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Li J, Sun SL, Tian JH, Yang K, Liu R, Li J

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[Intervention Review]

Cell salvage in emergency trauma surgery

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ABSTRACT

Background

Trauma is the leading cause of death in people under the age of 45 years. Over the past 20 years, intraoperative autologous transfusions (obtained by cell salvage, also known as intraoperative blood salvage (IBS)) have been used as an alternative to blood products from other individuals during surgery because of the risk of transfusion-related infections such as hepatitis and human immunodeficiency virus (HIV). In this review, we sought to assess the effects and cost of cell salvage in individuals undergoing abdominal or thoracic surgery.

Objectives

To compare the effect and cost of cell salvage with those of standard care in individuals undergoing abdominal or thoracic trauma surgery.

Search methods

We ran the search on 25 November 2014. We searched the Cochrane Injuries Group's Specialised Register, Cochrane Central Register of Controlled Trials (CENTRAL, *The Cochrane Library*), Ovid MEDLINE, Ovid MEDLINE In-Process & Other Non-Indexed Citations, Ovid MEDLINE Daily and Ovid OLDMEDLINE, EMBASE Classic + EMBASE (OvidSP), PubMed, and ISI Web of Science (SCI-Expanded & CPSI-SSH). We also screened reference lists and contacted principal investigators.

Selection criteria

Randomised controlled trials comparing cell salvage with no cell salvage (standard care) in individuals undergoing abdominal or thoracic trauma surgery.

Data collection and analysis

Two authors independently extracted data from the trial reports. We used the standard methodological procedures expected by The Cochrane Collaboration.

Main results

Only one small study (n = 44) fulfilled the inclusion criteria. Results suggested that cell salvage did not affect mortality overall (death rates were 67% (14/21 participants) in the cell salvage group and 65% (15/23) in the control group) (odds ratio (OR) 1.07, 95% confidence interval (CI) 0.31 to 3.72). For individuals with abdominal injury, mortality was also similar in both groups (OR 0.48, 95% CI 0.11 to 2.10).

Less donor blood was needed for transfusion within the first 24 hours postinjury in the cell salvage group compared with the control group (mean difference (MD) -4.70 units, 95% CI -8.09 to -1.31). Adverse events, notably postoperative sepsis, did not differ between groups (OR 0.54, 95% CI 0.11 to 2.55). Cost did not notably differ between groups (MD -177.81, 95% CI -452.85 to 97.23, measured in GBP in 2002).

Authors' conclusions

Evidence for the use of cell salvage in individuals undergoing abdominal or thoracic trauma surgery remains equivocal. Large, multicentre, methodologically rigorous trials are needed to assess the relative efficacy, safety and cost-effectiveness of cell salvage in different surgical procedures in the emergency context.

PLAIN LANGUAGE SUMMARY

In people undergoing emergency surgery to the chest or abdomen, how effective is transfusing a person's own blood compared with donor blood

Background

Trauma is the leading cause of death in people under the age of 45 years. Over the past 20 years, transfusions using an individual's own blood, salvaged during surgery through a process called 'cell salvage' (also known as intraoperative blood salvage), have been used as an alternative to blood products donated from other individuals (standard care) during surgical procedures. Many people prefer this because of the risk of transfusion-related infections such as hepatitis and human immunodeficiency virus (HIV) from donor blood. In this review, we aimed to determine how effective cell salvage is, compared with usual care, in individuals undergoing abdominal or thoracic (chest) trauma surgery. We considered outcomes including the survival of the individual, their need for extra blood and the costs of this procedure compared with standard care.

Search date

Evidence in this review is current to 25 November 2014.

Study characteristics

We identified one randomised controlled trial, which involved people with a penetrating injury to the chest. In this study, 44 people (mostly male and with similar characteristics in terms of type of injury) were given either their own reprocessed blood (through cell salvage) or standard care using donated blood. The study was conducted at a hospital in Johannesburg, South Africa in 2002.

Results

Results indicated no important differences between the two groups of participants with regard to survival, postoperative infection, or cost. There was a reduction in the amount of banked blood (blood that has been donated and stored) required for transfusion within the first 24 hours following injury among people receiving cell salvage. Data on other adverse events were not reported.

We believe that larger, multicentre, methodologically rigorous trials are needed to assess the relative efficacy, safety and cost-effectiveness of cell salvage in trauma surgery and other surgical procedures.

Quality of the evidence

The quality of the one study identified was high, but the number of participants was not large. No firm conclusions can be drawn as to the safety and effectiveness of cell salvage in individuals undergoing abdominal or thoracic trauma surgery.

BACKGROUND

Description of the condition

Trauma is the leading cause of death in people under the age of 45 years (Soyuncu 2007). Chest trauma constitutes about 10% to 15% of injury cases and is responsible for about 25% of trauma deaths (Ziegler 1994). A further 10% of deaths result from abdominal injury (Ong 1994; Soyuncu 2007), which may be blunt (84%) or penetrating (16%) (Rozycki 1993). Uncontrolled bleeding is a major cause of death after trauma, and there is a correlation between the transfusion of blood products and morbidity (Moore 1997; Bowley 2006). Approximately 40% of the 11 million units of blood transfused in the USA each year are used for the emergency resuscitation of patients (Schulman 2002). The demand for blood is increasing, but the population of eligible, willing and healthy donors is in decline (Bowley 2006).

Description of the intervention

Donated blood is a scarce and expensive resource. Over the past 20 years, intraoperative autologous transfusions (obtained by cell salvage, also known as intraoperative blood salvage) have been used as an alternative to blood products from other individuals because of the risk of transfusion-related infections such as hepatitis and human immunodeficiency virus (HIV) (Freischlag 2004). The incidence of hepatitis B and hepatitis C viruses per unit of blood is estimated at 1 in 220,000 and 1 in 1,600,000 respectively, whereas the risk of HIV transmission is 1 per 1,800,000 units (Busch 2003). Many individuals who, for religious reasons, will not accept donor blood or autologous donated banked blood, may accept the use of autotransfusion devices to restore their blood volume during an operation (Freischlag 2004).

