Hematocrit interference in coagulation tests: what else can we do?

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ABSTRACT

The required blood to anti-coagulant ratio in the tubes for coagulation tests, is 9:1; any deviation from this ratio should be avoided as it may lead to erroneous analytical results. One of the variables influencing the ratio is an elevated hematocrit (>55%), because the elevated concentration of citrate in the plasma specimen can cause clotting times falsely increased. These erroneous results can lead to possible misdiagnosis, incorrect patient treatment and/or the performance of additional unnecessary investigations. We present the case of a 46-year-old man referred to the laboratory for a pre-surgery check. The presence of elevated values in his coagulation tests led to delayed surgery and to additional tests. Once the error was detected, a root cause analysis was performed. The main contributing factors to the pre-analytical error were identified using Ishikawa method; factors related to the organization, staff and environment were identified and analyzed. Preventive actions (safety barriers) were designed to prevent the error from recurring. The safety barriers implemented were: an automatic flag displayed in the information laboratory system (LIS) in cases of elevated hematocrit (>55%), to enhancement of the possible error detection plus additional laboratory staff training. At the best of our knowledge, since these safety barriers were applied three years ago, no coagulation test results interfered by high hematocrit have been released from our laboratory.
This case demonstrates the importance of implementing safety barriers to prevent errors arising from situations that, although already described and well known, may go unnoticed by the laboratory staff.

Keywords: *safety barriers, coagulation, high hematocrit*

CASE PRESENTATION

Samples from a 46-years man were received at the laboratory for a pre-surgery routine control. The patient was diagnosed with *polycythemia vera* 3 years before. The requested analysis included coagulation and hematology tests.

Coagulation parameters were all measured on Sysmex CS-2100 (Siemens Healthcare A/S, Ballerup, Denmark) using optical technology. For hematologic parameters we used ADVIA 2120 (Siemens Healthcare A/S, Ballerup, Denmark). The results released from the coagulation analyzer were: Prothrombin Time (PT) ratio: 1.33, (reference values: 0.80-1.20) and activated thromboplastin time (aPTT) ratio:1.36 (reference values:0.80-1.20). The hematocrit value was 65% (0.65). Since other preanalytical interferences such as clots presence were not detected and the tube filling was correct, results were automatically released by the Laboratory Informatics' System (LIS) according to the validation rules in place at that time. Due to the increased clotting time of PT and aPTT and the associated risk of bleeding, the patient's surgery was postponed, and the patient was also referred to a hematologist to investigate the cause of the alteration.

DISCUSSION

Most errors in the clinical laboratory process occur in the pre- and post-analytical phases and these errors can have a major impact on patient safety (1). Hemostasis tests play a fundamental role in the diagnosis of

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hemorrhagic and thrombotic diseases. The correct plasma to citrate ratio is a critical factor for the accuracy of the coagulation results (2,3). The correct filling of the coagulation samples is a well-established criterion for samples acceptance and it is included as the pre-analytical phase quality indicators usually monitored in clinical laboratories (4-6). However, incorrect plasma to citrate ratio, mainly due to a high hematocrit, is a preanalytical factior that can go unnoticed causing falsely prolonged clotting times due to the excess of anticoagulant in the plasma specimen. This event may represent a patient safety problem in terms of the performance of unnecessary additional tests, surgery delay or the introduction of an inadequate treatment.

The effect of elevated hematocrit on the coagulation test results is well known (7); however, this circumstance was not detected by the laboratory staff before the delivery of the result. The patient was then referred to the hematologist, who ordered a new coagulation study to confirm the previous results. The second coagulation sample from the patient was analyzed and this time, the interference was detected. Once the laboratory was aware of the problem a root-cause analysis was carried out to detect possible points of failure in the process and to remove them.

A problem-solving team was formed by the medical doctor responsible of the quality system and risk management and by the laboratory hematologists; the team leader was the head of the laboratory. Failure investigations started with a brainstorming exercise to identify the causal factors. Brainstorming, devised in 1919 by Alex F. Osborn, is a creative thinking technique used to stimulate the production of a large number of ideas. It is based on the premise that a group of people can generate more and better ideas than a single person independently. In a second step possible causes of failure were included in an Ishikawa diagram (Figure 1). The Ishikawa or "fishbone" diagram is a root-cause analysis tool able to map cause and effect in a visual way. It allows the identification and ranking of specific problems and/or potential risks (8,9,10).

