

Neglected Safety Aspects in Hemodialysis Machines and Their Related Problems

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The technology of modern hemodialysis systems, with their redundant alarms, self test modes, and fail-safe engineering desensitizes us to the inherent dangers of the process, and leads to an almost total dependence on the machines. In this paper, reported or published adverse events are used to highlight risks that can not be mitigated sufficiently by safety monitors of the hemodialysis machines.

Introduction

Today's hemodialysis machines comprise monitors to reduce the risks for patients and users caused by malfunctions of parts of the hemodialysis system. Originally, the alarm limits on these monitors were set by the user and monitors could even be switched off. This led to accidents not caused by any machine malfunction but by wrong user reaction to an alarm. Such events were more common whenever a new machine control function was introduced to the market (e.g., when dialysate was changed from acetate buffer to bicarbonate buffer).

Modern electronics allowed the automation of tests and adjustments originally performed by users. These improvements further reduced the number of device related serious accidents. Design safety is the result of basic safety research which originated in the nuclear industry and is now carried on in all fields of technology, e.g., the airline industry.

Unlike aircraft pilots, hemodialysis users (nurses, doctors, patients) cannot regularly train with fault simulating dialysis systems. Adverse events in hemodialysis

are often related to the lack of awareness of problems that are not detected by machine monitors.

Limits of Safety Achievable by Monitoring

Most hazards in hemodialysis are not caused by machine malfunction but are rather related to user errors which include poor fixation of cannulas and incorrect setting of control values and alarm limits.

The risks related to the operation of an extracorporeal system and related to machine malfunction (1) have been successfully mitigated by industry. No report involving a patient's death could be found in the MAUDE (2) database of FDA for 2004 as result of a machine fault. (The FDA's Manufacturer and User Facility Device Experience Database, or MAUDE, represents reports of adverse events involving medical devices. The data consists of voluntary reports since June 1993, user facility reports since 1991, distributor reports since 1993, and manufacturer reports since August 1996.)

Adverse events leading to death or serious injury that became known in the recent years were related to user errors or manufacturing/quality control problems for disposables or a combination of device faults and user errors.

In general, safety monitors cannot prevent adverse events. They can only detect adverse events and mitigate the related harm. Safety monitors in hemodialysis machines detect the deviation of a measurable value from either a controlled value or a "normal" value. Audible and optical alarms are generated if the deviation of the measured value exceeds a pre-set limit for a minimum length of time (usually not adjustable). In addition, the machine is switched into an operational mode regarded as "safe under fault condition." An example for an adverse event that cannot be prevented by monitoring

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Practical Matters

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is blood loss through a dialyzer blood leak. The blood leak detector will, however, prevent excessive blood loss.

The following examples describe the most common problems that cannot be mitigated sufficiently by monitoring. Most cases were taken from the MAUDE database. The MDR report key number is given as reference.

Blood Loss to the Environment

The causes for blood losses to the environment are:

- a) Cannulas slipping from the fistula or graft
- b) Leaks in the extracorporeal circuit
- c) Disconnection of blood lines from blood access devices

The accepted safety monitor for prevention of excessive blood loss is the “venous pressure” monitor. Under favorable circumstances, the venous pressure will drop when a leak in the system occurs. This drop must exceed a minimum of 10-20 mmHg to be detected—provided the lower alarm limit of the venous pressure monitor is appropriately set.

The monitor will not alarm in these instances:

- a) If the venous pressure alarm limit is not properly set. Even complete disconnection of blood lines from catheters or cannulas resulting in total loss of the extracorporeal blood flow may go undetected (MAUDE 515860).
- b) Even with properly set alarm limits, the venous pressure monitor may not alarm if the venous cannula slips from the fistula or graft, which may happen if the cannula is not properly fixated (MAUDE 557216). Pressure drop caused by this event is usually too small to be detectable by the venous pressure monitor.
- c) Small leaks with blood loss rates less than ~10% of blood flow may not be detected because the related change of venous pressure is too low. Such leaks are usually caused by manufacturing errors, bad connections, or damaged connectors and puncture sites in the extracorporeal system (MAUDE 504298).

Recommendation: Never set “wide” alarm windows for the venous pressure monitor. Check blood access and extracorporeal system whenever blood flow or alarm limits are re-set. Secure and check blood tubing connections and cannula position. Avoid covering the blood access site with blankets.

