VIA MEDICA
REVIEW / OBSTETRICS
Ginekologia Polska
2017, vol. 88, no. 8, 446–452

ISSN 0017–0011
DOI: 10.5603/GP.a2017.0082

Efficacy and safety of blood transfusion in obstetric patients: systematic review of the literature

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ABSTRACT

Objectives: To evaluate the efficacy of blood transfusion compared to no intervention in obstetric patients.

Material and methods: A systematic review was performed with Cochrane Database of Clinical Trials, PubMed, EMBASE and LILACS databases searched as of September, 2016. Two authors independently selected relevant clinical trials, assessed their methodological quality and extracted data, using the GRADE approach.

Results: Five studies within a total of 6,297 met the inclusion criteria, with women generally aged 20–40 years. Three included studies allocated women to receive blood transfusion or no intervention. Two other studies allocated women with either restricted or full blood supplies. The major issue regarding risk of bias was the extent of concealment of randomization and blinding. There was no statistically significant difference between blood transfusion versus no transfusion or restricted blood supply on mortality (relative risk 0.82 [95% confidential interval 0.32 to 2.09], p = 0.68; two studies; I^2 = not applicable).

Conclusions: Very low-quality evidence suggests no significant difference between blood transfusion and no intervention in obstetric patients, underlining the need for more robust clinical trials evaluating this area.

Key words: blood transfusion, obstetric labor, systematic review, randomized controlled clinical trials

Ginekologia Polska 2017; 88, 8: 446–452

INTRODUCTION

International rates of obstetric transfusions vary from 0.1 to 1.9% and have increased in recent years [1]. Transfusion of blood products is associated with extremely severe maternal morbidity and at least 26% of deaths secondary to postpartum haemorrhage are due to absence of blood transfusion [2]. The goal of transfusion is to increase patient survival while seeking the diagnosis and/or therapy to become effective. However, blood transfusion should not be administered unnecessarily, as it is a risk factor for hospital infection and recurrence of cancer and leads to complex changes in the immune system and are. In addition, there is no consensus on patient profiles warranting blood transfusion, and what haemoglobin concentration is most effective and safe to decrease the likelihood of morbidity and mortality. As pregnancy is an aggravating situation to the clinical picture of patients and may trigger additional complications to them, the fetus and the newborn [3], we focus this study on this clinical situation. The purpose of our systematic review is to evaluate the efficacy and safety of

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blood transfusion compared to no intervention in obstetric labour patients.

MATERIAL AND METHODS

This systematic review of the literature on interventional studies was conducted in accordance with the PRISMA (Preferred Reposting Items for Systematic Reviews and Meta-analysis) statement [4].

Eligibility criteria

- Study designs: randomized controlled trials (RCTs) and controlled clinical trials (CCTs) studies.
- Participants: obstetric patients, regardless of indication for blood transfusion (e.g. anemia, shock, postpartum haemorrhage).
- Interventions: women receiving blood transfusion.
- Control group: women not receiving blood transfusion (i.e. no intervention) or restricted blood product.
- Outcomes:
  - Mortality after delivery;
  - Cardiovascular complications (myocardial infarction; needing cardiovascular devices; severe arrhythmia; or congestive heart failure);
  - Physical fatigue postpartum; and
  - Other related clinical outcomes reported by the included studies.

Studies were excluded if there were duplicate publications of a study that had already been included, or was an animal study, case report or review article.

Search strategy

The search was performed in the following electronic databases: Cochrane Database of Clinical Trials (CENTRAL, 2015, issue 09), PubMed (1966 to 2015), EMBASE (1980 to 2015), and LILACS (1982 to 2015). The databases were searched for available published and unpublished studies until September 2nd, 2015. The search was conducted using multiple combinations of the following key words: triggers; blood transfusion and; obstetric patients (Table 1). There was no restriction on language, year of publication or publication status.

In addition, a manual search of the bibliographic pages of the selected articles and the content pages of major journals was conducted. Study authors were contacted to identify additional studies.

Study selection and data extraction

The titles and abstracts were reviewed by two researchers to identify potentially relevant papers. The papers were obtained and independently read in full by the two reviewers. Differences were resolved by discussion and a third party if necessary. Reasons for exclusion were identified. The data were also extracted independently by paired reviewers based on the *a priori* inclusion and exclusion criteria defined above.

