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PHARMACOECONOMIC IMPLICATIONS GENERATED BY PRIMARY OPEN-ANGLE GLAUCOMA ON WORKERS

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Glaucoma is an optic neuropathy which due to the irreversible loss of visual acuity, the direct and consequential costs associated with the treatment and the indirect losses because of the reduced productivity generates social and pharmacoeconomic burdens. The study was designed to assess pharmacoeconomic implications generated by primary open-angle glaucoma on workers. It is a cross sectional study, which included 190 male and female respondents with primary glaucoma, aged 28-67, with visual acuity > 6/18 (0.33), according to the ICD-10 classification, conducted in the period August-November 2020 in North Macedonia. Thirty-four point twenty one percent of the respondents received low income, 40.53% average and 25.26%, high income. Pharmacological costs for treatment of binocular glaucoma amounted to 24.1-45.4 Euros per month, which accounted for 10.26-19.32% of the respondents' low income and < 4.82-9.08% of the respondents' high income. In 21.05% the economic burden resulted in existential crisis for the family and 25.79% of the respondents were treated inadequately with generic alternative medicine or inadequate doses of medication due to financial reasons. Loss of productivity was registered in 25.79% of the respondents, while 21.58% of whom, due to their inability to carry out the essential work duties, received lower monthly income. Glaucoma generates a huge pharmacoeconomic burden, which is a consequence of direct and other medical costs for treatment and indirect losses from productivity, which requires the use of screening programs for timely diagnosis and adequate regular treatment, which will help maintain visual acuity and work ability, thus reducing the pharmacoeconomic burden.

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Introduction

Glaucoma is a heterogeneous group of diseases of various etiologies characterized by damage to the papilla of the optic nerve, specific defects in the visual field and progressive and irreversible loss of vision (1, 2, 3).

Glaucoma is classified into congenital, secondary and primary (4, 5), and based on the width of the ventricular angle in the anterior chamber, primary glaucoma is divided into primary open-angle glaucoma, which accounts for more than 75% of all primary glaucoma and closed-angle primary glaucoma (6, 7).

Glaucoma, after cataract, is the second most common cause of global blindness in the population, which accounts for 13-18% of all cases of global blindness; it affects 1-2% of the population and is characterized by chronic progression and long asymptomatic period due to which, in addition to the diagnosed, there are more than 60% of undiagnosed cases of the disease (8, 9).

Due to the chronic, progressive, long asymptomatic period and nonspecific clinical symptoms in the initial stage, glaucoma is most commonly diagnosed after the age of 40 and has a particularly high frequency over the age of 60, in both male and female; consequently 50-55% of all glaucoma cases are female, while in primary closed-angle glaucoma, female patients predominate by 70% of the overall cases (9, 10).

The economic burden of glaucoma is a consequence of direct medical costs, other direct costs associated with treatment and indirect losses resulting from decreased work ability, reduced income due to productivity losses and increased treatment costs originating from the lifelong treatment of glaucoma. Direct medical costs include: the costs for diagnostics and outpatient treatment, medication, laser therapy, surgery, hospital treatment and other medical procedures during the treatment (11, 12).

The pharmacoeconomic costs of the treatment with medications arise not only from their long-term, most often lifelong, use and price, but they also depend on whether the patients receive prescription or over-the-counter medications, i.e. how much the use of these medications is co-financed by the health insurance funds. There are different co-financing criteria in every country, while in RNM the medications are covered by 0-80% (13, 14, 15).

Other direct costs associated with the treatment of glaucoma include the costs of transporting patients to work and accompanying them to medical examinations, procurement of medications, eye and tactile aids, tuition for learning the Morse code, computer skills, IT and audio information technology, costs for escorts, care and assistance in daily activities, costs for accommodation in nursing homes, etc. (16, 17, 18, 19).

Indirect losses are an additional economic burden resulting from the imbalance between the reduced income, productivity losses and the increased costs, which are a consequence of the health condition caused by the visual impairment to which patients are exposed, and can be individual and social (11, 20).

