Polish Patients with Epilepsy Opinion on the Generic Medications

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Article

Polish Patients with Epilepsy Opinion on the Generic Medications

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Abstract: Aim: The majority of medicines used in Poland are generic drugs – substitutions of the original. Objective of the study was to obtain information on the current knowledge about generic medicines among Polish patients with epilepsy. Material and Methods: The study was conducted based on a self-developed questionnaire. The questionnaire consisted of 25 questions, including questions regarding their knowledge about generics, their previous experience and the factors behind these choices. Results: Overall, 1220 questionnaires were analyzed. Among all patients, 66.39% reportedly heard about generics. Of these 61.48% of patients had used the generic drugs in past. A significant proportion of participants had never been recommended to switch to a generic medicine by their health care professional (22.95% physician and 13.93% pharmacist). Statistically relevant differences were observed regarding the respondents' kind and level of education, place of residence, and net income per household. Conclusions: Significant gaps were identified in the knowledge and perceptions among patients regarding generic medicines especially in relation to efficacy and safety of generic medicines. Efforts must be directed towards increasing public awareness of generic medicines and should also focus on educating patients about generic medicines.

Keywords: generic medicines; opinions; patients; epilepsy; Poland

1. Introduction

Generic medicines are extremely popular in Poland and the share of generic medicines in Poland is the highest in the European Union [1]. It is proved that the costs of medicine are one of the main expenditures of healthcare systems [2] and of households' in different countries [3–5]. Generic substitution allows patients to buy much cheaper medicines. Studies show that generic substitution can reduce the cost of medicines to the health care systems, as well [6,7]. The average price of a generic in Poland is 2.6 times less than the price of a brand-name drug [8]. Many governments encouraged generic use to enhance health equality and minimize health expenditure. The lack of knowledge and acceptance of generic medicines are the main barriers to their use.

The aim of the study was to assess patient with epilepsy knowledge on generic medications. The specific objective was to examine which socio-demographic variables are independently related to the acceptance of generic drugs.

2. Materials and Methods

After an extensive literature review on this topic, a questionnaire was drawn up to assess knowledge and perceptions of generic drugs. The questionnaire was divided into three parts: 1)

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socio-economic data, 2) knowledge about generic medicines, and 3) experience with generic medicines. The questions in the survey concerned on generic medicines in general, not generic antiepileptic drugs. The study used the CAWI technique (Computer Assisted Web Interview). The study was anonymous and participation was voluntary. Completion of survey was deemed to be agreement of consent from the participants. The study was conducted between January 2022 and June 2023 in selected online websites, a forum for people suffering from epilepsy. A total of 1220 out of 1500 patients participated in the study, giving a response rate of 78.7%.

2.1. Statistical analysis

The data were analyzed through the statistical package StatSoft. Inc STATISTICA software (version 13.03) and Excel spreadsheet. Quantitative variables were characterized by mean, standard deviation, median, mode, minimum and maximum value (range). Variables of the qualitative type were presented by means of the number and percentage values. Chisquare tests of independence were used for categorical variables. Additionally, a correlation analysis was used to calculate the Pearson and/or Spearman correlation coefficients. Statistically significant values were P-values <0.05. Respondent's answers were correlated with socioeconomic characteristics of the respondents: age, sex, marital status, level and kind of education, place of residence, and net income-per-household-member.

2.2. Ethical approval

The study was approved by the Ethics Committee, Medical University of Warsaw (ref no. AKBE/159/16).

3. Results

3.1. Characteristics of participants

The survey was completed by 1220 participants, 900 (73.77%) were females. Mean age of respondents was 38.15 yrs (SD=17,31; median 32; mode 23; min. 20, max. 88). The most of respondents (n=510; 41.8%) lived in a marriage relationship. The majority (n=940; 77.05%) of the individuals who took part in the survey lived in the city > 500 thousand residents. Education-wise, almost ¾ (n=900; 73.77%) of the total respondents were university education, while 210 (17.21%) medical education. The PLN 2001-3000 was the most declared average monthly income per respondent (n=340; 27.87%). An equal number of respondents (n=430; 35.25% each), is ill chronically - disease other than epilepsy and took the medicines in relation to a chronic disease - medication other than antiepileptic drugs. More than half (n=590; 56.56%) of the respondents affirmed that benefited from both at public and private health units, and 30 (2.46%) stated that they were not treated at any type of healthcare facility.

