REVIEW ARTICLE

Perioperative Point of Care Coagulation Testing

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SUMMARY

Background: Conventional laboratory tests of blood coagulation yield only partial diagnostic information. "Point of care" (POC) devices are increasingly being used at the bedside perioperatively for rapid, detailed testing of hemostatic function and for treatment monitoring in patients with coagulopathies. In this review, we discuss the benefits and limitations of POC coagulation testing—in particular, its effects on the rate of perioperative transfusion of allogeneic blood products, on the frequency of other types of hemostatic treatment, and on the clinical outcome.

Methods: This article is based on a selective review of pertinent literature retrieved by a search in PubMed.

Results: The clinical value of preoperative POC screening for coagulopathies has not yet been examined in a prospective, randomized clinical trial. On the other hand, studies in patients with coagulopathies undergoing (mainly cardiac) surgery have shown that algorithm-based hemostatic treatment based on viscoelastic POC coagulation testing reduces both perioperative blood loss and the rate of transfusion of allogeneic blood products. None of the studies published to date had adequate power to reveal any independent effect of POC coagulation testing on perioperative morbidity or mortality.

Conclusion: Despite certain limitations that must be borne in mind, POC techniques are a valuable means of testing various aspects of hemostasis rapidly and in detail. Their implementation in hemostatic treatment algorithms may reduce both the rate of transfusion of allogeneic blood products and the total cost of treatment for blood loss and coagulopathies. The putative effect of POC testing on perioperative morbidity and mortality has not yet been demonstrated.

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Perioperative coagulopathies may necessitate the transfusion of allogeneic blood products and are an independent risk factor for perioperative mortality (1, 2). Coagulopathies usually have multiple causes. Besides disturbances in physiological basic conditions for hemostasis (pH, concentration of ionized calcium, temperature and hematocrit), multifactorial causes for coagulopathy include: (3)

- disturbances of primary hemostasis, e.g., pre-existing or perioperatively acquired disturbances of platelet function;
- abnormalities of blood plasma, e.g., isolated or global clotting-factor deficits;
- complex coagulopathies, e.g., disseminated intravascular coagulation or hyperfibrinolysis.

Blood clotting is conventionally tested with two global tests, the International Normalized Ratio (INR) and the activated partial thromboplastin time (aPTT), along with the platelet count and, in some cases, the fibrinogen concentration. This battery of tests is of limited use for the prediction and detection of perioperative coagulopathies and for the monitoring of their treatment (3, 4). Furthermore, analysis at a standardized temperature of 37° Celsius impedes the detection of coagulopathies induced by hypothermia.

The global tests, aPTT and INR/Quick, reflect only the initial formation of thrombin in plasma and are unaffected by any of the corpuscular elements of the blood. The platelet count is purely quantitative and cannot detect pre-existing, drug-induced, or perioperatively acquired platelet dysfunction. Nor do the conventional coagulation tests convey any information about clot stability over time: they say nothing about fibrinolysis and thus cannot detect hyperfibrinolysis.

In Germany, coagulation test results typically become available 40 to 60 minutes after blood drawing. This turnaround time is so long that the results may not reflect the current state of the coagulation system and lead to inappropriate treatment (5).

The use of bedside tests, also called point of care (POC) tests, may partly compensate for the methodological limitations and diagnostic shortfalls of conventional coagulation testing (6, 7). None of the currently available methods of POC coagulation testing can alone provide an adequate picture of the entire coagulation spectrum; thus, multiple methods must be used together for a comprehensive diagnostic evaluation. Strictly speaking, the simple tests with which the INR

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and the activated clotting time (ACT) have been measured for decades, involving the use of test strips and small apparatus, actually do meet the definition of POC coagulation testing. This review article, however, will focus on the more complex, viscoelastic whole-blood techniques for the combined analysis of plasma coagulation, clot stability, and fibrinolysis, and on techniques for the analysis of primary hemostasis. These are commonly called POC techniques even though they do not satisfy the classic criteria of laboratory medicine for this designation (including easy measurement of a value, easy interpretation of the measured value, and no handling of reagents by the user). We will discuss the impact of the perioperative use of these techniques on blood loss, the rate of transfusion of allogeneic blood products, the use of clotting-factor concentrates and other hemotherapeutic agents, and the clinical outcome of patients with coagulopathies.

