21 Cell Salvage (CS) n=17

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Definition:

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

Death n=0

Major morbidity n=0

Seventeen cases were reported (12 female; 4 male; 1 not specified); on review none were withdrawn, nor transferred to or from other categories. All cases reported were related to the use of intraoperative cell salvage (ICS), possibly reflecting the reduced usage of postoperative devices in orthopaedic procedures.

The number of reported cases (n=17) is likely to represent only a small fraction of the number of incidents and under-reporting of cell-salvage incidents remains a concern. There is currently no national reporting scheme capturing denominator data, although the introduction of the office of population censuses and surveys (OPCS) clinical codes for cell salvage, available since 2014, and recommended by the UK Cell Salvage Action Group (UKCSAG), can provide data so long as this coding has been consistently used.

Obstetrics reports predominate. Of the 8 obstetrics incidents only 3 cases used a leucocyte depletion filter, and all 3 reported incidents related to its use; 2 resulted in hypotension and 1 slowed re-infusion and led to time-expiry.

Machine failures and human factors related to managing ICS emphasise the importance of competency-based training and the need to provide learning opportunities.

Cell salvage cases by speciality

Table 21.1: Specialty for cell salvage reports

Speciality	Elective	Emergency
Obstetrics	6	2
Orthopaedic	1	
*Other	3	1
Trauma		2
Urology	1	
Vascular	1	
Total	**12**	**5**

**Other comprised 3 spinal surgeries and an emergency laparotomy*

Types of cell salvage

All cases involved the use of washed ICS techniques. No reports were received for postoperative cell salvage (PCS).

Cell salvage adverse events and reactions

There were 14 adverse events comprising 7 machine failures, 5 operator errors and 2 others.

Within the category of machine failure all devices were under service contracts, however it was also of note that some of these devices were approaching expiry and were due to be replaced. It was reported in one instance of machine failure that a patient received an avoidable allogeneic blood transfusion. In 5 other incidents patients were put at risk of receiving allogeneic blood as autologous blood was discarded. Reporters stated that only 2 of the 7 machine failures were reported to the Medicines and Healthcare Products Regulatory Agency (MHRA) under the Yellow Card Scheme.

Information received from the MHRA Devices Division revealed 7 reported incidents related to cell salvage devices in 2017. It is not clear whether this represents a further 5 cases not reported to SHOT. It should however be noted that cell-salvage machines are classified as medical devices and an adverse incident that caused, or almost caused, injury to a patient or wrong or delayed treatment of a patient is reportable under the Yellow Card Scheme (England & Wales) or regulatory equivalent (Scotland and Northern Ireland).

Of the adverse events attributed to operator error, 2 involved incorrect assembly of equipment, 1 related to the use of non-intravenous (IV)-grade saline for swab washing, in another the suction line was dropped, and finally a failure to address slow administration of the cell-saved blood resulted in time-expiry. No adverse consequences were reported, although in the case of the dropped suction line the reporter stated that the patient received two units of blood intraoperatively which may have been avoided if autologous red cells had been available. All operators involved in these incidents had been trained and competency-assessed.

In the further 2 adverse events, both in obstetrics, unforeseeable factors resulted in patients not receiving their own blood back. In 1 case a patient underwent a caesarean section with hysterectomy and experienced an intraoperative haemorrhage of approximately 3L. Salvaged red cells were reinfused under pressure and an extravasation injury occurred resulting in approximately 300-400mL of red cells being infused into the subcutaneous tissue of the patient's forearm. Although cannula extravasation is not exclusive to blood transfusion, infusing cell salvaged blood under pressure is not recommended.

In a second obstetric case, a patient's unusual lipid profile caused technical difficulties with the cell-salvage process. During an elective caesarean section for twins, cell salvage was used and the operating department practitioner noted that the blood in the collection chamber of the cell-salvage machine was clotting, despite adequate titration of heparinised saline. The collection volume was estimated to be large enough to process and this was commenced intraoperatively in the usual way. Drawing the blood from the collection chamber into the bowl required additional heparinised saline and it was noted the waste bag was pink and milky looking in appearance. The final product for re-infusion looked dilute and had small clots of blood within. A sample taken from the processed autologous blood could not be analysed due to clotting. A decision was made to discard the autologous blood and not re-infuse.

On dismantling the cell-salvage processing equipment, a large fatty substance was found occluding the outflow tubing. Analysis of this substance of light brown tissue 55x10x5mm, showed under microscopy, eosinophils, debris, red cells, mixed inflammatory cells, and was nondescript.

Samples for full blood count (FBC), clotting, urea and electrolytes, and amylase from the mother in recovery were all normal, however the samples were all lipaemic and showed very high triglycerides and cholesterol levels. Consequently, a diagnosis of hyperlipidaemia was made and the cell-salvage blood discarded.

Comment: The lipaemic maternal blood appeared to affect the cell-salvage machine-processing mechanism producing a series of unusual events recognised by the clinical team and ultimately providing an opportunity to diagnose maternal hyperlipidaemia. An awareness of cell-salvage blood quality is important for both operators and clinicians, with decisions to re-infuse cell-salvaged blood taken in the context of each individual case.

Minor or moderate morbidity n=3

There were 3 clinical reactions, all in obstetric patients. All were classed as having minor or moderate morbidity at the time of the reaction and all recovered.