How the intervention might work

In cell salvage, an individual's own blood is suctioned out of the body (e.g. if there is internal bleeding), filtered and then returned to that individual intravenously. Cell salvage could be utilised in trauma surgery to provide life saving blood (Harasawa 2005). One study has shown that cell salvage is highly effective in reducing the need for transfusion (Liu 2001).

Why it is important to do this review

A number of studies have evaluated cell salvage in various ways, but none has included data on its effectiveness in individuals undergoing abdominal or thoracic trauma surgery. One study found that cell salvage had no discernible effect on rates of postoperative infection or mortality (Bowley 2006). Another study recommended limiting cell salvage transfusion to less than ten units to reduce the risk of coagulopathy (Horst 1992). When salvaged blood is contaminated with bacteria from injured intestines, or other matter, its transfusion is contraindicated (Napier 1997; Vanderlinde 2002). Red blood cells should be washed before reinfusion, but this process is expensive.

One Cochrane review suggested that cell salvage was effective in reducing the need for allogeneic red blood cell transfusion in adult elective surgery (Carless 2010), but did not include individuals with penetrating abdominal or thoracic trauma, and cost was not included as an outcome. We therefore set out to conduct a systematic review to assess the effects and cost of cell salvage in individuals undergoing abdominal or thoracic trauma surgery.

OBJECTIVES

To compare the effects and cost of cell salvage with those of standard care in individuals undergoing abdominal or thoracic trauma surgery.

METHODS

Criteria for considering studies for this review

Types of studies

We included all randomised controlled trials (RCTs), regardless of publication status or language of publication.

Types of participants

Individuals undergoing abdominal or thoracic trauma surgery.

Types of interventions

The index intervention of cell salvage was compared with no cell salvage (standard care).

Types of outcome measures

Primary outcomes

- Mortality

Secondary outcomes

- The amount of allogeneic and/or autologous blood transfused
- Adverse events (in particular, postoperative complications, e.g. thrombosis, infection, renal failure, non-fatal myocardial infarction and transfusion-related adverse events)
- Costs

We acknowledge that investigators are likely to report on the outcomes above using a variety of metrics and timeframes, and we sought to report this information transparently in the review.

Search methods for identification of studies

In order to reduce publication and retrieval bias, we did not restrict our search by language, date or publication status**.**

Electronic searches

The Cochrane Injuries Group's Trials Search Co-ordinator searched the following:

1. Cochrane Injuries Group Specialised Register (25 November 2014);
2. Cochrane Central Register of Controlled Trials (CENTRAL, *The Cochrane Library*) (issue 11 of 12, 2014);
3. Ovid MEDLINE, Ovid MEDLINE In-Process & Other Non-Indexed Citations, Ovid MEDLINE Daily and Ovid OLDMEDLINE) (1946 to 25 November 2014);
4. Embase Classic + Embase (OvidSP) (1947 to 25 November 2014);
5. PubMed (25 November 2014);
6. ISI Web of Science: Science Citation Index Expanded (SCI-Expanded) (1970 to November 2014);
7. ISI Web of Science: Conference Proceedings Citation Index-Science (CPCI-S) (1990 to November 2014).

The authors searched the following:

1. The Chinese Bio-medical Database (October 2014);
2. Clinicaltrials.gov (www.clinicaltrials.gov) (3 December 2014).

We report the search strategies used in (Appendix 1). We adapted the MEDLINE search strategy as necessary for the other databases. To the MEDLINE search strategy we added the Cochrane Highly Sensitive Search Strategy for identifying randomised trials (Lefebvre 2011) and to the Embase strategy we added the search strategy study design terms as used by the UK Cochrane Centre (Lefebvre 2011).

Searching other resources

We checked the reference lists of all relevant reviews and trials. We contacted authors of relevant trial reports in order to identify additional published or unpublished data.

Data collection and analysis

Selection of studies

Two review authors (Li and Tian) independently screened the titles and abstracts of the citations identified by the search to determine which papers met the predetermined inclusion criteria. In cases of doubt or disagreement, we obtained a copy of the full article for inspection. We obtained the full text of all potentially relevant studies and independently assessed them to determine whether they met the inclusion criteria. In the event of a disagreement, we consulted a third author (Yang) to resolve the issue.

Data extraction and management

In keeping with the guidance of the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2011a), we used a predesigned standardised study record form for data extraction. Two authors (Li and Liu) extracted data from the trial reports, consulting a third author (Yang) in the event of disagreement. We contacted investigators for missing data, where appropriate.

Our form collected the following information.

1. *Administrative details* - titles; authors; publication details (year, volume number, issue number, and page numbers (where published) or titles, investigators, year in which the study was conducted (if not published)); and details of other relevant papers
2. *Study details* - country, location and setting of the study; study design and details related to risk of bias within studies (e.g. randomisation, allocation concealment, blinding); inclusion and exclusion criteria; number of participants; characteristics of participants (including age, sex, type of trauma); dropouts; duration, frequency and completeness of follow up
3.*Intervention details* - for both the cell salvage group and for that receiving standard or alternative care, with no cell salvage
4. *Outcome data* - primary and secondary outcomes

Assessment of risk of bias in included studies

Three authors (Li, Liu and Sun) independently assessed the risk of bias of included studies according to methods suggested in the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2011b), consulting a third author (Yang) when disagreements arose.

For the one study that met our inclusion criteria, we assessed the following items.