Methods

This review article is based on a selective search of the PubMed database for publications on the perioperative use of POC techniques for coagulation testing in patients with coagulopathies. Articles published before 10 September 2011 were sought that contained the keywords “thromboelastometry/-graphy,” “aggregometry,” “point of care coagulation testing,” “blood loss,” and “blood transfusion.” Guidelines and a systematic Cochrane review have also been published on this topic.

Point of care techniques

There are many POC techniques for coagulation testing that can be used in all phases of perioperative patient care. POC techniques can be used preoperatively to screen for coagulopathies (4); in the resuscitation room, the operating room, and the intensive care unit, they are mainly used to detect coagulopathies and to monitor their treatment.

No single POC technique can provide adequate information about all aspects of the complex process of blood clotting. From the pathophysiological point of view, coagulation can be broken down into four components: primary hemostasis, thrombin generation, clot formation/stabilization, and fibrinolysis.

Bedside aggregometric testing of whole-blood samples is used perioperatively mainly to study platelet function (8, 9). In patients with a history of bleeding whose hematocrit is stable (above 30%) and whose platelet count exceeds 100/nL, such tests can be used to screen for disorders of primary hemostasis, e.g., von Willebrand syndrome. The available aggregometric POC tests differ mainly in the agonists that are used to activate platelets in the test cells, such as collagen, adenosine phosphate, epinephrine, arachidonic acid, and thrombin, and in the shearing forces that are generated in the test cells.

Viscoelastic POC techniques are based on thromboelastography, which was described decades ago by Hartert (10). They are used to measure the time until clot formation begins, the dynamics of clot formation,

and the solidity and stability of clots over time. They enable parallel measurements to be performed on a single blood sample after clotting has been activated with a variety of agonists. A special advantage of viscoelastic techniques is that they can directly detect hyperfibrinolysis; no conventional coagulation test can do this reliably (7). Rotation thrombelastometry, a type of viscoelastic POC technique, was approved by the United States Food and Drug Administration (FDA) in August 2011 for use as a supplementary diagnostic test of hemostatic function.

A combination of aggregometric and viscoelastic methods yields a far broader diagnostic spectrum than the conventional laboratory testing of blood clotting.

The general advantages and disadvantages of point of care testing

Only a small volume of whole blood (1–5 mL) is needed for POC testing. POC techniques can be used in a wide variety of situations; aside from this, their main advantage is the rapid availability of results. Transporting the blood sample to a laboratory is no longer necessary, nor are the pre-analytical steps that are an obligate part of conventional laboratory testing, including the centrifugation of the specimens and the time-consuming preparation of reagents. POC tests can be carried out by persons without any special training in medical technology and are, as a rule, easy to learn. Most of the results that will have an immediate effect on therapeutic decisions are available within ten minutes of the start of pipetting, even for the more complex viscoelastic techniques (7). POC tests can be carried out in a central laboratory or in the immediate vicinity of the patient in the operating room or intensive care unit (5). Regular equipment maintenance and adherence to prescribed quality-control measures are easier to ensure in a central laboratory setting, which has the further advantage that only a small number of people need to be taught to perform the test. On the other hand, the transport of specimens to a central laboratory can take a long time, and the central laboratory may not be able to perform tests outside of regular working hours. POC tests must always be performed under the surveillance of a comprehensive quality-management system.

No single currently available POC coagulation test covers the functioning of the entire hemostatic system. In the perioperative setting, coagulopathy is often multifactorial, and a thorough diagnostic evaluation generally requires the combined use of multiple tests whose findings complement one another. Even such combinations, however, may fail to detect a number of potential causes of perioperative coagulopathy, including the anticoagulant effect of low-molecular-weight heparins, factor Xa inhibitors, direct or indirect thrombin inhibitors, antithrombin, isolated clotting-factor deficiencies, and protein C/S.

