Safety management in mechanical heart valve replacement and oral anticoagulant therapy

Cromheecke, M.E.

Citation for published version (APA):

General rights
It is not permitted to download or to forward/distribute the text or part of it without the consent of the author(s) and/or copyright holder(s), other than for strictly personal, individual use, unless the work is under an open content license (like Creative Commons).

Disclaimer/Complaints regulations
If you believe that digital publication of certain material infringes any of your rights or (privacy) interests, please let the Library know, stating your reasons. In case of a legitimate complaint, the Library will make the material inaccessible and/or remove it from the website. Please Ask the Library: https://uba.uva.nl/en/contact, or a letter to: Library of the University of Amsterdam, Secretariat, Singel 425, 1012 WP Amsterdam, The Netherlands. You will be contacted as soon as possible.
Chapter 4

Liability for Failed Mechanical Heart Valves: an Accident and Risk Perception Analysis

M.E. Cromheecke\textsuperscript{1,2}, A.P. Yazdanbakhsh\textsuperscript{1}, B.A.J.M. de Mol\textsuperscript{1,2}

\textsuperscript{1}Department of Cardiothoracic Surgery, Academic Medical Center of the University of Amsterdam, the Netherlands, \textsuperscript{2}Safety Science Group, Delft University of Technology, the Netherlands

4.1 INTRODUCTION

Heart valve replacement by means of implantation of a mechanical prosthesis is beneficial to large numbers of patients. The rare failure of such prostheses, however, can impose life-threatening risks on patients and may generate individual as well as public outrage. Therefore, one must learn from the relatively few completely documented cases of failure. This paper reports on the use of industrial-risk control methods and the relevance of patient communication and risk perception on understanding the causes of failure, its sequelae, and the potential liability of the medical profession [1,2]. Although failure of a mechanical heart valve might seem primarily a shortcoming of the manufacturer, a multifactorial aetiology, including doctor's failure, appears more likely for patient injury [3-5].

4.2 PATIENTS AND METHODS

Between April 1993 and April 1997, the following eight mechanical heart valves failures were examined:
- three St. Jude Medical (SJM) mechanical heart valves (all placed in the aortic position)
- two Medtronic Hall (MH) valves (one in the aortic and one in the mitral position)
- three fractured Björk-Shiley convexo-concave (BScc) valves (one in the aortic position and two in the mitral position).

The SJM valve is a bileaflet valve, whereas the MH and BScc valve have a tilting disk, which occludes the valve opening.

Valves and medical records came from five different hospitals and were examined by members of the interuniversity working group on Cardiovascular Implant Retrieval Analysis, in which expertise is combined from the departments of Cardiology, Cardiopulmonary Surgery, and Cardiovascular Pathology of the Academic Medical Center of the University Amsterdam, and the departments of Material Science and Safety Science of the Delft University of Technology, The Netherlands.

Details of heart and mechanical valve became available by means of autopsy or photography and transesophageal echocardiography in case of repeat valve replacement. Retrieved valves were also subjected to non-destructive examination by means of scanning electron microscopy (SEM).

The Product Life-Cycle and Hazard Barrier Analysis Model were used, because device failure and not operator failure determined the appearance of the incident [2,5,7,10-12]. A product life cycle consists of four phases:

- phase A: design and manufacturing
- phase B: regulation and marketing

46
phase C: implantation and patient risk control
phase D: follow-up, adverse-event control, and input for redesign

Within these phases, components, such as institutions, persons, and resources, are identified, which may act as functional barriers to prevent accidents and to minimize damage (table 1).

Table 1: Phases A-D represent the main evolutionary stages of the mechanical heart valve's life cycle. In each phase, the key processes for carrying out evaluation, risk assessment, and risk control are described. These processes imply control barriers operated by professionals. These professionals may be held responsible for failure of their control tasks or, in case of a very critical failure, of the complete system.

