SELF-MEDICATION WITH OVER-THE-COUNTER ANALGESICS: A SURVEY OF PATIENT CHARACTERISTICS AND CONCERNS ABOUT PAIN MEDICATION

Running title: Self-medication with OTC analgesics

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ABSTRACT

Pain is a common reason for self-medication with over-the-counter (OTC) analgesics. However, this self-treating population has remained largely uncharacterized. This cross-sectional observational study investigated individuals who self-medicate their pain with OTC analgesics to elucidate their pain characteristics and medication use. In addition, presence of and risk factors for concerns about pain medication were examined. The clinical profile of the participants (n=1889) was worse than expected with long-standing pain complaints (median pain duration of 9 years), pain located at multiple body sites (median of 4, and 13% with ≥10 painful body areas), about one third suffering from daily pain and about 40% experiencing substantial pain-related disability. Head (58.6% of sample), low back (43.6%) and neck (30.7%) were the most common pain locations. About 73% had a physician diagnosis, mainly migraine and osteoarthritis. Paracetamol (used by 68.6% of patients) and NSAID (46.8%) were the most frequently used pain medications. About 40% of our sample showed substantial concern about the perceived need for pain medication and the perceived potential for harmful effects (e.g. fear for addiction). These findings highlight the importance for health professionals to systematically probe pain patients about their self-medication practices and explore attitudes about pain medication.

Perspective

This study found that the clinical picture of people who self-medicate their pain with OTC analgesics looked worse than expected. We also identified substantial concerns about pain medication. Therefore, we recommend that health professionals systematically probe pain patients about their self-medication practices and explore concerns about pain medication.

INTRODUCTION

Pain is a major healthcare problem. According to the most recent Global Burden of Disease Study, several of the most common conditions are pain problems (such as tension-type headache, migraine and low back pain). Also, pain is the leading cause of disability, with low back pain (first), migraine (second), neck pain (sixth), and other musculoskeletal disorders (seventh) dominating the top ten of most important causes of Years Lived with Disability (YLD). [4]

Medication is by far the most applied treatment method for pain. There are various medications available for pain relief; these include over-the-counter (OTC) (e.g. paracetamol, aspirin, certain NSAIDs) as well as prescription medications (e.g. NSAIDs, opioids). Over the past years, several population-based studies have shown that self-medication with OTC analgesics is common [2, 7, 22]. Prevalence estimates for the use of OTC analgesics vary substantially between countries and according to definitions used. For example, in the Norwegian HUNT-3 Study (2006-2008) the prevalence of using OTC analgesics at least once per week in the last month was 47% [7]. A population survey of adults in Germany (2008-2011) found that 12.2% had used an OTC analgesic in the previous week [22]. According to an analysis of Spanish data retrieved from the 2009 European Health Survey, 23.7% of persons with current pain self-medicated with OTC analgesics [2]. Self-medication of pain is common, and it will probably further increase as patients are stimulated to take an active role in their ill-health. However, the individuals who self-medicate their pain are poorly characterized. Population-based studies focus on determining prevalence of and factors associated with use of OTC analgesics. Other studies investigated whether OTC analgesics are used safely and appropriately [12, 15, 21, 23, 26]. A thorough characterization of individuals who self-medicate their pain, has not been performed yet. Many questions remain unanswered: Do these patients suffer from occasional or chronic pain? From mild or severely disabling pain? Did they ever see a physician for their pain complaints? Do they combine several pain medications? How often do they use their pain medication? Do they have concerns about their pain medications (e.g. fear for addiction, tolerance or potential side

effects). Identification of these patient features may provide an avenue for improving care. This information may be relevant for physicians, who are often not aware of the self-medication practices of patients, as well as for community pharmacists, who can play a significant role in coaching self-medication. In this study, we aimed to characterize the patients who self-medicate their pain. We conducted a questionnaire-based survey among individuals who self-medicate pain complaints to elucidate their pain characteristics and medication use. In addition, we determined presence of and risk factors for concerns about pain medication.

