Rotational thromboelastometry and thromboelastography for patients undergoing surgical procedures: an indirect meta-analysis

Tromboelastometria rotacional e tromboelastografia para pacientes submetidos a procedimentos cirúrgicos: uma metanálise indireta

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Aknowledgements
This research was funded by the Brazilian research promoting organizations *Conselho Nacional de Desenvolvimento Científico e Tecnológico* (CNPq; protocol 381587/2018-5) and *Instituto de Avaliação de Tecnologias em Saúde* (IATS). No pharmaceutical companies contributed in any way with this research. The author declares to have no conflicts of interest that could influence these results.

Abstract: ***Background:*** There is no consensus in the literature on the superiority between viscoelastic haemostatic assay (VHA) devices and several authors have performed meta-analyzes including them within the same group, assuming that their effects are similar. ***Objective:*** The objective of this study is to compare the efficacy of the protocols guided by rotational thromboelastometry with the protocols guided by thromboelastography for the control of the coagulation on patients undergoing surgical procedures. ***Methods:*** An indirect meta-analysis was conducted under a frequentist approach. Weights were calculated using the inverse variance method and adjusted using the DerSimonian and Laird random effects model. The measure of association used was the Odds Ratio (OR). All analyzes were performed in R. ***Results:*** No significant difference was observed between ROTEM® and TEG® in the indirect meta-analysis for the outcomes mortality (OR=0.6482, 95%CI=0.2213-1.8984), acute kidney injury (OR=0.5282, 95%CI=0.0858-3.2522), thromboembolic events (OR=0.2759, 95%CI=0.0051-14.9529), reoperation for bleeding (OR=1.0719, 95%CI=0.3589-3.2013), risk of RBC transfusion (OR=1.0044, 95%CI=0.5346 to 1.8872), FFP (OR=0.6964, 95%CI=0.1258-3.8554), or platelets (OR=1.1956, 95%CI=0.4524 to 3.1597), or volume of RBC transfusion (MD=-0.0847, 95%CI=-3.6879 to 3.5185). ***Conclusion:*** No difference was observed between thromboelastography and rotational thromboelastometry in any of the outcomes included. This result suggest that they might be combined into a single meta-analysis. Nevertheless, there is much imprecision in the data for a robust conclusion.

Keywords: Blood Coagulation, Blood Coagulation Tests, General Surgery, Thrombelastography, Review.

Introdução
Não há consenso na literatura sobre a superioridade entre dispositivos utilizados para realizer testes viscoelásticos (TVE) e vários autores realizaram metanálises incluindo-os dentro do mesmo grupo, assumindo que seus efeitos são semelhantes. **Resumo:** ***Objetivo:*** O objetivo deste estudo é comparar a eficácia dos protocolos guiados por tromboelastometria rotacional com os protocolos guiados por tromboelastografia para o controle da coagulação em pacientes submetidos a procedimentos cirúrgicos. ***Métodos:*** Uma meta-análise indireta foi conduzida sob uma abordagem frequentista. Os pesos foram calculados usando o método

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da variância inversa e ajustados pelo modelo de efeitos aleatórios DerSimonian e Laird. A medida de associação utilizada foi o Odds Ratio (OR). Todas as análises foram realizadas em R. ***Resultados:*** Não foi observada diferença significativa entre a tromboelastometria rotacional e a tromboelastografia na metanálise indireta para os desfechos mortalidade (OR=0,6482, IC95%=0,2213-1,8984), lesão renal aguda (OR=0,5282, IC95%=0,0858-3,2522), eventos tromboembólicos (OR=0,2759, IC95%=0,0051-14,9529), reoperação por sangramento (OR=1,0719, IC95%=0,3589-3,2013), risco de transfusão de hemácias (OR=1,0044, IC95%=0,5346 a 1,8872), FFP (OR=0,6964, IC95%=0,1258-3,8554) ou plaquetas (OR=1,1956, IC95%=0,4524 a 3,1597) ou volume de transfusão de hemácias (MD=-0,0847, IC95%=-3,6879 a 3,5185). ***Conclusão:*** Não foi observada diferença entre a tromboelastografia e a tromboelastometria rotacional em nenhum dos desfechos incluídos. Este resultado sugere que eles podem ser combinados em uma única metanálise. No entanto, há muita imprecisão nos dados para uma conclusão robusta.

Palavras-chave*:* Coagulação Sanguínea, Testes de Coagulação Sanguínea, Cirurgia Geral, Trombelastografia, Revisão.

