Migraine

Study details	Patients	Interventions	Outcome measures	Effect size	Comments
Ref ID: Brighina et al. 2007[108] **Study design:** Validation study (cross-sectional) **Setting:** 8 headache centres in Sicily (tertiary care)	**Patient group:** Headache patients aged 18-65 **Inclusion criteria:** Patients referred to the headache centres and reporting at least 2 headache attacks in the last 3 months. Must have experienced at least one headache that interfered with their life. **Exclusion criteria:** NR **All patients** **N:** 222 **Age (mean):** 38.68±12.02 **F/M:** 163/59 **Drop outs:** 0	**Group 1 – ID migraine** Italian version of the ID Migraine (translated by Pfizer who own original copyright). Response to each item treated as a binary variable: 'no' assigned to responses of 'never' or 'rarely' and 'yes' assigned to 'less than half the time' or 'half the time or more'. **Group 2 – ICHD II** Complete clinical evaluation according to the ICHD II criteria. Patients were evaluated by a board-qualified headache specialist (always the same in each centre), blind to the result of the ID migraine. Full assessment included medical history, physical examination including additional diagnostic tests if clinically indicated.	**Sensitivity** (95%CI)	Migraine (2 items positive): 0.95 (0.91-0.98) Other primary headache: 0.20 (0.09-0.32) Secondary headache: 0.48 (0.29-0.67)	**Funding:** Pfizer (copyright holders of ID Migraine) **Limitations:** No serious limitations **Additional outcomes:** Diagnostic outcomes for nausea, photophobia and disability as individual measures. Accuracy. Sub-groups of age and sex. **2x2 table:** completed by NCGC
			Specificity (95%CI)	Migraine (2 items positive): 0.72 (0.62-0.82) Other primary headache: 0.12 (0.08-0.17) Secondary headache: 0.22 (0.16-0.28)	
			Positive predictive value (95%CI)	Migraine (2 items positive): 0.88 (0.82-0.93) Other primary headache: 0.05 (-0.02-0.09) Secondary headache: 0.08 (0.04-0.13)	
			Negative predictive value (95%CI)	Migraine (2 items positive): 0.87 (0.78-0.95) Other primary headache: 0.39 (0.26-0.51) Secondary headache: 0.75 (0.64-0.87)	

Abbreviations: NR=not reported, NA=not applicable, M/F=male/female, N=total number of patients randomised, SD=Standard deviation, SE=Standard error, CI=Confidence interval, ICHD II=2nd edition of the International Classification of Headache Disorders

Study details	Patients	Interventions	Outcome measures	Effect size	Comments
Ref ID: Ertas et al. 2009[263] **Study design:** Validation study (cross-sectional) **Setting:** Multicentre outpatients; opthalmology, ENT and neurology. 11 centres in Turkey	**Patient group:** > 17 years old with headache **Inclusion criteria:** > 17 year old, presenting to neurology, ear nose and throat (ENT) or ophthalmology clinics, passing the pretest screening questions for headache: if one was affirmative the participants were enrolled for the ID migraine test and examination by a neurologist: (i) Do your headaches limit your ability to work, study or enjoy life? (ii) Do you want to talk to your healthcare professional about your headaches? **Exclusion criteria: <**18 years old, or not capable of communicating. **All patients (with headache)** N: 1585 Drop outs: 564 (did not pass pretest questions) **Neurology clinic** N: 530 (after pretest) Age, mean (SD): 46.5 (17) F (%): 63.8 **ENT Clinic**	**Group 1 – ID migraine** Including three screening questions: during the last 3 months, (i) Did you feel nauseated or sick to your stomach with your headache? (ii) Did light bother you when you had a headache (drastically more than when you did not have headaches)? (iii) Did your headache limit your ability to work, study or do what you needed to do for at least 1 day? The cut off point for diagnosis of migraine was 2 or more positive responses. **Group 2 – ICHD II** Neurologists or trained neurology residents interviewed patients using a symptom checklist based on a diagnostic headache evaluation prepared according to IHS criteria (ICHD II).	**Sensitivity** Migraine (>2 items positive) **Specificity** Migraine (>2 items positive) **Positive predictive value** Migraine (>2 items positive) **Negative predictive value** Migraine (>2 items positive)	Neurology: 87.87 ENT: 86.62 Opthalmology: 79.87 Neurology: 73.96 ENT: 74.38 Opthalmology: 75.95 Neurology: 0.86 ENT: 0.80 Opthalmology: 0.86 Neurology: 0.76 ENT: 0.83 Opthalmology: 0.67	**Funding:** Pfizer **Limitations:** Original data not reported Not clear if patients could be diagnosed with more than one headache type (assumed they could due to n values reported). Headache not always the primary complaint (no data presented separately for those in which it was). Not specifically stated that diagnosis was made blinded to other test result, but assumed. **Additional outcomes:** Localization of headache. Severity of headache. Breakdown of ID migraine items. Headache characteristics. Trigger factors. Percentage using medication for headaches. **2x2 table:** Completed by NCGC

