected current practice at that time, some of the results were included in the guidelines.

About 1 1/2 years after the publication of the guidelines, the survey was repeated to document the clinical impact of the guidelines. Another objective was to find out how the guidelines were incorporated in clinical routine and what improvement is needed in order to achieve a better acceptance.
Guidelines in general have the potential to improve the care received by patients by promoting intervention of proven benefit and discouraging ineffective or potential harmful interventions. In times of limited financial resources, it is important for the medical societies how to best use these resources to maximize the potential beneficial effects for the individual patient. Several factors need to be considered. Besides the definition of clinical areas in which quality improvement initiatives are necessary, attention should be given to the likely effectiveness of different dissemination and implementation strategies. In order to answer these questions, evidence about the effects of quality improvement strategies and the clinical impact of guideline implementation are necessary. Uncertainty remains about the ideal implementation strategy of guidelines.

The presented survey covers in most parts the same topics as the one done prior to the publication of the guidelines. Additionally, some questions about the physician’s perceptions on the guidelines and on the implementation are included in this survey.

Methods

Data collection
From an address database, a postal questionnaire was sent by the two societies, DGAI and DGTHG, to the leading physicians of 80 intensive care units (ICUs) supplying care to patients after cardiac surgery. This database was the same as the one used for the survey in 2005. There was a covering letter explaining the aims of the study and a stamped addressed return envelope for return postage. The letters were sent to the hospitals in the period between 01 April 2008 and 31 May 2008. All letters were delivered by mail, and no letters were returned because of an invalid address. The completed questionnaires were collected by the societies and then returned to the authors of the study. As the acquisition of the data was performed anonymously and the questionnaires were collected by the societies, no estimate of survey characteristics for nonrespondents and respondents can be made to assess the potential nonresponse bias.

Questionnaire
The questionnaire consisted of 37 questions covering four major areas: the different basic and advanced hemodynamic monitoring techniques, different volume replacement strategies, and the use of vasopressor or inotropic drugs in different clinical situations. The questions of the previous questionnaire on the administrative data and the number of patients treated were omitted. Questions are new, covering the field of the implementation of the guideline. The questionnaire itself is provided as Appendix S1. The questionnaire was filled out and returned anonymously to the societies. The evaluation was performed anonymously after having collected all the returned sheets.

Statistical analysis
The completed data were collected and analyzed using the Statistical Package for Social Sciences (SPSS 14.0 for Windows, SPSS, Inc., Chicago, IL, USA). Because of the specific characteristic of the survey, univariate statistical analyses were carried out depending on the scaling of the data, using either the Mann–Whitney U-test or the chi-square test. Analyses were assigned as exploratory. Therefore, no adjustments for multiple testing were carried out. Statistical significance (in the sense of exploratory analyses) was set at a P value of greater than 0.05. Results were expressed as frequency (in %) and as mean values with 95% confidence interval, respectively.

Results

General remarks
We obtained 62 completed questionnaires representing 77.5% of the surveyed ICUs. In 2005, the return rate for the completed questionnaires was 69%. Because the data were collected anonymously, no estimate can be made about the nonresponder bias. As all the questionnaires were sent to ICUs taking care of patients after cardiac surgery, there should be no nonresponder bias.

Hemodynamic monitoring
Basic monitoring procedures used in the ICU after cardiac surgery included electrocardiogram (ECG), pulse oximetry SpO₂, central venous pressure (CVP), fluid balance and temperature in more than 97.9% (Fig. 1). Comparing the data from 2005 to 2008 when asked in how many patients the monitoring of the central venous oxygen saturation (ScvO₂) is used, one can note a significant increased use from 55.1% (95% CI: 44.6–65.6%) (2005: 20.9%, 95% CI: 10.6–31.1%; P < 0.001), along with an increased use of monitoring of temperature in 98.4% (95% CI 95.2–100%) (2005: 94.8%, 95% CI 89.3–100%; P = 0.035) and SpO2 in 62.8% (95% CI: 49.6–73.0%) (2005: 95%, 95% CI: 68.8–89.3%; P = 0.047). In contrast, when
asked in how many of the patients the monitoring of the left atrial pressure (LAP) was used, the use decreased to a mean of 12.3% (95% CI 6.2–18.5%) (2005: 23.3%, 95% CI 13.8–32.8%; \( P = 0.043 \)) (Fig. 1).

