# 23 Cell Salvage (CS) n=26

*Author: Sarah Haynes*

## 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

| | |
|---|---|
| **AAA** | Abdominal aortic aneurysm |
| **BP** | Blood pressure |
| **CS** | Cell salvage |
| **ICS** | Intraoperative cell salvage |
| **IV** | Intravenous |
| **LDF** | Leucocyte depletion filter |
| **MHRA** | Medicines and Healthcare products Regulatory Agency |
| **NICE** | National Institute for Health and Care Excellence |
| **PCS** | Postoperative cell salvage |
| **UKCSAG** | United Kingdom Cell Salvage Action Group |

## Key SHOT messages

- Cell salvage is a safe and effective alternative to allogeneic blood when used correctly and appropriate resources are available
- The risks associated with cell salvage are low but need to be considered and managed appropriately
- Most incidents reported to SHOT are avoidable, however, unforeseen reactions can occur, and vigilance is necessary

## Recommendations

- Cell salvage policies and procedures should include information on potential risks, including cell salvage related hypotension and the simple measures that need to be taken should it occur

**Action: Cell salvage leads, cell salvage practitioners and theatre teams**

- Organisations should review their policies to confirm that they are up to date with current practices and guidance

**Action: Cell salvage leads, hospital transfusion teams, hospital transfusion committee**

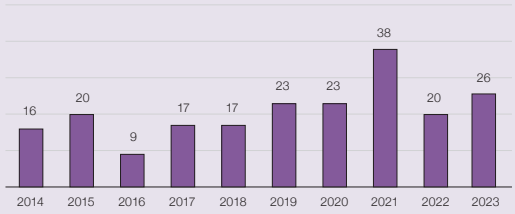
- Organisations should review local incident reporting processes to ensure cell salvage incidents can be identified as blood transfusion related and inform the hospital transfusion team who should be included in the investigation process

**Action: Cell salvage leads, hospital transfusion teams, hospital transfusion committee, governance leads**

### Headline data 2023

Number of reports n=26
Deaths n=0
Major morbidity n=3

### CS reports by year




### Demographic data

Male n=7
Female n=19
Adults n=24
Paediatric n=2

### Blood component data

Red cells n=26
Platelets n=0
Plasma n=0
Multiple components n=0
Other n=0

## Introduction

In 2023, 26 incidents were submitted by 16 different reporting organisations. One organisation submitted 5 reports, one organisation submitted 3 reports, four organisations submitted 2 reports, and the rest submitted 1 each.

There were 2 reports related to paediatric patients, the rest were adult patients. The age range was 11-85 years, with 19 females and 7 males.

The greatest number of incidents reported were in obstetrics, vascular and orthopaedic (including spinal and trauma) surgery (Table 23.1). There was an even split between elective (n=12) and emergency (n=14) surgeries. This is in contrast with 2022 where most reports were from elective procedures.

There were 21 adverse events, of which 11 were attributable to avoidable errors, 10 machine/disposable failures, and 5 adverse reactions all of which were hypotension not related to hypovolaemia. Of these reactions, 4 occurred when using a LDF. Hypotensive reactions following reinfusion of cell salvaged blood remain the most reported reactions.

Table 23.1: Cell salvage cases by speciality in 2023 (n=26)

| Specialty | Elective | Emergency | Total |
|---|---|---|---|
| Obstetrics | 4 | 6 | **10** |
| Vascular | 2 | 4 | **6** |
| Orthopaedic | 3 | 1 | **4** |
| Spinal | 2 | | **2** |
| Trauma | | 1 | **1** |
| Cardiac | | 1 | **1** |
| General | | **1** | **1** |
| Hepatobiliary | 1 | | **1** |
| **Total** | **12** | **14** | **26** |

## Deaths related to transfusion n=0

There were no cases reported where a patient died because of cell salvage.

## Major morbidity n=3

In 3 cases, severe hypotension following infusion of salvaged red cells contributed to the need for postoperative high-dependency care.

## Types of cell salvage

All incidents related to the use of centrifugal washed cell salvage systems; 25 intraoperatively and 1 in the postoperative setting.

## Cell salvage adverse events n=21

There were 11 avoidable incidents and 10 equipment-related reports.

### Avoidable errors n=11

In 2 cases, both emergencies, cell salvage was not available. This resulted in a potentially avoidable transfusion of allogeneic red cells in an orthopaedic patient. In the second case, the patient died following a ruptured AAA. It was difficult to assess the benefit that cell salvage could have provided.

Three incidents related to contamination of the collected blood which was then discarded. The contraindicated substances aspirated were non-IV grade saline, chlorhexidine, and surgical glue respectively.

In an elective caesarean section, blood was collected, processed and reinfusion was started when it was realised that the set of disposables being used was a non-sterile set intended to be used for training purposes only. The reinfusion was stopped immediately, and the remaining red cells discarded. As a result of this incident, training materials are no longer kept near sterile consumables.