Table 1. Search strategy for all electronic databases

(((Blood Transfusions OR Blood Transfusion OR Trigger Blood Transfusions OR Trigger Blood Transfusion OR Replacement of blood loss OR transfusion OR transfusion therapy OR red blood cell transfusion OR blood products OR blood transfusion practices OR Packed- Blood-Cell Transfusion OR Packed Blood Cell Transfusion OR hemotransfusions OR transfusion of red blood cells OR exchange transfusion) AND (Pregnancy OR Pregnancies OR Gestation OR pregnant women OR parturient OR parturients OR caesarean section OR cesarean delivery OR normal birth OR normal childbirth OR normal delivery OR natural childbirth OR postpartum blood transfusion OR postpartum haemorrhage OR anaemic women OR anaemia in pregnancy OR anaemic parturient OR anaemicparturients OR obstetric patients OR obstetric patient OR women with acute anaemia OR acute postpartum anemia OR maternal hemorrhage)) AND (randomized controlled trial [Publication Type] OR controlled clinical trial [Publication Type] OR randomized controlled trials [MeSH Terms] OR random allocation [MeSH Terms] OR double blind method [MeSH Terms] OR single blind method [MeSH Terms] OR clinical trial [Publication Type] OR clinical trials [MeSH Terms] OR (clinical* [Text Word] AND trial* [Text Word]) OR single* [Text Word] OR double* [Text Word] OR treble* [Text Word] OR triple* [Text Word] OR placebos [MeSH Terms] OR placebo* [Text Word] OR random* [Text Word] OR research design [MeSH Terms] OR comparative study [MeSH Terms] OR evaluation studies [MeSH Terms] OR follow-up studies [MeSH Terms] OR prospective studies [MeSH Terms] OR control* [Text Word] OR prospectiv* [Text Word] OR volunteer* [Text Word])) AND (human OR humans)

Risk of bias in individual studies

Paired reviewers independently assessed the risk of bias of included RCTs using a modified version of the Cochrane Collaboration's instrument (http:/distillercer.com/resources/) [5, 6]. The instrument includes nine domains: adequacy of sequence generation, allocation sequence concealment, blinding of participants and caregivers, blinding of data collectors, blinding for outcome assessment, blinding of data analysts, incomplete outcome data, selective outcome reporting, and the presence of other potential sources of bias not accounted for in the previously cited domains [6].

When information regarding risk of bias or other aspects of methods or results was unavailable, we attempted to contact study authors for additional information.

Assessment of heterogeneity

We quantified inconsistency among pooled estimates by using the I^2 statistic. This illustrates the percentage of variability in effect estimates that results from heterogeneity rather than from sampling error [7, 8]. We intended to examine forest plots for CI overlap and to calculate the Chi^2 test for homogeneity with a 10% level of significance.

Certainty of evidence

We summarized the evidence and assessed its certainty for bodies of evidence from RCTs. We were not able to perform a summary of findings table for controlled clinical trials (CCTs) as there was no further data provided by them. We used the Grading of Recommendations Assessment, Development and Evaluation (GRADE) methodology to rate certainty of the evidence for each outcome as high, moderate, low, or very low [9]. Detailed GRADE guidance was used to assess overall risk of bias [10], imprecision [11], inconsistency [12], indirectness [13] and publication bias [14], and to summarize results in an evidence profile.

We planned to assess publication bias through visual inspection of funnel plots for each outcome in which we identified 10 or more eligible studies; however, we were not able to do so, due to an insufficient number of studies to allow for this assessment.

Data synthesis and statistical analysis

We analyzed all outcomes as dichotomous variables. We calculated pooled Mantel-Haenszel risk ratios (RRs) and associated 95% CIs using random-effects models. We considered studies that allocated women to full blood supply as the intervention group, and those studies that allocated women to restricted blood supply as the control group.

We assessed variability in results across studies by using the I^2 statistic and the p-value for the chi square test of heterogeneity provided by Review Manager. We used Review Manager (RevMan) (version 5.3; Nordic Cochrane Centre, Cochrane) for all analyses [15].

RESULTS

Search results

Figure 1 presents the process of identifying eligible studies, including citations identified through search in electronic databases, and studies identified through contact with experts in the field. Based on title and abstract screening, we assessed 31 full-texts of which we included five publications describing three RCTs [16–18] involving 1,090 participants and, two CCTs [19, 20] with a total of 5,207 participants.

Characteristics of included studies

Table 2 describes study characteristics related to design of study, setting, number of participants, mean age, gender, inclusion and exclusion criteria, and follow-up. Two studies [19, 20] were conducted largely in Asia, two others in Africa [16, 18], and one in Europe [17]. Randomized trials sample size ranged from 50 [18] to 521 [17], and controlled clinical trials studies from 1,769 [20] to 3,438 [19], and typically included females between the ages of 20 and 40 years. Studies followed participants for six weeks in one study [17]; the other studies did not report follow-up duration.

