# Costly coagulation profile tests prior to performing breast biopsies

## *Do we really need it?*

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## ABSTRACT

**الأهداف:** تهدف الدراسة التي نقدمها إلى إعادة تقييم الحاجة إلى فحص تجلط الدم بشكل روتيني للمرضى الذين يخضعون لعمليات فحص الثدي عن طريق الأشعة التصويرية.

**الطريقة:** قمنا بإجراء دراسة مقطعية استرجاعية. رُفعت البيانات من سجلات المرضى في قسم الأشعة وكذلك من السجلات الإلكترونية للمرضى – وحدة تصوير الثدي – بمستشفى جامعة الملك عبد العزيز، جده، المملكة العربية السعودية. واشتملت الدراسة على عمليات فحص الثدي التصويرية التي جرت في الفترة الممتدة من نوفمبر 2013م حتى أكتوبر 2014م. وقد استُبعد المرضى الذين يتعاطون عقاقير مضادة لتجلط الدم أو مخفضات تراكم الصفائح الدموية وكذلك المرضى الذين لديهم ميول صحية لحدوث نزيف. وقد حُللت النتائج باستخدام برنامج IBM SPSS بالنسخة رقم 22.

**النتائج:** يبلغ مجموع المرضى المشاركين في الدراسة 136 مريضاً. وجدنا أنه لا يرتبط أي من زمن تجلط الدم الجزئي أو الصفيحات الدموية بتجلط الدم بقيمة إحصائية 0,536 لتجلط الدم الجزئي و0,997 للصفيحات الدموية. ترتبط حجم الإبرة المستعملة في الخزعة بشكل كبير مع تقدير النزيف بقيمة إحصائية تبلغ 0,020.

**الخلاصة:** ننصح بعدم القيام بفحوصات تجلط الدم بشكل روتيني. ويعد تقييم النزيف الشامل أكثر جدوى، ويفضل القيام بالفحص وفقاً للتاريخ المرضي للمريض والنتائج المتوصل لها.

**Objectives:** To reassess the need for routine coagulation profile testing in patients undergoing image-guided breast biopsies.

**Methods:** This is a retrospective cross-sectional study. Data was collected from the logbook of patients that underwent image-guided biopsies in the breast unit at the Department of Radiology, King Abdulaziz University Hospital, Jeddah, Saudi Arabia. Patients' electronic records between November 2013 and October 2014 were included in the study. Exclusion criteria were those on anticoagulants, or platelet aggregation inhibitors, and patients with known primary, or secondary bleeding diathesis. The study was analyzed using the IBM Statistical Packages for Social Sciences Version 22 (IBMCorp, Armonk, NY, USA).

**Results:** A total of 136 patients were included in our study. Neither partial thromboplastin time (PTT), or thrombocytopenia was related to bleeding with *p*-values of 0.536 PTT and 0.997 thrombocytopenia. Needle gauge was found to be significantly related to bleeding episodes with a $p$=0.020.

**Conclusion:** We advise against the routine use of coagulation profiles to predict bleeding risk. A thorough bleeding assessment is more advantageous. Laboratory tests should be tailored according to the patient's history and examination findings.


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Image guided biopsies employ the use of ultrasound (US), stereotaxis, or MRI to access lesions that would otherwise be subjected to surgery. It has been proven to be cost-effective and reliable for diagnosing suspicious breast lesions with the advantage of avoiding invasive surgery and its risks. The complication rate of infection and bleeding with the procedure is rare.[1] The incidence of clinically significant bleeding with image-guided biopsies has been reported as being less than 1%.[2] The literature also suggests that image guided biopsies are safe in patients taking anticoagulants with

