Devising and validating a headache diary in a series of patients with chronic daily headache from Colombia

Diseño y validación de un diario de cefalea en pacientes con cefalea crónica diaria en Colombia

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ABSTRACT

Objective: To devise and test the reliability and validity of a brief headache diary in a series of Colombian patients with chronic daily headache. **Methods:** The study was designed in five stages: selection of domains (group of patients and experts); initial devising of the items (writing group); identification of non-understandable items (n=20); assessment of internal consistency (n=100); assessment of validity and assessment of sensitivity to change during seven consecutive days (n=25, 175 observations). **Results:** Five domains were selected: headache presence, severity and length of pain, analgesics intake, and missing workdays. The headache diary is internally consistent (≈75% of rotated variance), correlates with the medical interview (Spearman's rho and Kendall's tau over 0.8 for each domain) and it has an adequate and stable sensitivity and specificity (82 to 96%). **Conclusions:** This headache diary is a reliable and valid instrument and represents the most important features affecting Colombian patients with chronic daily headache.

Key words: Colombia, diagnosis, headache disorders, medical records, reproducibility of results, validation studies.

RESUMEN

Objetivo: Diseñar y testar la validez y reproducibilidad de un diario de cefalea en una serie de pacientes Colombianos con cefalea crónica diaria. **Métodos:** El estudio fue diseñado en cinco fases: selección de los dominios (grupo de pacientes y expertos); diseño inicial de los ítems (grupo redactor); identificación de ítems no comprensibles (n=20); determinación de la consistencia interna (n=100); determinación de la validez y la sensibilidad al cambio durante siete días consecutivos (n=25, 175 observaciones). **Resultados:** Fueron seleccionados cinco dominios: presencia, severidad y duración del dolor, ingesta de analgésicos y días laborales perdidos. El diario tiene una adecuada consistencia interna (≈75% de la varianza), se correlaciona con la entrevista médica (rho de Spearman y tau de Kendall >0.8 para cada dominio) y tiene sensibilidad y especificidad estables y satisfactorias (82 a 96%). **Conclusiones:** Este diario de cefalea es un instrumento confiable y registra las principales características de las cefaleas en pacientes con cefalea crónica diaria.

Palabras-Clave: Colombia, diagnóstico, cefalea, registros médicos, reproducibilidad de resultados, estudios de validación.

The chronic daily headache (CDH) affects from 4 to 7% of general population worldwide and it is a common cause of consultation in outpatient clinics[1-4]. Patients with CDH score worse in physical functioning and general health perceptions of quality of life scales than those with migraine and healthy controls[5,6]. Several factors might affect the internal validity of studies in CDH patients, among them the lack of reliable measurement instruments.

Lipton et al. defined CDH as headaches that occur for ≥4 hours a day on ≥15 days a month over three months[7]. In the next decade,

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20% of the patients with episodic headaches will develop CDH[8]. CDH at baseline, coexisting migraine, not being married and sleeping problems increase the risk of worst prognosis.

Several instruments have been developed to evaluate the burden of headaches in patients with migraine[9-13]. However, an adequately validated instrument to assess the headache frequency in Colombian patients with CDH has not been determined yet. To assess the main characteristics of headache episodes and their impact on work activities, we devised and tested the reliability and validity of a brief headache diary (HD) in a series of Colombian patients with CDH.

METHODS

Patients aged 18 years or older that fulfilled the International Headache Society (IHS) criteria for migraine or tension type headache with CDH were recruited for this study[14]. Patients with history of cognitive deficit, severe visual impairment and inability to telephone contact were excluded. The protocol was approved by the Ethics Committee from Hospital Santa Clara, Universidad Nacional de Colombia and Hospital El Tunal, in Bogotá, Colombia.

Devising the items

Selection of domains

Fifteen patients with CDH were individually interviewed on the most important issues that a HD should include (group of patients). Likewise, a group of 12 people composed by neurologists and general practitioners, with experience in headache treatment and diagnosis, were individually contacted and interviewed about the most important issues in a HD (group of experts). The proposed domains were gathered and a group of eight people (writing group) performed the initial drafting, including at least three items for each domain.