METHODS

Study design and study population

The design of the present study has been described elsewhere [20]. Briefly, a cross-sectional observational study was carried out from December 2012 until May 2013 in 202 community pharmacies in Belgium. Community pharmacists consecutively invited pharmacy customers purchasing an OTC systemic analgesic to participate in the study. Of note, persons presenting with a prescription for an OTC systemic analgesic were not eligible. OTC systemic analgesics available in Belgium are paracetamol, acetylsalicylic acid, ibuprofen 200-400 mg, naproxen 200 mg, and fixed dose combinations of simple analgesics with caffeine. Persons were eligible when meeting the following inclusion criteria: purchasing the analgesic for themselves, being aged ≥18 years, and suffering from pain during at least one full day in the last month. It was planned to recruit 10 patients from each of the pharmacies.

In Belgium, the sale of OTC medicines is limited to pharmacies. Therefore, pharmacies are an ideal setting to recruit a representative sample of persons with intentions to self-medicate.

The study protocol was approved by the Ethics Committees of Ghent University Hospital (for Flanders) and CHU Liege (for Wallonia), and all patients gave written informed consent.

Data collection

Participants completed a self-administered questionnaire that was developed by the multidisciplinary research team (a neurologist, a pain psychologist, a general practitioner, a clinical pharmacologist and pharmacists). Participants answered questions on their sociodemographics (gender, age, marital status, employment status and education level) and self-rated health ("How in general would you rate your health?'' with response options of "excellent, very good, good, fair, or poor" [8]). They indicated the location(s) of their current pain on a full body manikin (front and back views; separated into 45 mutually exclusive areas [18]; see online addendum) and reported physician diagnosis of current pain (if available), pain duration and pain frequency. Pain disability was assessed by the Von Korff Pain Grading Scale [25]. This 7-item questionnaire measures the degree of pain intensity and activity-related disability in the past three months. Six items are scored on 11-point Likert scales (0 = "no pain/disability" and 10 = "worst pain/total disability"). The seventh item asks for the number of days that pain has kept respondents from their typical activities. Total scores classify respondents into one of four levels of pain disability (grade I: low disability and low pain intensity, grade II: low disability and high pain intensity, grade III: high disability and moderate limitation of activities, grade IV: high disability and severe limitation of activities).

Respondents also reported their current pain medication (OTC and prescribed) with frequency of use during the prior month, and on whose advice they used the medication. Participants' attitudes about pain medication were determined using items from the Pain Medication Attitude Questionnaire (PMAQ) [19]. The PMAQ assesses concerns held by patients regarding their pain medication. It has 47 items grouped into seven domains (addiction, need, scrutiny, side effects, tolerance, mistrust and withdrawal). Each item is scored on a 6-point Likert scale ranging from 0 ("never true") to 5 ("always true"). We did not use the complete PMAQ but selected a number of items that were considered of relevance to our study. Item selection was done by a multidisciplinary consensus panel comprising a neurologist (KP), pain psychologist (GC) and pharmacist (EM). Firstly, each member of the panel independently selected one or more items

from each PMAQ domain, based on their own expertise and experience. Secondly, the panel developed a consensus on item selection during a face-to-face meeting (psychometric properties of the items from the original PMAQ [19] were used to support the discussion). This resulted in a final selection of ten PMAQ items which are displayed in Table 4. We grouped the selected items according to the domains used in the original PMAQ [19]. We calculated an overall PMAQ score as the mean of the ten individual item scores. As two of the ten items only applied to patients who also use prescription pain medication (Table 4, items marked with [b]), we also recalculated the overall PMAQ score by excluding these two items in determining the mean of the individual item scores (i.e. mean of the eight individual item scores that could be completed by all respondents).

