

Content Validation of the Selwan Hamza's Bleeding Risk Assessment Tool (SH-BRAT)

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Abstract

Background: Bleeding complications significantly contribute to increased morbidity, mortality, and healthcare costs. Early identification of at-risk patients is essential; however, standardized, nurse-led bleeding risk assessment tools applicable across diverse clinical settings remain scarce. **Aim:** To establish the content validity of the Selwan Hamza's Bleeding Risk Assessment Tool (SH-BRAT) for use in nursing practice. **Design:** A descriptive methodological study incorporating both quantitative expert scoring and qualitative feedback. **Setting:** The expert panel review was conducted electronically at King Saud Medical City (KSMC), a major tertiary care hospital in Riyadh, Saudi Arabia. **Participants:** A purposive sample of eight multidisciplinary experts—including a cardiothoracic surgeon, ICU physician, oncology and endoscopy nursing specialists, and senior nursing educators—all with a minimum of six years of clinical experience. **Methods:** Experts independently assessed the SH-BRAT using a structured review form evaluating item clarity, relevance, and comprehensiveness. The Scale-Level Content Validity Index (S-CVI/Ave) was calculated, and qualitative feedback was thematically analyzed to inform tool refinement. **Results:** The SH-BRAT demonstrated excellent content validity (S-CVI/Ave = 0.94). Expert consensus affirmed the tool's relevance to clinical nursing practice, while qualitative feedback yielded actionable suggestions for minor refinements. **Conclusion:** The SH-BRAT is a valid, nurse-centered tool for early identification of bleeding risk. Its structure supports seamless integration into routine nursing workflows across various clinical contexts. **Recommendations:** Further research is recommended to pilot the tool, evaluate its reliability, and assess its clinical utility in real-world settings.

Keywords: Bleeding Risk Assessment; Nursing Assessment; Clinical Decision-Making; SH-BRAT; Content Validity; Patient Safety; Saudi Arabia

Introduction

Bleeding complications constitute a significant and persistent threat to patient safety in hospital settings, directly contributing to increased morbidity, mortality, and substantial healthcare resource utilization through prolonged hospital stays and escalated costs. Critically ill patients—particularly those in intensive care units (ICUs) and individuals with hematological malignancies—are disproportionately vulnerable. Recent data indicate that in-hospital bleeding affects approximately 3–4% of acutely ill medical patients, with incidence rising to 10.8% among ICU patients diagnosed with hematologic malignancies (Villiger et al., 2023; Vigneron et al., 2024). This vulnerability is further exacerbated by evolving clinical trends, including the growing use of anticoagulant therapies, an aging and increasingly complex patient population, and the routine application of invasive procedures. These factors collectively highlight the urgent need for early, accurate, and actionable bleeding risk assessment to facilitate timely

preventive interventions. Although the importance of bedside risk stratification tools is well recognized, many existing instruments fall short in clinical applicability—particularly within nursing workflows. Available tools are often physician-centric, disease-specific, or overly complex for routine nursing use. Nurses, by virtue of their continuous bedside presence, are ideally positioned to detect early indicators of bleeding risk. However, a critical gap remains: the lack of a standardized, nurse-led, and broadly applicable bleeding risk assessment tool that is validated for use in diverse clinical environments. This deficiency limits proactive nursing interventions and poses a significant barrier to improving patient safety outcomes related to preventable bleeding events.

Nurses play a pivotal role in the early identification and management of bleeding risks in hospitalized patients. Their continuous presence at the bedside positions them uniquely to observe subtle clinical changes, assess for signs of bleeding, and implement timely interventions.

This proactive involvement is essential, especially considering the complexities associated with anticoagulant therapies and the diverse patient populations at risk. Despite their integral role, studies have highlighted gaps in nurses' knowledge and confidence regarding bleeding risk assessment. For instance, a survey revealed that nearly half of the nursing participants reported suboptimal skills in assessing bleeding risks for patients with inherited bleeding disorders, indicating a pressing need for enhanced education and training in this area (**Schaefer et al., 2019**). To address these challenges, the development and implementation of standardized, nurse-led bleeding risk assessment tools have been advocated. Such tools aim to provide structured frameworks that guide nurses in systematically evaluating patients' bleeding risks, thereby facilitating early detection and prompt management. The integration of these tools into clinical practice not only empowers nurses but also contributes to improved patient outcomes by minimizing the incidence and severity of bleeding complications. Moreover, organizations like the Association of Women's Health, Obstetric and Neonatal Nurses (AWHONN) have developed specific risk assessment tools, such as the Postpartum Hemorrhage Risk Assessment Tool, to aid nurses in identifying and managing bleeding risks in specialized populations (**AWHONN, 2025**). These resources underscore the importance of equipping nurses with the necessary tools and knowledge to effectively mitigate bleeding risks across various clinical settings.

Several established bleeding risk assessment tools guide clinical decision-making, including the HAS-BLED score for atrial fibrillation, the CRUSADE score for acute coronary syndrome, and the IMPROVE bleeding risk score for hospitalized medical patients. While demonstrating acceptable predictive validity within their target populations, these tools exhibit significant limitations, including disease specificity, operational complexity, and frequent reliance on laboratory parameters that may lack immediate availability across diverse clinical settings (**Subherwal et al., 2009; Spyropoulos et al., 2018; Villiger et al., 2023**). For example, the HAS-BLED tool is explicitly designed for anticoagulated atrial fibrillation patients, restricting its utility in broader inpatient cohorts.

Similarly, the CRUSADE score—developed specifically for non-ST-elevation myocardial infarction—incorporates variables like baseline hematocrit and creatinine clearance, which can impede real-time nursing assessment (**Subherwal et al., 2009**). Furthermore, instruments such as IMPROVE necessitate extensive clinical and historical data, potentially diminishing feasibility in high-acuity or resource-constrained environments. Consequently, despite bleeding prevention being an increasing clinical priority, no universally adopted, nurse-practical tool currently exists that integrates ease of use, broad applicability, and evidence-based risk indicators.

The complexity and heterogeneity of current bleeding risk assessment tools underscore the pressing need for a universal instrument that is both comprehensive and accessible to frontline nursing staff. Many existing tools, while statistically robust, were primarily designed for physicians and require data inputs that may not be readily available during initial nursing assessments—such as lab-based scores or physician-only diagnoses (**Spyropoulos et al., 2018**). This creates a clinical gap, particularly in high-acuity settings where nurses are the first to evaluate patients and initiate preventive actions. A nurse-led tool should balance clinical sensitivity with operational simplicity, allowing for rapid risk identification without compromising accuracy. Furthermore, tools tailored to nurses' workflows can empower them to proactively detect and escalate cases at risk of bleeding, thereby enhancing multidisciplinary care coordination and reducing adverse events (**Schaefer et al., 2019**). The development of a tool that incorporates easily observable clinical indicators, avoids overreliance on complex computations, and reflects the dynamic nature of nursing assessment is essential. Such a tool would not only address current gaps but also promote a culture of shared responsibility in bleeding prevention strategies.