Table 1. Characteristics of the examined group.

Variables	Answers	N	%
Sex	Female	900	73.77
	Male	320	26.23
Marital status	Single	450	36.89
	In an informal relationship	190	15.57
	Married	510	41.80
	Divorced	40	3.28
	Widowed	30	2.46
Place of living	Rural area	150	12.30
	City < 50 thous. residents	70	5.74
	City 50-100 thous. residents	10	0.82
	City 100-500 thous. residents	50	4.10
	City > 500 thous. residents	940	77.05

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Level of education	University	900	73.77
	Seconadary	260	21.31
	Vocational	40	3.28
	Primary	20	1.64
Kind of education	Medical	210	17.21
	Non-medical	1010	82.79
Income (monthly after tax) in PLN	< 500	30	2.46
	501-1000	60	4.92
	1001-2000	180	14.75
	2001-3000	340	27.87
	3001-4000	250	20.49
	4001-5000	150	12.30
	> 5001	210	17.21
Chronic illness other than epilepsy	Yes	430	35.25
	No	790	64.75
Long term use of medication other than antiepileptic drugs	Yes	430	35.25
	No	790	64.75
Healthcare facility where you receive outpatient care	I do not use healthcare	30	2.46
	Public healthcare	390	31.97
	Public and private healthcare	690	56.56
	Private healthcare	110	9.02

3.2. Knowledge about generic medicines

In this study, only 810 (66.39%) patients had already heard about generic medicine, but 410 (33.61%) had never heard about these medications. Among the respondents, only 570 (46.72%) knew the term generic medicine. Most of respondents (n=420; 34.43%), obtained information on generic medicines from medical practitioners. More than half of the surveyed population (n=620; 50.82%), agreed with the statement that a generic medicine can be produced freely, once the branded product patent protection period has expired, and must be similar to the branded medicine in order to obtain the same therapeutic effect. The overwhelming percentage of respondents (n=790; 64.75%) believed that the generic drug contains the same substance as the branded medicine.

An equal number of respondents (n=640; 52.46% each), stated that generic medicines were just as good quality and just as safe as reference medicines. Almost ¾ of the respondents (n=890; 72.95%), considered that generic medicines are less expensive than reference medicines. Table 2 presented knowledge about generic medicines of the respondents.

Table 2. Knowledge about generic medicines of the respondents.

Variables	Answers	N	%
Have you ever heard about generic medicines?	Yes	810	66.39
	No	410	33.61
Do you have knowledge of generic medicines?	Yes	570	46.72
	No	650	53.28
How did you obtain information on generic medicines?	Healthcare practitioner (eg. Pharmacist, Physician)	420	34.43
	Media (eg. Internet, Television)	150	12.30
	Friends / Neighbors	30	2.46
	I have never obtained	410	33.61
	Professional knowledge	210	17.21
A generic medicine can be produced freely, once the branded	Yes	620	50.82
	Don't know	560	45.90

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product patent protection period has expired, and must be similar to the branded medicine in order to obtain the same therapeutic effect. Is this information correct?	No	40	3.28
Does the generic medicines contain the same substance as the branded medicines?	Yes	790	64.75
	Don't know	350	28.69
	No	80	6.56
Compared to the branded medicine do you think that the generic medicine is good quality?	Don't know	410	33.61
	Same	640	52.46
	Lower	130	10.66
	Better	40	3.28
Compared to the branded medicine, do you think that the generic medicine is safe?	Less	90	7.38
	Same	640	52.46
	Don't know	400	32.79
	More	90	7.38
Do you think that the price of the generic medicine is...	Less than the branded medicines	890	72.95
	Don't know	290	23.77
	More than the branded medicines	40	3.28

3.3. Experience with generic medications

Less than half of respondents (n=470; 38.52%) claimed they had never used a generic medicines or does not know about it.

Among respondents who had an experience with generic medicines, only 2.46% (n=30) of study populations always buy generic drugs.

When asked whether generic medicines are prescribed by doctors, near one third of patients (n=400; 32.79%) was not sure.

The pharmacists always recommended generics for only 1.64% (n=20) of the respondents.

Most of the patients never asked his/her doctor or pharmacist (n=600; 49.18%) to prescribe/distribute generic medicines.

