18. Autologous Transfusion

Definition

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

DATA SUMMARY

Total number of cases	28

Implicated Components	
Autologous Red cells	**28**
FFP	
Platelets	
Other *(specify)*	
Unknown	

Mortality / morbidity	
Deaths due to transfusion	**0**
Deaths in which reaction was implicated	**0**
Major morbidity	**0**

Gender	
Male	**16**
Female	**12**
Unknown	**0**

Age	
16 years+ to 18 years	**0**
1 year+ to 16 years	**2**
28 days+ to 1 year	**0**
Birth to 28 days	**0**
Total	**2**

Emergency vs. routine and core hours vs. out of core hours	
Emergency	**4**
Routine	**24**
Not known	**0**
In core hours	**14**
Out of core hours	**2**
Not known/applicable	**12**

Where transfusion took place	
ED	
Theatre/ITU/NNU/HDU/Recovery	**25**
Wards	**3**
Community	
Other	
Not known	

A total of 28 questionnaires were received and all have been analysed. There were no reports submitted during this reporting period that related to adverse events while undertaking acute normovolaemic haemodilution (ANH) or preoperative autologous donation (PAD). Both these methods are rarely undertaken and are not recommended as routine techniques.

Cell salvage adverse events pilot

The intraoperative and postoperative cell salvage (ICS and PCS respectively) adverse events pilot was a joint initiative between the UK Cell Salvage Action Group (UK CSAG) and SHOT. Cell salvage, both intraoperative and postoperative, is one of the techniques being more regularly employed by hospitals as part of their blood conservation programme. While these techniques are very safe when used by trained and competent staff, to date there has been no systematic collection of data relating to adverse incidents in these areas.

A survey commissioned by the UK CSAG in 2007 involved 212 hospitals, of which 113 said they use ICS (53.3%), 43 said they did not use ICS (20.2%) and 56 did not reply (26.4%).

The 6 month pilot commenced in June 2008 and all hospitals in the UK were invited to participate. Sixty-two hospitals agreed to participate.

The following were defined as adverse events:

- abandoned procedures due to operator error (incorrect assembly, use of non-intravenous (IV) solutions, incorrect anticoagulant, collection time exceeded)
- abandoned procedures due to machine failure (clotted lines/reservoirs)
- adverse clinical events or reactions (hypotension, air embolus, etc.)