<table>
<thead>
<tr>
<th>Evaluation</th>
<th>Risk control</th>
<th>Risk assessment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Science</td>
<td>Design</td>
<td>Engineering</td>
</tr>
<tr>
<td>Design</td>
<td>Clinical tests</td>
<td>Certification</td>
</tr>
<tr>
<td>Engineering</td>
<td>Certification</td>
<td>Distribution</td>
</tr>
<tr>
<td>Production</td>
<td>Distribution</td>
<td></td>
</tr>
</tbody>
</table>

Table: Product Life-Cycle-based HAZARD BARRIER ANALYSIS

<table>
<thead>
<tr>
<th>A</th>
<th>B</th>
<th>C</th>
<th>D</th>
</tr>
</thead>
<tbody>
<tr>
<td>Design / Manufacturing</td>
<td>Certification / Marketing</td>
<td>Implantation</td>
<td>Follow-up</td>
</tr>
<tr>
<td>Technical tests</td>
<td>Purchase</td>
<td>Use Device</td>
<td></td>
</tr>
<tr>
<td>Clinical tests</td>
<td>Referral</td>
<td>Check-up Patient</td>
<td></td>
</tr>
<tr>
<td>Certification</td>
<td>Informed Consent</td>
<td>Information Supply</td>
<td></td>
</tr>
<tr>
<td>Distribution</td>
<td>Surgery</td>
<td>Emergency</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Postoperative Care</td>
<td>Referral</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Retrieval Analysis</td>
<td></td>
</tr>
</tbody>
</table>

The Hazard Barrier Analysis Model exposes the control measures supposed to be taken by those components in order to prevent failure and/or to reduce its consequences. At this level, also operator and organisational failure may be investigated. By means of a questionnaire, which was also used to document certain facts for legal purposes, patients and relatives were assessed with respect to their knowledge about heart valve and risk of failure [8,13].

4.3 RESULTS

St. Jude Medical valve
Three patients (aged 59, 63 and 69 years) had undergone implantation of a SJM aortic valve. Seventeen months after implantation, two patients, both from the same hospital, had to undergo repeat valve replacement due to severe valve leakage and haemolysis. Moderate
leakage had been observed immediately after the initial operation, but this had not been thought to be of clinical relevance. During repeat surgery of the first patient, no abnormalities had been observed. Valve leaflets had moved freely. On transesophageal control echocardiography, however, blood pressure-dependent valve insufficiency had been present. In the second patient, blood pressure-dependent valve insufficiency had been diagnosed already preoperatively. Both patients had made an uneventful postoperative recovery. Because we were unaware of earlier cases of this type of valve failure, we reviewed the medical records of 69 patients who had undergone implantation of a SJM valve during the same one-year period [14], but no further cases of valve leakage or signs of relevant haemolysis were found. Small SJM valves (diameter 19-21 mm) showed an average peak gradient of 35 mm Hg (range 20-52) and a mean gradient of 23 mm (range 15-36), which may be considered normal. In these two patients, who both had suffered from severe left ventricular hypertrophy, high gradients across the native valve, and a heavily calcified aortic annulus, we contemplated the possibility of surgical error because the valves had been implanted by the same surgeon. At this stage, our attention was drawn to a third patient with the same history, who was operated on by the same surgeon in another hospital. Further examination revealed that all three valves had been placed in an atypical direction, with the pivot area between the muscular ventricular wall and the stiff, calcified, non-coronary aortic annulus. The surgeon had taken a lot of effort to place the largest possible valve in the narrow aortic annulus, without using the sizers recommended by the manufacturer.

In our opinion, this procedure may very well have led to implantation of oversized valves. We speculate that in these three patients, compression had prevented leaflet closure. Increased susceptibility to external forces as well as leaflet escape in the SJM valve due to high-impact trauma have been reported earlier [14-16].

Patients had not considered the doctors' initial failure to recognize and explain their physical deterioration a medical shortcoming, nor had they perceived their initial valve replacement as such. Instead, they had considered their "difficult heart" to be the primary cause of valve failure.

The fact that repeat surgery had been successful had erased negative feelings, if any, in all three patients. Claims for financial compensation had not been considered.

