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Cari tutti,
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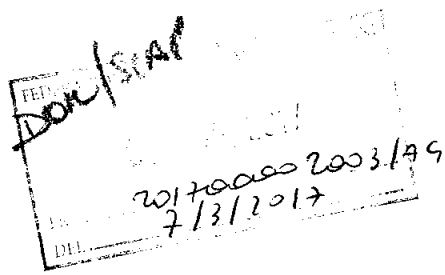

Community pharmacies as epidemiological sentinels of headache: first experience in Italy

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Community pharmacy, medication overuse headache, migraine.

Abbreviations:

MOH medication overuse headache, OTC over-the-counter.

Conflicts of interest:

All the authors certify that there is no actual or potential conflict of interest in relation to this article.

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Summary

Migraine is a disabling neurovascular syndrome which affects 12-15% of the global population and it represents the third cause in years lived with disability in both males and females aged 15-49 years.
Among migraineurs, the symptomatic drug abuse may be a risk factor in the development of medication overuse headache (MOH).
Detecting cases of MOH is not straightforward; community pharmacists may therefore be in a strategic position to identify individuals who self-medicate, particularly with respect to prevent the development of MOH.
In 2014, our group published the results of a survey conducted in Piedmont, Italy, on the patterns of use and dispensing of drugs in patients requesting assistance from pharmacists for relief of a migraine attack.
We decided, now, to expand the scope of the model to a national level. The study is based on cross-sectional face to face interviews using questionnaires, presented in this paper, consisting of a first part regarding the socio-economic situation and a second part which aimed to classify the disease and any excessive use of drugs.
Of the 610 pharmacists trained with an online course, 446 gathered a total of 4425 correctly compiled questionnaires.
The participation of community pharmacies has highlighted various criticalities especially of an organisational nature; however, it also revealed the power of this method as a means of gathering epidemiological data with a capillarity which few other methods can match.
The objective was also to identify each territory's requirements and facilitate the decision-making process in terms of understanding what patients/citizens actually require.

INTRODUCTION

Migraine headache is a disabling neurovascular syndrome which affects 12-15% of the global population; women are especially prone with a rate of 18-20% among the female population. According to a recently published study in *The Lancet* [1], migraine headache represents the third most commonly cited cause in years lived with disability in both males and females aged 15-49 years.
A *review* evaluated which other countries in Europe, and in the world, have utilised community pharmacies to identify headache sufferers as a means to make an early identification of the pathology [2].

The early identification of this pathology could potentially lead to enormous savings for the National Health System as well as a marked improvement in the quality of life for the subjects affected by this condition [3].
Among migraineurs, the overuse of medication, a reward seeking behaviour, may be a risk factor in the development of daily migraine and chronic migraine. Indeed, while truly effective medication does exist for the treatment of migraine, its overuse, both in terms of frequency and therapy duration, may have the paradoxical effect of worsening the situation rather than improving it. This condition, called medication overuse headache (MOH), is a growing problem, with an estimated incidence of 1-2% in the general population and up to 30-50% in tertiary headache centres.
Detecting cases of MOH is not straightforward as the majority of migraineurs tend to rely on self-medication with over-the-counter analgesics (OTC) and, in the course of their lifetime, may never turn to a specialist pain centre or even consult their family doctor [2]. Community pharmacists may therefore be in a strategic position to identify and advise individuals who self-medicate, particularly with respect to prevention and early detection of medication overuse to prevent the development of the MOH. Furthermore, they could have an invaluable role by evaluating through simple tests the risk amongst the chronic migraine population of obesity, which leads to significant costs for the healthcare system and induces major disabilities for the affected subject.
Moreover, exploiting the network of community pharmacies makes it possible to identify those "real life" individuals who for socio-economic reasons are unlikely to turn to a tertiary treatment centre such as a headache centre for treatment. This could help to reduce the social divide in terms of those who seek treatment for headaches.
In 2014 our group published the results of a survey conducted in Piedmont, Italy, on the patterns of use and dispensing of drugs in patients requesting assistance from pharmacists for relief of a migraine attack.
The survey was supported by the Italian Headache Foundation (FICEF), in collaboration with the Order of Pharmacists of Turin, Regional Deputy, and the Department of Scienza e Tecnologia del Farmaco, University of Turin.
The study entailed the administration of a 9-item questionnaire, the first part of which comprised items from the ID Migraine Screener test [4, 5] which investigates the different types of headache and whether the subject suffers from migraine headache according to symptom occurrence and severity. On this basis, subjects were categorized as having "Definite migraine" or "Probable migraine".