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	N: 263 (after pretest) Age, mean (SD): 47.3 (18) F (%): 58.1 **Opthalmology clinic** N: 228 (before pretest) Age, mean (SD): 43.3 (16) F (%): 52.9				

Abbreviations: NR=not reported, NA=not applicable, M/F=male/female, N=total number of patients randomised, SD=Standard deviation, SE=Standard error, CI=Confidence interval, IHS=International Headache Society, ICHD II=2nd edition of the International Classification of Headache Disorders, ENT=Ear Nose & Throat

Study details	Patients	Interventions	Outcome measures	Effect size	Comments
Ref ID: Gil-Gouveia et al. 2010[321] **Study design:** Validation study (cross-sectional) **Setting:** 2 headaches outpatient clinics in Portugal	**Patient group:** Adults with headache **Inclusion criteria:** Adults reporting at least 2 headache attacks in the last 3 months attending headache outpatient clinics. **Exclusion criteria:** Age <18 years, current uncontrolled medical or psychiatric illness, illiteracy, headache syndromes with no clear diagnosis or not fulfilling definite ICHD-II diagnostic criteria and the presence of more than one headache type or current medication overuse headache (MOH). **All patients** N: 142 Age, mean (SD): 39.2 (13.9) F/M: 119/23 (83.8% F) Drop outs: 11 excluded due to MOH or not fulfilling ICHD criteria **Included in analysis** N: 131 Age mean (SD): 38.2 (13.2) F/M: 110/21 (84% F) Disease duration, mean(SD) yrs: 13.6(10.8)	**Group 1 – ID migraine** Portuguese version obtained by consensus translation process. Participants asked to complete the questionnaire before the first clinical visit to the headache specialist. 1 point scored for each affirmative answer, ≥2 considered a positive diagnostic test. **Group 2 – ICHD II** Headache specialist blinded to ID-migraine results performed medical and neurological history and examination. ICHD-II diagnosis made and other demographic factors recorded.	**Sensitivity** (95%CI) Migraine (>2 items positive)	0.94 (0.87-0.97)	**Funding:** Pfizer approved use of ID migraine, not mention of funding. **Limitations:** Patients not fulfilling definite ICHD-II criteria excluded from analysis. **Additional outcomes:** Age at symptom onset. Headache frequency, duration and intensity. Use of prophylactic treatment. **2x2 table**: Yes
			Specificity (95%CI) Migraine (>2 items positive)	0.60 (0.46-0.73)	
			Positive predictive value (95%CI) Migraine (>2 items positive)	0.80 (0.71-0.87)	
			Negative predictive value (95%CI) Migraine (>2 items positive)	0.85 (0.70-0.94)	

Abbreviations: NR=not reported, NA=not applicable, M/F=male/female, N=total number of patients randomised, SD=Standard deviation, SE=Standard error, CI=Confidence interval, ICHD II=2nd edition of the International Classification of Headache Disorders, MOH=Medication overuse headache

