

## SAFETY OF OTC ANALGESIC DRUGS IN THE OPINION OF POLISH PATIENTS - PRELIMINARY STUDY

MARIOLA DROZD<sup>1\*</sup>, KAZIMIERZ DROZD<sup>2</sup>, MONIKA SZKULTECKA-DĘBEK<sup>3</sup>, ANNA KIJEWSKA<sup>1</sup>  
and NINA KIEPURSKA<sup>3</sup>

<sup>1</sup> Department of Applied Pharmacy, Medical University of Lublin, 1 Chodźki St., 20-093 Lublin, Poland

<sup>2</sup> Department of Materials Engineering, Lublin University of Technology, Poland

<sup>3</sup> Dermatology, Military Institute of Medicine, Warszawa, Poland

**Abstract:** The aim of the paper was to determine the Polish patients' attitude towards self-medication with OTC products. The research was based on a questionnaire for adult patients. In all, 363 questionnaires were collected between February-April 2011. There were used three data collection methods. Direct interviews were performed by an interviewer. Additionally, respondents provided answers to the questionnaire in a self-administered way and questionnaires were filled by the Internet users. The collected data were analyzed in the MS Excel program. Women comprise a group using more frequently analgesics and medicines against common cold; however, men present more symptoms caused by an improper use of these drugs. People over 60 years mostly use simultaneously products having the same active compound, thinking that OTC products are safe. Respondents' education is the major differentiating factor. People with primary and secondary education usually combine 2-3 products during common cold treatment and in their opinion OTC drugs are safe and difficult to overdose. Respondents with high school education more frequently use the drugs according to their own choice and abuse them in case of symptoms exacerbation. In the article, Polish patients' attitude towards the use of self-medication products available without prescription has been presented. The respondents use analgesics and products against common cold in a way, which significantly differs from the recommendations. The reports about overdosing, misuse of medicines and polypharmacy phenomenon should induce more intensive efforts of pharmacists in providing advice to patients who are using OTC products in treating themselves.

**Keywords:** over the counter drugs, pharmacovigilance, self-medication, analgesic drugs, opinion of patients

The main objective of health care system is the health safety of the general population. There are two main objectives and functions of the system identified at the same time. One of them is to meet individual health needs resulting from illness or accidents, and the second one is to ensure the collective health care needs including, for example, living conditions, employment, housing, nutrition, rest. Pharmacotherapy occupies an important place in the process of health care and the parameter that characterizes the value of the drug, in addition to its effectiveness is its safety profile (1).

Self-medication is a vital part of the health care system, which has dynamically evolved in recent years. However, in Poland, patients' knowledge about the health and the use of drugs is rather low, compared to Western Europe. This is due to insufficient access to reliable information about medicines. Moreover, in contrast to, for example, the United

Kingdom, the policy of the Polish government is still not focused on promoting self-medication. Therefore, its development is not proceeding in Poland as a natural process, but it is due to lack of adequate access to medical care, and therefore often regarded as a necessary evil (2, 3).

Self-use of various therapies involves benefits and risks. The majority of Polish people try to solve their health problems themselves. Patients have increasing access to drugs, but despite the increased availability of medicines outside pharmacies, it is the pharmacist and the doctor who should verify the safety of medicines usage.

An important element of self-medication is the use of non-prescription medicines. Modern drugs belonging to the OTC (over the counter) drugs or medicines accepted to trading without a prescription, are widely available and can be found in almost any grocery store or gas station. From the patient's

\* Corresponding author: e-mail: mariola.drozd@umlub.pl

perspective, these changes are very beneficial, because the access to OTC products becomes unlimited. However, from the point of view of pharmacology safety, a wide and unlimited access to medicines is the cause of some health problems (4).

When using OTC drugs, patients can prevent minor disorders, cure them, and thereby improve their quality of life. Patients are no longer passive spectators controlled by health care entities, but are actively involved in the treatment process and become partners for a physician and a pharmacist. They take the responsibility in the process of their treatment and, based on their own or the expert opinion, they have the possibility to decide on the drugs to be used. The process of self-medication is also cost-effective for the National Health Fund (NHF), because apart from reducing the cost of pharmacotherapy reimbursed by shifting its financing, patients can avoid unnecessary visits to the doctor. Prophylactic drugs that reduce the risk of disease and even hospitalizations also have rated benefits (2).

It is therefore important to introduce pharmaceutical care, which, due to widely carried patient education and advising, could significantly limit the risk that accompanies the acquisition of OTC medicines outside pharmacies. Grocery store, hypermarket and gas station do not employ qualified persons. A pharmacist is the person who can instruct how to take the medicine, not to mention its right choice. Outside pharmacy, patients themselves make decisions based on what they or their family know about medicines and pharmacotherapy (5).

Another equally important part of pharmaceutical care is to monitor the safety of pharmacotherapy. This obligation is regulated by the Act of the Pharmaceutical Law where the Article 88 lists that one of the responsibilities of the pharmacy is to provide the President of the Office for Registration of Medicinal Products with adverse event information about a medicinal product or a medical device (ADR) (6). In addition, The Health Ministry Order dated 17 February 2003 on the drug safety monitoring, paragraph 9.4, requires that doctors, pharmacists and other health professionals report adverse reactions of medicinal products. Such a legal regulation does not exist in relation to institutional staff for sales out of pharmacies, however, the European Parliament and the Council 2010/84/EU has given the patients the right to direct reporting of adverse drug reactions.

In the era of transition, when an increasing number of drugs are changing the status from prescription only medicines (POM) (Rx) to OTC, the

obligation to report data on adverse reactions lies increasingly with the pharmacist. Communication of information to patients about the side effects of OTC drugs and interactions between the drugs, also with those issued on prescription, is particularly important because it raises the standards of health care (7). The studies performed in the European Union and the United States have shown that the side effects of self-medication are one of the leading causes of deaths, with about half of them which could have been avoided (8, 9). The fact that the drug has been registered does not mean that it has been tested in every possible way. Definitely, it had to undergo many tests and meet certain strict standards, but the knowledge about all possible interactions and side effects (sometimes, also those very distant) is possible to be collected only during the post-registration phase of research (7).

