21 Cell Salvage (CS) n=23

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Definition:

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

Key SHOT messages

- Cell salvage devices and consumables are classed as medical devices and so are covered by relevant organisational policies. In common with all medical devices, cell salvage machines and equipment have significant potential to cause harm when used incorrectly. Risks can be minimised through robust training, safe operation and management
- It is recognised that there is significant under-reporting of cell salvage incidents. Operators and all other staff involved with cell salvage are encouraged to report any equipment failures and all clinical incidents
- Procedures for checking, labelling, prescribing, administration, and monitoring of cell salvage red cells should be identical to that used when transfusing allogeneic blood. Policies should be in place to reduce the potential for human error in the journey of blood from machine to recipient

Abbreviations used in this chapter

ACE	Angiotensin converting enzyme	**PCS**	Postoperative cell salvage
CS	Cell salvage	**LDF**	Leucocyte depletion filter
ICS	Intraoperative cell salvage	**MHRA**	Medicines and Healthcare products Regulatory Agency
IV	Intravenous		

Death n=0

Major morbidity n=0

Twenty-three cases were reported; on review none were withdrawn, and 1 was transferred from the near miss reporting category. A single cardiac case was reported using cell salvage postoperatively, with the remaining cases related to the use of intraoperative devices.

There were 16 reports for female patients (15 adult, 1 paediatric) and 7 male (all adult).

As with previous Annual SHOT Reports, the small number of cases reported raises concerns around under-reporting of cell salvage incidents.

The majority of reports this year came from orthopaedics or trauma (14/23), whereas in previous years obstetric reports were the most frequently reported. It is possible less centres are using cell salvage during obstetric procedures, and those that do no longer use the leucocyte depletion filter (LDF). There was only 1 report of hypotension upon reinfusion with a LDF.

As in previous years (Figure 21.1), adverse events, notably equipment issues and human errors, predominate.

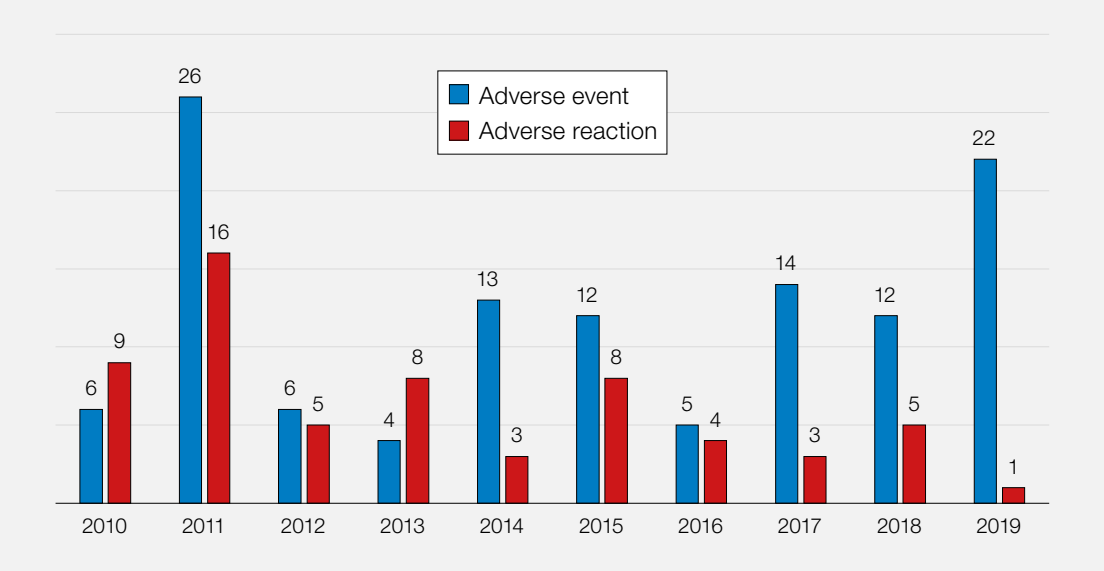

Figure 21.1: Cell salvage incidents by type of report 2010-2019

Cell salvage cases by speciality

There were 23 cases reported as shown in the table below.

Speciality	Elective	Emergency
Orthopaedic/trauma	9*	5
Obstetrics	3	0
Urology	2	0
Cardiac	0	1
Gynaecology	1	0
Vascular	0	1
Unknown	1	0
Total	**16**	**7**

**Includes 1 spinal case*

Table 21.1: Specialty for cell salvage reports

Types of cell salvage

The use of washed cell salvage techniques involved 22 intraoperative and 1 in the intra/postoperative setting. No reports were received for postoperative filtration cell salvage alone.

Cell salvage adverse events n=22

Equipment failure n=4

There were 2 incidents involving machine errors when processing the blood collection: in both cases the red cells were not reinfused. Only 1 was declared to be reported to the Medicines and Healthcare products Regulatory Agency (MHRA) under the Yellow Card Scheme. Interestingly, the MHRA had 3 reports in the same period which may or may not include the incident reported to SHOT. Operators recognised the machine errors and the final products were considered not to be of the usual standard. Neither patient required allogeneic blood transfusion. In the 3rd case machine failure occurred during an emergency aortic aneurysm repair resulting in just 200mL to reinfuse from a large blood loss. This machine fault was not reported to the MHRA despite a fault in a pump mechanism being identified requiring repair. The patient received three units of allogeneic blood which wouldn't have been necessary if all the blood loss had been processed. In another case, a fluid accounting issue consistently overestimated

the volume of processed red cells available to reinfuse. Despite only 1 case being detailed, the reporter stated that this was the 6th similar incident and the manufacturer had failed to identify any mechanical failure within the device or disposables used.

