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Evaluation of a screening tool for bleeding disorders in a US multisite cohort of women with menorrhagia

Dr. Claire S. Philipp, MD, **Dr. Ambarina Faiz, MD, MPH**, **Dr. John A. Heit, MD**, **Dr. Peter A. Kouides, MD**, **Dr. Andrea Lukes, MD**, **Dr. Sidney F. Stein, MD**, **Ms. Vanessa Byams, MPH**, **Dr. Connie H. Miller, PhD**, and **Dr. Roshni Kulkarni, MD**

Division of Hematology, UMDNJ-Robert Wood Johnson Medical School, New Brunswick, NJ (Drs Philipp and Faiz); Division of Cardiovascular Diseases, Mayo Clinic, Rochester, MN (Dr Heit); the Mary M. Gooley Hemophilia Center and Rochester General Hospital, University of Rochester School of Medicine, Rochester, NY (Dr Kouides); Department of Obstetrics and Gynecology, Duke University School of Medicine, Durham, NC (Dr Lukes); Department of Hematology and Medical Oncology Emory University School of Medicine, Atlanta, GA (Dr Stein), and the Division of Blood Disorders, National Center on Birth Defects and Developmental Disabilities, Centers for Disease Control and Prevention, Atlanta, GA (Ms Byams, Drs Miller, and Kulkarni; and Department of Pediatrics and Human Development, Michigan State University, East Lansing, MI (Dr Kulkarni)

Abstract

OBJECTIVE—The purpose of this study was to determine the usefulness of a simple screening tool for bleeding disorders in a multisite population of women with menorrhagia.

STUDY DESIGN—Women with menorrhagia between the ages of 18 and 50 years from 6 geographically diverse US centers underwent hemostatic testing for bleeding disorders, complete blood cell count, and ferritin. A questionnaire that contained all elements of the 8-question screening tool was administered. Sensitivity of the screening tool, a screening tool with a pictorial blood assessment chart (PBAC) score of >185, and a screening tool with serum ferritin were calculated for hemostatic disorders.

RESULTS—Two hundred and seventeen women who were identified with a PBAC score of ≥100 participated in the study. The sensitivity of screening tool was 89% for hemostatic defects, and sensitivity increased to 93% and 95% with a serum ferritin level of ≤20 ng/mL and PBAC score of >185, respectively.

CONCLUSION—This study confirms the usefulness of a short screening tool for the stratification of women with menorrhagia for hemostatic evaluation.

Keywords

bleeding disorder; ferritin; hemostatic evaluation; menorrhagia

Reprints: Claire Philipp, MD, Division of Hematology, UMDNJ-Robert Wood Johnson Medical School, PO Box 19, MEB Rm 378, New Brunswick, NJ 08903. philipp@umdnj.edu.

The findings and conclusions in this report are those of the authors and do not necessarily represent the views of the Centers for Disease Control and Prevention.

It is estimated annually that approximately 5% of reproductive-age women seek medical attention for menorrhagia.[1,2] Underlying hemostatic abnormalities, which include decreased von Willebrand factor (VWF), platelet dysfunction, and decreased coagulation factors, are found commonly in women with menorrhagia.[1,3–5] Yet, most women with menorrhagia seek medical attention for their symptoms from gynecologists and primary care physicians, rather than from hematologists. Furthermore, few of these women are referred for hemostatic evaluation, despite the high prevalence of hemostatic abnormalities in this population[6]; the average delay from onset of bleeding symptoms to diagnosis of a bleeding disorder has been reported to be 16 years.[7] Barriers to referral for hemostatic evaluation include difficulties gynecologists and primary care physicians have in determining whom to refer, lack of recognition by gynecologists and primary care physicians of menorrhagia as a symptom of a bleeding disorder, the size of the population with complaints of menorrhagia, and the lack of simple laboratory tests to screen for hemostatic abnormalities in this population. Given the under-recognition and delay in diagnosis of bleeding disorders and the potential for bleeding complications with surgery, childbirth or invasive procedures in women with menorrhagia, and unidentified bleeding disorders, a standardized screening tool to assist in the determination of which women to refer for hemostatic evaluation would be useful for the practicing gynecologist. Using data from women with menorrhagia at a single institution, a simple easy-to-administer screening tool comprised of 8 questions in 4 categories has been developed to help gynecologists assess which women with menorrhagia to refer for a comprehensive hemostatic evaluation.[8] The purpose of the current study was to test the screening tool in a prospectively recruited US multisite population of women with menorrhagia. Additionally, we examined potential modifications to the screening tool to increase the sensitivity of the identification of women with potential bleeding disorders.

