Headache diaries as an aid to management of people with primary headaches

Study details	Patients	Methods	Outcomes	Effect size	Comments
Author & Year: Baos et al, 2005[58] **Study design:** Open label prospective study, survey **Section of question:** Patient and physician experience **Setting:** Primary care setting in urban Spain **Duration of follow-up:** One and half months	**Patient group:** Adults with migraine, previous clinical trial participants **Inclusion criteria:** Aged ≥18 years with experienced migraine, with or without aura as defined by International Headache Society criteria. Never used a triptan. Recruited by 22 primary care physicians from group practices in 12 cities in Spain. Each physician could enrol 10 patients. Patients originally recruited for a open label study comparing rizatriptan with non-triptan therapy for migraine. **Exclusion criteria:** Current use of propranolol. Any contradiction to triptan use. **All patients** **N:** 118 (enrolled); 97 (completed the study and included in the analysis) **Age (mean±SD, range):** 39±12(18-73) **Drop outs:** 19	Patients used a diary to record clinical responses and satisfaction with therapy for three consecutive migraine attacks during the study, the first and third treated with rizatriptan 10-mg wafer and the second with usual non-triptan therapy. Patients completed a self- administered questionnaire regarding migraine history and the most recent pre-study migraine attack at baseline visit. They were given a diary containing three self administered questionnaires one for each of the three study migraine attacks. At each migraine attack patients recorded: • Headache pain intensity (mild/moderate/severe). • Grade of functional disability (none/mild/ severe/ require bed rest) • Associated symptoms (photophobia, phonophobia, nausea and vomiting) at time of taking migraine medication. • Timing. • Type and amount of medication and any additional medications taken after 24 hours of taking migraine medication. • Response to the medication (onset of pain relief and pain free, associated symptoms and return to usual activities) • Impact of attack on work hours (hours worked with migraine, hours of work	**Patient more satisfied with level of care provided by doctor as compared to before the study** Positive response/Number responded; (Percentage)	59/84 (70%)	**Funding:** Merck Sharpe and Dohme de Espana, S.A) **Limitations:** Small sample size. No control group. Recruited from an ongoing study, therefore, effects observed may be influenced by treatment given. Study may not be generalisable to population. Participants were known to physicians and this may have influenced responses.
			Migraine diary helped patient communicate better with physicians Positive response/Number responded; (Percentage)	70/80 (88%)	
			Of the patients who reported the diary to be useful, 80% were more satisfied with present medical care than pre-study care Of the patients who did not find the diary to be useful, or who did not answer, 11% were more satisfied with present medical care as compared to pre-study care		
			Diary enabled physician to communicate better with patients about migraine Positive response/Number responded; (Percentage)	20/22 (91%)	
			Diary enabled physician to assess differences in pain intensity and disability across attacks within the same patient	100%	
			Difference in evaluation and differentiation between headaches pre and post study	10/22 (46%)	

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	Gender (F): 80 (83%) **Headache pain intensity at baseline:** Moderate 36 (38%), Severe 60 (63 %)	missed, amount of difficulty working and rating of job effectiveness on a scale of 0-100%) • Impact on quality of life and satisfaction with treatment Questions on work related disability and quality of life were selected from validated questionnaires. Physicians also completed a baseline migraine history and treatment questionnaire for each patient at first visit. At the end of the study after evaluating 10 patients, physicians completed a questionnaire regarding the usefulness of the migraine diary.	Positive response/Number responded; (Percentage) **Diary influenced decisions regarding prescription medication for migraine** Positive response/Number responded; (Percentage)	 15/22 (68%)	

Abbreviations: NR=not reported, NA=not applicable, M/F=male/female, N=total number of patients randomised, SD=Standard deviation

