NKR09_Blodkomponenter_PICO 4 TEG/ROTEM for Blood transfusion

Characteristics of studies

Characteristics of included studies

Ak 2009

Methods	
Participants	
Interventions	
Outcomes	
Notes	See Wikkelsøe, A et al "Thromboelastography (TEG) or rotational thromboelastometry (ROTEM) to monitor haemostatic treatment in bleeding patients" Cochrane review 2016

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	High risk	See Wikkelsøe, A et al "Thromboelastography (TEG) or rotational thromboelastometry (ROTEM) to monitor haemostatic treatment in bleeding patients" Cochrane review 2016
Allocation concealment (selection bias)	High risk	See Wikkelsøe, A et al "Thromboelastography (TEG) or rotational thromboelastometry (ROTEM) to monitor haemostatic treatment in bleeding patients" Cochrane review 2016
Blinding of participants and personnel (performance bias)	Low risk	See Wikkelsøe, A et al "Thromboelastography (TEG) or rotational thromboelastometry (ROTEM) to monitor haemostatic treatment in bleeding patients" Cochrane review 2016
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Incomplete outcome data (attrition bias)	Low risk	See Wikkelsøe, A et al "Thromboelastography (TEG) or rotational thromboelastometry (ROTEM) to monitor haemostatic treatment in bleeding patients" Cochrane review 2016
Selective reporting (reporting bias)	Low risk	See Wikkelsøe, A et al "Thromboelastography (TEG) or rotational thromboelastometry (ROTEM) to monitor haemostatic treatment in bleeding patients" Cochrane review 2016
Other bias	Unclear risk	See Wikkelsøe, A et al "Thromboelastography (TEG) or rotational thromboelastometry (ROTEM) to monitor haemostatic treatment in bleeding patients" Cochrane review 2016

Avidan 2004

Methods	
Participants	
Interventions	
Outcomes	
Notes	See Wikkelsøe, A et al "Thromboelastography (TEG) or rotational thromboelastometry (ROTEM) to monitor haemostatic treatment in bleeding patients" Cochrane review 2016

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De 2016

Methods	**Study design:** Randomized controlled trial **Study grouping:** Parallel group
Participants	**Baseline Characteristics** TEG/ROTEM ● *Age*: 57.8 ● *Males %*: 53.3 Conventional analysis ● *Age*: 58.6 ● *Males %*: 73.3 Overall ● *Age*: ● *Males %*: **Included criteria:** Enrollment criteria were age between 18 and 80years; histological or imaging-proven liver cirrhosis ofany etiology; and INR>1.8 and/or PLT503109/L **Excluded criteria:** Exclusion criteria were ongoing bleeding; previous orcurrent thrombotic events defined as any documentedblood clot in a venous or arterial vessel; antiplatelet or -coagulant therapy at the time of enrollment or that hadbeen discontinued less than 7 days before evaluation forthe study; presence of documented infection or sepsisaccording to ACCP-SCCM criteria18; or hemodialysisin the previous 7 days. **Pretreatment:** No other apparent differences at baseline between the groups
Interventions	**Intervention Characteristics** TEG/ROTEM ● *Description*: Patients in the TEG group received FFP at a dose of10 mL/kg of ideal body weight when r time was greaterthan 40 minutes and they would receive platelet transfu-sion in the amount of 1 apheresis unit (i.e., the equiva-lent of six or more units of platelets from whole blood,3-631011platelets) when MA was shorter than30 mm. ● *Longest follow-up*: Conventional analysis ● *Description*: n the SOC group, all patients received FFPand/or PLT: Patients received FFP at the dose of 10 mL/kg of ideal body weight when the INR was higher than1.8 and/or received PLT in the amount of 1 unit whenplatelet count was below 503109/L. ● *Longest follow-up*:
Outcomes	*Mortality* ● **Outcome type**: DichotomousOutcome *No. of patients transfused, RBC, n* ● **Outcome type**: DichotomousOutcome *No. of patients transfused, platelets, n* ● **Outcome type**: DichotomousOutcome *No. of patients transfused, plasma, n* ● **Outcome type**: DichotomousOutcome *Severe adverse events, n* ● **Outcome type**: DichotomousOutcome *Blood volume/blood loss* ● **Outcome type**: ContinuousOutcome
Notes	