Study Details	Patients	Interventions	Outcome measures	Effect size	Comments
Ref ID: Karli et al. 2007[420] **Study design:** Validation study (cross-sectional) **Setting:** 41 neurology outpatient clinics in Turkey	**Patient group:** Adults with headache **Inclusion criteria:** Adults presenting to neurological outpatients clinics over 17 years of age and able to communicate. Must have had 2 or more headaches in the last 3 months and answer yes to at least one of the following questions: (i) Do your headaches limit your ability to work, study or enjoy life? (ii) Do you want to talk to your healthcare professional about your headaches? **Exclusion criteria:** Not capable to communicate, younger than 17 years of age. **All patients** N: 3683 screened, 1816 included (answering pre-screening questions positively) Age, mean (SD): 45.2 (17) F/M(%): 62.9/37.1 Headache as primary cause of admission: 35.1%	**Group 1 – ID migraine** Completed by all patients passing the pre-test questions. Migraine was diagnosed if there were at least 2 positive responses to the 3 ID migraine questions. **Group 2 – ICHD II** All patients who completed the ID migraine were interviewed by a neurologist or trained neurology resident using a symptom checklist based on a semi-structured diagnostic headache evaluation according to the ICHD-II criteria, and assigned a clinical diagnosis of migraine, tension type or other headache.	**Sensitivity** Migraine (2 items positive)	91.82	**Funding:** Pfizer **Limitations:** No serious limitations **Additional outcomes:** Diagnostic outcomes for all three questions of ID migraine. Subgroup analysis based on gender and years of education. Numbers diagnosed with each headache type separated by subgroup according to diagnosis and reason for admission. **2x2 table:** Completed by NCGC
			Specificity Migraine (2 items positive)	63.40	
			Positive predictive value (ratio) Migraine (2 items positive)	0.72	
			Negative predictive value (ratio) Migraine (2 items positive)	0.88	

Abbreviations: NR=not reported, NA=not applicable, M/F=male/female, N=total number of patients randomised, SD=Standard deviation, SE=Standard error, CI=Confidence interval, ICHD II=2nd edition of the International Classification of Headache Disorders

Study Details	Patients	Interventions	Outcome measures	Effect size	Comments
Ref ID: Khu et al. 2008[435] **Study design:** Cross-sectional **Setting:** 57 GP clinics in Singapore	**Patient group**: Patients presenting to GP clinics with headache (aged >8) **Inclusion criteria:** Primary complaint of headache **Exclusion criteria:** Non-consenting **All patients** **N:** 584 **Age, mean (SD):** 37 (11) Range 8-74 (5% under 20yrs) **F/M (%):** 74.5/24.5 **Duration of headaches** (%): <1 yr 20.7, 1-5yrs 28.6, >5yrs 49.1 **MIDAS:** minimal disability 53.9%, mild 22.6%, moderate 19.7%, severe 11.6% **Drop outs:** 0	**Group 1 – ID migraine** Completed by patients after instruction by clinician or clinic assistant. Also included questions on demographics, headache duration, frequency, MIDAS, doctor-hopping behaviour, headache treatment and social burden of headaches. >2 positive answers on ID migraine confirmed diagnosis. **Group 2 – ICHD II** Questionnaire completed by physician according to study coordinator instruction. Included headache feature, clinical diagnosis and management details. Attention was paid to overusage of acute pain medication and perceived need for prophylactic treatment.	**Sensitivity*** Migraine (2 items positive)	0.50 (0.45-0.55)	**Funding:** Janssen-Cilag **Limitations:** Results reported as percentage diagnosed – diagnostic outcomes calculated by NCGC. Assumed questionnaires interpreted independently, but only states they were collected independently. Physician diagnosis considered as a separate item to IHS diagnosis. Not clear who assigns IHS diagnosis. **Additional outcomes**: Reasons for dissatisfaction with current headache treatments. Prophylaxis and indications for taking. Headache profile. **Notes:** * Calculated by NCGC from % prevalence values presented **2x2 table completed**:Yes
			Specificity* Migraine (2 items positive)	0.84 (0.78-0.88)	
			Positive predictive value* Migraine (2 items positive)	0.85	
			Negative predictive value* Migraine (2 items positive)	0.52	

Abbreviations: NR=not reported, NA=not applicable, M/F=male/female, N=total number of patients randomised, SD=Standard deviation, SE=Standard error, CI=Confidence interval, ICHD II=2nd edition of the International Classification of Headache Disorders