Patients using non-prescription medicines believe that if the products can be bought without a prescription, they are safe and do not pose a risk in relation to their use. Even the vitamins can cause damage if taken in excess. The fact that some of the analgesics are used in committing suicides should raise awareness on how dangerous they can be, e.g., paracetamol is in the UK the most common cause of suicidal drug poisoning (7, 10). Due to adverse reactions after ingestion of drugs in the group of non-steroidal anti-inflammatory drugs (NSAIDs), 30 thousand of hospitalizations are recorded annually. After using NSAIDs, 1.2-2 thousand of deaths per year are noted in relation with adverse drug reactions (approximately the same size of deaths as due to AIDS). In Poland, the estimated number of deaths due to NSAIDs caused adverse reactions is 200-3000 deaths per year (11). These data indicate the magnitude of the problem we are facing. In Poland, the most commonly used medicines available at pharmacies without prescription are the analgesics. It is estimated that about 30% of the older patients' population are taking these drugs habitually (12).

On the pharmaceutical market, there is currently a large selection of analgesics available. Among them, the most important are the NSAIDs, especially paracetamol, ibuprofen and metamizole sodium. They are used principally to control headache, muscular pain, dental pain, menstrual disorders, or to reduce fever. Advertisements in the mass media present them as drugs which are safer, smarter, and that ideally appeal to pain location. In principle, their use should not cause major problems, but the reality is different. Bleeding from the gastrointestinal tract, liver damage, kidney failure, are some of the side effects that may occur quite frequently (13,

14). After using NSAIDs, rarely some serious adverse reactions in the skin can be observed, such as maculopapular rash, Stevens-Johnson syndrome (bullous erythema multiforme), toxic epidermal necrolysis, cutaneous hypersensitivity reactions including skin rash (15). The occurrence of these side effects is not always associated with an OTC NSAIDs drug usage.

Risk in relation with the use of medicines, especially the NSAID group, appears when patients very commonly use simultaneously a combination of several drugs from the same group, which increases the risk of adverse reactions, rather than strengthening the therapeutic effect. In order to improve safety of the pharmacotherapy and to minimize adverse drug reactions, the methods for a proper drugs use should be carefully analyzed. The expertise of doctors and pharmacists is indispensable since patients are not able to solve these problems by themselves. Appropriate use of medicines and medication reduce the risk of pharmacotherapy errors committed by both patients and health care professionals.

### Objective

The aim of this study was to evaluate patients' perception of the safety of analgesics available without prescription.

### Methods

The research material comprised data collected on the basis of an original questionnaire addressed to adults. This questionnaire was validated in a group of 50 people. Overall, there were analyzed 364 questionnaires completed by the interviewer in a direct interview with the patient or individually by the respondent. The survey was conducted between February and April 2011, mainly among the patients in outpatient clinics, as well as among the Internet users at the social networking site "Facebook" and

www.insomnia.pl forum. The data obtained were statistically analyzed using the MS Excel 2007.

## RESULTS

The study presents the results collected in a heterogeneous group, i.e., with a different way of access to the respondents. In this study, it can be assumed that only the age of the respondents could have an impact on this method, affecting the answers to the other questions in the survey related to the perception of analgesics. Therefore, it should be considered that the study relates more to the young Polish population. The data collection methods did not affect the remaining features like gender, education and place of residence.

### Demography

The results of demographic characteristics of respondents are shown in Table 1.

As shown in the presented data, the thesis placed in the introduction part of the results was confirmed. The respondents are mainly young people, which indicates the calculated median of 29 years.

### Use of OTC drugs

In this research, it was decided to ask the respondents about the frequency of using analgesics acquired without a medical prescription. The results are shown in Table 2.

In the interview, we found that among the respondents who most frequently used the analgesics, the medicines containing paracetamol were mainly preferred. Their application was not always consistent with the indications. For example, one of the patients for over a year had taken "Apap night" every single day as a hypnotic drug. It is a formulation containing paracetamol and diphenhydramine used in the short-term pain causing difficulty in falling asleep. The use of this drug can cause com-

Table 1. Characteristics of respondents (n = 364 persons).

|            |   |
|------------|---|
| Age (year) | min = 18<br>average = 36.3<br>max = 85<br>median = 29<br>SD = 15.5  |
| Sex        | female = 228<br>male = 136  |
| Degree     | education primary = 21<br>education secondary = 139<br>education higher – incomplete = 66<br>education higher = 138 |
| Abode      | city over 100 thousand inhabitants = 185<br>city under 100 thousand inhabitants = 80<br>country = 99                |

Table 2. Frequency of use of analgesics OTC.

