



Hemorrhagic Complications Following Ultrasound-Guided Breast Biopsy: A Prospective Patient-Centered Study

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Objective: We aimed to evaluate the clinical and imaging factors associated with hemorrhagic complications and patient discomfort following ultrasound (US)-guided breast biopsy.

Materials and Methods: We prospectively enrolled 94 patients who were referred to our hospital between June 2022 and December 2022 for US-guided breast biopsy. After obtaining informed consent, two breast radiologists independently performed US-guided breast biopsy and evaluated the imaging findings. A hemorrhagic complication was defined as the presence of bleeding or hematoma on US. The patients rated symptoms of pain, febrile sensation, swelling at the biopsy site, and dyspnea immediately, 20 minutes, and 2 weeks after the procedure on a visual analog scale, with 0 for none and 10 for the most severe symptoms. Additional details recorded included those of nausea, vomiting, bleeding, bruising, and overall satisfaction score. We compared the clinical symptoms, imaging characteristics, and procedural features between patients with and those without hemorrhagic complications.

Results: Of 94 patients, 7 (7%) developed hemorrhagic complications, while 87 (93%) did not. The complication resolved with 20 minutes of manual compression, and no further intervention was required. Vascularity on Doppler examination ($P = 0.008$), needle type ($P = 0.043$), and lesion location ($P < 0.001$) were significantly different between the groups. Patients with hemorrhagic complications reported more frequent nausea or vomiting than those without hemorrhagic complications (29% [2/7] vs. 2% [2/87], respectively; $P = 0.027$). The overall satisfaction scores did not differ between the two groups ($P = 0.396$). After 2 weeks, all symptoms subsided, except bruising (50% 2/4 in the complication group and 25% [16/65] in the no-complication group).

Conclusion: US-guided breast biopsy is a safe procedure with a low complication rate. Radiologists should be aware of hemorrhagic complications, patient discomfort, and overall satisfaction related to this procedure.

Keywords: Breast; Ultrasonography; Biopsy; Hemorrhage; Patient-centered care

INTRODUCTION

Ultrasound (US)-guided breast biopsy is a popular procedure to evaluate the histopathological features of suspicious breast lesions. Compared with surgical excision, it is easier, less invasive, and cost-effective and

is thus preferred by clinicians and patients [1]. Unlike mammography or magnetic resonance imaging-guided biopsy, US offers real-time imaging of the lesion and the biopsy needle along with a multidirectional approach [1,2]. Furthermore, the supine position improves patient comfort over the prone position.

Complications during or after US-guided biopsy are uncommon but may include hematoma, infection, abscess, milk fistula, pneumothorax, and malignant seeding along the biopsy tract [3]. Among these, bleeding is the most common complication [2,4]. According to a meta-analysis of over 20000 breast biopsies by Fang et al. [5], the pooled rate of bleeding complications was 10.9%, while another study reported a rate of less than 4% of significant hematoma requiring manual compression > 10 minutes or interventions [6]. In another systematic review, the rate of uncontrolled

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bleeding complications was < 1% without any reported deaths [7].

While prior studies have focused on the diagnostic accuracy [8-11] and safety [11] of breast biopsy, less attention has been paid to comprehending patients' perspectives and optimizing their experiences during this procedure [12]. Additionally, there is a general paucity of studies on biopsy-related complications or patient satisfaction in Asian women [13,14]. Recently, patient-centered care has gained prominence with a shift from volume-based to value-based medicine, prioritizing patient experiences, and optimizing their satisfaction [15]. Therefore, this prospective study in Asian women aimed to assess the clinical and imaging factors associated with hemorrhagic complications and patient discomfort following US-guided breast biopsy and the evolution of such discomfort over time.

MATERIALS AND METHODS

This prospective study was approved by the Institutional Review Board of our hospital (IRB No. 2205-179-1331) and informed consent was obtained from the patients after explaining the procedure to them.