MATERIALS AND METHODS

Study population

Women between the ages of 18 and 50 years at 6 centers in the United States with a physician diagnosis of menorrhagia were approached for participation. A pictorial blood assessment chart (PBAC) score of ≥100, uterine size ≤12 weeks of gestation, and an otherwise negative pelvic examination and normal Papanicolaou smear test within 1 year of participation were required for eligibility. Nonsteroidal antiinflammatory agents, aspirin, and all antiplatelet medications and herbal agents were discontinued for a minimum of 10 days before initial laboratory testing. Women who could not discontinue antiplatelet agents were excluded from participation. Women with previously diagnosed bleeding disorders and those who were on hormonal therapy that included estrogen and/or progesterone contraceptives within the last 3 months or who were using an intrauterine device or planning pregnancy were also excluded. Women with a history of malignancy, uncontrolled hypertension, insulin-dependent diabetes mellitus, chronic liver or renal disease, a seizure disorder, venous or arterial thromboembolism, and/or anticoagulation therapy or vascular disease were excluded from participation as well. This study was performed as a substudy of a US multisite menorrhagia management study.[9] The study was approved by the

institutional review boards of the respective centers and the Centers for Disease Control and Prevention. The study was explained to eligible women, and informed consent was obtained.

Four hundred twelve women were identified as eligible to participate; of these, 343 women provided informed consent; 80 women withdrew consent. Of the remaining women, 28 did not meet PBAC score criteria for menorrhagia. Among the women who underwent hemostatic testing, 3 women had incomplete laboratory testing. Analysis was performed on 217 women with complete questionnaire and laboratory data.[9]

PBAC

Participants completed the pictorial chart with their next menses after study entry. Blood loss was determined by visual self-assessment and scoring of sanitary pad and tampon saturation, as previously described.[10] All participants were provided with uniform pads and tampons to be used during the study. Participants were not receiving any treatment for their menorrhagia when the PBAC was recorded. A PBAC score of ≥100 was required for further participation in the study.

Laboratory testing

Participants who met study criteria, which included a PBAC score of ≥100, underwent testing for low VWF, platelet function defects, and coagulation factor deficiencies that have been previously described.[1,5] Coagulation testing, including VWF testing, was performed at the Centers for Disease Control. Briefly, the activities of factors II, V, VII, VIII, IX, X, and XI were assayed by 1-stage methods with appropriate factor-deficient plasmas (Precision Biologic, Dartmouth, Nova Scotia, Canada) on an automated analyzer (STA Compact; Diagnostica Stago, Parsippany, NJ). VWF antigen was measured on the STA-R Evolution (Diagnostica Stago) by latex bead-immunoassay (LIATest; Diagnostica Stago). VWF ristocetin cofactor activity was also measured on the STA-R Evolution. Platelet aggregation with adenosine triphosphate release and platelet function analyzer (PFA)–100 closure times were performed at each site with uniform instrumentation, methods, and agonist concentrations.[9] PFA-100 closure times were determined with the collagen/epinephrine and collagen/adenosine diphosphate cartridges (Dade-Behring, Deerfield, IL). Platelet aggregation and adenosine triphosphate release was assessed in platelet-rich plasma in a lumiaggregometer with collagen, adenosine diphosphate, arachidonic acid, and epinephrine (Chrono-Log Corp, Havertown, PA). Additionally, platelet aggregation was measured using ristocetin, and adenosine triphosphate release was measured with thrombin (Chrono-Log Corp) as previously described.[5,9] A complete blood cell count and serum ferritin test were also performed on blood samples from all study participants.

Questionnaire

A questionnaire that elicited information on demographics, medical history, menstrual history, bleeding history, and family history was administered in-person to each study participant.