|  | Every day<br>n (%) | Few times<br>a week<br>n (%) | Once a<br>week<br>n (%) | Few times<br>a month<br>n (%) | Once a<br>month<br>n (%) | Few times<br>a year<br>n (%) | I do not<br>use<br>n (%) | $\chi^2$ | df | p        |
|--|--------------------|------------------------------|-------------------------|-------------------------------|--------------------------|------------------------------|--------------------------|----------|----|----------|
| Total (n = 364) (27)                       | 10 (2.7)           | 23 (6.3)                     | 9 (2.5)                 | 94 (25.8)                     | 64 (17.6)                | 135 (37.1)                   | 29 (8.0)                 | -        | -  | -        |
| Female (n = 228)                           | 8 (3.5)            | 17 (7.5)                     | 9 (3.9)                 | 66 (28.9)                     | 47 (20.6)                | 72 (31.6)                    | 9 (3.9)                  |          |    |          |
| Male (n = 136)                             | 2 (1.5)            | 6 (4.4)                      | 0 (0)                   | 28 (20.6)                     | 17 (12.5)                | 63 (46.3)                    | 20 (14.7)                | 30.8     | 6  | < 0.0001 |
| Primary education<br>(n = 21)              | 1 (4.8)            | 2 (9.5)                      | 0 (0)                   | 7 (33.3)                      | 2 (9.5)                  | 9(42.9)                      | 0 (0)                    |          |    |          |
| Secondary education<br>(n = 139)           | 8 (5.8)            | 11 (7.9)                     | 5 (3.6)                 | 35 (25.2)                     | 23 (16.5)                | 43 (30.9)                    | 14 (10.1)                |          |    |          |
| Incomplete higher<br>education (n = 66)    | 0 (0)              | 2 (3)                        | 1 (1.5)                 | 17 (25.8)                     | 13 (19.7)                | 25 (37.9)                    | 8 (12.1)                 |          |    |          |
| Higher education<br>(n = 138)              | 1 (0.7)            | 8 (5.8)                      | 3 (2.2)                 | 35 (25.4)                     | 26 (18.8)                | 58 (42)                      | 7 (5.1)                  | 21.9     | 18 | 0.238    |
| City over 100,000<br>inhabitants (n = 185) | 2 (1.1)            | 6 (3.2)                      | 5 (2.7)                 | 44 (23.5)                     | 32 (17.3)                | 77 (41.6)                    | 19 (10.3)                |          |    |          |
| City under 100,000<br>inhabitants (n = 80) | 1 (1.3)            | 3 (3.8)                      | 4 (5)                   | 26 (20)                       | 16 (20)                  | 26 (32.5)                    | 4 (5)                    |          |    |          |
| Country (n = 99)                           | 7 (7.1)            | 14 (14.1)                    | 0 (0)                   | 24 (24.2)                     | 16 (16.2)                | 32 (32.3)                    | 6 (6.1)                  | 33.8     | 12 | 0.001    |
| Age 18-30 (n = 190)                        | 0 (0)              | 5 (2.6)                      | 1 (0.5)                 | 44 (23.2)                     | 47 (24.7)                | 77 (40.5)                    | 16 (8.4)                 | 71.4     | 18 | < 0.0001 |
| Age 31-45 (n = 66)                         | 1 (1.5)            | 4 (6.1)                      | 3 (4.5)                 | 24 (36.4)                     | 6 (9.1)                  | 24 (36.4)                    | 4 (6.1)                  |          |    |          |
| Age 46-60 (n = 71)                         | 3 (4.2)            | 8 (11.3)                     | 4 (5.6)                 | 18 (25.4)                     | 11 (15.5)                | 23 (32.4)                    | 4 (5.6)                  |          |    |          |
| Age over 61 (n = 38)                       | 6 (15.8)           | 6 (15.8)                     | 1 (2.6)                 | 9 (23.7)                      | 0 (0)                    | 11 (28.9)                    | 5 (13.2)                 |          |    |          |

mon side effect in the form of somnolence, disturbance in attention, dizziness, dryness of mucous membranes in the mouth, throat and nose and rare hypersensitivity reactions i.e., rash, hives, swelling and angioedema.

The statistical analysis has shown that at the level of statistical significance  $\alpha = 0.05$  you cannot reject the hypothesis that the tested variables are independent of sex, age and place of residence. On the other hand, there is no reason to reject the null hypothesis that the tested variables are independent of the education of the respondents.

In this study, the respondents were asked about the frequency of using OTC drugs containing NSAIDs in case of common cold. The results are shown in Table 3.

The statistical analysis results as regards to gender, education and place of residence have demonstrated that the tested variables are on the border of statistical significance. Assuming the statistical significance at the level of  $\alpha = 0.05$ , the null hypothesis that the tested variables are independent of the studied ranges must be rejected.

Subsequently, the respondents were asked about the use of OTC drugs containing paracetamol

in their composition, taken during a common cold. The results are shown in Table 4.

The statistical analysis has shown that at the level of statistical significance  $\alpha = 0.05$  there is no reason to reject the null hypothesis that the tested variables are independent of the gender, age and place of residence. On the other hand, the hypothesis that the tested variables are independent of the education of respondents must be rejected.

In the next phase of the research, the respondents answered the question on the use of medicines containing paracetamol to treat headaches caused by alcohol consumption. The results are shown in Figure 1.

The statistical analysis of the results shown in the graph has confirmed that studied variables at significance level  $\alpha = 0.05$  are dependent on gender, education and age, but there is no reason to reject the null hypothesis that the tested variables are independent of the place of residence.

#### **Risk of adverse reactions after OTC medicines use assessed by patients**

In the following research phase, the patients were interviewed about the safety and risks associ-