Detection of ambiguous or non-understandable items

Ten patients answered the initial draft and explained with their own words the meaning of each item. No other instruction was given. Items that were not understood by each patient were rewritten by the writing group. This second draft was applied to a new series of ten patients until each one of the items was completely understood.

Internal consistency

Since this instrument has been designed as a multiple domains instrument, the internal consistency was determined through a factor analysis[15]. To this end, the items devised in the previous section were applied to a different set of 100 patients[16]. Analysis of the main components with a Varimax rotation was applied to this set of data. The factors were selected keeping at least one for each domain. The items with loadings ≥ 0.8 (or otherwise selected as providing information about quantitative pain characteristics) on each factor were kept in the final version of the HD.

Validity

Two types of validity were tested: criterion (using the neurologist's interview as a golden standard) and construct (using logic construct of intensity, length of pain and analgesic intake). Sensitivity to change was tested assuming that every patient was initiated on prophylactic drugs or at least the dose of previous medication was adjusted. We formally tested the change in severity and length through the follow-up. Test-retest reliability was not tested because of the high variability of the symptoms across time. To test the criterion validity, a group of 28 patients answered the HD during seven consecutive days. By the end of this period, a phone or a personal contact was made by a neurologist. During this interview, presence, length of pain, severity, analgesics intake, and missing workdays were determined for the previous seven days. To test the construct validity, the relationship between severity of symptoms and analgesics intake and length of pain were formally tested. These analyses were repeated for each of the seven days to evaluate consistency through multiple observations.

Statistical analysis

To determine the relationship between the data in the HD and the golden standard, Spearman's rank correlation coefficient (Spearman's rho) was used for binary variables and Kendall's rank correlation coefficient (Kendall's tau) was used for the ordinal ones. Confidence intervals were calculated according to Altman and Siegel for Spearman and Kendall correlations, respectively[17,18]. The severity of pain was divided into quartiles. The other variables were dichotomized to improve the power of their correlations. To obtain an overall estimate of sensitivity and specificity, which takes into account the variability between each day of fulfilling the HD, an approach based on Generalized Estimating Equations (GEE) was used. To this end, the proportion of positive answers were determined through them along the positive answers in the golden standard (sensitivity). Likewise, the proportion of negative answers was determined with the negative answers in the golden standard (specificity)[19].

We explored the effect of the day of fulfilling the HD, age, abuse of analgesics, headache subtype, and site of recruitment over the estimates of sensitivity and specificity. Modifications over 20% of the univariate estimates were considered significant. To determine the construct validity, multiple binomial logistic regressions were calculated using analgesic intake as a dependent variable and severity and length of pain individually as explanatory variables. To determine sensitivity to change, ANOVA repeated measures were used with severity and length of pain as dependent variables and time as an independent one[15]. A p-value <0.05 was considered significant for all tests. Calculations were performed using Stata, version 8.0.

RESULTS

Devising the items

Domains selection

The groups of patients and experts determined that a HD, which includes the presence, length and severity of pain, analgesics intake and missing workdays, would assess the main characteristics of headache episodes and their impact on work activities in patients with CDH. The proposed items to assess pain intensity were devised to be expressed on a five-point visual analogue scale, once the patient has accepted to have a headache. Therefore, the four-point scale proposed by the International Classification of Headache (including 0 as no pain) was not used[14].

Detection of ambiguous or non-understandable items

During the first interview (n=10), two items related to length of pain were identified as non-understandable by two patients: "At what time did the headache begin? At what time did it end?" and "the pain lasted: half morning, the entire morning, half afternoon, the entire afternoon, all day?". The writing group did not find an alternative way of rephrasing these questions, so they were excluded from the internal consistency analysis. A second set of questions was applied to a new group of patients (n=10). All patients understood these items.