Study details	Patients	Methods	Outcomes	Comments
Author & Year: Coeytaux et al, 2007[155] **Study design:** Qualitative study, focus groups **Section of question:** Patient experience **Setting:** University-based, tertiary care headache clinic in USA **Duration of follow-up:** 12 weeks for clinical trial	**Patient characteristics:** Adults with frequent headaches **Inclusion criteria:** Experienced 15 or more days of headache prior to clinical trial. Participants had recently participated in a clinical trial evaluating the effectiveness of medical management plus acupuncture compared to medical management without acupuncture. **Exclusion criteria:** NR **All patients** **N:** 34 Number attending 1 out of 4 scheduled focus group discussions: 19 **Age (range):** 22-83 years **Sex M/F:** 20/14 (26/74%) **Drop outs:** 14	Objective of the study was to identify clinical outcomes considered to be most important by patients who experience frequent headaches to help inform clinicians which of available headache assessment instruments may be most appropriate in assessing change over time. Patients were asked to keep a daily pain diary during the 12 week trial and had to record 'the pain severity of your worst headache that day, with 0=no headache and 10=very severe pain'. Focus group discussions were facilitated by two of the study authors and social scientists who were not directly involved in the RCT. Discussion focused on 5 topics: • Severity of pain associated with headaches • Definition of meaningful symptom relief • Uncertainty regarding timing and severity of headaches • Devaluation of the impact of headaches on sufferers, especially by health care professionals • Assessments of pain and its effects meaningful to participants	**Patients views:** Pain diary was useful and not overly burdensome to complete. Diary provided a meaningful expression of their level of pain and was useful in measuring pain severity and frequency. Diary allowed them to see improvement of which they might have been otherwise unaware.	**Funding:** National Institute of Health and GlaxoSmithKline **Limitations:** Participants were recruited from a clinical trial, may not be generalisable to the population. No information provided on whether participants were known to study authors. Focus group discussions may not have been able to elicit individual experiences. No mention of validation of the diary. Participants also completed the HIT-6, SF-36 and MIDAS questionnaires simultaneously and this may have influenced their understanding of the questions in the diary and their responses.

Abbreviations: NR=not reported, NA=not applicable, M/F=male/female, N=total number of patients randomised, SD=Standard deviation, SE=Standard error, ITT=Intention to treat analysis, HIT6=headache impact test, SF-36=short form-36, MIDAS=migraine disability assessment

Study details	Patients	Methods	Outcomes	Effect size	Comments
Author & Year: Jensen et al, 2011[400] **Study design:** Randomised study; survey **Section of question:** Patient and physician experience **Setting:** 16 headache centres in 9 countries (Europe and Latin America). **Duration of follow-up:** Four weeks or more	**Patient characteristics:** Adults with headache awaiting consultation at headache clinics **Inclusion criteria:** Age 18-65 years **All patients** **N:** 626 **Group 1- Diary +clinical interview** **N:**321 **Age (median, range):** 37 (16-74) **M/F:** 250/71 **Years with headache(median, range):** 11 (1-52) **Headache days per month(median, range):** 9(1-30) **Days with drug intake per month(median, range):** 7 (0-30) **Group 2- Clinical interview** **N:** 305 **Age (median, range):** 37 (17-72) **M/F:** 238/67 **Years with headache(median, range):**12 (1-50**)** **Headache days per month(median, range):** 10(2-30) **Days with drug intake per month(median, range):** 6 (0-30)	**Group 1** A basic diagnostic headache diary was developed based on ICHD-II criteria and tested in a pilot study. Based on results of pilot study the diary was modified slightly to collect information relevant to ICHD-II diagnostic criteria for migraine, TTH and medication overuse headache and on the consumption of symptomatic medication and also included a set of simple detailed instructions. Patients were sent the diary by post a month before first consultation; were asked to complete it every day for 4 weeks and bring it along for their first consultation. Diagnosis was made on the basis of data from diary +clinical interview. **Group 2** Patients did not receive diary. Diagnosis was made on the basis of clinical interview alone. **All** All patients and physicians were given separate questionnaires at the end of the first visit to assess usability and usefulness of the diary.	**Adequacy of information for diagnosis** (% who found information adequate for diagnosis) **Patient experiences:** • 97.5% of patients reported no difficulty in understanding the diary and providing information. • Patients evaluated diary as useful for making them aware of medication usage and less useful for understanding headache triggers or deciding when to treat headache. **Physician experiences:** • 97% of physicians reported no difficulty in understanding the diary and interpreting information. • Physicians evaluated diary as being helpful in diagnosing medication overuse headache and informing patients about medication intake; regarded it as less useful in informing about headache triggers.	**Group 1:** 97.7% **Group 2:** 86.8%	**Funding:** Grant from the European commission (Eurohead project) and the Italian ministry of health (Ricerca Corrente 2008) **Limitations:** •Period of use of diary may not have allowed enough time for diagnosis of episodic/chronic headache. •Study was conducted in a specialised headache research unit in a university hospital and the study sample may not be representative of all headache patients. **Notes:** As in the pilot study, the criteria for chronic TTH and MOH were modified on account of the short recording period; chronic TTH was diagnosed when TTH was present on ≥50% of days in the recording period; MOH was diagnosed when headache was present on ≥15 days per month and when the medication overuse criteria was met.