Table 3. Frequency of use of OTC drugs during a cold composed containing NSAIDs

|  | In exceptional cases:<br>severe pain, high fever<br>n (%) | Every time I am ill<br>n (%) | I do not use<br>n (%) | $\chi^2$ | df | p     |
|--|---|------------------------------|-----------------------|----------|----|-------|
| Total (n = 364)                            | 199 (54.7)  | 159 (43.7)                   | 6 (1.6)               | -        | -  | -     |
| Female (n = 228)                           | 117 (51.3)  | 109 (47.8)                   | 2 (0.9)               | 5.8      | 2  | 0.054 |
| Male (n = 136)                             | 82 (60.3)   | 50 (36.8)                    | 4 (2.9)               |          |    |       |
| Primary education<br>(n = 21)              | 8 (38.1)  | 11 (52.4)                    | 2 (9.5)               | 12.6     | 6  | 0.051 |
| Secondary education<br>(n = 139)           | 82 (59)   | 56 (40.3)                    | 1 (0.7)               |          |    |       |
| Higher education – incomplete<br>(n = 66)  | 35 (53)   | 29 (43.9)                    | 2 (3)                 |          |    |       |
| Higher education<br>(n = 138)              | 74 (53.6)   | 63 (45.7)                    | 1 (0.7)               | 8.3      | 4  | 0.081 |
| City over 100,000<br>inhabitants (n = 185) | 110 (59.5)  | 71 (38.3)                    | 4 (2.2)               |          |    |       |
| City under 100,000 inhabitants<br>(n = 80) | 35 (43.8)   | 45 (56.2)                    | 0 (0)                 |          |    |       |
| Country (n = 99)                           | 54 (54.5)   | 43 (43.4)                    | 2 (2.1)               | 7.3      | 6  | 0.291 |
| Age 18-30 (n = 190)                        | 102 (53.7)  | 85 (44.7)                    | 3 (1.6)               |          |    |       |
| Age 31-45 (n = 66)                         | 38 (57.6)   | 25 (37.9)                    | 3 (4.5)               |          |    |       |
| Age 46-60 (n = 71)                         | 42 (59.2)   | 29 (40.8)                    | 0 (0)                 |          |    |       |
| Age over 61 (n = 37)                       | 18 (47.4)   | 20 (52.6)                    | 0 (0)                 |          |    |       |

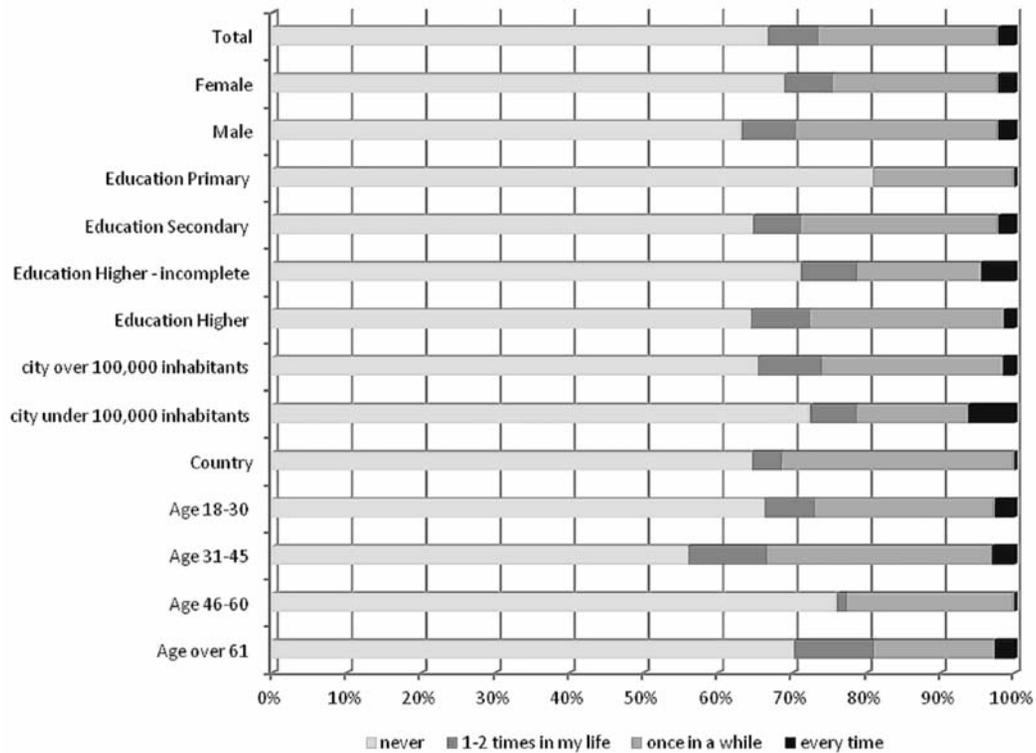


Figure 1. Frequency of analgesics' containing paracetamol use as a treatment for headaches caused by alcohol (Statistical analysis: gender:  $\chi^2 = 1.37$ ; df = 3; p = 0.714; education:  $\chi^2 = 7.6$ ; df = 9; p = 0.577; place of residence:  $\chi^2 = 43.3$ ; df = 6; p < 0.00001; age:  $\chi^2 = 11.4$ ; df = 9; p = 0.247)

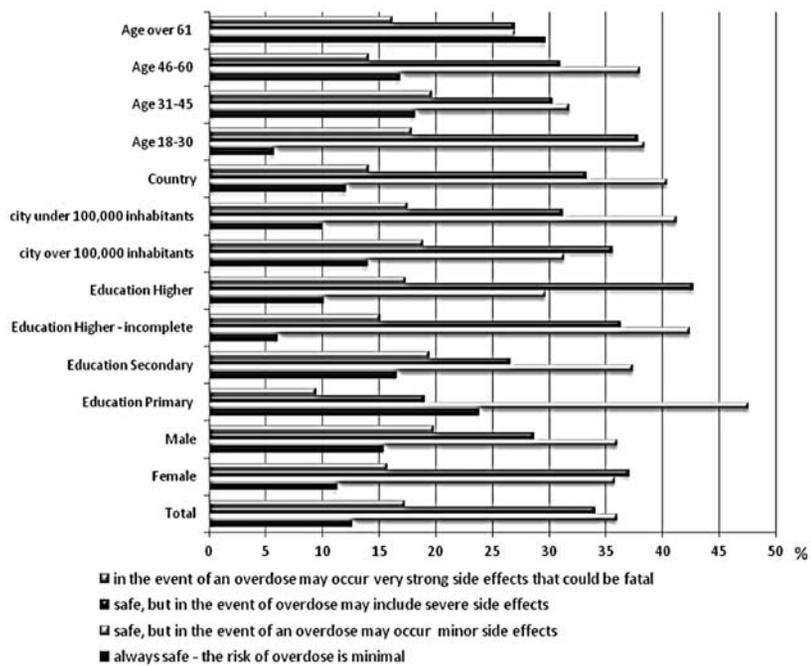


Figure 2. The risk assessment of the analgesics' use and medications against common cold containing paracetamol (Statistical analysis: gender:  $\chi^2 = 4.0$ ; df = 3; p = 0.26; education:  $\chi^2 = 17.9$ ; df = 9; p = 0.036; place of residence:  $\chi^2 = 4.2$ ; df = 6; p = 0.649; age:  $\chi^2 = 22.9$ ; df = 9; p = 0.007)

ated with the very common self-medication by the patients. The results are summarized in Figure 2.

