Cell Salvage (CS) n=16

28

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Definition:

Any adverse event or reaction associated with autologous transfusion including intraoperative and postoperative cell salvage (washed or unwashed), acute normovolaemic haemodilution or preoperative autologous donation.

In addition specific definitions for cell salvage events are as follows:

- **Adverse events due to operator error, machine failure and non-availability of trained staff where the event impacts on the care of the patient**
- **Adverse clinical events during the cell salvage process**
- **Pathological reactions to reinfused blood**

Note that for the purposes of the European Union (EU) legislation, serious adverse reactions (SAR) are defined as any reactions in patients that are 'life-threatening, disabling or incapacitating, or which result in or prolong hospitalisation or morbidity.' These must be reported to the Medicines and Healthcare products Regulatory Agency (MHRA) (a legal requirement).

Sixteen cases were reviewed and none was withdrawn. No case was transferred to another category. There were no reports of adverse events related to acute normovolaemic haemodilution or preoperative autologous donation.

Specialty involved in the event

The 16 cases were distributed across the following specialties:

- 7 orthopaedic
- 3 vascular
- 5 obstetric
- 1 urology

Adverse reactions n=3

3 adverse reactions were reported

Case 1: Total knee replacement

Fifteen minutes after starting reinfusion of unwashed red cells the patient started to become short of breath, complained of chest pains, became hypotensive, nauseous and was feeling anxious. The transfusion was stopped, the patient was given paracetamol and 100% oxygen and a chest X-ray was requested. Within 2 hours the patient had recovered and was under close observation.

Case 2: Caesarean section

The patient had 1.5L blood loss. The decision was made to use salvaged blood. The woman suffered an episode of hypotension (with severe nausea and vomiting) when the salvaged blood was reinfused. Sodium chloride 0.9% was given using the same administration set as was used for reinfusion of salvaged blood. A skin rash was noted around the intravenous cannula site. The patient was given chlorphenamine to treat the allergic reaction and 40% oxygen was administered. The patient made a complete recovery.

Case 3: Radical cystectomy

Cell salvaged blood was infused with a leucocyte filter in situ using acid citrate dextrose (ACD) as the anticoagulant. A profound fall in blood pressure (BP) to 60/40mmHg occurred which was unresponsive to vasopressors. The transfusion was stopped and BP recovered. The transfusion was restarted 3 times with a fall in BP each time. The leucocyte filter was then removed and the reinfusion restarted with no hypotension.

Excessive time to reinfuse n=2

In 2 cases of postoperative cell salvage the red cells were reinfused >6 hours after collection.

Machine failure n=8

Six of these 8 machine failures were reported by one reporting organisation.

The centrifuge bowl leaked causing contamination in four cases (2 reported to Medicines and Healthcare products Regulatory Agency (MHRA) devices). There was a failure of suction in 3 cases (2 reported to MHRA devices). There was one reported fault which was not fully described (reported to MHRA devices).

The MHRA is currently investigating the reports of various leaks in bowls sent to them and it should be noted these are not machine faults.

Operator error n=1

Inappropriate use of suction (contaminated area) = 1

COMMENTARY

Completed reports this year exclusively relate to cell salvage and not other autologous techniques, which are now less popular. Cell salvage using modern equipment is clearly very safe as the denominator (number of cell salvage procudures) is very high. Cell salvage is now standard of care in many specialties with a good safety record which should encourage its use if clinically indicated.

In 15/16 cases the reported cases were reviewed by the Hospital Transfusion Team/Hospital Transfusion Committee or other appropriate group e.g. cell salvage group or anaesthetic clinical group.

It is reassuring that the pattern of reports remains the same and that the low level and consistent problems reported have helped to encourage increased use as well as improved recognition and treatment of the adverse events.

No fatality has been reported due to cell salvage in either obstetric haemorrhage or use in urological surgery.