

NATIONAL INSTITUTE FOR CLINICAL EXCELLENCE

INTERVENTIONAL PROCEDURES ADVISORY COMMITTEE

Interventional procedure overview of intraoperative blood cell salvage in obstetric procedures

Introduction

This overview has been prepared to assist members of IPAC advise on the safety and efficacy of an interventional procedure previously reviewed by SERNIP. It is based on a rapid survey of published literature, review of the procedure by one or more specialist advisor(s) and review of the content of the SERNIP file. It should not be regarded as a definitive assessment of the procedure.

Date prepared

This overview was prepared in December 2004

Procedure name

- Intraoperative blood salvage,
- Intraoperative autotransfusion,
- Intraoperative red cell salvage.

Specialty societies

- British Society of Haematology,
- Royal College of Midwives
- Royal College of Obstetricians and Gynaecologists
- Association of Anaesthetists of Great Britain and Ireland

Indications

Intraoperative cell salvage is a commonly used technique in cardiac and orthopaedic surgery. However cell salvage has not been routinely adopted in the obstetric field for use in women at risk of postpartum haemorrhage following Caesarean section, where there may be specific safety concerns regarding embolism, or haemolytic disease as a result of re-infusion of foetal cells, or amniotic fluid.

Postpartum haemorrhage (PPH) is defined as a blood loss of more than 500 ml after vaginal delivery and more than 1,000 ml after caesarean delivery. Massive uncontrolled haemorrhage after childbirth is a leading cause of pregnancy-related death. The potential advantages of intraoperative cell salvage are reduced incidence of transfusion reactions and transfusion related infection, as may result from the use of banked blood.

Current Treatments and Alternatives

Commonly banked blood transfusion (allogeneic transfusion) is carried out. Intraoperative cell salvage is an alternative to conventional transfusion from a donor; with blood that has

been taken from the same patient before her operation (pre-donation); or transfusion of blood removed from the patient at the time of the operation with volume replacement with intravenous fluids (acute normovolaemic haemodilution).

What the procedure involves:

Intra-operative cell salvage is the process whereby shed surgical field blood is collected, filtered, and washed to produce autologous red blood cells for transfusion to the patient. During intra-operative blood cell salvage during Caesarean section, blood that is lost during the operation is aspirated from the surgical field using a catheter. The blood is then suctioned in a reservoir in which a filter removes gross debris. The filtered blood is then washed and re-suspended in saline for transfusion, which may be re-transfused either during or after the operation.

A leukocyte depletion filter may also be used in this process to reduce the number of leukocytes in transfused blood which may reduce adverse reactions to re-infused blood and limit disease transmission.

Efficacy

A three centre comparative study found that the median volume of reinfused blood was between 250 and 450ml per patient. No significant difference in hospital length of stay, time on ventilatory support, intravascular coagulation, or infection morbidity was found between women receiving salvaged blood and controls(1)

In a comparative study of women having a Caesarean section among 34 receiving blood cell salvage the blood haemoglobin level fell from 10.7 g/dl at baseline to 10.2 g/dl postoperatively, whereas in the same number of women receiving standard transfusion the haemoglobin level fell from 11.7 to 8.6 g/dl(2). Hospital length of stay was significantly shorter with the blood cell salvage procedure being 5.3 days Vs 7.3 days in women without blood cell salvage ($p < 0.003$). During this study foetal haemoglobin was found in 20% (3/15) patients who had blood salvaged but not re-infused, where the foetal levels were 1.8 to 2.0% of total haemoglobin.

Safety

In the blood cell salvage arm of a comparative study of women having Caesarean sections 3% (1/34) of patients had cystitis with pyrexia, and the same proportion subfascial parietal haematoma. No complications due to re-infusion were noted(2).

There were no instances of acute respiratory distress or amniotic fluid embolism in 139 women in the cell salvage arm of a controlled trial but some cases did not require homologous transfusion during their procedure(1)

No complications were reported using salvaged blood treated with a leukocyte depletion filter in four reported cases(3)

Literature review

Rapid Review of Literature

The medical literature was searched to identify studies and reviews relevant to Intraoperative blood salvage. Searches were conducted via the following databases from commencement to 12 December 2004: MEDLINE, PREMEDLINE, EMBASE, Cochrane Library and Science

Citation Index. Trial registries and the Internet were also searched. No language restriction was applied to the searches.