1. Randomisation method (selection bias)

- Low risk of bias - the method of randomisation allowed participants to have the same opportunity to receive either intervention; the investigators describe a random component in the sequence generation process, such as the use of random-number tables, a computer random-number generator, coin tossing or shuffling cards or envelopes, throwing dice, drawing of lots, etc.
- High risk of bias - the investigators describe a non-random component in the sequence generation process. Usually, the description involved some systematic, non-random approach, such as by odd or even date of birth, some rule based on date (or day) of admission, hospital or clinic record number. Other non-random approaches are used much less frequently than the systematic approaches mentioned above and tend to be obvious. They usually involve judgement or some method of non-random categorisation of participants, such as allocation by judgement of the clinician, preference of the participant, the results of a laboratory test or a series of tests, or the availability of the intervention. If an open random allocation schedule (e.g. a list of random numbers) was used or assignment envelopes were used without appropriate safeguards (e.g. if envelopes were unsealed or non-opaque, or not sequentially numbered), or any other explicitly unconcealed procedure, we classified the randomisation method as at high risk of bias
- Unclear risk of bias - the investigators provide insufficient information about the sequence generation process to permit a judgement of low risk or high risk to be made (e.g. reporting the use of randomisation but providing no detailed information on the method used)

2. Allocation concealment (selection bias)

- Low risk of bias: participants could not foresee the randomisation method (e.g. central allocation including telephone, web-based or pharmacy-controlled randomisation; the use of sequentially numbered drug containers of identical appearance; sequentially numbered, opaque, sealed envelopes)
- High risk of bias: participants randomised through a method such as use of assignment envelopes without appropriate safeguards (e.g. if envelopes were unsealed or non-opaque, or not sequentially numbered), by alternation or rotation, date of birth or case record number, or any other explicitly unconcealed procedure
- Unclear risk of bias: the investigators provide insufficient information about allocation concealment, such as alternation methods or unsealed envelopes; or studies in which there is any information indicating that the investigators or participants could have influenced the composition of the comparison groups

3. Blinding (performance bias)

- Low risk of bias: no blinding or incomplete blinding, but the review authors judge that the outcome is not likely to be influenced by lack of blinding; blinding of participants and key study personnel is ensured, and it is unlikely that the blinding could have been broken
- High risk of bias: no blinding or incomplete blinding of participants and people administering the treatment, and the outcome is likely to be influenced by lack of blinding

- Unclear risk: insufficient information is available to permit a judgement of low risk or high risk, or no useful information has been obtained from the authors

4. Incomplete outcome data (attrition bias)

- Low risk of bias: no missing outcome data; missing outcome data balanced in numbers across intervention groups; missing outcomes not enough to have a clinically relevant impact on the final results for dichotomous and continuous outcome data; missing data have been imputed using appropriate methods
- High risk of bias: reason for missing outcome data related to the true outcome, with either an imbalance in numbers or reasons across intervention groups; missing outcomes enough to induce clinically relevant bias in the results for dichotomous and continuous outcome data; inappropriate methods were used to deal with the missing data
- Unclear risk: insufficient information is available to permit a judgement of low risk or high risk

5. Selective outcome reporting (reporting bias)

- Low risk of bias: all outcomes were reported in the article (if the study protocol was available) or all expected outcomes were mentioned in the published reports (the study protocol was not available)
- High risk of bias: one or more outcomes failed to be included or were not reported
- Unclear risk: insufficient information is available to permit a judgement of low risk or high risk

6. Other biases

- Low risk of bias: no other sources of bias were identified which might be expected to affect results in any direction
- High risk of bias: sources of bias were identified and are likely to bias results
- Unclear risk: sources of potential bias were identified but it is unclear in which direction the bias might affect results

Dealing with missing data

For the one study included in the present version of this review, no data appeared to be missing (i.e. data are provided on all surviving participants (n = 15) and reasons for death of those who did not survive are given (n = 29)).

In future updates of this review, we will assess missing data and attrition rates for each included study, and the number of participants who are included in the final analysis will be reported as a proportion of all participants in the study. Reasons given for missing data will be provided in the narrative summaries and we will seek to ascertain the extent to which the results are altered by missing data. We will also assess the extent to which studies have conformed to intention-to-treat analysis.

Assessment of heterogeneity

Only one study was identified that met our inclusion criteria. For future updates of this review, should sufficient data become available, we will use the Chi^2 test to assess heterogeneity between trials and the I^2 statistic to assess the extent of inconsistency. We will use a fixed-effect model for calculating summary estimates and their 95% confidence intervals (CIs) unless significant heterogeneity is present, in which case results will be calculated using a random-effects model.

Assessment of reporting biases

Only one study was identified that met our inclusion criteria. For future updates of this review, should sufficient data become available, we plan to draw funnel plots when data from 10 or more studies are available by outcome. Funnel plots help to investigate any relationship between effect size and study precision (closely related to sample size) (Egger 1997). Such a relationship could be due to publication or related biases, or due to systematic differences between small and large studies. If a relationship is identified, we will further examine the clinical diversity of the studies as a possible explanation and described this in the text.

Data synthesis

We analysed the data available using Review Manager version 5.3. We expressed results for dichotomous outcomes as odds ratios (ORs) with 95% CIs and those for continuous outcomes as weighted mean differences (WMDs).

Subgroup analysis and investigation of heterogeneity

We planned to carry out the following subgroup analyses and these will be conducted in future updates of this review, should data become available. We intend to explore important clinical differences among trials that might alter the magnitude of the treatment effect such as:

- injury type (abdominal/thoracic trauma);
- injury severity;
- method used to wash the red blood cells;
- the use of transfusion protocols.

We have selected these factors as each has been identified as being important because they may influence a person's inclination or opportunity to receive, and possibly benefit from, cell salvage.

Sensitivity analysis

In order to assess the robustness of our conclusions in the future we plan to consider performing sensitivity analyses to assess the impact of missing data regarding important aspects of risk of bias (including allocation concealment) on reported treatment effect(s).

If significant heterogeneity still exists after subgroup and sensitivity analyses and reasons for heterogeneity cannot be found, we will report the results of the studies narratively (rather than pool data inappropriately).