The statistical analysis of the results shown in the graph has demonstrated that the studied variables at significance level  $\alpha = 0.05$  are dependent on gender and place of residence, but there is no reason to reject the null hypothesis that the tested variables are independent of the education and age of the respondents.

## DISCUSSION

Self-medication is one of the elements of the health care system important for both the patient and the State. Continuous increase of patients' access to medicines results in reduction of the burden on doctors' visits in relation to symptoms that patients assess as minor and where they themselves are able to diagnose. Therefore, self-medication is one of the potentials for saving public finances and at the same time, allowing a conscious patients responsibility for their own health (16).

Among the respondents more than 54% of the interviewed said that they used drugs during treatment only in exceptional cases, such as severe pain and high fever treatment, and nearly 44% use them

every time they get sick, regardless of the severity of symptoms. Less than 2% of respondents reported that they did not use drugs during a common cold. It is worth mentioning that the use of antipyretics may not always be beneficial. It is necessary to make patients aware that high temperature, which is accompanied by a viral infection, is only a defensive reaction of the organism and it should not be lowered every time, e.g., temperature 39°C induces the production of interferon, which shortens the course of the disease (17). Only in case of small children, in persons with lowered threshold for seizures, and with cardiovascular diseases, fever increase should be avoided as it may compromise the health or even patient's life (18).

Respondents when asked about the use of compound preparations containing paracetamol answered in nearly 62% that in case they used a combined preparation it was always the same choice. Twenty-eight percent of patients combined two products, and 3% indicated that they combined even three products. However, 7% of respondents did not use complex formulas. It should be emphasized that a combination of two products containing paracetamol is wrong, since it can result in exceeding the threshold for paracetamol dose (1000

Table 4. Usage of common cold preparations with paracetamol.

|   | I do not use<br>n (%) | Always uses only one particular drug<br>n (%) | Sometimes I combine the two drugs<br>n (%) | Sometimes I combine the three drugs<br>n (%) | $\chi^2$ | df | p     |
|---|-----------------------|---|--|--|----------|----|-------|
| Total (n = 364)                         | 27 (7.4)              | 223 (61.3)                                    | 102 (28)                                   | 12 (3.3)                                     | -        | -  | -     |
| Female (n = 228)                        | 11 (4.8)              | 150 (65.8)                                    | 61 (26.8)                                  | 6 (2.6)                                      | 8.7      | 3  | 0.033 |
| Male (n = 136)                          | 16 (11.8)             | 73 (53.7)                                     | 41 (30.1)                                  | 6 (4.4)                                      |          |    |       |
| Primary education (n = 21)              | 2 (9.5)               | 9 (42.9)                                      | 8 (38.1)                                   | 2 (9.5)                                      | 9.7      | 9  | 0.378 |
| Secondary education (n = 139)           | 7 (5)                 | 87 (62.6)                                     | 41 (29.5)                                  | 4 (2.9)                                      |          |    |       |
| Higher education – incomplete (n = 66)  | 6 (9.1)               | 36 (54.5)                                     | 21 (31.8)                                  | 3 (4.5)                                      |          |    |       |
| Higher education (n = 138)              | 12 (8.7)              | 91 (65.9)                                     | 32 (23.3)                                  | 3 (2.2)                                      |          |    |       |
| City over 100,000 inhabitants (n = 185) | 17 (9.2)              | 120 (64.9)                                    | 43 (23.2)                                  | 5 (2.7)                                      | 10.6     | 6  | 0.100 |
| City under 100,000 inhabitants (n = 80) | 5 (6.3)               | 51 (63.8)                                     | 20 (25)                                    | 4 (5)  |          |    |       |
| Country (n = 99)                        | 5 (5.1)               | 52 (52.2)                                     | 39 (39.4)                                  | 3 (3)  |          |    |       |
| Age 18-30 (n = 190)                     | 10 (5.3)              | 113 (59.5)                                    | 62 (32.6)                                  | 5 (2.6)                                      | 16.7     | 9  | 0.053 |
| Age 31-45 (n = 66)                      | 9 (13.6)              | 46 (69.7)                                     | 10 (15.2)                                  | 1 (1.5)                                      |          |    |       |
| Age 46-60 (n = 71)                      | 6 (8.5)               | 44 (62)                                       | 17 (23.9)                                  | 4 (5.6)                                      |          |    |       |
| Age over 61 (n = 38)                    | 2 (5.3)               | 20 (52.6)                                     | 13 (34.2)                                  | 3 (7.9)                                      |          |    |       |

mg/day) and will intensify the effects of drug-induced toxicity without increasing efficacy (19). Complex medicinal products, used against common cold containing in their composition paracetamol and available on the Polish pharmaceutical market include 250 to 1000 mg of pure substances in a single dose (17). In a study performed at the Department of Dermatology of Military Institute of Medicine in Warsaw, the costs of dermatologic drug reactions were assessed. Among others, it was found that in the case of dermatological adverse reactions as erythema multiforme, which could be an adverse reaction after using paracetamol, the generated cost of the adverse event treatment ranged from 2853.03 PLN to 5277.54 PLN. In case of other drug reaction, like toxic-allergic dermatitis, the treatment cost generated was at the level ranging from 2814.87 PLN to 3003.87 PLN (20).