The following selection criteria were applied to the abstracts identified by the literature search. Where these criteria could not be determined from the abstracts the full paper was retrieved

Inclusion criteria for identification of relevant studies

Characteristic	Criteria
Publication type	Clinical studies included. Emphasis was placed on identifying good quality published studies. Abstracts were excluded where no clinical outcomes were reported; the paper was a review, editorial, laboratory or animal study. Conference abstracts were also excluded due to the difficulty in appraising methodology.
Patient	Women undergoing Caesarean section for delivery, ruptured ectopic pregnancy, or post partum haemorrhage
Intervention/test	Intraoperative blood salvage
Outcome	Articles were retrieved if the abstract contained information relevant to the safety and/or efficacy
Language	Non-English language articles will be excluded unless they are thought to add substantively to the English language evidence base.

List of studies included in the overview

4 studies were identified for inclusion in the overview . All studies were uncontrolled studies.

Existing reviews on the procedure

Carless PA, Henry DA, Moxey AJ, O'Connell DL, Fergusson DA. Cell salvage for minimising perioperative allogeneic blood transfusion (Cochrane Review).

This review however only included patients in whom surgery was elective or non-urgent, thereby excluding trials in obstetrics, and is therefore not included in this overview.

Summary of key efficacy and safety findings obstetrics

Abbreviations used: CS – cell salvage; PAD – preoperative autologous donation; RBC – red blood cells

Study details	Key efficacy findings			Key safety findings	Comments																		
Rainaldi et al (1998) (2) Women having a caesarean section. 68 patients 'randomly' allocated to two groups 34 patients earmarked for cell salvage if required Mean age: 33.6 years (22-43 years) 34 patients for whom intraoperative blood was not to be salvaged Mean age: 31.9 years (16-41 years) Technology: Blood was salvaged using the Dideco machine.	Outcomes reported: amount of blood salvaged, haemoglobin levels, number of patients receiving homologous blood, hospital stay <table><tr><td>Outcomes</td><td>Cell salvage</td><td>Non salvage</td></tr><tr><td>Blood salvaged</td><td>363 ml (125-800ml)</td><td>-</td></tr><tr><td>No. of patients homologous blood</td><td>1 patients</td><td>8 patients (p=0.01)</td></tr><tr><td>Mean base haemoglobin level</td><td>10.7</td><td>11.7 p>0.0001</td></tr><tr><td>Mean postoperative haemoglobin level</td><td>10.2</td><td>8.6 p<0.0001</td></tr><tr><td>Length of stay (days)</td><td>5.3</td><td>7.3 P<0.003</td></tr></table> Analysis of blood; 15 patients (salvaged not reinfused) Foetal haemoglobin was absent, except in three patients in which it was 1.8-2.0%. In these three patients foetal haemoglobin was also present in maternal blood. 9 patients had homologous red blood cells during (1 blood salvage and 8 no blood salvage)			Outcomes	Cell salvage	Non salvage	Blood salvaged	363 ml (125-800ml)	-	No. of patients homologous blood	1 patients	8 patients (p=0.01)	Mean base haemoglobin level	10.7	11.7 p>0.0001	Mean postoperative haemoglobin level	10.2	8.6 p<0.0001	Length of stay (days)	5.3	7.3 P<0.003	Complications Cell salvage 1 patients had cystitis with pyrexia 1 patient had subfascial parietal haematoma No complications due as a result of re-infusion of salvaged blood. Non salvage 2 patients hyperpyrexia (after transfusion of homologous blood) 1 patients pulmonary oedema	Randomisation method not described. In 15 patients blood was salvaged, not reinfused by subjected to a series of tests. No inter-group comparison of change in haemoglobin level from baseline was made, only follow up vs baseline was calculated for each group
Outcomes	Cell salvage	Non salvage																					
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Abbreviations used: CS – cell salvage; PAD – preoperative autologous donation; RBC – red blood cells