Despite the availability of structured tools, clinical judgment remains a cornerstone in bleeding risk assessment, particularly when patient presentations are atypical or complex. Nurses and physicians often rely on experience, intuition, and subtle patient cues that may not be captured in standard scoring systems. According to **Croskerry (2009)**, cognitive processes such as pattern recognition and heuristics play a pivotal

role in rapid decision-making in clinical environments. However, this reliance on individual judgment introduces variability and potential bias. Studies have shown that human factors - including fatigue, cognitive overload, and clinical inexperience - can significantly impact risk estimation and clinical decision-making accuracy (Norman et al., 2017). Therefore, while clinical insight is invaluable, integrating human judgment with evidence-based tools offers a more balanced and standardized approach to patient safety and bleeding risk detection.

Content validation is a foundational process in the development of health measurement tools, especially when the instrument is intended for clinical decision-making. It ensures that the tool accurately reflects the domain it intends to measure and that each item included is both relevant and representative of the construct being assessed (Polit & Beck, 2006). In clinical tools, content validation often involves input from a multidisciplinary expert panel to review clarity, relevance, comprehensiveness, and alignment with clinical practice. Best practices in content validation emphasize a structured and systematic approach. This includes the use of established metrics such as the Content Validity Index (CVI), both at the item level (I-CVI) and scale level (S-CVI/Ave), which quantifies expert agreement on the essentiality of each item (Lynn, 1986). According to widely accepted standards, an I-CVI of 0.78 or above is considered acceptable when more than six experts are involved (Polit & Beck, 2006). Moreover, integrating qualitative feedback alongside numerical ratings enhances the tool's refinement, allowing developers to capture nuanced insights from the clinical field. Qualitative suggestions can guide the removal of redundant items, rewording for clarity, and alignment with evolving clinical guidelines. This dual approach ensures that the instrument is both statistically sound and practically applicable. Finally, content validation is not a one-time event but a critical step in an iterative development cycle. It often precedes further psychometric evaluations such as reliability testing, construct validity, and usability assessments. Following these best practices is essential to build credible, evidence-based tools that can safely support clinical judgments in high-stakes environments.

Significance of the Study

Bleeding complications represent a critical clinical challenge in hospitalized patients. Global epidemiological data estimate that hospital-acquired bleeding occurs in approximately 4% to 8% of admissions, with significantly higher rates among surgical, critically ill, and oncology patients (Villiger et al., 2023). These events are strongly associated with adverse outcomes, including prolonged hospital stay, increased need for transfusion, higher healthcare costs, and elevated mortality risk. In particular, a recent study among acutely ill patients confirmed that in-hospital bleeding significantly contributes to clinical deterioration and complicates medical management (Villiger et al., 2023).

Despite these concerns, current bleeding risk assessment tools remain largely disease-specific and were originally developed for physician use in specialized contexts such as cardiology or anticoagulation management. Tools like HAS-BLED and CRUSADE, while widely accepted, are limited in their applicability to general hospital populations and often rely on laboratory or diagnostic data not readily available to nursing staff (Lip et al., 2011; Subherwal et al., 2009). This leaves frontline nurses - who are often the first to assess, observe, and act - without a validated, user-friendly, and nurse-specific tool for bleeding risk evaluation.

The Selwan Hamza's Bleeding Risk Assessment Tool (SH-BRAT) was designed specifically to bridge this gap. Its development and content validation address a critical unmet need in clinical nursing practice by offering a structured, evidence-based framework for early identification of bleeding risk. If integrated into routine care, SH-BRAT has the potential to standardize nursing assessments, improve interdisciplinary communication, and support timely interventions that may reduce complications and enhance patient outcomes. Moreover, the paucity of research focused on nurse-led bleeding risk assessment tools reinforces the academic and clinical significance of this study. It not only responds to an existing gap but also provides a scalable foundation for future research, including psychometric evaluation, pilot implementation, and broader validation across healthcare settings.

Aim of the study

This study aims to establish the content validity of the Selwan Hamza's Bleeding Risk Assessment Tool (SH-BRAT) through a structured expert panel review. The objective is to ensure that the tool's items are clear, relevant, and comprehensive for clinical application by nurses in diverse healthcare settings. By developing a standardized, nurse-friendly instrument for early bleeding risk identification, this study seeks to bridge a critical gap in nursing practice and contribute to safer, more proactive patient care.

Research questions

1. To what extent do expert reviewers rate the items of the SH-BRAT tool as clear, relevant, and comprehensive for assessing bleeding risk in clinical nursing practice?
2. What is the overall Content Validity Index (CVI) of the SH-BRAT tool based on expert evaluation?
3. What qualitative feedback do experts provide regarding the clinical applicability and usability of the SH-BRAT tool in real-world healthcare settings?
4. Does the SH-BRAT tool adequately address the contextual and cultural considerations relevant to nursing practice in diverse clinical environments?

Design

A descriptive methodological research design was employed to establish the content validity of the Selwan Hamza's Bleeding Risk Assessment Tool (SH-BRAT). This design was selected to systematically collect both quantitative ratings and qualitative feedback from expert reviewers, aiming to evaluate the clarity, relevance, and comprehensiveness of the tool's items within clinical nursing contexts. The methodological framework facilitated iterative tool refinement based on expert consensus, aligning with best practices in instrument development.

Setting

This study was conducted electronically with the participation of expert panel members from King Saud Medical City (KSMC), Riyadh, Saudi Arabia. KSMC is one of the largest tertiary care hospitals under the Ministry of Health, offering specialized medical services across various

departments including surgery, oncology, and intensive care. The selection of this setting ensured access to a diverse panel of senior clinical experts actively engaged in patient care and healthcare quality improvement.

Subjects

This study utilized a purposive sample of expert healthcare professionals selected based on their clinical expertise and relevance to bleeding risk assessment. A total of eight experts were recruited from King Saud Medical City (KSMC) in Riyadh, Saudi Arabia—one of the largest tertiary healthcare institutions under the Ministry of Health. The panel included a thoracic surgeon, an ICU physician, senior nurse educators, a rotating nursing supervisor, a pediatric oncology staff nurse, and the head nurse of the oncology department. All participants possessed a minimum of six years of professional experience in clinical practice or healthcare education and demonstrated subject-matter expertise in bleeding management, anticoagulant therapy, or patient safety. Their diverse backgrounds provided multidisciplinary perspectives that enriched the content validation process of the Selwan Hamza's Bleeding Risk Assessment Tool (SH-BRAT), ensuring its clarity, clinical applicability, and contextual relevance in nursing settings.

Inclusion and Exclusion Criteria

Inclusion Criteria

Experts were eligible for inclusion if they met all of the following criteria:

- Licensed healthcare professionals (nurses or physicians) currently engaged in clinical practice or education.
- Minimum of six years of professional experience in clinical or academic healthcare settings.
- Recognized experience or specialization in bleeding management, anticoagulation, or patient safety.
- Affiliation with King Saud Medical City (KSMC), Riyadh.
- Provided informed consent and agreed to voluntary participation.

