Short Article

Root Cause Analysis of an Aberrant Thromboelastogram Tracing – Lessons Learnt

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Abstract

Thromboelastography is a viscoelastic test which uses whole blood sample for routine coagulation screening purpose. Even though it is an easy procedure, many critical steps affect the final result of the test and we describe such an incident in this report. The root cause analysis of two aberrant TEG reports on two different occasions was initiated; the tracing initially was normal but developed an abnormal pattern toward the middle portion. The graph suddenly dropped to the baseline and from there, it was demonstrating an abnormal pattern. This can be due to power failure, vibrations during the test, cup dislodging from the pins during run, no validation prior to each test, and out of calibration. The root cause was identified as improper fixing of cups and pins leading to dislodging from the pins during the run and prevention of such incidents can be achieved by individual training of the staffs and periodical evaluation of their competency.

Keywords: *Coagulation, hemostasis, quality assurance, root cause analysis, thrombelastography (TEG)*

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Introduction

Thrombelastogram (TEG® 5000, Hemonetics, USA) is a whole blood-based viscoelastic testing method which graphically depicts the *in vivo* hemostatic potential of the patient contributed by the enzymatic as well as cellular factors.[1] There has been a lot of modifications in the TEG technique to provide more reproducibility to the analysis. Of them, Citrated Kaolin with recalcification method is commonly used for routine purpose because of the test reproducibility and reagent stability.[2] We have developed age- and gender-matched normal reference ranges for our population [Table 1].[3] As with any other coagulation assays, various pre-analytical and critical analytical factors may influence the final TEG result[1] which needs to be addressed in the routine laboratory practice. Technicians should be given special training in sample collection, handling of the test consumables, and how to properly run the test, etc., before implementing TEG in the department. Technically, TEG is a simple test to perform, but often, we have overlooked many simple steps. Likewise, we present a report on how missing out small, simple steps might result in aberrant TEG results.

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Case Report

After a period of training and standardization of TEG, testing was started in our department, and on the 2nd month, we noticed an aberrant tracing during routine working hours. Figure 1 represents aberrant TEG tracing observed on two separate occasions [Figures 1a, b and 2a, b] and depicts the TEG repeated on the same samples after immediate corrective action. There was no error message, and the "e-test" was validated by the technician before running the sample. The initial parameters of the tracing appeared normal [Figure 1a and b], but something went wrong while the test was going on. Confounding factors associated with such tracings have been identified as external vibrations during the test, improper fixing of cups and pins to machine resulting in dislodgment, and power failure during the tests.[1]

After a 360° observation and evaluation, we have identified the reason as improper fixing of cup and pin leading to dislodgment during the test. The manufacturer

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Table 1: Normal reference range for thromboelastography

Parameter	Definition	Reference range[3]
R	Time taken from initiation to 2 mm clot strength	3.8-10.6 min
K	Time period from 2 mm to 20 mm amplitude	1.2-3.1 min
Alpha angle	Angle between a tangent to the 2 mm amplitude and horizontal line (clot dynamics)	44.9-72°
MA	Greatest vertical width (amplitude) achieved on the tracing reflecting maximum clot strength	41.2-64.5
Coagulation index	Description of global coagulation state in dynes/second	−3.7-3.4
Lysis 30	Percentage reduction in amplitude 30 min after MA	0%-9.9%

