Quality assurance in clinical perfusion

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Abstract

Objective: To investigate the properties and usefulness of prospective routine registration of incidents related to cardiopulmonary bypass and its clinical significance as a quality assurance instrument. Methods: Incidents or deviations from the normal course observed during cardiopulmonary bypass procedures were registered in a computer database. Each incident was classified according to 14 pre-defined categories. The cause of each incident was evaluated, as well as patient outcome. The general- and category-related incidence rate was calculated for the observation period 1989–1997 encompassing 6918 cardiopulmonary bypass procedures. Results: The general incidence rate varied between 4.5–7.6% per year during the registration period. Most incidents (57%) occurred during established, or start of, cardiopulmonary bypass, whereas the remaining proportion of incidents were detected either before (27%) or when terminating (16%). The most common category of incidents was oxygenator failure (1.6%), followed by mechanical (1.4%) and surgical (1.2%) incidents. Accidents and fatal outcomes occurred in 0.03% of the cases. Conclusions: Routine registration of incidents yields a clinically attractive instrument of controlling safety aspects and quality measures in cardiopulmonary bypass. The observed incidence rates are somewhat higher than previously reported, probably primarily related to the methodology implemented in this study. © 1998 Elsevier Science B.V. All rights reserved

Keywords: Safety; Cardiopulmonary bypass; Incident; Quality assurance; Oxygenator

1. Introduction

Risk containment in clinical perfusion is traditionally evaluated through surveys [1–3]. The method of retrospective analysis using surveys is associated with several limitations [4]. Results are based on sources that are not directly controlled. Completing questionnaires when not having direct access to facts may interfere with data quality. The recollection of minor incidents, especially over an extended period of time may be subject to criticism. Record keeping may also be badly organised or simply missing. Most surveys involve dropouts, inducing results based on a non-representative population. Use of modern computer technology enables easy and reliable data control. Statistics of incidents can be calculated and successfully implemented as a feedback of medical activity [5]. In this article we present a system for routine registration of incidents or deviations from the norm in clinical perfusion and demonstrate how such a registry of incidents in cardiopulmonary bypass (CPB) can be used as a tool for quality assurance.

2. Material and methods

An incident is defined [6] as an unexpected situation, deviating from the normal course of a clinical perfusion, jeopardizing the safety of the patient. Incidents leading to permanent or temporal injury are denoted accidents. The general- and category-related incidence rate was calculated for the observation period 1989–1997 encompassing 6918 cardiopulmonary bypass procedures. Results: The general incidence rate varied between 4.5–7.6% per year during the registration period. Most incidents (57%) occurred during established, or start of, cardiopulmonary bypass, whereas the remaining proportion of incidents were detected either before (27%) or when terminating (16%). The most common category of incidents was oxygenator failure (1.6%), followed by mechanical (1.4%) and surgical (1.2%) incidents. Accidents and fatal outcomes occurred in 0.03% of the cases. Conclusions: Routine registration of incidents yields a clinically attractive instrument of controlling safety aspects and quality measures in cardiopulmonary bypass. The observed incidence rates are somewhat higher than previously reported, probably primarily related to the methodology implemented in this study. © 1998 Elsevier Science B.V. All rights reserved
General causation is evaluated and categorised in the following groups: error of judgement, fault of technique, failure to check equipment and equipment fault. Patient outcome is determined as no injury, transient injury (lasting less than 24 h), transient injury (lasting more than 24 h), permanent injury or death. Patient outcome is verified by a post-operative bedside visit by the perfusionist and is performed for all patients with a recorded incident.

2.1. Statistics

The incidence rate is calculated: (a) per category of incidents during the observation period, (b) for all incidents per year regardless of category, entitled the general incidence rate (c) for all patients per year with an observed incident, entitled the case incidence rate. Incidence rate is generally given in percent (%), with corresponding absolute numbers.
3. Results

The total number of patients included for analysis of adverse events in conjunction with CPB reached 6918. Patient population per year is listed in Table 1.

The yearly general incidence rate during the period 1989–1997 varied between 5.4 and 15.3%, whereas the case incidence rate fluctuated less (4.5–7.6%) and reached a maximum in year 1991 (Fig. 2).

Most incidents (57%) occurred during established, or start of, CPB. Approximately one-quarter (27%) of all incidents was detected before the onset of bypass. Coming off CPB, and the period immediately thereafter, were both periods experienced as uneventful. The distribution of incidents related to time is illustrated in Fig. 3.