Exclusion Criteria

Participants were excluded if they:

- Had less than six years of clinical or academic experience.
- Lacked direct or indirect involvement in bleeding-related decision-making.
- Provided incomplete, inconsistent, or missing responses in the expert review tool.
- Withdrew consent or declined participation at any point in the study.

Tool of the study

This study utilized two primary instruments for data collection:

- (1) Selwan Hamza's Bleeding Risk Assessment Tool (SH-BRAT)
- (2) Expert Panel Review Form.

1. Selwan Hamza's Bleeding Risk Assessment Tool (SH-BRAT)

The SH-BRAT is a structured, nurse-friendly clinical checklist developed by the researcher to support frontline nursing staff in the early identification of hospitalized patients at risk of bleeding. The tool was designed after an extensive review of current literature, existing bleeding risk scores, WHO guidance, and nursing practice standards in acute care settings (Polit & Beck, 2017; Schober et al., 2021). It consists of three main assessment sections and a scoring system:

Section 1: Medical History and Risk Factors

This section includes 10 risk factors such as: Currently receiving anticoagulant medications, Known bleeding disorder, Advanced liver or chronic kidney disease (Stage 3 or higher)

, Cardiovascular disease with complications, Uncontrolled hypertension (systolic BP ≥ 160 mmHg or diastolic BP ≥ 100 mmHg), Thrombocytopenia (platelet count $< 100,000/\mu\text{L}$), Morbid obesity (BMI ≥ 40), Recent major surgery (within 30 days) or significant trauma, Receiving chemotherapy or radiation therapy

Section 2: Clinical Indicators (Signs and Symptoms)

This includes 3 observable symptoms:

Unexplained or easy bruising (spontaneous or minor trauma), Frequent nosebleeds or

spontaneous gum bleeding, Presence of blood in urine (hematuria) or stool (melena/hematochezia)

Section 3: Age

Age ≥ 75 years is scored independently due to its physiological and predictive relevance to bleeding risk.

Scoring System:

One point is assigned for each "Yes" response.

0–2 points = Low risk → Routine monitoring

3–4 points = Moderate risk → Close monitoring and consider lab investigations

≥ 5 points = High risk → Immediate intervention and physician consultation

The tool is intended for use during initial nursing assessments upon patient admission and periodically thereafter. Its simplicity, clarity, and clinical alignment make it practical for rapid implementation in real-world hospital settings.

2. Expert Panel Review Form

The second tool was a structured Expert Panel Review Form, specifically designed to assess the content validity of the SH-BRAT tool. It was administered to a panel of eight licensed healthcare professionals with at least 5 years of clinical or academic experience in nursing, medicine, or patient safety. The form included:

Part 1: Expert Demographics

Area of expertise, years of experience, and nationality. Part 2: Overall Assessment of the SH-BRAT Tool

Part 2: Overall Assessment of the SH-BRAT Tool

In the second part of the expert panel review form, participants were invited to assess six key aspects of the SH-BRAT tool using a standardized 5-point Likert scale (1 = Not at all, 2 = Slightly, 3 = Moderately, 4 = Considerably, 5 = Very Much). The evaluated dimensions included:

Clarity: Experts rated the clarity and comprehensibility of the language used throughout the tool.

Relevance: Experts assessed how relevant the SH-BRAT tool is in accurately evaluating bleeding risk among the target patient population.

Ease of Use: The extent to which the tool can be easily used by nursing staff in clinical practice was rated.

Potential for Risk Identification: Experts evaluated the effectiveness of the tool in identifying patients at risk for bleeding.

Scoring System: Clarity and appropriateness of the tool's scoring system were reviewed.

Risk Level Categories: Experts rated the clarity and suitability of the defined bleeding risk levels (Low, Moderate, High).

In addition to numerical ratings, qualitative feedback and open-ended comments were encouraged to guide refinement of the tool. This multi-dimensional evaluation helped ensure the SH-BRAT tool is clear, clinically relevant, feasible to apply in practice, and methodologically sound.

The results of this assessment were used to inform further validation procedures and are quantitatively analyzed in the Instrument Validity and Reliability section of the study

Part 3: Assessment of Tool Elements

Each of the SH-BRAT's three main sections was evaluated for importance using a 5-point Likert scale:

- Medical History and Risk Factors
- Clinical Indicators (Signs and Symptoms)
- Age

Part 4: Comprehensiveness and Suggestions

Experts provided written comments on: Missing risk elements, Appropriateness of the 1-point scoring system, Additional recommendations for improvement

This structured form ensured both quantitative and qualitative input from experts, following best practices for content validation in clinical tool development (Lynn, 1986; Yaghmaie, 2003).

Scoring System

1. Scoring System for the SH-BRAT Tool

The Selwan Hamza's Bleeding Risk Assessment Tool (SH-BRAT) is structured as a binary checklist composed of three core sections:

Section I: Medical History and Risk Factors – 7 items

Section II: Clinical Indicators (Signs and Symptoms) – 3 items

Section III: Age – 1 item

Each item is rated as "Yes" = 1 point and "No" = 0 points. The total bleeding risk score is calculated by summing the points across the three sections, resulting in a cumulative score ranging from 0 to 11.

Based on the total score, patients are categorized into three risk levels:

Low Risk: 0–2

Moderate Risk: 3–4

High Risk: ≥5

This straightforward scoring system enhances the usability of the tool in clinical nursing practice by enabling rapid risk stratification, facilitating timely preventive interventions, and supporting evidence-based decision-making. Its binary nature is supported by prior literature advocating for simplicity and clarity in risk assessment tools used at the bedside (Polit & Beck, 2017).

2. Scoring System for the Expert Panel Review Form

Scoring System for: Over all Assessment of the SH-BRAT Tool

Part 2 of the Expert Panel Review Form evaluates the general quality and usability of the SH-BRAT tool through six key dimensions:

1. Clarity
2. Relevance
3. Ease of Use
4. Potential for Risk Identification
5. Scoring System Appropriateness
6. Risk Level Categories

Each expert rated these aspects using a 5-point Likert scale, where: 1 = Not at all 2 = Slightly 3 = Moderately 4 = Considerably 5 = Very Much

The scores for each item are aggregated across all expert responses. Descriptive statistics (mean, standard deviation, and frequency distribution) are calculated for each item to evaluate the consensus level and perceived quality of the SH-BRAT tool components. Higher mean scores indicate greater expert agreement on clarity, clinical relevance, and practical utility of the tool.

Each expert rated the SH-BRAT tool using a structured 5-point Likert scale:

1 = Not at all

2 = Slightly

3 = Moderately

4 = Considerably

5 = Very much

This scale was applied to evaluate key dimensions including:

Clarity of each item, Relevance to clinical practice, Ease of use, Effectiveness for risk identification, Appropriateness of the scoring system.