**Medtronic Hall valve**

The first patient was a 53-year-old man who had undergone implantation of a 29 mm aortic MH valve for aortic insufficiency and mild aortic stenosis, as well as coronary artery bypass grafting. He had died suddenly three weeks after the operation. Post-mortem examination of the heart had revealed a closed disk, which had been blocked into the ring due to entrapment of a suture without a knot. The second patient was a 45-year-old woman who had undergone repeat valve replacement due to an increased gradient of 30 mm Hg and insufficiency of a
BScc valve in the mitral position. At surgery, pannus overgrowth at the ventricular side of the valve had been observed. Much effort had been required to replace the BScc valve via left atriotomy by a 27 mm MH valve. Two weeks after the operation and following discharge to a community hospital, the patient had deteriorated rapidly and died. Post-mortem examination had revealed that the disk had been locked-in in the ring due to entrapment of a tissue and felt pledgets used for reinforcement. Both MH valves were intact. Accident analysis supported the validity of the hypothesis that in both patients valve failure had been due to surgical error [17]. The surgery in the first patient had been a routine case. In the second patient, however, surgery had been unexpectedly complex, even though echocardiography had indicated retrospectively that it would be difficult anyhow, because of anatomical abnormalities due to a small left atrium and a small hypertrophic left ventricle.

We found that limited experience on the part of the surgeon, the difficult anatomical exposure, and the application of a routine suture technique, which perhaps should not have been used in this particular patient, had been the basis of poor surgical outcome. The relatives of both patients had argued that the course of events, in particular in view of the lethal outcome, should have been avoided under all circumstances and they had pressed for legal charges. In the first case, both experts and judges had considered it a minimum safety standard of performance for qualified cardiac surgeons to make absolutely sure that sutures are knotted. In the second case, they had judged that the shortcoming had been due primarily to the patient's disease and anatomical abnormalities.

**Björk-Shiley convexo-concave valve**

The mitral BScc valves of the three patients involved (aged 55, 62, and 72 years), two with a diameter of 31 mm and one with a diameter of 29 mm, had been known to carry an increased risk of fracture. After fracture had occurred indeed, all patients had undergone initially successful emergency surgery in a cardiac surgical unit. Postoperative recovery, however, had been complicated and all patients had died within one week to up to three months.

Due to metallurgical fatigue subsequent to poor welding and also due to poor quality assessment during the manufacturing process, valves with minor damage, similar to signs of wear, had been released onto the market for clinical use. As time progressed, this type of minor damage had developed into crack and fracture, which had caused strut fracture and disk escape, leading to heart failure with often lethal consequences [18,19].

In The Netherlands, BScc valves of this particular type were implanted between 1979 and 1984. On several occasions, patients have been informed about the risk of fracture and its implications with respect to litigation. Uncertainty among the medical profession had related mainly to advising patients about the possibility of prophylactic valve replacement. Repeat surgery would have a roughly 5% risk of instant death or serious disability, whereas the likelihood of future valve fracture is an accumulated risk over a number of years, which,
given enough time, will exceed the reoperation risk [20].
No strategies had been made available on how to counsel and to instruct the vast majority of
patients who, for different reasons, had not undergone prophylactic explantation and who thus
had continued to be exposed to risk of valve fracture.
Accident analysis revealed shortcomings in terms of risk communication and risk control
among all parties involved, i.e. manufacturer, cardiac surgeons, cardiologists, and health
authorities. Although relatives had stated in interviews to consider the lack of adequate
instructions for the instant diagnosis of valve fracture and the doctor delays examples of
substandard care, they had pointed to manufacturer negligence as the primary cause of valve
failure. This then may serve as an explanation of the fact that the relatives had made the
manufacturer their target for litigation.