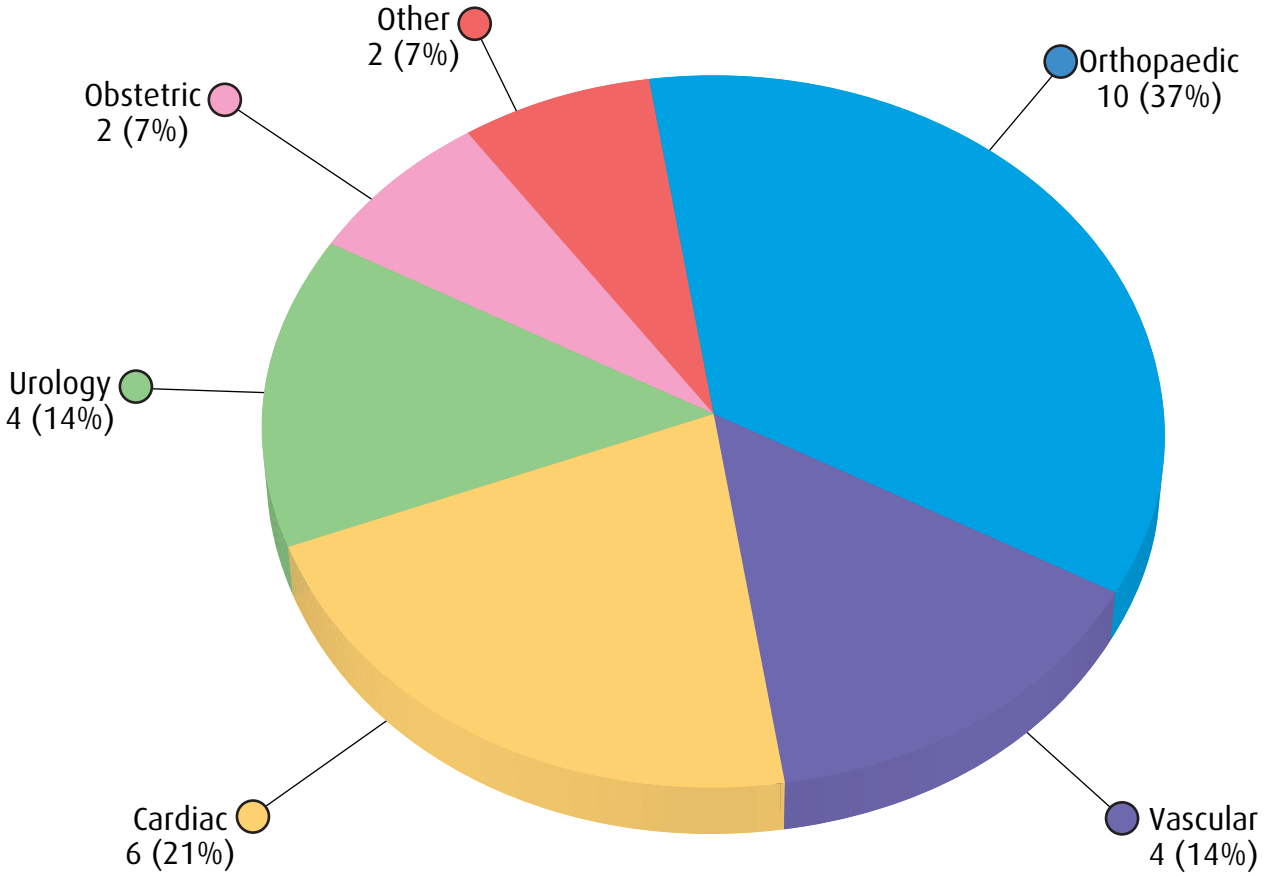
Overview of results

There were 28 reports from 15 participating hospitals. Of these, 3 incidents were reported to MHRA (2 machine failures and 1 reaction), 18 were not reported to MHRA (12 machine failures and 1 reaction), and 7 did not include a response. The operator errors could all be considered to relate to training issues. Of the incidents caused by machine errors, 5 incidents relating to clotting could equally be attributable to operator error if insufficient anticoagulation was incorporated/undertaken within the blood collection system.

Cell salvage type *n* = 28

- 25 intraoperative (washed) including 3 using a combined system (washed)
- 3 postoperative (unwashed)

Figure 25
Adverse events by specialty *n* = 28



Machine types and operators

Machine operators *n* = 32*

- 12 operating department practitioner (ODP)
- 3 perfusionist
- 2 consultant anaesthetist
- 11 nurse
- 4 manufacturer (commercial)

** In 4 procedures there were two operators:*

- *nurse plus manufacturer in 3 cases*
- *ODP plus perfusionist in 1 case*

Postoperative systems *n* = 3

- 2 Bellovac™ ABT, Astratech
- 1 Donor™, Van Straten Medical

ICS Machines *n* = 25

- 1 Fresenius C.A.T.S®
- 14 Haemonetics Cell Saver®
- 3 Haemonetics OrthoPAT®
- 7 Sorin Electa

Postoperative cell salvage incidents (PCS) *n* = 3

Operator error *n* = 3

- 2 bag fell off
- 1 collection bag not labelled

There were no machine or clinical adverse events or reactions from PCS in the pilot.