Air Embolism

In the absence of machine errors, air can only enter the

extracorporeal system through leaks (usually in a luer connection) in the negative pressure part of the blood tubing system. All machines in use today have air detectors that stop the blood pump if air is sensed during dialysis. Most machines also have a venous clamp that closes automatically in case of a “blood side” alarm. Although the machine will generate an alarm and stop blood flow (if alarm limits are appropriately set) in case of the separation of the blood tubing from a catheter, the patient may suffer from air embolism caused by air ingress through the open end of the catheter (MAUDE 544739).

Many machines still in use do not sense proper insertion of the blood tubing into the clamp. Some machines also comprise a colorimetric detector that will suppress the audible alarm signal during the priming phase of the extracorporeal system when the lines are not filled with blood. Most machines in use today allow automatic and/or manual setting of drip chamber levels with built in air pumps and/or valves.

A combination of machine and user errors has caused the death of a patient: The level adjust pump was erroneously pumping air into the venous drip chamber. The air detector generated an alarm and stopped the blood pump. Apparently, the blood tubing was not inserted into the clamp and the colorimetric detector. Air was pumped into the patient resulting in death (MAUDE 508650). Further investigation showed that the pump failure was caused by fluid ingress into the electronics of the machine because of a missing screw.

Recommendation: Report even minor technical defects (e.g., a missing screw). Be aware that even minor user errors may result in serious injury or death if a second error occurs.

Blood Damage

Acute blood damage in the extracorporeal circuit can be the result of exposure to disinfectants, low osmolar dialysate, high temperature, or high shear forces.

Although none of these causes should be excluded in case of an adverse event, the most likely cause is mechanical hemolysis, usually caused by obstructions in the extracorporeal circuit such as kinked or twisted blood lines. Manufacturing errors have been reported as a cause of hemolysis as well.

Mechanical hemolysis is the most frequently reported cause of blood damage within the last decade.

Blood is not damaged by pressure. Pressure drops in

the extracorporeal circuit are proportional to flow resistance and blood flow. Unusually high pressure drops in the extracorporeal circuit indicate high flow resistances resulting in high shear forces. If an obstruction occurs downstream of the venous pressure monitor, it will be indicated by increased venous pressure and, if the upper alarm venous pressure alarm limit is appropriately set, the venous pressure monitor will generate an alarm.

If the flow resistance is between the blood pump and the venous pressure monitor, the venous pressure will not change unless the pressure exceeds the maximum pressure that can be generated by the blood pump (usually ~2 atmospheres ~30 psi ~1500 mmHg). In this case, the venous pressure will drop because the pump flow will decrease.

Some dialysis machines comprise additional sensors upstream of the dialyzer but this sensor will not indicate obstructions between the blood pump and the point of pressure measurement.

If a single hemolysis event occurs in a dialysis clinic, human error should be suspected. Human error includes use of an inappropriate blood tubing set as well as inappropriate set-up of the tubing set (MAUDE 507135). If, however, several events occur with the same type of machine and blood tubing within a day or week, manufacturing errors are the most likely cause (MAUDE 173039 from 1998).

Recommendation: Use blood tubing specified for the machine. Use tubing organizers on the machine. Check tubing for kinks, especially between blood pump and venous drip chamber.

Parameter Settings

Programmable machines usually require parameter confirmation, e.g., by pressing “YES” or “NO” buttons. The sequence of this confirmation process becomes routine over time and is then done without paying proper attention.

Dialysis machines are often connected to central computers that register machine and patient parameters on-line allowing “paperless dialysis.” This too may facilitate user errors to go undetected.

An event has been reported where the ultrafiltration goal was set to 9 liters rather than 0.9 liters as prescribed, resulting in an ultrafiltration rate of more than 3 liters/hour (MAUDE 555253).

Some machines allow the programming of parameter limits. If properly set this could limit parameter settings

according to applicable clinical or unit specific standards. Some new machines allow automatic settings of machine parameters either from a central computer and/or by using a “patient” card containing the data. Although this reduces the likelihood of wrong settings, the user must confirm that the machine is indeed programmed for treatment of the patient sitting in the chair.

Recommendation: Set up procedures that avoid “automatic” confirmation of treatment parameters.

“Non-Standard” Machine Functions

The basic control and monitoring functions of hemodialysis machines are described by national (3) and international (4) standards.