The availability of advanced hemodynamic monitoring, which is important for cardiac surgery patients, has a high degree of implementation and does not show any significant differences between the two questionnaires. In the 2008 survey, a pulmonary artery catheter (PAC) is available in 100%, the PiCCO® (PULSION Medical Systems SE, Munich, Germany) in 80%, the transesophageal echocardiography (TEE) in 100%, the transthoracic echocardiography in 98% and the indocyanine green (ICG) clearance measurement in 27% of the units.

In advanced hemodynamic monitoring, the changes in the use of the different methods did not reach statistical significance, but the data show certain trends: when asked in how many patients with advanced hemodynamic monitoring a PAC is used, the mean answer from the questionnaires was 47.5% (95% CI 38.6–56.4%) (2005: 58.2%, 95% CI 48.9–67.5%; \( P = 0.101 \)) of the cases. When asked in how many cases the TEE was used, the mean answer increased to 44.7% (95% CI 35.9–53.6%) (2005: 32.7%, 95% CI 25.2–40.1%; \( P = 0.110 \)), and the use of the PiCCO system increased to 19.2% (95% CI 13.4–25.0%) (2005: 13.0%, 95% CI 9.1–16.8%, \( P = 0.147 \)) (Fig. 2). When asked for the first-choice indication for PAC, there was significant difference concerning the indications of this monitoring device in the answers: in 2005, this device was the first-choice indication for measurement of systemic vascular resistance in 14.5% of the answers; in 2008, there were no answers for this indication (\( P = 0.039 \)) (Fig. 3). The primary indication for PAC for monitoring hemodynamic instability also decreased significantly. When asked for the first-choice indication for the use of the transpulmonal thermodilution (e.g. PiCCO system), no statistical differences could be shown, but trends can be seen in the measurement of cardiac output/cardiac index, which was the first-choice indication in 22.6% (in 2005: 16.4%, \( P = 0.087 \)) in the answers for the use of this monitoring device. The availability of an around-the-clock
available TEE specialist in the ICU was 72.6%, which did not change significantly from 2005 (63.6%, P = 0.369).

**Volume monitoring and replacement strategies**

For monitoring of fluid therapy, there was an increased use of the systolic pressure variation with 32.6% (95% CI 22.0–43.1%) (in 2005: 14.6%, 95% CI 6.2–23.1%; P = 0.006), of the left ventricular end-diastolic area index with the TEE in 13.6% (95% CI 9.1–18.2%) (in 2005: 8.3%, 95% CI 9.1–18.2%; P = 0.027) and of the intrathoracic blood volume/extravascular lung water with transpulmonary thermodilution (e.g. PiCCO system) in 14.1% (95% CI 9.1–19.2%) (in 2005: 8.1%, 95% CI 3.8–12.4%; P = 0.025).

There have been some considerable changes in the answers regarding the topic of volume therapy. In the 2005-survey the first choice for volume replacement was hydroxyethyl starch (HES) with 65.3% of answers given. In the 2008 survey the use of HES dropped to 38.7% (P = 0.007). Corresponding to these findings the use of crystalloids increased to 41.9% (in 2005: 22.4%, P = 0.042) and the use of gelatin-products for volume therapy increased, without reaching statistical significance (Fig. 4). There was no statistical difference for the use of albumin for volume replacement.

**Vasopressors/inotropes**

The first-choice drug for treating low cardiac output syndrome has not changed and is epinephrine, which is given as the first-choice answer in about 40%. In 2005, physicians stated that they use enoximone in 47.3% of the patients with low cardiac output independent of the priority; in 2008, this figure dropped to 25.8% (P = 0.047). When asked if norepinephrine for the indication low cardiac output was used, the use decreased from 43.6% in 2005 to 19.4% in 2008 without reaching statistical significance (P = 0.133), and the use of dopamine for this indication dropped from 29.1% in 2005 to 9.7%
in 2008 ($P = 0.074$). In the combination therapies for low cardiac output syndrome (LCOS), there were no statistical differences between the questionnaires. The most often marked combination therapy was epinephrine and a phosphodiesterase (PDE) inhibitor (33.9%). For treatment of a systemic inflammatory response syndrome (SIRS), the first choice is unchanged norepinephrine in both surveys, the use of the combination of norepinephrine and vasopressin increased to 33.9% (compared with 16.7% in 2005, $P = 0.035$). For treatment of right-heart failure, there is no statistical significant change in the treatment, PDE inhibitors are used by 31.7% of the ICUs, and the use of inhalative drugs has not changed.