Intraoperative cell salvage incidents (ICS) *n* = 25

Operator errors *n* = 5

- 2 equipment not assembled correctly
- 2 non-IV saline used
- 1 surgeon dropped sucker

Machine errors *n* = 14

- 4 clotting of lines/centrifuge
- 1 clotting of filters
- 5 machine stopped working (3 OrthoPAT®)
- 2 failure not specified
- 2 other (harmony suction failure x 1, would not recognise bowl x 1)

Clinical adverse events and reactions *n* = 6

- 1 air embolus (minor morbidity)
- 5 hypotensive episodes (1 minor morbidity)

Case 1

Possible air embolus resulting from use of pressure bag during reinfusion

The patient was in ITU and extremely unwell with ischaemic bowel following emergency AAA repair. The BP and CO_2 dropped and the ITU team were called and noticed that the reinfusion bag was empty and still pressurised, suggesting that air had been forced into the central venous line. The reaction was attributed to air embolus. However, an echocardiogram failed to show the presence of air in the heart, and the hypotension and hypocarbia responded to increased inotropes, both of which would be unusual in symptomatic air embolus. Treatment was later withdrawn due to irreversible acidosis associated with ischaemic bowel. The possible air embolus has been classified as minor and not contributory to the death. Use of a pressurised system is against the manufacturer's instructions and Trust policy.

There were 5 reports of hypotension apparently caused by the reinfusion of cell-salvaged blood. This was the most common clinical incident reported. An attempt has been made to analyse the clinical scenarios and the common factors appear to be:

- use of acid citrate dextrose (ACD) as an anticoagulant
- use of a leucodepletion filter (LDF) during the reinfusion of autologous washed red cells

However, it appears that there are a number of other clinical issues:

1. Use of bedside LDF, which is known to cause hypotension when used with allogeneic blood occurring in 80 out of 20 million transfusions (0.0004%).[33]
2. These patients may have been hypovolaemic and therefore more susceptible to the vasoactive cytokines reinfused.
3. All patients experienced transient but significant hypotension corrected by the cessation of infusion plus or minus the administration of vasopressors
4. No long-term sequelae of this hypotension were noted.

These incidents will require further analysis. At this stage it is important that the possibility of an adverse event or reaction is recognised by the responsible clinician and treated by discontinuation of the infusion of the salvaged red cells and use of appropriate vasopressors and resuscitation fluid.

Denominator data

At the end of the pilot the participants were asked to provide denominator data for:

- total number of intraoperative cases undertaken during the period of the pilot
- total number of postoperative cases undertaken during the period of the pilot

Of the 62 hospitals taking part, 16 provided denominator data for the pilot period.

ICS procedures accounted for 2328 procedures with a range of 7–700 procedures per hospital, and this group accounted for denominator data for 13/25 reported incidents. The other 12/25 incidents did not supply denominator data.

PCS procedures accounted for 1412 procedures with a range of 4–450 procedures per hospital, and this group accounted for denominator data for all 3 reported incidents.

The paucity of data on the number of procedures undertaken, together with the very small number of procedures undertaken by some hospitals, may be a cause for concern. Further review of the data is required over a longer period to identify whether there is any correlation between the number of procedures undertaken and the frequency of adverse incidents. It is possible that organisations undertaking relatively few procedures have a disproportionate risk of adverse incidents due to infrequent use and lack of regular experience leading to operator error. This information gives strength to the work of the UK CSAG in:

- the need for education and competency assessments; these are already developed and available on the Better Blood Transfusion Toolkit at www.transfusionguidelines.org.uk
- a comprehensive UK reporting system for cell salvage.

RECOMMENDATIONS

- All cell salvage operators must undertake initial and regular update training and be assessed as competent. There should be documented evidence of competence in the form of a training record. Competency assessment workbooks are available for both ICS and PCS at www.transfusionguidelines.org.uk.

- All ICS and PCS related adverse events should be reported to SHOT.

- Monitoring of patients is as important for the reinfusion of red cells collected by ICS or PCS as it is for allogeneic red cells.

- Cell salvage machines are classified as Medical Devices, so all adverse events attributable to machine errors and failures should be reported to the MHRA as well as SHOT.

Whereas the pilot has concluded, data collection has not concluded and reporting of these adverse events will now form part of routine SHOT reporting.