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Judgement Comment: 'Randomly assigned.' 'Randomization was performed electronically by block of 4 in a 1:1 rate. No difference between intervention and control group
Allocation concealment (selection bias)	Unclear risk	Judgement Comment: Nothing mentioned
Blinding of participants and personnel (performance bias)	High risk	Judgement Comment: Open-label RCT Unblinded, but outcomes are not likely influenced by lack of blinding, as treatment was given according to a well-defined algorithm.
Blinding of outcome assessment (detection bias)	High risk	Judgement Comment: Open label RCT. Unblinded, but outcome assessment likely not influenced by lack of blinding.
Incomplete outcome data (attrition bias)	Low risk	Judgement Comment: No missing data
Selective reporting (reporting bias)	Low risk	Judgement Comment: No other apparent sources of bias
Other bias	Low risk	Judgement Comment: No other apparent sources of bias

Girdauskas 2010

Methods	
Participants	
Interventions	
Outcomes	
Notes	See Wikkelsøe, A et al "Thromboelastography (TEG) or rotational thromboelastometry (ROTEM) to monitor haemostatic treatment in bleeding patients" Cochrane review 2016

Risk of bias table

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Other bias	Unclear risk	See Wikkelsøe, A et al "Thromboelastography (TEG) or rotational thromboelastometry (ROTEM) to monitor haemostatic treatment in bleeding patients" Cochrane review 2016

Gonzalez 2016

Methods	**Study design:** Randomized controlled trial **Study grouping:** Parallel group
Participants	**Baseline Characteristics** TEG/ROTEM ● *Age*: 41.0 ● *Males %*: 66.0 Conventional analysis ● *Age*: 38.0 ● *Males %*: 74.5 Overall ● *Age*: ● *Males %*: **Included criteria:** Injured patients at least18 years of age that met criteria for MTP activation upon ED arrival during a 3-year period ending July 30, 2014, were enrolled in the study. MTP activation was based on the Resuscitation Outcome Consortium criteria18 [systolic blood pressure (SBP) 70 mm Hg or SBP 70–90 mm Hg with heart rate (HR) ≥ 108 beats/min], in addition to any of the following injury patterns: penetrating torso wound, unstable pelvic fracture, or abdominal ultrasound suspicious of bleeding in more than one region. **Excluded criteria:** Patients were not eligible if they were prisoners or pregnant; patients were removed from the study if these criteria became known after activation of the MTP. **Pretreatment:** No apparent difference at baseline
Interventions	**Intervention Characteristics** TEG/ROTEM ● *Description*: TEG yields the following variables: activated clotting time (ACT; the time to beginning of clot formation, seconds), angle (rate of clot strength increase, degrees), maximum amplitude (MA; maximal clot strength achieved, millimeters), and percent clot lysis 30 minutes after reaching MA (LY30, %). Studies have correlated ACT with coagulation factor activity and thrombin generation, angle with fibrinogen concentration and function, MA with platelet—fibrin interactions, and LY30 with fibrinolysis ● *Longest follow-up*: 24 hours Conventional analysis ● *Description*: In the CCA group, the following parameters triggered the following transfusions: INR equal or greater than 1.5 = 2 units of plasma; fibrinogen less than 150 mg/dL = 10-pack of cryoprecipitate; platelet count less than 100,000/µL = 1 unit of apheresis platelets. Antifibrinolytic medication (tranexamic acid, 1 g, intravenous) was administered in the setting of suspicion of fibrinolysis with an elevated D-dimer (>0.5 µg/mL). These thresholds for transfusion represent parameters that are considered standard of care based on published consensus guidelines.24–29 In general, CCA results are available approximately 30 to 45 minutes from collection ● *Longest follow-up*: 24 hours
Outcomes	*Mortality* ● **Outcome type**: DichotomousOutcome *No. of patients transfused, RBC, n*

	● **Outcome type**: DichotomousOutcome *No. of patients transfused, platelets, n* ● **Outcome type**: DichotomousOutcome *No. of patients transfused, plasma, n* ● **Outcome type**: DichotomousOutcome *Severe adverse events, n* ● **Outcome type**: DichotomousOutcome *Blood volume/blood loss* ● **Outcome type**: ContinuousOutcome
Notes	

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	High risk	Quote: "by the same clinicians. Thus, individual randomization was considered unsafe for this trial, and a process of randomization by weekly alternation of the 2 treatment modalities was devised. For example, patients enrolled during"
Allocation concealment (selection bias)	High risk	Judgement Comment: Randomization done by investigators
Blinding of participants and personnel (performance bias)	High risk	Judgement Comment: No blinding, high risk of 'no blinding' influencing treatment.
Blinding of outcome assessment (detection bias)	Unclear risk	Judgement Comment: Nothing mentioned
Incomplete outcome data (attrition bias)	Low risk	Judgement Comment: Dropouts have been accounted for
Selective reporting (reporting bias)	Low risk	Judgement Comment: No other apparent sources of bias
Other bias	Low risk	Judgement Comment: No other apparent sources of bias