Case 21.1: Possible allergic reaction to salvaged red cells

A patient undergoing emergency caesarean section developed anaphylactic-like symptoms within a few minutes of commencement of reinfusion of salvaged red cells. The patient reported difficulty in breathing and tongue swelling and the infusion was stopped with a prompt resolution of symptoms. When reviewed the following day the patient revealed that the effects of a high epidural had caused numbness in her face and hands, she panicked and this affected her breathing. She also stated this reaction started before the infusion of the salvaged red cells commenced.

Comment: Whilst it may be unlikely, an allergic reaction to the autologous transfusion cannot be entirely ruled out. It is difficult to speculate as to the possible allergen responsible, but the final salvaged red cell product can contain trace amounts of any substrate entering the system including citrate anticoagulant.

Case 21.2: Hypotension on reinfusion of salvaged red cells

A patient with placenta praevia underwent elective caesarean section with cell salvage. Intraoperative blood loss was approximately 800mL and a reinfusion of 200mL of salvaged red cells was commenced using a leucocyte-depletion filter. The patient experienced a sudden and profound hypotension and the infusion was stopped. The patient's blood pressure was normalised with vasoconstrictors and other obvious causes of hypotension ruled out. The leucocyte-depletion filter was removed and the remainder of the autologous red cells reinfused without further incident.

Comment: Since 2010, when SHOT started to report on cell-salvage incidents, there have been 27 ICS hypotensive incidents; 20 occurred with the use of a leucocyte-depletion filter with citrate anticoagulant on 18 occasions (Haynes et al. 2017). This is a further reported case where a leucocyte-depletion filter was used and citrate was the anticoagulant. In this scenario a pragmatic decision was taken to abandon the filter and continue with the reinfusion with no further incident. National Institute for Health and Care Excellence (NICE) guidance on cell salvage in obstetrics published in 2005 states that 'A leucocyte-depletion filter is nearly always used in this process to reduce the amount of amniotic fluid contaminants in transfused blood to levels approaching those found in maternal blood.' However, a pragmatic cell-salvage study in obstetrics, the SALVO (Cell SALVage in Obstetrics) trial (Khan et al. 2017) reported that in 26 UK obstetric units leucocyte-reduction filters were used in only 54.9% of cases randomised to receive cell salvage. This data illustrates current practices in obstetric cell salvage and a move away from the use of leucocyte-depletion filters in this setting, presumably as a result of concerns over hypotensive reactions.

Case 21.3: Hypotension resulting from reinfusion of salvaged red cells confirmed by a secondary challenge

A patient with a grade IV placenta praevia underwent elective caesarean section. As the patient was being transferred from theatre, reinfusion of 361mL of autologous red cells via a leucocyte-depletion filter commenced. The patient then complained of nausea and vomiting, looked unwell and became slightly less responsive. Monitoring revealed sinus tachycardia with a heart rate of 165 beats per minute (bpm) with systolic blood pressure (BP) of 78mmHg. The red cell infusion was stopped and the symptoms resolved with a bolus infusion of 60 micrograms of phenylephrine. Having stabilised the patient in the recovery area (heart rate 78bpm, systolic BP 98mmHg), the autologous red cell transfusion was recommenced. This resulted in rapid rise in heart rate to 150bpm with concomitant hypotension. The infusion was stopped immediately with rapid resolution of symptoms. The remaining 150mL of autologous red cells was then discarded. The reporter noted that cell salvage was carried out following standard protocols, however, at the end of the case a partial bowl was washed without using the 'concentrate' function and the saline wash volume was not increased to compensate for this.

Comment: This is a further confirmed case of hypotension associated with reinfusion of salvaged red

cells through a leucocyte-depletion filter where citrate was used in the collection of the salvaged blood. The second challenge with the red cell infusion provides compelling evidence. It is not clear whether the use of a partially full bowl and single wash added to this reaction. The use of partial bowls is discouraged as it is thought to result in inadequate clearance of contaminants as washing processes in bowl based cell salvage systems are thought to be aided by red cell packing and exclusion of fluid. Limited work in this field, however, suggests that a good quality product can be produced from a partially full bowl when the wash volume is doubled (Serrick et al. 2005).

Recommendations

- Cell-salvage devices are medical devices and as such any failures should be additionally reported to the appropriate regulatory authority responsible for monitoring medical device safety
- Cell-salvage operators should be trained and have documented evidence of competency assessment. Organisations should review ongoing competence and institute re-training or update training as necessary to ensure patient safety
- Cell salvage should be performed to standard protocols identified by the organisation to reflect best practice. Variations in practice to suit an individual patient's circumstances should be discussed prior to intervention and risks and benefits considered
- Cell-salvage operators and clinicians must be alert to unusual unpredictable events related to patient factors. Monitoring of the process in relation to quality of the reinfused product is just as important as monitoring the reinfusion itself
- Organisations should consider whether a failure in provision of cell salvage, as a result of adverse event or logistics, puts a patient at risk of an avoidable allogeneic transfusion and report to SHOT accordingly
- Organisations should ensure that clinical coding for cell salvage is used consistently (office of population censuses and surveys (OPCS) codes X36.4 and X33.7) to assist with establishing national denominator data

Action: Cell salvage teams

References

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