Hematuria Grading Scale: A New Tool for Gross Hematuria

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OBJECTIVE To develop a new tool for gross hematuria, the Hematuria Grading Scale (HGS), and evaluate its consistency in assessing hematuria samples.

METHODS The HGS was developed on the basis of an evaluation of sample brightness and saturation using a cyan, magenta, yellow, key (black) color model. Thirty hematuria samples were prepared from human blood by diluting with saline using a standard method. Twenty examiners (5 in each group, including laypeople, nurses, general practitioners, and urologists) participated. Each scored 30 hematuria samples using the HGS under the same conditions without communicating with one another. The intraclass correlation coefficient (ICC) was calculated to assess the reliability of the datasets. Questionnaires for usefulness (Q1) and simplicity (Q2) were obtained from all examiners using a 5-point Likert scale.

RESULTS The ICC for pooled examiner scores showed a high agreement rate (99.7%, 95% confidence interval [CI] 0.996-0.999). ICC values by group were 99.3% (95% CI 0.989-0.997) for laypeople, 98.8% (95% CI 0.980-0.994) for nurses, 99.1% (95% CI 0.984-0.995) for general practitioners, and 99.2% (95% CI 0.987-0.996) for urologists. Mean Q1 and Q2 scores were 4.70 $\pm$ 0.66 and 4.30 $\pm$ 1.03, respectively, indicating general satisfaction with the HGS among all examiners.

CONCLUSION Evaluations of gross hematuria using the HGS were in high agreement among examiners of all types, and all examiners found the HGS simple and easy to use. The HGS should be a helpful tool for assessment and communication of gross hematuria. UROLOGY 82: 284−289, 2013.

Hematuria is one of the main symptoms or an accompanying symptom for which patients require medical consultation or treatment in departments of urology or nephrology.[1] Gross hematuria, in particular, can be an important initial symptom or sign for various urologic diseases, such as urologic malignancies, urinary stones, or urinary tract infection,[2] and is frequently encountered in hospitalized urology patients.[3] According to previous studies, the prevalence of gross hematuria is approximately 4%-20% in patients visiting urology departments.[4] Patients with gross hematuria have been reported to account for 13% of all urologic outpatients in a Japanese population.[5] These patients also constitute 10% of all after-hours telephone calls received by residents from outpatients and the emergency room, ranking it third overall.[6] Notably, because antiplatelet agents have shown a beneficial effect on recurrent myocardial infarction, strokes, and other vascular ischemic events in the geriatric population,[7] the incidence of anticoagulant therapy-related gross hematuria has been increasing, reaching approximately 20%-30%.[8]

However, no satisfactory tool for assessing gross hematuria has been presented to date, leaving medical personnel and patients uncertain as how to objectively express and communicate the degree of gross hematuria. Physicians frequently find it difficult to decide whether immediate management is needed on receiving a message about patients with severe gross hematuria from nurses or the patients themselves. In fact, in the physicians' view, some gross hematuria are so mild that they can be managed with simple fluid therapy, despite the alerts from nurses and complaints of anxious patients. Thus, there is an undeniable potential for misunderstanding owing to a lack of communication. Effective communication between physicians and patients improves patient health outcomes[9]; the same can be said of the communication between physicians and nurses.[10] This is especially true for the hospital care of inpatients who have undergone a urologic surgery, where communication among patients, nurses, and physicians is important for evaluating post-operative gross hematuria and making decisions about removal of urethral Foley catheters.

Several scaling systems for visual or verbal communication of gross hematuria have been proposed; however, none has been widely adopted in general

Financial Disclosure: *The authors declare that they have no relevant financial interests.*

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Submitted: February 5, 2013, accepted (with revisions): April 29, 2013

0090-4295/13/$36.00
http://dx.doi.org/10.1016/j.urology.2013.04.048

practice. Previous tools for hematuria were difficult to put to practical use, and simpler tools for real practice have proven difficult to make. Therefore, we developed a new scaling system for gross hematuria, termed the Hematuria Grading Scale (HGS). This study was conducted to introduce the newly developed HGS and to evaluate the degree of agreement regarding the assessment of various hematuria samples obtained by laypeople, nurses, general practitioners, and urologists.