RESULTS

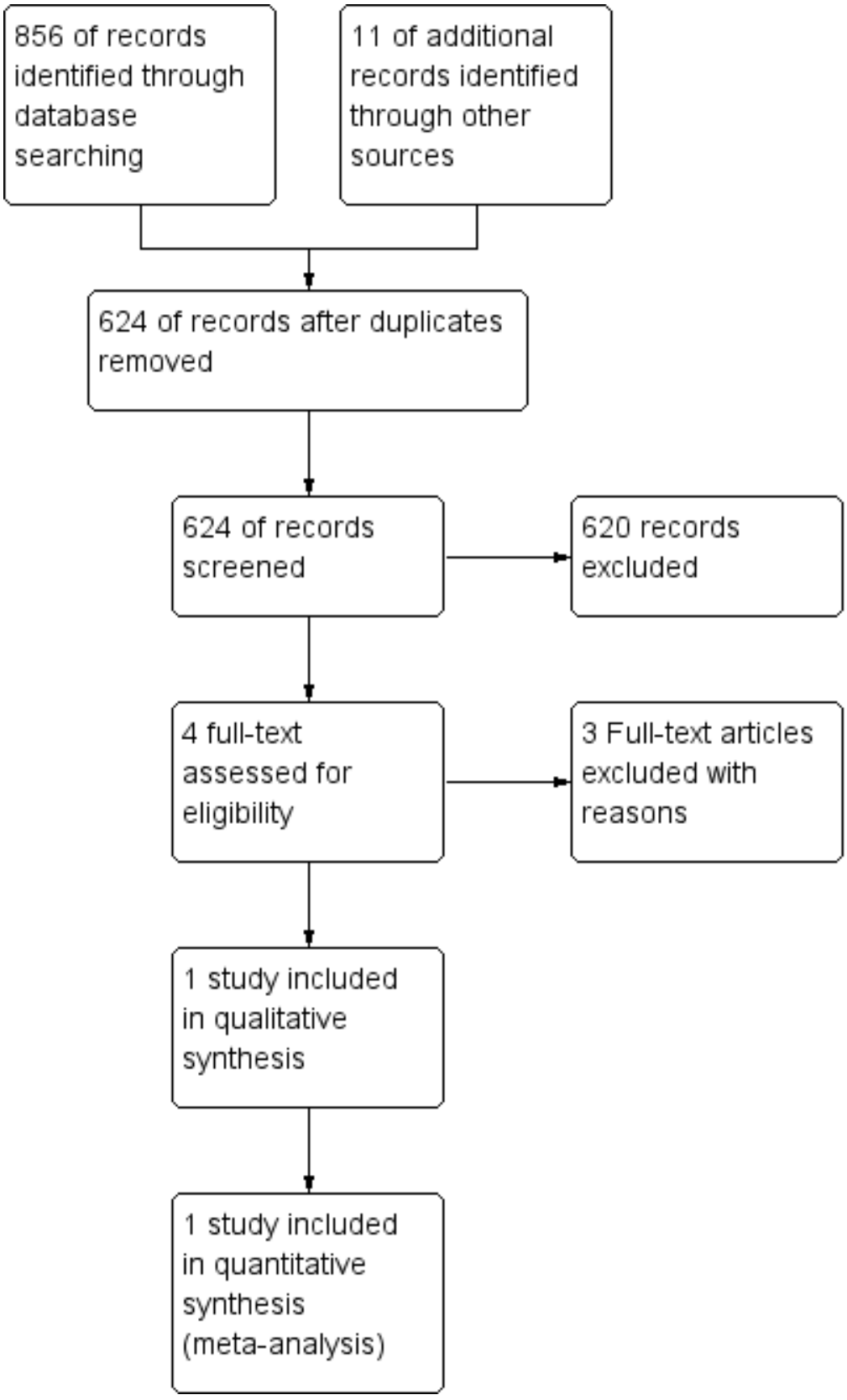
Description of studies

See: 'Characteristics of included studies'.

Results of the search

We show the results of the electronic searches in Figure 1.

Figure 1. Study flow diagram.



After screening based on titles and abstracts, we identified three potential relevant studies and reviewed them further. Two of the three potential citations were excluded due to their designs (Harasawa 2005 was a case report and Hughes 2001 was a retrospective study). Thus, only one study (Bowley 2006) fulfilled our inclusion criteria. Following correspondence with a trial investigator (Bowley 2014 [pers comm]) we identified one further reference which, though of interest, we also excluded due to its design (Bhangu 2013).

Included studies

We identified Bowley 2006 as the only study that met our inclusion criteria.

Design, sample size and setting

Bowley 2006 is a parallel RCT of 44 participants. Sample size was determined following calculations conducted by investigators in which they determined that *"there would need to be 20 patients in each arm of the study"* (based on an assumption that cell salvage *"would result in a 40% reduction in blood requirement"* (standard deviation 4.5 units) (Bowley 2006, p. 1075).

The study was conducted in 2002, in an urban setting, within the Johannesburg Hospital Trauma Unit (South Africa), and had approval from an ethical review board.

Participants

The vast majority of participants were male (40/44) and the median age was 30 years (range 20 to 54 years). Groups were assessed as equivalent at baseline in terms of demographic and injury details (including abdominal injury), as well as median emergency room to operating theatre times. Mode of transportation to hospital was reported as not having had an effect on survival.

Intervention (n = 21)
The intervention (cell salvage) group underwent cell salvage using a Cell Saver 4 machine (Haemonetics, Braintree, MA, USA) with transfusion of both autologous and donor blood, as required.

Control (n = 23)
Donor blood transfusion at the discretion of the attending medical staff.

Outcomes

Investigators measured: death; cause of death (exsanguination or multiorgan failure); amount of banked blood used for transfusion in the first 24 hours postinjury; postoperative blood culture results; and costs.