In the case of NSAIDs, caution should be kept. Even one taken tablet may be harmful if patient suffers from peptic ulcer disease, renal or cardiovascular disease. The problem may concern also potentially healthy patients, unaware of the risk related to treatment with the medicines as recalled by J. Woroń (21). Patients should not combine NSAIDs with alcohol as this combination represents some risk (22) and in some cases, even a single use can cause serious health problems (23). In response to a question about the use of medicines containing paracetamol to treat headaches caused by alcohol consumption, only 2.2% of the interviewed answered that they used it every time, 24.2% of respondents did this from time to time and 6.9% so far took these drugs only 1-2 times in their life. Among the respondents, 66.9% of them denied taking paracetamol after drinking alcohol.

When analyzing the results with respect to gender, it has been found that women often use the medications for common cold. The percentage of interviewed subjects using these products whenever they become ill is 47.8% and in exceptional cases, such as severe pain or high fever – 51.5%. Only 0.9% of women do not use any OTC drugs during a common cold. Men often responded that they used products to treat common cold only in exceptional cases – 60.3%, and each time they had common cold symptoms they were using them in only 36.8%, while 2.9% declared not using any drugs. Both women (2.6%) and men (4.4%) rarely combine three preparations containing paracetamol. More often, they use two products at the same time, men 30.1% and women 26.8%. However, a significant differences are marked by the use of those medications in general, 11.8% of men stated that during the common

cold did not use any drug containing paracetamol, and in case of women, the figure is 4.8%. Men compared with women are slightly more often using drugs for headaches caused by alcohol consumption. This is because men consume more frequently and bigger amounts of alcohol (24) and become addicted to alcohol 2.5 times more likely than women (25). Among men, the answer that the product is used from time to time was positive in case of 27.2% of the respondents, among women it was 22.3%. People who use products fighting headache every time they experience headache caused by alcohol are 2.2% in both sexes.

Based on the results of the research it was found that most frequently medications for common cold treatment were used by elderly patients: 52.6% of people over 60 years take the medicines each time in the event of a cold, while 47.4% of this population use the medicines only in exceptional cases. Rarely products for common cold treatment are used by those aged 31-45 years. The usage of medicines each time common cold affects them is declared by 37.9% of people, while 4.5% of people do not use any drugs in the event of illness. It can be observed that the group of people who most frequently combine three formulations of paracetamol comprises people over the age of 60 years (7.9%) and aged 46-60 years (5.6% of respondents). The lowest percentage of people using a combination of three formulations is in the range of 30-45 years (1.5%). Concomitant treatment with two or more NSAIDs can lead to their competition for binding and inhibition of the COX enzymes and altered time course of the pharmacological effects (26). The respondents aged 30-45 years who did not use any products containing paracetamol constituted 13.6%. In the group of respondents over 60 years, 34.2% of patients are using simultaneously two products, and this is the highest percentage in the group of respondents, while 5.6% of them declare using even three preparations at the same time. Also in this age group there was reported the least number of respondents who always used only one medication (52.6% of respondents). The analysis of responses by age groups indicated that the group that most often used medicines for headaches as pain relief drugs after drinking alcohol, were young people. Taking medication from time to time in the above-mentioned indication was declared by 30.3% of respondents in the age range of 31-45 years. Slightly less, 24.2% of these people are aged between 18-30 years. The percentage of respondents, who never used medication for that purpose, is as follows: 18-30 years – 66.3%, 31-45 years – 56.1%. The proportion of those who

declared that it never happened to them to take medicines in case of headache after alcohol consumption is the highest in the 45-60 years interval and it is 76.1%; however, looking at those who declared using the medication for that purpose from time to time, it is still applicable to 22.5% of respondents. Respondents over 60 years of age rarely use drugs with paracetamol for a headache caused by alcohol consumption, although studies show that an older age (> 65 years) male abuse of alcohol is about four times more often than women. The prevalence of alcohol abuse decreases with age and for the elderly it is about 3% (24). Among them there is a very high percentage of people who have never used such preparations for the mentioned above purpose (70.3%). The answer that they use it from time to time was positive only in 16.2% of respondents, and the answer that they used it 1-2 times in their whole life was 10.8%. The percentage of people who use it every time after drinking alcohol is fixed at 2.7%. The exceptions are those aged 45-60 years as none of the people here did answer "every time."

Analyzing the results by the level of respondents' education, those with primary education often use drugs for common cold treatment (52.4%), however, within this group, there is also the largest number of people (9.5%) not using any medication in case of illness. In the other groups, no significant differences have been observed. People with primary and secondary education, often combine several drugs containing paracetamol. In the primary education group, the percentage of people who used only one product is 42.9%, while 38.1% of people use a combination of two different products containing paracetamol. In this group, the percentage of respondents declaring the use of three products at the same time is the highest, and it is 9.5%. The respondents with secondary education constitute the largest group using only one medication (62.6%). In the group of respondents with higher education and in the higher incomplete education group, half of them used one (high education incomplete – 54.5%, university degree – 65.9%) or two preparations (high incomplete – 31.8%, university degree – 23.2%). The proportion of respondents who declared using a total of three preparations is 4.5% among those with incomplete high education, and only 2.2% in the group with university degree.