We prospectively included 94 patients who underwent US-guided breast biopsy at our hospital between June and December 2022. Two radiologists (S.M.H and H.Y with 7 and 2 years of experience in breast imaging, respectively) performed the breast biopsy (Supplementary Fig. 1). Details of the procedures of US-guided breast biopsy and imaging features are described in Supplementary Methods. Following the biopsy, the histopathology reports were reviewed to determine whether the lesion was benign or malignant.

Immediately after undergoing the biopsy, the patient firmly compressed the biopsy site for hemostasis. Subsequently, the patients were requested to complete a questionnaire about the immediate symptoms, such as pain, febrile sensation, swelling at the biopsy site, dyspnea, nausea or vomiting, bleeding, and bruising. Pain, febrile sensation, swelling, and dyspnea were assessed using a visual analog scale (VAS) with 0 indicating no symptoms and 10 representing the most severe symptoms (Supplementary Fig. 2). Additional details obtained included those regarding nausea, vomiting, bleeding, and bruising. For self-reported bleeding, the patients were asked if they could feel a palpable lump at the biopsy site; if they were unable to assess it, they were asked to look at the site and remove the bandages to

evaluate for the presence of bleeding or oozing. Bruising was defined as discoloration of the skin. After 20 minutes, the same questionnaire was administered to track changes over time. After 2 weeks, the patients were contacted via a phone call to repeat the questionnaires and offer a subjective satisfaction score related to the biopsy procedure (rated from 0 to 5; 5 indicates the highest level of satisfaction).

The two radiologists evaluated the complications at the biopsy site using US twice—immediately and 20 minutes later. When a new fluid collection or a considerable amount of infiltration was detected around the biopsy site, it was regarded as the imaging-apparent presence of bleeding or hematoma and was defined as a hemorrhagic complication (Supplementary Fig. 3).

Patients were categorized into two groups based on hemorrhagic complications, and their symptoms were compared. Fisher's exact test or Wilcoxon's rank-sum test or linear-by-linear association was used to analyze categorical and continuous variables, respectively. To examine the temporal changes in patient discomfort after 2 weeks, we used McNemar's test and the Wilcoxon signed-rank test for categorical and continuous variables, respectively. All statistical analyses were performed using SAS v9.4 (SAS Institute, Cary, NC, USA).

RESULTS

Of 94 patients, 7 (7%) developed hemorrhagic complications, while 87 patients (93%) had no complications. Of the 7 patients with complications, 2 (28%) developed bleeding seen as infiltration on US immediately after the biopsy, and 5 (72%) developed a hematoma after 20 minutes. The mean size of the hematoma was 2.3 ± 0.6 cm (range, 1.7–3.2 cm). None of the patients required medical interventions. An average of 5.1 specimen cores (range, 4–9) were acquired in those without complications, while 4.9 specimen cores (range, 4–5) were acquired in those with complications. The final diagnoses included 73 benign and 22 malignant lesions.

Comparison of Clinical, Radiologic, and Procedural Features in Patients with and Those without Hemorrhagic Complications

Table 1 summarizes the clinical, radiologic, and procedural features of the patients in the hemorrhagic complications and no-complications groups. Of the 7 patients with hemorrhagic complications, 3 (43%) lesions were in

Table 1. Comparison of clinical, radiologic, and procedural features in patients with and those without hemorrhagic complications