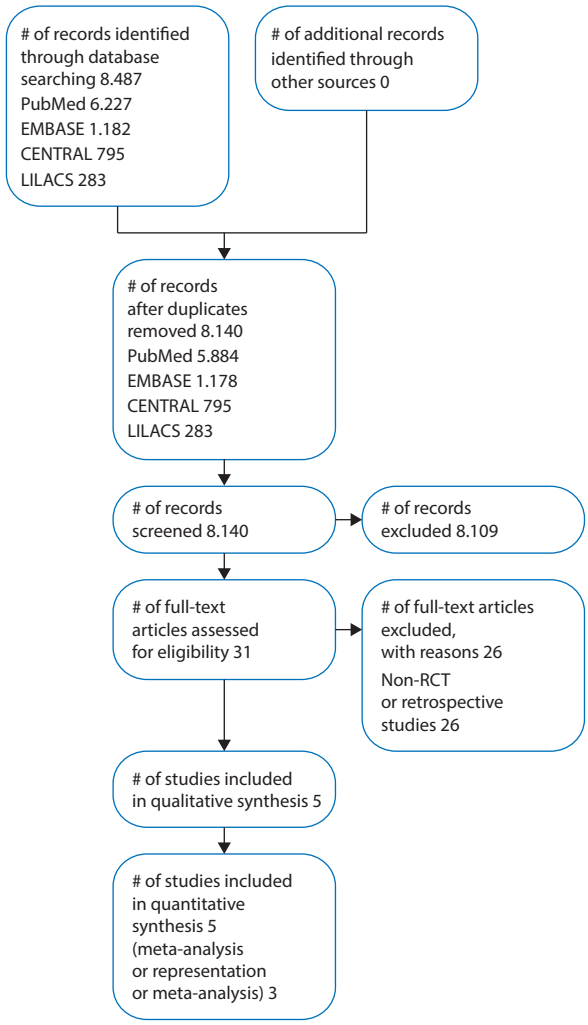

Figure 1. Flowchart of the review

Three included studies [17, 19, 20] allocated women to receive blood transfusion or no intervention and two others [16, 18] provided women with either restricted or full blood supplies (Table 2).

Risk of bias in included studies

Figure 2 and Table 3 describe the risk of bias assessment for the RCTs and CCTs. The major issue regarding risk of bias was the extent of allocation concealment and blinding of participants, caregivers, data collectors, statistician, and outcome assessors in all the included studies [16–20]. Only one study [18] had additional problems of missing outcome data, and three other studies [16, 19, 20] had issues related to generation of allocation.

Effectiveness of interventions

Mortality after delivery

Figure 3 shows the meta-analysis comparing blood transfusion versus no transfusion or restricted supply blood

Table 2. Study characteristics related to design of study, country, number of participants, mean age, inclusion and exclusion criteria, and follow-up

Author, year	Design of study	Location	No.* participants	Mean age	Inclusion criteria	Exclusion criteria	Follow-up
Randomized controlled trials (RCT)							
Osei, 2013 [16]	Parallel RCT	Africa	T: 249 NT: 270	30 (not specified by group)	All patients who received blood during the study periods were eligible and were included unless refusing consent	Patients who refused consent	NR
Prick, 2010 [17]	Parallel RCT	Europe	T: 259 NT: 262	T: 30.7 NT: 30.9	Women, older than 18 years of age, who deliver in hospital or are transferred after home delivery because of primary postpartum haemorrhage (PPH), are eligible. Patients will be included with an Hb between 3.0 and 5.0 mmol/L (4.8 and 8.1 g/dL), determined 12 to 24 hours after vaginal delivery or caesarean section, and a decrease in Hb of at least 1.2 mmol/L (1.9 g/dL) and/or a total peripartum blood loss of at least 1000 mL. The initial Hb value will be determined when the patient is admitted during the first stage of labour at the labour ward. In other instances, when an initial Hb is absent, inclusion is purely based on the total amount of blood loss. Finally, good working knowledge of the Dutch language is required	Exclusion criteria include severe (anaemic) physical complaints, previous RBC transfusion directly after delivery, severe pre-eclampsia, severely active infectious disease, congenital haemolytic disease, severe compromised immunological status, malignancy, severe co-morbidity (ASA II/III), peripartum death or critical condition of the newborn. Severe (anaemic) physical complaints were defined as fatigue, headache, dizziness, confusion, dyspnoea, syncope, orthostatic complaints, tachycardia (> 100 bpm), angina pectoris and/or transient ischemic attacks (TIA)	Six weeks
Philpott, 1966 [18]	Parallel RCT	Africa	T: 25 NT: 25	25.7 (not specified by group)	All patients whose haemoglobin level was below 4.4 g/100 mL (30%), who did not manifest evidence of shock, and who had been admitted to the gynaecological and obstetric units at King Edward VIII Hospital, Durban	NR	NR
Controlled clinical trials (CCT)							
Ismail, 2014 [19]	CCT	Asian	T: 397 NT: 3041	T: 28.7 NT: 27.6	All patients undergoing emergency and elective CS during the study period	NR	NR
Goundan, 2011 [20]	CCT	Asian	T: 216 NT: 1553	T: 26.78 NT: 27.01	All women who underwent cesarean delivery during the period between May 2007 and November 2008	NR	NR