Internal consistency

The five factors identified by the factor analysis explained 75% of rotated variance. The first factor explained 27% of variance and had high loading on "How many hours did you have the headache today?" (number of hours with headache) (0.9). The second factor accounted for 17% of variance with a high loading on "Did you have a headache today?" (yes/no) (0.8). The third one explained 12% of the variance and had a high loading on "What medications did you have to take today to improve your headache?" (the name of the medication) (0.9). The forth explained 10% of the variance and with high loadings on "Did the headache prevent you from leaving your home?" (yes/no) (0.8) and "How strong was your headache today?" (very mild/ mild/ moderate/ severe/ very severe) (0.4). The last one accounted for 8% of the variance and had a high loading on "Did the headache prevent you from going to work today?" (yes/no) (0.9).

Validity

Criterion validity

Thirty-two patients received the HD and were asked to answer it during seven consecutive days, 25 patients returned the HD and allowed telephone interviews (175 observations). Patients for this phase were mostly women (76%), had chronic migraine (84%) and had a median age of 44.6 years-old (interquartile range – IQR=25–75: 28.9–50.6). The median of Spearman's rho through the seven days of fulfilling the HD for presence was 0.8 (IQR 25–75: 0.7–0.9), for severity of pain was 0.7 (IQR 25–75: 0.5–0.7), for analgesics intake was 0.8 (IQR 25–75: 0.7–0.9). The median of Kendall's tau for length of pain through the follow-up was 0.8 (IQR 25–75: 0.7–0.8) (Fig 1).

The sensitivity of each item, which is defined as the proportion of positive answers among the positive ones in the golden standard, varied from 82 to 95%. Likewise, the specificity, which is defined as the proportion of negative answers among the negative ones in the golden standard, varied from 86 to 96% (Table 1). After adjusting each of the main covariates (age, gender, day of fulfilling the HD, analgesic abuse, subtype of chronic headache, and recruitment site), modifications over 20% from the original estimates were not found on the bivariate models where convergence was achieved.

Construct validity

The relationship between severity of pain and analgesics intake was statistically significant for most of the days when the HD was fulfilled (OR=1.7–11). Similarly, the relationship between length of pain and analgesics intake was significant for all the days (OR=2.5–14), as it can be seen in Fig 2. A statistically significant relationship was not found between the items devised to measure headache related missing workdays and the golden standard (data not shown).

Sensitivity to change

The p-values for the repeated measures ANOVA for time as covariate were <0.001, for length of pain and 0.08, for severity of the headache episodes.

DISCUSSION

In this study we have shown that this HD is a valid and reliable instrument in Colombian patients with CDH and it

Table 1. Accuracy of each item from the headache dairy.

Item	Sensitivity (95% CI)	Specificity (95% CI)
Did you have a headache today?	95% (90–98)	86% (78–94)
How many hours did you have the headache today?	82% (73–91)	91% (86–95)
What medications did you have to take today to improve your headache?	84% (74–93)	91% (87–94)
How strong was your headache today (very mild/ mild/ moderate/ severe/ very severe)? ¶	82% (64–100)	93% (90–97)