Individual indirect losses can originate from various economic indicators such as reduced income due to early retirement and productivity losses due to decreased work ability (WAI - Work Ability Index), absence from work due to sick leave, reduced income during a period with lower health status adopted to the disability (Disability-Adjusted Life Years/DALYs), etc. (16, 17, 21, 22).

The aim of the study

The study was designed to identify the pharmacological and economic implications generated by primary open-angle glaucoma on employed workers.

Materials and methods

It is a cross sectional study with a quantitative analytical approach conducted in the period August-November 2020 on the territory of North Macedonia, which includes 190 employed workers, male and female respondents with primary glaucoma, aged 20-67.

The research was conducted using respondents' clinical history and appropriate, custom designed surveys, while the patients' diagnosis was confirmed by an ophthalmological examination and accompanying medical history. The research was carried out during the periodic systematic examinations of the respondents, who had different educational and professional background, during which the level of their visual impairment was determined according to the ICD 10 classification and it ranged from 0.7 to 0.3. All respondents were diagnosed with primary open-angle glaucoma at different clinical stages, with the disease progressing over a period from 2 to 20 years.

The research covered various socio-pharmacological and economic indicators: gender, age, clinical stage of the disease, method of therapy, type of prescribed medications, medication and medical procedure costs, monthly costs for treatment, personal income and the impact of the monthly costs on the personal budget, indirect losses due to decreased productivity, analysis of the consequences caused by non-fulfillment or poor performance of commitments with reduced personal income, assessment of the family burden and economic consequences in relation to an inadequate treatment due to economic reasons and other parameters.

The statistical data processing was performed using descriptive and comparative statistical procedures. In addition, statistical programs such as statistics for Windows 7.0 and SPSS 17.0 were also used.

Pearson Chi-Square test for homogeneity was used to determine the differences in the attributive values of dichotomous features (variables) in male and female respondents, while the non-parametric Mann-Whitney U test was used to test the significance of the differences in the independent features (variables). To assess the statistical significance, a level of significance is determined $p < 0.05$. The obtained results are presented numerically and in a table.

Results

The study included 190 respondents with primary angle-angle glaucoma, aged 20-67, of whom 88 (16.32%) were male and 102 (53.68%) were female. They were organized into 3 age groups, 20-50, 51-60 and 61-67 (Table 1).

Of the total 190 respondents, 88 (46.32%) were male and 102 (53.68%) were female. Of these, 36 (18.95%) were up to 50 years of age, 79 (41.58%) were aged 51-60 and 75 (39.47%) aged 61-67. The statistical analysis showed that there was no significant difference between the two genders in terms of age structure (Pearson Chi-Square = 5.24943, df = 2, p = 0.072465).

A descriptive analysis was also carried out on the individual age of all respondents involved in the study (Table 2).

The average age of the male respondents who participated in the study was 58.05, SD 6.143, median 59, minimum age 44 and maximum age 67, while the average age of the female respondents was 57.63, SD 6.658, median 59, minimum age 44 and maximum age 67.

The statistical analysis showed that there was no significant difference between the two genders in terms of age (Mann-Whitney U Test: Z = 0.262557 p = 0.792892).

The respondents who were included in this scientific study, depending on the clinical stage in which they were diagnosed with glaucoma, used medical therapy for a period of 1-20 years and the analysis of this parameter is shown in Table 3.

Table 1. Division of respondents according to age groups

Age group		Gender		Total
		Male	Female	
Age 20-50	Number	15	21	36
	%	7.90	11.05	18.95
Age 51-60	Number	39	40	79
	%	20.53	21.05	41.58
Age 61-67	Number	34	41	75
	%	17.89	21.58	39.47
Total	Number	88	102	190
	%	46.32	53.68	100

Pearson Chi-Square = 5.24943, df = 2, p = 0.072465

Table 2. Descriptive analysis of the age of the respondents

Gender	No of people	Average value (Means)	Standard deviation (SD)	Standard Error (SE)	Median	Min	Max
Male	88	58.05	6.143	1.255504	59	44	67
Female	102	57.63	6.658	1.418532	59	44	67
Total	190	57.82	6.426	0.944411	59	44	67

