NKR09 Blodtransfusion_PICO 2_Kronisk hjertesygdom

Characteristics of studies

Characteristics of included studies

Almeida 2015

Methods	
Participants	
Interventions	
Outcomes	
Notes	For more information see Carson JL, Stanworth SJ, Roubinian N, Fergusson DA, Triulzi D, Doree C, Hebert PC. Transfusion thresholds and other strategies for guiding allogeneic red blood cell transfusion. Cochrane Database of Systematic Reviews 2016, Issue 10. Art. No.: CD002042. DOI: 10.1002/14651858.CD002042.pub4.

Risk of bias table

Bias	Authors' judgement	Support for judgement
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Blinding of participants and personnel (performance bias)	Unclear risk	For more information see Carson JL, Stanworth SJ, Roubinian N, Fergusson DA, Triulzi D, Doree C, Hebert PC. Transfusion thresholds and other strategies for guiding allogeneic red blood cell transfusion. Cochrane Database of Systematic Reviews 2016, Issue 10. Art. No.: CD002042. DOI: 10.1002/14651858.CD002042.pub4.
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Bracey 1999

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Bush 1997

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Carson 2011

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Gregersen 2015

Methods	
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Hajjar 2010

Methods	
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Holst 2014

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Hébert 1999

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Jairath 2015

Methods	
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Johnson 1992

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Blinding of outcome assessment (detection bias)	Unclear risk	Carson JL, Stanworth SJ, Roubinian N, Fergusson DA, Triulzi D, Doree C, Hebert PC. Transfusion thresholds and other strategies for guiding allogeneic red blood cell transfusion. Cochrane Database of Systematic Reviews 2016, Issue 10. Art. No.: CD002042. DOI: 10.1002/14651858.CD002042.pub4.
Incomplete outcome data (attrition bias)	Unclear risk	Carson JL, Stanworth SJ, Roubinian N, Fergusson DA, Triulzi D, Doree C, Hebert PC. Transfusion thresholds and other strategies for guiding allogeneic red blood cell transfusion. Cochrane Database of Systematic Reviews 2016, Issue 10. Art. No.: CD002042. DOI: 10.1002/14651858.CD002042.pub4.
Selective reporting (reporting bias)	Low risk	Carson JL, Stanworth SJ, Roubinian N, Fergusson DA, Triulzi D, Doree C, Hebert PC. Transfusion thresholds and other strategies for guiding allogeneic red blood cell transfusion. Cochrane Database of Systematic Reviews 2016, Issue 10. Art. No.: CD002042. DOI: 10.1002/14651858.CD002042.pub4.
Other bias	Low risk	Carson JL, Stanworth SJ, Roubinian N, Fergusson DA, Triulzi D, Doree C, Hebert PC. Transfusion thresholds and other strategies for guiding allogeneic red blood cell transfusion. Cochrane Database of Systematic Reviews 2016, Issue 10. Art. No.: CD002042. DOI: 10.1002/14651858.CD002042.pub4.

Koch 2017

Methods	**Study design:** Randomized controlled trial **Study grouping:** Parallel group
Participants	**Baseline Characteristics** Intervention 1 ● *Age*: 59, 15 (mean,SD) ● *Gender*: 37% women Control 1 ● *Age*: 60, 13 (mean,SD) ● *Gender*: 34% women **Included criteria:** The trial enrolled adults aged 18 years and older sched-uled for elective isolated heart valve procedures, coronaryartery bypass graft surgery (CABG) with or without valveprocedures, and ascending aorta replacement. **Pretreatment:** Baseline characteristics, clinical factors, and procedureswere generally similar between trigger groups
Interventions	**Intervention Characteristics** Intervention 1 ● *Description*: Hematocrit trigger 24% ● *Length of treatment*: For the duration of hospitalization (mean 10 days) ● *Longest follow-up after end of treatment*: none Control 1 ● *Description*: Hematocrit trigger 28% ● *Length of treatment*: For the duration of hospitalization (mean 10 days) ● *Longest follow-up after end of treatment*: none
Outcomes	*Mean units transfused* ● **Outcome type**: ContinuousOutcome *No. of patients receiving transfusion* ● **Outcome type**: DichotomousOutcome *Stroke* ● **Outcome type**: DichotomousOutcome *Infection* ● **Outcome type**: DichotomousOutcome
Notes	

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "Randomization was stratified by site, using within each site randomly sized blocks of 6, 8, 10, and 12 so that at any given time, approximately equal numbers of patients were randomized into each transfusion trigger group."

