

Article Title:

Why patients do not comply with headache diaries?

Authors: Claudia Borbinha¹, MD, Isabel Pavão Martins MD PhD²

Authors Affiliations:

1 - Hospital Egas Moniz, CHLO, Lisboa, Portugal

2 - Headache Outpatient Clinic, Neurology Department, Hospital Universitário de Sta Maria, CHLN, Lisboa, Faculdade de Medicina da Universidade de Lisboa

Corresponding Author: Cláudia Borbinha (claudiaborbinha3@gmail.com; +351933286949)

Abstract

Background: Headache calendars are part of good clinical practice in headache clinics.

However, patients' compliance is rather variable. We aim to identify factors associated with poor compliance.

Methods: Consecutive patients observed in follow-up visits of a tertiary headache center were divided into two groups; with a fulfilled calendar (Calendar compliers, CC) and without calendar (Calendar noncompliers, CNC). Incomplete /forgotten records were excluded. Demographic and clinical variables were compared, and CNC were asked the reasons for not filling the calendar.

Results: From 93 patients (45.6±13.3 years, on average; 83 females), the majority with migraine (96.8%), 61.3% were CC. CNC were more likely to have medication overuse (34.5% vs. 12.3%, p=0.01) and had a tendency to be paid workers (79.3% vs. 52.6%, p=0.05) compared to CC. Most CC considered calendars useful to improve doctors and patients knowledge about headaches.

Conclusions: Although these results need to be evaluated in other contexts, they suggest that patients with medication overuse have a more denial attitude towards headache records and may need additional reinforcement.

Key words: Headache; Headache diaries/calendars; Headache impact; Good clinical practice

Introduction

The management of primary headaches is mostly determined by headache impact and severity, often a combination of headache intensity, frequency, and duration. Moreover, the diagnosis of certain types of headaches, such as episodic or chronic types of migraine or tension-type headache, depends on the frequency of headaches, which is often challenging to elicit by memory. Patients tend to describe the last or the worst episodes and do not remember all events. The use of headache calendars is a way to overcome this difficulty,¹ and in fact headache diaries are considered part of the good clinical practice, according to the International Headache Society.²

Diaries may have different formats and details, supported on paper or digital. Nowadays, patients can record their attacks on a mobile phone or other electronic devices and transcribe them to a doctor's format.³ Although headache calendars may not convey all aspects of headache attacks or their impact, they contain essential and objective information for a joint discussion between patient and doctor. They show headache fluctuations with time, their relation with certain triggers and acute medication intake, also allowing for the diagnosis of medication overuse.³ They may also document treatment failures, a criteria to upgrade prophylactic medication, and to check criteria for specific treatments like monoclonal antibodies or botulinum toxin for migraine.^{4,5} However, despite doctors' efforts to provide the calendars and explain their relevance, patient compliance with this low-tech tool is often inadequate.⁶

In this study, we aimed to identify the profile of headache diary non-compliers, which may help us anticipate which patients need more education concerning this aspect of headache management.

Methods

Study design:

Prospective observational study on the use of headache calendars in the follow-up visits of a University Hospital's headache outpatient clinic.

Participants:

Consecutive patients diagnosed with primary headaches (with or without medication overuse headache) observed on follow-up visits or treatment sessions were invited to participate and signed informed consent. As part of the center clinical practice, all headache patients are offered a calendar at each first or follow up visits and are requested to fill it and bring it in follow up visits.

Methods:

The following variables were collected prospectively: Demographic: age, gender, years of education, occupation, socioeconomic status and need to care for children/elderly; Electronic devices use and regular writing habits: regular use of mobile phone, tablet, and computer, and carrying a pen/pencil (yes/no) with them; Clinical data: Headache diagnosis (according to the ICHD-3),⁷ estimated headache frequency in the last month (by calendar or by memory), Headache impact (HIT-6, Migraine-Specific quality-of-life Questionnaires),^{8,9} Depressive symptoms (Zung questionnaire),¹⁰ current medication and reason for visit (consultation or scheduled treatment of Botulinum toxin or monoclonal antibodies). Headache intensity was rated, based on the typical calendar, using a three grades categorical scale of 1 = mild (no impact on daily activities), 2 = moderate (daily activities are carried with effort and difficulty), or 3 = severe (daily activities cannot be undertaken). A severity index was computed for each patient multiplying by 1, 2 or 3, the number of headaches of mild, moderate, or severe intensity, respectively. This index, varying between 0 and 90, could not be calculated for patients without a calendar.