CCT — controlled clinical trial; NR — not reported; NT — not transfused; RCT — randomized controlled trial; T — transfused

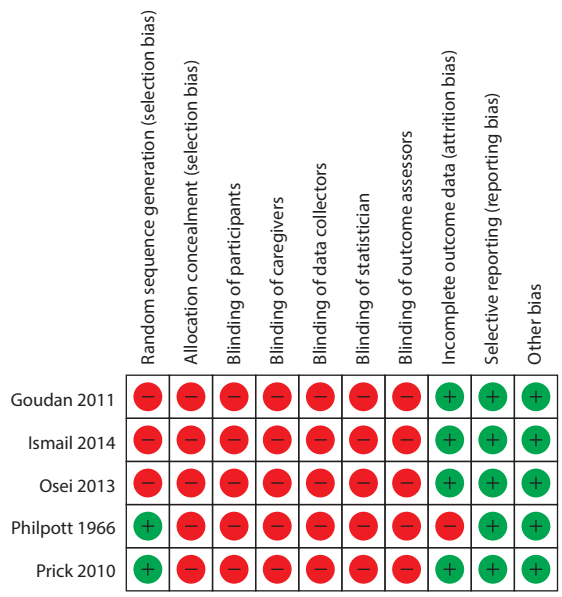

Figure 2. Risk of bias graph review authors' judgments about each risk of bias item presented as percentages across all included studies. The answers "probably yes" were considered as "definitely yes" and "probably no" as " definitely no"

on mortality. There was no statistically significant difference between both studied groups (RR 0.82 [95% CI 0.32 to 2.09], p = 0.68; two studies [16, 18]; I^2 = not applicable).

Cardiovascular events and physical fatigue

Only Philpott 1966 et al.'s study [18] reported on cardiovascular complications; the study reported no events in each of the studied groups. Prick et al.'s 2010 [17] study reported a mean physical fatigue score at day three and one week postpartum as reduced by 0.8 and 1.06, respectively, in the transfusion arm compared to women receiving no intervention.

DISCUSSION

Main findings

Based on pooled data from two randomized trials with 569 participants, we did not find evidence for a possible benefit in clinical outcomes with blood transfusion in comparison to no intervention for obstetric patients (Figure 3). The evidence was of very low certainty: the 95% confidence interval of the relative risk crossed 1.0 and the high risk of bias associated with allocation concealment and blinding yielded results that were inconsistent (Table 4).

Relation to prior work

A systematic review [21] about the effectiveness of interventions for management (e.g. pharmacologic or medical management, but not limited to transfusion) of postpartum haemorrhage, using Medline, EMBASE, Cumulative Index to

Table 3. Risk of bias assessment for the randomized controlled trials

Author, year	Was the randomization sequence adequately generated?	Was allocation adequately concealed?	Was there blinding of participants?	Was there blinding of caregivers?	Was there blinding of data collectors?	Was there blinding of statistician?	Was there blinding of outcome assessors?	Was loss to follow-up (missing outcome data) infrequent?*	Are reports of the study free of suggestion of selective outcome reporting?	Was the study apparently free of other problems that could put it at a risk of bias?
Randomized controlled trials (RCTs)										
Prick, 2010 [17]	Definitely yes	Probably no	Definitely no	Definitely no	Definitely no	Definitely no	Definitely no	Definitely yes	Definitely yes	Definitely yes
Philpott, 1966 [18]	Probably yes	Probably no	Probably no	Probably no	Probably no	Probably no	Probably no	Probably no	Definitely yes	Definitely yes
Osei, 2013 [16]	Definitely no	Definitely no	Definitely no	Definitely no	Definitely no	Definitely no	Definitely no	Probably yes	Definitely yes	**Definitely yes**
Controlled clinical trials (CCTs)										
Ismail, 2014 [19]	Definitely no	Definitely no	Definitely no	Definitely no	Definitely no	Definitely no	Definitely no	Definitely yes	Definitely yes	Definitely yes
Goundan, 2011 [20]	Definitely no	Definitely no	Definitely no	Definitely no	Definitely no	Definitely no	Definitely no	Probably yes	Definitely yes	**Probably yes**