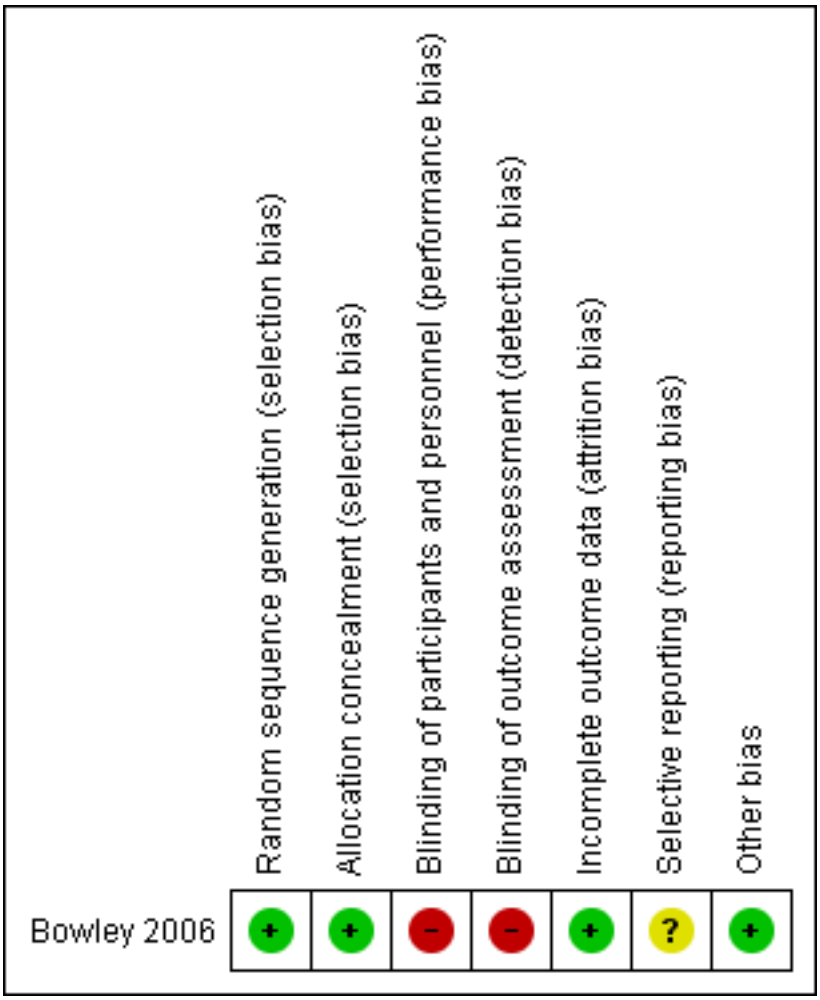
Excluded studies

Three studies were excluded. See 'Characteristics of excluded studies'.

Risk of bias in included studies

Our assessment of the risk of bias is described in Figure 2.

Figure 2. 'Risk of bias' summary: review authors' judgements about each risk of bias item for each included study.



Allocation

The sequence was generated within the one included study by a computer-generated random numbers table and allocation was concealed by envelopes containing *"dedicated data collection sheets previously assigned to either group"* by such sequence generation. We assessed the risk of bias for both these domains as low (Bowley 2006).

Blinding

Blinding of clinicians for this intervention is not possible and the risk of bias is thus high; however, blinding of outcome assessors is not necessary for certain outcomes, mortality being the most important. Investigators did not report details of blinding of outcome assessors concerning outcomes such as postoperative blood culture, and our correspondence with the primary investigator indicated that assessors were not blinded. We therefore assessed the overall risk for this criterion to be high.

Incomplete outcome data

No data appear to be missing from this study, so we assessed the study as being at a low risk of bias for this domain.

Selective reporting

We have confirmed that a protocol for the one included study does not exist (Bowley 2006); however, we know the study to have received ethics approval prior to its conduct. We therefore have assessed the study as having an unclear risk of bias for this criterion.

Other potential sources of bias

We did not identify any other sources of bias for this study.

Effects of interventions

Primary outcomes

Mortality

Results suggest that there was no difference in mortality between participants receiving cell salvage and those in the control group receiving standard care (OR 1.07, 95% CI 0.31 to 3.72) (Analysis 1.1). For individuals with abdominal injury, mortality was also similar in both groups (OR 0.48, 95% CI 0.11 to 2.10) (Analysis 1.2).

Secondary outcomes

Amount of allogeneic and/or autologous blood transfused (measured in standard units)

The number of standard units of banked blood transfused within the 24 hours following injury was significantly lower in the cell salvage group than in the control group (mean difference (MD) -4.70 units, 95% CI -8.09 to -1.31) (Analysis 1.3).

Adverse events (in particular, postoperative complications (e.g. thrombosis, infection, renal failure, non-fatal myocardial infarction))

Odds ratios of postoperative infection were measured by the investigators. The results do not differ between the two groups (OR 0.54, 95% CI 0.11 to 2.55) (Analysis 1.4).

Costs

There was no difference in cost between the study groups (MD -177.81, 95% CI -452.85 to 97.23) (Analysis 1.5). Cost was calculated in British Pound Sterling in 2002.

DISCUSSION

Summary of main results

The one (small) study in this review compared mortality, the amount of donor blood used and cost in individuals who underwent cell salvage or standard care during trauma surgery.

There was no difference in mortality between groups. There was a reduction in the amount of a reduction in the amount of banked blood (blood that has been donated and stored) required for transfusion within the first 24 hours following injury among people receiving cell salvage.

The authors reported the incidence of postoperative sepsis, which did not show a difference between the two groups. However, no data on thrombosis, infection, renal failure or non-fatal myocardial infarction (which are thought to be the most frequent adverse events of cell salvage) were provided in the trial report, and the investigator has since confirmed these data were not collected (Bowley 2014 [pers comm]).

There was no difference in cost between the two groups.

Overall completeness and applicability of evidence

Although cell salvage has the potential to diminish the volume of donor blood necessary to replace massive haemorrhage during emergency surgery (Smith 1997), the efficacy of cell salvage has not yet been studied sufficiently in RCTs. The number of participants in the one included study was small (Bowley 2006), which may have led to bias. The cost of using cell salvage was the same as donor blood. Adverse event data were not fully reported for either group, so we are unable to fully judge the effectiveness and safety of cell salvage. Whether cell salvage should be used in clinical practice as a front-line treatment in individuals undergoing trauma surgery will depend on the results of future, large, well-conducted RCTs.

Quality of the evidence

The one study included in this review seems to have been well conducted and well reported, although concerns about the lack of blinding of the outcome assessors remains. In any case, one small study cannot possibly answer all questions relating to this important topic.