Screening tool

A screening tool was constructed as previously reported,[8] based on different combinations of symptoms to maximize sensitivity and to minimize the number of women with menorrhagia and abnormal hemostasis that were missed by the tool, given the reported delay in diagnosis of bleeding disorders and potential complications of undiagnosed bleeding disorders. The screening tool contains 8 questions in the following 4 categories: (1) severity of menorrhagia, (2) family history of a diagnosed bleeding disorder, (3) personal history of excessive bleeding after specific challenges, and (4) history of treatment for anemia. The *severity* of menorrhagia was defined by a duration of menses of ≥7 days and either flooding or bleeding through a tampon or napkin in ≤2 hours. A positive family history of a diagnosed bleeding disorder required the presence of a known diagnosed bleeding disorder such as von Wille-brand disease in a family member. A history of excessive bleeding after a challenge was based on the following specific challenges: delivery, miscarriage, surgery, tooth extraction, or dental surgery. All elements of the screening tool were contained in the questionnaire that was administered prospectively to the study participants. A screening tool was considered positive for a study subject if an affirmative response was obtained in any 1 of the 4 categories (Table 1).

Hemostatic abnormalities

Hemostatic defects were classified as platelet function defects, decreased VWF, coagulation factor deficiencies, and/or abnormal PFA-100 results. *Platelet function defects* were defined as defects in platelet aggregation and/or platelet adenosine triphosphate release with ≥1 agonists. *Low VWF* was defined as VWF antigen and/or VWF ristocetin cofactor <0%. A prolonged PFA-100 was defined if a prolonged PFA-100 was demonstrated in the absence of low VWF, platelet function defects, or coagulation factor deficiencies.

Statistical analysis

The data were analyzed with an SAS statistical package (version 9.1; SAS Institute, Cary, NC). The means and standard deviations for the age of participants, age at menarche (years), duration of menses (days), hemoglobin (grams per deciliter), ferritin (nanograms per milliliter) and PBAC scores were calculated. Sensitivity, specificity, positive predictive value, and negative predictive value of the screening tool, screening tool with a serum ferritin ≤20 ng/mL, and screening tool with a PBAC score of >185, which was a cutoff point that was used by Janssen et al,[11] was calculated for hemostatic disorders for white and black women.

RESULTS

The study included 217 participants between the ages of 18 and 50 years with menorrhagia that had been identified by a PBAC score of ≥100; the study was conducted at 6 medical centers within the United States. There were 169 white (78%) and 35 black (16%) women who participated in the study. Characteristics of the study population are shown in Table 2. The mean hemoglobin level was 12.1 ± 1.5 g/dL (7.4 –15.6; n = 155); 56% of women were anemic with a hemoglobin level <12 g/dL. The mean serum ferritin level (n = 155) was 20.6 ± 19.8 ng/mL (1–152); the serum ferritin level ≤20 ng/dL in 64% of women.

On laboratory testing, 71% of the participants (154/217) were found to have ≥1 hemostatic abnormalities. Fifty-five percent of the women (120/217) had a platelet function defect; 5% of the women (11/217) demonstrated low VWF, and 5% of the women (11/217) had coagulation factor deficiencies. Sixty-six percent of the white women (112/169) had ≥1 hemostatic abnormalities that included 50% of the women (84/169) with platelet function defects, whereas 91% of the black women (32/35) had ≥1 hemostatic abnormalities, which included 86% with platelet function defects (Table 3).

The screening tool demonstrated 89% sensitivity for hemostatic abnormalities; the positive predictive value was 72%. Among 190 women who had a positive screening tool, 137 women had abnormal hemostatic testing results. The specificity of the screening tool was 16% for hemostatic defects, and the negative predictive value was 37% (Table 4). When a PBAC score of >185 was combined with the screening tool, sensitivity was increased to 95% for hemostatic defects, and the positive predictive value remained unchanged (Table 4). When a low serum ferritin level (≤20 ng/mL) was combined with the screening tool, there was a similar increase in sensitivity without a change in positive predictive value. Combining both a PBAC score of >185 and serum ferritin level ≤20 ng/mL as additional elements of the screening tool did not increase the sensitivities beyond what was observed with the PBAC score of >185 and the screening tool. The PFA-100 did not add to the sensitivity of the screening tool. For white women, the sensitivity of the screening tool was 87% for hemostatic and platelet function defects and 70% for low VWF. Sensitivity increased to 93% when a PBAC score of >185 was added to the screening tool. Black women had sensitivities of 93% and 94%, respectively, for hemostatic and platelet function defects, and the sensitivity was 100% for low VWF. All black women who were studied had a PBAC score of >185 (Table 5). When serum ferritin level was added to the screening tool, the sensitivity of the screening tool increased from 87–90% in white women and 93–100% in black women.

