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Easy tools to screen Italian women suffering from migraine with and without aura in early reproductive age

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ABSTRACT

Objective: Early diagnosis of migraine with (MA)/without aura (MO) is vitally important to prevent adverse events during combined hormonal contraceptive (CHC) use and to provide personalized surveillance programs during pregnancy. The aim of this study is to provide clinicians with simple and fast tools to diagnose MO and MA in daily clinical practice.
Study design: This study was based on a questionnaire to women of early reproductive age (18–35 years old) then randomized to undergo a neurological consultation. The ID-migraine questionnaire (PIN) and visual aura rating scale (VARS) were used.
Results: A total of 240 subjects were included in the study, with a total prevalence of MO diagnosed by PIN of 67.0% of subjects with headache, 49.2% of the total study population, and of MA by VARS of 12.5% subjects with headache, 9.2% of the total study population. Eighty-seven neurological examinations were randomly performed: PIN showed a sensitivity of 85.7% (95% CI 75.3%–92.9%) and a specificity of 52.9% (95% CI 27.8%–77.0%), while VARS displayed a sensitivity of 100.0% (95% CI 69.2%–100.0%) and a specificity of 45.5% (95% CI 16.8%–76.6%).
Conclusion: High sensitivity, in particular for the presence of MA, associated with low specificity suggest that PIN and VARS questionnaires can be effective tools to identify those young patients who require specific neurological examinations in view of the prescription of a CHC or pregnancy planning.
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Introduction

Migraine (M) is an idiopathic headache presenting with unilateral attacks of pulsating, moderate or severe pain, lasting from 4 to 72 h and associated with autonomic symptoms like nausea, vomiting, photophobia and phonophobia [1]. In about the 30% of patients, M attacks are preceded by focal neurological symptoms, mainly visual, which indicate a clinical sub-entity defined as migraine with aura (MA). Indeed, if such symptoms are not present, a diagnosis of migraine without aura (MO) can be made [1], with MO and MA even co-occurring in 10% of cases [2]. MO and MA onset typically occurs between 13–25 years of age [2], with MO attacks mainly occurring before 40 years of age and subsequently declining after menopause [3]. The higher prevalence of MO during the reproductive years is closely related to the fluctuating hormonal environment of the fertile age in women. In contrast, the prevalence of MA increases with age, rising from 13% of M attacks in the age between 18 and 29 years, to 20% in the age between 40 and 49 and 41% above the age of 70 [4,5].

A correct diagnosis of the type of M is very important in ob/gyn clinical practice, because evidence supports an increased risk of ischemic stroke associated with MA [6,7]. For MO, the interpretation of available data is more complex, as in some studies this association was not confirmed [8–10].

The use of combined hormonal contraceptives (CHCs) is an independent risk factor for the occurrence of ischemic stroke, with

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ORs ranging between 1.56 [95% CI 1.61–1.89] for CHCs containing 20 μg of ethinyl-estradiol (EE) and 1.75 [95% CI 1.36–1.79] for those containing 30 μg of EE [11].

Moreover, MO and MA have been associated not only with gestational ischemic stroke, but with a wide range of other diseases or complications during pregnancy and puerperium compared with healthy populations [12]. Indeed, other cardiovascular diseases [12,13], hypertension [13–15] preeclampsia (PE) [12–18], preterm delivery [19,20], low birth weight [14,21], nausea and hyperemesis gravidarum [22] and the development of depression as well as anxiety [23] are comorbid with M.

By virtue of a higher risk of possible complications such as the above during CHCs use, pregnancy and puerperium, an early diagnosis of MO or MA is vitally important to prevent adverse events and to provide personalized surveillance programs in high-risk populations.

The International Headache Society (IHS) has developed criteria for the diagnosis of M [1], but these are better suited to the research field than to common clinical practice. The aim of this study is to provide clinicians (general practitioners and gynecologists) with simple and fast tools to diagnose MO and MA in daily clinical practice.

Materials and methods

This was an experimental study based on a questionnaire to women of early reproductive age enrolled in the Gynecology Clinic of the University Hospital Policlinico of Modena. The women were enrolled during routine gynecological visits to outpatient services of our Clinic (Center for Contraception, Center for Abnormal Uterine Bleeding, General Gynecological Service).