The standardized temperature of 37° Celsius at which the viscoelastic and aggregometric tests are carried out hinders the detection of coagulopathies due to hypo- or hyperthermia. Nor can these tests detect

coagulopathies caused by abnormalities in the physiological basic conditions for hemostasis, such as an abnormal pH, calcium ion concentration, or hematocrit.

In the absence of prospective, randomized trials, adequate data are not yet available regarding the use of POC techniques to screen for coagulopathies that are already present before surgery, or the predictability of an individual's risk of bleeding or thrombosis. Pre-existing coagulopathies are usually due to a disorder of primary hemostasis, e.g., iatrogenic platelet dysfunction or a hereditary condition such as von Willebrand syndrome.

When a critically ill patient needs a transfusion urgently because of massive blood loss, there may not be enough time to analyze and document the results of POC testing before the transfusion is given.

The total cost of POC testing (devices, reagents, test tubes, control solutions, maintenance, etc.) exceeds that of conventional coagulation testing. Thorough, combined viscoelastic and aggregometric coagulation testing costs €25 to €35 overall, while a conventional test battery (aPTT, fibrinogen, thrombin time, Quick value, complete blood count) generally costs less than €10. These increased costs, however, may be compensated for by the lower costs of a clinically more rational transfusion regimen and the more efficient use of other hemotherapeutic agents which, it is hoped, will result from the use of POC testing (11, 12). Only a small number of prospective randomized trials of POC coagulation testing have been performed to date on study populations of sufficient size. Multiple such trials have shown that the implementation of viscoelastic techniques in hemotherapeutic algorithms lowers the utilization of blood products, but the algorithm-based use of aggregometric techniques has not yet been adequately studied.

The clinical benefits of point of care testing

Two measures of the usefulness of perioperative coagulation therapy are perioperative blood loss and the rate of transfusion of allogeneic blood products. One or both of these measures were used as primary endpoints in the few prospective, randomized, controlled clinical trials of perioperative POC coagulation testing that have been published to date. The secondary endpoints in these trials included the following:

- changes in laboratory values,
- the overall use of hemostatic therapy,
- the re-thoracotomy rate,
- the frequency of postoperative neurological, respiratory, and renal complications,
- the duration of artificial ventilation,
- the duration of intensive care, and
- postoperative mortality (*Table*).

POC-associated complications were not reported in any trial.

Eight prospective randomized trials of perioperative POC coagulation testing have been published to date (13–20): six involved POC testing for (mostly) elective cardiac surgery, one for hepatic surgery, and one for

thoracic and vascular surgery. As coagulopathies have many causes, the findings of these trials may not apply to other kinds of patients, such as trauma patients.

In only two of these eight trials did the patients in the control group receive coagulation therapy according to a treatment algorithm based on conventional laboratory testing (14, 17). In six trials, the patients who underwent POC testing consumed less fresh-frozen plasma (FFP) than the controls; they had a lower platelet-concentrate (PC) transfusion rate in five trials, and a lower erythrocyte-concentrate transfusion rate in two. More detailed information about the intergroup differences in the rates and quantities of allogeneic blood-product transfusions are found in the *Table*.

The trial of Nuttal et al. (16) revealed a beneficial effect of POC coagulation testing on postoperative blood loss. This was the only trial that was restricted to patients with coagulopathies. Patients were included in the other seven trials solely on the basis of the type of surgery that they were to undergo (typically, operations with a moderate-to-high risk of bleeding), regardless of their coagulation status. Viscoelastic POC techniques were used in all eight trials; in one, aggregometric testing was performed as well. Thus, these trials cannot easily be compared with one another, in view of the heterogeneity of subjects and of the type, extent, and timing of the POC coagulation tests that were performed.

Economic aspects

The findings of the prospective randomized trials listed in the *Table* do not allow any firm conclusions about the putative economic savings resulting from the use of POC coagulation testing. A number of retrospective studies have compared the costs of hemotherapy before and after the implementation of POC-based hemotherapeutic algorithms (11, 12, 21), albeit with partially conflicting results. These studies varied with respect to

- the hemotherapy algorithms,
- the choice of laboratory tests guiding therapy and the cutoff values used,
- the degree of attention paid to factors besides the physiological basic conditions for hemostasis that can affect blood coagulation, and
- the hemostatic treatment options.