COMMENT

This study evaluates, in a multisite US cohort, the usefulness of a short 8-question screening instrument for the stratification of women with menorrhagia for hemostatic evaluation. The study also demonstrates the utility of a low serum ferritin level to increase the sensitivity of the screening tool and confirms the value of a PBAC score of >185 as an adjunct to the screening tool. With the use of the screening tool, 8% of women (17/217) in this study who had a hemostatic abnormality would not have undergone hemostatic evaluation; 89% of women (137/ 154) with a hemostatic abnormality would have been stratified correctly for testing. Adding a PBAC score of >185 to the screening tool would have reduced to 4% (8/217) the proportion of affected women who were not referred for hemostatic evaluation; 95% of women (146/ 154) with a hemostatic abnormality would have been stratified correctly for testing. Supplementation of the screening tool with a low serum ferritin level yielded very similar results: 5% of the women (11/217) with hemostatic defects would have been missed; 93% of the women (143/154) with a hemostatic defect would have been stratified correctly for evaluation. As previously reported,[7] no additional benefit of adding the PFA-100 to the screening tool was found.

In the present study, the specificity was low for the screening tool either alone or in combination with a PBAC score of >185 or a low serum ferritin level. One limitation of low specificity is the potentially high rate of false-positive screens. However, with a high positive predictive value for the screening tool, a low specificity reflects the small number of true-negative and false-positive results in this population with a high prevalence of bleeding disorders. Although it would be desirable to have a tool with both a high sensitivity (low false-negative results) and a high specificity (low false-positive results), there is usually a trade-off between missing patients with disease (false-negative results) and having patients with false-positive results, depending on the purpose of the tool. Because the screening tool was designed to minimize false-negative results and thus to avoid missing women with menorrhagia who have bleeding disorders in a population with a high prevalence of these disorders, a high sensitivity and low specificity of the screening tool would be appropriate to achieve the goal. If the tool were also being used by the hematologist to diagnose bleeding disorders in lieu of laboratory testing or possibly to predict bleeding risk, a high specificity would be warranted.

Despite differences in study design and study cohorts (which included a lack of inclusion of adolescents, study entry criteria, and identification of menorrhagia), results of the current multicenter study are similar and confirm those previously determined with the development of the screening tool.[8] Similar results for the screening tool were obtained whether defining menorrhagia based on a PBAC score of ≥100, as was done in this study, or basing menorrhagia on a physician diagnosis as was used in the development of the screening tool.[8] The utility of the serum ferritin level as an adjunct to screening for hemostatic abnormalities has not been demonstrated previously and may provide a similarly effective, but clinically more feasible, supplement to the screening tool than the PBAC score. Although less cost-efficient than a PBAC score, a serum ferritin level may offer the clinician the possibility of a more rapid evaluation and decision for hematologic referral without awaiting a menstrual cycle for a prospectively completed PBAC score.

Both a low ferritin level and an elevated PBAC score have been demonstrated to be associated with menstrual blood loss of >80 mL per cycle,[10–12] which objectively defines menorrhagia. The PBAC score has been shown to have 80% sensitivity and specificity for menorrhagia.[10,11] A combination of low serum ferritin level, clots, and rate of change of protection needed during full flow has been reported to have a 60% sensitivity and 86% specificity for menorrhagia.[12] In this study, approximately two-thirds of women with menorrhagia had a low serum ferritin level. We found that a low serum ferritin level and increased menstrual flow as measured by PBAC score increased the sensitivity of the screening tool for hemostatic defects. In addition, the screening tool incorporates several other parameters that are predictive of menorrhagia and include duration of menses more than 7 days, flooding, and rate of bleeding through protection. The current study demonstrates that multiple clinical parameters that are associated with increased menstrual blood loss are useful in screening for hemostatic disorders in this population.

