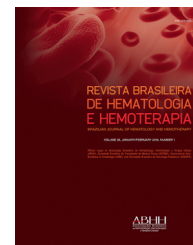




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Original article

Validation of the Brazilian version of the VERITAS-Pro scale to assess adherence to prophylactic regimens in hemophilia

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ABSTRACT

Introduction: Prophylaxis is the treatment of choice for patients with severe hemophilia. Low adherence may limit the effectiveness of the prophylactic regimen, thereby compromising outcomes.

Objective: The objective of this study was to validate the Brazilian version of the VERITAS-Pro prophylaxis adherence scale, originally an American questionnaire that can be answered by the individual responsible for prophylaxis as well as by an observer.

Methods: The scale has 24 questions divided into six subscales: Routine, Dosage, Plan, Remember, Skip and Communicate. Participants were recruited at a blood center in south-eastern Brazil for validation and reliability analyses. Validation measures included the results obtained using analog visual scales of adherence, interval between medication dispensed by the treatment center pharmacy and the percentage of recommended doses administered and infusions registered in the patients' logs.

Results: The study included 32 individuals responsible for prophylaxis and five observers. The internal consistency was very good for the VERITAS-Pro total score, excellent for the Remember, Skip and Communicate subscales, good for the Dosage subscale, and acceptable for the Routine and Plan subscales. Twelve participants answered the questionnaire on more than one occasion to evaluate reproducibility. The intraclass correlation coefficient was excellent. Regarding convergent validity, the VERITAS-Pro scores were moderately correlated with the global adherence scale and with infusion log records, but showed a weak correlation with pharmacy dispensation records.

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Conclusion: The Brazilian version of VERITAS-Pro is a valid and reliable instrument, enabling the understanding of specific factors related to non-adherence and allowing targeted interventions for proper treatment.

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Introduction

Prophylaxis in hemophilia consists of regular infusions of clotting factor VIII or IX concentrate for a period longer than eight consecutive weeks in order to prevent bleeding.^{1,2} The benefits of prophylaxis include decreased frequency of bleeding episodes, decreased need for emergency room visits and hospitalizations, prevention of arthropathy, increased physical activity and school attendance, and improved academic performance.^{1,3-5} Prophylaxis reduces long-term morbidity, thus improving quality of life.^{6,7} The World Health Organization recommends prophylaxis as standard therapy for people with severe hemophilia.^{2,8}

Non-adherence to the prophylactic regimen may limit the effectiveness of treatment with less prevention of bleeding.⁹ The lack of standardized methods to assess adherence to hemophilia prophylaxis limits the understanding of factors that facilitate or hinder the therapeutic program. Lack of awareness of adherence as a determining factor in health outcomes can lead to a waste of human and economic resources as well as underutilization of available medications.^{10,11}

VERITAS-Pro is a questionnaire created in the United States, based on focus groups, to assess specific components of adherence as well as global adherence to the proposed prophylactic regimen.¹² The objective of this study was to describe the psychometric properties of the Brazilian version of the VERITAS-Pro, demonstrating its usefulness as an instrument for clinical practice and research.

Methods

Translation and adaptation

VERITAS-Pro, originally developed in English, was translated into Brazilian Portuguese according to international translation and adaptation guidelines.¹³ Two independent translations to Brazilian Portuguese were prepared by native Brazilians. There were no relevant differences between the translations. The two resulting versions were combined, corrected by experts, and translated back into English by an American translator without knowledge of the original document. The Brazilian version has 24 questions divided into six subscales: Time, Dose, Plan, Remember, Skip, and Communicate, just as in the original questionnaire. The questions were written in a way that made it possible for both the individual responsible for the patient's prophylaxis and an observer to respond. The answers are presented as five-point Likert scales ranging from 'never' to 'always'. An 'always' response reflects the best possible adherence for some items, and the worst for

others. For each item, a numerical classification was assigned to the Likert scale, giving one point to the response representing the best adherence and five points to the worst adherence. Possible scores of each subscale range from 4 to 20 points, and the total score of the instrument, from 24 to 120 points, where 120 represents the worst adherence.

Participants

Participants were recruited at the *Hemocentro Regional de Juiz de Fora* (HRJF) in southeastern Brazil. The individuals considered eligible were those responsible for the prophylaxis of patients with hemophilia with a severe phenotype, A or B, in a home infusion regimen for at least six months. Patients in on-demand treatment, those not qualified to receive home infusions, and those with inhibitors were excluded.

Participant recruitment and data collection

The study was approved beforehand by the Research Ethics Committee of the *Fundação Centro de Hematologia e Hemoterapia de Minas Gerais* – HEMOMINAS. The participants were asked to respond to the questionnaire during their usual visits to the blood center. All signed a free and informed consent form, allowing access to their infusion logs, and received a guarantee of confidentiality of any individual information. Parents gave their consent to include data from patients under 18 years of age, and adolescent patients (12–17 years old) gave their agreement to participate. Sociodemographic and health data were collected from the patients, as well as sociodemographic data from those responsible for prophylaxis, in the case of under 18-year-old and incapacitated patients. Participants answered a questionnaire and a visual analog scale on global adherence to prophylaxis. For the test-retest evaluation, participants were asked to respond the questionnaire a second time on their next visit to the blood center. Data collection occurred between October 2015 and November 2016.

Other measures of adherence to prophylaxis

Analog scale of global adherence to prophylaxis

After completing the VERITAS-Pro, participants were reminded of the details of the prescribed prophylaxis. An analog scale with values ranging from zero (never follow the prescription) to 10 (always follow the prescription) was then presented and the participants were asked to rate their adherence in the previous three months.

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