Study details	Key efficacy findings	Key safety findings	Comments												
Rebarber et al (1998) (1) Patients were those who had undergone a caesarean section. Also each centre had a control group 3 centres - Yale New Haven Hospital 12 patients (29 controls) - Good Samaritan Hospital 6 patients (11 controls) - Hinsdale Hospital 121 patients (47 controls) Technology: cell saver	Outcomes reported Salvaged blood cells reinfused (ml) <table><thead><tr><th></th><th>Median</th><th>Range</th></tr></thead><tbody><tr><td>Yale New Haven</td><td>250</td><td>125-4750</td></tr></tbody></table> 4 (33%) patients completely avoided homologous transfusion 41% of blood was cell salvaged <table><tbody><tr><td>Good Samaritan</td><td>543</td><td>225-1160</td></tr></tbody></table> 3 (50%) patients completely avoided homologous transfusion 27% of blood was cell salvaged <table><tbody><tr><td>Hinsdale Hospital</td><td>450</td><td>200-11,250</td></tr></tbody></table> Unclear how many people avoid homologous transfusion. 31% of blood was cell salvaged Hospital admission There was no significant difference reported between women receiving cell salvage and controls in length of stay, time on ventilatory support, intravascular coagulation, or infection morbidity		Median	Range	Yale New Haven	250	125-4750	Good Samaritan	543	225-1160	Hinsdale Hospital	450	200-11,250	Complications Authors noted that there was no case of acute respiratory distress syndrome or amniotic fluid embolism. One maternal death occurred in Hinsdale hospital (unrelated). One patient from Yale New Haven Hospital developed a case of heparin toxicity. There was one case of heparin toxicity.	Retrospective review Different models of the cell saver had been used over the different years – and the method used differed between the three sites – Yale New Haven hospital used an additional filter. Differences in postoperative care among the three sites. Differences between patients and controls.
	Median	Range													
Yale New Haven	250	125-4750													
Good Samaritan	543	225-1160													
Hinsdale Hospital	450	200-11,250													
Catling et al (1999) (3) 4 maternity unit patients - 3 caesarean sections - 1 post partum haemorrhage Technology: Washed Haemonetics Cell Saver 5 (Braintree, MA, USA) Filtered using a leukocyte depletion filter	Outcomes reported: case details Four case reports – patients received varying amounts of salvaged blood.	Complications No complications as result of salvaged blood were reported.	Limited information.												

Validity and generalisability of the studies

- No randomised controlled trials
- Older case series may have utilised older technology
- No data to determine the benefit of leukocyte filter
- There may be different efficacy and safety profiles for use in different obstetric indications, but the majority of the data relates to blood cell salvage in Caesarean section

Specialist advisors' opinions

- Theoretical safety concerns include inadvertent infusion of foetal cells with potential haemolytic disease in future pregnancy, or infusion of amniotic fluid causing amniotic fluid embolus.
- Efficacy may depend on nature and volume of blood loss during procedures, and coagulation factors may still be required where there is large blood loss
- Blood cell salvage may potentially reduce incidence of anaemia
- Patient selection may be important and the numbers suitable for salvage may effectively turn out to be quite small, however, if found to be safe and efficacious will be taken up by most district general hospitals
- A service will require a pool of trained staff, and with many cases on an emergency basis planning may be difficult.

Issues for consideration by IPAC

- Risk of VCJD infection and shortage of donor supplies makes intraoperative blood cell salvage a pertinent issue
- Pre-operative blood cell salvage is not considered in this overview.

References

- (1) Rebarber A, Lonser R, Jackson S, Copel JA, Sipes S. The safety of intraoperative autologous blood collection and autotransfusion during cesarean section. *American Journal of Obstetrics & Gynecology* 1998; 179(3 Pt 1):715-720.
- (2) Rainaldi MP TPS. Blood salvage during caesarean section. [see comments.]. *BJA: British Journal of Anaesthesia* 1998; 80(2):195-198.
- (3) Catling SJ, Freitas O, Krishnan S, Gibbs R. Clinical experience with cell salvage in obstetrics: 4 Cases from one UK centre. *International Journal of Obstetric Anesthesia* 2002; 11(2):128-134.