Statistical analysis

Multivariate linear regression was used to evaluate the relationship between the level of concern about medication (defined as the overall PMAQ score) and all other patient factors. The dependent variable was the overall PMAQ score. Independent variables included age, gender, marital status, employment status, education level, self-rated health, having a physician diagnosis of current pain, recent physician consultation for pain (i.e. <6 months ago), number of pain regions, pain location (limited to the 3 most common pain locations), pain duration, pain frequency, pain disability (Von Korff Pain Grading Scale), number and type of pain medications (limited to the 3 most frequently used medications), and combined use of OTC analgesics and prescription pain medication. We used a manual F-test-based backward elimination method and nonsignificant factors ($P > 0.05$) were consecutively removed. Prior to the analysis, variables were assessed for co-linearity. We also checked for relevant 2-way interactions between the variables retained in the model. In addition, the analysis was redone using the recalculated version of overall PMAQ score (i.e. mean of the eight individual item scores that could be completed by all respondents). This was done to check whether or not this yielded the same patient factors associated with overall PMAQ score. The analyses were performed by using R software (version 3.2.0; www.r-project.org).

RESULTS

In the 202 participating pharmacies, 10423 patients were consecutively contacted and screened for eligibility, of which 3580 (34%) matched the inclusion criteria. About 53% (n=1889) of them agreed to participate (Figure 1). The basic characteristics of the study population are displayed in Table 1.

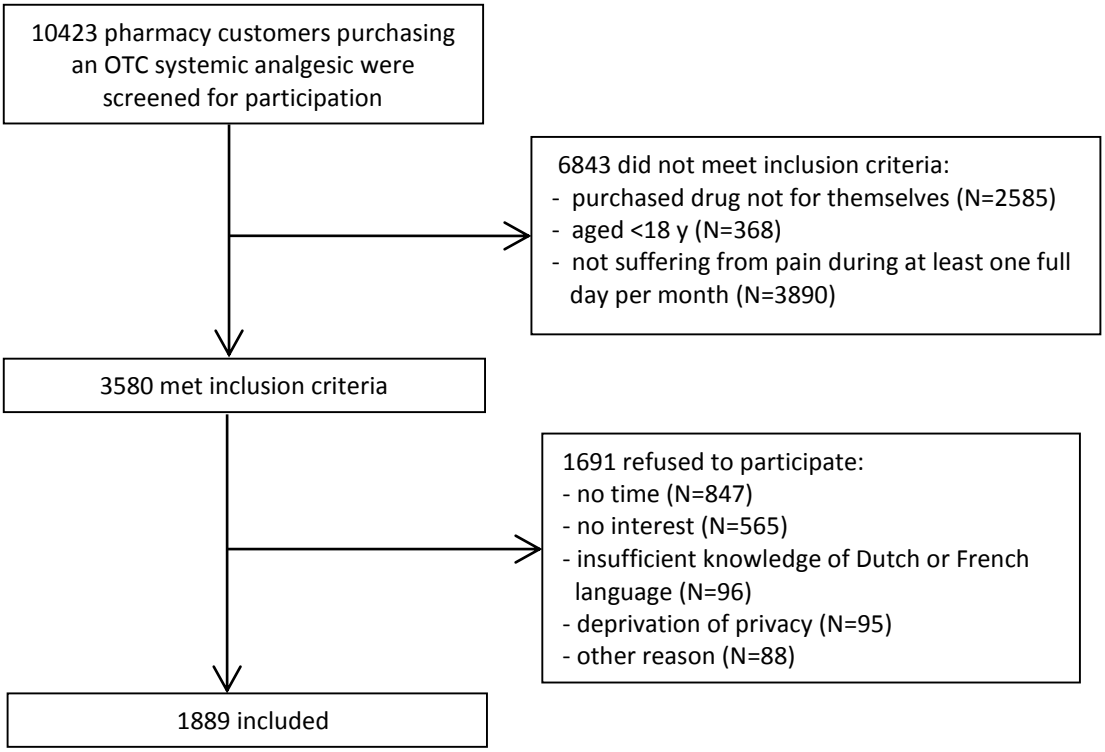

Figure 1: Flow scheme of the participant recruitment process.