Potential biases in the review process

We conducted electronic searches, online trial searches and manual searches, but identified only one study suitable for inclusion. It is possible that we did not identify unpublished data and, as a result, there is some chance that selection bias may exist in our review.

Agreements and disagreements with other studies or reviews

We have not identified any other systematic reviews on the use of cell salvage in individuals undergoing abdominal and thoracic trauma surgery. However, our conclusions are in agreement with a recent large systematic review of trauma haemorrhage in general in which the authors concluded that *"no clear correlation has been demonstrated between transfusion requirements and mortality"* and that *"the global trauma community should consider a coordinated and strategic approach to conduct well designed studies with pragmatic endpoints"* (Curry 2011, p. 1).

AUTHORS' CONCLUSIONS

Implications for practice

Evidence for the use of cell salvage in individuals undergoing abdominal and thoracic trauma surgery remains equivocal. The findings of a reduction in demand for donor blood transfusion with cell salvage compared with standard care after abdominal trauma surgery in the one study identified requires replication.

Implications for research

We identified only one study that met the inclusion criteria for this review. In the future, multicentre, methodologically rigorous trials are needed to assess the relative efficacy, safety and cost-effectiveness of cell salvage in different surgical procedures.

ACKNOWLEDGEMENTS

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* Indicates the major publication for the study

CHARACTERISTICS OF STUDIES

Characteristics of included studies *[ordered by study ID]*

Bowley 2006

Methods	Randomised controlled trial
Participants	**Participants:** 44 participants (21 allocated to intervention group; 23 to control) **Age:** range 20 to 54 years (median 30 years) **Demographics:** 40 of 44 participants were male. Other demographics as well as injury patterns and severity were apparently equivalent at baseline between the two groups **Unit of allocation:** individual **Number randomised:** 44 **Number completing:** 15 survived; 29 died **Setting:** Johannesburg Hospital Trauma Unit, Dept of Surgery, University of the Witwatersrand, South Africa. Study recruited within the first seven months of 2002 **Inclusion criteria:** Participants were *"assessed on arrival in the Emergency Room by a single investigator and enrolled in the study if they had penetrating torso injury requiring a laparotomy and had exhibited hypotension (< 90 mmHg) either pre-hospital or on arrival and in whom there was considered to be significant blood loss"* (p. 1075) **Exclusion criteria:** Participants aged < 18 years; participants with injuries > 6 hours old.
Interventions	**Intervention** (n = 21): the intervention group underwent cell salvage using a Cell Saver 4 machine (Haemonetics, Braintree, MA, USA) with transfusion of both autologous and allogeneic blood as required **Control** (n = 23): allogeneic blood transfusion at the discretion of the attending medical staff
Outcomes	**Primary** *Exposure to allogeneic blood up to the first 24 hours postinjury* **Secondary** *Mortality (all cause and cause-specific (e.g. multiorgan failure or exsanguination)* *Postoperative sepsis* *Costs*

Bowley 2006 *(Continued)*

Notes

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Randomisation was by computer-generated random number tables
Allocation concealment (selection bias)	Low risk	Allocation was concealed by means of envelopes which contained dedicated data collection sheets
Blinding of participants and personnel (performance bias) All outcomes	High risk	It is not feasible to blind this intervention to personnel
Blinding of outcome assessment (detection bias) All outcomes	High risk	Insufficient information was available in the published paper to determine this. Contact with the primary investigator indicates no attempts at blinding outcome assessors to outcomes e.g. postoperative sepsis
Incomplete outcome data (attrition bias) All outcomes	Low risk	No data were missing from this study
Selective reporting (reporting bias)	Unclear risk	Contact with trial investigator has established that no trial protocol exists (Bowley 2006)
Other bias	Low risk	No other sources identified

Characteristics of excluded studies *[ordered by study ID]*

Study	Reason for exclusion
Bhangu 2013	Not an RCT (prospective 'proof of concept' single group study involving 130 combat personnel)
Harasawa 2005	Not an RCT (single case report)
Hughes 2001	Not an RCT (retrospective study)

RCT = Randomised controlled trial

DATA AND ANALYSES

Comparison 1. Cell salvage versus control group

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Mortality	1		Odds Ratio (M-H, Fixed, 95% CI)	Totals not selected

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
2 Mortality in individuals with abdominal injury	1		Odds Ratio (M-H, Fixed, 95% CI)	Totals not selected
3 Standard units of donor blood transfusion in first 24 hours postinjury	1		Mean Difference (IV, Fixed, 95% CI)	Totals not selected
4 Postoperative sepsis	1		Odds Ratio (M-H, Fixed, 95% CI)	Totals not selected
5 Costs (GBP£)	1		Mean Difference (IV, Fixed, 95% CI)	Totals not selected

Analysis 1.1. Comparison 1 Cell salvage versus control group, Outcome 1 Mortality.

Study or subgroup	Cell salvage n/N	Standard care n/N	Odds Ratio M-H, Fixed, 95% CI	Odds Ratio M-H, Fixed, 95% CI
Bowley 2006	14/21	15/23		1.07[0.31,3.72]
	Favours cell salvage		0.5 0.7 1 1.5 2	Favours standard care

Analysis 1.2. Comparison 1 Cell salvage versus control group, Outcome 2 Mortality in individuals with abdominal injury.

Study or subgroup	Cell salvage n/N	Standard care n/N	Odds Ratio M-H, Fixed, 95% CI	Odds Ratio M-H, Fixed, 95% CI
Bowley 2006	11/18	13/17		0.48[0.11,2.1]
	Favours cell salvage		0.05 0.2 1 5 20	Favours standard care

Analysis 1.3. Comparison 1 Cell salvage versus control group, Outcome 3 Standard units of donor blood transfusion in first 24 hours postinjury.

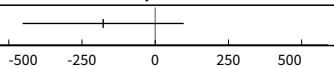
Study or subgroup	Cell salvage N	Cell salvage Mean(SD)	Standard care N	Standard care Mean(SD)	Mean Difference Fixed, 95% CI	Mean Difference Fixed, 95% CI
Bowley 2006	21	6.5 (5.4)	23	11.2 (6.1)		-4.7[-8.09,-1.31]
		Favours cell salvage			-20 -10 0 10 20	Favours standard care

Analysis 1.4. Comparison 1 Cell salvage versus control group, Outcome 4 Postoperative sepsis.