Kultufan Turan 2006

Methods	
Participants	
Interventions	
Outcomes	
Notes	See Wikkelsøe, A et al "Thromboelastography (TEG) or rotational thromboelastometry (ROTEM) to monitor haemostatic treatment in bleeding patients" Cochrane review 2016

Risk of bias table

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Nuttal 2001

Methods	
Participants	
Interventions	
Outcomes	
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Royston 2001

Methods	
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Outcomes	
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Shore-Lesserson 1999

Methods	
Participants	
Interventions	
Outcomes	
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Wang 2010

Methods	
Participants	
Interventions	
Outcomes	
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Weber 2012

Methods	
Participants	
Interventions	
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Westbrook 2009

Methods	
Participants	
Interventions	
Outcomes	
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Footnotes

Characteristics of excluded studies

Footnotes

Characteristics of studies awaiting classification

Footnotes

Characteristics of ongoing studies

Footnotes

Summary of findings tables

Additional tables

References to studies

Included studies

Ak 2009

Published data only (unpublished sought but not used)

[Empty]

Avidan 2004

Published data only (unpublished sought but not used)

[Empty]

De 2016

De, Pietri L.; Bianchini M.; Montalti R.; De, Maria N.; Di, Maira T.; Begliomini B.; Gerunda G.E.; di, Benedetto F.; Garcia-Tsao G.; Villa E.. Thrombelastography-guided blood product use before invasive procedures in cirrhosis with severe coagulopathy: A randomized, controlled trial. Hepatology 2016;63(2):566-573. [DOI: http://dx.doi.org/10.1002/hep.28148]

Girdauskas 2010

Published data only (unpublished sought but not used)

[Empty]

Gonzalez 2016

Gonzalez, Eduardo; Moore, Ernest E.; Moore, Hunter B.; Chapman, Michael P.; Chin, Theresa L.; Ghasabyan, Arsen; Wohlauer, Max V.; Barnett, Carlton C.; Bensard, Denis D.; Biffl, Walter L.; Burlew, Clay C.; Johnson, Jeffrey L.; Pieracci, Fredric M.; Jurkovich, Gregory J.; Banerjee, Anirban; Silliman, Christopher C.; Sauaia, Angela. Goal-directed Hemostatic Resuscitation of Trauma-induced Coagulopathy: A Pragmatic Randomized Clinical Trial Comparing a Viscoelastic Assay to Conventional Coagulation Assays. Annals of Surgery 2016;263(6):1051-9. [DOI: https://dx.doi.org/10.1097/SLA.0000000000001608]

Kultufan Turan 2006

Published and unpublished data

[Empty]

Nuttal 2001

Published data only (unpublished sought but not used)

[Empty]

Royston 2001

Published data only (unpublished sought but not used)

[Empty]

Shore-Lesserson 1999

Published and unpublished data

[Empty]

Wang 2010

Published data only (unpublished sought but not used)

[Empty]

Weber 2012

Published and unpublished data

[Empty]

Westbrook 2009

Published data only (unpublished sought but not used)

[Empty]