Allocation concealment (selection bias)	Unclear risk	Quote: "Randomization was stratified by site, using within each site randomly sized blocks of 6, 8, 10, and 12 so that at any given time, approximately equal numbers of patients were randomized into each transfusion trigger group. A" Judgement Comment: Nothing mentioned
Blinding of participants and personnel (performance bias)	Low risk	Quote: "Therefore, surgeons were blinded to the study arm, as were personnel assessing patient outcomes and the patients themselves."
Blinding of outcome assessment (detection bias)	Low risk	Quote: "Therefore, surgeons were blinded to the study arm, as were personnel assessing patient outcomes and the patients themselves. However,"
Incomplete outcome data (attrition bias)	Low risk	Judgement Comment: Dropouts equal distributed across groups and accounted for
Selective reporting (reporting bias)	Low risk	Quote: "The trial was approved by the Institutional Review Boards of each center and was registered at clinicaltrials.gov (#NCT00651573)." Judgement Comment: Matches study protocol
Other bias	Low risk	Judgement Comment: No other apparent sources of bias

Laine 2018

Methods	**Study design:** Randomized controlled trial **Study grouping:** Parallel group
Participants	**Baseline Characteristics** Intervention 1 ● *Age*: 70.5, median ● *Gender*: 37.5% female Control 1 ● *Age*: 64.5, median ● *Gender*: 30% female **Included criteria:** After registering the study at the Hospital District ofHelsinki and Uusimaa (§94,9.05.2014) and receiving approvalfrom the institutional Ethics Committee for Surgery inHelsinki University Hospital 2014 (D-number 58/13/03/02/2014), the authors gathered 80 patients scheduled for non-emergency coronary artery bypass grafting (CABG), simpleone valve (aortic or mitral) replacement or both, requiringcardiopulmonary bypass (CPB) **Excluded criteria:** Exclusion criteriaincluded any hereditary or acquired hemostatic disorders, anymalignancies, and severe chronic kidney disease (glomerularfiltration rateo30 mL/min). Patients'medical history and severityof the surgery was described with European System for CardiacOperative Risk Evaluation, (numeric) EuroSCORE I **Pretreatment:** eachgroup. All 80 patients were included in the analyses. Char-acteristics of the patients were fairly similar between the bothgroups, with the exception of the patients in Group 80 being older and having a higher Euro-SCORE
Interventions	**Intervention Characteristics** Intervention 1 ● *Description*: Restrictive blodtransfusion 80 g/d*L* ● *Longest follow-up after end of treatment*: 7 days after surgery Control 1 ● *Description*: Restrictive blodtransfusion 100 g/dL ● *Longest follow-up after end of treatment*: 7 days after surgery
Outcomes	*Mean units transfused, SD* ● **Outcome type**: ContinuousOutcome *Total number of units transfused, n* ● **Outcome type**: DichotomousOutcome
Notes	