	No complications (n = 87)	Complications (n = 7)	P
Age, yr	47.1 ± 10.9 (24–76)	51.6 ± 11.5 (34–67)	0.250
Lesion type			> 0.999
Mass	66 (76)	6 (86)	
Non-mass	21 (24)	1 (14)	
Lesion size, cm	1.4 ± 0.9 (0.3–5.1)	0.9 ± 0.3 (0.6–1.4)	0.105
Glandular tissue component			> 0.999
Low (minimal & mild)	40 (46)	3 (43)	
High (moderate & marked)	47 (54)	4 (57)	
Laterality			0.706
Right	46 (53)	3 (43)	
Left	41 (47)	4 (57)	
Quadrant			< 0.001
Upper outer quadrant	30 (35)	0 (0)	
Upper inner quadrant	15 (17)	0 (0)	
Lower outer quadrant	11 (13)	3 (43)	
Lower inner quadrant	6 (7)	0 (0)	
Subareolar	3 (3)	0 (0)	
12 o'clock	16 (18)	0 (0)	
3 o'clock	1 (1)	3 (43)	
6 o'clock	1 (1)	0 (0)	
9 o'clock	4 (5)	1 (14)	
Location			0.874
Anterior	50 (57)	3 (43)	
Middle	26 (30)	2 (29)	
Posterior	11 (13)	2 (29)	
Nipple distance, cm	2.9 ± 1.6 (0.2–8.0)	2.6 ± 1.0 (1.0–4.0)	0.660
Skin distance, cm	0.5 ± 0.4 (0–2.0)	0.5 ± 0.3 (0.2–1)	0.677
Chest wall distance, cm	0.6 ± 0.4 (0–1.8)	0.6 ± 0.4 (0.2–1.2)	0.932
Echogenicity			0.724
Hypo-	71 (82)	7 (100)	
Iso-	5 (6)	0 (0)	
Hyper-	0 (0)	0 (0)	
Hetero-	11 (13)	0 (0)	
Vascularity			0.008
No vascularity	35 (40)	1 (14)	
One circumferential or central vessel	26 (30)	6 (86)	
Two or more circumferential or central vessels	26 (30)	0 (0)	
Elastography			> 0.999
Shaded green	34 (39)	3 (43)	
Mosaic pattern	34 (39)	3 (43)	
Entirely blue	19 (22)	1 (14)	
Needle size, gauge			> 0.999
12	5 (6)	0 (0)	
14	80 (82)	7 (100)	
16	2 (2)	0 (0)	
Gun type			0.043
ACE-CUT*	84 (97)	5 (71)	
Marquee†	3 (3)	2 (29)	

Table 1. Comparison of clinical, radiologic, and procedural features in patients with and those without hemorrhagic complications (continued)

	No complications (n = 87)	Complications (n = 7)	P
Number of biopsy			0.552
4	5 (6)	1 (14)	
5	70 (81)	6 (86)	
6	11 (13)	0 (0)	
9	1 (1)	0 (0)	
BI-RADS category			0.841
3 (probably benign)	2 (2)	0 (0)	
4A (low suspicion)	67 (77)	6 (86)	
4B (moderate suspicion)	6 (7)	1 (14)	
4C (high suspicion)	5 (6)	0 (0)	
5 (highly suggestive of malignancy)	7 (8)	0 (0)	
Pathology			0.194
Benign	65 (75)	7 (100)	
Malignant [†]	22 (25)	0 (0)	

Data are mean ± standard deviation (range), or number of patients (%).

*ACE-CUT; TSK laboratory, [†]Marquee; BD, [‡]22 malignant lesions were as follows: invasive ductal carcinoma, n = 15; ductal carcinoma in situ, n = 5; invasive lobular carcinoma, n = 1; mixed ductal and lobular carcinoma, n = 1.