Patients were asked to fill a brief structured questionnaire to evaluate the use and patients' attitudes towards headache calendars: A) Did the patient bring the calendar (Yes/No), in case "Yes" was it in paper or digital). B) What main advantage do you see in filling a calendar? (1 - improve my knowledge about my headache; 2 – help the discussion with my doctor; 3 - gives me some control of medication intake; 4 - other). In case "No", there were other options (1- the calendar was not explained on a previous visit / I didn't understand the task; 2 - I registered

headaches but forgot/lost the calendar; 3 - I didn't have enough space for registration; 4 - I didn't remember to register; 5 - I did not have time; 6 - I consider the calendar irrelevant).

Statistics

Patients were divided into three groups: users (Calendar Compliers, CC), non-users (Calendar Non-Compliers, CNC) and partial users (patients who bring the calendar with incomplete information, not filling in the last 30 days even if they have registered the previous months since the last visit or those who stated they left it home). CC were compared to CNC regarding demographic factors, lifestyle factors, clinical data, and headache impact. Partial compliers were excluded from this dichotomic analysis since it was not possible to know if they had filled it. Patients re-evaluated in a second visit were considered only once (only the first evaluation was considered for statistical purposes). Differences in characteristics between groups were assessed using the Chi-square for categorical data and the t-test for continuous variables normally distributed. Logistic regression analyses tested predictors of compliance. All analyses were performed using SPSS 20.0 (Armonk, NY: IBM Corp.).

Results

We analyzed data from 93 patients comprising 83 females (89.2%) with a mean age of 45.6 ± 13.3 years and 12.7 ± 4.7 years of education (Table 1). Fifty-seven (61.3%) patients were considered CC, 29 patients (31.2%) were CNC and 7 patients (7.5%) were partial users. Only one patient used an electronic calendar. Nine women were re-evaluated in a second visit; 8 had concordant results in the two medical visits (CC in both visits), and one was CNC in the first visit and CC in the second visit.

Clinical data

A total of 50 (53.8%) patients had chronic migraine, 32 (34.4%) had episodic migraine (25 without aura and 7 with aura), 8 (8.6%) patients had \geq two primary headaches (migraine and tension-type headache), 2 patients (2.2%) had cluster headache and 1 (1.1%) had nummular headache; 17 (18.3%) patients had medication overuse, and 52 (55.9%) patients were taking prophylactic medication including 47 (50.5%) with Botulinum toxin and 4 (4.3%) patients with monoclonal antibodies. Non-users and partial users reported an estimated headache frequency in the last 30 days of 15.9 ± 12.6 days, by interview. CC reported 12.5 ± 11.3 days by interview and 12.5 ± 11.4 days according to calendars (mean severity index of 29.0 ± 28.1).

Characterization of calendar noncompliers

Medication overuse headache (MOH) was the main factor associated with lower adherence (34.5% of CNC had MOH, vs. 12.3% of CC); OR [95% CI] = 4.6 [1.4-15.0]. CNC were also more likely to be employed (table 1). Socioeconomic status, literacy, mobile phone, tablet, computer, and carrying a pen/pencil had no impact on adherence. The diagnosis (chronic vs. episodic headache) also did not influence compliance.

When CNC were asked about specific reasons for poor compliance, the main responses were: I didn't remember to register (n=17, 58.6%), I did not have time (n=0, 0%), I consider the calendar irrelevant (n=4, 13.8%), The calendar was not explained on a previous visit / I didn't understand the task (n=1, 3.4%).

Discussion

In this study, we assessed the compliance to a headache calendar, identifying the profile of noncompliers. In a sample of 93 patients the majority, 61.3%, brought a fulfilled calendar. Non-users were more likely to suffer from MOH and, with marginal significance, to have regular paid employment than CC. Users considered the calendar important to the doctor's knowledge in a more significant percentage than non-users.

Other studies reported higher compliance levels. However, in these studies, participants knew the aims before they brought the calendars.^{1,6} Our patients only knew about the purpose of the study on the day of the calendar delivery visit.

