

Section 7

Indications and Contraindications

Aim

- To highlight the surgical areas where Intraoperative Cell Salvage (ICS) is indicated or may be contraindicated

Learning Outcomes

- To identify the indications for ICS
- To identify the relative contraindications for ICS
- To outline when the risks/benefits of using/not using ICS change

Introduction

The routine use of ICS is recommended in many surgical procedures providing there are no local factors which may make its use inappropriate e.g. lack of competent staff. There is evidence from randomised controlled trials (RCT)¹ and observational reports² of decreases in allogeneic (donor) blood transfusion when ICS has been used.

The decision to collect blood is often based on a number of factors including:

- The anticipated blood loss for a particular surgical procedure
- Patient factors including:
 - Risk factors for bleeding
 - A low preoperative haemoglobin
 - Religious or other objections to receiving allogeneic (donor) blood

These factors are discussed in more detail in this section.



Each organisation should have a policy in place for ICS which includes the indications and contraindications for use.

A generic policy is available within the UKCSAG section of the JPAC website at:

<http://www.transfusionguidelines.org.uk/transfusion-practice/uk-cell-salvage-action-group>

7.1 Indications and Patient Selection

- ICS systems may be used in elective and/or emergency surgical procedures where the surgical field is not contaminated by faecal or infective matter and where no other contraindications exist (see 7.2).
- Patient selection for ICS is at the discretion of the surgeon and anaesthetist caring for the patient.
- Providing that none of the contraindications listed in Section 7.3 exist, patients to be considered for ICS include:
 - Adult and paediatric patients undergoing elective or emergency surgical procedures, where the anticipated blood loss is greater than 20% of the patient's estimated blood volume.
 - Adult and paediatric patients undergoing elective or emergency surgical procedures who have risk factors for bleeding or low preoperative haemoglobin levels.
 - Patients who have rare blood groups or multiple antibodies for whom it may be difficult to obtain allogeneic (donor) blood.
 - Patients who, for moral, religious or other reasons, are unwilling to receive allogeneic (donor) blood and have given their consent to receiving autologous blood collected using ICS (all such decisions should be documented). Reference should be made to the patient's Advance Medical Directive where one exists.
 - ICS is used in laparoscopic surgery as well as open surgery.
 - Areas where there seems little debate that ICS can be employed are listed below (this is not an exhaustive list).
- Total knee replacement (if no tourniquet is used)
- Revision total hip replacement
- Total hip replacement
- Spinal surgery
- Abdominal aortic aneurysm surgery
- Traumatic liver or spleen injury not associated with perforated bowel
- Thoracic aneurysm surgery
- Cardiac surgery
- Benign urological surgery

7.2 Patient Consent

If a patient is likely to have cell salvage as part of their operation the process should be discussed with them pre-operatively whenever possible and documented accordingly. A patient information leaflet from the UK Cell Salvage Action Group to support this is available to be downloaded from the transfusionguidelines.org.uk website.

If it is not possible to discuss the process with the patient pre-operatively (e.g. in an emergency procedure), it is good practice to inform the patient retrospectively.

Autologous transfusion may be accepted for use by Jehovah Witnesses, but must be discussed pre-operatively with the individual and their decision documented accordingly. If the Jehovah's Witness patient does not already have an advance decision document or another document indicating treatments that are acceptable, this should also be discussed. Cell salvage itself will not prevent patients from donating blood once they have fully recovered from their operation, but associated perioperative treatments that necessitate deferral as a blood donor should be discussed with the patient. This includes transfusion of allogeneic blood.

7.3 Relative Contraindications, Warnings and Cautions

The risk/benefit ratio of ICS should be assessed for each individual patient by the surgeon and anaesthetist responsible for the patient's care.

Relative Contraindications

ICS should not be used in the following situations:

- Bowel contents in the surgical field (this is discussed in more detail later – see 7.3)
- Infected surgical fields - the use of ICS in the presence of infection may result in bacterial contamination of the salvaged blood. The aspiration of blood from an infected site should be avoided and antibiotics should be given as appropriate.
- Sickle cell disease - there are concerns relating to the use of ICS in patients with sickle cell disease (SCD). Several reports have been published describing successful cell salvage use in patients with sickle cell trait. However, in SCD, limited case reports describe no useable red blood cells recovered with a high percentage of cells showing characteristic sickle shape under light microscopy after processing. The use of ICS in patients with abnormal red cell disorders should be made on a clinical, individual patient basis.
- Heparin induced thrombocytopenia if heparin is the only available anticoagulant for ICS (a citrate anticoagulant solution may be used instead)

Warnings

- ICS should be temporarily discontinued when substances not licensed for intravenous (IV) use are used within the surgical field and could potentially be aspirated into the collection reservoir. The standard theatre suction should be used to aspirate the surgical field and the wound should be irrigated with copious IV normal saline (0.9% NaCl) before resuming ICS.