In a study of 1422 patients undergoing elective cardiac surgery, Spalding et al. found that the implementation of POC coagulation testing lowered the cost of allogeneic blood products and other hemotherapeutic agents by about 50% (12). On the other hand, Görlinger et al., in a retrospective study of 3865 cardiac surgical patients, found that the implementation of POC coagulation testing was followed by a 34.3% drop in the cost of allogeneic blood products, but simultaneously by a 104.6% rise in the cost of clotting-factor concentrates. The net cost of hemotherapeutic agents was 6.5% lower (21).

None of these studies considered the so-called secondary costs that might be reduced if patients enjoyed better clinical outcomes as a result of the use of POC

TABLE

Overview of prospective randomized trials of perioperative POC coagulation testing, sorted by publication date

First author, year	Patients	Methods	Endpoints	Summary of findings, conclusions
Shore-Lesserson, 1999 (13)	107 patients undergoing elective, complex cardiac surgical procedures	TEG-based hemotherapy (53 patients) vs. coagulation therapy based on conventional laboratory testing (52 patients); 2 patients excluded	primary: reduced transfusion requirement secondary: TEG and laboratory values, postoperative blood loss	summary of findings: Postoperatively, the TEG group consumed less FFP (transfusion in 4/53 vs. 16/52 pts.; transfused volume 36 ± 142 mL vs. 217 ± 463 mL) and PC (transfusion in 7/53 vs. 15/52 pts.); there was no difference in postoperative blood loss. conclusion: POC-based coagulation therapy is rapid and efficient. The use of a TEG-based algorithm is recommended for patients undergoing complex cardiac surgical procedures.
Royston, 2001 (15)	60 patients undergoing elective, complex cardiac surgical procedures	TEG-based transfusion algorithm (30 patients) vs. coagulation therapy without algorithm (30 patients)	primary: overall consumption of hemostatic therapy secondary: TEG and laboratory values, postoperative blood loss	summary of findings: fewer FFP and PC transfusions in the TEG group (transfusions in 5 patients; total, 5 FFP and 1 PC) than in the control group (transfusions in 10 patients; total, 16 FFP and 9 PC) conclusion: bedside coagulation testing recommended
Nuttall, 2001 (16)	836 patients undergoing elective cardiac surgery were screened; 92 were included in the study when found to have a tendency to microvascular bleeding after extracorporeal circulation	partially TEG-based transfusion algorithm (41 patients) vs. coagulation therapy without algorithm (51 patients)	primary: postoperative requirement for transfusion of allogeneic blood products secondary: TEG and laboratory values, postoperative blood loss, re-thoracotomy rate	summary of findings: The TEG group received fewer transfusions of FFP (0 [0/7] [median (25/75 percentile)] units vs. 3 [0/10] units) and PC (4 [0/12] units vs. 6 [0/18] units) and had less blood loss in the 24 hours after surgery (590 [240/2335] mL vs. 850 [290/10190] mL) and fewer re-thoracotomies (0% vs. 11.8%). conclusion: Algorithm-based hemotherapy lowers both the PC transfusion rate and postoperative blood loss.
Avidan, 2004 (17)	102 (210) patients undergoing elective cardiac surgery (ACVB)	HEPCON/TEG and PFA-100 algorithm (51 patients) vs. algorithm based on conventional coagulation testing (51 patients) vs. retrospective case-control group without coagulation algorithm (108 patients)	primary: blood loss, transfusion rate secondary: conventional laboratory values, TEG values	summary of findings: no difference between the two algorithm groups; significantly higher erythrocyte-concentrate transfusion rate in the group without an algorithm conclusion: The use of a transfusion algorithm is recommended.
Ak, 2009 (18)	224 patients undergoing elective cardiac surgery (ACVB)	TEG-based transfusion algorithm (114 patients) vs. standard therapy without coagulation algorithm (110 patients)	primary: blood loss, frequency of blood transfusion secondary: volume of transfused blood, respiratory complications, frequency of renal failure, 30-day mortality	summary of findings: The TEG group had significantly fewer transfusions of FFP (transfusions in 19/114 vs. 31/110 pts.; 1 [1/1] vs. 1 [1/2] transfused units) and PC (transfusions in 17/114 vs. 29/110 pts.; 1 [1/1] vs. 1 [1/2] units transfused). conclusion: The routine use of TEG lowers the perioperative transfusion requirement and may also improve clinical outcomes and lower the cost of coagulation therapy.
Westbrook, 2009 (19)	69 patients undergoing elective cardiac surgery	TEG-based hemotherapy (32 patients) vs. coagulation therapy based on conventional laboratory testing without algorithm (37 patients)	blood loss, re-sternotomy rate, minimum Hb concentration, duration of postoperative ventilation and ICU stay	summary of findings: no significant intergroup differences in any endpoints, but a 52% reduction in mean blood-product consumption per patient (not significant; ARR, 1.27 blood products per patient) conclusion: Strict adherence to a TEG-based algorithm might lower blood-product consumption.
Wang, 2010 (14)	28 patients undergoing elective orthotopic liver transplantation	TEG-based hemotherapy (14 patients) vs. coagulation therapy based on conventional laboratory testing (14 patients)	transfusion requirement, intraoperative IV fluid requirement, blood loss, urine production, 3-year survival rate	summary of findings: fewer FFP transfusions in the TEG group (12.8 ± 7 vs. 21.5 ± 12.7 units); no other intergroup differences conclusion: TEG-based hemotherapy lowers the FFP transfusion rate without affecting 3-year survival