BI-RADS = Breast Imaging Reporting and Data System

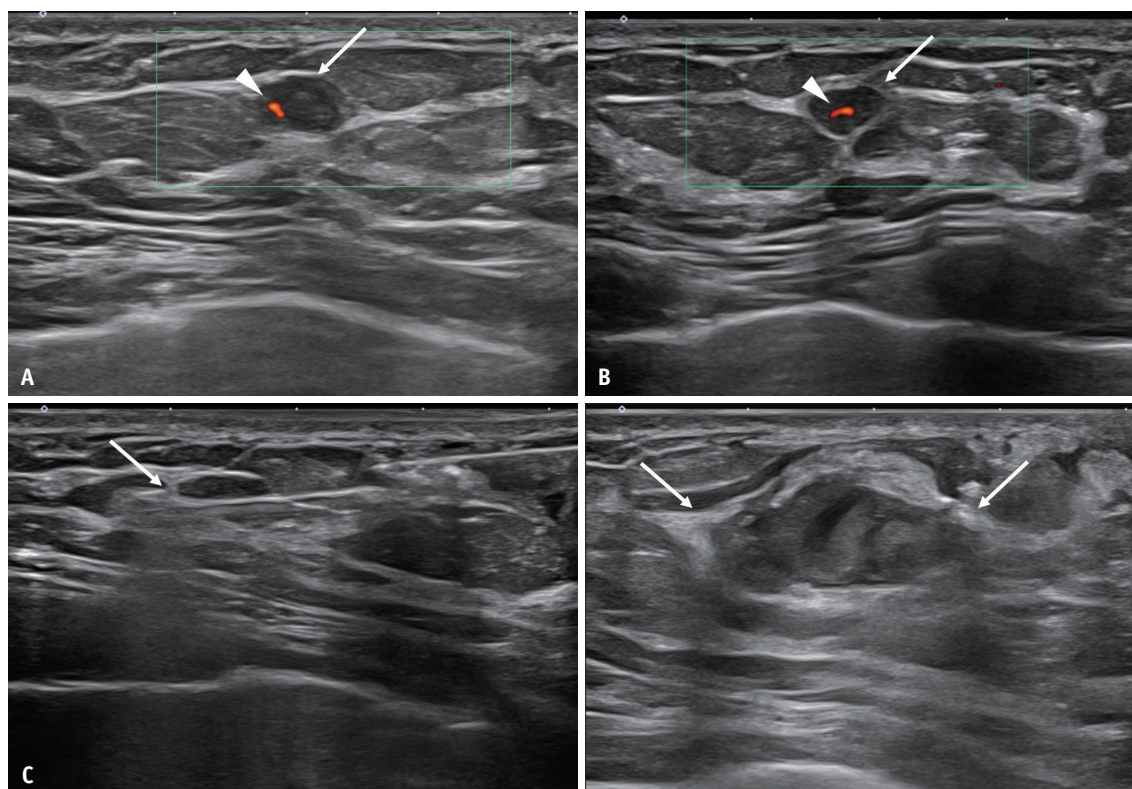


Fig. 1. A 46-year-old woman presented with a right breast mass. **A, B:** Transverse (**A**) and longitudinal ultrasound (**B**) images show a solid mass (arrows) with a central vessel (arrowheads). **C:** Post-fire image shows the mass within the 14-gauge needle (arrow). **D:** Post-biopsy image shows a hematoma (arrows). Pathologic assessment revealed it to be a fibroadenoma.

the lower outer quadrant, 3 (43%) were in the 3 o'clock position, and 1 (14%) was in the 9 o'clock position ($P < 0.001$). In the complications group, six patients had positive

vascularity on Doppler, defined as one circumferential or central vessel crossing the lesion (86%, 6/7, $P = 0.008$) (Fig. 1). In contrast, 35 patients in the no-complications

group had no vascularity (40%, 35/87). There were no significant differences in the needle size ($P > 0.999$) or the number of biopsies performed ($P = 0.552$) between the two groups; however, the gun type used in them was different ($P = 0.043$).

Comparison of Symptoms in the Hemorrhagic Complications vs. No-Complications Groups

Table 2 summarizes the symptoms of patients with or without hemorrhagic complications at each time point (immediately, 20 minutes, and 2 weeks after the biopsy). Immediately after the biopsy, there were no discernible differences in the VAS scores for pain between the two groups ($P = 0.886$). Nausea was more frequent in the complications group than in the no-complications group (29% [2/7] vs. 2% [2/87], respectively; $P = 0.027$). Self-reported bleeding symptoms were noted in 29% (2/7) of patients in the complications group and none in the no-complications group ($P = 0.005$).

After 20 minutes of the procedure, in patients with hemorrhagic complications, the pain score increased slightly (1.4 ± 1.3 to 1.7 ± 1.5) but not significantly ($P = 0.571$). The incidence of self-reported bleeding was 57% [4/7] in the complications group ($P < 0.001$).