Table 1: Basic characteristics (N=1889)

Female sex[a]	1405 (74.8)
Age (years)	
Mean±SD	51.7±16.3
<25	125 (6.6)
25-40	340 (18.0)
41-55	674 (35.8)
56-70	486 (25.8)
>70	260 (13.8)
Marital status[a]	
Alone	364 (19.5)
Married or cohabiting	1177 (63.2)
Divorced	156 (8.4)
Widowed	166 (8.9)
Employment status[a]	
Employed	992 (52.8)
Unemployed	72 (3.8)
Retired	490 (26.0)
Not working due to ill health	100 (5.3)
Househusband/housewife	157 (8.4)
Student	68 (3.6)
Education level[a]	
Primary education	215 (11.4)
Secondary education	1073 (57.0)
Higher education	595 (31.6)
Self-rated health	
Excellent	47 (2.5)
Very good	258 (13.7)
Good	797 (42.2)
Fair	647 (34.3)
Poor	140 (7.4)

Data are presented as N (%), unless indicated otherwise.

[a] Subject to missing data

Pain characteristics

Participants marked a median of 4 painful areas (from 45) on the body manikin (Table 2). Head (58.6% of the sample), low back (43.6%) and neck (30.7%) were the most common pain locations. About 60% (n=1089) of patients had had their current pain complaints longer than 5 years. The median number of pain days in the past 3 months was 36, and about one third (n=678) of participants reported daily pain for the last 3 months. Forty-one percent experienced substantial pain-related disability (i.e. grade III or IV on the Von Korff Pain Grading Scale).

The vast majority of participants (1742/1889; 92.2%) had consulted a physician for their current pain complaints. Their last pain-related consultation was less than 6 months ago (1167/1742; 67.0%), between 6 and 12 months ago (237/1742; 13.6%), between 1 and 2 years ago (108/1742; 6.2%) and more than 2 years ago (183/1742; 10.5%). Some patients failed to remember (47/1742; 2.7%). Almost 75% (n=1386) reported a physician diagnosis of current pain complaints. Migraine (436/1386; 31.5%), osteoarthritis (226/1386; 16.3%), hernia (119/1386; 8.6%) and fibromyalgia (55/1386; 4.0%) were the most prevalent diagnoses.

Table 2: Pain characteristics

N° of pain areas marked on body manikin (range 1-45)	
Median (IQR)	4 (5)
1-3	729 (38.6)
4-6	685 (36.3)
7-9	222 (11.8)
≥10	253 (13.4)
Pain location	
Abdomen	216 (11.4)
Chest	75 (4.0)
Foot	282 (14.9)
Forearm	172 (9.1)
Genital area	65 (3.4)
Hand	249 (13.2)
Head	1107 (58.6)
Hip	331 (16.5)
Low back	823 (43.6)
Lower leg/ankle	352 (18.6)
Neck	580 (30.7)
Shoulder	483 (25.6)
Upper arm	187 (9.9)
Upper back	207 (11.0)
Upper leg/knee	461 (24.4)
Pain duration (years)[a]	
Median (IQR)	9 (17)
0-5	742 (40.5)
6-10	301 (16.4)
11-15	229 (12.5)
16-20	130 (7.1)
>20	429 (23.4)
Pain frequency (n° of pain days in the past 3 months)[a]	
Median (IQR)	35 (80)
0-15	643 (34.2)
16-30	290 (15.4)
31-60	194 (10.3)
61-89	73 (3.9)
90	678 (36.1)
Pain disability (Von Korff Pain Grading Scale)[a,b]	
Grade I	445 (23.9)
Grade II	654 (35.2)
Grade III	398 (21.4)
Grade IV	362 (19.5)

Data are presented as N (%), unless indicated otherwise.