no clinically significant bleeding episodes noted post biopsy.[3,4] Bruising was more commonly encountered in those on anticoagulants, they can still safely undergo core needle breast biopsy without anticipation of clinically significant bleeding.[2-4] Even in those patients, abnormal coagulation tests did not predict bleeding.[2] Nevertheless, screening for coagulation profiles remains a common practice before performing breast biopsies. Coagulation panels have poor positive predictive values in estimating bleeding risk and do not correlate well with bleeding complications after procedures.[5,6] It is more acceptable to perform these tests when clinically indicated according to patient risk factors rather than as a routine assessment. Other risk factors such as the use of anticoagulant medications and a personal, or family history of bleeding diathesis, may be more reliable in predicting hemorrhagic complications.[5-8] Pre-procedure coagulation screening may not be cost-effective, and may even delay biopsies of potentially malignant lesions, which could have been caught earlier. Our study will reassess the need for routine coagulation profile testing in those patients undergoing image-guided breast biopsies. This will impact future decision making regarding ordering these laboratory tests as well as ensure the cost-effectiveness of our practice.

**Methods.** After obtaining the ethical approval from the unit of biomedical ethics in King Abdulaziz University, Jeddah, Saudi Arabia, the data was collected from the logbook of patients that underwent image-guided biopsies in the breast unit, Department of Radiology, King Abdulaziz University Hospital, Jeddah, Saudi Arabia. Additional laboratory and pathology results were retrieved from patients' electronic records. Variables of interest were the patient's age, biopsy technique, needle gauge, final pathology results, medications, medical conditions such as hypertension and bleeding tendencies, results of coagulation profile, and of bleeding post-biopsy. Bleeding post biopsy was categorized as none, minor, or hematoma. A minor bleed was defined as prolonged oozing of blood. A hematoma was defined as any palpable blood clot of any size. Patients with image guided breast biopsies between November 2013 and October 2014 were included in this study. Exclusion criteria were those on anticoagulants, or platelet aggregation inhibitors, and patients with known primary, or secondary bleeding diathesis. All patients who underwent biopsies had their blood pressure taken before the procedure. A high blood pressure required rebooking. The study was analyzed using IBM SPSS Statistics for Windows version 22.0 (IBMCorp, Armonk, NY, USA). A simple descriptive method was used to define the characteristics of the study variables through a form of counts and percentages for the categorical and nominal variables, while continuous variables were presented by mean and standard deviations. To establish a relationship between categorical variables, this study used Chi-square test. While comparing more than 2 groups, one-way analysis of variance with least significant difference (LSD) as a post hoc test was used. These tests were performed with the assumption of normal distribution. Otherwise, Games Howell for multiple groups was used as an alternative for the LSD test. A conventional $p$-value <0.05 was the criteria to reject the null hypothesis.

**Disclosure**. Authors have no conflict of interests, and the work was not supported or funded by any drug company.

**Results.** A total of 136 patients were included in our study. Patients that were included in the study either underwent US guided breast biopsies using a 14-gauge needle (69.1%), or stereotactic breast biopsies using an 11-gauge needle (9.6%). The remaining patients (21.3%) underwent fine needle aspiration, abscess drainage, needle localization, or clip insertion. Benign breast pathology was exhibited in 52.6% of our sample, and malignancy was noted in the remainder 47.4%. Of those who had available coagulation profiles in their electronic records, 4% showed abnormal results while 96% had normal results. Of those who had bleeding outcomes stated in their records post-biopsy, no bleeding was noted in 97.6%, minimal bleeding was observed in 1.6%, and a post biopsy hematoma formed in 0.8%. All patients had normal prothrombin time (PT) and international normalized ratio (INR) profiles. A prolonged partial thromboplastin time (PTT) was noted in 0.8% and thrombocytopenia in 3.2%. However, neither PTT, or thrombocytopenia was related to bleeding with $p$-values of 0.536 PTT, and 0.997 thrombocytopenia (**Table 1**). In addition, the type of breast pathology (benign versus malignant) did not correlate with bleeding ($p$=0.584) (**Table 2**).

Needle gauge was found to be significantly correlated to bleeding episodes with a $p$ value of 0.020 (**Table 1**). In addition, bleeding episodes were only encountered in those who underwent procedures with 11 or 14 gauge needles. Of the remaining 29 (22%), none (0%) had bleeding episodes.