Other efforts to improve the diagnosis of bleeding disorders through bleeding questionnaires have resulted in the development of a bleeding score.[13–15] The bleeding score, a quantification of bleeding symptoms based on a 17-page questionnaire that takes

approximately 40 minutes to administer,[14] has been condensed recently to a 6-page questionnaire.[15] However, the bleeding score was developed in patients with known type-1 von Willebrand disease compared with normal, healthy individuals and has not been validated in undiagnosed women with symptoms of menorrhagia or in other hemostatic disorders besides type-1 von Willebrand disease. The usefulness of the bleeding score in the clinical gynecology or primary care setting to screen women with menorrhagia for hemostatic defects, which may often not be type-1 von Willebrand disease in multiracial populations, has not been demonstrated.

The screening tool that was used in the current study may be useful to gynecologists and primary care providers in the identification of subgroup of women with menorrhagia who should be referred for hemostatic evaluation. In contrast with the 0.6–1.3% estimated prevalence of von Willebrand disease[16–18] and the 1% estimated prevalence of platelet function defects[19] that was observed in the general nonmenorrhagia population, the frequency of these bleeding disorders in women with menorrhagia is high (Table 3). Undiagnosed bleeding disorders, which includes von Wille-brand disease and platelet function defects in particular, are common in women with menorrhagia and may impact women's lives adversely because of bleeding complications after childbirth and surgery, blood transfusions, and chronic iron deficiency anemia.[14,20] In addition to preventing the bleeding complications of surgery and childbirth with appropriate hemostatic management, being able to make the diagnosis of a bleeding disorder, such as a platelet function disorder or von Willebrand disease, affords the physician the opportunity to provide effective hemostatic management of menorrhagia. Both intranasal desmopressin and tranexamic acid, an antifibrinolytic agent, have been demonstrated to reduce menstrual flow in women with menorrhagia who have been found to have a bleeding disorder.[9] The incorporation of a screening program into clinical gynecology practice would simplify and standardize criteria for hematologic referral and hemostatic testing in women with menorrhagia. Furthermore, universal referral is problematic, given the technical requirements, specialized technical expertise, and expense of the comprehensive hemostatic testing (which includes platelet function testing) that are required for the diagnosis of bleeding disorders in the menorrhagia population. However, several assumptions are implicit with the incorporation of such a screening tool, and they must be recognized by providers. Neither a positive screening tool itself nor a positive screening tool with the addition of the PBAC score and ferritin level are sufficient to diagnose a bleeding disorder; women who have a positive screening result must undergo comprehensive hemostatic testing to determine whether they have a bleeding disorder. Furthermore, the screening tool is not useful to predict the future risk of excessive bleeding. In addition, the screening tool, which was developed and tested in women with menorrhagia, may not be valid in patients with other bleeding symptoms. Despite these limitations, incorporation of a screening tool for bleeding disorders provides a useful, standardized method for the stratification of women with otherwise unexplained menorrhagia whose condition is evaluated by gynecologists. These results support the incorporation of the screening tool along with either a serum ferritin level and/or the PBAC score into clinical practice to help providers identify which women with menorrhagia should be referred for hemostatic evaluation.

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TABLE 1

Screening tool

Q1. How many days did your period usually last, from the time bleeding began until it completely stopped?
Q2. How often did you experience a sensation of “flooding” or “gushing” during your period?
Q3. During your period did you ever have bleeding where you would bleed through a tampon or napkin in ≤2 hours?
Q4. Have you ever been treated for anemia?
Q5. Has anyone in your family ever been diagnosed with a bleeding disorder?
Q6. Have you ever had a tooth extracted or had dental surgery?
Q6a. Did you have problem with bleeding after tooth extraction or dental surgery?
Q7. Have you ever had surgery other than dental surgery?
Q7a. Did you have bleeding problem after surgery?
Q8. Have you ever been pregnant?
Q8a. Have you ever had bleeding problem after delivery or after a miscarriage?

TABLE 2

Demographic characteristics of study participants (n = 217)

Variable	n	Mean ± SD	Range
Age, y		36.83 ± 7.1	18.5–49.9
Age at menarche, y	216	12.5 ± 1.5	8–17
Duration of menses, d	214	7.0 ± 3.3	3–33
Race			
White	169 (78%)		
Black	35 (16%)		
Other	13 (6%)		
Anemia[a,b]	60 (39%)		
Hemoglobin, g/dL[b]		12.1 ± 1.5	7.4–15.6
Ferritin, ng/mL[b]		20.6 ± 19.8	1–152
Pictorial blood assessment score		306.8 ± 237.6	100–2036

[a] Hemoglobin <12 g;

[b] n = 155.