In another obstetric case, a new cell salvage device was being trialled for 2 weeks. The device was used in a caesarean section over a weekend by an operator with limited training. The operator failed to confirm the correct bowl size resulting in inadequate volumes of wash being used potentially affecting the quality and safety of the red cells that were reinfused. This was only discovered when the machine data was reviewed by the company representative later.

There were 2 similar incidents where the cell salvage device displayed a ‘long empty cycle’ warning, indicating that the quality of the reinfusion product may have been compromised. The usual process for dealing with this (rewashing with new disposables) was not followed, and red cell volumes of 194mL and 244mL respectively reinfused with no discernible consequence.

Incidents occurred in the final 2 cases at the time of reinfusion. In an elective caesarean section, a 1500mL blood loss was collected and processed. Unfortunately, the reinfusion exceeded the time permitted according to local protocol and the remaining red cells were discarded. It was also stated that the blood had coagulated in the bag, suggesting that inadequate anticoagulation or washing may have occurred.

In an emergency laparotomy for a ruptured spleen, massive blood loss was managed using a rapid infusion device, and 866mL of salvaged red cells were given via a device that had a 250-micron inline filter. Concern was raised that the salvaged red cells were not given back via a 40-micron filter as specified by local policy.

Rapid infusion devices allow fast infusion of warmed fluids in circumstances where large volume replacement is needed quickly. Generally, administration of salvaged red cells should meet the minimum standards required for administration of allogeneic packed red cells. If an organisation routinely uses a rapid infusion device for allogeneic red cells, then its use with salvaged red cells might also be acceptable depending on the mode of action of the infusion device. If there is no guidance from the manufacturer of the infusion device, a risk assessment should be undertaken bearing in mind that salvaged red cell infusion bags contain air and are not manufactured to withstand pressurisation. Also of note is that gravity-fed filters, such as the LDF, are not compatible with rapid infusion systems.

## Learning points

- Safe cell salvage practice relies on staff involved in the process having adequate knowledge and understanding of their role. Vigilance, communication, and situational awareness is required
- Individuals must be either fully trained, or supported by someone who is, to use the cell salvage equipment safely. This is applicable to all devices, including those being trialled
- In the absence of manufacturer's guidance, a risk assessment should be performed when considering the use of infusion devices with salvaged red cells

### Equipment incidents n=10

There were 3 incidents where leaks in the cell salvage disposable set prevented satisfactory processing of the collected blood and reinfusion of red cells to the patient. In 1 of these cases, a report was made to the MHRA Yellow Card scheme. In the other 2 cases, it could not be determined whether damage to the disposable set from mishandling had occurred. One of these cases involved a paediatric patient undergoing spinal surgery who received a unit of allogeneic red cells which may have been avoided.

There were 5 machine issues, including power outages, error codes and sensor failures that made the machines unusable. One of these incidents happened at setting up, allowing a replacement machine to be found. A further 3 cases failed intraoperatively, causing loss of cell salvage completely on 1 occasion and reduced contribution of cell salvage on 2 occasions. In another case, the device appeared to be giving misleading fluid volume readings in relation to postoperative bleeding in a cardiac setting. This was reported to the MHRA Yellow Card scheme.

In the final 2 cases, there were concerns over quality of the red cells for reinfusion as black particles were seen in the reinfusion bag. One of these reports came from a centre where this is an ongoing issue and a further MHRA report has been made.

## Cell salvage adverse reactions n=5

There were 5 reports of adverse reactions, all of which comprised of severe hypotension on reinfusion not related to hypovolaemia. These events occurred in 3 elective procedures (obstetric, orthopaedic, and hepatobiliary surgeries) where a LDF was deployed. In 2 of these elective cases the reaction contributed to the patient needing high-dependency care postoperatively.

**Case 23.1: Hypotensive reaction in a patient receiving allogeneic and salvaged red cells**

*A patient was undergoing invasive internal surgery and experienced significant blood loss. Cell salvage was being used and a major shock pack was requested. During transfusion of a unit of red cells from the shock pack and the cell salvaged blood, a dramatic fall in BP from 90mmHg to 45mmHg was observed. This was managed with bolus infusions of adrenaline. It is not clear whether the reaction was due to the allogeneic blood, or the salvaged red cells given through a LDF.*

There were also 2 incidents of hypotension in emergency procedures, 1 in vascular surgery (without a LDF), the other in obstetrics where high-dependency postoperative care was required.

The most reported adverse reaction associated with cell salvage is hypotension. The incidents this year bring the total number of hypotensive reactions reported to SHOT since 2010 to 39. The majority of these, but not all, also feature the use of LDF.