Mann-Whitney U Test: Z = 0.262557, p = 0.792892

Table 3. Descriptive analysis of the duration of medical therapy

Duration of therapy		Gender		Total
		Male	Female	
1-5 years	Number	15	21	36
	%	7.90	11.05	18.95
6-10 years	Number	39	40	79
	%	20.53	21.05	41.58
11-15 years	Number	34	41	75
	%	17.89	21.58	39.47
> 15 years	Number	88	102	190
	%	46.32	53.68	100
Total	Number			
	%			

Pearson Chi-Square = 5.48451, df = 2, p = 0.182760

Fifteen (7.90%) of the male respondents used therapy in duration of 1-5 years, 33 (17.37%) for 6-10 years, 29 (15.26%) for 11-15 years and 11 (5.79%) for a period > 15 years, while 25 (13.16%) of the female respondents used therapy in duration of 1-5 years, 34 (17.89%) for 6-10 years, 32 (16.84%) for a period of 11-15 years and 11 (5.79%) for a period > 15 years.

No statistically significant difference was observed between male and female respondents in relation to the periods of prescribed treatment (Pearson Chi-Square = 5.48451, df = 2, p = 0.182760).

An analysis of the average, minimum and maximum duration of medical therapy was

performed on the entire sample of 190 included respondents (Table 4).

The average duration of the medical therapy of the male respondents was 9.99, SD 4.278, median 10.0, minimum 3 and maximum 19 years, and the average duration of treatment of the female respondents was 9.75, SD 4.556, median 9.0, minimum 2 and maximum 20 years.

Regarding the duration of treatment, there was no statistically significant difference between male and female respondents (Mann-Whitney U Test: Z = 0.151446 p = 0.671781).

The patients with primary open-angle glaucoma were prescribed daily treatment with Timolol 0.5% and Brinzolamide every 12 hours and prostaglandins (Xalatan) every 24 hours, one drop in the glaucomatous eye. This means that patients with monocular glaucoma used one vial per month, whereas patients with binocular glaucoma used 1.2 vials in form of drops. Depending on the clinical picture, patients were prescribed artificial tears, antibiotics, vitamins and other medications, which increased the monthly medication costs by an additional 10-20%. The monthly costs for medical therapy are shown in Table 5.

The monthly costs for the medical therapy of people with monocular primary open-angle glaucoma were 19.4-25.8 Euros, whereas for people with binocular glaucoma were 23.3-26 Euros. The respondents who were entitled to co-payment the monthly costs for medical therapy for monocular glaucoma were 12.1-17.2 Euros, and for binocular glaucoma 14.3-20.5 Euros.

Depending on the vocational education, occupation and work place, the respondents earned different personal income monthly: low personal income/235 Euros, average/up to 420 Euros and high personal income/over 421 Euros, and the analysis of the monthly personal income with reference to gender is shown in Table 6.

Table 4. Descriptive analysis of the duration of therapy of the entire sample of respondents

Gender	No of people	Average value (Means)	Standard deviation (SD)	Standard Error (SE)	Median	Min	Max
Male	88	9.99	4.278	1.255504	10.0	3	19
Female	102	9.75	4.556	1.418532	9.0	2	20
Total	190	9.86	4.430	0.944411	9.0	2	20

Mann-Whitney U Test: Z = 0.151446, p = 0.671781

Table 5. Monthly costs for medical therapy

Type of Medicine	Monocular glaucoma/Euro	Biocular glaucoma/Euro
Timolol	1.7-2.5*	2-3*
Brinzolamide	7-7.5*	8.4-9*
Prostaglandins (Xalatan, Travatan)	7.5-11.5**	9-13.8**
Other medication	3.2-4.3**	3.9-4.3**
Total	19.4-25.8	23.3-26