*Generalized estimating equations of the proportion of positive answers in headache diary among positive answers in the gold standard (sensitivity), and negative answers among negative answers in gold standard (specificity). Unstructured working correlation matrix and identity link functions were used for calculations. ¶An exchangeable correlation matrix was used; CI: confidence interval.
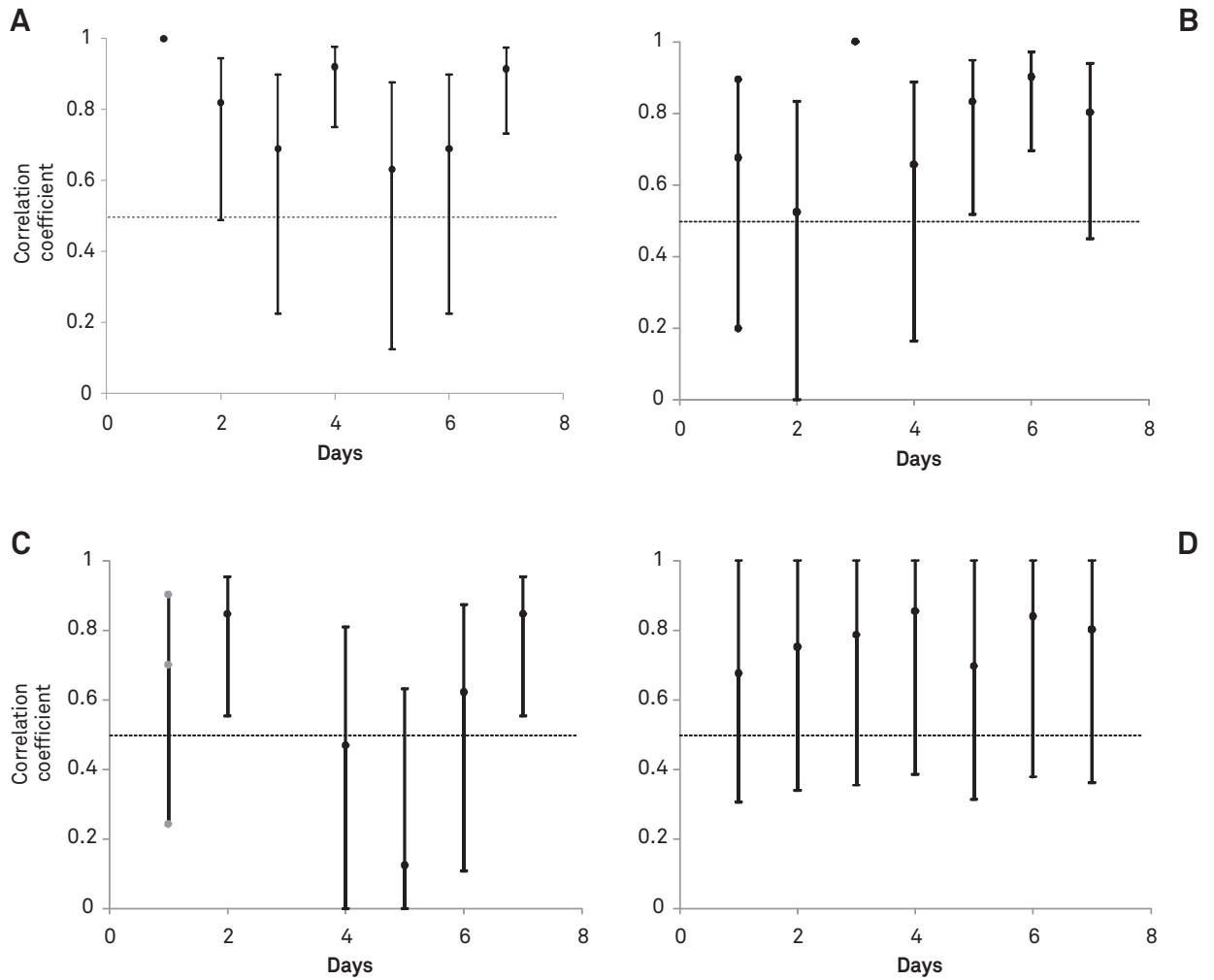
Fig 1. Correlations between the headache dairy and the clinical interview through the seven days of fulfilling it. A: presence; B: analgesics intake; C: severity of pain; D: length of pain.
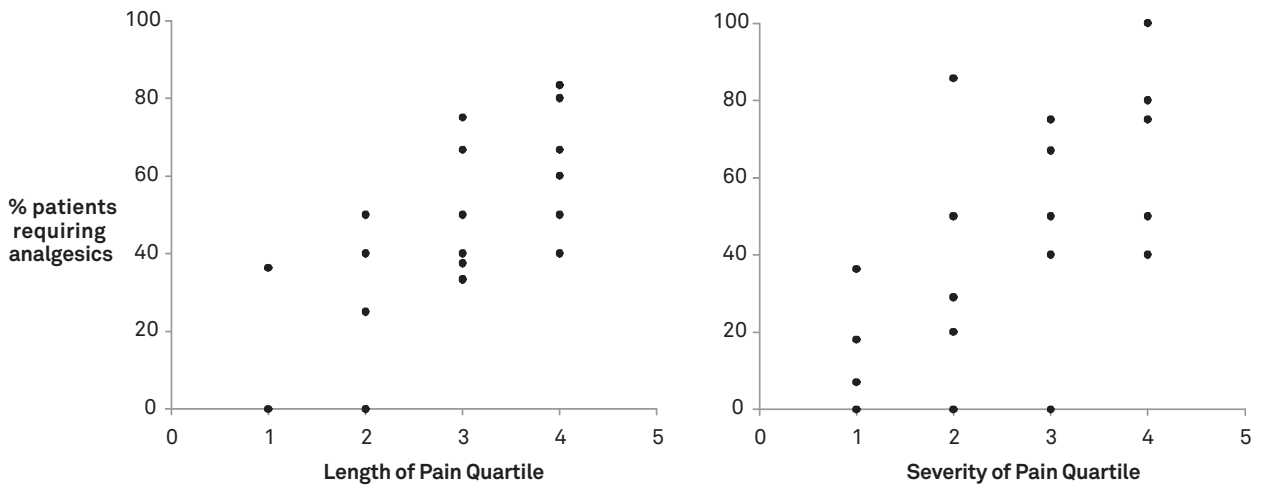