The most common categorical incident discovered in our series was oxygenator failure (1.6%/112), followed by mechanical (1.4%/96) and surgical incidents (1.2%/82). Summaries of all categories of incidents are presented in Fig. 4.

Oxygenator problems were dominated by abnormally increased trans-membrane pressure drop (0.4%/29) possibly caused by fibrin generation (0.4%/29). Change of oxygenator was performed in 20 cases (0.3%/20). Remaining oxygenator incidents were gas-exchange dysfunction (0.2%/14) and non-specific (0.3%/20). Mechanical failures were primarily related to tubing (0.5%/37), connectors (0.4%/25), pump failures (0.1%/7) and miscellaneous (0.4%/27). Surgical incidents encompassed mal-positioning of venous/arterial canulae (0.4%/27) or tubing clamp (0.3%/22), air trapping after a de-airing manoeuvre (0.2%/15), excessive bleeding (0.03%/2) and other (0.3%/17) (Fig. 5).

Gas embolism incidents were mostly a question of air-entrainment or air introduced via the venous line into the extra-corporeal circuit or air in the arterial canulae post-CPB (0.9%/59). A non-vented cardiotomy reservoir was evident in four cases (0.06%/4) and emptying of the venous reservoir was seen twice (0.03%/2).

Patient outcome is presented in Table 2. Conduct of extra-corporeal circulation was determined to have contributed to two cases each of fatal outcome (0.03%/2) and transient injury (0.03%/2).

Transient injury was apparent in the following two cases. (1) Pressurised venous reservoir: at the start of CPB venous blood was observed to pass in a retrograde direction, rapidly emptying the venous reservoir, pushing a huge amount of air through the venous line into the right ventricle, causing an immediate circulatory collapse. Due to prompt action from the surgical team, the air could rapidly be eliminated and normal CPB re-instituted. The patient experienced a temporarily post-operative confusion without major sequel. Cause of the elevated cardiotomy pressure is still unknown, despite extensive investigations. (2) Abnormally elevated trans-membrane oxygenator pressure drop: at the beginning of CPB, the blood pressure gradient across the oxygenator membrane exceeded normal values. Debris could be seen in the membrane compartment of the oxygenator, possibly generated by fibrin. Post-operatively, the patient suffered...
from a left-sided hemi-plegia, though was in complete regress at discharge.

Fatal outcome: (1) Clot formation in RVAD. The patient was supported with a right ventricular assist device (RVAD) using a Medtronic centrifugal pump treated with Carmeda bio-active surface (CBAS). On the first post-operative day, pump-failure developed due to clots localized both in the centrifugal pump-head and connecting catheters. On removal of the intra-cardiac connections, the patient suffered a devastating blood loss. (2) Insufficiency of venous/cardiotomy reservoir. A patient with a history of suspect coagulopathy demonstrated pre-CPB abnormally elevated heparin requirements and clot rate. At termination of a completely normal CPB, a major surgical bleeding in the right cardiac atrium necessitated re-establishment of cardiopulmonary bypass. Despite ACT level within our own normal limits and after giving a bolus of heparin, the cardiotomy reservoir was, within minutes, obstructed with blood clots. The reservoir was exchanged during a short circulatory arrest, after which normal CPB could be re-instituted. After successful completion of the surgical intervention, the patient was transferred to the ICU, though never regained consciousness and died.

4. Discussion

The incidence rate in CPB reported in previous investigations varies from ≈ 0.3% [2] to ≈ 1% [3]. In a more recent publication by Jenkins and colleagues [7] the incidence rate is estimated to be 2.9%. Still, this is far below our findings ranging between 4.5 and 7.6%. The reason for this difference seems mainly to be of a methodological origin. Our rigorous criteria for including an incident in our registry including anything not normal before, during or when terminating CPB, may therefore include incidents, which other observers would have overlooked.

We have previously presented [5] how routine registration of deviations from the norm in cardiac surgery was implemented in the year 1994 and how this has given us a tool for continuing follow-up on different patient quality measures. We view the treatment of patients as a normal process and anything deviating from this norm has been our focus of interest. The same reasoning has been introduced into the domain of CPB and used as the basis for quality assurance.

Previous publications on this subject have primarily used surveys as the scientific method. Surveys involve various limitations one being the response rate, which can fluctuate considerably. In a summary of over 20 perfusion surveys during the last two decades, the response rate ranged from 100% down to 30% [8]. Using sub-populations for statistical analysis may lead to unpredictable results. However, the overwhelming problem is probably related to inadequate data quality. Answers in surveys may in theory be a one-person opinion or a joint opinion answer. Few hospitals keep data records of incidents. Reliable information is therefore difficult to obtain. Interestingly enough, Jenkins’ report [7] mimics most closely our own observations. Several of the answers given in this survey were in fact based on routine incident registrations. One obvious possibility is that there may exist a true difference among cardiac centres, regions and over time.