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "Randomization was done in blocks of 20 patients and using closed envelopes (Fig 5)."
Allocation concealment (selection bias)	Low risk	Quote: "Randomization was done in blocks of 20 patients and using closed envelopes (Fig 5). Use"
Blinding of participants and personnel (performance bias)	High risk	Quote: "The study was unblinded due to the Finnish practice of anesthetists performing transfusions themselves."
Blinding of outcome assessment (detection bias)	Low risk	Quote: "The clinical staff was blinded to the ROTEM data. Other data collected during the study period were the amount of bleeding during the surgery (estimate done by surgeons/ anesthetists) and postoperatively from the chest tubes, RBC and blood product transfusions, diuresis, and cumulative fluid balance. Patient data during the surgery and intensive care were collected with PI Client Information System (Caresuite 8.2, PiCIS Inc, San Francisco, CA)."
Incomplete outcome data (attrition bias)	Low risk	Judgement Comment: No one lost to FU - see flowchart
Selective reporting (reporting bias)	Low risk	Judgement Comment: No apparent sources of bias
Other bias	Low risk	Judgement Comment: No other apparent sources of bias

Mazer 2017

Methods	**Study design:** Randomized controlled trial **Study grouping:** Parallel group
Participants	**Baseline Characteristics** Intervention 1 ● *Age*: 72, 10 (Mean, SD) ● *Gender*: 63,9% male Control 1 ● *Age*: 72, 10 (Mean, SD) ● *Gender*: 65,3% male **Included criteria:** We enrolled participants 18 years of age or olderwho were scheduled to undergo cardiac surgerywith cardiopulmonary bypass and who had a preoperativeadditive EuroSCORE I of 6 or higher. **Excluded criteria:** We excluded patients if they were unableto receive blood products, declined bloodproducts, were involved in a preoperative autologousdonation program, were undergoing hearttransplantation, were having surgery solely for theinsertion of a ventricular assist device, or werepregnant or lactating. Written informed consentwas obtained from all the participants beforeenrollment **Pretreatment:** The characteristics of the patients at baselinewere similar in the two groups
Interventions	**Intervention Characteristics** Intervention 1 ● *Description*: Restrictive blodtransfusion 7.5 g/dl ● *Length of treatment*: During surgery or ICU ● *Longest follow-up after end of treatment*: 28 days after surgery Control 1 ● *Description*: Liberal blodtransfusion 9.5 g/dl ● *Length of treatment*: During surgery or ICU ● *Longest follow-up after end of treatment*: 28 days after surgery
Outcomes	*Mortality, 30 days* ● **Outcome type**: DichotomousOutcome *No. of patients receiving transfusion* ● **Outcome type**: DichotomousOutcome *Mean number of units transfused* ● **Outcome type**: ContinuousOutcome *Myocardial infarct* ● **Outcome type**: DichotomousOutcome *Stroke* ● **Outcome type**: DichotomousOutcome *Infektion* ● **Outcome type**: DichotomousOutcome
Notes	

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Judgement Comment: Before surgery, eligible patients were randomlyassigned to one of two red-cell transfusion strategies,in a 1:1 ratio with the use of a concealedcentralized, Web-based system, stratified accordingto center, with computer-generated randompermuted blocks of varying sizes from two to six.
Allocation concealment (selection bias)	Low risk	Judgement Comment: Before surgery, eligible patients were randomlyassigned to one of two red-cell transfusion strategies,in a 1:1 ratio with the use of a concealedcentralized, Web-based system, stratified accordingto center, with computer-generated randompermuted blocks of varying sizes from two to six.
Blinding of participants and personnel (performance bias)	High risk	Judgement Comment: Itwas not possible to use formal blinding of theassigned transfusion strategy with regard to theparticipants and medical staff. However, participantswere not actively informed about the treatmentassignment Open label study
Blinding of outcome assessment (detection bias)	Low risk	Judgement Comment: outcome adjudicators were unaware of the trial-group assignments.
Incomplete outcome data (attrition bias)	Low risk	Judgement Comment: No one lost to FU and conducted ITT analyses
Selective reporting (reporting bias)	Low risk	Judgement Comment: Trial registered at clinicaltrials.gov number NCT02042898. No apparent sources of bias
Other bias	Low risk	Judgement Comment: No apperent sources of bias