Introduction

Hemorrhage is a major concern in patients undergoing surgery that, if not properly treated, may cause disastrous outcomes for patients [1,2]such as overall mortality and bleeding events, conducted subgroup and sensitivity analyses, examined the role of bias, and applied trial sequential analyses (TSAs. Bleeding control is achieved through surgical hemostasis and transfusion of blood products and blood components. These transfusions can be driven by algorithms based on clinical decisions associated or not to standard laboratory tests (SLTs) or viscoelastic haemostatic assays (VHAs) [1,3]749 of them included in 7 randomized controlled trials (RCTs. The fast and comprehensive results made the VHAs popular for monitoring the coagulation in patients undergoing cardiac surgery, liver transplantation and obstetric procedures [4]. They can distinguish between major coagulopathies, such as thrombocytopenia, deficiency of coagulation factors, heparin effect, hypofibrinogenemia, and hyperfibrinolysis, and guide a targeted, individualized and timely intervention [5,6]. Despite that, many health services still use a protocol based on clinical decision and/or SLT. These SLTs can take up to 45 to 60 minutes to be available and this delay in the management of coagulopathies diminishes their usefulness in urgent settings [1,2,5–10]thromboelastography or rotational thromboelastometry in bleeding patients. We searched for randomised, controlled trials irrespective of publication status, publication date, blinding status, outcomes published or language from date of inception to 5 January 2016 in six bibliographic databases. We included 17 trials (1493 participants.

Two different VHAs are most commonly cited in the medical literature. These are the rotational thromboelastometry (ROTEM®) and thromboelastography (TEG®). It has been argued that the use of VHAs near the patient, can improve the response time up to 15 to 20 minutes [2,11]EMBASE (Ovid. Some very recent reviews showed divergent results for the technologies and raised questions about the efficacy of the VHAs in terms of final outcomes [1,2,12,13]such as overall mortality and bleeding events, conducted subgroup and sensitivity analyses, examined the role of bias, and applied trial sequential analyses (TSAs. In face of this conundrum, our team conducted a comprehensive systematic review and found that VHAs improve mortality rates (RR=0.64, 95%CI=0.43-0.96, p-value=0.03; I^2=0%, p-value=0.52; 10 studies, 888 patients), risk of acute kidney injury (RR=0.53, 95%CI=0.34-0.83, p-value=0.005; I^2=0%, p-value=0.43; five studies, 449 individuals), risk of red blood cell (RBC) (RR=0.91, 95%CI=0.85-0,97, p-value=0.004; I^2=0%, p-value=0.48; 12 studies, 937 patients), platelets (RR=0.68, 95%CI=0.52-0.90, p-value=0.007; I^2=40%, p-value=0.07; 13 studies, 997 patients) and fresh frozen plasma (FFP) transfusion (RR=0.44, 95%CI=0.25-0.78, p-value=0.005; I^2=87%, p-value<0.001; 11 studies, 926 patients) [14,15]. These results are not only statistically significant but also clinically relevant. There also seems to be a bigger advantage for patients with coagulation problems and high-risk of bleeding [15]. Other systematic reviews also showed this advantage in terms of transfusion of blood products and components and acute kidney injury [1,2,7,12,13,16]such as overall mortality and bleeding events, conducted subgroup and sensitivity analyses, examined the role of bias, and applied trial sequential analyses (TSAs, but only one had shown the advantage in terms of mortality [1,7]thromboelastography or rotational thromboelastometry in bleeding patients. We searched for randomised, controlled trials irrespective of publication status, publication date, blinding status, outcomes published or language from date of inception to 5 January 2016 in six bibliographic databases. We included 17 trials (1493 participants.

Another issue is that there is no consensus in the literature on the superiority between rotational thromboelastometry and thromboelastography, so most reviews included both within a generic VHA category [1,2,7,12–14,16]such as overall mortality and bleeding events, conducted subgroup and sensitivity analyses, examined the role of bias, and applied trial sequential analyses (TSAs. The objective of this study is to compare the efficacy of the protocols guided by rotational thromboelastometry with the protocols guided by thromboelastography for the control of the coagulation on patients undergoing surgical procedures.

Methods

This is a *post hoc* analysis of the data collected by Santos et al. [14]. The complete information on the search strategy, selection process and data collection can be found elsewhere [14]. In this study, an indirect meta-analysis was conducted with data from randomized controlled trials (RCTs) to compare protocols guided by thromboelastography and rotational thromboelastometry for the control of coagulation in patients undergoing surgical procedures. This report followed the principles of the *PRISMA Extension Statement for Reporting of Systematic Reviews Incorporating Network Meta-analyses of Health Care Interventions* [17].