Perception of the guideline

The last part of the survey included questions about the physician’s attitude toward the guidelines and the implementation process. When asked about the relevance of the guideline, 43.5% of the responding physicians marked ‘high’, 50.0% marked ‘medium’, and 6.5% marked ‘low’. In the next question, the physicians were asked whether the therapy algorithms were changed after the implementation of the guideline. Seventy-four percent of the physicians marked that the guidelines did not influence their therapy; the rest with 26% said that the guideline changed the therapeutic regime. The changes influenced the field of therapy in the following way: monitoring was marked in 18%, therapy with inotropes and vasopressors in 25%, and fluid therapy in 13%. One question covered the reasons for changes in therapy since the last survey before the publication of the guideline. The most important reason was medical education and publication that was marked by 22.6% of the physicians (Table 1). To the question whether the guidelines restrict the medical decision process, 8% of the answering doctors marked ‘yes’ ($n = 61$); the other 92% felt that they were not restricted in the treatment process by the guidelines. Table 2 shows how the attention of the physicians was drawn on the guideline after publication. Internet and print media are equally important in the dissemination.

Discussion

The most important results of this survey after the publication of guideline are that clinical practice can be influenced by this interdisciplinary guideline despite the fact that the practice in hemodynamic monitoring and therapy still vary between ICUs taking care of patients after cardiac surgery. The majority of the respondents judged the clinical relevance of this interdisciplinary guideline as ‘high’ or ‘medium’.

Unchanged between the two surveys are the key elements of basic monitoring, including the monitoring of the ECG, the central venous pressure and the invasive measurement of the blood pressure. These results represent the published standards for monitoring that are given by the societies. After the publication of the guidelines, the monitoring of the central or mixed venous oxygen saturation increased. The reason for this development is speculative. The work of Rivers et al., who demonstrated the beneficial outcome improvement using a goal-oriented therapy concept, including the central venous oxygen saturation as a therapy goal, has been published in 2001, several years before the publication of the guidelines. The guidelines reviewed the available literature and made recommendations on the treatment of the patients. This fact alone is not enough evidence to confirm that the effects seen in this survey are induced by the publication of the guideline. There is little known about the exact time it takes for new therapeutical interventions to be implemented in a widespread manner. Tricoci et al. investigated the guideline adherence and care delivery for patients with myo-

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cardial infarction and clearly demonstrated a gap between guideline-recommended treatment and intervention to manage patients, and was able to demonstrate that broader scale implementation may result in significant improvement of patient outcomes.

The monitoring of the LAP was used by 23.3% ICUs in 2005, and in 2008, this figure is 12.3%. The guidelines\(^1\) gave no recommendation on using this monitoring possibility, as there are no clinical trials that clearly show the benefit for this measurement. The reason for the declining use again is speculative.

After the publication of the guidelines, the PAC was less often used, and correspondingly, the use of echocardiography and transpulmonary thermodilution (e.g. PiCCO system) increased. This is an interesting aspect, as the guidelines state that the use of PAC for patients with a low perioperative risk is not justified (evidence level C and recommendation level B) and the grade of recommendation in the guidelines for the use of transpulmonary thermodilution (e.g. PiCCO system) is evidence level ‘C’. The clinical advantages and disadvantages are described in detail in the guidelines. This survey is designed to describe the different aspects of treatment. By its design, one can not conclude why the patients are treated differently.

This aspect becomes evident looking at the changes in volume therapy. There is a clear reduction in the use of HES for volume therapy, and at the same time, there is an increased use of crystalloids. This is an important finding as the guidelines do not give a clear recommendation on what type of volume is to be used.\(^1\) In the beginning of 2008, Brunkhorst et al.\(^9\) published the results of the trial intensive insulin therapy and pentastarch resuscitation in severe sepsis. This multicenter trial was stopped early for safety reasons. In this study using pentastarch, HES therapy was associated with higher rates of acute renal failure and renal replacement therapy.\(^9\) The various aspects of this study, like the employed HES solution and the amount infused to the patients, have induced an intensive discussion.\(^10\) One has to bear in mind that this study included septic patients and it is unclear if all the aspects are valid for cardiac post-operative patients. The effects of this discussion may influence the observed results in our survey, to what extent remains speculative. The observed results are plausible as the use of gelatin-solution increased at the same time. The guidelines made no recommendation on which colloid solutions should be preferred, as there is not enough evidence to give a good recommendation.\(^1\)

In this survey, 2 years after the publication of the guidelines, there is a decreased use of dopamine for patients after cardiac surgery. The guidelines state that the use of dopamine is not indicated in a low dose in cardiac surgery patients to prevent or treat renal failure, with an evidence level A. Looking at the guidelines of the European Society of Cardiology, the use of dopamine is only indicated for patients with acute heart insufficiency and hypotension with a class of recommendation IIb.\(^11,12\) The guidelines for patients after cardiac surgery\(^1\) state that PDE-III inhibitors should be given to patients who are on a beta-blockade or are unresponsive to treatment with dobutamine. The first-choice drug for treating low cardiac output syndrome has not changed and is epinephrine. The use of a combination therapy of a catecholamine and a PDE-III inhibitor increased to 37.35% after the introduction of the guidelines.