Murphy 2015

Methods	**Study design:** **Study grouping:**
Participants	**Baseline Characteristics** Intervention 1 ● *Age*: 69.9 median ● *Gender*: 69.3% male Control 1 ● *Age*: 70.8 median ● *Gender*: 67.8% male **Included criteria:** Patients older than 16 years of age who were undergoing nonemergency cardiac surgery were eligible to participat **Excluded criteria:** exclusion criteria are de-scribed in Table S1 in the Supplementary Appen-dix, available at NEJM.org **Pretreatment:** The baseline characteristics were similar in the two groups
Interventions	**Intervention Characteristics** Intervention 1 ● *Description*: Restrictive blodtransfusion 7.5 g/dl ● *Longest follow-up after end of treatment*: 3 months after randomisation Control 1 ● *Description*: Liberal blodtransfusion 9 g/dL ● *Longest follow-up after end of treatment*: 3 months after randomisation
Outcomes	*Mortality, 30 days* ● **Outcome type**: DichotomousOutcome *Mean units transfused* ● **Outcome type**: ContinuousOutcome *No. of patients receiving transfusion* ● **Outcome type**: DichotomousOutcome *Myocardial infarct* ● **Outcome type**: DichotomousOutcome *Stroke* ● **Outcome type**: DichotomousOutcome *Infection* ● **Outcome type**: DichotomousOutcome
Notes	

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "Patients were randomly assigned to either the liberal transfusion-threshold group (threshold hemoglobin level, 9 g per deciliter) or the restric- tive transfusion-threshold group (threshold he- moglobin level, 7.5 g per deciliter) by means of a secure Internet-based system that concealed assignments and used cohort minimization to balance assignments according to center and type of surgery."
Allocation concealment (selection bias)	Low risk	Quote: "Patients were randomly assigned to either the liberal transfusion-threshold group (threshold hemoglobin level, 9 g per deciliter) or the restric- tive transfusion-threshold group (threshold he- moglobin level, 7.5 g per deciliter) by means of a secure Internet-based system that concealed assignments and used cohort minimization to balance assignments according to center and type of surgery. Physicians and" Judgement Comment: Allocation concealment
Blinding of participants and personnel (performance bias)	Unclear risk	Quote: "Physicians and nurses were aware of the group assignments. We intended participants to be unaware of the group assignments and tested our success in keeping the study groups blinded by asking the patients if they were aware of the group they were in."
Blinding of outcome assessment (detection bias)	High risk	Quote: "Physicians and nurses were aware of the group assignments. We"
Incomplete outcome data (attrition bias)	Low risk	Judgement Comment: All anlayses are based on the ITT. No apparent sources of bias
Selective reporting (reporting bias)	Low risk	Quote: "Research Health Technology Assessment program; Current Controlled Trials number, ISRCTN70923932.) a bs t r ac" Judgement Comment: Matches study protocol
Other bias	Low risk	Judgement Comment: No other sources of bias. No conflicts of interest

Parker 2013

Methods	
Participants	
Interventions	
Outcomes	
Notes	Carson JL, Stanworth SJ, Roubinian N, Fergusson DA, Triulzi D, Doree C, Hebert PC. Transfusion thresholds and other strategies for guiding allogeneic red blood cell transfusion. Cochrane Database of Systematic Reviews 2016, Issue 10. Art. No.: CD002042. DOI: 10.1002/14651858.CD002042.pub4.

Risk of bias table

Bias	Authors' judgement	Support for judgement
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Other bias	Low risk	Carson JL, Stanworth SJ, Roubinian N, Fergusson DA, Triulzi D, Doree C, Hebert PC. Transfusion thresholds and other strategies for guiding allogeneic red blood cell transfusion. Cochrane Database of Systematic Reviews 2016, Issue 10. Art. No.: CD002042. DOI: 10.1002/14651858.CD002042.pub4.