*Defined as less than 10% loss to outcome data or difference between groups less than 5% and those excluded are not likely to have made a material difference in the effect observed. All answers as: **definitely** yes (low risk of bias), probably yes, probably no, definitely no (high risk of bias)

Study or subgroup	Red blood cell transfusion Events	Total	No transfusion/restricted Events	Total	Weight	Risk Ratio M–H, Random, 95%CI
Osei 2013	8	270	9	249	100%	0.82 [0.32, 2.09]
Philpott 1966	0	25	0	25		Not estimable
Total (95% CI)		**295**		**274**	**100%**	**0.82 [0.32, 2.09]**
Total events	8		9			
Heterogeneity: Not applicable						
Test for overall effect: Z = 0.42 (P = 0.68)						

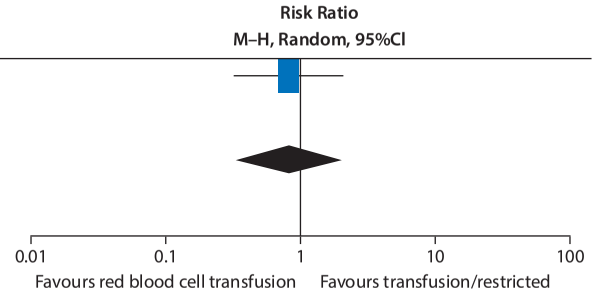

Figure 3. Meta-analysis comparing blood transfusion versus no transfusion or restricted supply blood on mortality

Table 4. GRADE evidence profile for RCTs: blood transfusion versus no intervention in obstetric patients

Quality assessment						Summary of findings					Certainty in estimates
						Study event rates		Relative risk (95% CI)	Anticipated absolute effects		
No of participants (studies) Range follow-up time	Risk of bias	Inconsistency	Indirectness	Imprecision	Publication bias	No intervention†	Blood transfusion		No intervention†	Blood transfusion	OR Quality of evidence
Mortality											
569 (2) NR	Serious limitations‡	No serious limitations	No serious limitations	Serious imprecision§	Undetected	9/274	8/295	**0.82** (0.32–2.09)	36 per 1000	7 fewer per 1000 (25 fewer to 39 more)	VERY LOW

†The estimated risk control was taken from [16]; ‡High risk of bias in generation of allocation [16], allocation concealment [16, 18], blinding [16, 18], and missing data [18]; §95% CI for absolute effects include clinically important benefit and no benefit; NR — not reported

Nursing and Allied Health Literature (CINAHL) databases for only articles published in English, identified a total of 68 studies. The authors concluded that the literature comprised studies of high risk of bias with a small number of participants and, therefore no conclusions could be drawn from the actual evidence.

Strengths and limitations

Strengths of our review include a comprehensive search; assessment of eligibility, risk of bias, and data abstraction independently and in duplicate; assessment of risk of bias; and use of the GRADE approach in rating the certainty of evidence for each outcome.

The primary limitation of our review is the very low certainty consequent on study limitations. We identified only a small number of studies with heterogeneous outcomes measurements, making only possible a meta-analysis with only two RCTs for mortality and resulting in wide confidence intervals. Moreover, high risk of bias in terms of allocation concealment and blinding limited the certainty of the evidence, making it challenging to draw credible inferences.

CONCLUSIONS

Given the low quality of the available evidence, our findings provide very limited support for the hypothesis that blood transfusion may be more effective than no intervention for obstetric patients. This review underlines the urgent need to conduct well-designed trials in the use of blood transfusion.

Acknowledgments

We would like to thank Dr Babette W. Prickand Dr Frances E. Likis for replying to our requests.

Funding

Fapesp student scholarship (2015/06764-8); Regina El Dib received a Brazilian Research Council (CNPq) scholarship (310953/2015-4).

Conflict of interest

The authors declare no conflicts of interest in the elaboration of this systematic review.

Authors' contributions

All authors contributed to all aspects of this study, including conducting the literature search, study design, data acquisition, data analysis & interpretation, and preparation, drafting, critical revision and final approval of the manuscript. Conception & design was led by Dr. Regina El Dib.

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