* - patients pay 20% + VAT, and the co-payment is 80%
** - patients pay 100%
*** - the ophthalmological examination is 10 Euros. Patients pay 10%

Table 6. Descriptive analysis of the monthly personal income of the respondents

Monthly income		Gender		Total
		Male	Female	
Low income/235 Euros	Number	31	34	65
	%	16.32	17.89	34.21
Average income/420 Euros	Number	35	42	77
	%	18.42	22.11	40.53
High income/ > 421 Euros	Number	22	26	48
	%	11.58	13.68	25.26
Total	Number	88	102	190
	%	46.32	53.68	100

Pearson Chi-Square = 2.55, df = 1, p = 0.1099

Sixty-five (34.21%) of the respondents earned low personal income, 77 (40.53%), average personal income and 48 (25.26%) earned high personal income.

The economic burden on the monthly personal income borne by the respondents' costs for medical therapy was also calculated (Table 7).

The economic burden caused by the medical costs for the therapy, depending on the price and type of medication, participated with 8.72-16.81% in the monthly personal income of people with monocular glaucoma, whereas with binocular glaucoma 10.26-19.32% and was statistically significantly higher when compared to the costs of high-income earners (Pearson Chi-Square = 9.1722, df = 2, p = 0.028986).

Depending on the clinical stage and severity of the disease, the lost visual acuity reflected on the productivity and quality of the work performed by the respondents, and consequently, some of them were reassigned to lower positions and received lower monthly income, and the results of those tests are shown in Table 8.

The economic implications/burden on the monthly personal income was typically manifested by lower personal income and reduced income due to productivity loss, with statistically significant importance in the third clinical stage after 11-15 years (Pearson Chi-Square = 9.97, df = 2, p = 0.0161) and in the fourth clinical stage after more than 15 years from the diagnosis and treatment of the disease (Pearson Chi-Square = 9.41, df = 2, p = 0.0180), in relation to the other clinical stages.

Table 7. Economic burden on the monthly personal income of the respondents

Monthly income	Monocular glaucoma/%	Biocular glaucoma/%
Low income/235 Euros	8.72-16.81 %	10.26-19.32 %
Average income/420 Euros	4.88-9.40 %	5.74-10.81 %
High income/ > 421 Euros	< 4.1-7.9 %	< 4.82-9.08 %

Pearson Chi-Square = 9.1722, df = 2, p = 0.028986

Table 8. Economic implications for monthly personal income

Clinical stage		Economic implications	
		Reduced personal income	Loss of productivity
1-5 years	Number	0	0
	%	0	0
6-10 years	Number	3	5
	%	1.58	2.63
11-15 years	Number	16	19
	%	8.42	10
> 15 years	Number	22	25
	%	11.58	13.16
Total	Number	41	49
	%	21.58	25.79

Pearson Chi-Square = 9.97, df = 2, p = 0.0161; Pearson Chi-square = 9.41, df = 2, p = 0.0180

Table 9. Economic implications generated by therapy costs

Economic implications		Gender		Total
		Male	Female	
Burden on the family budget	Number	19	21	40
	%	10	11.05	21.05
Inadequate treatment	Number	23	26	49
	%	12.11	13.68	25.79
Total	Number	42	47	89
	%	22.11	24.73	46.84

Pearson Chi-Square = 2.935, df = 2, p = 0.0988

Due to the low personal income and the impact of the high medical costs for the therapy on the monthly personal budget, the economic burden caused by the medical costs on certain patients negatively impacted their family budget or due to economic reasons, they were treated inadequately with cheaper alternative medications or with lower therapeutic dose (Table 9).

In 40 respondents, the medical costs for the therapy burdened the family budget, and 49 respondents, due to high medical costs and economic reasons, were treated inadequately using cheaper alternative medications or lower doses of the therapy. The statistical analysis showed that in relation to these two economic indicators, there was no significant difference between the respondents of both genders (Pearson Chi-Square = 2.935, df = 2, p = 0.0988).