Shehata 2012

Methods	
Participants	
Interventions	
Outcomes	
Notes	Carson JL, Stanworth SJ, Roubinian N, Fergusson DA, Triulzi D, Doree C, Hebert PC. Transfusion thresholds and other strategies for guiding allogeneic red blood cell transfusion. Cochrane Database of Systematic Reviews 2016, Issue 10. Art. No.: CD002042. DOI: 10.1002/14651858.CD002042.pub4.

Risk of bias table

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Walsh 2013

Methods	
Participants	
Interventions	
Outcomes	
Notes	Carson JL, Stanworth SJ, Roubinian N, Fergusson DA, Triulzi D, Doree C, Hebert PC. Transfusion thresholds and other strategies for guiding allogeneic red blood cell transfusion. Cochrane Database of Systematic Reviews 2016, Issue 10. Art. No.: CD002042. DOI: 10.1002/14651858.CD002042.pub4.

Risk of bias table

Bias	Authors' judgement	Support for judgement
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Footnotes

Summary of findings tables

Additional tables

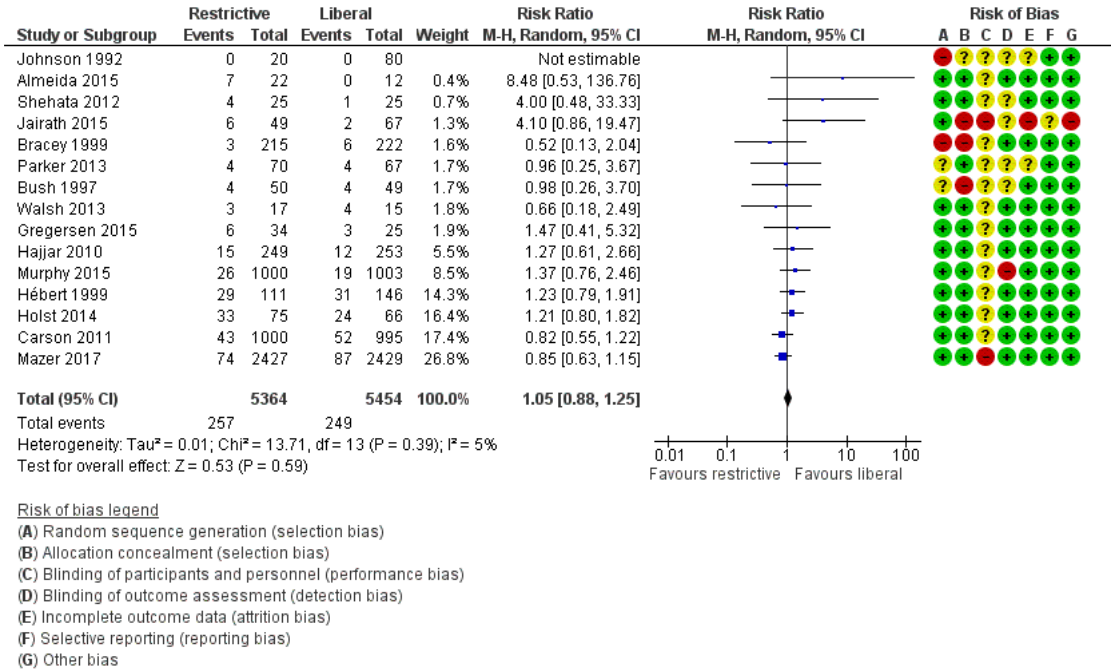
Data and analyses

1 Restrictive vs liberal

Outcome or Subgroup	Studies	Participants	Statistical Method	Effect Estimate
1.1 30-day mortality	15	10818	Risk Ratio (M-H, Random, 95% CI)	1.05 [0.88, 1.25]
1.2 Myocardial infarction	11	9799	Risk Ratio (M-H, Random, 95% CI)	1.10 [0.90, 1.34]
1.3 Congestive heart failure or lung oedema	4	2544	Risk Ratio (M-H, Random, 95% CI)	0.74 [0.35, 1.55]
1.4 Mean units of blood transfused	7	8225	Mean Difference (IV, Random, 95% CI)	-0.60 [-0.94, -0.27]
1.6 No. participants exposed to blood transfusion	9	10713	Risk Ratio (M-H, Random, 95% CI)	0.67 [0.57, 0.77]
1.7 Stroke	8	10582	Risk Ratio (M-H, Random, 95% CI)	0.93 [0.70, 1.23]
1.8 Infection	6	10410	Risk Ratio (M-H, Random, 95% CI)	1.03 [0.89, 1.18]