[a] Subject to missing data; [b] Grade I: low disability low intensity, Grade II: low disability high intensity, Grade III: high disability moderately limiting, Grade IV: high disability severely limiting

Use of pain medication

The 1889 participants in this study were taking a total of 3795 pain medications, which corresponds to a mean of 2.0 (SD 1.1) per subject. Sixty-two percent only used OTC pain medication, and 38% combined OTC analgesics with pain medication on prescription. Paracetamol (used by 68.6% of the study population), NSAID (46.8%) and fixed dose combinations of simple analgesics with caffeine or codeine (21.9%) were the most frequently used medications (Table 3). Only few participants used preventive pain medication, such as certain antiepileptics or antidepressants (Table 3). Most medications were taken on medical doctor's (2516/3746; 67.2%) or pharmacist's advice (539/3746; 14.4%). Almost 30% (n=525) of the study population reported daily use of pain medication.

Table 3: Pain medication

	N (%)
Type	
Paracetamol	1296 (68.6)
Acetylsalicylic acid	73 (3.9)
Oral NSAIDs	884 (46.8)
Combination analgesics[a]	413 (21.9)
Caffeine-containing combinations	342 (18.1)
Codeine-containing combinations	87 (4.6)
Opioids	245 (13.0)
Triptans	101 (5.3)
Ergots	11 (0.6)
Muscle relaxants	47 (2.5)
Topical analgesics (NSAID or salicylates)	86 (4.6)
Antiepileptics	41 (2.2)
Antidepressants	38 (2.0)
Frequency of use (n° of medication days in past month)	
Median (IQR)	10 (25)
0-9	779 (41.2)
10-19	378 (20.0)
20-29	207 (11.0)
30	525 (27.8)

[a] Fixed dose combinations of simple analgesics with caffeine or codeine.

Concerns about pain medication

Our sample showed the highest level of concern about the need for pain medication. For example, in response to the item "I could cope without my pain medication(s)", 61% indicated "never true", "almost never true" or "seldom true". In addition, a substantial proportion (about 30 to 40%) answered "often true", "almost always true" or "always true" to the items about addiction, tolerance and side effects (Table 4).

Table 4: Concerns about pain medication (items selected from the Pain Medication Attitude Questionnaire, PMAQ).

	Mean (SD) Likert score[a]	**% of patients responding**	
		'never true', 'almost never true' or 'seldom true'	*'often true', 'almost always true' or 'always true'*
Addiction			
"I am concerned that taking medication for a long time will lead to addiction"	1.7 (1.7)	61.9	38.1
Need			
"I would be unwilling to reduce my pain medication(s)"	2.2 (1.9)	54.5	45.5
"I could cope without my pain medication(s)"	3.3 (1.5)	60.9	39.0
"I feel that I need more pain medication(s) than my doctor is giving me" [b]	1.3 (1.5)	74.1	25.9
Scrutiny			
"I worry what others think about my use of pain medication(s)"	0.7 (1.2)	88.6	11.5
Side effects			
"I have concerns about the side effects from my pain medication(s)"	1.6 (1.5)	67.4	32.7
"I am afraid that I do not know enough about side effects"	1.6 (1.4)	68.8	31.2
Tolerance			
"It worries me that I have to increase the dose to get the same pain relief"	1.9 (1.7)	57.8	42.2
Mistrust			
"I am afraid that I am being prescribed the wrong pain medication(s)" [b]	0.9 (1.2)	85.6	14.4
Withdrawal			
"I worry that I will have some withdrawal symptoms if I stop my medication"	1.0 (1.5)	79.6	20.4

[a] Each item was answered on a 6-point Likert scale, ranging from 0 (''never true'') to 5 (''always true'').

[b] This item was only answered by patients taking prescribed medicines.

The results of the multivariate linear regression model for determining patient characteristics associated with concerns about pain medication are shown in Table 5. Poorer self-rated health and higher levels of disability were the factors most strongly associated with higher concerns about pain medication. Concerns about pain medication were also higher in patients who had recently consulted a physician for their pain-related complaints, patients using caffeine-containing combination analgesics, patients with headache, patients combining OTC analgesics with prescription pain medication, patients using their pain medication frequently and divorced patients.