Inclusion Criteria were as follows: non-pregnant women 18–35 years old with regular menstrual cycle (between 25 and 35 days), who were referred to us for routine gynecological consultation.

Ethics

All women provided informed consent to participate in the study. The study design was approved by the Ethics Committee of the Policlinico of Modena on 28 March 2017 (Protocol n. 36/17).

Part I – the questionnaire

The questionnaire consisted of 31 questions investigating age, smoking status, anthropometric measures, gynecologic history, characteristics of pain during menstruation and the presence of headache. The last questions included two questionnaires evaluating the presence of MO and/or MA (ID-Migraine and visual aura rating scale).

ID-migraine is a valid and reliable symptom-based screener for M developed for use in primary care and based on the three best predictors for diagnosing M, i.e. photophobia (P), impairment (I) and nausea (N): a simple acronym for the ID-migraine questionnaire is PIN. This questionnaire was previously validated in the Italian language in a mixed population of men and women [24].

For MA diagnosis, we used the visual aura rating scale (VARS), based on the International Headache Society's diagnostic criteria. The VARS score is the weighted sum of the presence of five visual symptom characteristics: duration 5–60 min (3 points), gradual development over at least 5 min (2 points), scotoma (2 points), zig-zag lines (2 points), and homonymous hemianopia (1 point). A VARS score of 5 or more out of a maximum score of 10 points has a sensitivity of 96% [95% CI 92–99%] and a specificity of 98% [95% CI 95–100%] for migraine aura [25]. To date, this questionnaire has never been validated in the Italian language.

Part II - randomized neurological evaluations

Assuming a prevalence of headache in our population of at least 60% and not being able to subject all of them to a specialist neurological examination due to lack of funds, we decided to randomize about 2/3 of them to a specialist visit. The study sample with headache has been then divided into one group that has received the intervention being studied by a neurological examination (the visited group) and another group that has not received the intervention (the not visited group). Randomization in this context means that care is taken to ensure that no pattern exists between the assignment of subjects into groups and any characteristics of those subjects. Every subject is as likely as any other to be assigned to the visited or not visited group, in order to make these groups comparable, permitting to get results from a more limited group as if it were the whole group. For this reason, some women with headache ("Yes" answer to question 19) were randomly selected by an author (G.G.). They were contacted by phone to take part in a neurological consultation free of charge at the Headache Center with a physician experienced in headache diagnosis and treatment (M.C., L.A.P., C.B., S.G.). Randomization was performed through a block randomization list with a casual list of the questionnaires with subjects reporting headache.

Statistical analysis

The characteristics of women with or without headache were analyzed and compared. In the descriptive analysis, the continuous variables were summarized by means of mean and standard deviation (SD), while the categorical variables were reported as absolute and percent values. The distribution of continuous covariates by group was compared using one-way ANOVA (analysis of variance). The comparison of categorical variables across groups was performed using the Chi square test or Fisher's exact test, when appropriate. Statistical analysis was performed using the statistical package StatView (v 5.01.98; SAS Institute Inc, Cary, NC). Correlations were considered to be significant at $P < 0.05$. The results of continuous data are expressed as mean ± standard deviation (SD).

Results

A total of 240 subjects were included in the study and completed the questionnaire. The mean time taken by patients to carry out the questionnaire was not specifically measured during the study but it has been estimated around 5 min. The features of the subjects included in the study are reported in Table 1. The total prevalence of headache in our population was

Table 1
Features of subjects responding to the study questionnaire (n = 240).

Features of the study population	
Age (years)	26.9 ± 7.4 (range 17-35)
Body mass index (BMI) (Kg/m^2)	21.5 ± 3.7 (range 16.4-34.4)
Age at menarche (years)	12.5 ± 1.4 (range 9-17)
Smoking	Never 159 (66.2%) Past smokers 22 (9.2%) Occasionally 17 (7.1%) < 10 cigarettes/day 36 (15%) > 10 cigarettes/day 6 (2.5%)
Hormonal contraception users	97 (40.4%)
Nulliparous	203 (84.5%)
Menstrual cycles lenght (days)	28.3 ± 4.9
Menstrual flow lenght (days)	4.6 ± 1.3
Menstrual pain	In all cycles 111 (46.3%) In some cycles 110 (45.8%) Never 19 (7.9%)

176/240 (73.3%). One-hundred twenty-three (123/176, 69.9%) of these subjects reported that headache worsened during the menstrual cycle and 141/176 (80.1%) needed medications for the treatment of headache. The most widely used drugs for headache treatment were nonsteroidal anti-inflammatory drugs [Ibuprofene (59, 33%), Ketoprofene (49, 27.8%), Paracetamol (46, 26.1%)] or Triptans (19, 10.8%) (Table 2). Only 51/176 (29.0%) of women previously sought medical consultation with a physician experienced in headache diagnosis and treatment.

