Cell Salvage (CS) n=38

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Definition:

Any adverse events or reactions associated with cell salvage (autologous) transfusion methods, including intraoperative and postoperative cell salvage (washed or unwashed).

Abbreviations used in this chapter

ACD	Acid-citrate-dextrose	MHRA	Medicines and Healthcare products
ICS	Intraoperative cell salvage		Regulatory Agency
IV	Intravenous	PCS	Postoperative cell salvage
LDF	Leucocyte depletion filter	UKCSAG	United Kingdom Cell Salvage Action Group



Key SHOT message

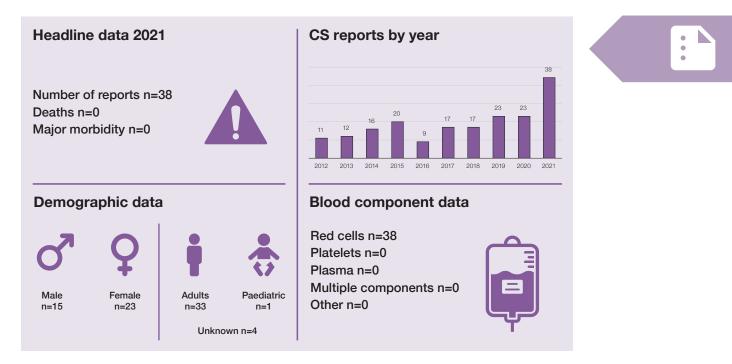
• Autologous red cell salvage is not without risk. Transfusion to the right patient, at the right time, in the right manner is equally important as for any blood transfusion



Recommendations

- Organisations should have defined processes in place for the safe administration of salvaged red cells
- All autologous transfusion bags must be accurately labelled with patient identifiers matching the patient's wristband to allow positive patient identification on reinfusion
- Labelling should also include an expiry time when the transfusion should be terminated
- All staff involved in the autologous cell salvage process must have adequate training to perform their role safely
- When handing a patient over to another staff member, communication relating to autologous blood transfusions must be clear and concise, including details about how to proceed

Action: Cell salvage leads, hospital transfusion teams, hospital transfusion committees



Introduction

Thirty-nine incidents were reported; on review 1 case was withdrawn. The reports were submitted from eight different reporting centres, with one centre submitting 23 reports. This is the largest number of cell salvage reports submitted to SHOT since 2011.

Most reports came from patients undergoing obstetric or gynaecological procedures (17 combined), with orthopaedic and trauma specialities submitting 14 reports. Twenty-one incidents occurred in emergency situations, with 17 occurring in elective settings.

As with previous years, adverse events dominate, with equipment issues being the largest reporting category. This year 1 adverse reaction was reported, with hypotension in an obstetric patient receiving salvaged red cells through a LDF.

Specialty	Elective	Emergency	Total	
Gynaecology	2		2	
Obstetrics	7	8	15	
Orthopaedic	3	1	4	
Other		1	1	
Trauma		10	10	
Vascular	5	1	6	
Grand total	17	21	38	

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Deaths related to transfusion n=0

There were no reported deaths associated with cell salvage in 2021.

Major morbidity n=0

There were no cases reported with major morbidity associated with cell salvage in 2021.

Types of cell salvage

Thirty-seven reports related to the use of ICS, with 1 case in PCS. This is the first report related to the use of a filtered PCS device since 2014.

Cell salvage adverse events n=37

Most adverse events related to machine failure (n=26). Of the remaining adverse events, 7 were preventable.

Equipment failure n=26

There were 26 reports of equipment failures, 10 in elective procedures and 16 in emergency situations. Eighteen related to device malfunction and 8 were reported as disposable manufacturing faults. All were reported to the MHRA under the yellow card scheme. For the same reporting period the MHRA received 43 user reports for autologous transfusion equipment suggesting that these are under-reported to SHOT.

Sixteen incidents related to 'long empty' cycles potentially effecting the quality of the reinfused blood. There were 9 reports of this type in the 2020 Annual SHOT Report (Narayan et al. 2021). There were 4 further reports of unidentified black particles in the reinfusion bag which were attributed to machine failure in 3 cases and reported as an adverse event in 1 case (see below). Other reported equipment issues included premature activation of the wash cycle (5), low haematocrit of the reinfusion product and a mechanical failure.

These equipment issues resulted in 2 patients receiving allogeneic blood that could have been potentially avoided.

Procedural errors n=7

In 2 cases incidents were attributed to errors made by the cell salvage operator. In the first, the operator labelled the reinfusion bag with the previous patient's details leading to a patient identification error. The error was noticed, and the red cells (100mL) were discarded. The cell salvage operator stated that they had been distracted by the presence of a student within the operating theatre. In the second incident, incorrect use of equipment resulted in a bag of unwashed red cells being handed to an anaesthetist and connected to an obstetrics patient for reinfusion. Timely intervention by theatre staff prevented infusion of a product that could have contained amniotic fluid and anticoagulant. In both of these cases the operators were trained and competency-assessed.

In a further 5 incidents, errors or inexperienced staff involved in the cell salvage process were contributory. In 2 cases, non-IV substances entered the blood collection from the operating table thereby contaminating the collection and making it unfit for purpose.

In a further 2 cases reinfusion times exceeded the 4-hour time limit. An obstetric patient was given red cells over a 9-hour period when the infusion was slow, possibly due to the position of the cannula. The patient was transferred back to the ward with the infusion running, the receiving staff member was new and unaware of cell salvage time limits. In the 2nd case, handover of a patient to recovery staff inexperienced with cell salvage had failed to highlight the expiry time written on the reinfusion bag. By the time the labelling was noticed, the reinfusion had exceeded the expiry time by 1 hour.