TABLE 3

Frequencies of hemostatic defects in all women (n = 217), white women (n = 169) and black women (n = 35)

Variable	All women, n (%)	White women, n (%)	Black women, n (%)
Platelet function defects	120 (55.3)	84 (50)	30 (86)
Low von Willebrand factor[a]	11 (5.1)	10 (6)	1 (3)
Coagulation factor defect	11 (5.1)	9 (5.3)	0
Platelet function analyzer–100 abnormality[a]	12 (5.5)	9 (5.3)	1 (3)
Bleeding disorder[b]	154 (71.0)	112 (66.3)	32 (91)

[a] Prolonged platelet function analyzer–100 time without any other hemostatic defect;

[b] Platelet function defects, von Willebrand factor antigen, or von Willebrand factor ristocetin cofactor <50, coagulation defects, or prolonged platelet function analyzer–100 time.

TABLE 4

Sensitivity, specificity, positive predictive value, and negative predictive value for screening tools

Variable	Sensitivity[a]	Specificity[a]	Positive predictive value[a]	Negative predictive value[a]
Screening tool				
Bleeding disorder[b]	89 (83–93)	16 (8–27)	72 (65–78)	37 (19–58)
Low von Willebrand factor	73 (39–94)	12 (8–17)	4 (2–8)	89 (71–98)
Platelet function defects	89 (82–94)	14 (8–23)	56 (49–63)	52 (32–71)
Screening tool combined with pictorial blood assessment score >185				
Bleeding disorder[b]	95 (90–98)	6 (2–15)	71 (65–77)	33 (10–65)
Low von Willebrand factor	91 (59–100)	5 (3–9)	5 (2–9)	92 (62–100)
Platelet function defects	94 (88–98)	5 (2–12)	55 (48–62)	42 (15–72)
Screening tool combined with ferritin ≤20 ng/mL				
Bleeding disorder[b]	93 (89–97)	11 (3–19)	72(66–78)	39 (16–61)
Low von Willebrand factor	91 (59–100)	8 (4–12)	5 (2–8)	94 (84–100)
Platelet function defects	92 (87–97)	8 (3–14)	55 (48–62)	44 (21–67)
Screening tool combined with platelet function analyzer–100				
Bleeding disorder[b]	89 (84–94)	16 (7–25)	72 (66–78)	37 (19–55)
Low von Willebrand factor	73 (46–99)	12 (7–16)	4 (1–7)	89 (77–100)
Platelet function defects	89 (84–95)	14 (7–21)	56 (49–63)	52 (33–71)

[a] Data are given as percentage (95% confidence interval);

[b] Platelet function defects, von Willebrand factor antigen, or von Willebrand factor ristocetin cofactor <50, coagulation defects, or prolonged platelet function analyzer–100 time.

TABLE 5

Sensitivity of screening tools for white (n = 169) and black (n = 35) women

	Sensitivity[a]	
Variable	**White women**	**Black women**
Screening tool		
Hemostatic abnormality[b]	87 (72–92)	94 (79–99)
Low von Willebrand factor	70 (35–93)	100 (3–100)
Platelet function defects	87 (78–93)	93 (78–99)
Screening tool combined with pictorial blood assessment score >185		
Hemostatic abnormality[b]	93 (86–97)	100 (89–100)
Low von Willebrand factor	90 (56–100)	100 (3–100)
Platelet function defects	92 (84–97)	100 (88–100)
Screening tool combined with ferritin level ≤20 ng/mL		
Hemostatic abnormality[b]	90 (85–96)	100 (89–100)
Low von Willebrand factor	90 (74–100)	100 (3–100)
Platelet function defects	88 (81–95)	100 (88–100)

A simple screening tool in combination with a ferritin or a pictorial blood assessment chart is useful for the stratification of women with menorrhagia for hemostatic evaluation.

[a] Data are given as percentage (95% confidence interval);

[b] Platelet function defects, von Willebrand factor antigen, or Von Willebrand factor ristocetin cofactor <50, coagulation defects, and prolonged platelet function analyzer–100 time.