PIN questionnaire results

Photophobia during headache was reported by 116/176 (65.9%) women, impairment by 114/176 (64.8%) women and nausea by 69/176 (39.2%) women. The concomitant presence of symptoms is depicted in Fig. 1. Photophobia and impairment (P + I) were found in 48 women (27.2%), photophobia + nausea (P + N) in 6 women (3.4%), impairment and nausea (I + N) in 11 women (6.3%) and the three complaints together (P + I + N) in 53 women (30.1%) with headache. These figures resulted in a total prevalence of MO diagnosed by ID-migraine of 118 women, 67.0% of subjects with headache (Fig. 1), 49.2% of the total study population.

VARS questionnaire results

Of the subjects with headache, 31/176 (17.6%) reported visual symptoms during attacks. In particular, these included duration 5–60 min (25/31, 80.6%), gradual development over at least 5 min (19/31, 61.3%), scotoma (12/31, 38.7%), zig-zag lines (14/31, 45.2%) and homonymous hemianopia (16/31, 51.6%). Mean VARS score was 5.8 ± 2.4 points, with 22/31 (71.0% of subjects with visual symptoms, 12.5% of those with headache, 9.2% of the general population) averaging ≥ 5 points (MA diagnosis).

Results of specialized neurological consultation

Of a total of 100 randomly selected women with headache, thirteen subjects refused to participate in consultation, leaving a total of 87 neurological examinations performed by the same group of physicians. MA was diagnosed in 7/87 (8.0%) subjects, MO in 58/87 (66.7%), migraine combined with and without aura in 5/87 (5.7%) and other types of headache (most of all tensive cephalagia) in 17/87 (19.5%). General features of women with and without M are reported in Table 2: they are comparable between groups.

PIN [2 or 3 symptoms (P + I, P + N, N + I, P + I + N)] sensitivity in the diagnosis of M was 85.7% (95% CI 75.3%–92.9%), specificity 52.9% (95% CI 27.8%–77.0%), positive predictive value 88.2% (95% CI 81.8%–92.6%), negative predictive value 47.4% (95% CI 30.3%–65.1%) with an accuracy of 79.3% (95% CI 69.3%–87.3%).

VARS sensitivity in the diagnosis of MA was 100.0% (95% CI 69.2%–100.0%), specificity 45.5% (95% CI 16.8%–76.6%), positive predictive value 62.5% (95% CI 49.3%–74.1%), negative predictive value 100%, with an accuracy of 71.4% (95% CI 47.8%–88.7%).

A prophylactic treatment for M was then prescribed to 16/87 (18.4%) women, while a treatment “as needed” during headache attacks to 81/87 (93.1%). The specific treatments prescribed by the physicians experienced in headache treatment are reported in Table 3, in comparison to baseline questionnaire reports: we observed a significant increase in triptans and combinations of NSAIDs and triptans, with a decrease in the exclusive use of NSAIDs ($p = 0.003$) in the subjects who were visited.

Discussion

Our study is the first report about the accuracy of PIN and VARS scores for the diagnosis of M, in particular MO and MA, in a population of Italian women in young reproductive age. The high sensitivity (> 85%), in particular for the presence of aura (VARS score), associated with low specificity (< 52%) suggest that these easy questionnaires can be effective tools to identify those young patients who require specific neurological examination, in view of the prescription of a CHC or pregnancy planning.