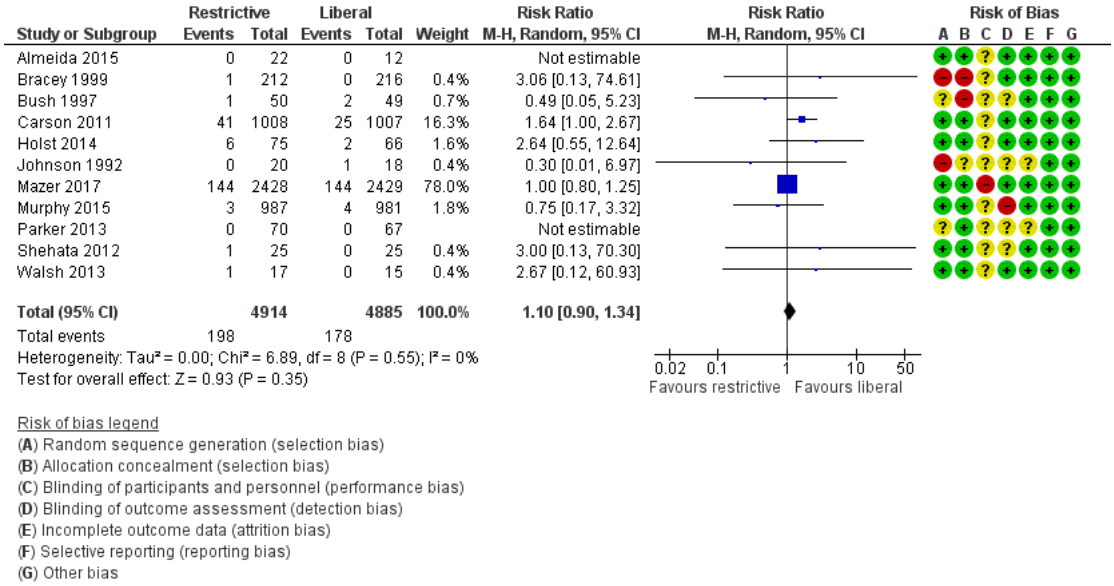
Figures

Figure 1 (Analysis 1.1)



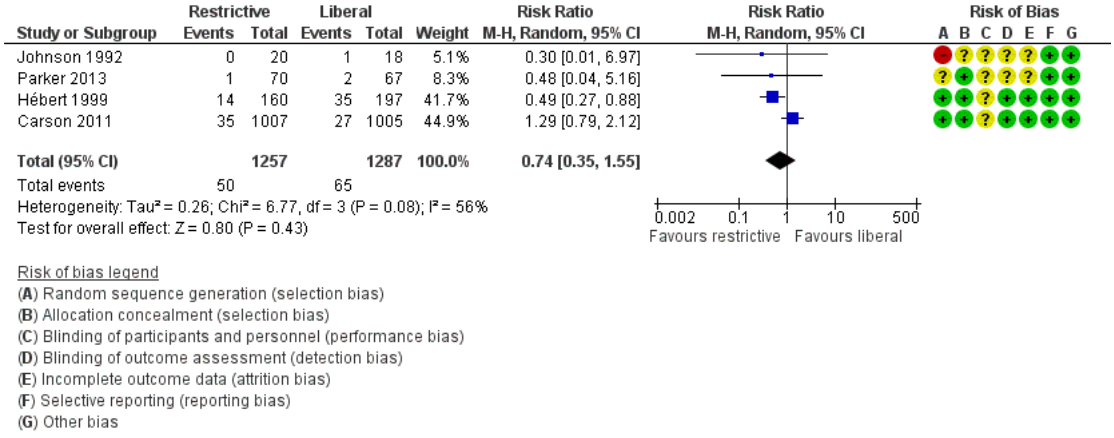
Forest plot of comparison: 1 Restrictive vs liberal, outcome: 1.1 30-day mortality.