Thanks to the interesting findings of that study, both from an epidemiological perspective and a public policy viewpoint [6, 7], the decision was taken to expand the scope of the model to a national level in agreement with the Federation of the Orders of Italian Pharmacists (FOFI), the Department of Scienza e Tecnologia del Farmaco, University of Turin (DSTF), the Italian Foundation for Headaches (FI.CEF), the Epidemiology Unit, ASL TO3, (ASL S.C. a D.U. Servizio Sovrazonale di Epidemiologia), ATF Informatics Society and the Order of Pharmacist of Turin.

MATERIALS AND METHODS

1. *DESIGN OF THE STUDY - QUESTIONNAIRE*

The study was designed as a *cross-sectional survey* based on face-to-face interviews using questionnaires drawn up by experts and based on the scientific literature; given the unusual nature of the centres responsible for recruiting the subjects, i.e. community pharmacies, it was decided to carry out a specific training course for the data gatherers in order to ensure that the data was collected with the most standardised procedure possible.

2. *RECRUITMENT CRITERIA*

The subjects were recruited at a maximum rate of 5 patients per pharmacy per month amongst those entering the pharmacy requesting medicine for self-medication of a headache.

3. *TRAINING*

The training course made use of an online platform which the pharmacists could log on to by compiling a form including their regional code; health service code and AIFA code (see *RECRUITMENT OF PAHARMACIES IN THE AREA – CREATION OF A PHARMACY DATABASE*). The training consisted of an audio file supported by explanatory slideshow. This standard training course for all territories provided through distance learning methods assured an optimised and uniform training time.

4. *RECRUITMENT OF THE PHARMACIES IN THE EXPERIMENTAL AREA - CREATION OF A PHARMACY DATABASE*

For this purpose, the AIFA code was used (http://www.dati.salute.gov.it/dati/dettaglioDataset.jsp?menu=dati&idPag=5 - last date consulted 30/01/2017-). This is an open source system of unique identity codes for each community pharmacy made available by the Ministry of Health.

5. *LOGISTICS ORGANISATION*

To ensure greater control at the level of the individual provinces, a provincial coordinator was appointed, who reported directly to the head of project coordination.

RESULTS AND DISCUSSION

1. *DESIGN OF THE STUDY - QUESTIONNAIRE*

With respect to the previous study [6], some modifications to the questionnaire were made (Table 1). In particular, a section regarding the socio-economic situation of the recruited subjects was added (questions 1-6) in order to understand which were the determining factors in the prevalence of headaches.
The socio-economic questions are the product of studies carried out over an extended time span by the research group of the Epidemiology Unit, experienced in the analysis of social disparities in health treatment, [8] and discussions between university, neurologists and pharmacists. These questions have already been included in other studies carried out in community pharmacies with the aim to investigate the correlation between social factors and the pathology under investigation.

Regarding the second part of the questionnaire, which aimed to classify the pathology and any overuse of medication, some new questions were added compared to the previous version used in other studies (Table 2).
No changes were made to the ID Migraine Screener test [4] which investigates the different types of headache and whether the subject suffers from migraine headache according to symptom occurrence and severity. On this basis, subjects were categorized as having "Definite migraine" or "Probable migraine" [5].
The other questions serve to ascertain whether the subject suffering from migraine is in treatment by a medical professional and whether the MOH condition is acute [9]. The overall objective is to optimise the investigative efficiency of this questionnaire.

2. *RECRUITMENT CRITERIA*

Each pharmacy had the objective to recruit a maximum of 5 subjects/month for each month of the 6-month experiment.
Obviously the maximum numerosity of the questionnaire is disproportionate compared to the potential migraineurs, considering the high prevalence of primary headache among the population.

3. *TRAINING*

Following registration in the database of Pharmacies, the pharmacists underwent a 3-hour training course with a nationally uniform structure for all areas of the country.

The online training course consisted of 3 1-hour sections using a slide presentation:

1) classification and epidemiological assessment of primary headaches;
2) clinical physio-pathology of primary headaches;
3) headache medication and the headache questionnaire.

After completing each section, the pharmacist had to answer 3 multiple-choice questions correctly in order to proceed to the successive section in the training course. Only after passing all 3 sections was the pharmacist deemed to have completed the training course (Table 3-A).

After completing the training procedure, each pharmacist was provided with a unique username and password linked to the Pharmacy database (AIFA code). These could be used to log on to the Questionnaire database in order to access the questionnaire to be filled in online (Tables 1-2). The study was designed in such a way that it was possible to trace the location of the pharmacies and to gather questionnaires systematically so as obtain the maximum amount of location-specific information possible.