There are two areas of application where LDF have been routinely used. In surgery involving malignancy, a LDF is used to reduce the potential risk of infusing malignant cells. In obstetrics, the theoretical risks of amniotic fluid embolus were thought to be mitigated by use of these filters. Indeed, NICE guidance on cell salvage in obstetrics stated that a LDF is nearly always used to reduce the amount of amniotic fluid contaminants in the transfused blood to levels approaching those in maternal blood (NICE, 2005). There has been no substantial revision of this guidance since publication. However, reports of hypotension have more recently called into question the risks and benefits of the continued use of LDF in the obstetric

setting. The MHRA produced a safety guidance one liner in January 2011 stating that hypotension was a rare side effect of using LDF for cell salvage reinfusion, and the use of these filters for the purpose of removing amniotic fluid contaminants was not validated (MHRA, 2011). A survey of practice published by the UK cell salvage action group in 2015 found that of 73 hospitals using cell salvage in obstetrics, 66% continued to use the LDF, 22% sometimes used it and 12% never used it routinely (UKCSAG, 2015). The most recent professional guidance, published in 2018 by the Association of Anaesthetists, did not recommend the routine use of LDF in obstetric practice (Klein, et al., 2018).

### Learning points

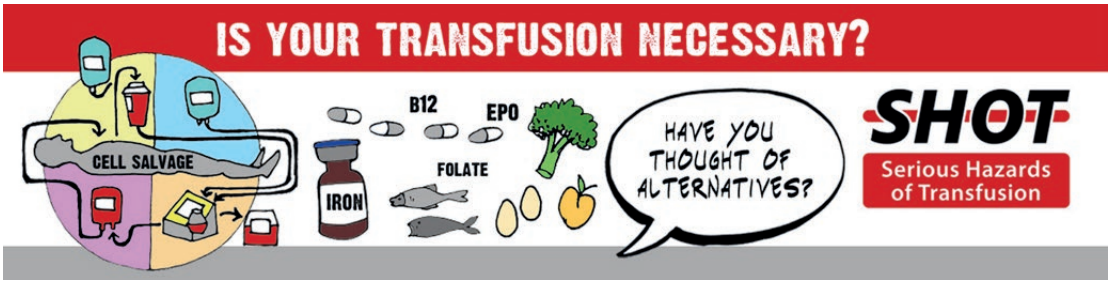
- Hypotension is the most reported adverse reaction associated with cell salvage. The use of a LDF is often (but not always) associated with this reaction
- If hypotension occurs, stop the infusion, and resuscitate with fluids and vasopressors if necessary (the reaction may be transient). Consider resuming the infusion without the LDF

## Conclusion

The safe execution of cell salvage relies on everyone involved in the process understanding their role and responsibilities. The quality of the collected blood, the correct processing of that blood and the safe reinfusion of the washed red cells can be influenced by all those involved. It is imperative to provide adequate and appropriate training, including updates, to support all staff involved in the cell salvage process.

SHOT has not identified any mortality related to cell salvage in the years this reporting category has been active. This year, there were 3 cases where hypotension following infusion of salvaged red cells via a LDF contributed to the need for postoperative high-dependency care. This underlines the need for continued vigilance when using cell salvage. 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 among staff and with laboratories. The correct labelling and prescription of autologous blood, with clear instructions to those caring for patients is vital in these situations. Consideration of any requirement for anti-D Ig is also vital in patients undergoing cell salvage especially when ICS has been used during caesarean section in D-negative, previously non-sensitised individuals and where cord blood group is confirmed as D-positive (or unknown).

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 optimise learning from haemovigilance reports.



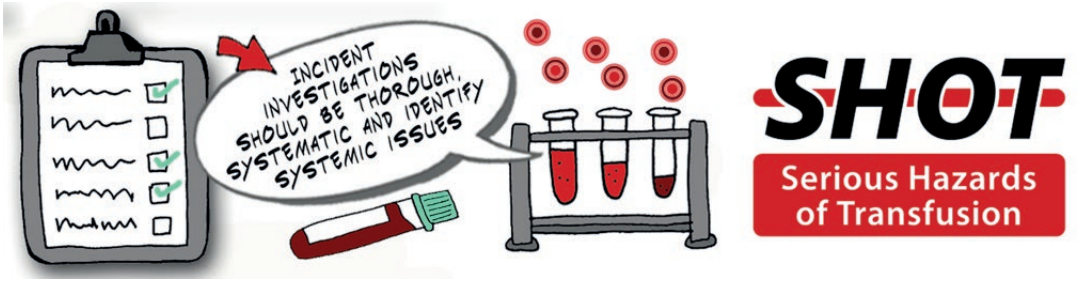
## Recommended resources

**SHOT Video: Haemovigilance in cell salvage**
https://www.shotuk.org/resources/current-resources/videos/

**UK Cell Salvage Action Group: Technical factsheets and Frequently asked questions**
https://www.transfusionguidelines.org/transfusion-practice/uk-cell-salvage-action-group/technical-factsheets-and-frequently-asked-questions-faq

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

**Intraoperative cell salvage: a survey of UK practice**
https://doi.org/10.1016/j.bja.2024.01.042

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