Abbreviations: NR=not reported, NA=not applicable, M/F=male/female, N=total number of patients randomised, SD=Standard deviation, SE=Standard error, ICHD=international classification of headache disorders, TTH=tension type headache, MOH=medication overuse headache

Study Details	Patients	Interventions	Outcomes	Effect size	Comments
Author & Year: Porter et al, 1981[635] **Study design:** Survey **Section of question:** Patient experience **Setting:** Specialist care, Boston, USA **Duration of follow-up:** Four weeks	**Patient group**: Patients who had sought specialised headache care **Inclusion criteria:** Patients who had been in contact with the study authors during the previous four years for specialised headache care. Patients had varied diagnosis (not specified) which are thought to account for most recurrent headaches. **All patients** **N:** 1148 (total number of chronicles mailed); **Sex M/F:** 57/177 **Age (mean):** 49 years **Drop outs:** Returned and usable chronicles (n): 234. Not returned (n): 798. Returned but not usable: 47 (27 refused, 12 had no name, 4 had no consent form, 4 did not follow directions). Returned undelivered by the postal service: 69 (3 died, 66 address unknown).	Headache chronicle with letter of invitation for participation in study and consent form was mailed to all participants. Headache chronicle consisted of one self- reporting page for each week followed with open ended questions. The chronicle had sections reporting pain intensity, how much the pain interfered with participants' usual activities, whether they experienced nausea, and when and what did participants do for prevention and relief of headache. The chronicle also reported to what extent the participants felt a range of negative emotions. Participants completed the headache chronicles on a day-to-day basis over a period of four weeks. To evaluate how completing the chronicle affected the description of headaches, the severity and occurrence reported in the chronicles was compared between the first and second two-week periods.	**Percentage who thought the chronicle was helpful**	38%	**Funding:** Government **Limitations:** No mention of validation or piloting of the questionnaire. Participants were known to the study authors previously, may have influenced their answers and response rate. Sample not representative of all those who suffer from headache. No mention of any medication/ treatment regime/additional care that was provided for the management of migraine. Relationship between negative feelings and headache intensity cannot be classified as causal due to cross sectional nature of survey.
			Percentage who thought the chronicle was a hindrance	8%	
			Percentage who thought the chronicle would be helpful to their physician	69%	
			Headache intensity Average level of headache pain over second two weeks as compared to first two weeks	Decreased: 127/234 (54.2%) Increased: 95/234 (40.5%) Unchanged: 12/234 (5.1%)	
			Headache frequency Number of days with any level of headache over second two-week period	Increased: 96/234 (41%) Decreased: 53/234 (22.6%) Unchanged: 85/234 (36.3%)	
			Average level of negative feelings Over second two week period	Increased: 96/234 (41%) Decreased: 118/234 (50.4%) Unchanged: 20/234 (8.5%)	

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