Excluded studies

Studies awaiting classification

Ongoing studies

Other references

Additional references

Other published versions of this review

Classification pending references

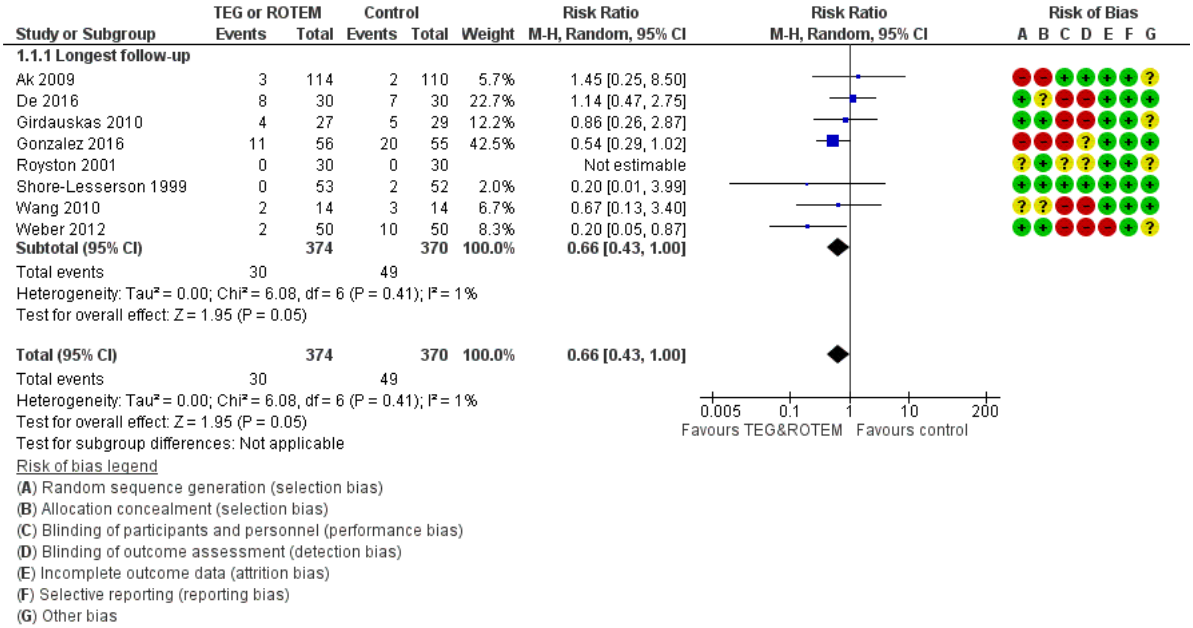
Data and analyses

1 TEG or ROTEM versus any comparison

Outcome or Subgroup	Studies	Participants	Statistical Method	Effect Estimate
1.1 Mortality	8	744	Risk Ratio (M-H, Random, 95% CI)	0.66 [0.43, 1.00]
1.1.1 Longest follow-up	8	744	Risk Ratio (M-H, Random, 95% CI)	0.66 [0.43, 1.00]
1.2 Patients receiving RBCs	7	687	Risk Ratio (M-H, Random, 95% CI)	0.88 [0.81, 0.96]
1.2.1 Longest follow-up	7	687	Risk Ratio (M-H, Random, 95% CI)	0.88 [0.81, 0.96]
1.3 Patients receiving FFP	6	647	Risk Ratio (M-H, Random, 95% CI)	0.42 [0.28, 0.62]
1.3.1 Longest follow-up	6	647	Risk Ratio (M-H, Random, 95% CI)	0.42 [0.28, 0.62]
1.4 Patients receiving platelets	7	687	Risk Ratio (M-H, Random, 95% CI)	0.66 [0.51, 0.86]
1.4.1 Longest follow-up	7	687	Risk Ratio (M-H, Random, 95% CI)	0.66 [0.51, 0.86]
1.6 Blood loss, ml	10	854	Mean Difference (IV, Random, 95% CI)	-115.15 [-183.10, -47.20]
1.8 Severe adverse events	1	60	Risk Ratio (M-H, Fixed, 95% CI)	0.20 [0.01, 4.00]