To assess the content validity of the SH-BRAT, quantitative analysis also included:

- Item-Level Content Validity Index (I-CVI): Calculated as the proportion of experts rating an item as 4 or 5.
- Scale-Level Content Validity Index (S-CVI/Ave): The average of all I-CVI scores across the entire tool.
- A CVI value of ≥ 0.78 was considered acceptable, following established standards for expert panel validation involving more than six reviewers (Lynn, 1986; Polit & Beck, 2006).

Instrument Validity and Reliability

Instrument Validity and Reliability

Content Validity

To establish the content validity of the Selwan Hamza's Bleeding Risk Assessment Tool (SH-BRAT), two complementary tools were utilized:

1. The SH-BRAT Tool: The instrument being validated, developed by the principal investigator to assess bleeding risk based on clinical and historical criteria.
2. Expert Review Form: A structured validation checklist used by experts to assess the SH-BRAT's clarity, relevance, ease of use, scoring system, and comprehensiveness.

A total of eight experts participated in the validation process, representing diverse clinical backgrounds such as thoracic surgery, hematology, oncology, pediatric and adult critical care, gastrointestinal endoscopy, and nursing education. Their years of experience ranged from 6 to over 20 years, and they were selected for their direct relevance to bleeding risk assessment in clinical practice.

Experts rated each of the 13 tool items using a 5-point Likert scale, and the following indices were calculated:

- Item-level Content Validity Index (I-CVI): Calculated for each item based on the proportion of experts who rated it 4 or 5.

- Scale-level Content Validity Index (S-CVI/Ave): Calculated as the average of all I-CVI values.

> Results:

I- CVI values ranged from 0.75 to 1.00, indicating high agreement across all items.

The S-CVI/Ave for the entire tool was 0.96, which exceeds the threshold for excellent content validity.

Qualitative Feedback from Expert Panel

In addition to the numerical ratings, all experts provided written comments on both individual items and the overall structure and purpose of the SH-BRAT tool. This feedback was thematically analyzed and revealed four key recommendations:

1. Item Merging: Suggestions to combine overlapping elements such as "recent major surgery" and "significant trauma".
2. Rewording for Clarity: Proposed simplification of complex medical terms to enhance readability for bedside nurses.
3. Reassignment of Items: Some experts recommended reclassifying items to more appropriate sections (e.g., moving "age" or "obesity").
4. Cutoff Clarification: Multiple experts questioned the rationale behind using "age ≥ 75 " and suggested the inclusion of sex as a factor, particularly for age-related bleeding tendencies.

> For example, one expert commented:

- "Why 75? Add the sex: male or female."

Another noted:

"Family history should be considered in the clinical indicators."

This comprehensive qualitative feedback strengthened the content representativeness, face validity, and clinical practicality of the SH-BRAT tool. All suggested modifications were documented in Table 5 and visually summarized in Figure 2.

Reliability

The current phase of this study focused solely on evaluating the content validity of the SH-

BRAT tool through expert panel review. Reliability testing was not performed at this stage.

However, a follow-up study is planned under the title:

“Pilot Testing and Reliability Analysis of the SH-BRAT: A Nursing Risk Assessment Tool for Bleeding”.

This future research will include a pilot study aimed at examining the inter-rater reliability, internal consistency, and clinical applicability of the SH-BRAT tool when applied by nursing staff in real-world clinical settings.

The ethical research consideration include the following

Ethical Considerations

This study was conducted in accordance with internationally accepted ethical principles governing research involving human participants. The following measures were ensured:

1. Institutional Review Board Approval

Prior to initiation, the study protocol was reviewed and ethically approved by the Institutional Review Board (IRB) at King Saud Medical City (KSMC). The research complied with the Declaration of Helsinki, Good Clinical Practice (GCP) guidelines, and relevant national regulations.

2. Informed Consent

All expert participants received a formal invitation outlining the study objectives, methodology, and their voluntary role. Written informed consent was obtained before participation.

3. Confidentiality and Data Protection

All expert ratings and qualitative feedback were anonymized and handled with strict confidentiality. No identifying information was included in the final dataset.

4. Voluntary Participation

Participation was fully voluntary, and experts retained the right to withdraw at any stage without penalty or obligation.

5. Risk-Free Participation

The study posed no risk - physical, psychological, or professional - to any

participant. All activities were conducted respectfully and without coercion.

6. Tool Usage Permissions

All assessment tools and materials used in the study were developed by the principal investigator and utilized with full authorship rights. No third-party permissions were required.

7. Expert Acknowledgment

Experts provided written email consent to be acknowledged by name in the final research paper. This voluntary agreement was granted after a clear explanation of how their insights would be credited.

Field Work

The fieldwork phase of this study was conducted between May 12, 2025 and May 21, 2025, following a structured validation plan. It involved the systematic collection of both quantitative and qualitative data from a panel of expert reviewers to assess the content validity of the Selwan Hamza's Bleeding Risk Assessment Tool (SH-BRAT).

A total of eight experts were purposefully selected based on their clinical expertise in fields such as hematology, oncology, thoracic surgery, gastrointestinal endoscopy, critical care, and palliative nursing, as well as their years of professional experience and leadership roles. Experts were invited via email and provided with a comprehensive evaluation package that included the following:

- A standardized cover letter outlining the study objectives.
- A full description of the SH-BRAT tool and its intended use.

Two structured assessment forms:

Part 2: A six-dimension global rating scale assessing Clarity, Relevance, Ease of Use, Risk Identification Potential, Scoring System, and Risk Level Categories.

Part 3: An item-level importance rating using a 5-point Likert scale, evaluating all 13 items across the tool's three domains:

- Medical History and Risk Factors (9 items)
- Clinical Indicators (3 items)
- Age (1 item)

An open-ended comment section for qualitative feedback and suggestions for improvement.

All responses were collected electronically and entered into a secured database. Data accuracy was ensured through manual cross-verification and completeness checks. The collected data were analyzed using the Item-Level Content Validity Index (I-CVI) and the Scale-Level CVI (S-CVI/Ave) to quantify expert agreement. Qualitative comments were coded and categorized into themes such as merging items, rewording, repositioning, and justifying scoring cutoffs.

This rigorous and well-documented fieldwork process contributed to ensuring the credibility, methodological integrity, and scientific validity of the tool's content validation phase.

Administrative Design

This study was planned and executed under the administrative oversight of the Research Department at King Saud Medical City (KSMC). Prior to initiation, formal coordination was established with institutional authorities to ensure alignment with organizational policies and research governance protocols. The research team obtained the necessary administrative approvals for expert recruitment and data collection. All communications with expert participants were conducted through official email channels, and documentation was systematically maintained to ensure transparency, accountability, and adherence to institutional standards. The study adhered to all required ethical and administrative procedures, including data security, confidentiality, and responsible handling of all research materials throughout the validation process.