Is a high incidence rate compatible with a low accident rate? Judging from what we have experienced it seems reasonable – the majority of registered incidents are not linked to obvious patient injury. Our accident rate of 0.06% resembles previous findings: 0.06%–0.1% [9].

The dominating category of incidents in our series was oxygenator failure with a mean incidence rate of 1.6%. Looking over time, we observed a marked variation (Fig. 6).

The inference of time might be down to the use of different oxygenator design. One particular brand of oxygenator

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**Table 2**

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<th>Patient outcome and incidence rate of accidents</th>
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<td>Transient</td>
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**Fig. 5. Distribution of gas embolism incidents. Labels indicate the incidence rate (%) for each category of gas embolism incident.**

**Fig. 6. Oxygenator incidence rate (1989–1997).**
was predominately used during the year 1991, giving rise to the highest incidence rate for the observed time period [10]. The use of this oxygenator was subsequently discontinued. The influence of modern oxygenator design on functionality has also been suggested by Palanzo and co-workers [11]. Discussions as to why various oxygenators sometimes fail may, among other things, be related to different anti-coagulation regimes or predisposition of the patient [12,13].

Mechanical failure is another dominating category of incidents, though generally harmless, as the majority is identified already in advance of established CPB. The time of discovery for the major part (39%) of all incidents is either pre- (12%) or start (27%) of cardiopulmonary bypass.

One way of optimizing the likelihood of detecting incidents in time is the inclusion of pre-bypass checklists. The acceptance of its use is verified through several reports and seems to be advocated in about 80% of all CPB-procedures [3,7,14]. Use of checklists is, in our opinion, a state-of-the-art feature.

Our results identify two instances of inadvertently emptying the venous reservoir which, in theory, should not happen. The use of a low level alarm should be a gold standard. Negligence in its use or it not being activated through the whole course of CPB is questionable. Alternative safety devices for protection against systemic emboli employ arterial line bubble detection, bubble trap, centrifugal pump and closed venous reservoirs. A growing interest in using closed circuits for CPB may explain why only 60.2% of the perfusionists were using low level detection in a recent US survey [15].

Sources of air embolism can either involve the process of surgery, CPB or the management of anaesthesia [16]. A high incidence of air embolism was evident during the early era of cardiac surgery [17]. However, the contribution of air embolism due to a CPB related cause has since then decreased dramatically [3,7]. Nevertheless, we still have not been able to eliminate its existence. Looking at our results, one might get the impression that air embolism incidents have been a major issue. As mentioned previously, the majority of the incidents have been categorised as air-entrainment via the venous line. In theory, air introduced via this route can follow the blood stream through the venous reservoir, the membrane oxygenator and finally through an existing arterial line filter. The amount of air eventually reaching the patient’s arterial circulation depends on the filterability of the included chain of components. Use of arterial line filtration has traditionally been advocated, among other things, to eliminate micro-bubbles [18]. In situations when arterial line filtration is not employed, the filter capabilities of the remaining components become important. The ability of various venous reservoirs and oxygenators to separate air from blood seems to vary to a great extent [19]. For this reason, care should be taken with respect to the air handling capabilities of all included components in an extra-corporal circuit design. Venous line air entrainment is at times unavoidable. Its possible deleterious effect on cerebral function because of air emboli has, in our experience, been difficult to determine from a broad clinical perspective. A more thorough examination would, in that case, be intended to establish causality or at least a possible dose response curve.

Adverse reactions of CPB originating from the limitation of present perfusion technology involving theoretical and surface activating processes giving rise to a body inflammatory response [20] have not, per se, been addressed in this article, even if such mechanisms may play an important role in determining the post-operative status of the patient. The reported mortality rate of 0.03% should therefore be regarded as the direct involvement of a CPB incident.

In conclusion, the information gained through consecutive incident registration serves primarily as a tool of assuring, and verifying, safety aspects in cardiopulmonary bypass. In the wider perspective, this policy introduced at other hospitals would open up possibilities of exchanging valuable information. Registries documenting advances and results in cardiac surgery, like the STS registry, are already a generally accepted practice. A similar routine covering different aspects of safety and quality within different areas of perfusion activities seems therefore logical.

References