**Table 1 -** Risk of bleeding in relation to partial thromboplastin time (PTT), platelet count, and needle gauge.

| Variables | Total | Bleeding n (%) | | | *P*-value |
|---|---|---|---|---|---|
| | | None | Minimal | Hematoma | |
| **Total** | **129** | **126 (97.7)** | **2 (1.6)** | **1 (0.8)** | N/A |
| ***PTT*** | | | | | 0.536 |
| Low | **57** | 57 (100.0) | 0 (0.0) | 0 (0.0) | |
| Normal | **57** | 54 (94.7) | 2 (3.5) | 1 (1.8) | |
| High | **1** | 1 (100.0) | 0 (0.0) | 0 (0.0) | |
| ***Platelets*** | | | | | 0.997 |
| Low | **3** | 3 (100.0) | 0 (0.0) | 0 (0.0) | |
| Normal | **84** | 81 (96.4) | 2 (2.4) | 1 (1.2) | |
| High | **1** | 1 (100.0) | 0 (0.0) | 0 (0.0) | |
| ***Gauge*** | | | | | 0.020† |
| 14 | **89** | 87 (97.8) | 2 (2.2) | 0 (0.0) | |
| 11 | **11** | 10 (90.9) | 0 (0.0) | 1 (9.1) | |
| Others | **29** | 29 (100.0) | 0 (0.0) | 0 (0.0) | |

PTT †significant using Chi-square test at <0.05 level. Variables do not sum up due to missing values N/A - not applicable

**Table 2 -** Type of breast pathology (benign versus malignant) in relation to pathology.

| Variables | Total | Bleeding n (%) | | | *P*-value |
|---|---|---|---|---|---|
| | | None | Minimal | Hematoma | |
| **Total** | **129** | **126 (97.7)** | **2 (1.6)** | **1 (0.8)** | **N/A** |
| ***Pathology*** | | | | | |
| Benign | 66 | 65 (98.5) | 1 (1.5) | 0 (0.0) | 0.584 |
| Malignant | 62 | 60 (96.8) | 1 (1.6) | 1 (1.6) | |

**Discussion.** The introduction of image-guided breast biopsies has greatly improved patient management and reduced the number of surgeries with their associated risks.[1] To further optimize their utility and to avoid delaying procedures unnecessarily, we address the issue of pre-procedure coagulation screening and the risk of bleeding. In our institution, a complete coagulation profile costs SAR355 (which approximates USD95). This aggregates to at least a total of SAR178,000 (approximately USD47,000). These costs can greatly be reduced with the tailored and patient-specific use of coagulation profiles. It is important to take into consideration that laboratory assays do not accurately predict bleeding risk. Hemostasis is the body's reaction to excess bleeding and the available coagulation assays (PT, activated PTT, INR) are in vitro representations of how the body would react and not how it actually does. Bleeding post invasive procedures has been similar in those with normal and abnormal coagulation profiles.[5-8] These findings led to the discouragement of solely depending on laboratory results as predictors of bleeding, but rather to put into account other factors such as structured bleeding history that includes personal and family history, medications, and medical conditions known to affect hemostasis.[8] Similar to other studies,[1,2] we did not find any relationship between abnormal coagulation profiles and bleeding episodes in patients undergoing image guided breast biopsies (**Tables 1& 2**).

Limitations of the study include the lack of bleeding information for all patients due to the retrospective nature of the study.

In conclusion, the risk of bleeding may not be related to laboratory results, but rather dependent on other patient factors in the patient's history such as the use of anticoagulants, or a known bleeding diathesis. However, we found a statistical significance between needle gauge and bleeding ($p$=0.02). Hematomas are encountered after oftenly with larger gauge needles.[4] Even then, the risk of clinically significant bleeding is still minimal, and most encountered bleeding episodes are manageable with good compression.[1,2]

For future research, we aim to collect data prospectively and include only those who underwent core needle biopsies. In addition, we could also compare results of breast biopsies to other organs.

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