First author, year	Patients	Methods	Endpoints	Summary of findings, conclusions
Girdauskas, 2010 (20)	56 patients undergoing high-risk aortic surgery with hypothermic circulatory arrest (31 elective and 25 emergency operations)	intra- and post-operative, ROTEM-based transfusion algorithm (27 patients) vs. coagulation therapy based on laboratory tests without algorithm (29 patients)	primary: cumulative transfusion rate of allogeneic blood products secondary: consumption of clotting factor concentrates, postoperative blood loss, re-thoracotomy rate, duration of post-operative ventilation, frequency of neurological and renal complications, length of ICU stay	summary of findings: The ROTEM group received significantly less FFP (transfusion in 9/27 vs. 25/29 pts.; 3 [0/12] vs. 8 [4/18] units transfused) and PC (transfusion in 14/27 vs. 23/29 pts.; 1 [0/4] vs. 2 [1/3] units transfused) (44% cumulative reduction in the consumption of allogeneic blood products; ARR, 7 units); no intergroup differences in blood loss, re-thoracotomy rate, or clinical outcome. conclusion: A ROTEM-based algorithm lowered the rate of transfusion of allogeneic blood products and the frequency of massive transfusion.

ACVB, aortocoronary venous bypass; FFP, fresh-frozen plasma; PC, platelet concentrate; pts., patients; ICU, intensive-care unit; IV, intravenous. TEG and ROTEM are viscoelastic techniques; HEPCON is a single-use cassette test for the monitoring of the therapeutic effect of heparin and its antagonism with protamine; PFA-100 is an aggregometric test of primary hemostasis

coagulation testing. For example, the study of Görlinger et al. revealed a significantly lower frequency of thrombotic/thromboembolic events and unplanned reoperative thoracotomies in the patients treated according to POC-based hemotherapy algorithms (21).

When the findings of the prospective randomized trials and retrospective studies discussed above are considered together, it appears that POC-based coagulation therapy indeed lowers the rate of transfusion of allogeneic blood products overall (mainly by lowering the FFP and PC transfusion rates), but simultaneously increases the use of clotting-factor concentrates (mainly fibrinogen and prothrombin-proconvertin-Stuart factor-antihemophilic factor B [PPSB]). The economic savings from the reduced use of allogeneic blood products may compensate for or outweigh the increased expenditures for clotting-factor concentrates.

The effect on clinical outcomes

In the retrospective study of Görlinger et al., the POC group had fewer postoperative thrombotic/thromboembolic complications than the control group (28 of 1582 patients in the POC group versus 46 of 1441 patients in the group receiving conventional coagulation therapy, $p = 0.015$) (21). The groups did not differ, however, with respect to perioperative mortality. Data on postoperative mortality are available from five of the prospective randomized trials (13–15, 18, 20)—with differences in the duration of postoperative observation, which ranged from the duration of the hospital stay (20) to three years after surgery (14). No beneficial effect of POC-based coagulation therapy on postoperative mortality was revealed by the individual studies or by a systematic review (22).