4 RECRUITMENT OF PHARMACIES IN THE EXPERIMENTAL AREAS - CREATION OF A PHARMACY DATABASE

Utilising the AIFA code in the Pharmacy database allowed the identification of the location of the pharmacy in Italy. Through the code, it is possible to determine the region, province, city and street address of the pharmacies present in the database.
The system was conceived to reduce the time to a minimum and this allowed rapid access to all the areas involved in the study. In addition to that, the registration process for the pharmacies did not require detailed information which would have made it time-consuming and overly complex. The information requested was, however, sufficient to enable geo-localisation; for the socio-economic stratification, by cross-checking the geographical data and the data gathered in the questionnaires, it was possible to obtain a figure for the evaluation of the requirements.

5 LOGISTICS ORGANISATION

90 provincial coordination officers were appointed thanks to whom it was possible to recruit participants in 59 out of the total of 107 Italian provinces. The number of participating pharmacies was 514, with a total of 610 pharmacists trained (Table 3-B). Of the 610 pharmacists, 446 gathered questionnaires. The total number of correctly compiled questionnaires amounted to 4425. As it is possible to note in Table 4, there is a downward gradient running from north to south of the country both in terms of participating pharmacies/trained pharmacists and the number of questionnaires returned.

Stratification based on socio-economic characteristics is essential in determining how effective the community pharmacy may be in eliminating social disparities.

CONCLUSION

The participation of community pharmacies, which was on an entirely voluntary basis, in an area-specific project shed light on various criticalities especially of an organisational nature; however, it also revealed the power of this method as a means of gathering epidemiological data with a capillarity which few other methods can match.
One of the most critical points which must be evidenced is the complexity in creating a pharmacy database: in future, greater use of IT instruments must be made in order to prevent errors in data entry for the pharmacy and personal information.

The use of the AIFA code was an important instrument in tracing the origin of the information entered. However, it became clear that pharmacists had some difficulty in finding their own AIFA code. In any case, this code remains a powerful tool for the future mapping of a territory's requirements based on community pharmacies.
The objective, therefore, was not only to gather data, but to identify each territory's requirements and, hence, facilitate the decision-making process in terms of understanding what patients/citizens actually require.

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1) **Sex** M F
2) **Age** [actual age]
3) **Height** [in cm] and **weight** [in kg]
4) **Education** [the highest qualification attained]
University degree or higher
.....
4-5-year High School Diploma valid for third-level education
.....
2-3-year High School Diploma not valid for third-level education .....
Junior High School Diploma (or apprenticeship/job) .....
Primary school exam .....
No qualification .....
5) **Occupation**
If employed:
Manual labourer .....
Employee non-manual (conceptual/intellectual).....
Self-employed:
Businessperson .....
Professional .....
Self-employed worker .....
Unemployed .....
Homemaker .....
Student .....
Retired .....
Other (military service, invalid etc.) .....
6) How many members are there in your family? Number of people in your household (including patient)?

Table 1. "Headache and Community Pharmacies" Questionnaire part 1 -Social Questionnaire-.

7) **ID Migraine screener test**
Did you have the following with your headaches:
You felt nauseated or sick to your stomach? YES/NO
Light bothered you (a lot more than when you didn't have headaches)? YES/NO
Your headaches limited your ability to work, study, or do what you needed to do for at least 1 day? YES/NO
If the patient answers YES to at least three questions, there is a 95% probability that he/she suffers from migraines
8) **How long have you been having headaches**? <1 year; 1-4 years; 5-9 years; ≥10 years.
9) **How many days have you had a headache in the last 3 months**? ....n°
10) **How many days each month do you take pain medication for a headache**? up to 3; from 4 to 10; more than 10.
11) **Does the headache go away after you have taken pain medication?** Yes: Often: Rarely: No.
12) **Which medicines do you usually take when you have an acute attack?** NONSTEROIDAL ANTI-INFLAMMATORY DRUGS (NSAIDs); ERGOT-DERIVATIVES; TRYPTANS; COMBINATION DRUGS; OTHER ANALGESICS [more than one answer is permitted] .
13) **Are you being treated by a medical professional?** [more than one answer is allowed] NOBODY; MY FAMILY DOCTOR; A SPECIALIST; A HEADACHE CENTRE
14) **Do you regard your headache as an illness?** YES/NO.

Table 2. "Headache and Community Pharmacy" Questionnaire part 2.