Fig 2. Relationship between length and severity of pain and analgesics intake through the seven days of fulfilling the headache diary.

records the main characteristics of headache episodes for patients and treating physicians. The domains have been selected by a representative sample of patients and by physicians with experience in diagnosis and treatment of primary headaches (content validity). The selected items were understood by each patient. Validity has been tested through the application of the HD during seven consecutive days and the accuracy estimates have proved to be independent of age, gender, day of fulfilling and recruitment site (Fig 1 and 2).

Importantly, we believe that testing the performance of the HD longitudinally might provide more accurate estimators of accuracy and adherence (≈80% in this sample). To this end, we used an approach based on the binomial family of GEE. Previous authors have proposed GEE as a valid method to determine proportions of dichotomous variables of correlated data[19]. Even thought, to the best of our knowledge, GEE has not been previously used as a method to determine accuracy estimates for single studies, since these are proportions, they provide the rationale for the use of GEE (Table 1). Likewise, a regression model based on GEE might provide a method to evaluate the effect of covariates over such estimates.

Sensitivity to change was tested using a multiple measures approach[15]. Despite the short time of follow-up, a change in the headache severity and a trend to a decreased length of pain were observed in this study after the beginning of therapy or modification of previous treatment. This change, on a week to week basis, has been observed by other authors[20].

There are two important issues about the validity of this HD. First, although the expert group selected impacts on work activities as a domain that should be included in the HD, devised items did not correlate with the golden standard (data not shown). We believe that this domain is a complex construct and a single question might not account for it (from low performance to total absence). Nevertheless, we kept the item: "Did the headache prevent you from going to work today" in the final version of this HD, because of internal consistency and because it provides valuable information for research and statistical purposes.

Second, the highly variable nature of this symptom on a day to day basis prevented us to evaluate the stability of the data provided by the HD (test-retest reliability). However, the stability of the correlations through the follow-up as well as the adequate internal consistency of this instrument might account for a high reliability of the HD.

In summary, we have shown a brief HD that assesses the main characteristics of headaches. This diary includes the main domains identified by patients and treating physicians, it also has a high internal consistence and is a valid instrument in Colombian patients with CDH. We believe that this instrument might help patients with adequate feedback of headache progress, allow treating physicians a better assessment of a goal-directed therapy and allowing them to improve the reliability of results from future researches in Colombian patients with CDH.

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