MA: Maximum amplitude

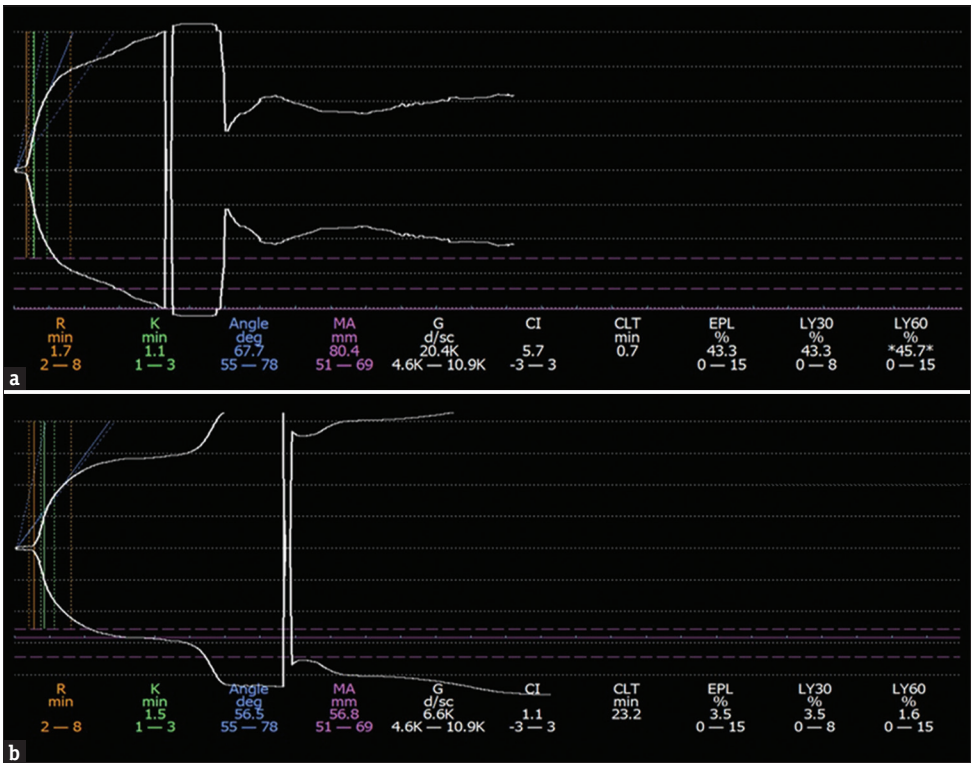

Figure 1: (a and b) Aberrant TEG tracing

recommends that cups and pins have to be properly fixed by pressing onto the respective position and ensure it fits properly. Aberrant tracing appears when the cup gets dislodged from the pin as the impedance increases, and hence, the initial part will be normal.[2] Power failure and external vibrations will lead to abnormal tracing for that particular point of time, which were ruled out as a probable cause, as there was no interruption in power supply, and the machine was not disturbed during the run. Noncalibrated equipment might also lead to aberrant tracing, and in this case, calibration was done 2 months prior. When issues related to disposable material occur, an error message will appear on screen, indicating the user that cups and pins are not placed properly. We had two abnormal tracing without any error message and it may be due to the fact that the initial placement was satisfactory but loosely fixed onto the positions, thereby dislodging when clot strength resistance increases.[4]

Once the problem was identified, the current run was stopped and the test was repeated from the same sample obtained after informed consent from the patients, using fresh cups and pins, and the repeat run came as normal [Figure 2a and b]. The root cause analysis was initiated and the results were issued after the corrective action. The deviation was documented in the TEG register and Ishikawa chart was plotted [Figure 3]. The root cause was identified as a technical error (man) and initiated the Plan–Do–Check–Act (PDCA cycle). A preventive action plan was charted, and the retraining of the staffs by the technical expert with specific attention given to individual technical person followed by their competency and skill evaluation was completed. Six months after implementing the preventive action, no such issues have been identified so far in the routine practice.