Examples of non-IV materials that should not be aspirated into the ICS system include:

- Antibiotics not licensed for IV use
- Iodine
- Topical clotting agents
- Orthopaedic cement

A list of potential contaminants and their associated problems can be found in the UK Cell Salvage Action Group document “Technical Factsheet 9 – Contraindications to ICS”¹.

- Gastric/pancreatic secretions should not be aspirated into the system as they may cause enzymatic haemolysis and are not reliably removed by the washing procedure.
- Pleural effusions should not be aspirated and should be drained prior to cell salvage. However, blood which subsequently accumulates in the pleural space may be aspirated.
- Metal fragments from implants can be present in the surgical field in some orthopaedic procedures, e.g. Although metallosis is rare, with an incidence of around 5% for metal on metal joint implants, it is unclear as to how successful ICS devices are in removing metal fragments. If there is evidence of metallosis, in most situations cell salvage should be avoided or the risk benefit carefully assessed in cases of high blood loss

Cautions

- The use of Hartmann’s Solution will inhibit the action of citrate based anticoagulants (e.g. ACD) if used as an irrigant or wash solution.
- Air will be present in the primary reinfusion bag when it is still connected to the cell saver or when it has been disconnected but air has not been evacuated. Where possible, all air should be evacuated from the primary reinfusion bag prior to reinfusion. Manufacturers advise NOT to use a pressure cuff as there is a risk of air embolus and some devices may also detect a back pressure if the reinfusion line is open.
- Manual mode – It is recommended that ICS devices are not run in manual mode as this may lead to reduced quality, insufficient washing of the final red blood cell product and the possible reinfusion of potentially harmful contaminants e.g. heparin. Machines should be run in automatic mode and manual mode should only be used when the benefits of doing so outweigh the risks, e.g. emergency situations where the need to reinfuse the red cells quickly outweighs the risks associated with running the machine in manual mode.

7.4 Areas for Further Consideration

The remainder of this section examines the use of ICS in procedures where there is the potential for contamination from within the surgical field.



The decision to use blood that is potentially contaminated with bacteria, amniotic fluid or malignant cells should be made by the clinicians caring for the patient, taking into account the latest evidence and considering the risk and benefits for the individual patient. Where possible, the options should be discussed with the patient prior to surgery.

Bowel Contamination

As outlined earlier, the use of ICS in the presence of bowel contents is contraindicated. However, in cases of catastrophic haemorrhage, a clinical decision to use ICS may be made as the benefit may outweigh the risk of bacterial contamination.

If deemed clinically necessary the following practical tips may help:

- Initial evacuation of the soiled abdominal contents
- Additional washing (increasing the volume of IV normal saline (0.9% NaCl) the machine uses to wash the salvaged blood)
- Reinfuse using a leucodepletion filter⁴ (Waters *et al*).
- Ensure use of broad spectrum antibiotics

It is unlikely that bowel contamination in such traumatised individuals will lead to problems in decision making about the use of ICS, but hopefully the points raised can enable all concerned to make informed management choices.

Malignancy

The use of ICS in patients undergoing surgery for malignant disease is not recommended by the manufacturers of ICS devices. This is due to concern about the possibility of malignant cells being reinfused and giving rise to metastases. However, there are now a number of published reports outlining the use of ICS in cancer surgery without obviously leading to early metastasis, some hospitals now use ICS routinely during surgery for malignant disease. Aspiration of blood from around the tumour site should be avoided to minimise contamination of salvaged blood with malignant cells. The salvaged blood should be reinfused through a leucodepletion filter to minimise the reinfusion of any malignant cells which may have been aspirated into the collection reservoir.

