Medicines & Healthcare products
Regulatory Agency

Haemodialysis and haemofiltration machines: Actions to take following pressure-related alarms to avoid unintentional alteration of alarm limits

Devices Details

Haemodialysis and haemofiltration machines
All manufacturers and models are affected

Summary

Venous and arterial pressure limits may be altered unintentionally following acknowledgement of the alarm in some haemodialysis and haemofiltration machines. If the cause of the alarm is not addressed, the machine may not re-alarm to alert the user to an ongoing problem.

Explanation of identified safety issue

The MHRA is aware of instances of venous line disconnections resulting in excessive loss of blood even at a typical flow rate. The same connection problems can occur with arterial lines. All haemodialysis machines on the market in the UK will alarm to alert the user to the loss of pressure below the set limits in either the venous or arterial line. However, the choices available to the user in the event of an alarm and the subsequent response of the machine are not uniform across different models.

Following input from the user to restart therapy after the pressure alarm, some haemodialysis machines automatically re-centre the alarm limits around the current venous or arterial pressure. If the cause of the problem is not resolved, the pressure will remain below safe limits. If these lower limits are critically low, the machine may not re-alarm until it is too late to prevent excessive blood loss. The MHRA is aware of serious events, including some with a fatal outcome, where following an alarm, the lower pressure limits suggested by the machine were too low.

Information provided by manufacturers indicates that some models will automatically alter the alarm limits without highlighting this change to the user, some do not do this automatic change, and some machines give the user a choice on whether to continue with current limits or to accept altered limits. The MHRA continues to engage on this issue with manufacturers known to supply haemodialysis machines in the UK to improve the safer use of these devices.

Consideration should also be given to the potential for misreading the alarm type. Following consultation, the UK Kidney Association’s Kidney Patient Safety Committee confirmed that high venous pressure alarms occur very frequently, for example due to patient movement, and may be dismissed as nuisance alarms. It is therefore possible that a low venous pressure alarm may be misinterpreted as a high venous pressure alarm and silenced without resolving the underlying problem.

Although all machines are equipped with alarms, it is important users do not rely on the haemodialysis machine to detect disconnection issues leading to blood loss. Partial or full dislodgement of lines may not cause a pressure drop significant enough to set off the lower venous or arterial pressure alarm. Healthcare professionals are reminded about additional protective measures to detect venous needle dislodgement, see MHRA dialysis guidance for further detail.

Actions

Actions for heads of Renal units and Renal nursing staff

- Review the alarm section in the instructions for use of machines used in your facility.
- Identify how your machines react to user input following an alarm and share this information with all staff involved in acting on alarms.
- If the guidance in the instructions for use is not clear, contact the manufacturer for clarification and report to your national incident reporting authority as appropriate: England, Scotland, Northern Ireland, Wales.
- If a pressure related alarm is activated
    - check the condition of the patient
    - identify whether a high or low- pressure event has occurred
    - check the integrity of the blood lines
        - if high pressure, check for kinks and clots in the line
        - if low pressure, check for loose connections, disconnections, leaks or needle dislodgement
        - If the lines are covered by clothes, blankets or similar, lift these to ensure that a problem is not missed.
    - Once the cause of the alarm is resolved, restart the therapy, and once the pumps are running again, **verify that the updated pressure reading is acceptable**. Do not continue the treatment if the pressure reading is lower than expected, as this may indicate that the blood leak is still present.
    - Be aware that in some machines the alarm limits may re-centre around the current venous or arterial pressure when therapy is restarted. If the cause of the problem is not resolved, the venous pressure remains low and the new alarm limits may not be appropriate. In this case, the alarm will not reactivate if the problem remains until the venous or arterial pressure drops to the new low level.
    - The lower venous or arterial pressure alarm limit should not be below levels which would detect blood loss as this effectively disables the alarm.

- Be aware of user desensitisation due to frequent alarms and **do not repeatedly cancel or reset alarms without identifying and resolving the cause**. Always respond to and act on pressure related alarms while protecting the patient as per local clinical protocol and clinical competencies.

- Risk assess your patients for secure fixing of needles and bloodlines. Unit dialysis patients should have their circuit visible during the whole dialysis process. Where this could conflict with maintaining patient dignity, such as patients with femoral lines, a risk assessment should be carried out and all mitigations recorded and enacted. Be aware that sleeping, agitated or confused patients and patients in side rooms or in difficult to observe areas may be more at risk.

- Only staff whose training and competence with the equipment (inclusive of correct management of alarms) has been established and recorded should be permitted to carry out treatment. They should receive education and continued support with regular reassessment of clinical competencies.

- Contact patients using these devices at home to ensure these patients understand the steps to take in response to an alarm and provide refresher training where necessary within the shortest possible timeframe.

- It is also recommended that all existing in-unit patients should be reminded not to silence alarms.

- Report adverse events related to the issue covered in this publication through your local incident reporting system and/or your national incident reporting authority as appropriate: England, Scotland, Northern Ireland, Wales. You should also report directly to manufacturers.

Information for patients
The advice in this DSI is aimed at the renal healthcare team who are responsible for providing your dialysis treatment. If you have any concerns about this advice, contact your renal specialist team for assistance.