After 2 weeks of the procedure, 25 patients could not be reached via the phone, thus resulting in 65 patients in the no-complications group and four patients in the complications group. All symptoms except bruising subsided, and the VAS scores reduced to 0. Overall, 89% (58/65) of patients in the no-complications group and 75% (3/4) of patients in the complications group were very satisfied with the biopsy procedure ($P = 0.396$).

Temporal Changes in Symptoms Following Breast Biopsy

Figure 2 illustrates the temporal changes at three time points: immediately, 20 minutes, and 2 weeks after the biopsy. By 20 minutes of the procedure, the mean VAS score of pain decreased from 1.6 ± 1.8 to 1.5 ± 1.7 ($P = 0.758$); furthermore, the febrile sensation and swelling marginally increased, whereas dyspnea decreased; however, these changes were not clinically significant. Self-reported bleeding was present in two patients immediately after the biopsy (2%, 2/94) and in four patients (4%, 4/94) 20 minutes later ($P = 0.157$) (Supplementary Table 1). All symptoms of nausea or vomiting and dyspnea except bruising subsided by 2 weeks of the procedure. Supplementary Figure 4 presents histograms of VAS scores following breast

biopsy at three time points.

DISCUSSION

In our prospective longitudinal study of 94 patients, 7 (7%) patients had hemorrhagic complications on breast US following US-guided breast biopsy. Notably, patients with hemorrhagic complications had a higher incidence of lesions with a circumferential or central vessel on Doppler (86% vs. 30%, $P = 0.008$). Regarding symptoms, nausea or vomiting (29% vs. 2%, respectively, $P = 0.027$) and patient self-reported bleeding were more frequent in the complications group (29% vs. 0%, respectively, $P < 0.005$) immediately after biopsy than in the no-complications group. After 20 minutes, patient self-reported bleeding was persistently higher in the complications group than in the no-complications group (57% vs. 0%, respectively, $P < 0.001$). No clinically significant delayed hematoma was observed within 2 weeks of follow-up. More than 75% of patients in both groups were satisfied with the biopsy procedure. Therefore, US-guided breast biopsy is an effective and safe procedure with a very low complication rate and a high satisfaction score.

Various factors, including the needle size, number of samples collected, and biopsy-guiding modality have been proposed as potential risk factors for bleeding during and after a breast biopsy. Chetlen et al. [16] reported that a larger biopsy needle size (≥ 9 gauge) was associated with a higher risk of complications (odds ratio [OR], 2.1 vs. 0.5, respectively) than a smaller needle (10–14 gauge). Conversely, other studies found no clear association between biopsy needle size, number of biopsies, or lesion location [17–19]. Similarly, our study revealed that needle size and number of biopsies were not related to complication rates; however, the complications group had a higher proportion of lesions in the lower outer quadrant than the no-complications group. Therefore, the location of a lesion within the breast may affect the risk of hemorrhagic complications following a biopsy.

The imaging factors associated with hemorrhagic complications in our study included the presence of circumferential or central vessels across the lesion on Doppler. A previous study reported a lower risk of hematoma following US-guided biopsy (OR, 0.26), which may be due to the ability to avoid vascular structures in real-time using US [20]. Furthermore, the European Society of Breast Imaging guidelines recommend [21] carefully planning the needle track to avoid vessels identified on Doppler. Therefore, if a

Table 2. Comparison of symptoms in the hemorrhagic complications vs. no-complications group