Statistical Analysis

Quantitative data were analyzed using descriptive and inferential techniques to assess the content validity of the SH-BRAT tool. Item-level Content Validity Index (I-CVI) was calculated for each of the 13 items by dividing the number of experts rating the item as either 4 (considerably important) or 5 (very important) by the total number of experts ($N = 8$). A cutoff of $I-CVI \geq 0.78$ was considered acceptable, as recommended in instrument validation literature (Polit & Beck, 2006). To assess the overall content validity of

the instrument, the Scale-level Content Validity Index using the averaging method (S-CVI/Ave) was computed by averaging the I-CVI values of all items. An $S-CVI/Ave \geq 0.90$ was interpreted as excellent content validity (Lynn, 1986). Descriptive statistics including means, standard deviations, and percentage agreement were used to summarize expert responses across the six global assessment dimensions (Clarity, Relevance, Ease of Use, Risk Identification, Scoring System, and Risk Stratification Categories). Qualitative data from the open-ended comment sections were analyzed using a thematic content analysis approach. Comments were grouped into recurrent categories such as rewording, merging items, repositioning, and justification of cutoff points, which were then synthesized to guide future refinement of the tool. All data were entered and analyzed using Microsoft Excel 365, ensuring accuracy through double-entry verification.

Results

Table 1: summarizes the demographic and professional background of the eight expert panel members who evaluated the SH-BRAT tool. Experts were drawn from six distinct departments within King Saud Medical City, providing diverse and specialized insights into the tool's clinical applicability. All experts had advanced experience in their fields, spanning cardiothoracic surgery, intensive care, oncology, gastroenterology, and nursing education. The average years of professional experience among experts was 14.5 ($SD = 4.6$), ranging from 6 to 20 years. Such diversity ensures the tool's content validity is informed by real-world, cross-disciplinary expertise, aligning with best practices in clinical tool development as endorsed by peer-reviewed standards (Polit & Beck, 2006).

Table 2: presents the descriptive statistics derived from expert evaluations of the SH-BRAT tool across six core dimensions: Clarity, Relevance to Clinical Practice, Ease of Use, Effectiveness in Risk Identification, Scoring System Soundness, and Risk Level Stratification Clarity. Panel members who had a minimum of 6 years' clinical experience provided ratings using a 5-point Likert scale (1 = Not at all, 5 = Very Much). For each dimension, the mean, standard deviation (SD), and the percentage of experts rating the item as 4 or 5 were calculated. The

highest consensus was observed in “Ease of Use” (Mean = 4.75, SD = 0.46; 100% of experts rated it ≥ 4), reflecting the tool’s operational feasibility. Other dimensions such as Clarity, Relevance, and Scoring System also received high evaluations (Mean range = 4.38–4.63), reinforcing the tool’s applicability and comprehensibility in clinical settings. “Risk Level Categories” received slightly lower agreement (Mean = 4.25, %Rated ≥ 4 = 75%), highlighting an area for refinement in future revisions. These findings support the methodological soundness and clinical utility of the SH-BRAT tool, aligning with best practices in content validation literature (Lynn, 1986; Polit & Beck, 2006).

Table 3: presents the item-wise Content Validity Index (I-CVI) ratings for the 13 elements of the SH-BRAT tool, based on expert evaluations (N = 8). I-CVI values were computed as the proportion of experts rating the item as either 4 (considerably important) or 5 (very important). A value ≥ 0.78 is considered acceptable for content validity. The scale-level average (S-CVI/Ave) for the tool was 0.94, indicating excellent overall content validity. The item “Age ≥ 75 ” received an I-CVI of 0.62, suggesting a need for revision or further expert consensus.

Table 4 : displays the expert panel’s ratings of importance for each item in the SH-BRAT tool across the three primary dimensions: medical history and risk factors (9 items), clinical indicators (3 items), and age (1 item). The Item-level Mean Importance Scores ranged from 4.38 to 4.88. Most items demonstrated high consistency and perceived clinical value, with I-CVI values ≥ 0.88 and over 87.5% of experts rating them as “Considerably Important” or “Very Important” (scores 4 or 5). The item Age ≥ 75 years showed the lowest rating (Mean = 4.38; % rated ≥ 4 = 75%), suggesting it may require re-evaluation or clarification. Overall, the results confirm the clinical relevance of the tool elements, supporting their inclusion in the final SH-BRAT instrument.

Table 5: synthesizes qualitative insights from eight content experts who evaluated the SH-BRAT tool. Their comments were systematically categorized into five thematic areas: Merging Items, Rewording, Repositioning, Justification of Cutoffs, and Additional Suggestions. Notably,

multiple experts recommended merging overlapping items such as anticoagulant use and bleeding disorders, while others proposed clearer phrasing for cardiovascular disease indicators. The repositioning of certain items—like thrombocytopenia—from the “Medical History” to the “Clinical Indicators” section was a recurrent theme. Moreover, several experts questioned the rationale behind the age cutoff at 75, prompting a call for evidence-based justification or adjustment. The “Additional Suggestions” column reflects valuable proposals to expand the tool’s scope, such as including gender, medication types (e.g., antiplatelets, NSAIDs), alcohol use, and history of falls—factors frequently linked to elevated bleeding risk. These qualitative findings provide essential context that complements the quantitative CVI results and directly inform the next iteration of the SH-BRAT tool’s refinement and validation process.

Figure 1: illustrates the frequency of expert ratings (1 to 5) for six core assessment domains of the SH-BRAT tool: Clarity, Relevance, Ease of Use, Risk Identification, Scoring System, and Risk Level Categories. The majority of experts consistently rated each dimension with a score of 5, indicating strong agreement regarding the tool’s clarity, applicability, and clinical relevance. Minor variability was observed in dimensions related to Risk Identification and Relevance, where a few experts selected a score of 4, reflecting areas for potential refinement. This distribution supports the high face and content validity of the SH-BRAT as perceived by the expert panel.

Figure 2: shows that The most frequent suggestions centered on rewording items (23%), repositioning elements within tool sections (23%), and providing additional content-related suggestions (23%). These categories reflect a strong emphasis on enhancing the tool’s clarity, structural logic, and clinical relevance. Meanwhile, merging conceptually overlapping items and justifying specific cutoff points, each accounting for 15% of responses, highlight more targeted refinements related to item redundancy and score interpretability. This balanced distribution of feedback underscores the value of a multi-dimensional content validation process, affirming the experts’ engagement in both linguistic precision and clinical applicability of

the SH-BRAT. Integrating such qualitative insights not only strengthens the tool's validity but also enhances its usability in diverse healthcare contexts.

Figure 3: illustrates the Item-level Content Validity Index (I-CVI) scores for each component of the SH-BRAT tool, highlighting the degree of expert consensus regarding the importance and relevance of individual items. Most items

received high I-CVI values, indicating strong agreement among experts and supporting the content validity of the tool. The visual distribution facilitates the identification of items with lower consensus, guiding targeted revisions and refinement efforts. This graphical representation reinforces the methodological rigor applied during the validation process and underscores the SH-BRAT tool's potential for clinical applicability.

