Safety management in mechanical heart valve replacement and oral anticoagulant therapy

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Summary

Since the development of the heart-lung machine in the fifties and early sixties of the 20th century open-heart surgery became a large-scale surgical procedure. Many of the heart diseases are characterised by failing native heart valves, for which valve replacement by means of a mechanical valve is the mode of treatment. In many cases mechanical heart valves are used because of the custom ready availability and lifelong durability.

In spite of the technical progress there is still a need for improvement of mechanical heart valves. Adverse effects of treatment by means of mechanical heart valves and failures due to design, material or surgical shortcomings generate the development of new devices. This thesis reflects research on the steps or phases that are essential for recognizing critical safety risks as well as the ways to apply safety management.

Chapter 2 describes what difficulties arise in recognizing negative outcomes as a safety risk due to the complexity of the system and the potential conflicts of interests. However, the product life cycle-based safety management concept also clarifies who are stakeholders to control risks and how they interact with other players and disciplines. Surgeons and designers/manufacturers have a pivotal role. This also has consequences for appreciating the role of the healthcare administration and the need for professional safety boards.

Chapter 3 investigates whether technical analysis of failures and failed valves has contributed to an increased knowledge of failure modes. Also the impact such knowledge may have on (re)design of valves and clinical practice is explored. So far, no structural effort has been undertaken to retrieve valves and to analyse them in order to assess whether they meet the expected wear specifications. Therefore, it takes too long before technical problems valves become recognized and initiatives for a market withdrawal or redesign are undertaken.

A number of failed valve cases are described in chapter 4. Failed technology often results in questions as who is to be held responsible, and is there someone to blame. Product liability is an issue for mechanical heart valve development. However, whether a surgeon and/or a manufacturer will be sued depends on a number of circumstances such as information to the patient, attempts to avoid morbidity and mortality due to the failure, public outrage, and last but not least, communication within the triangle surgeon, patient, and manufacturer. Basically, the patient's and/or his relative's perception of the "accident" that occurred determine the risk of litigation. The threat of litigation influences the speed accountable parties will
Summary

apply to control risk and to reduce damage in general and for individual patients.

In the current situation, surgical implantation modes for mechanical heart valves are hardly an issue. However, perioperative complications are responsible for a considerable risk of mortality. Chapter 5 gives an example of the meta-analysis technique as method to acquire clinically relevant knowledge on how to reduce the risk of perioperative bleeding and re-exploration. Besides the method also the outcome is relevant for the way surgeons can reduce risks of adverse outcome in mechanical heart valve replacement therapy.

After the implantation the patient and the surgeon rely on the built-in safety capability or intrinsic safety of the mechanical heart valve. Assuming that the valve technically performs according to the expectations, adverse events in the sense of complications still may occur. This thesis focuses on the optimal regulation of the anticoagulant therapy by means of patient self-management. The CoaguChek® provides the technical basis. However, before encouraging the use of an additioned device to neutralize unwanted side effects of mechanical heart valve therapy, the technical risks of failure of the devices and potential difficulties with the treatment concept must be made clear to prescribers and patients. Chapter 6 shows that functional analysis, a failure mode & effect analysis, and a fault tree analysis, are easy to conduct for interested clinicians. The use of these methods proved an insight in the potential dangers, but also provides a framework to assess reported near accidents and adverse events.

After having answered the safety questions with respect to the technology, one has to establish the efficacy and safety of the technology in practice. Chapter 7 describes the way in which the reliability and accuracy of patient self-monitoring of the INR has been assessed. It is essential to compare new technologies with the existing practices, especially when the latter have been proven to be safe enough and highly satisfactory. The INR values obtained by means of patient self-monitoring do not significantly differ from INR values obtained in the hospital laboratory setting.

A crossover comparison study was conducted to establish whether the safety and efficacy of the patient self-management concept could match the level obtained in management by the Trombosis Service in the Netherlands. Chapter 8 shows that outcome and efficacy in both management strategies are good.

Patient self-management of anticoagulant therapy is also advocated for selected patients, as it may contribute significantly to an improvement of the quality of life. Comparing quality of life in a group of patients on patient self-management with CoaguChek® and patients attending the Trombosis Service confirms the claims of increased freedom to move and good
feeling about patient self control. \textit{Chapter 9} provides a method to assess the quality of life for patients on anticoagulant therapy. It also confirms the impression that the concept of self control by educated patients indeed improves quality of life and can be accomplished with devices such as CoaguChek®.

In conclusion, this thesis aims to increase awareness of safety risks within a treatment track such as mechanical heart valve replacement is. It describes how the professionals in the individual disciplines can carry out a part of the safety concept within the framework of the system approach. This multidisciplinary study on the safety management of mechanical heart valve prostheses also aims to convince clinicians, engineers and administrators that they may operate safety management in their day-to-day practice.