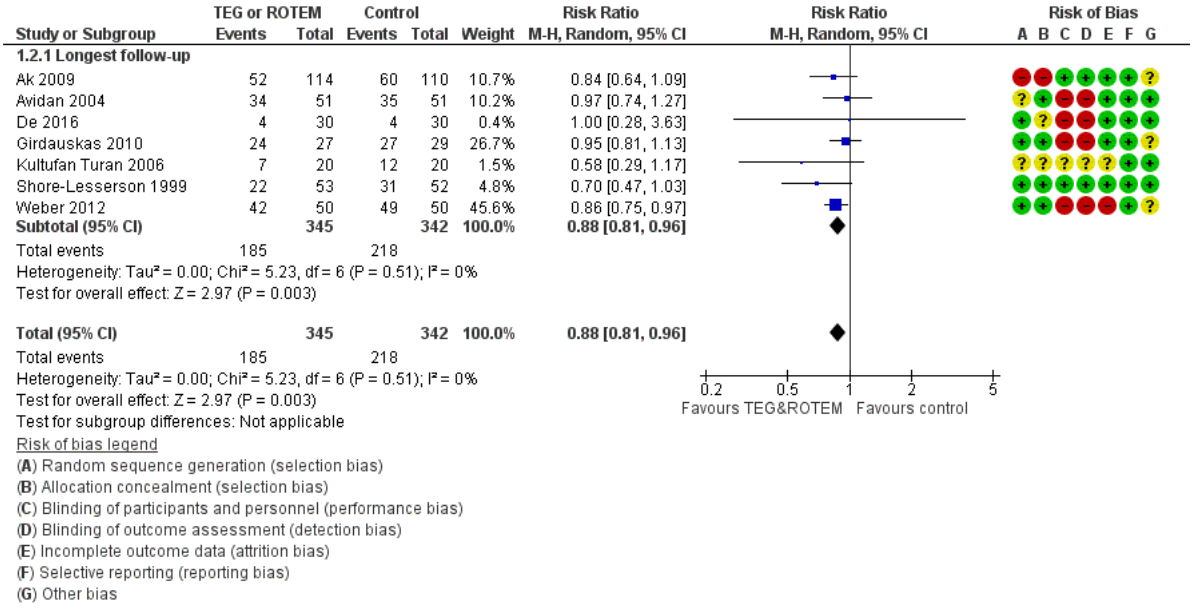
Figures

Figure 1 (Analysis 1.1)



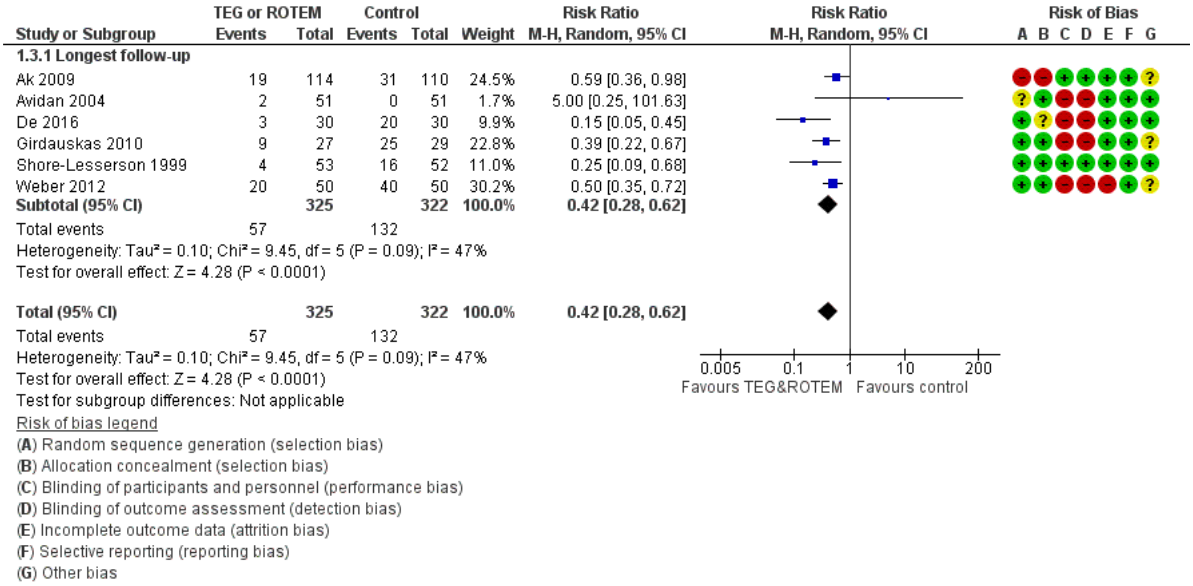
Forest plot of comparison: 1 TEG or ROTEM versus any comparison, outcome: 1.1 Mortality.

Figure 2 (Analysis 1.2)



