



Changes Over Time of Prescription and Nonprescription Analgesics for Headache With or Without Other Somatic Pain: Effects of Prescription Regulatory Changes

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Abstract: The aim of this study was to examine the association and changes over time between headaches with or without somatic pain and the self-reported use of pain medication. The study further examined whether the law amendment in 2003 in Norway releasing the sale of nonprescription drugs to shops has changed these relationships. The study is on the basis of repeated self-report cross-sectional studies from 1998 to 2012 in Norway. A total of 27,247 adults were included. As expected, there was a strong association between headache, especially headache with comorbid somatic pain and consumption of prescription versus nonprescription analgesics, although the overall consumption decreased slightly after 2003. We conclude that the strong association between especially headache, whether complicated by somatic pain or not, and the consumption of prescription-free analgesics did not seem to be negatively affected by the prescription regulatory changes. The very high use of nonprescription medication among headache patients suggests the need for continued observation and information regarding the risk of medication-overuse headache.

Perspective: In Norway, headache was strongly associated with use of over-the-counter analgesics, for other somatic pain prescription analgesics were equally common. Between 1998 and 2012 headache and related analgesic consumption was reduced and other somatic pain increased. Making over-the-counter analgesics available outside pharmacies in 2003 did not increase the self-reported intake.

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Key words: Headaches, somatic pain, pain medication, adults, analgesics.

Headaches are common health problems with a global prevalence of 47%.¹³ Headaches have been classified according to the International Classification of Headache Disorders-II.¹¹ The new classification, International Classification of Headache Disorders-III, also exists in a beta version which was not available when the present study was performed.¹² The

most common headaches are primary headaches, especially migraine and tension type headache.^{15,21} These headaches are subdivided, on the basis of frequency, into episodic and chronic forms. A much debated chronic headache entity is medication overuse headache (MOH).⁵ This is a chronic headache (headache frequency > 15 days per month), which has developed in parallel with overuse of headache medication.¹¹ It is well known that removal of the overuse leads to headache improvement in most cases, thus illustrating the partly causative association between medication intake and headache frequency.⁴ MOH prevalence is estimated at approximately 1 to 2% of the general population with higher prevalence among women than among men.¹ Several studies show that medication overuse occurs in

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17 to 62% of those with chronic headache.¹ In Norway, paracetamol and ibuprofen, which are available as prescription-free over-the-counter medications, are the most common medications associated with MOH in the general population.⁷

In 2003, a law amendment was enacted in Norway that released the sale of selected nonprescription drugs, including commonly used analgesics, from pharmacies to general food stores. The purpose of the amendment was to increase availability, providing Norway with one of the most liberalized regulations in the European Union on the sale of prescription-free medication. Criticism was voiced against this decision, because increased availability may increase overuse and intoxication. A recent report reveals that the percentage of medication sold outside pharmacies has increased from 25% in 2004 to 50% in 2012.¹⁸ Analgesics are among the most used prescription-free medications¹⁸ and a study performed in Denmark showed that 27% of the women and 18% of the men had a regular monthly use of pain medication.¹⁰

The aims of the present study were to evaluate the effects of the law amendment of 2003 on consumption of prescription-free analgesics and whether the change has affected the prevalence of headaches with or without somatic pain and their inter-relations in the population. A hypothesis was that the regulatory change may have led to higher consumption of prescription-free analgesics.

Methods

Design, Participants, and Procedures

This study is on the basis of data retrieved from a series of cross-sectional health surveys conducted in Norway under the name Norway Living Conditions Surveys. These surveys are performed approximately every 3 years and data from 1998, 2002, 2005, 2008, and 2012 were used. The data are representative for age, gender, and regional distribution in Norway. The samples were randomly drawn from Statistics Norway (SSB) demographic/population base. Two separate samples (main and auxiliary selection), each with 5,000 people aged 16 years and older were selected for each year. SSB's 2-stage selection scheme was used.²³ The sampling plan divided the whole country into a set of sampling areas; these were again grouped into 109 strata. In the first stage a sample of each stratum was drawn and in the second step the samples were drawn randomly from all 109 strata. The studies included an interview and a postal questionnaire. Everyone who participated in the interview was assigned a postal questionnaire after the interview.

Measures

Pain Assessments

To assess headache as a dependent variable, the headache item from the Hopkins Symptom Checklist (HSCL)-25 was used,^{3,24} asking: "Have you during the past 14 days had any of the following problems?" with

headache as one of the available choices. The reply options were on a scale of 1 to 4 where 1 = not bothered, 2 = little bothered, 3 = quite troubled, and 4 = very troubled. For association with somatic pain, the subjects answered the following question: "Have you during the past 3 months had any of these problems?" with somatic pain as one of the listed problems. Dichotomous responses were given ("no" and "yes"). We also computed a combined variable for headache and somatic pain with 4 response categories. The categories were defined as "none," "headache alone," "headache with somatic pain," and "somatic pain alone." Headache severity was assessed using the headache question from the HSCL-25 battery and the cutoff was defined as "not or little bothered" as opposed to "quite and very troubled."

Use of Analgesics

To assess the use of analgesics we used the question "During the past 4 weeks, how often have you used the following drugs?" Pain medication with and without prescription were possible options. In Norway, analgesics not requiring prescriptions are mainly paracetamol and ibuprofen, whereas stronger nonsteroidal anti-inflammatory drugs, all opioids, including codeine, and triptans require prescriptions. Responses were given on a 4-point scale ("not used over the past four weeks," "weekly but not daily," "at least every week," and "daily").

Demographic Characteristics

Finally, we used demographic variables such as gender, age, and education. Age was treated as a continuous variable. Education was categorized into 3 groups. Low educational level (up to 9 years of education), medium educational level (10–12 years of education), and high educational level (completed a college or university degree).

Ethical Issues

The Living Conditions Surveys was conducted after approval from the Regional Ethics Committee. Participation was voluntary and all questionnaires were anonymous. For this particular study we were permitted to withdraw data from Statistics Norway Living Conditions Surveys 1998–2012 from the Norwegian Social Science Data Service (NSD) before analyses. (The data used here are taken from Living Conditions Surveys, 1998, 2002, 2005, 2008, and 2012 cross-sectional themes: health. SSB conducts the surveys. Data are organized and made available in anonymous form of the NSD. Neither SSB nor NSD are responsible for the analyses of the data sets or the interpretations made here.) The author and supervisor signed separate disclosure agreements. The assistant supervisor had separate access via the National Institute of Public Health.

Statistical Analyses

Logistic regression analyses were performed to investigate associations between the dependent

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