Contributing factors related to the organization (poor communication between hematology and coagulation laboratory sections, or the time taken to validate coagulation and hematology tests), to the staff (lack of a specific training and procedures) or to the environment (work overload) were identified as the main potential causes of the failure (Figure 1).

Once the possible contributing factors were identified and placed in the fishbone diagram, each was prioritized by the problem-solving team according to the possible contribution to the error. Preventive actions (barriers) were assigned for the highest priorities (Table 1).

These barriers were mainly identified in order to enhance the detection capability of this risk: i.e., coagulation results interfered by high hematocrit samples. For this purpose, a LIS-based algorithm was developed (11,12), and an automatic flag is displayed in the LIS for the condition “hematocrit >55%” when coagulation tests are demanded. This way, all the laboratory staff performing the tests and checking coagulation results are aware of the high hematocrit condition.

Second, additional laboratory staff training was developed: a specific instruction for the high hematocrit patient management was prepared and educational sessions were programmed for the laboratory staff. The document included details about sample drawing and a citrate correction related to hematocrit chart.

Successful results have been obtained since no more coagulation test results interfered by elevated hematocrit have been released from our laboratory since the procedure was implemented three years ago, so patient safety has not been compromised. Staff from different laboratory sections is aware of the preanalytical issues

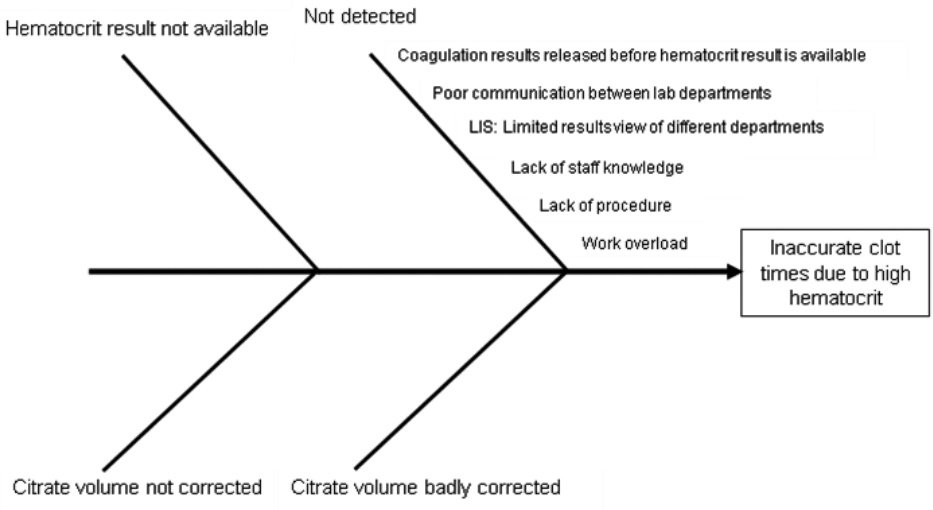

Figure 1
Ishakawa diagram for inaccurate coagulation results event related to high hematocrit.

Table 1
Corrective actions for the possible failure mode

Priority	Failure	Corrective actions
1	Preanalytical interference of high hematocrit not detected	LIS flag
2	Lack of procedure	Issuing of a specific procedure
3	Lack of staff knowledge	Staff training
4	Poor communication between laboratory sections	LIS flag
5	Work overload	Not applied

thanks to the internal notification and the specific procedure put in place has highlighted the importance of the preanalytical phase possible errors.

Of course, the adopted procedure has an important limitation: it cannot be used when the hematocrit value is not available.

This case demonstrates that clinical laboratories should have strategies to detect potential pre-analytical errors. Upon the occurrence of such an error, a detailed analysis of the safety failures should be carried out and new safety barriers should be designed to prevent recurrence (7).

The following recommendations can be deduced from the analysis performed:

- for the laboratory: implement additional barriers to the manual detection of the preanalytical interference and improve the staff training;
- for the tube manufacturers: beside the filling mark, a “maximum hematocrit mark” should be added to the tube label;
- for the clinician: hematocrit value should be considered when evaluating unexpected coagulation tests.

CONFLICT OF INTEREST

None.

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