More than half (n=660; 54.1%) of the respondents stated that they buy generic drugs because of the price.

Almost none of the respondents who took generic medicines (n=730; 59.94% with all participants) did not feel that switching from a brand name to generic medicines changed the outcome of therapy.

It found that patients who took generic medicines did not saw increased rates of medicine-related side effects (n=690; 56.56% with all participants).

The practice related questions and the responses of the participants are summarized in Table 3.

Table 3. Practice-related questions and frequency of responses.

Variables	Answers	N	%
Have you already taken generic medicines?	No or Don't know	470	38.52
	Yes	750	61.48
How often do you buy generic medicines?	Never or Don't know	470	38.52
	Always	30	2.46
	Sometimes	360	29.51
	Rarely	260	21.31
	Frequently	100	8.2
Has your physician already prescribed/or is	Never	280	22.95
	Don't know	400	32.79
	Frequently	40	3.28

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prescribing a generic medicines for you?	Rarely	190	15.57
	Sometimes	310	25.41
Has you pharmaceutist proposed you switch generic medicines?	Sometimes	520	42.62
	Rarely	170	13.93
	Don't know	190	15.57
	Frequently	150	12.3
	Never	170	13.93
	Always	20	1.64
Are you suggesting doctor or pharmacist switching from a branded medicine to a generic medicine?	Sometimes	350	28.69
	Always	50	4.10
	Never	600	49.18
	Rarely	140	11.48
	Frequently	80	6.56
Substituted a branded medicines with a generic because	the generics is cheaper	660	54.10
	pharmacist recommend it	90	7.38
	I had never used a generic medicines or does not know about it	470	38.52
Did you feel that switching from a brand name to generic medicines changed the outcome of therapy?	I had never used a generic medicines	470	38.52
	No	730	59.84
	Yes	20	1.64
Did you feel side effect, when you take generic medicines?	I had never used a generic medicines	470	38.52
	No	690	56.56
	Yes	60	4.92

3.4. Results of statistical analysis

There was a statistically significant association in terms of the knowledge of generic medicines and the kind of education of the respondents. The respondents with medical education have knowledge of generic medicines (in all questions $p<0.02$).

The level of education statistically differentiated the choice and knowledge of respondents. Individuals with a university degree significantly often:

- claimed that the generic medicine is good quality compared to the branded medicine ($p=0.000$);
- claimed that the generic medicine is same safe compared to the branded medicine ($p=0.00011$);
- claimed that the price of the generic medicine is less than the branded medicines ($p=0.00000$);
- taken generic medicines ($p=0.04441$);
- were buying generic medicines ($p=0.00148$).

Statistically significant associations were found between the place of residence of the respondents and choice, and the answers to the question about the generic medicines. The respondents who lived in in the city > 500 thousand residents significantly often:

- claimed that the generic medicine is good quality compared to the branded medicine ($p=0.01304$);
- claimed that the price of the generic medicine is less than the branded medicines ($p=0.00231$);
- taken generic medicines ($p=0.00893$).

Net income per household was another factor which significantly differentiated respondent choices. Individuals with up to PLN 2000 net income per household significantly more often declared that heard about generic medicine ($p=0.04917$).

No statistically significant differences were found between other variables ($p>0.05$).

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4. Discussion

The Polish study on generic medicines in the opinion of patients was conducted in 2011 yrs among 500 patients [9], in 2013 yrs in population of 1000 patients [10], while the discussed study was conducted in January 2022 - June 2023, and 1220 patients took part in it.

Among the respondents in own study, 66.39% (n=810) had already heard about generic medicines. Worse this aspect noted in Auckland, New Zealand, where only 51% of the respondents had heard of the phrase "generic medicines" [11], and in Malaysia, where noted that 85.8% did not know the term "generic medicines" [12]. However, better this aspect noted in studies conducted in Brazil. In study Lira et al., 99.6% of the respondents had already heard about generic medicine [13], and similarly in study da Rocha et al. demonstrated that 95.7% of the respondents had heard about them [4].

With regard to the definition of a generic drug, 46.72% of the respondents in present study declared that had knowledge of generic medicines. Findings similar to those presented in this study were described in a study conducted in Malaysia of 216 people, 32.5% stated that they knew what generic drugs were [15].