Multivariate analysis using the recalculated version of overall PMAQ score yielded exactly the same patient factors associated with concerns about pain medication (data not shown but available on request).

Table 5: Patient characteristics associated with concerns about pain medication [a].

	Estimate (SE)[b]	P value[c]
Self-rated health		**<2.2 x e^{-16}**
Excellent	[Reference]	
Very good	0.06449 (0.11701)	0.581585
Good	0.19071 (0.11134)	0.086895
Fair	0.34344 (0.11445)	0.002730
Poor	0.48084 (0.13036)	0.000232
Pain disability (Von Korff Pain Grading Scale)		**<2.2 x e^{-16}**
Grade I	[Reference]	
Grade II	0.16773 (0.04649)	0.000317
Grade III	0.29724 (0.05387)	3.92 x e^{-8}
Grade IV	0.46152 (0.06094)	5.75 x e^{-14}
Recent physician consultation for pain (i.e. <6 months ago)		**2.37 x e^{-7}**
No	[Reference]	
Yes	0.08893 (0.03935)	0.023588
Uses caffeine-containing combination analgesics		**1.73 x e^{-6}**
No	[Reference]	
Yes	0.21043 (0.04647)	6.34 x e^{-6}
Headache as pain location		**2.143 x e^{-6}**
No	[Reference]	
Yes	0.14894	5.93 x e^{-5}
Combines OTC analgesics with prescription pain medication		**9.014 x e^{-5}**
No	[Reference]	
Yes	0.11493 (0.03776)	0.002372
Frequency of pain medication use		**0.0001161**
≤7 medication days in past month	[Reference]	
8-15	0.05387 (0.04768)	0.258656
>15	0.19308 (0.04688)	3.98 x e^{-5}
Marital status		**0.0007470**
Alone	[Reference]	
Married or cohabiting	0.06248 (0.04428)	0.158407
Divorced	0.17807 (0.07085)	0.012046
Widowed	-0.05215 (0.07011)	0.457106

[a] Table reports results of a multivariate linear regression model of patient factors associated with concerns about pain medication (defined as the overall PMAQ score). The dependent variable was the overall PMAQ score. Independent variables included age, gender, marital status, employment status, education level, self-rated health, having a physician diagnosis of current pain complaints, recent physician consultation for pain (<6 months ago), n° of pain areas, pain location, pain duration, pain frequency, pain disability (Von Korff Pain Grading Scale), n° and type of pain medications, and combining OTC analgesics with prescription pain medication.

[b] Estimates indicate how much the dependent variable (i.e. overall PMAQ score) varies with the independent variable, when all other independent variables are held constant. The higher the absolute value of the estimate, the stronger the effect on overall PMAQ score. For example, there is an increase in overall PMAQ score of 0.48084 in patients with poor self-rated health compared to patients with excellent self-rated health. P values for the estimates are displayed in column 'P values' (regular font, not bold).

[c] P values in bold represent p values for the F-test. These indicate the strength of association of the patient factor with overall PMAQ score; the lower the p value, the stronger the association with overall PMAQ score. In this Table, patient factors are arranged in decreasing order of strength of association with overall PMAQ score. P values in regular font (not bold) are P values for the estimates (see column 'Estimate (SE)').

DISCUSSION

This study aimed to characterize patients who self-medicate with OTC analgesics for their pain. There were some interesting and surprising results. The head was by far the most prevalent pain location, with almost 60% reporting headache. Moreover, almost one quarter of the total sample reported to be diagnosed with migraine. The actual migraine prevalence in our study population is likely to be higher because migraine is generally known to be an underdiagnosed condition [3, 9, 16]. Altogether these findings confirm that headache is a very common reason for self-medication with OTC analgesics. Although often viewed as a trivial complaint, headache can cause significant distress with substantial impact on quality of life [4] as well as economic burden due to lost productivity and direct healthcare costs [1, 13]. Therefore, our findings call for a well-organized and effective integrated care pathway for headache that is focused primarily within the primary care setting, including adequately educated health professionals that are easily accessible to the public and that work in cooperation with specialist care [5]. Community pharmacists can play a key role in such care pathway. They are well-placed to detect and advise people who self-medicate (e.g. informing about the appropriate use of OTC analgesics, discouraging overuse, timely referral to a physician).