Appendix A:
Additional papers on selective international radiation therapy not included in the summary tables

Study details	Number of patients	Outcomes	Comments
Waters JH, Biscotti C, Potter PS, Phillipson E. Amniotic fluid removal during cell salvage in the cesarean section patient.[comment]. Anesthesiology 2000; 92(6):1531-1536.	15 patients undergoing elective caesarean section	Bacterial contaminations was significantly less for the prostfiltrations and maternal samples when compared with the prewash sample.	Leukocyte depletion filtering of cell-salvaged blood obtained from caesarean section significantly reduces particulate contaminants to a concentration equivalent to maternal venous blood.
Bernstein HH, Rosenblatt MA, Gettes M, Lockwood C. The ability of the Haemonetics(TM) 4 Cell Saver System to remove tissue factor from blood contaminated with amniotic fluid. Anesthesia & Analgesia 1997; 85(4):831-833.	29 women undergoing caesarean section	Tissue factor was reduced by 100-89% by using the cell saver system.	Authors concluded that the cell saver system can remove tissue factor from blood contaminated with amniotic fluid.
Catling SJ, Williams S, Fielding AM. Cell salvage in obstetrics: An evaluation of the ability of cell salvage combined with leucocyte depletion filtration to remove amniotic fluid from operative blood loss at caesarean section. International Journal of Obstetric Anesthesia 1999; 8(2):79-84.	27 elective caesarean sections	Fetal squames could not be completely removal by cell-salvage combined with leucocyte depletion filtration.	Autotransfusion by cell salvage with leucocyte depletion filtrations should be considered life threatening obstetric haemorrhage and offered to Jehovah's witnesses.
Jackson SH, Lonser RE. Safety and effectiveness of intracasean blood salvage [1]. Transfusion 1993; 33(2):181.	64 patients From Hinsdale and Good Samaritarin hospital	No clinical evidence of amniotic fluid embolus or any other adverse outcome.	Letter to editor Maybe the same patients as in later paper
Oei, G., Wingen CBM, Kerkkamp HEM, Catling S. Cell salvage: How safe in obstetrics? (multiple letters). International Journal of Obstetric Anesthesia 2000; 9(2):143-144.	1 patient – case report	Maternal death – possibly due to amniotic fluid embolism	Case report – limited details.
Fuhrer Y, Bayoumeu F, Boileau S, Dousset B, Foliguet B, Laxenaire MC. [Evaluation of the blood quality collected by cell-saver during cesarean section]. [French]. Annales Francaises d Anesthesie et de Reanimation 1996; 15(8):1162-1167.	20 patients undergoing caesarean section	Results were very heterogeneous and after washing some salvaged units contained very high concentrations of alpha-fetal-protein or tissue factor.	Labortory study French

Appendix A: Search history.

This search was updated to 12/12/04 using the initial search strategy and with studies relating to the use of blood cell salvage in Oncology removed by eye.

#	Search History	Results	Display
1	blood transfusion autologous.mp. or exp Blood Transfusion, Autologous/	5134	Display
2	cell salvage.mp.	97	Display
3	autologous blood.mp.	3162	Display
4	or/1-3	6653	Display
5	autologous blood.ti.	1357	Display
6	5 or 2	1445	Display
7	neoplasms.mp.	161894	Display
8	cancer.mp.	395354	Display
9	tumo?r\$.mp.	674781	Display
10	recurrence.mp.	154297	Display
11	or/7-10	1095015	Display
12	exp Obstetrics/ or gyneecology.mp. or exp Gynecology/	12437	Display
13	obstetric\$.mp.	42642	Display
14	amniotic fluid.mp.	19208	Display
15	or/12-14	63841	Display
16	6 and 11	166	Display
17	15 and 4	58	Display
18	hematopoietic stem cell transplantation.mp. or exp Hematopoietic Stem Cell Transplantation/	10952	Display
19	stem cell transplantation.mp. or exp Stem Cell Transplantation/	13443	Display
20	stem cell.mp. or exp Stem Cells/	114437	Display
21	or/18-20	118061	Display
22	16 not 21	94	Display
23	17 not 21	58	Display