Symptoms	No complications (n = 87)	Complications (n = 7)	P
Immediate			
Pain	1 [0–3]; 1.6 ± 1.8	1 [0–3]; 1.4 ± 1.3	0.886
Febrile sensation	0 [0–1]; 0.7 ± 1.1	0 [0–1]; 0.3 ± 0.5	0.501
Swelling	0 [0–1]; 0.4 ± 0.7	0 [0–1]; 0.6 ± 1.1	0.769
Dyspnea	0 [0–0]; 0.4 ± 1.1	0 [0–1]; 0.3 ± 0.5	0.823
Nausea/vomiting			
No	85 (98)	5 (71)	
Yes	2 (2)	2 (29)	
Bleeding*			
No	87 (100)	5 (71)	0.005
Yes	0 (0)	2 (29)	
Bruise			
No	87 (100)	7 (100)	
Yes	0 (0)	0 (0)	
After 20 mins			
Pain	1 [0–2]; 1.5 ± 1.7	2 [0–3]; 1.7 ± 1.5	0.571
Febrile sensation	0 [0–1]; 0.8 ± 1.3	0 [0–2]; 0.6 ± 1.0	0.557
Swelling	0 [0–1]; 0.5 ± 0.8	0 [0–2]; 0.6 ± 1.0	0.953
Dyspnea	0 [0–0]; 0.3 ± 0.9	0 [0–0]; 0.1 ± 0.4	0.861
Nausea/vomiting			
No	85 (98)	6 (86)	
Yes	2 (2)	1 (14)	
Bleeding*			
No	87 (100)	3 (43)	< 0.001
Yes	0 (0)	4 (57)	
Bruise			
No	87 (100)	7 (100)	
Yes	0 (0)	0 (0)	
After 2 weeks (n = 65)[†]			
Pain	0 [0–0]; 0.2 ± 0.9	0 [0–0]; 0 ± 0	> 0.999
Febrile sensation	0 [0–0]	0 [0–0]	
Swelling	0 [0–0]	0 [0–0]	
Dyspnea	0 [0–0]	0 [0–0]	
Nausea/vomiting			
No	65 (100)	4 (100)	
Yes	0 (0)	0 (0)	
Bleeding*			
No	65 (100)	4 (100)	
Yes	0 (0)	0 (0)	
Bruise			
No	49 (75)	2 (50)	0.277
Yes	16 (25)	2 (50)	
Satisfaction score (1–5)			
Satisfied (score 4)	7 (11)	1 (25)	0.396
Very satisfied (score 5)	58 (89)	3 (75)	

Data are median [interquartile range], mean ± standard deviation, or number of patients (%).

*Refers to self-reported symptoms of bleeding. Patients were asked if the patient could feel a palpable lump at biopsy site and in cases in which the patient was not able assess, the patients were asked to look at the site and remove the bandages for the presence of any bleeding or oozing to answer the question, [†]25 patients were excluded due to no follow-up.