Importance of M diagnosis in ob/gyn practice

M and CHC prescription

The quality of current evidence regarding the risk of ischemic stroke in women with M associated with the use of CHCs is low. Available data suggest that CHCs may further increase the risk of ischemic stroke in those affected by M, specifically MA. According to a recent Consensus Statement [26], although it cannot be excluded that currently available low-dose CHCs are safer and future recommendations may be less restrictive, caution is mandatory. In fact, even though the absolute risk associated with the use of CHC may not be high (14.5/100,000 women with MA and 10/100,000 women with MO), the consequences of an ischemic stroke, especially in young women, may be devastating for patients and their families. For this reason, the presence of MA is at present a contraindication (category 4) to CHC use at any age, according to the main international Medical Eligibility Criteria for Contraceptive Use [27–29].

M and pregnancy

In the largest study investigating the relationship between M and pregnancy complications, Bushnell et al. retrospectively

Table 2
Features of subjects with or without migraine (M) diagnosis after neurological examination (n = 87).

	Women without M (n = 17)	Women with M (n = 70)	p
Age (years)	28.3 ± 5.2	30.4 ± 4.1	0.39
Body Mass Index (Kg/m^2)	21.2 ± 2.9	21.6 ± 3.4	0.65
Age at menarche (years)	12.4 ± 1.4	12.3 ± 1.5	0.84
Smoking	Never 11 (64.8%)	49 (70%)	0.41
	Past smokers 0 (0%)	5 (7.1%)	
	Occasionally 3 (17.6%)	4 (5.7%)	
	< 10 cigarettes/day 3 (17.6%)	11 (15.7%)	
	> 10 cigarettes/day 0 (0.0%)	1 (1.4%)	
Hormonal contraception users	9 (52.9%)	32 (45.7%)	0.59
Nulliparous	16 (94.1%)	55 (78.6%)	0.14
Menstrual cycle lenght (days)	28.6 ± 2.8	27.8 ± 4.4	0.59
Menstrual flow lenght (days)	4.1 ± 1.4	4.6 ± 1.3	0.20
Menstrual pain	In all cycles 7 (41.2%)	35 (50%)	0.33
	In some cycles 10 (58.8%)	30 (42.9%)	
	Never 0 (0.0%)	5 (7.1%)	

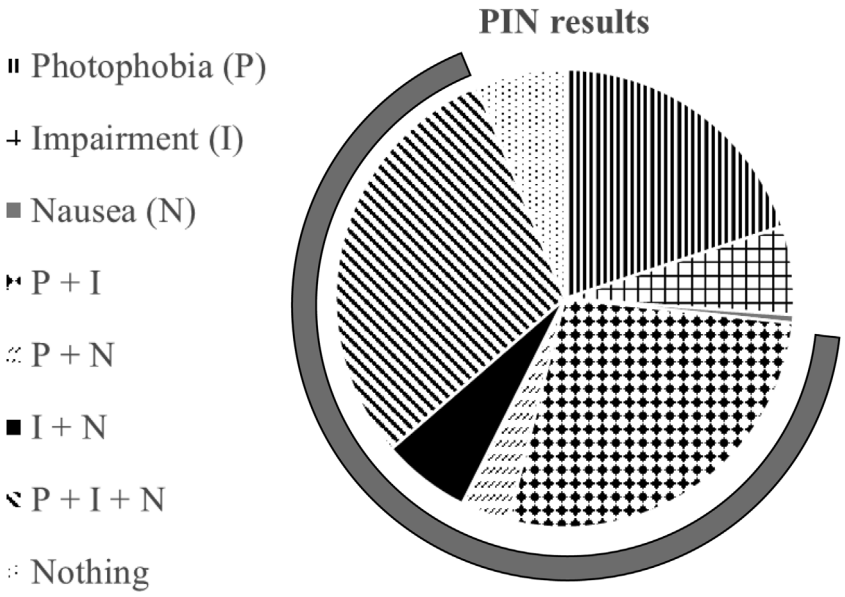

Fig. 1. PIN score results. Prevalence of Photofobia (P), Impairment (I) and Nausea (N), alone or associated, in women with headache (n = 176). Grey circle line indicates the total prevalence of M diagnosed by PIN score (118/176, 67%).

Table 3
Types of drugs "as needed" used before neurological consultation (before neurological consultation) and prescribed by the neurologist during specialized consultation (after neurological consultation) in women with headache selected for specialized evaluation (subjects = 87).