A generic drug is defined as a medication that is produced freely after expiry of the patent protecting the branded product [16]. In this study, only 50.82% knew about it. More than half of the respondents (64.75%) stated that generic drugs had the same substance as reference medicines. In study by Lira et al. 56.5% of respondents defined generics as medications with the same active ingredient(s) as original medicines [13]. A generic medicine is a product that is launched with no intellectual property or other protection after the protection expires on the originator medicine. The original and generic medicine may differ in name, manufacturer and price. However, the active substance contained in them, which is responsible for the action of the drug, and its amount will always be the same [17].

Generic medicines were considered "same in quality" to brand-name products by 52.46% of respondents. In 1994, in study by Muirhead generic products were considered "equal in quality" to brand-name products by 29% of consumers, and 45% indicated that the two were "about the same" [18]. However, 14.4% of respondents in study Lira et al. thought that generic drugs were poorer quality than reference drugs [13]. Fortunately, in this study knowledge of respondents is better than that noted in other countries, only 10.66% of respondents thought that generic drugs were poorer quality than reference drugs. Similarly, he difference in quality between generic and original drugs is not seen by 11.6% of the study group by Grzywinska [9]. Among the respondents, 640 (52.46%) believed that generic medicines were just as safe as reference medicines, however in study by Lira et al. 75.2% [13]. Generic medicines have the same quality and performance as brand name medicines [17].

Generic medications typically cost less. When asked about price, 72.95% of respondents stated that generics medications are less than the branded medicines. In study Naing et al. 86.9% of respondents did not know about price differences between generic and reference drugs [12], however in study Lira et al. 88.8% stated that generic drugs are less expensive than reference drugs [13]. While asking the respondents about the reasons for generic substitution, as many as 660 per 1220 respondents (which is 54.1%) mentioned that they the generics is cheaper. Generic alternatives are often cheaper than brand-name medicines, because the manufacturers have not spent money on research and development of the medicine or buying the rights to sell it [19]. In Poland, most patients are directed by price in medicines choice [20,21].

The question: "Have you already taken generic medicines?" was aimed at verification of the number of patients who reach for these medicines. This question also qualified for answering the subsequent questions. Analysis of responses indicated that 61.48% patients admitted that they used a generic medicines, but 38.52% of respondents claimed that they had never used or don't know about it a cheaper generic substitute for an original drug. This result is similar to that obtained in other study conducted in Poland in 2015 year [10]. Among patients who applied generic medications, as many as 360 respondents, i.e., 29.51%, sometimes buy generic drugs. In Poland, the use of generics is high. According to 2017 data, among the reimbursed prescription medicines the share of generics

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was 27% by value and 89% by volume in hospitals and, respectively, 66% and 76%, in outpatient pharmacies [22].

In Poland, physicians have an individual choices for prescribing drugs which is largely based on brand. In Poland, it is the doctor decides which medicine he will prescribe to the patient. In own study, 22.95% (n=280) of patients declared that their doctor never offered them a generic drug during the visit. On the other hand, in other study conducted in Poland, in a group of 119 doctors, shows that almost 70% of the surveyed doctors (n=83) admit that they prescribe mostly generic drugs to their patients [9]. In Greece, overall, 75% of physicians claimed that they were not affected by the sales representatives from drug companies and that Greek patients do not interfere with their prescribing, but often complain about the drug cost [23].

In Poland, there is no obligation to replace original drugs with generics; nevertheless, the pharmacists have the right to switch from branded to generic medicines unless the prescriber has specified otherwise [24,25]. In present study, the pharmacists sometime recommended generics for 42.62% of the respondents. Whereas, Grzywinska evaluated community pharmacists' practices on generic medicines in Poland [9]. Of the pharmacists surveyed, 65% recommended generics over original brands. It was found that the 66% pharmacists recommended the substitution of a prescribed branded drug by a different form of the same active substance, often or very often, but only 25.41 percent of respondents replied that their doctors talk to them about generic medications and prescribed this medicines sometime. The study carried out in Poland "Factors affecting the opinions of family physicians regarding generic drugs – a questionnaire based study" by Lewek et al. shows that 73.0% of physicians were considering prescribing generics and 71.1% regularly informed patients of this possibility. The physicians who considered generics when prescribing a drug tended to report doing so either often or always (in 50-100% of cases; $p<0.001$) and were more ready to inform patients about generic substitution ($p<0.001$) [26]. It should be noted that generic substitution of branded products has play an important role in limiting the cost of medicines.