Figure 2 (Analysis 1.2)



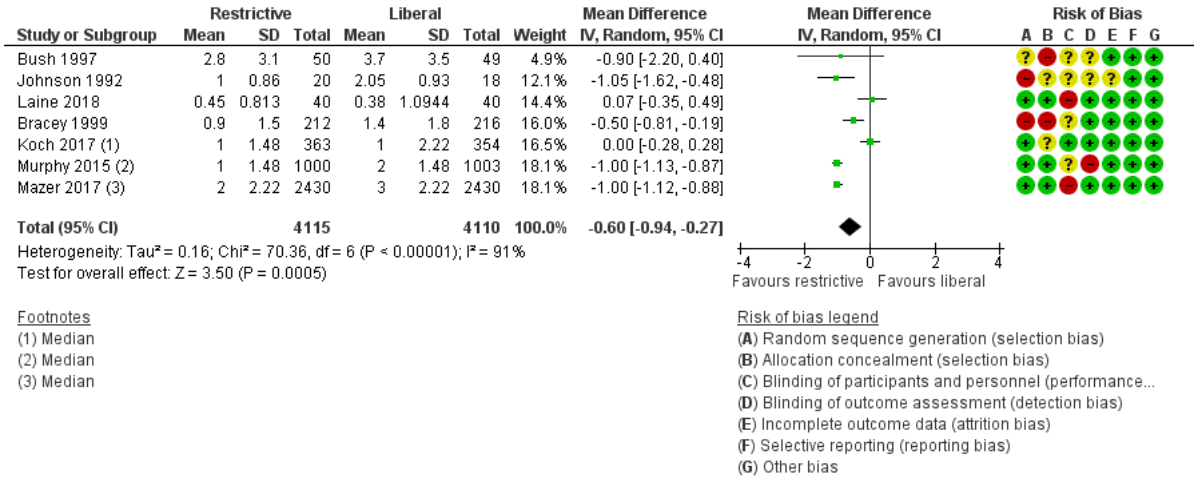
Forest plot of comparison: 1 Restrictive vs liberal, outcome: 1.2 Myocardial infarction.

Figure 3 (Analysis 1.3)



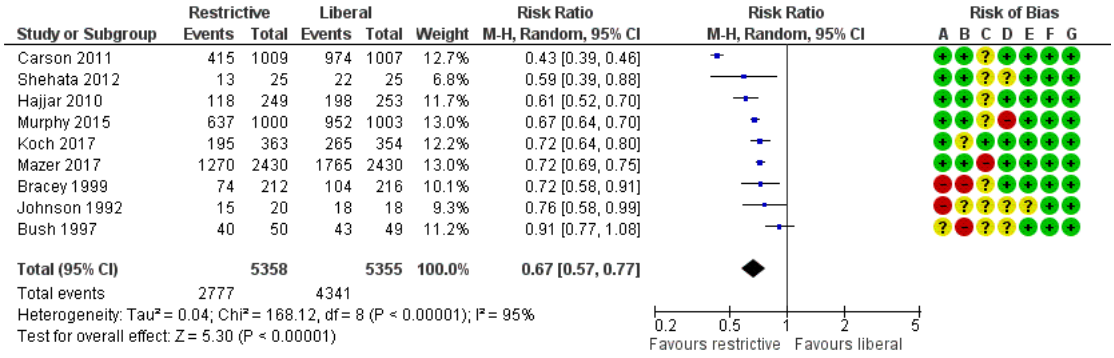
Forest plot of comparison: 1 Restrictive vs liberal, outcome: 1.3 Congestive heart failure or lung oedema.