The overall clinical picture of our sample is worse than expected, with long-standing pain complaints (median pain duration of 9 years), pain located at multiple body sites (median of 4, and 13% with ≥10 painful body areas), about one third suffering from daily pain and about 40% experiencing substantial pain-related disability. Intuitively, one would associate the use of OTC analgesics with occasional and/or mild pain. This, however, clearly was not the case in the present study. One might assume that the considerable level of pain-related disability is caused by the high number of individuals with headache in the sample. Headache is both common and disabling. However, the percentage of participants with higher disability levels (i.e. grade III or IV on the Von Korff Pain Grading Scale) in the subgroup with headache

and the subgroup without headache was found to be quasi identical (39.4% vs 43.6%), thus rejecting this hypothesis.

The sample's medication use seems not to match with their clinical profile. It is remarkable that only very few respondents consumed preventive pain medication. The use of migraine-specific acute medication (triptans) was also low (5%), despite the considerable number of migraineurs in the sample. The question is, why do people with disabling chronic pain self-treat with OTC analgesics? Our participants seem not completely lapsed from medical care: 80% had consulted a physician for their pain complaints in the past year. So exclusive self-medication without seeing a doctor cannot explain our findings. The easy accessibility of OTC drugs (i.e. no doctor's consultation required) could be an explanation. Another possible explanation, however, may lie in the participants' concerns about pain medication. The results of the PMAQ questionnaire revealed a high perceived need for pain medication and substantial concerns about (perceived) potential harms (i.e. addiction, tolerance and side effects). From this perspective, individuals with chronic pain might use OTC analgesics as a harm reduction strategy, by seeking some level of pain relief while also avoiding or reducing the potential harms associated with prescription pain medication. Such harm reduction strategy has been described previously by chronic pain sufferers in a qualitative interview study [10]. Participants of that qualitative study cited several reasons to avoid prescription pain medication, including: (a) maintaining awareness of pain to monitor symptoms and avoid further damage; (b) saving medication for when really needed; (c) perception of medication as less effective if taken often; (d) concern that pain medications impair ability to function normally; and (e) concern about addiction. They regarded prescription pain medication as a poor coping strategy, as they know pain would return as soon as medication wore off. Instead, participants chose to use OTC pain medications, still with reluctance, to mitigate downside risks while still gaining some level of relief [10]. Such benefit/risk trade-offs are in line with the necessity-concerns framework that is currently prevailing in drug adherence research [11, 14]. There is evidence that necessity and concern beliefs about medicines are

correlated with adherence in a wide variety of conditions [11, 14]. In addition, similar observations have been reported by a recent study about migraine sufferer's willingness to take migraine prophylactic medication [24]. Migraine patients were informed about the likelihood of experiencing side effects for several migraine prophylactic drugs and were subsequently asked if they would be willing to take the medication for a given headache reduction level. Strikingly, less than 60% of participants were willing to take any of these medications when they would provide about 50% reduction in headache days/month, while this is a realistic and clinically relevant outcome with migraine prophylaxis [24]. Moreover, the idea of taking a pill each and every day for many years or even lifelong to prevent only half of migraine attacks might also contribute to patients' reluctance towards preventive medication, especially in young patients [6].