Study Details	Patients	Interventions	Outcome measures	Effect size	Comments
Ref ID: Kim & Kim 2006[436] **Study design:** Diagnostic (cross-sectional) **Setting:** TMJ and orofacial pain clinic in Korea	**Patient group:** Adults with TMD or orofacial pain and headache **Inclusion criteria:** Adults attending TMJ and orofacial pain clinic who reported two or more headaches in the previous 3 months. In addition, the subjects had to either wish to consult a doctor about their headaches or report that the headaches interfered with their lives. Patients had to be able to read and write Korean. **Exclusion criteria:** NR **All patients** N: 176 Age, mean(SD): 30.7 (9.3) F/M: 143/33 Drop outs: 0	**Group 1 – ID migraine** Self-administered questionnaire consisting of nine questions referring to the severity and nature of their headache pain and the presence of associated migraine symptoms. **Group 2 – IHS criteria** A headache specialist completed the semistructured diagnostic questionnaires and examined the patients and assigned clinical diagnosis of migraine according to IHS criteria.	**Sensitivity** (95%CI) Migraine (2 items positive)	0.58 (0.45-0.72)	**Funding:** NR **Limitations:** NPV not presented. †PPV presented differed to that calculated by NCGC (paper reported 93.9%). Unclear if interpretation of results made blinded to other test results. Patients have TMD and orofacial pain as primary complaint (indirect). NPV not presented. **Additional outcomes:** Sensitivity and specificity of each of the 9 items on the original ID-Migraine. **2x2 table:** Completed by NCGC * calculated by NCGC
			Specificity (95%CI) Migraine (2 items positive)	0.98 (0.76-1)	
			Positive predictive value (95%CI) Migraine (2 items positive)	*†86%	
			Negative predictive value (95%CI) Migraine (2 items positive)	*91%	

Abbreviations: NR=not reported, NA=not applicable, M/F=male/female, N=total number of patients randomised, SD=Standard deviation, SE=Standard error, CI=Confidence interval, IHS =International Headache Society, TMJ=temporomandibular joint, TMD=temporomandibular disorders

Study details	Patients	Interventions	Outcome measures	Effect size	Comments
Ref ID: Lipton et al. 2003[505] **Study design:** Development study **Setting:** Primary care practice (21 practices in the US)	**Patient group:** Adults aged 18-55 with headache **Inclusion criteria:** Men and women aged 18-55 visiting a primary care practice office for any reason. Patients had to be able to read and write English, and not have participated in a previous Pfizer-sponsored migraine study. They must report 2 or more headaches in the previous 3 months. In addition, eligible subjects had to indicate that they had experienced a headache that had limited their ability to work, study, or enjoy life, or that they might wish to speak with a healthcare professional about their headaches. **Exclusion criteria:** Participation in previous Pfizer-sponsored migraine study. After one third of the sample had been enrolled, an additional entry criterion was added that excluded patients with a previous diagnosis of migraine (to ensure that a high proportion of patients had not previously been diagnosed with migraine). **All patients**	**Group 1 – ID migraine** In the primary care practice patients were asked to complete the migraine screener (on questionnaire). Consisting of 9 questions developed by consensus panel based on IHS criteria. There were additional questions on age, sex, race, previous diagnosis and frequency of headache, not used for diagnosis. Questionnaire was reviewed for completeness by the primary care practitioner or a member of their staff. **Group 2 – IHS** The patient was referred to a headache specialist for a structured diagnostic headache evaluation within 2 weeks of the screening. Results of the screening questionnaire were not available to the headache specialist. The appointment included a medical history, physical examination, comprehensive neurologic history and examination and a semi-structured interview that included the IHS features of migraine supplemented by	**Sensitivity (95%CI)** Migraine (2 items positive) **Specificity (95%CI)** Migraine (2 items positive) **Positive predictive value (95%CI)** Migraine (2 items positive) **Negative predictive value (95%CI)** Migraine (2 items positive)	0.81 (0.77-0.85) 0.75 (0.64-0.84) 93.3 (89.9-98.5) *51.08%	**Funding:** Pfizer **Limitations:** Additional exclusion criteria added after 1/3 of patients had been recruited. Reasons for the 8 patients with missing data not stated. **Additional outcomes**: Diagnostic outcomes on each item of the questionnaire individually. MSQ MIDAS Migraine-related work productivity questionnaire. Henry Ford Hospital headache disability inventory. Test-retest reliability (on a subset of patients). **Notes:** 9 item version of screener used initially. NB. Study included for information rather than analysis. **2x2 table:** Completed by NCGC

	N: 563 eligible, 550 screened, 451 completed both index test and reference standard (validation sample) **Age mean (SD):** 39.3 (10.1) **F/M:** 341/110 (75.6/24.4%) **Drop outs**: 99 completed screener but did not attend their neurology appointment (for reference standard) 17.7% 8 Missing data from one test (1.4%)	additional questions relating to family history and medical treatment history. The headache expert was encouraged to probe for clinical information necessary to clarify the differential diagnosis.			* Calculated by NCGC