We found that the persons with primary education take most rarely analgesics for the headache after alcohol intake. No respondents in this group reported using them "every time" and 19% do it "from time to time". However, the answer that "it never happened" was in case of 81% respondents,

the highest score in this patient population. The group, which most frequently used products with paracetamol, includes people with secondary and university education, the percentage of people who use it "from time to time" is 26.1-26.6%. However, the largest proportion of respondents who use them "every time" is among those with incomplete university education (4.5%). When analyzing this information, it was demonstrated that regardless of the place of residence the highest percentage of respondents used NSAIDs without medical prescription few times a year or several times a month. Almost one third of people living in rural areas indicated the answer "from time to time", none of them stated that "every time". The respondents living in rural areas declared that they never used NSAIDs (64.6%). The highest percentage of people not using NSAIDs is among the urban population up to 100 thousand. To the question about the use of OTC medicines for common cold, 59.5% of people living in large cities and 54.4% of people living in rural areas said that they used them in case of high fever or pain. However, 56.2% of residents of smaller cities use them whenever they suffer from a common cold, and it is the highest percentage of respondents. When analyzing the answers regarding combining products containing NSAIDs, it was found that most respondents used one particular formulation. Only those living in the countryside almost double the percentage of using two products at the same time than urban residents. Among respondents taking medicines containing paracetamol for pain associated with alcohol consumption, most people, regardless of their place of residence, answered that they "do not use it". However, "from time to time" the medicines are used by 31.3% of rural residents, while none of this group answered using them every time.

Later in the study, there was an attempt to assess patients' knowledge about the safety of OTC use. Safety depends also on the place of drug acquisition. The place most frequently mentioned by patients where NSAIDs were purchased is a pharmacy (27). In the assessment of the safety of OTC drugs, the interviewed responded very differently. Most of them stated that in their opinion, the OTC products were safe, however detailed opinions about the possible side effects were different. A possibility of observing minor side effects during treatment was confirmed by 36% of respondents, while 34.1% chose the answer that "severe side effects" could happen. Among the respondents, 17.3% said that an overdose can lead to death of the patient and 12.6% believed that these drugs were always safe and the

risk of overdosing is minimal. During the interview, respondents very often stressed that it was a very difficult question for them to answer, because they did not have sufficient knowledge to be able to assess the risks caused by an overdose of analgesics and of products used for the common cold treatment. It should be noted that patients using pharmacist's services (purchased from a pharmacy) had the opportunity to get complete and reliable information on the drug, which they wanted to acquire. This is one of the important aspects of pharmacist's profession, to provide advice in the process of self-medication (28).

The analysis has demonstrated that the analgesics cause the highest concern among young people. In the group of respondents aged 18-30 years, 17.9% of people defined analgesics as very dangerous in case of overdosing. These results can be explained by the fact that young people often use the Internet and other sources of information, choose by themselves the medication and treatment methods. Perhaps this is the reason of their greater knowledge about the medicines than among the elderly. Older people often rely on the expertise of pharmacists and physicians, as mentioned by the respondents while completing the questionnaire (27). However, only 5.8% of them think that the analgesics are safe, and the risk of overdose is minimal. Very similar results regarding the possibility of experiencing adverse drug reaction were obtained from respondents aged 31-60 years and in the youngest group (18-30 years), but the opinion about safety and the impossibility of overdosing was three times higher. The biggest differences regarding the answers related to safety, possible overdose and adverse effects were in the group of respondents over 60 years of age. In these patients' group 16.2% declared that in their opinion these drugs could be life threatening, and 29.7% considered them to be very safe. The obtained result is quite worrying, as according to previous studies, this is the group using analgesics most commonly and in the largest quantities (29, 30). Such observation is also confirmed by this research – those over 60 years of age combine several NSAIDs in higher percentage than the younger people.

In the assessment of OTC drugs safety also an analysis according to patients' education level was performed. The analysis indicates that the higher the level of education of respondents, the higher risk awareness about the use and abuse of analgesics and drugs against common cold. People with primary education have the greatest confidence towards medicines as 23.8% believe that the NSAIDs are completely safe and the risk of overdose is minimal,

minor side effects are expected by 47.6% of the respondents in this group of patients. On the other hand, 19% think that an overdose can give strong side effects, but only 9.5% said that its abuse could be fatal. In comparison, within the group of patients with incomplete university education the percentage of those who think that medicines are safe is only 6.1%. Among people with university education it corresponds to 10.1%, however, the vast majority of respondents within this group have chosen the answer confirming that there is risk awareness, 42.8% believe that there may be severe side effects, and 17.4% believe that an overdose can be fatal. The most diverse in terms of response was a group with high school education: 16.5% of respondents considered the NSAIDs to be always safe and 19.4% - as unsafe and potentially life threatening in case of an overdose. Minor side effects are expected by 37.7% of them, and the severe – by 26.6%. It is worrying that regardless of the place of residence for almost 40% of people the use of OTC drugs is safe, in case of overdosing there may be slight side effects. In addition, for 10% of respondents living in small towns and over 14% of those living in large cities, the studied OTC drugs are considered to be always safe and according to them, the risk of overdosing is minimal.

## CONCLUSION

This paper presents the importance of self-medication and attitude of Polish people towards drugs available without a prescription in the Polish health care system. It can be easily observed that the way in which respondents use analgesics and drugs against cold differs significantly from the recommendations, even if they are included in the leaflets. Polish people during the process of self-medication typically use medical products only in exceptional cases, and to a lesser extent, each time whenever they become sick. Generally, they use paracetamol in complex preparations of their choice. Quite often, they combine two or even three of such preparations. The vast majority denies receiving paracetamol after alcohol consumption, although it is clear that a single drug abuse or combining the medicine with alcohol does not significantly affect the health of the patient. However, if done frequently, it can cause some unexpected side effects.

Patients believe that OTC NSAIDs are safe, although opinion on the possibility of adverse effects indicates them not to be fully safe. These drugs arouse the biggest concern among the young people. Therefore, reports of overdose, abuse and

polypharmacy phenomenon should lead to the adoption of intensive work of a pharmacist in providing information to patients who use the OTC products in self-medication process.

### Acknowledgment

The authors thank Bartosz Bator for providing the database.