Discussion

The pharmacoeconomic burden of primary glaucoma arises from the cost of medication, laser and surgical therapy, and inpatient treatment (13, 14).

The medical therapy includes administration of various groups of antiglaucoma medications: beta blockers, miotics, carbonic anhydrase inhibitors, alpha 2 agonists, prostaglandin analogues, neuroprotective, multivitamin and more than 15 other types of medication (23, 24, 25, 26, 27).

The application of laser therapy generates the lowest costs for treatment of glaucoma compared to other types of treatments and at the same time gives the greatest comfort and quality of life, especially to people who are educated and adhere to a hygienic-diet regime in accordance with the vision condition, because after its application, the following 5-7 years, there is no need for prescription medication (28, 29).

The economic burden of the medical treatment for glaucoma to date is almost identical to the cost of surgical treatment, but due to the uncertain prognosis from surgery, the studies conducted in European countries indicate that in practice, the most effective way to treat glaucoma is with therapy of newer generation of anti-glaucoma medications, regardless of the fact that the economic burden of this treatment is very high, because it is lifelong (30, 31, 32).

Varma R., Grekova D., Sarenac V.T., Lam B.L. and others indicate that the economic, individual and social burden in the advanced clinical stages of glaucoma is progressively increasing, when compared to the cost of treatment in the initial clinical stage of the disease (20, 33, 34, 35).

In the scientific studies conducted by Bagnis A., Hirsch JD. and others, it was determined that medical costs of the glaucoma patients treated with medical therapy accounted for 42 to 56% of total direct medical costs and that the economic costs of glaucoma treatment were directly correlated with the clinical stage in which they were treated and that the same, as the disease progressed, continued to further increase (36, 37).

Traverso C.E. and associates, in the analysis of the economic burden on glaucoma patients in European countries, say that the costs for glaucoma patients in the early stages are 455, and in the advanced stages of the disease - 969 Euros, while in a similar study in the US, they report that the cost of treatment of glaucoma in the early stages is 625, and in the advanced stages, 2,511 Dollars, and annually from the budget, for the treatment of glaucoma, 2.5 billion dollars are allocated, of which 1.9 billion dollars are allocated to direct medical costs (38).

A retrospective study in Mexico, 462 hospitalized glaucoma patients found that the cost of hospital treatment was very high and the direct medical costs for one-month treatment accounted for 49.8% of monthly budget of the patients with average personal income, while the costs in low-income patients were 61% (39).

In India, in a scientific study of glaucoma patients with low-income in urban areas (New Delhi) the direct medical costs for hospital treatment accounted for 18.4% of the monthly budget, and for hospital treatment in rural areas, the cost was 41.9% (40).

A study on the economic burden of glaucoma conducted in Denmark, Germany, Italy, England, Ireland, France and Spain states that the economic burden on social communities and individuals is immense, and in terms of social cost, it varies from 11,758 to 19,111 Euros, and annual direct medical costs of the individuals ranged from 429 to 523 Euros, while the individual burden from productivity loss was between 7,436 and 10,200 Euros (41).

A study on individual productivity loss leading to lower-income was conducted in the United States in 2004. It included 125,882 visually impaired and 40,671 blind people, including glaucoma patients. It was reported that the visually impaired received lower annual income of $ 9,851 and the blind people received $ 12,121 less, compared to people with normal vision, with a total loss of more than $ 1.7 billion (42).

Analyzing the productivity losses and monthly income of people with primary glaucoma in the Mexican state of River, Gomez found that 61.5% of glaucoma patients earned low personal income, 19.5% average personal income, 7.9% high personal income, while others did not earn any personal income (38). Similar results were found by Nayak B with associates in India, confirming that hospitalized primary glaucoma patients earned lower personal income when compared to other hospitalized people (39, 40).

Conclusion

Primary open-angle glaucoma generates a significant individual and social economic burden as a consequence of direct and other medical costs during treatment and indirect losses from reduced productivity as a result of visual impairment.