Learning point

- Operators, medical staff and theatre personnel must be vigilant and take joint responsibility for ensuring the quality of the cell salvage collection and processing before reinfusion

Operator errors n=9

Of the 9 adverse events attributed to operator error, 5 involved incorrect labelling, prescribing and administration. In 1 case a leucocyte depletion filter was not used where it might have been indicated.

Cell salvage operators and theatre staff must be aware that labelling, prescribing and administration of autologous blood must be performed as for allogeneic blood and undergo the same stringent bedside checking procedures. Autologous red cells are not tested for serology or transmissible infection and could do serious harm if transfused into the wrong patient.

There were 3 cases citing inadequate operator training, 1 when the operator was not trained or competent to use the machine, and 2 when contra-indicated substances were aspirated into the collection. A further case was reported due to a suspected machine failure that resulted from operator inexperience. Uncertainty that the machine was washing correctly resulted in cell salvage being possibly denied in 2 cases. Investigation revealed that alteration of the programming parameters had set the wash cycle to zero.

Learning points

- Operators, clinicians and theatre staff must have adequate training covering all aspects of the cell salvage process consistent with their role, including standards for labelling, prescribing and administering autologous red cells
- Training on trouble shooting with medical devices is imperative. Operators should be sufficiently familiar with devices and their standard programming parameters to check the device is fit for purpose when first switched on

Other adverse events n=9

There were 6 reports from one centre detailing contamination of the processed blood with black particles: 4 orthopaedic/trauma, 1 gynaecological and 1 obstetric. Whilst all machines were from the same manufacturer, there was no common denominator in terms of an individual device or consumable lot numbers. The affected salvaged red cells were not reinfused in 5 cases, in 1 case the disposable was changed and cell salvage continued without an issue. One patient received an avoidable transfusion of allogeneic blood whilst all were denied the potential benefits of an autologous reinfusion. In most cases the affected red cells were sent to the laboratory for analyses, the consumables retained and the manufacturer informed. Independent analysis revealed no components within the blood samples emanating from the disposables suggesting the particles were derived from the collected blood. The hospital continues to monitor the situation and operators are alert to this potential problem.

SHOT has received 3 similar reports of particulate matter contamination in 2011, 2012 and 2013. In 2 of these cases, reporters theorised that these particles where micro-clots associated with haemostatic products being aspirated into the blood collection.

One patient received autologous blood through a giving set which was not suitable for blood transfusion. In another non-intravenous (IV) grade saline had been aspirated into the blood collection. A decision was made to abandon cell salvage and the patient received two units of allogeneic blood intraoperatively. A further patient scheduled for spinal surgery was unable to receive cell salvage despite a request in advance, as there were no available staff.

Learning points

- Cell salvage operators and theatre staff should be vigilant and routinely check the appearance of the red cells prior to reinfusion and report any unusual appearance or potential contamination
- It is good practice to retain consumables and samples for analyses where quality issues are suspected

Cell salvage reactions n=1

Case 21.1: Hypotension on reinfusion with a filter and ACE inhibitors

A man in his 70s, with known coronary artery disease on angiotensin converting enzyme (ACE) inhibitors, underwent a cystectomy for bladder cancer. Cell salvage was used with citrate as an anticoagulant and a LDF for reinfusion. During heavy bleeding and cell salvage reinfusion the patient became very hypotensive. Following treatment with fluid, inotropes and calcium, this resolved. A second similar hypotensive episode occurred at the end of the procedure when the last bowl from the cell salvage machine was reinfused. The transfusion was stopped and the patient quickly stabilised. The patient went to intensive care intubated and ventilated. He was extubated the following day and went on to make a good recovery.

The reaction was thought to be possibly related to the reinfusion of cell salvaged blood.

Since SHOT started collating cell salvage incidents in 2010, the most reported adverse reaction has been hypotension (n=30). Although hypotension has been reported without the use of a specialised filter, usually the LDF is used with citrate as the anticoagulant. In this case, an additional contributing factor may have been the ACE inhibitors. There is some evidence suggesting that bradykinin, released from platelets exposed to the negatively charged LDF medium, accumulates and causes vasodilation due to ACE inhibitors reducing its metabolism (Iwama 2001).

The use of LDF in cancer surgery may reduce the risk of infusing malignant cells, although there remains some debate about the role of malignant cells in metastatic spread (Zaw et al. 2017). More research is needed and clinicians are advised to evaluate the relative risks and benefits for individual patients.

Learning point

- The use of leucocyte depletion filters (LDF), particularly in conjunction with citrate, may be associated with hypotensive reactions. Without denominator data, the relative incidence of this is not known. Clinicians should be aware of this potential and balance risks and benefits accordingly

Conclusion

Cell salvage is a valuable blood conservation method which is often under-utilised. All cell salvage operators must undertake initial and regular update training and be assessed as competent with documented training records. All hospitals where ICS and PCS are undertaken should report adverse events to SHOT. Staff should be aware that monitoring of patients is as important for the reinfusion of red cells collected by ICS or PCS as it is for allogeneic red cells and practitioners need to revisit previous Annual SHOT Reports particularly related to autologous transfusion to ensure historic incidents are not repeated.

Recommended resources

UK Cell Salvage Action Group
https://www.transfusionguidelines.org/transfusion-practice/uk-cell-salvage-action-group

References

Iwama H. (2001) Bradykinin-associated reactions in white cell reduction filter. *J Crit Care* 2001;**16(2)**:74-81.

Zaw AS, Bangalore Kantharajanna S, Kumar N. (2017) Is Autologous Salvaged Blood a Viable Option for Patient Blood Management in Oncologic Surgery? *Transfus Med Rev* 2017;**31(1)**:56-61.