The last part of the survey covered general questions about the guideline and the implementation process. When asked if the therapy algorithms changed after the implementation of the guideline, 74.0% of the physicians marked that the guidelines did not influence their therapy. This is in contrast with the other findings of the survey, which focus on the clinical aspects of therapy. There have been some changes if one compares the survey from 2005 to 2008. These changes cannot be quantified in absolute figures. This is an interesting aspect of the guideline implementation. We were able to document changes in clinical routine, but the opinion leaders felt that this was not induced by the guidelines. These findings are in contrast with the representative survey from Brunkhorst et al. on the perceived and practical adherence to treatment recommendations for patients with severe sepsis.\(^13\) The authors were able to demonstrate that there is a poor correlation between what the ICU directors perceive as adherence to guidelines and the actual treatment algorithms. Our survey cannot be compared with the survey by Brunkhorst et al. as our results rely on the answers of the survey questions and no audits to measure the implementation were performed, and the study from Brunkhorst did not evaluate change of treatment over a given time after the implementation of a guideline.

From research on guidelines, it is known that improvement of care is often observed, suggesting that dissemination and implementation of guidelines can promote compliance with recommended
practice. The ideal implementation strategy is not known. Educational materials, audits and feedback appear to result in modest effects on improvement of care. Despite 30 years of research in the area of guideline implementation, there is still a lack in a robust, generalizable evidence base to inform decision-makers about the ideal way of quality improvement strategies. The translation of knowledge regarding the best approach to provide patient care through evidence-based guidelines remains complex. The CRUSADE quality initiative intended to provide a method to observe, research and improve the bench-to-bedside translation of the complex American College of Cardiology/American Heart Association (ACC/AHA) guidelines on the treatment of unstable angina and non-ST segment elevation myocardial infarction. The goal of this initiative was to provide a continuous cycle of data collection, audit, feedback and educational interventions, and more than 200,000 patients have been included in the database. Previously, there was little data to show the hospital process performance and outcome. After the evaluation of patient outcomes demonstrating that decreased mortality was associated with higher levels of guideline adherence by a hospital, significant interest and enthusiasm for quality initiative were achieved at all levels, including the physicians at the local hospitals and the national health care payers. One important lesson learned from these patients is that the measurement and timely feedback to the hospitals of practice patterns can decrease the gap between usual and evidence-based care. An important requirement for such a system to work is the availability of valid data on the actual treatment of the patients, as well as defined outcome parameters. Future guidelines should include such defined practice parameters to determine the effectiveness of the guideline implementation.

A positive aspect of this survey was the fact that the guideline has a good acceptance and almost all physicians do not feel themselves limited in their therapy by the guideline. Important factors for the dissemination of the guideline were print media and the Internet.

Limitations
There are some limitations to this study. First of all, only leading physicians were asked. The variability was not measured, as this was only a survey and no prospective trial. To ensure a rather short questionnaire, only a limited number of aspects were asked, and only lead positions were asked. No outcome parameters were investigated so no information about the clinical impact of the guidelines as in a before/after study is available. As the survey was anonymous, we do not know if the same departments that answered in the first survey were included, which might have an effect the comparisons.

In conclusion, this questionnaire has demonstrated that treatment practices for patients after cardiac surgery have changed during the course of 2 years. Whether this change was induced by the publication of the guideline or if other factors also play an important role cannot be concluded with certainty. Guidelines should be able to improve the quality of treatment of patients after cardiac surgery. The implementation may be beneficial for each patient and will probably provide beneficial economic effects, as unnecessary and potentially harmful treatments can be avoided. Further research, however at least a data registry for evidence-based monitoring and treatment, needs to be performed in order to define the implementation barriers and needs, and what factors need to be considered during the implementation process.

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Supporting Information
Additional Supporting Information may be found in the online version of this article:
Appendix S1. Questionnaire.