It should be pointed out, however, that the studies did not include enough patients to detect a potential benefit with respect to perioperative mortality. Moreover, the study populations were highly inhomogeneous, particularly with respect to the expected risk of

perioperative bleeding. Some studies included patients about to undergo elective coronary artery bypass grafting, a procedure with a low risk of bleeding, while others included only patients with a high risk of bleeding or an already diagnosed coagulopathy. Measures of clinical outcome, such as mortality, were not a primary endpoint in any of the studies, not least because improved postoperative mortality (unlike reduced blood loss or transfusion requirement) is not a primary goal of POC coagulation testing.

Quality control

The German Medical Association's guidelines for quality assurance in quantitative medical laboratory testing (*RiliBÄK-Labor*) (23) establish obligatory requirements for quality control that also apply to POC techniques for coagulation testing. Internal quality checks must be performed at regular intervals, generally with quality-control instruments that are supplied by the manufacturers. Moreover, participation in round-robin testing for external quality assurance is also recommended. As whole blood is not very stable over time and therefore cannot be used for round-robin tests, lyophilized plasma is recommended for use as test material in round-robin tests of viscoelastic POC techniques. When lyophilized plasma is used, test results can be profitably compared across centers (24). POC tests of blood coagulation for which an analogous non-POC laboratory test already exists can be externally checked by a comparison of their results with those of the analogous conventional tests.

Guidelines

In the German Medical Association's cross-sectional guidelines for treatment with blood components and plasma derivatives, it is stated that, aside from fibrinogen measurement, the measurement of D-dimers and/or a thromboelastogram can be a useful means of

assessing fibrinogen turnover and fibrinogen formation (e1). A number of guidelines from Germany (e2, e3) and abroad (e4, e5) take a position on viscoelastic POC testing in the perioperative care of patients with coagulopathies. For the most part, recommendations are given concerning the treatment of trauma patients. As there have been only a few prospective randomized trials of POC testing for patients with coagulopathies, these recommendations are necessarily based on evidence of a relatively low level: they are all grade 0 recommendations to the effect that viscoelastic POC techniques can be used for the diagnostic evaluation of a coagulopathy and for the monitoring of treatment for coagulopathy.

Overview

Multiple prospective randomized trials have revealed that the algorithm-based use of viscoelastic POC testing of blood coagulation leads to lower perioperative blood loss and a lower rate of transfusion of allogeneic blood products. A systematic Cochrane review did not reveal any effect of the use of POC testing on perioperative morbidity and mortality. POC coagulation testing is faster and more comprehensive than the conventional laboratory tests of blood coagulation in the perioperative setting and enables effective, economical treatment. It thus seems justified to recommend the implementation of POC testing in hemotherapy algorithms that are adapted for use in particular types of patients with specific perioperative coagulation disorders.

Conflict of interest statement

Dr. Weber has received lecture honoraria and reimbursement of travel and accommodation costs from the CSL Behring company.

Prof. Zacharowski has received payment for serving as chairman for scientific symposia sponsored by CSL Behring.

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KEY MESSAGES

- Conventional routine testing of blood coagulation is not suitable for preoperative screening, for the detection of perioperative coagulopathies, or for the monitoring of their treatment.
- The diagnostic shortfalls of routine coagulation testing can be partially compensated for with point of care (POC) coagulation testing.
- No single POC technique provides information about the function of the entire clotting system. Multiple POC techniques may need to be used in combination, depending on the potentially multifactorial origin of the underlying coagulopathy.
- Guidelines from Germany and abroad have taken a position on the use of POC techniques, recommending that viscoelastic techniques be used for the detection of perioperative coagulopathies and the monitoring of their treatment (recommendation grade 0).
- The single systematic review of this subject that has been published to date did not reveal any effect of POC coagulation testing on perioperative morbidity and mortality.

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