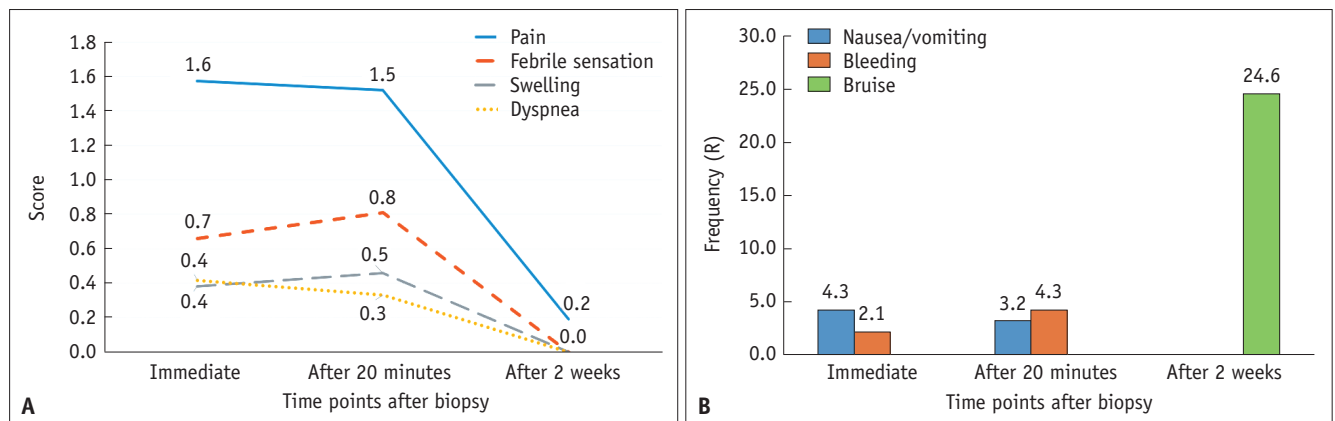


Fig. 2. Temporal changes in symptoms. **A:** Temporal changes in the VAS scores at three time points: immediately, 20 minutes, and 2 weeks after the breast biopsy. This graph illustrates the temporal evolution of patient symptoms (pain, febrile sensation, swelling at the biopsy site, and dyspnea) at each time point. The VAS score remained consistent immediately after the biopsy and 20 minutes later. After 2 weeks, the patients' discomfort was resolved. **B:** The histogram depicts the temporal evolution of patient discomfort (nausea/vomiting, bleeding, and bruise). Nausea/vomiting and bleeding resolved after 2 weeks with bruising remaining as the sole symptom. VAS = visual analogue scale

prominent blood vessel is visible along the needle path, the radiologist must use an alternative directional approach. Despite anticipating a high risk of hemorrhage in breast malignancies with angiogenesis and friability of tumor vasculature, all observed hemorrhagic complications in this study were associated with benign lesions. Although it is difficult to draw conclusions due to the small number of cases and subjective assessments of vascularity by two radiologists, this finding may suggest that bleeding can occur irrespective of the lesion's histopathology.

Many studies have assessed pain levels during US-guided breast biopsy on a scale of 0–10 and reported scores of 0.8–2.4, which indicates minimal pain [22–25]. Interestingly, patients often experience significantly lower pain during the biopsy procedure than the anticipated pain triggered by pre-biopsy anxiety (1.2 vs. 4.4, respectively, on a 0–10 scale) [22]. Consistent with prior reports, a majority of patients in our study experienced mild symptoms (< 2), and fewer than 5% of patients experienced adverse symptoms related to biopsy. In our study, the symptoms were tolerable and manageable in both the short-term (after 20 minutes) and long-term (after 2 weeks) follow-up.

This study had some limitations. First, this study was conducted at a single tertiary hospital and included a relatively small number of participants. Additionally, feedback was received from only 73% of the patients 2 weeks after the procedure. Second, we did not assess the quantity of local anesthesia that substantially lowered pain levels, which may have resulted in the formation of a hematoma. Third, the apparent hematoma on breast US

and the patients' self-reported bleeding symptoms were subjective assessments. Finally, the effects of antiplatelet and antithrombotic drugs were not considered in the analyses. Indeed, there is no widely established standard protocol to guide antithrombotic therapy in patients who undergo breast biopsy. Thus, radiologists recommend discontinuation of antithrombotic drugs on a case-by-case basis before performing a biopsy. Yet, discontinuing such a therapy before biopsy is associated with potential thromboembolic events and a delay in breast cancer diagnosis. However, recent reports have suggested that the risk of severe bleeding complications is low in patients on antithrombotic therapy [26,27]. Our findings emphasize the safety of a breast biopsy. Nonetheless, patients who require full-dose antiplatelet drugs during biopsy or are elderly or if a radiologist plans to use a larger needle, the patient should be informed of a greater risk of hemorrhage and the radiologist should still take preventive steps to reduce bleeding irrespective of the anticoagulation status [26,27].

In conclusion, our findings suggest that US-guided breast biopsy offers a balance between safety and effectiveness while minimizing invasiveness. Radiologists require a comprehensive understanding of the potential complications and discomfort factors associated with this procedure. Prioritizing patient-centered care during biopsy can help reduce patient discomfort and improve the overall experience and satisfaction with the procedure.

Supplement

The Supplement is available with this article at <https://doi.org/10.3348/kjr.2023.0874>.

Availability of Data and Material

The datasets generated or analyzed during the study are available from the corresponding author on reasonable request.

Conflicts of Interest

The authors have no potential conflicts of interest to disclose.

Author Contributions

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