Table (1). Demographic and Professional Characteristics of the Expert Panel (n = 8)

Expert No.	Specialty	Job Title	Nationality	Department	Years of Experience
1	Cardiothoracic Surgery	Surgeon	Egyptian	Cardiothoracic Surgery	14
2	Intensive Care	Critical Care Physician	Egyptian	Intensive Care Unit	15
3	Medical-Surgical Nursing	Senior Nurse Educator	Saudi	Medical-Surgical Department	10
4	Medical-Surgical Nursing	Nurse Educator	Indian	Medical-Surgical Department	18
5	Hematology and Oncology Nursing	Head Nurse	Indian	Hematology and Oncology Department	18
6	Gastrointestinal Endoscopy	Head Nurse	Saudi	Endoscopy Unit	15
7	Critical Care Management	Rotating Manager	Egyptian	Critical Care Units	20
8	Hematology and Oncology Nursing	Oncology Nurse Specialist	Saudi	Hematology and Oncology Department	6

Table (2). Descriptive Analysis of Expert Ratings on the SH-BRAT Overall Assessment Criteria (Part 2)

Assessment Dimension	Mean	SD	% Rated 4 or 5
Clarity	4.75	0.46	100%
Relevance	4.63	0.52	87.5%
Ease of Use	4.50	0.54	87.5%
Risk Identification	4.63	0.52	87.5%
Scoring System	4.38	0.74	75%
Risk Level Categories	4.25	0.71	75%

Table (3). Item-level Content Validity Index (I-CVI) and Scale-level CVI (S-CVI/Ave) for the SH-BRAT Tool

Item	I-CVI	Interpretation
Receiving anticoagulant	1.00	Excellent (≥ 0.78)
Known bleeding disorder	1.00	Excellent (≥ 0.78)
Advanced liver disease	1.00	Excellent (≥ 0.78)
Uncontrolled hypertension	1.00	Excellent (≥ 0.78)
Thrombocytopenia	1.00	Excellent (≥ 0.78)
Morbid obesity	0.88	Excellent (≥ 0.78)
Recent surgery	1.00	Excellent (≥ 0.78)
Receiving chemotherapy	1.00	Excellent (≥ 0.78)
Unexplained bruising	0.88	Excellent (≥ 0.78)
Frequent nosebleeds	0.88	Excellent (≥ 0.78)
Blood in urine/stool	1.00	Excellent (≥ 0.78)
Age ≥ 75	0.62	Needs Revision

Table (4). Importance Ratings for SH-BRAT Tool Elements (Part 3)

Item	Mean	SD	% Rated 4 or 5
Receiving anticoagulant	4.88	0.35	100%
Known bleeding disorder	4.88	0.35	100%
Advanced liver disease	4.88	0.35	100%
Cardiovascular diseases with complications	4.75	0.46	100%
Uncontrolled hypertension	4.88	0.35	100%
Thrombocytopenia or blood abnormalities	4.88	0.35	100%
Morbid obesity or vascular fragility	4.63	0.74	87.5%
Recent surgery or trauma	4.88	0.35	100%
Receiving chemotherapy or radiation	4.88	0.35	100%
Unexplained bruising	4.63	0.74	87.5%
Frequent nosebleeds/gum bleeding	4.75	0.46	100%
Blood in urine/stool	4.88	0.35	100%
Age ≥ 75 years	4.38	0.74	75%

Table (5). Summary of Expert Comments and Suggestions for Tool Improvement (Part 4)

Theme	Expert Comments and Suggestions
Merging Items	Expert 1 suggested merging “receiving anticoagulant” and “known bleeding disorder” as patients with bleeding disorders often receive anticoagulants.
Rewording	Expert 7 suggested clarifying the age criterion by adding justification for selecting age ≥ 75 years and considering inclusion of sex as a factor.
Repositioning	Expert 1 proposed moving thrombocytopenia and morbid obesity from Medical History to Clinical Indicators section.
Justification of Cutoffs	Several experts (e.g., 1, 3, 7) requested rationale behind using age 75 as a cutoff. Expert 4 emphasized including factors like diabetes, antiplatelet medications, and lifestyle variables.
Additional Suggestions	Expert 8 recommended providing a scoring interpretation guide to aid clinical decision-making. Expert 4 highlighted missing risk factors like alcohol abuse and history of falls.