MATERIALS AND METHODS

Design of the Visual Hematuria Scale

With the use of a cyan, magenta, yellow, and key (black) color model, we created a prototype-scaling tool. This tool applies 5 points to a sample with pure red color (C 0%, M 100%, Y 100%, K 0%) and a score of 0 to 4 to samples with different degrees of saturation corresponding to different values of M and Y, at constant intervals of 80%, 60%, 40%, 20%, and 0%. Scores of 6 to 10 are applied to pure red samples (100% M, 100% Y) with different degrees of brightness corresponding to constant intervals of K values of 20%, 40%, 60%, 80%, and 100%. In a preliminary study using the prototype scale, using a score of 10 to correspond to pure black proved inferior in practice. On the basis of a shared opinion that a scale for expressing hematuria should have a midpoint between a score of 0 and 1, we modified the scale, creating the HGS. We also added a score of 0y corresponding to a light yellow to make it easier to express regular urine color (Table 1). The resulting HGS was printed using a photo printer (Epson Stylus Pro 4880; Seiko Epson Co., Suwa, Japan) and used to score samples (Fig. 1A). We also offer an HGS mobile edition, which is licensed under a Creative Commons Attribution-NonCommercial-NoDerivs (CC BY-NC-ND) 3.0 Unported License and is available online (http://hgscale.blogspot.com/; Fig. 1B).

Preparation of Hematuria Samples From Blood for Testing

Hematuria samples for testing were prepared using blood samples from a volunteer. Blood samples were serially diluted with normal saline using a quarter-logarithmic ($10^{0.25}$-fold) dilution. To generate a dark hematuria color, we converted hemoglobin in sampled blood into deoxyhemoglobin by refrigerating venous blood for 2 weeks. Thirty hematuria samples were produced for our study, and prepared samples were put in vacutainer tubes (SPM, Gimje, South Korea; Fig. 1C). The researcher who produced the hematuria samples (J.S.C.) did not participate in the agreement test to prevent any contact with the study participants (examiners) and thereby to reduce bias.

Study Participants

Assuming a correlation coefficient of 0.99, and α and β values of 0.05 and 0.10 for type I and II errors, respectively, the minimal sample size required to achieve the desired statistical power (0.80) was n = 5.[11] We selected 5 laypeople without medical knowledge, 5 ward nurses, 5 general practitioners, and 5 urologists as test examiners.

Good Clinical Practice Protocols

The study was carried out in agreement with applicable laws and regulations and good clinical practices and ethical principles, as described in the Declaration of Helsinki. This study was approved by the Institutional Review Board of the hospital (approval number: 4-2012-0697). One of the principle investigators (K.S.C.) voluntarily provided his blood for the preparation of hematuria samples. Each examiner provided written informed consent for participation.

Assessment of Hematuria Samples

With the use of HGS, each examiner scored the 30 hematuria samples according to 11 grades (0-10) in the same setting at an ambient illumination of 100,000 lux without communicating with one another. The experiment was conducted under the supervision of 1 researcher (J.Y.L.).

Interobserver Variability

Interobserver reliability for assessments of the 30 hematuria samples among the 20 examiners was determined by calculating intraclass correlation coefficients (ICCs) according to a 2-way random effects model using MedCalc software (MedCalc version 11.2.1.0; MedCalc Software, Mariakerke, Belgium). ICCs are equivalent to weighted coefficients with quadratic weights.[12] ICCs were interpreted according to the method of Landis and Koch.[13] An ICC value less than 0.20 was considered poor, 0.21-0.40 fair, 0.41-0.60 moderate, 0.61-0.80 substantial, and 0.81-1.00 very good.

Reference Scale Using Absorbance

Each sample (2 μL) was distributed into wells of a 96-well plate in triplicate, and absorbance was measured at 490 nm using a spectrophotometer (VersaMax ELISA Microplate Reader; Molecular Devices Co., Sunnyvale, CA). Samples were sorted according the mean values of triplicate hematuria scores and compared. A reference scale was created to rescale the values of absorbance measurements to between 0 and 10. A spectrophotometric reference scale for hematuria samples was created for additional agreement and reliability tests, which were assessed using Cohen's kappa coefficient and Bland-Altman plots.[14]

Satisfaction Questionnaire Based on a 5-point Likert Scale

All examiners completed a usability questionnaire answering 2 questions on a 5-point Likert scale, where a '1' indicates low satisfaction and a '5' indicates high satisfaction.[15] Question 1 (Q1): How do you rate the usefulness of HGS? (Q2): How do you rate the simplicity of HGS?

RESULTS

Agreement Among Examiners

The results obtained by the 20 examiners considered collectively were in high agreement, with an overall reliability of estimates of 99.7% (95% confidence interval [CI] 0.996-0.999; P <.001). Considering the different examiner groups separately, the reliability was 99.2% (95% CI 0.987-0.996; P <.001) for urologists, 99.1% (95% CI 0.984-0.995; P <.001) for general practitioners, 98.8% (95% CI 0.980-0.994; P <.001) for nurses, and 99.3% (95% CI 0.989-0.997; P <.001) for laypeople.

Assessment of Comparisons with the Reference Scale

We calculated the mean absorbance for each hematuria sample and used these values to establish a reference scale