The current study also determined patient characteristics associated with concerns about medication. We were surprised to find that sociodemographic factors were not associated with medication-related concerns (except for marital status: divorced people were estimated to have slightly higher concerns than people who live alone). So from a clinician's point of view, it is important to realize that any patient can have worries about pain medication; irrespective of gender, age, employment status or education level. The factors that were most strongly associated with concerns about medication were linked with the patient's clinical condition, i.e. self-rated health status and disability level. More recent consultations with the medical doctor, which might be regarded as indicator for severity of the pain condition or for anxiety or depressive feelings, were also associated with higher concerns. It is unclear why having headache was associated with higher concerns. One possible explanation might be the recent increase in public attention for medication-overuse headache (a worsening of a pre-existing headache owing to overuse of pain relieving medication). Knowing that inappropriate use of pain medication is capable of deteriorating headaches increase concern. The other factors associated with increased concerns are linked to the medication itself, i.e. the use of combination analgesics, concomitant use of prescription pain medication and a high frequency of use.

The data from this study should be considered in the context of its limitations. First, we used self-reported data, which may be subject to recall bias. Physician diagnoses were also self-reported, so these should be interpreted with caution. For example, patients may have a tendency to report “any bad headache” as a migraine headache. However, it is reassuring that there is considerable evidence for the validity of self-reported diagnosis of migraine [17]. Second, a relatively high number of potential participants refused to participate in the study (47%). Potential bias caused by those who refused participation could not be assessed as our Ethics Committee prohibits data collection in study refusers. However, we did record reasons for refusal (‘no time’ and ‘no interest’ were the most commonly given reasons). Third, we did not use the complete version of the PMAQ questionnaire because many items were not relevant for people who only use OTC analgesics. Fourth, we did not assess whether the physician was aware of patients’ use of OTC analgesics.

A strength of this study is its large sample size in a population that is largely uncharacterized so far. Another asset is the exploration of patients’ attitudes and concerns towards pain medication, as recognizing such concerns is key to providing patient-centered care.

Our study design and setting aimed to minimize the risk of selection bias. However, the worse than expected clinical picture may suggest a selection bias by severity as we only included individuals suffering from pain during at least **one full day** in the past month. This inclusion criterion was chosen purposively to select patients with longer-lasting pain attacks because they are clinically more relevant and may be most in need of care. In addition, patients with more severe pain complaints may have been more motivated to participate in the study, which could be another potential reason for the worse than expected clinical profile. It is also relevant to note that only pharmacy customers coming themselves to the pharmacy were eligible for participation, so patients with poor mobility who rely on another person for their medication purchase will not be represented in our sample. Our data may thus reflect an underestimation of the situation in real life. In light of this, our findings may not be generalizable to all

individuals using OTC analgesics. Another possible limitation of generalizability is that our sample was predominantly female (75%). This is probably related to the fact that chronic pain and particularly headache are more common in women. Regarding generalizability to other countries with different health care systems, it is important to bear in mind that patients' out-of-pocket cost for doctor's visits and medication are low in Belgium (due to a compulsory health insurance that covers the entire population and with a broad benefits package). In countries with less accessible health care systems, people with pain might be less likely to seek medical care, and thus rates of doctor's consultation and diagnosis as well as the use of prescription pain medication may be lower.

In conclusion, we observed a high prevalence of headache as well as a high prevalence of long-standing, frequent and disabling pain among adults who self-medicate pain complaints (that at least lasted one full day). Furthermore, we noticed a high perceived need for pain medication and substantial concerns about its potential harms. Based on our findings we recommend that health professionals systematically and concretely probe pain patients about their self-medication practices (including dose and dosing frequency), and explore attitudes about pain medication in an open and nonjudgmental way, at the initiation of therapy and during (long-term) follow-up.

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FIGURE AND TABLE LEGENDS

Figure 1: Flow scheme of the participant recruitment process.

Table 1: Basic characteristics (N=1889).

Table 2: Pain characteristics.

Table 3: Pain medication

Table 4: Concerns about pain medication (items selected from the Pain Medication Attitude Questionnaire, PMAQ).

Table 5: Patient characteristics associated with concerns about pain medication [a].

ADDENDUM: Full body manikin used to define the 45 pain sites in the front and the back [18].