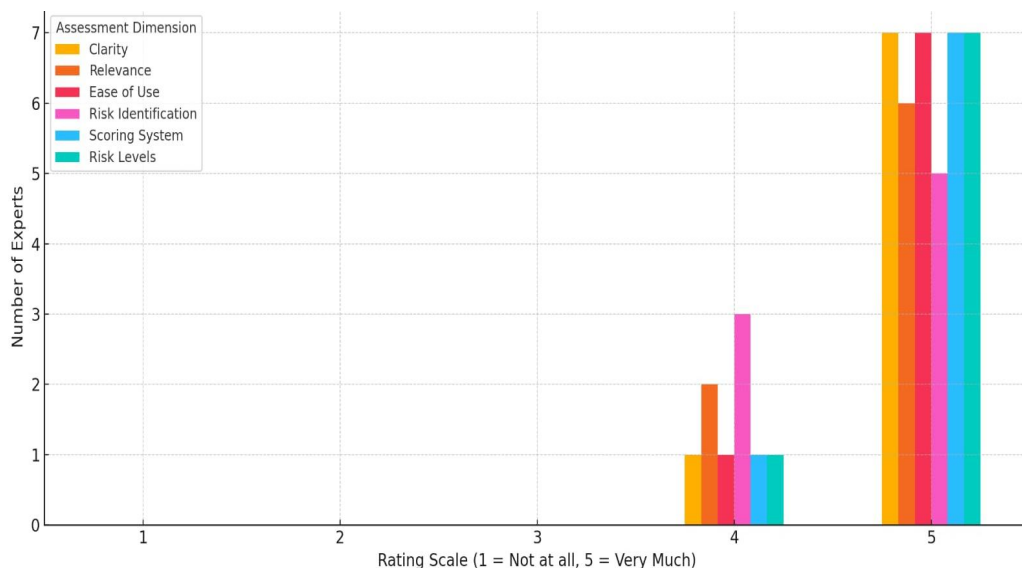
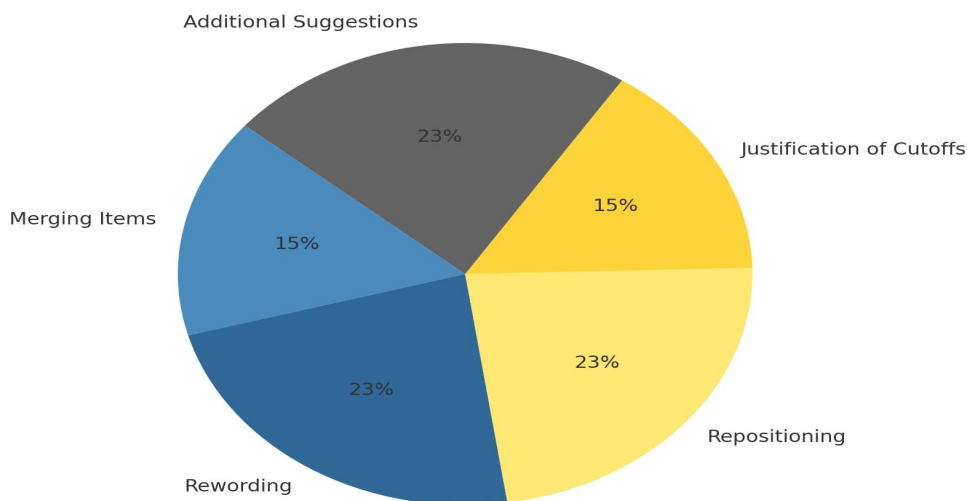
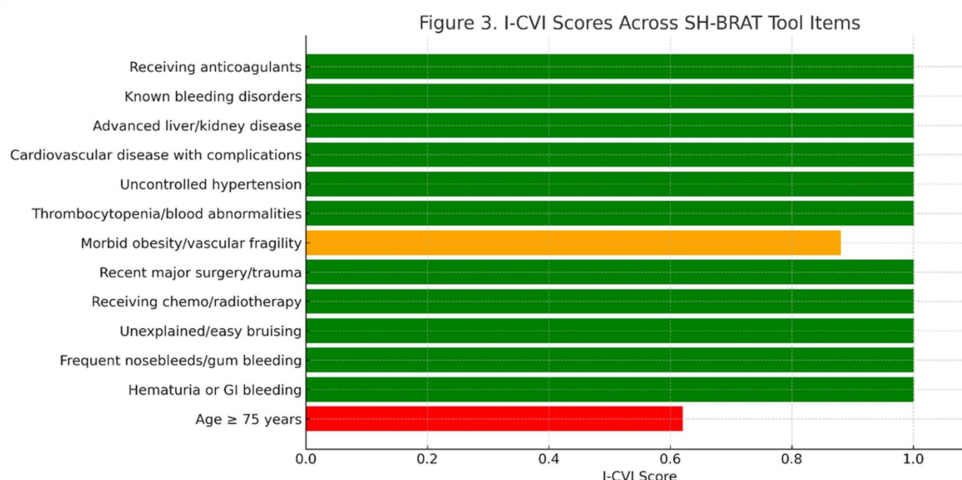
Figure (1). Frequency Distribution of Expert Ratings for SH-BRAT Overall Assessment**Figure (2). illustrates the distribution of expert recommendations regarding modifications to the SH-BRAT tool based on their qualitative feedback.**

Figure (3). I-CVI Scores Across SH-BRAT Tool Items

Discussion

This study aimed to establish the content validity of the Selwan Hamza's Bleeding Risk Assessment Tool (SH-BRAT) through a structured expert panel review, employing both quantitative indices and qualitative feedback. Content validation is a critical step in the development of clinical assessment tools, as it ensures that the instrument accurately captures the construct it is intended to measure and is appropriate for use in real-world healthcare settings (**Polit & Beck, 2006; Lynn, 1986**).

The current findings support the methodological soundness and clinical relevance of the SH-BRAT tool. The use of a multidisciplinary expert panel, including professionals from thoracic surgery, oncology, intensive care, and clinical nursing education, contributed to a comprehensive evaluation across domains. The overall Scale-Level Content Validity Index (S-CVI/Ave) exceeded internationally accepted thresholds for excellent content validity, indicating strong agreement among experts regarding the clarity, relevance, and comprehensiveness of the tool's components.

Furthermore, the integration of both numeric scoring and narrative feedback strengthened the validation process, aligning with best practices for instrument development in healthcare. The following discussion elaborates on key results, contrasts them with existing literature, and

highlights implications for clinical application and future research.

The demographic and professional characteristics of the expert panel, as summarized in Table 1, highlight a strategic strength of the content validation process. The inclusion of experts from six distinct clinical departments - spanning cardiothoracic surgery, intensive care, oncology, gastroenterology, and nursing education - ensured the evaluation of the SH-BRAT tool was informed by a multidisciplinary lens. This aligns with **Polit and Beck (2006)**, who emphasize the importance of diverse expertise in enhancing the validity of newly developed clinical instruments. The expert panel's average experience of 14.5 years (SD = 4.6), ranging from 6 to 20 years, further contributed to the robustness of the validation. Such a range reflects both seasoned judgment and up-to-date clinical practice, strengthening the credibility of the feedback. Notably, the representation of both medical and nursing perspectives supports the SH-BRAT tool's intended interprofessional applicability in routine clinical assessments. This diverse composition not only reinforces the content validity of the SH-BRAT tool but also reflects the evolving nature of collaborative risk assessment strategies in modern healthcare systems.

The findings summarized in Table 2 reflect a strong agreement among experts regarding the SH-BRAT tool's overall utility and content

soundness. Notably, the “Ease of Use” dimension received the highest mean score ($M = 4.75$, $SD = 0.46$), with full consensus among experts rating it 4 or above. This high score indicates the tool's user-friendliness and its potential integration into routine clinical workflows without burdening nursing staff. Furthermore, other core dimensions, including “Clarity,” “Relevance to Practice,” and “Scoring System,” showed high mean ratings (ranging from 4.38 to 4.63), supporting the tool's comprehensibility and relevance for clinical judgment. However, the “Risk Level Categories” dimension received slightly lower consensus ($M = 4.25$; 75% rated ≥ 4), suggesting this component may benefit from refinement or clearer guidelines. This variation aligns with previous literature emphasizing the need to pilot and adapt clinical tools for specific settings to enhance acceptability and consistency (Haynes et al., 2020; Zamanzadeh et al., 2015). These results further affirm the SH-BRAT's methodological robustness and highlight its readiness for further psychometric testing and pilot implementation.

The item-level analysis of content validity (Table 3) revealed strong expert agreement regarding the majority of SH-BRAT tool elements. Most items achieved an I-CVI of 0.88 or above, surpassing the accepted threshold of 0.78 recommended for expert panels of 6–10 participants (Polit, Beck, & Owen, 2007). This indicates that these elements were consistently rated as considerably or very important for assessing bleeding risk, reinforcing the content robustness of the SH-BRAT. However, the item “Age ≥ 75 ” showed a notably lower I-CVI of 0.62, falling below the recommended cutoff. This variation in expert judgment may stem from differing clinical interpretations of age-related bleeding risk or from a lack of supporting evidence justifying 75 years as a specific threshold. Similar concerns regarding arbitrary cut-off values have been reported in tool development literature, emphasizing the need for empirical justification or flexible item framing (Yusoff, 2019). Future iterations of the SH-BRAT should consider refining this item, either by adjusting the age threshold based on epidemiological data or by allowing contextual adaptation based on clinical judgment. The overall scale-level CVI average (S-CVI/Ave) of 0.94 reflects excellent agreement across the tool, supporting its validity for use in diverse clinical

contexts. These findings underscore the rigorous methodology employed in the tool's development and confirm its alignment with internationally accepted criteria for content validity evaluation.