Interventions

The rotational thromboelastometry system (ROTEM®, TEM International GmbH, Munich, Germany) is based on the thromboelastography technique (TEG®) that was first described in 1948 to investigate the processes of coagulation of unchanged whole blood, through a representation graph of the fibrin polymerization process [18–21]. In 1996, the term thromboelastography (TEG®) was registered by Haemoscope Corporation and has been used to describe the test developed by this company[19,21]. Thus, the previous ROTEG®, rotational thromboelastography, was renamed ROTEM®, rotational thromboelastometry. With ROTEM®, the signal from the pin suspended in the blood is transmitted by an optical detection system, and not by a torsion cable, and the movement is performed by the pin, not by the cuvette as occurs in TEG® [21–25].

Outcomes

The primary outcomes evaluated were mortality at the longest follow-up, acute kidney injury (AKI), thrombotic events, and reoperation for bleeding. Secondary outcomes include the risk of transfusion of RBC, FFP, and platelets. The volume of RBC transfused was also included, but as a less reliable outcome in face of the important heterogeneity in the data.

Data analysis

A network meta-analysis was conducted using a frequentist approach. The weights were calculated by the inverse variance method and adjusted by the DerSimonian and Laird random effects model. Since we used inverse variance to calculate the weights, when the heterogeneity is null, the result of the random-effects and fixed-effects model are equal. The data was presented as Odds Ratios (ORs) with confidence intervals of 95% (IC95%). All analyzes were conducted in R [26] with the netmeta package [27]. All the results, analyzes, and scripts used in this study are available at **Supplementary Materials**. The original data is available upon request.

Results

In total, 21 publications, referring to 21 studies, were included in the final analysis [14]. The study selection flowchart is available in Santos et al. [14] with the description of the included studies. Eleven studies used thromboelastography [4,28,37,29–36] we aimed to test the role of a routine thromboelastography (TEG and ten used rotational thromboelastometry [38–47]we evaluated effects of thromboelastometrically guided algorithm on transfusion requirements. METHODS: Fifty-six consecutive patients (25 with acute type A dissection as the VHA device. No statistical difference was observed between rotational thromboelastography and thromboelastometry in the indirect meta-analysis for mortality (OR=0.6482, IC95%=0.2213-1.8984), acute kidney injury (OR=0.5282, IC95%=0.0858-3.2522), thromboembolic events (OR=0.2759, IC95%=0.0051-14.9529), reoperation for bleeding (OR=1.0719, IC95%=0.3589-3.2013), risk of transfusion of RBC (OR=1.0044, IC95%=0.5346 a 1.8872), FFP (OR=0.6964, IC95%=0.1258-3.8554), platelets (OR=1.1956, IC95%=0.4524 a 3.1597), or the volume of RBCs tranfused (MD=-0.0847, IC95%=-3.6879 a 3.5185). The complete presentation of the results is available at **Supplementary Materials**.

Discussion

No difference was found between rotational thromboelastometry and thromboelastography in any of the outcomes included in the analysis. Therefore, there is no reason to believe that the type of equipment used as VHA acts as a modifier of effect. This result suggests that they are similar enough to be analyzed together as a single group in a meta-analysis. There is much imprecision in the data due to the relatively small number of studies and participants. This imprecision was particularly important for the assessment of acute kidney injury, thromboembolic events, and volume of RBC transfusion. No inconsistency was found in the data, but since the comparison was between two interventions and a single comparator, it was not expected anyway. The multiplicities of protocols used to guide transfusion and the population might help explain some of the heterogeneity, but it is not the only important modifier. Without the individual data, it is not possible to estimate the impact of most modifiers in the final analysis. Nevertheless, the protocols guided by VHAs seem to provide better outcomes than protocols guided by SOC, independently of their association to specific VHAs [1,2,7,12–14,16]such as overall mortality and bleeding events, conducted subgroup and sensitivity analyses, examined the role of bias, and applied trial sequential analyses (TSAs.

To our knowledge, this is the first meta-analysis that attempted to compare thromboelastography to rotational thromboelastometry. The technologies may have similar results, but the analyses are underpowered to demonstrate that clearly. Nevertheless, the most consistently reported outcomes (e. g. risk of transfusion of RBC, FFP and platelets) do not suggest a difference of effect at this moment.

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Enviado em: 30.10.2020
Aceito para publicação em 21.06.2021.