Study or subgroup	Cell salvage n/N	Standard care n/N	Odds Ratio M-H, Fixed, 95% CI	Odds Ratio M-H, Fixed, 95% CI
Bowley 2006	5/13	7/13		0.54[0.11,2.55]
	Favours cell salvage		0.01 0.1 1 10 100	Favours standard care

Analysis 1.5. Comparison 1 Cell salvage versus control group, Outcome 5 Costs (GBP£).

Study or subgroup	Cell salvage		Standard care		Mean Difference	Mean Difference
	N	Mean(SD)	N	Mean(SD)	Fixed, 95% CI	Fixed, 95% CI
Bowley 2006	21	812.2 (451.3)	23	990 (479.5)		-177.81[-452.85,97.23]



APPENDICES

Appendix 1. Search strategies

Cochrane Injuries Group Specialised Register
Cochrane Central Register of Controlled Trials (CENTRAL, The Cochrane Library)
#1MESH DESCRIPTOR Blood Transfusion, Autologous EXPLODE ALL TREES
#2MESH DESCRIPTOR Blood Loss, Surgical EXPLODE ALL TREES
#3MESH DESCRIPTOR Blood Transfusion EXPLODE ALL TREES
#4(Auto haemotransfusion* or Auto-haemotransfusion* or Auto hemotransfusion* or Auto-hemotransfusion* or Auto transfusion* or Auto-transfusion*):TI,AB,KY
#5((Autologous near3 (Blood or Plasma))):TI,AB,KY
#6((cell* or blood) near5 (transfusion or salvage or save*)):TI,AB,KY
#7#1 OR #2 OR #3 OR #4 OR #5 OR #6
#8MESH DESCRIPTOR Abdominal Injuries EXPLODE ALL TREES
#9MESH DESCRIPTOR Thoracic Injuries EXPLODE ALL TREES
#10MESH DESCRIPTOR Wounds, Penetrating EXPLODE ALL TREES
#11(abdominal or abdomen or chest or thoracic or trunk):TI,AB,KY
#12#10 AND #11
#13((Splenic or spleen or stomach or gastric) near5 (rupture* or burst*)):TI,AB,KY
#14(((heart or cardiac or aortic or aorta*) near5 rupture*)):TI,AB,KY
#15#8 OR #9 OR #12 OR #13 OR #14
#16#7 AND #15

Ovid MEDLINE, Ovid MEDLINE In-Process & Other Non-Indexed Citations, Ovid MEDLINE Daily and Ovid OLDMEDLINE
1. exp Blood Transfusion, Autologous/
2. exp Blood Loss, Surgical/
3. exp Blood Transfusion/
4. (Autohaemotransfusion* or Auto-haemotransfusion* or Autohemotransfusion* or Auto-hemotransfusion* or Autotransfusion* or Auto-transfusion* or (Autologous adj5 (Blood or Plasma))).ab,ti.
5. ((cell* or blood) adj5 (transfusion* or salvage or save*)).ab,ti.
6. 1 or 2 or 3 or 4 or 5
7. exp Abdominal Injuries/
8. exp thoracic injuries/
9. exp Wounds, Penetrating/
10. (abdominal or abdomen or chest or thoracic or trunk).ab,ti.
11. 9 and 10
12. ((abdominal or abdomen or chest or thoracic or trunk) adj3 (trauma* or injur* or penetrat* or stab*)).ab,ti.
13. ((Splenic or spleen or stomach or gastric) adj3 (rupture* or burst*)).ab,ti.
14. ((heart or cardiac or aortic or aorta*) adj3 rupture*).ab,ti.
15. 7 or 8 or 11 or 12 or 13 or 14
16. 6 and 15
17. randomized.ab,ti.
18. randomized controlled trial.pt.
19. controlled clinical trial.pt.
20. placebo.ab.
21. clinical trials as topic.sh.
22. randomly.ab.

23. trial.ti.
24. or/17-23
25. (animals not (humans and animals)).sh.
26. 24 not 25
27. 26 and 16

EMBASE Classic + EMBASE (OvidSP)
1. exp blood autotransfusion/
2. exp Bleeding/su [Surgery]
3. (Autohaemotransfusion* or Auto-haemotransfusion* or Autohemotransfusion* or Auto-hemotransfusion* or Autotransfusion* or Auto-transfusion* or (Autologous adj5 (Blood or Plasma))).ab,ti.
4. ((cell* or blood) adj5 (transfusion* or salvage or save*)).ab,ti.
5. 1 or 2 or 3 or 4
6. exp Abdominal Injury/
7. exp Thorax Injury/
8. exp Abdominal Penetrating Trauma/
9. exp Penetrating Trauma/
10. (abdominal or abdomen or chest or thoracic or trunk).ab,ti.
11. 9 and 10
12. ((abdominal or abdomen or chest or thoracic or trunk) adj3 (trauma* or injur* or penetrat* or stab*)).ab,ti.
13. ((Splenic or spleen or stomach or gastric) adj3 (rupture* or burst*)).ab,ti.
14. ((heart or cardiac or aortic or aorta*) adj3 rupture*).ab,ti.
15. 6 or 7 or 8 or 11 or 12 or 13 or 14
16. 5 and 15
17. exp Randomized Controlled Trial/
18. exp controlled clinical trial/
19. randomized.ab.
20. placebo.ab.
21. exp Clinical Trial/
22. randomly.ab.
23. trial.ti.
24. 17 or 18 or 19 or 20 or 21 or 22 or 23
25. exp animal/ not (exp human/ and exp animal/)
26. 24 not 25
27. 16 and 26