### REFERENCES

1. Arcab A., Maciejczyk A.: *Therapy and Drugs* 52, 2 (2002) (Polish).
2. Department of Health, Impact assessment of self care patient prospectus. Available from: [https://www.gov.uk/government/uploads/system/uploads/attachment\\_data/file/213865/dh\\_116685.pdf](https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/213865/dh_116685.pdf). Accessed: December 21, 2014.
3. Węgrzyk J.: Is self-medication needed? *On Health* 1 (2004) Available from: <http://www.nazdrowie.pl/artykul/czy-samoleczenie-jest-potrzebne>. Accessed December 21, 2014 (Polish); WHO, Guidelines for the regulatory assessment of medical products for use in self-medication. Geneva 2000. Available from: [http://apps.who.int/iris/bitstream/10665/66154/1/WHO\\_EDM\\_QSM\\_00.1\\_eng.pdf?ua=1](http://apps.who.int/iris/bitstream/10665/66154/1/WHO_EDM_QSM_00.1_eng.pdf?ua=1). Accessed December 8, 2014.
4. Nesterowicz K.: Drugs in non-pharmacy sales. Available from: <http://nazdrowie.pl/artykul/leki-w-sprzedazy-pozaaptecznej>. Accessed December 8, 2014 (Polish).
5. Act of 6 September 2001 Pharmaceutical law. *Dz. U.* 2001, 126, 1381 as amended. (Polish).
6. Szafarska D.: Self-medication. The safety of application. Available from: <http://www.farmacjajja.pl/poradnik-farmaceuty/akademia-farmaceuty/samoleczenie-bezpieczenstwo-stosowania.html>. Accessed: April 07, 2012 (Polish).
7. Responsible self-care and self-medication. A worldwide review of consumer surveys. Available from: <http://www.wsmi.org/pdf/wsmibro3.pdf>. Accessed: December 20, 2014.
8. Węgrzyk J.: The benefits of self-medication. Available from: [http://www.geoland.pl/dodatki/zdrowie\\_ii/pasmi.html](http://www.geoland.pl/dodatki/zdrowie_ii/pasmi.html). Accessed September 18, 2012 (Polish).
9. Magiera J.: Dangerous analgesics. Available from: <http://media.wp.pl/kat,1022943,wid,12994567,wiadomosc.html?ticaid=1c158>. Accessed: December 8, 2014 (Polish).
10. Kusiak M.: Pain is our last. Available from: <http://www.nie.com.pl/art10047.htm>. Accessed July 27, 2012; <http://wolnemediamedia.net/zdrowie/bol-to-jest-nasz-ostatni/> Accessed: December 8, 2014 (Polish).
11. Cielecka-Piontek J., Rajska-Neumann A., Wieczorowska-Tobis K.: *Medical News* 75, 1 (2006) (Polish).
12. Amar P.J., Schiff E.R.: *Expert Opin. Drug Saf.* 6, 341 (2007).
13. Szwedek-Trzaska A., Głowacka A.: in *Self-medication*, Krajewski-Siuda K. Ed., p. 193, Publisher: Sobieski Institute, Warszawa 2012 (Polish).
14. Characteristics of a medicinal product containing paracetamole. Characteristics of a medicinal product containing metamizole.
15. Characteristics of a medicinal product containing ibuprofen.
16. Bochenek T.: in *Self-medication*. Krajewski-Siuda K. Ed., p. 99, Publisher: Sobieski Institute, Warszawa 2012 (Polish).
17. Gumułka W.S.: in *Pharmacology. The base of pharmacotherapy*. Kostowski W., Herman Z., Eds., p. PZWL, Warszawa 2010 (Polish).
18. Antonucci R., Zaffanello M., Puxeddu E., Porcella A., Cuzzolin L. et al.: *Curr. Drug Metab.* 13, 474 (2012).
19. Singh B.K., Haque S.E., Pillai K.K.: *Expert Opin. Drug Metab. Toxicol.* 10, 143 (2014).
20. Wiśniewska N., Szkultecka-Dębek M., Owczarek W., Paluchowska E., Jahnz-Różyk K.: *Value in Health* 16, 7 (2013).
21. Chyłkiewicz J.: Don't swallow mindlessly. Available from: [http://www.newsweek.pl/artykuly/sekcje/newsweek\\_biznes/nie-lykaj-bezmyslnie,47097,1](http://www.newsweek.pl/artykuly/sekcje/newsweek_biznes/nie-lykaj-bezmyslnie,47097,1). Accessed December 8, 2014 (Polish).
22. Tomlinson K.L., Brown S.A.: *Addict. Behav.* 37, 179 (2012).
23. Prescott L.F.: *Br. J. Clin. Pharmacol.* 49, 291 (2000).
24. Cichoż-Lach H., Grzyb M., Celiński K., Słomka M.: *Alcoholism and Drug Addiction* 21 (1), 56 (2008) (Polish).
25. Krzystanek M.: Alcohol – host feathered snake. Available from: <http://www.psychiatria.pl/txt/a,833,0,alkohol-widmo-pierzastego-weza>. Accessed December 8, 2014 (Polish).
26. Stepensky D., Rimon G.: *Expert Opin. Drug Metab. Toxicol.* 11, 41 (2014).
27. Drozd M., Bator B., Olejniczak-Rabinek M.: *Journal of Health Policy and Outcomes Research* 2, 69 (2012).
28. Drozd M., Jaremek-Kudła J., Kijewska A.: In: *Self-medication*, Krajewski-Siuda K., Ed., p.

- 147, Publisher: Sobieski Institute, Warszawa 2012 (Polish).
29. Cielecka-Piontek J., Rajska-Neumann A., Wieczorowska-Tobis K.: *Medical News* 75, 1 (2006) (Polish).
30. Panaszek B., Machaj Z., Lindner K.: *Therapy* 10, 247 (2010) (Polish).

*Received: 21. 10. 2014*