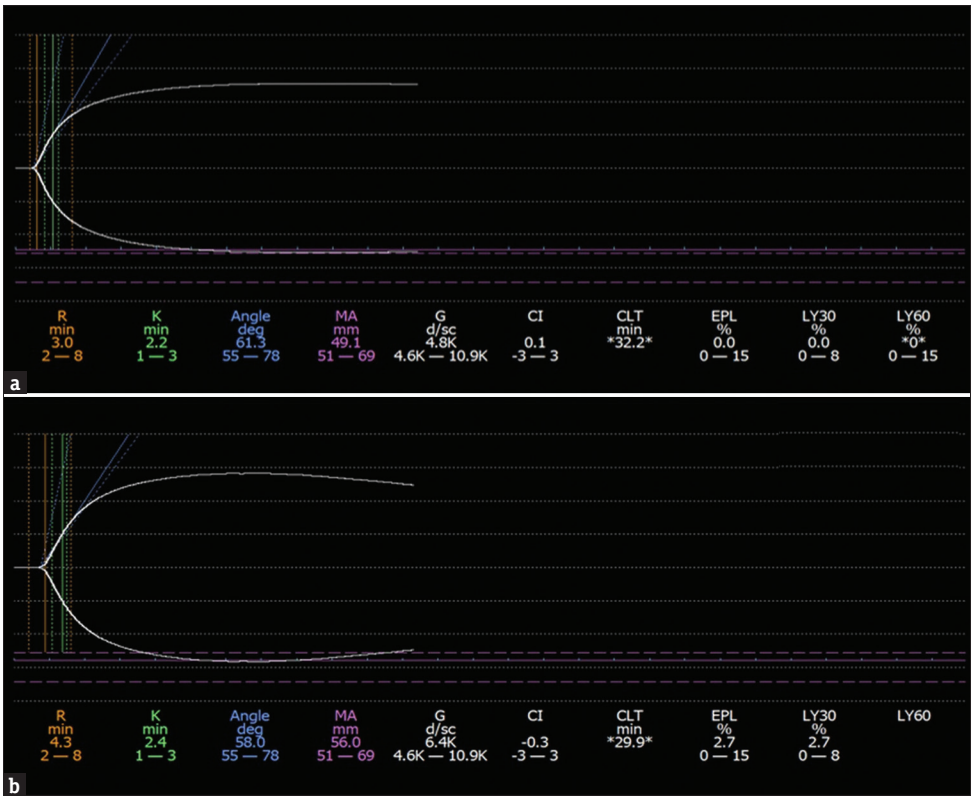

Figure 2: (a and b) Normal TEG tracing

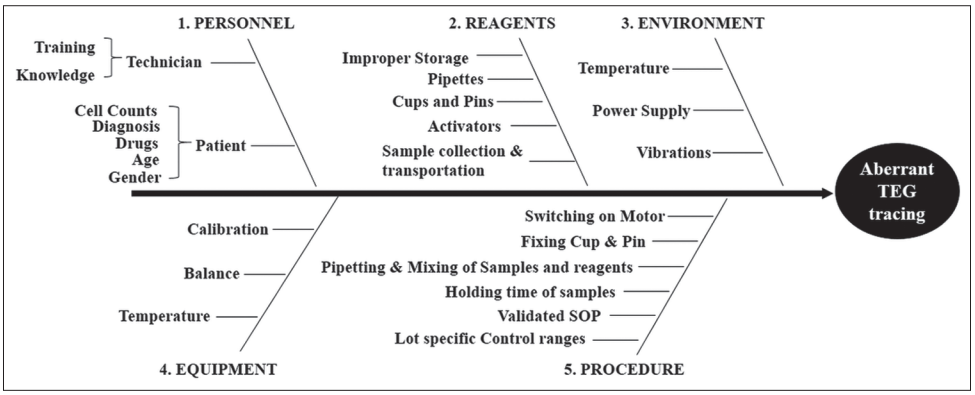

Figure 3: Root cause analysis of TEG

Discussion

Quality system essentials are one of the critical elements in sustaining and improving the quality of patient care. Deviations are said to happen in medical care, and various methods have been adopted to prevent the recurrence. PDCA cycle is one of the methods which helps us to continuously monitor the implemented corrective and preventive action and it is hassle free. The quality system ensures that a proper root cause analysis should be done whenever a deviation has been identified. Root cause analysis identifies the reason for such error or deviation, whereas our job is to prevent or minimize the deviation by implementing proper preventive action. Since ensuring quality is a dynamic evolving process and not a static one, continuous monitoring is required to ensure that the implemented actions are effective or not.

In our scenario, the observed deviation was cup and pin dislodgment during the TEG run without any error message. The other possible causes listed above were successfully ruled and the cause was a technical error of not appropriately fixing the cup and pin into the respective positions. The next thing was to implement preventive action, and hence, we conducted the training with individual attention and importance following each step, followed by an evaluation.

We also did a PDCA cycle assessment and we have not observed such deviations after the RCA. This report highlights the importance of quality system in transfusion medicine and its role in delivering patient care. This report also brings light into the technical errors that may be seen with any investigation which should not be overlooked.

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Conflicts of interest

There are no conflicts of interest.

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