Theoretical context

If there is concern that circulating malignant cells may lead to systemic spread then it is inadvisable to reinfuse any malignant cells. If the cancer cells are present in the final ICS blood for reinfusion, they must have been contaminating the collected blood prior to processing. These cells can only be present in the blood if:

- The tumour margins had been compromised at the time of resection making the whole operation palliative (as the likelihood of local recurrence would be high).
- The cancer cells were already blood borne at the time of surgery as resection of blood vessels distant from the tumour margins led to spillage of cancer cells directly from the circulating systemic blood.
- Cancer cells had already spread to the lymphatic system.

Practical Issues

- The use of a Leukoguard® RS filter (Haemonetics Ltd), a leucodepletion filter, is likely to lead to a 99.99% reduction in the number of nucleated (including malignant) cells present in the ICS blood for reinfusion.
- In large cancer centres it may be possible to safely organise irradiation of the collected blood. This would destroy all viable cancer cells within the ICS blood for reinfusion (see the 'Caution Box' on the next page). It has been recommended that a dose of 50Gy be used.⁵



Under European legislation⁶, the irradiation of red cells requires hospitals to register as a Blood Establishment and the irradiated ICS blood product would be subject to the requirements of the Medicines and Healthcare products Regulatory Agency (MHRA).

In addition, if the red cells are removed from the patients side (i.e. to another area of the hospital) to be irradiated, the risk of administration errors (the most frequently reported allogeneic (donor) blood incident) increases.

Obstetrics

The main concern surrounding the use of ICS during obstetric haemorrhage is the risk of reinfusing fetal contaminants with the theoretical risk of causing amniotic fluid embolus.

ICS is being increasingly used in the UK in obstetrics for women at risk from massive obstetric haemorrhage during caesarean section. In the year 2005-06, 38% of UK maternity units used ICS, and 28% included the use of ICS in their Massive Obstetric Haemorrhage (MOH) protocol. Early theoretical concerns over amniotic fluid embolism have not been borne out in clinical practice, and 80% of maternity units identified lack of training, rather than safety concerns as the barrier to more frequent use of ICS.

The use of ICS in obstetrics has been endorsed by:

- Centre for Maternal and Child Enquiries (CMACE) (formerly CEMACH) Joint Association of Anaesthetists of Great Britain and Ireland/Obstetric Anaesthetists Association (AAGBI/OAA) Guidelines
- National Institute for Health and Clinical Excellence (NICE)

It is strongly recommended that any health care professional involved with obstetric ICS is familiar with all these guidelines.

Patient Selection and Preparation

Wherever possible, the advantages and risks of ICS and allogeneic (donor) blood transfusion should be discussed with the woman prior to undergoing an obstetric surgical procedure (see section 7.2 Patient Consent).

Indications for ICS in Obstetrics

Case selection for ICS is at the discretion of the obstetrician and anaesthetist caring for the woman. The type of obstetric cases that should be considered for selection include:

- Emergency situations:
 - Ruptured ectopic pregnancy
 - Placental abruption
 - Any emergency caesarean section where there is:
 - An anticipated blood loss of >1000mls
- Or where any of the following are present:
 - Risk factors for bleeding
 - Low pre-operative haemoglobin
 - Rare blood group / multiple antibodies
 - The woman has objections to receiving allogeneic blood but has consented to receiving cell salvage blood
- Surgical management of postpartum haemorrhage Elective situations:
 - Patients with an anticipated blood loss of >1,000mls e.g. placenta praevia with placenta accrete/increta or percreta, large uterine fibroids, and other predictable causes of MOH.
 - Women who, for religious or other reasons refuse allogeneic blood and have consented to the use of ICS in elective or emergency bleeding situations or in the presence of significant anaemia.