Training of experienced nurses or technicians on the basic functions of a new machine is usually straightforward and consumes little time. In-depth training for “special” or proprietary functions is sometimes neglected. Examples of special functions are ultrafiltration and dialysate concentration profiles (sodium modeling) and, more recently, feedback control based on physiological models and parameters (bio-feedback).

A case was reported where the physician in charge prescribed an UF profile not knowing that this “profile” was a “UF only” (= no dialysis) program. The technician who operated the machine followed orders and did not understand the consequences of this setting. The patient expired after the 4th treatment. The cause of death was called “withdrew dialysis” (MAUDE 557949).

Recently, hemodialysis machines became available displaying “plasma Na” on the screen, a value calculated from dialysate sodium and dialyzer clearance, measured on-line. Unlike chemical analyzers used in clinical laboratories, this method has never been tested rigorously. Persisting machine or treatment errors not causing acute or short term patient problems are usually detected by routine blood analysis. This redundancy is lost if a blood parameter is calculated from a dialysate parameter. Persisting treatment errors may not be detected.

Recommendation: Avoid using non-standard machine functions if the methods and its limitations are not fully described by the instructions for use and/or sufficient training of everybody involved in the operation of the machine (including physicians) is missing.

Sudden Death During Dialysis

Sudden death occurs on dialysis and, if no device malfunction is suspected, is not reported to the FDA or

appropriate local agencies outside the U.S.

After such an event, dialysate concentration and electric safety parameters should be tested, especially if a catheter is used for blood access. This may save other patients' lives.

Wrong dialysate concentration: Conductivity monitors are used for protecting the patient against hazards caused by malfunctions of the dialysate mixing system. These monitors do not react to any non-conductive fluid or to any wrong composition resulting in the same overall conductivity of dialysate. Modern machines comprise additional monitors that protect against many—but probably not all—user errors. In addition, monitors cannot protect against production errors or wrong or deliberate “over spiking” of concentrate with potassium. Also, monitors will not detect water contaminants with no or low contribution to dialysate conductivity. Contamination of water for dialysis usually affects more than one machine and/or patient. It has been well described and documented.

A series of hyperkalemia caused by wrong concentrate was reported by the press in Austria several years ago (5). Because Austria was (and Europe is still) lacking an adverse event reporting system open to the public, the final cause of this event has not become known to the author. It was only detected after three fatal “heart attacks” on the same day when a fourth patient had a heart attack on the next day. This patient was successfully reanimated in the ICU. A fifteen-fold high potassium concentration was found in the dialysate. Concentrate production errors could be excluded.

Electric micro shock: About 70% of incident patients and 27% of prevalent patients in the U.S. are dialyzed with a catheter for blood access (6). The tip of permanent catheters is usually positioned in the right atrium or close to it. This establishes an electric pathway from the dialysis machine to the heart. Very low currents reaching the heart via this connection may cause fibrillation. This shock causes no tissue damage, which makes it unlikely that the true cause of death is found by autopsy.

Recommendation: Check the dialysate composition and electrical safety parameters of the machine after a case of sudden death without obvious cause.

Underdialysis and Patient Bleeding Related to Catheter Use

These seemingly unrelated problems are caused by the lack of information about catheter hydraulics in the

product literature.

Hemodialysis efficiency is directly related to blood flow through the dialyzer. It has been described frequently that blood flow deviates from displayed blood flow if the pre-pump negative pressure (arterial pressure) decreases (-150 mmHg or lower).

Product literature of catheter manufacturers may contain pressure versus flow data that has been measured using fluid mimicking plasma viscosity rather than blood viscosity (7). This data may motivate doctors to prescribe unrealistically high blood flows, resulting in low pre-pump pressure and low “true” blood flow and clearance.

Between treatments, catheters are filled with a “locking solution” to avoid clotting of blood inside the catheter. Highly concentrated heparin is commonly used for this purpose. The manufacturer's product literature informs the user about the filling volume of the catheter and it is believed that systemic anticoagulation can be avoided by avoiding overfilling. When systemic anticoagulation was clinically observed, wrong information about the catheter filling volume was suspected (MAUDE 558482). Recently, the author has shown that up to 25% of the injected locking solution spills out at the time of injection (8) but this information is not yet used by catheter manufacturers.

Recommendation: Always measure pre-pump negative pressure and report gross deviations from the manufacturers' literature. Take negative pressure effects on blood flow into account.

Be aware that catheter locking solution (heparin) spills from the catheter when injected, and ask the catheter manufacturer for quantitative data. ■

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