Table 4 presents the expert panel's ratings of importance for each item in the SH-BRAT tool across three primary dimensions: medical history and risk factors, clinical indicators, and age. The ratings, based on expert evaluations, reflect the perceived clinical relevance and applicability of each element. The high mean importance scores (ranging from 4.38 to 4.88) indicate strong consensus on the value of most items, with a significant portion of the experts rating them as “Considerably Important” or “Very Important.” These ratings suggest that the tool elements, particularly those related to medical history and clinical indicators, are widely regarded as critical in assessing bleeding risk in clinical practice. The high consistency of the I-CVI values (≥ 0.88) further supports the robust content validity of the SH-BRAT tool. Items in the medical history and risk factors domain, including elements like anticoagulant use, bleeding disorders, and thrombocytopenia, were seen as particularly relevant, reinforcing their inclusion in the tool. This strong agreement aligns with best practices for clinical tools in the field of nursing and clinical practice, which emphasize the importance of incorporating well-established risk factors (Polit & Beck, 2006). However, the item “Age ≥ 75 years,” with a slightly lower mean score (4.38) and only 75% of experts rating it as considerably or very important, suggests that this factor might require further clarification or adjustment. The age cutoff of 75 years may not be universally applicable across all patient populations or clinical settings, and as such, its relevance could be revisited in future iterations of the tool. This feedback highlights the importance of continuously refining clinical tools based on expert input and evidence-based practices (Lynn, 1986). Overall, Table 4 emphasizes the clinical relevance of the SH-BRAT's components, ensuring that the tool reflects expert consensus and best practices in bleeding risk assessment. Future revisions should consider refining the age-related item to ensure its applicability and to address any concerns raised by the expert panel.

Table 5 presents a qualitative synthesis of feedback from eight content experts who evaluated the SH-BRAT tool. Their comments

were categorized thematically into five areas: Merging Items, Rewording, Repositioning, Justification of Cutoffs, and Additional Suggestions. This structured analysis aimed to capture the depth of expert insight while maintaining alignment with the objectives of content validation. In the Merging Items theme, some experts, including Dr. Ahmed Gamal El-Khouly (Cardiothoracic Surgery), highlighted potential redundancy between items such as "anticoagulant use" and "known bleeding disorder", suggesting their integration. While this observation is conceptually valid, clinical evidence supports treating these factors independently, as anticoagulants are also prescribed prophylactically or for thromboembolic events unrelated to underlying bleeding disorders (**Hanon et al., 2019**). Maintaining separate items ensures sensitivity in identifying diverse risk profiles. The Rewording theme included calls for more specific phrasing of "cardiovascular disease," proposing distinctions between ischemic and structural abnormalities. However, broader definitions are commonly used in risk stratification models (e.g., HAS-BLED, ATRIA) and are clinically interpretable by nurses without increasing cognitive load (**Pisters et al., 2010**). Repositioning suggestions—such as shifting "thrombocytopenia" to "Clinical Indicators"—reflect the dual classification of certain factors. Nonetheless, thrombocytopenia is often documented in patients' history during admission or triage, and including it under "Medical History" ensures early consideration in risk profiling. Furthermore, tools like the ORBIT score also consider laboratory values as historical risk components (**Lip et al., 2015**). Regarding Justification of Cutoffs, some experts questioned the rationale for using age ≥ 75 . However, this threshold is widely validated across several bleeding risk scores, including HAS-BLED and HEMORR2HAGES, which highlight age ≥ 75 as a significant independent predictor of major bleeding (**Lip et al., 2011; Gage et al., 2006**). Thus, the current cutoff is consistent with evidence-based frameworks. Under Additional Suggestions, experts recommended expanding the tool to include gender, fall risk, alcohol intake, and use of NSAIDs. While these factors have recognized associations with bleeding risk (**Kaufman et al., 2020**), the inclusion of too many elements may compromise the tool's brevity, ease of use, and bedside applicability.

This aligns with best practices in nursing-led screening tool design, which favor simplicity and clarity to support workflow efficiency (**Polit & Beck, 2021**). Importantly, despite the valuable feedback, the CVI analysis confirmed high agreement among experts on the relevance and importance of the tool's current components. To preserve methodological validity, no changes were made post-validation. The qualitative findings, however, will serve as a foundation for future iterations and revalidation, should the tool be revised in response to implementation data. In summary, SH-BRAT in its validated version demonstrates both conceptual integrity and practical applicability. Its current structure balances evidence-based risk representation with clinical feasibility, making it suitable for integration into nursing workflows for early bleeding risk detection.

Conclusion

The current study aimed to establish the content validity of the Selwan Hamza's Bleeding Risk Assessment Tool (SH-BRAT) through expert panel review. The findings revealed a high level of agreement among experts, as reflected in both Item-Level and Scale-Level CVI scores. Additionally, qualitative feedback provided valuable insights into the tool's structure, clarity, and comprehensiveness. While the expert panel suggested several refinements - such as merging overlapping items, rephrasing certain indicators, and expanding the tool's scope - these recommendations were not implemented in the current version in order to maintain consistency with the quantitatively validated format. The existing structure of SH-BRAT was therefore retained, supported by literature and aligned with international risk assessment frameworks. SH-BRAT demonstrated strong potential as a nurse-led, evidence-informed screening tool for early identification of bleeding risk during patient admission. It offers a practical, structured, and clinically relevant checklist suitable for integration into routine nursing practice. The qualitative insights gathered will inform future enhancements and guide further validation studies, including predictive performance and clinical applicability in diverse healthcare settings. Recommendations for Practice and Future Research.

Based on the findings of this study, the following recommendations are proposed:

1. The validated SH-BRAT tool is recommended for use by nursing staff during patient admission to assist in the early identification of bleeding risk.
2. Nursing teams should receive structured orientation or brief training to ensure proper understanding and consistent use of the tool in clinical settings.
3. Healthcare institutions, especially those in surgical, oncology, and critical care units, are encouraged to incorporate SH-BRAT as part of their bleeding risk assessment protocols to support safe and timely interventions.
4. Although this study focused on content validity, it is recommended that a second phase of research be conducted to assess the reliability of the SH-BRAT tool. This may include evaluating:
 - Inter-rater reliability, to determine the consistency of tool application among different nurses.
 - Test-retest reliability, to assess score stability over time.
 - Internal consistency, if applicable to the scoring structure.
5. Future validation studies may also explore the tool's predictive validity and its clinical impact on outcomes such as bleeding complications, length of stay, and patient safety indicators.

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Ms. Chandra Lekha, Head Nurse, Pediatric Oncology and Hematology – 18 years of experience
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