Pharmacoeconomic costs depend on the type of medication, the doctrines applied, their prices and the length of therapy, and in our research they amount to 20.5-39.5 Euros for monocular glaucoma,

while 24.1-45.4 Euros per month for binocular glaucoma.

Due to the reduced productivity and non-fulfillment of work obligations, 34.21% received low personal income, whereas 25.26% high personal income. Among the respondents with low personal income with monocular glaucoma, the costs for medications in the monthly personal income participated with 8.72-16.81%, while with binocular glaucoma 10.26-19.32%. The share of the medication costs of respondents with high personal income was of much lower proportion, and for monocular glaucoma it was < 4.1-7.9%, while for binocular glaucoma it was < 4.82-9.08%.

The disproportion between the increased medical costs and the indirect losses due to the reduced income was reflected in existential endangerment and social family burden in 21.05%, whereas 25.79% of the respondents were treated inadequately with generic alternative medications or with inadequate dose of medications for economic reasons.

Productivity losses due to decreased work ability (WAI - Work ability index) which was 10-30% were recorded in 25.79%, while in 21.58% of the respondents, due to non-fulfillment or poor performance of tasks, were demoted to a lower position or received a reduced monthly personal income.

The use of screening programs for early detection and timely diagnosis, availability of medications, regular ophthalmological examinations and adequate treatment, will prevent the progression of the disease, vision loss and will help preserve the work ability, thus reducing individual social and economic losses and will improve the quality of life of glaucoma patients.

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FARMAKOEKONOMSKE IMPLIKACIJE GENERISANE OD STRANE PRIMARNOG GLAUKOMA OTVORENOG UGLA KOD RADNIKA

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Glaukom je optička neuropatija, koja zbog ireverzibilnog gubitka vidne oštrine, direktnih i drugih medicinskih rashoda povezanih sa lečenjem i indirektnih gubitaka, usled smanjene produktivnosti, generiše socijalno i farmakoekonomsko opterećenje kod obolelih osoba. Cilj rada bio je da se sagledaju farmakoekonomske implikacije generisane od strane primarnog glakoma otvorenog ugla kod radnika različitih profesija. Rad predstavlja studiju preseka sa kvantitativnim analitičkim pristupom (cross sectional study), u koju je uključeno 190 osoba muškog i ženskog pola, starosti od 38 do 67 godina, sa primarnim glaukomom otvorenog ugla, sa očuvanom oštrinom vida > 6/18 (0,33), prema klasifikaciji ICD-10, sprovedenoj u periodu avgust – novembar 2020. godine, na teritoriji Severne Makedonije. 34,21% ispitanika zarađivalo je minimalni, 40,53% prosečni, a 25,26% visok lični dohodak. Farmakološki rashodi lečenja biokularnog glaukoma iznosili su od 24,1 evro do 45,4 evra mesečno, koji učestvuju sa 10,26% – 19,32% kod osoba sa minimalnim i < 4,82% – 9,08% kod osoba sa visokim mesečnim ličnim dohotkom. U 21,05% slučajeva ekonomsko opterećenje manifestovalo se egzistencijalnom ugroženošću porodice, a 25,79% ispitanika, iz ekonomskih razloga, lečilo se neadekvatnim generičkim, alternativnim lekovima ili neadekvatnim dozama. Gubitak produktivnosti registrovan je kod 25,79% ispitanika, a njih 21,58%, zbog neispunjavanja radnih obaveza, zarađivalo je smanjeni lični dohodak. Glaukom generiše ogroman farmakoekonomski teret, koji je posledica direktnih i drugih medicinskih rashoda lečenja i indirektnih gubitaka zbog smanjene produktivnosti, što zahteva primenu skrining programa za pravovremenu dijagnozu i adekvatnu, redovnu oftalmološku terapiju, koja će doprineti održavanju oštrine vida i radne sposobnosti, a time će se smanjiti i farmakoekonomsko opterećenje obolelih.

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Ključne reči: *primarni glaukom, farmakoekonomske implikacije, terapija, rashodi, smanjenje produktivnosti*