The patients themselves may also request generic versions of the prescribed medication when they are either with the doctor or when they visit the pharmacy to collect their prescription, or buy over-the-counter drugs. In own study, only 4.1% (n=50) of patients always request a switch from an original drug to the generic drug from their doctor or pharmacist.

The results in the previously mentioned study are different, 25.6% of patients asked their doctor for a cheaper drug often or very often, while 15.2% of patients never asked a doctor for a generic drug [9]. In the same study, doctors and pharmacists were also asked how often patients themselves ask for a generic substitution. It turned out that, according to physicians, patients ask them to replace the drug with a cheaper equivalent often or very often in almost half of the cases, i.e. in 47.9% of cases, while ¼ of the surveyed pharmacists (25%) stated that patients themselves rarely ask them to change an innovative drug to generic [9]. Another Polish survey conducted among 22 pharmacists showed that 59% of pharmacy employees stated that patients "never" on their own initiative sought information about the possibility of replacing the drug with its cheaper equivalent [27].

Most of respondents in this study (n=420; 34.43%), obtained information on generic medicines from medical practitioners. In study conducted by Kjoenniksen et al., 24% of participants indicated that their physicians had given them information about generic substitution, while a larger proportion (53%) indicated that the pharmacist had done so [28]. Grzywinska shown that 30% of pharmacist declared that patients ask them often or very often about the difference between generics and branded medicines [9]. Firstly, the health care professionals are a reliable source of information of generic substitution. Secondly, studies conducted in Poland shows that the pharmacists have a position of public trust and are fully competent to provide information on medications in patients opinion [20]. Similarly, most of the patients trust their doctors [29].

Among patients with previous experience with generic switching, within only 1.64% of respondents felt the impact of changing brands medicines and only 4.92% felt side effects. From the manuscript "A review of patient perspectives on generics substitution: what are the challenges for optimal drug use" it follows that between 8–34% of patients reported poorer effects and/or new side

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effects after a change-except for antiepileptic drug users from which the number of reports was even higher [30].

Out of various factors that may affect knowledge of generic drugs and their used, high education, medical education, place of residence (city > 500 thousand residents) and net income per household (up to PLN 2000 = about 500 USD) were statistically significant. The results was consistent with a study conducted by Iosifescu et al., where observed that negative beliefs about generic medications were associated with lower education and low income [31]. Similarly, a meta-analysis Dunne and Dunne evaluating perceptions of physicians, pharmacists, and patients found that patients with less education were more skeptical of generic medications [32].

In this study, there was no statistically significant relationship between the sex of respondents and responses of participants about generic medicines. Other studies were in line with our findings [9,28,33,34].

Additionally, in own study, there were no statistically significant differences between responses of respondents in terms of age, marital status, chronic illness other than epilepsy, long term use of medication other than antiepileptic drugs, healthcare facility where respondents receive outpatient care.

In Poland conducted studies on opinions on generic drugs among medical staff, however, there are not many studies conducted in the group of patients.

5. Conclusion

The presented study allow the drawing of the following conclusions: Patient with epilepsy knowledge concerning the generic medicines was moderate. According to the study findings, there were gaps in the patients with epilepsy knowledge of generic medicines. Incorrect information was common among patients with epilepsy about the safety, efficacy and quality of generic medicines. Despite the knowledge on generic medicines, our respondents showed mixed beliefs in generic medicines. Lack of knowledge about generic medicines may influence patients' negative perceptions of generic medicines. Thus, awareness campaign would be needed to expand patients knowledge about generic medicines.

6. Limitations

The study had some limitations. The questions in the survey concerned on generic medicines in general, not generic anti-epileptic drugs. However, it can provide useful data for doctors, pharmacist and health policy makers to further improve the use of generic medicines by considering the patients perspectives. However, the fact that this is the first and, so far, the only study on patient with epilepsy knowledge on generic medications conducted in Poland is worth a mention. Hence, it should constitute a foundation for further detailed research. This study had limitations due to a single group – patients with epilepsy and lack of a control group. Further research should be performed to compare the results of substitution of generics for brand-name drugs in the treatment of patients with epilepsy.

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