4.4 DISCUSSION

Cardiac surgery, which depends heavily on the availability and proper use of sophisticated,
potentially life-saving medical technology [2,21], draws much public attention in case of
failure [24]. So far, risk management efforts have been focused mainly on internal auditing,
bench marking, and finding ways to reduce the risk of operative mortality [22,23]. Recent
publications focus on methods to assess the personal-performance parameters of individual
surgeons in single institutions [25-27]. In case of suspected device failure, investigations
focus on device and technology, rather than on professionals. The Product Life-Cycle and
Hazard Barrier Analysis Model expose the people and organizations behind the technology at
the various phases of device evolution. Table 1 shows also a tentative list of the components
responsible for risk control during the four main evolutionary stages.

4.4.1 Accident analysis

In the three cases of failure of the SJM valve, the dominant cause of failure was found in the
implantation phase C, due to surgical error. Nevertheless, one might argue that also designers
in phase A failed, because the occurrence of compression under extreme circumstances was
not prevented. Furthermore, user instructions were found to have been inadequate with
respect to how to deal with failure. It appeared that in the preimplant licensing phase B, both
aspects had been overlooked. Also, during postoperative care (phase D) the early signs of
valve leakage had been misinterpreted. The patients, however, had perceived the course of
events and the complex interconnection as a rather unique combination of fate and their
complex heart problem. In the end, patients had felt as good as they had expected to become
after the initial valve replacement.
Liability for Failed Mechanical Heart Valves

In the two cases of failure of the MH valve, type of failure and outcome following suture entrapment had been perceived primarily as an avoidable surgical error and violation of a safety standard (phase C). One wonders, however, whether the occurrence of such an error can also be reduced by design adjustments (phase A).

In the three cases of failure of the BScc valve, primary responsibility of manufacturer (phase A) and surgeon during follow-up (phase D) was exposed, and they were both blamed for poor risk control. Patients and relatives had had high expectations regarding the safety of their valve and chances to avoid fracture. As the manufacturer had accepted liability for patient damage due to valve fracture, relatives had made use of the financial compensation scheme that had been made available for this purpose.

4.4.2 Risk perception

Although accident analysis exposed violation of professional safety standards, patient perception differed, depending on the degree of risk acceptance [9,28,29], which is influenced by the outrage factor associated with a particular accident. According to Sandman [30], public outrage increases when accidents are associated with

1. poor physical outcome (death or serious disability)
2. large-scale occurrence
3. the fact that the risk had been imposed (as opposed to for example the risks of sports)
4. the fact that the risk is considered unfair (other valves do not fail).

Vincent observed that in the cases in which doctors were sued, explanations for failure occurrence were considered satisfactory in less than 15% [9]. Concerns about the standard of care and the possibility that similar incidents would re-occur sometime in the future, as well as the need for explanations and the opinion that doctors should give account for their actions were the driving forces for holding the medical profession liable. Although risk communication is an important factor, liability is largely determined by the final injury, circumstances leading to failure, and disappointment regarding expectations about safety.

The Hazard Barrier Analysis Model has been developed primarily to investigate the impact of physical violence on vulnerable subjects (for example, electricity short-circuit violence on people). The method can be applied in conjunction with conventional epidemiological tools to a limited number of incidents, as was done in the cases of SJM valve failure [14].

Other methods, such as the Tripod Accident Causation Model (TRIPOD) and the Management Oversight Risk Tree (MORT), basically provide fault tree analysis. They require a higher number of incidents and victims, as they aim for a quantitative analysis [31,32].

Our study of risk perception was mostly based on structured interview techniques. Particularly when accidents are relatively rare, with few survivors, such as in the cases
presented in this paper, the absence of controls warrants caution. In a comparative study involving BSce valve patients at risk and a control group, the controls proved to worry more than their counterparts as they were not regularly informed [17].

4.5 CONCLUSION

The above-described accident analysis may be used in order to understand better and to prevent the risks of relatively rare device failures. The outcome of such an analysis may not match with the risk perception of patients, relatives, and the public. Therefore, apart from the manufacturer also doctors may be blamed. The perception that safety standards have been violated and an outlook on financial compensation determine litigation.

4.6 REFERENCES

Liability for Failed Mechanical Heart Valves