Practical Measures in Obstetric ICS

- Amniotic fluid and use of leucodepletion filter – Amniotic fluid should ideally not be aspirated into the ICS collection reservoir. A separate suction can be used to aspirate amniotic fluid prior to starting cell salvage. This recommendation will reduce the initial contamination, but it should be noted that the in vitro evidence suggests that the ICS process can effectively remove plasma phase elements of amniotic fluid (i.e. those less dense than red blood cells) whatever the initial load. Therefore, in life-threatening haemorrhage, a clinical decision to use ICS from the start of the procedure could be carefully considered and is supported by current in vitro evidence. The UK Cell Salvage Action Group is aware that since 2008, when the paper by Sullivan et al⁷ provided evidence that the one suction approach could be safely considered, a number of hospitals in the UK have adopted this approach irrespective of estimated blood loss.
- To ensure efficient washing, use a quality wash programme and consider increasing the standard saline wash volume. Do not process incomplete bowls as this will compromise the washing efficiency (use “concentrate” where appropriate).
- After processing, a Leukoguard® RS filter (Haemonetics Ltd) should be used to reinfuse the cell salvaged blood*. This is the only filter proved to effectively eliminate residual particulate elements of amniotic fluid⁸. It should be remembered that prior to the year 2000, this filter was not available, but over 250 cases worldwide had safely received cell-salvaged blood without a problem. This filter slows infusion rates considerably. When blood loss is rapid, the flow rate through the filter may not be sufficient to give back large volumes of blood quickly. Using a filter in each port will double the flow rate. The use of a pressure cuff is not advised due to the risk of air embolus and the unknown impact of pressure on the retention of amniotic contaminants within the filter. In life-threatening haemorrhage, however, where allogeneic blood may not be readily available or is refused, a clinical decision to remove the filter completely should be carefully considered.
- Rh Immunisation and Kleihauer testing – In any pregnancy, if the mother is RhD negative and the fetus is RhD positive there is a danger of RhD immunisation if the maternal circulation is exposed to fetal red cells. Antibodies against the fetal red cells can cause haemolytic disease of the newborn in subsequent pregnancies if untreated, consequently all RhD negative women who deliver an RhD positive baby will have a FMH test performed post delivery. FMH testing is required to establish the amount of fetal red cell exposure and ensure the recipient receives an appropriate dose of anti-D immunoglobulin (usually 125 iu/ml of fetal blood). Depending on the results of this (and if the baby is RhD positive) a minimum of 500iu anti-D will be given. The same protocol should apply for RhD negative women who have received salvaged red cells. If cell salvage is used in such women, exposure to fetal red cells is very likely because the cell saver centrifuge cannot distinguish fetal from maternal red cells. Where cell salvage is used and where cord blood group is confirmed as RhD positive (or unknown) an initial dose of 1500iu anti-D is recommended following reinfusion of the ICS blood. The sample for Kleihauer testing should be taken 30 – 40 minutes after the reinfusion of the ICS blood and depending on the results it may be that further doses of anti-D will need to be administered⁹. Administration of anti-D should occur within 72 hours of delivery.

It should be remembered that the risk of sensitisation to other antigens may also be higher as a result of cell salvage being used. It has therefore been suggested that all women receiving cell salvaged blood should be followed up between 4 – 6 months post-delivery to check for antibody formation, however this is not currently practicable in most centres.



The sample for Kleihauer testing should be taken after the reinfusion of ICS blood and administration of Anti-D should occur within 48-72 hours of delivery.

Key Points

- ICS is of proven benefit in certain elective and emergency surgical procedures where the predicted blood loss is in excess of 20% of the patient's estimated blood volume.
- ICS should only be used in malignancy when the benefits outweigh the risks.
- ICS should be available for obstetric cases where there is the potential for massive haemorrhage.

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Further reading

UK Cell Action Group Publications.

The following publications are available to download at:
www.transfusionguidelines.org.uk

- Policy for the provision of Intraoperative Cell Salvage
- Technical Factsheets:
 - 8 – Intraoperative Cell Salvage in Obstetrics
 - 9 – Contraindications to ICS

Meta-analyses and Reviews

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 - Saving Mothers' Lives: Reviewing maternal deaths to make motherhood safer 2003-2005 (2007) Confidential Enquiry into Maternal and Child Health (CEMACH)
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- ### Professional Standards and Guidelines
- Blood transfusion; NICE guideline, Published: 18 November 2015
[nice.org.uk/guidance/ng24](http://www.nice.org.uk/guidance/ng24)
 - American Association of Blood Banks – Standards for Perioperative Autologous Blood Collection and Administration 3rd Edition (ISBN-978-1-56395-248-7)

Self-Directed Learning



Do you Use ICS in obstetrics in your organisation? If so, for what procedures is ICS routinely set up for?



Do you keep leucodepletion filters in your department? If yes, describe how to prime the filter.



Is ICS in your organisation for cases of malignancy? If yes, what procedures are performed using ICS?