Figure 4 (Analysis 1.4)



Forest plot of comparison: 1 Restrictive vs liberal, outcome: 1.4 Mean units of blood transfused.

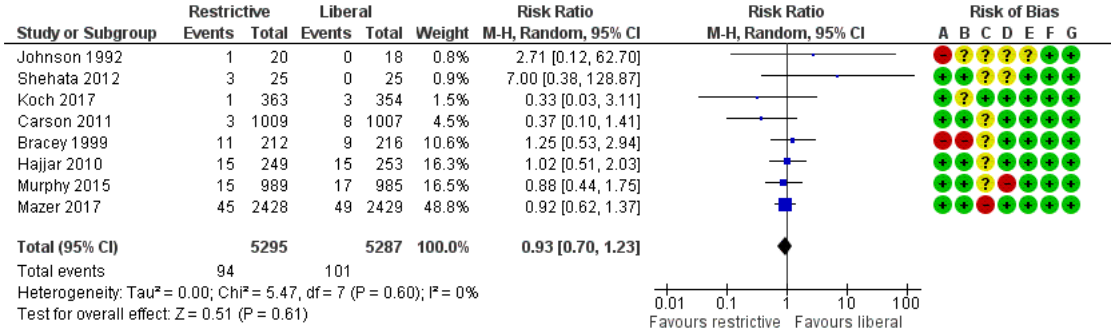
Figure 5 (Analysis 1.6)



Risk of bias legend
(A) Random sequence generation (selection bias)
(B) Allocation concealment (selection bias)
(C) Blinding of participants and personnel (performance bias)
(D) Blinding of outcome assessment (detection bias)
(E) Incomplete outcome data (attrition bias)
(F) Selective reporting (reporting bias)
(G) Other bias

Forest plot of comparison: 1 Restrictive vs liberal, outcome: 1.6 No. participants exposed to blood transfusion.

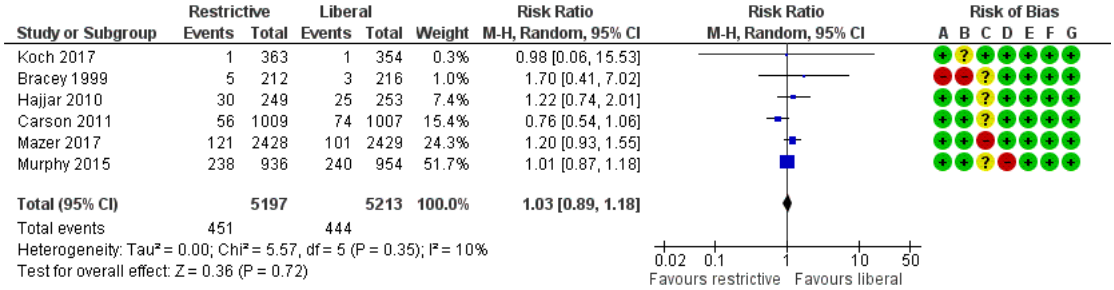
Figure 6 (Analysis 1.7)



Risk of bias legend
(A) Random sequence generation (selection bias)
(B) Allocation concealment (selection bias)
(C) Blinding of participants and personnel (performance bias)
(D) Blinding of outcome assessment (detection bias)
(E) Incomplete outcome data (attrition bias)
(F) Selective reporting (reporting bias)
(G) Other bias

Forest plot of comparison: 1 Restrictive vs liberal, outcome: 1.7 Stroke.

Figure 7 (Analysis 1.8)



Risk of bias legend
(A) Random sequence generation (selection bias)
(B) Allocation concealment (selection bias)
(C) Blinding of participants and personnel (performance bias)
(D) Blinding of outcome assessment (detection bias)
(E) Incomplete outcome data (attrition bias)
(F) Selective reporting (reporting bias)
(G) Other bias

Forest plot of comparison: 1 Restrictive vs liberal, outcome: 1.8 Infection.