Case 21.1: Near miss where a patient could have potentially received another patient's blood

A woman in her 30s underwent an emergency caesarean section and ICS was facilitated. Blood loss was estimated at 900mL. At the end of the surgical procedure the patient was moved to recovery before the ICS process was completed producing 226mL of salvaged red cells (O D-positive). An anaesthetist then took the labelled reinfusion bag from theatres to the bedside of what they thought was the correct patient in recovery. The bag was hung on a drip stand and connected to a cannula in the patient's arm, but the infusion was not commenced. The doctor was initially questioned by the patient 'is that mine?' and then challenged by the midwife. Checking the patient's details on the labelled blood bag against the wristband revealed that the doctor was in the wrong bay with a different patient (B D-positive). The infusion was disconnected and removed. The doctor had failed to follow the 4-point patient identity check at the bedside before connecting the transfusion. Timely intervention by the patient and the midwife prevented the transfusion of the wrong blood into the wrong patient. The process was updated following this incident whereby a patient receiving cell salvaged blood must leave theatre with the red cell transfusion connected and running.

This incident occurred at the end of a busy night shift and fatigue played a part. Salvaged red cells are untested in relation to blood group and infectious diseases. Infusion into the wrong patient could result in an ABO-incompatible reaction or transmission of infection. The questioning by the patient and the intervention by the midwife was crucial in this case and highlights the importance of positive patient identification.

Learning points

- Accurate labelling of the cell salvage reinfusion bag with correct patient identifiers is imperative for patient safety. The label should also include the expiry time. The UKCSAG has produced a standardised label that is available from all ICS manufacturers for customer use
- The transfusion of autologous red cells should follow the same processes as for allogeneic transfusion in relation to bedside checks to confirm patient identity. This is particularly important when the reinfusion bag has not been connected within theatre

Other adverse events n=4

In 2 cases, staff trained to operate the ICS equipment were not available for surgeries where ICS was indicated. In 1 of these incidents, the patient underwent complex total hip revision surgery and lost 1700mL during surgery. This patient required a one-unit allogeneic transfusion that may have been avoided if cell salvage had been facilitated.

In a 3rd case autologous blood transfusion drains (PCS) were used in a paediatric scoliosis patient. Postoperatively, 700-800mL of the patient's blood was available for reinfusion but not given before it expired due to lack of experience and poor communication at handover.

The 4th case related to the appearance of black particles in the reinfusion bag and was reported as an adverse event as opposed to an equipment failure.

Cell salvage adverse reaction n=1

Case 21.2: Hypotension on reinfusion of salvaged red cells with a LDF

A woman in her 20s underwent an elective caesarean section and experienced an intraoperative haemorrhage post-delivery of approximately 4000mL. ICS was utilised with anticoagulation by ACD with a collection volume of approximately 800mL. Three units of allogeneic red cells were transfused prior to commencing salvaged red cells. On commencement of the autologous transfusion through a LDF the patient exhibited a sudden drop in blood pressure and became tachycardic. The salvaged red cell infusion was stopped, and the patient received vasopressors and fluids and she quickly recovered. The cell salvage transfusion of approximately 200mL was recommenced slowly without incident. Towards the end of the infusion, the remainder of the volume within the bag was drawn into a 30mL syringe via a 3-way tap downstream of the filter. Infusion of this bolus resulted in a second hypotensive event accompanied with tachycardia. The patient was resuscitated with vasopressors and fluids and made a full recovery.

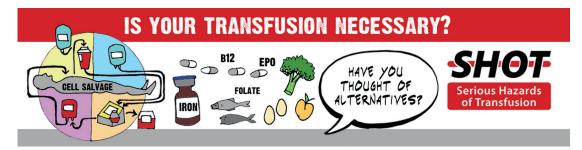
The reaction was reported as related to the reinfusion of salvaged red cells and not related to hypovolaemia following haemorrhage.

Use of a syringe to evacuate the reinfusion bag downstream of the LDF filter is outside of the manufacturer's indication of use of the LDF specifically designed for use with ICS. The effects of placing a negative pressure on the retained contents within the filter is unknown.

Hypotension on reinfusion is the most common adverse reaction reported to SHOT in relation to cell salvage. There have been 31 such reports since SHOT began collating cell salvage reports in 2010.

Conclusion

The majority of reports this year come from equipment issues and represent an increase of previous years' reporting. The adverse events relating to human errors or inexperience were preventable and again emphasise the importance of all staff within the process having sufficient knowledge and skills to perform their role safely. A few of this year's incidents relate to poor communication at handover to staff unfamiliar with cell salvage infusions. The correct labelling and prescription of autologous blood, with clear instructions to those caring for patients is vital in these situations.





Recommended resources

UKCSAG:

Factsheet 5 – Administration of Salvaged Blood (version 3) Factsheet 10 – Staff Responsibilities (version 1)

https://www.transfusionguidelines.org/transfusion-practice/uk-cell-salvage-action-group/technical-factsheets-and-frequently-asked-questions-faq

SHOT Bite No. 21: Cell Salvage

https://www.shotuk.org/resources/current-resources/shot-bites/

References

Narayan S (Ed), Poles D, et al. on behalf of the Serious Hazards of Transfusion (SHOT) Steering Group. The 2020 AnnualSHOT Report (2021). https://www.shotuk.org/shot-reports/ [accessed 06 May 2022].