PubMed
(((publisher[sb] NOT pubstatusnihms))) AND ((((((((((autohaemotransfusion*[Title/Abstract]) OR auto haemotransfusion*[Title/Abstract]) OR autohemotransfusion*[Title/Abstract]) OR auto hemotransfusion*[Title/Abstract]) OR autotransfusion*[Title/Abstract]) OR auto-transfusion*[Title/Abstract])) OR (((((blood loss[Title/Abstract]) AND surgical[Title/Abstract])) OR ((blood transfusion[Title/Abstract]) AND autologous[Title/Abstract])) OR (((((transfusion[Title/Abstract]) OR salvage[Title/Abstract]) OR save*[Title/Abstract])) AND ((cell[Title/Abstract]) OR blood[Title/Abstract])))))) AND (((((((abdominal injuries[Title/Abstract]) OR thoracic injuries[Title/Abstract])) OR ((((wounds[Title/Abstract]) AND penetrat*[Title/Abstract])) AND (((((abdominal[Title/Abstract]) OR abdomen[Title/Abstract]) OR chest[Title/Abstract]) OR thoracic[Title/Abstract]) OR trunk[Title/Abstract])))) OR ((((((((((trauma[Title/Abstract]) OR traumatic[Title/Abstract]) OR traumas[Title/Abstract]) OR injur*[Title/Abstract]) OR penetrat*[Title/Abstract]) OR stab[Title/Abstract]) OR stabbed[Title/Abstract]) OR stabbing[Title/Abstract])) AND (((((abdominal[Title/Abstract]) OR abdomen[Title/Abstract]) OR chest[Title/Abstract]) OR thoracic[Title/Abstract]) OR trunk[Title/Abstract])))) OR ((((rupture*[Title/Abstract]) OR burst*[Title/Abstract])) AND ((((splenic[Title/Abstract]) OR spleen[Title/Abstract]) OR stomach[Title/Abstract]) OR gastric[Title/Abstract])))) OR ((rupture*[Title/Abstract]) AND ((((heart[Title/Abstract]) OR cardiac[Title/Abstract]) OR aortic[Title/Abstract]) OR aorta*[Title/Abstract]))))) AND ((((((("Comparative Study"[Publication Type]) OR "Randomized Controlled Trial"[Publication Type]) OR "Controlled Clinical Trial"[Publication Type])) OR (((((((randomized[Title/Abstract]) OR randomised[Title/Abstract]) OR placebo[Title/Abstract]) OR randomly[Title/Abstract]) OR trial[Title/Abstract]) OR groups[Title/Abstract]) OR group[Title/Abstract])))))

ISI Web of Science: Science Citation Index Expanded & Conference Proceedings Citation Index-Science

	#8 AND #7 AND #6
#8	TS=((Blood Loss AND Surgical) or (Blood Transfusion AND Autologous)) OR TS=(Autohaemotransfusion* or Auto haemotransfusion* or Autohemotransfusion* or Auto hemotransfusion* or Auto-

(Continued)

	transfusion* or Auto-transfusion* or (Autologous and (Blood or Plasma))) OR TS=((cell or blood or plasma) AND (salvage or save or saving))
#7	TS=((abdominal or abdomen or chest or thoracic or thorax or trunk) AND (trauma or traumatic or traumas or injur* or penetrat* or stab or stabbed or stabbing)) OR TS=((Wounds AND Penetrat*) and (abdominal or abdomen or chest or thoracic or thorax or trunk)) OR TS=((heart or cardiac or aortic or aorta*) and (rupture*)) OR TS=((Splenic or spleen or stomach or gastric) and (rupture* or burst*))
#6	#5 AND #4
#5	TS=(human*)
#4	#3 OR #2 OR #1
#3	TS=((singl* OR doubl* OR trebl* OR tripl*) SAME (blind* OR mask*))
#2	TS=(controlled clinical trial OR controlled trial OR clinical trial OR placebo)
#1	TS=(randomised OR randomized OR randomly OR random order OR random sequence OR random allocation OR randomly allocated OR at random OR randomized controlled trial)

The Chinese Bio-medical Database

1. (zitishuxue* or zishenshuxue* or zitishishuxue* or zidongshuxue* or (zititongyuan adj5 (xueye or xuejiang))).ab,ti.

2. ((xibao* or xueye) adj5 (shuxue* or huishou or chucun*)).ab,ti.

3. 1 or 2

4. (fubu or xiafu or xiongbu or xiongkuo or qugan).ab,ti.

5. 3 and 4

6. (pizang or pi or wei).ab,ti.

7. (xinzang or xinxueguan or dadongmai).ab,ti.

8. 6 or 7

9. 5 and 8

10. suiji.ab,ti.

11. suijiduizhaoshiyan. pt.

12. duizhaolinchuangshiyan. pt.

13. anweiji.ab.

14. linchuangshiyan as topic.sh.

15. suiji.ab.

16. shiyan.ti.

17. 10 or 11 or 12 or 13 or 14 or 15 or 16

18. 9 and 17

Clinicaltrials.gov

(salvage OR tranfusion) AND INFLECT EXACT "Interventional" [STUDY-TYPES] AND (trauma OR injury OR injuries OR splenic OR gastric OR heart OR cardiac OR aortic OR aorta) [DISEASE]

WHAT'S NEW

Date	Event	Description
27 January 2015	Amended	Marked for re-publication, author address corrected.

CONTRIBUTIONS OF AUTHORS

All authors contributed to drafting the full review.

DECLARATIONS OF INTEREST

None known.

DIFFERENCES BETWEEN PROTOCOL AND REVIEW

Following comments from both the Coordinating Editor and a peer reviewer, the original protocol title has been changed from "Intraoperative blood salvage for penetrating abdominal and thoracic trauma" to "Cell salvage for emergency trauma surgery".

We have updated the version of the *Cochrane Handbook for Systematic Reviews of Interventions* used from 2008 to 2011.

INDEX TERMS

Medical Subject Headings (MeSH)

*Operative Blood Salvage [economics] [mortality]; Abdominal Injuries [mortality] [*surgery]; Blood Transfusion [statistics & numerical data]; Mortality; Randomized Controlled Trials as Topic; Thoracic Injuries [mortality] [*surgery]

MeSH check words

Adult; Female; Humans; Male; Middle Aged