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Study details	Patients	Interventions	Outcome measures	Effect size	Comments
Ref ID: Mostardini et al. 2009[574] **Study design:** Validation study (cross sectional) **Setting:** Headache clinic, post ED discharge (Italy)	**Patient group:** Patients discharged from ED with a diagnosis of primary headache **Inclusion criteria:** Attending headache clinic within 48 hours of discharge from ED with a diagnosis of primary headache. **Exclusion criteria:** Those who did not speak Italian fluently and subjects with an ICHD-II diagnosis of probably migraine. **All patients** **N**: 254† (199 calculated by NCGC) **Age mean (SD): 37 (15)** **F/M:** 2:1 (ratio) **Drop outs**: 0	**Group 1 – ID migraine** Self-administered and dichotomic questionnaire based on three questions regarding the presence of nausea, photophobia and disability during headache. Defined as positive when the answer to at least two out of the three questions is yes. **Group 2 – ICHD II** A headache expert blinded to the test made a diagnosis according to the ICHD-II criteria. The data used by the ED to make a diagnosis before discharging the patients were obtained.	**Sensitivity†** Migraine (2 items positive) For primary headaches	0.94 (0.94)	**Funding:** NR **Limitations:** †Discrepancies in results reported for primary headaches only – wrong total n used in paper (both values reported here). Patients with ICHD-II diagnosis of probably migraine excluded because ID-Migraine not validated for this category (but TTH etc included) **Additional outcomes**: Data analysed for those with IHS diagnosis of primary headache, and the whole population (including secondary headache). **Notes:** Analysis of those with primary headaches only reported here. **2x2 table:** Completed by NCGC
			Specificity† Migraine (2 items positive) For primary headaches	0.81 (0.83)	
			Positive predictive value† Migraine (2 items positive) For primary headaches	0.98 (0.99)	
			Negative predictive value† Migraine (2 items positive) For primary headaches For all of the above data is NCGC calculated value (study value)	0.54 (0.31)	

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Study Details	Patients	Interventions	Outcome measures	Effect size	Comments
Ref ID: Samaan et al. 2010[682] **Study design:** Validation study (cross sectional) **Setting:** Specialist headache clinic	**Patient group:** Patients referred to specialist headache clinic with significant headaches not managed by other health care providers. **Inclusion criteria:** All patients registered for the clinic eligible to participate. **Exclusion criteria:** NR **All patients** **N**: 200 randomised, 170 analysed **Age (mean):** NR **F/M:** NR **Drop outs**: 30 Not stated if they did not attend appointment or were unable to be diagnosed.	**Group 1 – The structured migraine interview (SMI)** Designed to answer the question 'did this person suffer from migraine at any time in his/her life'. 10 questions formed from ICHD criteria. The questionnaire was mailed to all patients at the migraine clinic. Responses from SMI were scored usinga computerised coding algorithm to generate migraine diagnosis. **Group 2 – Clinician diagnosis** A random sample of 200 subjects were selected from the respondents using a random list of ID numbers which concealed the participants' identity. These people were invited to see a migraine clinic headache specialist to provide the clinical diagnosis. They were blind to the SMI diagnosis.	**Sensitivity** **Specificity** **Positive predictive value** **Negative predictive value**	0.87 0.58 0.97 0.26	**Funding: NR** **Limitations:** Very specific patient group with significant headaches that could not be managed by other healthcare providers. Study does not specifically state that ICHD criteria used for reference standard, but assumed it would be in this clinic. Missing data for 30 patients, no reason given. **Additional outcomes**: Correlation with seld-reported migraine, migraine treatment and analgesic use. Comparison of face to face interview the SMI telephone interview. **Notes:** Clinical diagnosis only included migraine with aura, migraine without aura and non-migraine headache. There were no cases of probably migraine. For analysis the diagnoses were grouped as migraine (with or without aura) and non-migraine headache. **2x2 table:** Yes (in paper, verified by NCGC)

Abbreviations: NR=not reported, NA=not applicable, M/F=male/female, N=total number of patients randomised, SD=Standard deviation, SE=Standard error, CI=Confidence interval, ICHD II=2nd edition of the International Classification of Headache Disorders