MOH patients tend to experience more severe disability compared to migraine patients without medication overuse.¹¹ Although all patients have been informed about the MOH mechanism in order to reduce their acute medication intake, they adhered less to the doctor's request to complete a calendar. The stigma associated with medication overuse can be associated with a sense of embarrassment experienced by those with chronic headaches.¹² We hypothesize that this burden, difficulty overcoming medication overuse and a sense of hopelessness and futility of feeling a calendar can lead to poor calendar adherence. Yet, lack of record may maintain a lack of overuse awareness or a denial of evidence despite its significant impact on health and headache persistence.

This study's main strength points are a prospective design, with well-characterized patients from a socio-demographic (professional status and need to care for others) and clinical point of view. We also applied scales of headache impact and depression scales to understand if associated depression or headache impact could modulate calendar compliance. The main limitations are the relatively small sample size and the variable clinical contexts where the patients could be observed (treatment sessions or follow-up visits).

Conclusion

Although these results need to be evaluated in other contexts and cultures, they suggest that patients with medication overuse have a more negative or skeptical attitude towards headache records and may need additional reinforcement to keep a headache calendar. Lack of record may maintain lack of awareness of overuse despite its great impact on health, quality of life and headache persistence.

List of abbreviations:

CC Calendar compliers, CNC Calendar noncompliers, MOH Medication Overuse Headache.

Declarations:

Ethics approval and consent to participate: Written informed consent was obtained from each participant in this study and the study was approved by the local ethical committee.

Consent for publication: Not applicable.

Availability of data and materials: Anonymized data operated or analyzed are available from the Authors upon reasonable request.

Competing interests: Authors declare no competing interests.

Funding: This work was not supported by any source of funding.

Author contributions: Initial concepts, framework and design were developed by IPM. Analysis and interpretation were performed by CB and IPM. Manuscript was prepared by CB. Critical revision and final comments were performed by IPM.

Acknowledgements: The authors would like to thank all patients who participated in the study.

References

- 1- Jensen R, Tassorelli C, Rossi P, et al. A basic diagnostic headache diary (BDHD) is well accepted and useful in the diagnosis of headache. A multicentre European and Latin American study. *Cephalalgia* 2011; 31(15), 1549-1560.
- 2- Silberstein, SD. Practice parameter: evidence-based guidelines for migraine headache (an evidence-based review): report of the Quality Standards Subcommittee of the American Academy of Neurology. *Neurology* 2000; 55(6), 754-762.
- 3- Allena M, Cuzzoni MG, Tassorelli C, et al. An electronic diary on a palm device for headache monitoring: a preliminary experience. *J Headache Pain* 2012; 13(7), 537-541.
- 4- Sacco S, Bendtsen L, Ashina M, et al. European headache federation guideline on the use of monoclonal antibodies acting on the calcitonin gene related peptide or its receptor for migraine prevention. *J Headache Pain* 2019; 16;20(1):6.
- 5- American Headache Society. The American Headache Society Position Statement On Integrating New Migraine Treatments Into Clinical Practice. *Headache* 2019; 59(1):1-18.
- 6- Nappi G, Jensen R, Nappi RE, et al. Diaries and calendars for migraine. A review. *Cephalalgia* 2006; 26.8: 905-916.
- 7- Headache Classification Committee of the International Headache Society. The International Classification of Headache Disorders. *Cephalalgia* 2018; 38 (3rd edition): 1-211
- 8- Yang M, Rendas-Baum R, Varon SF, et al. Validation of the Headache Impact Test (HIT-6TM) across episodic and chronic migraine. *Cephalalgia* 2011; 31:357-367.
- 9- Martin BC, Pathak DS, Sharfman MI, et al. Validity and reliability of the migraine-specific quality of life questionnaire (MSQ version 2.1). *Headache* 2000; 40:204–15.
- 10- Zung WW. A self-rating depression scale. *Arch Gen Psychiatry* 1965; 12, 63-70.
- 11- Mose LS, Pedersen SS, Debrabant B, et al. The role of personality, disability, and physical activity in the development of medication-overuse headache: a prospective observational study. *J Headache Pain*. 2018 May 25;19(1):39.
- 12- Kempner J. What biology can't do. *Headache* 2016;56: 1047–1052.