Type of drug	Before neurological consultation	After neurological consultation	p
Triptans	9 (10.3%)	30 (34.5%)	0.0003
NSAIDs	57 (65.5%)	36 (41.4%)	
Combined	9 (10.3%)	16 (18.4%)	
Other	1 (1.1%)	1 (1.1%)	
Nothing	11 (12.8%)	4 (4.6%)	

examined more than 18 million pregnancies in the U.S. between 2000 and 2003. Peripartum M-sufferers compared with non-M subjects had a significantly higher OR of stroke [OR:15.1, 95%CI 8.6–27.4], myocardial infarction [OR:2.1, 95%CI 1.8–2.5], pulmonary embolus/venous thromboembolism [OR:3.2, 95%CI 2.1–7.1] and PE or gestational hypertension [OR:2.3, 95%CI 2.1–2.5] [13].

Other research groups independently explored the prevalence of M in PE-suffering women comparing with unaffected mothers. Facchinetti et al. compared PE-suffering patients with an equal number of controls, finding a higher OR of M in the first group [OR:5.1, 95%CI 2.3–11.0] [14]. Similarly, Adeney found 58 women suffering from M in 244 PE-sufferers, whilst only 76 M-sufferers were detected in 470 controls, yielding an adjusted OR:1.8 [95%CI 1.1–1.8] [15]. In 2005, Scher and collaborators performed a case-control study in a general population comparing 482 women with M and 2,517 controls, finding out an adjusted OR for gestational hypertension of 1.63 [95%CI 1.2–2.1] [16]. Moreover, Czerwinsky et al. found a significantly higher prevalence of PE in women with M [RR:2.5; 95%CI 1.4–4.6] [17]. Furthermore, even Sanchez and co-workers found a 3.5-fold [95% CI, 1.9–6.4] increased risk for PE in women suffering from M prior to pregnancy, with an even higher risk for women suffering from M during pregnancy [OR:4.0, 95%CI 1.9–8.2] [18]. A more recent systematic review published in 2015 confirmed those results: from the available literature, the OR between M-sufferers and controls was 7.9 to 30.7 for ischemic stroke, 1.2 to 1.7 for gestational hypertension and 1.1 to 3.5 for PE [12].

Even preterm birth has been associated with M, but with conflicting results. Facchinetti et al. found no significant association between preterm births and M [14]. A few years later, on the other hand, Chen [19] and Marozio [20] detected a higher OR of preterm births in the M group than for non-M sufferers [OR:1.2; 95% CI 1.1–1.4 and OR:3.2; 95%CI 1.2–8.2, respectively].

Apart from cardiovascular diseases and preterm births, M has been associated with a higher risk of nausea and hyperemesis gravidarum [22] and depression during pregnancy, along with increased rates of anxiety and stress, especially in cases of MA, probably due to common etiopathogenic dysfunctions in the serotonergic and dopaminergic system [23].

Accuracy of PIN-VARS scores

A 100%-sensitivity test correctly identifies all patients with the disease, with a low rate of false negatives. High sensitivity is clearly important where the test is used to identify a serious health risk such as the presence of M. Screening the female population by PIN and VARS scores can be a sensitive test. However, these are not very specific and a high proportion of women with a positive PIN-VARS will be not suffering from M (47%) or MA (54%). On the other hand, a 100% specificity test correctly identifies all patients without the disease, with a low rate of false positives.

The easy tools presented here showed high sensitivity but low specificity, resulting in many migraine-free patients being told that they may have the disease and undergoing further investigations. However, by reason of the unrealistic situation of a 100%-accurate test, a good alternative is for patients who are initially positive to undergo a test with high sensitivity/low specificity (a questionnaire) and a second test with low sensitivity/high specificity

(neurological visit). In this way, nearly all of the false positives may be correctly identified as disease negative.

These results point out that PIN and VARS scores are good tools to distinguish patients with MO or MA from those with common headaches. For these reasons, PIN and VARS scores can be considered good and easy screening tools for gynecologists and general practitioners to identify those young patients who require specific neurological examination before the prescription of a CHC or pregnancy scheduling.

Conclusions

The screening for subjects suffering from M, namely MO and MA, is possible and easy in daily clinical practice with the use of PIN and VARS questionnaires, allowing the doctor to select those patients who require further neurological examinations.

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Tweetable abstract

Screening for subjects suffering from migraine is easy in ob/gyn clinical practice, allowing to select those patients who require further neurological examinations.

Declaration of Competing Interest

Nothing to declare.

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