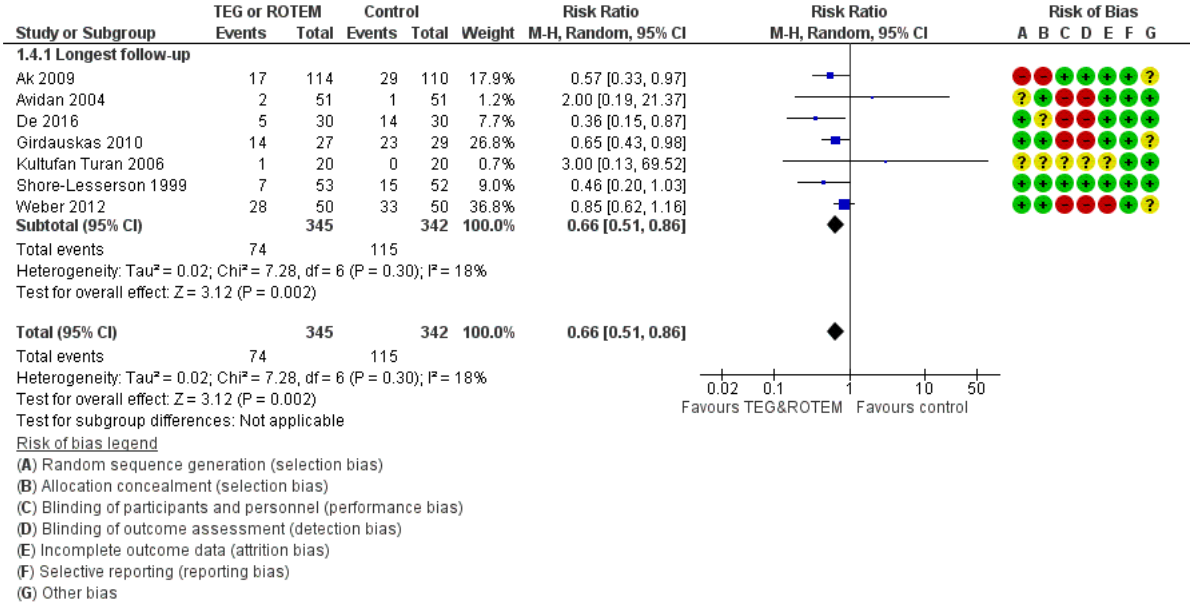
Forest plot of comparison: 1 TEG or ROTEM versus any comparison, outcome: 1.2 Patients receiving RBCs.

Figure 3 (Analysis 1.3)



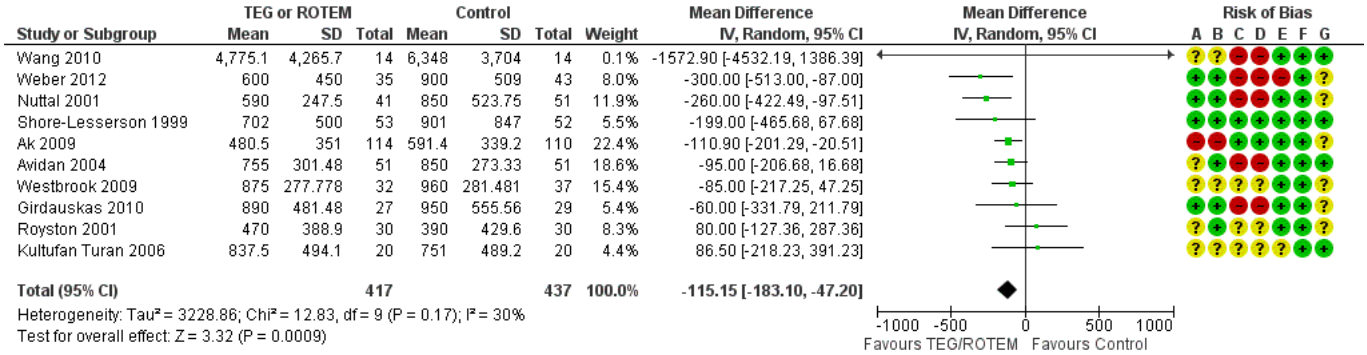
Forest plot of comparison: 1 TEG or ROTEM versus any comparison, outcome: 1.3 Patients receiving FFP.

Figure 4 (Analysis 1.4)



Forest plot of comparison: 1 TEG or ROTEM versus any comparison, outcome: 1.4 Patients receiving platelets.

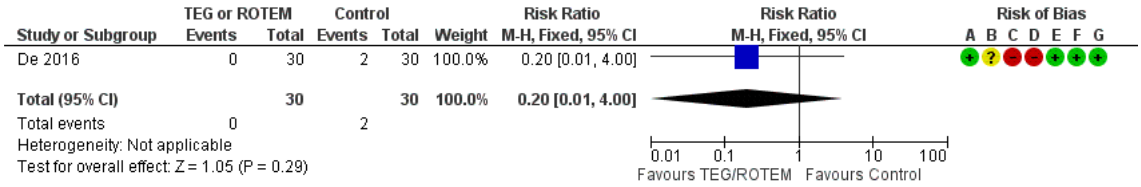
Figure 5 (Analysis 1.6)



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 TEG or ROTEM versus any comparison, outcome: 1.6 Blood loss, ml.

Figure 6 (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 TEG or ROTEM versus any comparison, outcome: 1.8 Severe adverse events.