https://doi.org/10.5114/ko.2019.93470

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Automated Screening of Diabetic Retinopathy and Age-related Macular Degeneration in Selected Vision Express Ophthalmic Out-patients Clinics in Poland – a Pilot Study

Automatyczny screening retinopatii cukrzycowej i zwyrodnienia plamki związanego z wiekiem w wybranych poradniach Vision Express w Polsce – badanie pilotażowe

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Abstract: Background: The aim of this pilot study was to evaluate the prevalence of age-related macular degeneration (AMD) and diabetic retinopathy (DR) in patients undergoing screening in selected Vision Express out-patients clinics in Poland with the artificial intelligence (AI) algorithm (RetinaLyze software).

Materials and Methods: The study design was a retrospective, comparative case series. All subjects had detailed eye examinations which included: intraocular pressure measurements, visual acuity testing, cover test, binocular vision assessments and color fundus photos of both eyes with digital cameras. All fundus photos were then analyzed by RetinaLyze software to detect signs of eye diseases (either AMD or DR).

Results: In total, 13850 of adult subjects underwent the eye screening programme between 1st of January 2019 to 30th of June 2019 in fifty three Vision Express (VE) clinics in fifteen regions of Poland and 2475 (17.9%) of them have been recognized by RetinaLyze software to have either DR or AMD lesions in the retina. The highest rates of patients recognized to have either DR or AMD were in South-East regions of Poland (Lubelskie, Małopolskie and Podkarpackie province as calculated by 31.8%, 39.0% and 40.1%, respectively). The lowest rate of patients (only 1.9%) recognized by AI to have DR or AMD was in Podlaskie province in North-East of Poland.

Conclusions: in summary, our study showed the total rate of patients with retinal diseases in population screened in selected VE out-patients clinics in Poland is higher than in general population.

Key words: AMD, diabetic retinopathy, artificial intelligence.

Abstrakt: Cel pracy: zbadanie częstotliwości występowania zwyrodnienia plamki związanego z wiekiem (AMD) i retinopatii cukrzycowej (DR) wśród pacjentów, którzy przeszli screeningowe badanie wzroku przez system sztucznej inteligencji (AI) w wybranych poradniach Vision Express w Polsce.

Materiał i metody: retrospektywna ocena serii przypadków. Wszyscy włączeni pacjenci przeszli pełne badanie narządu wzroku, które obejmowało m.in. badanie ciśnienia wewnątrzgałkowego, badanie ostrości wzroku, cover test, badanie widzenia obuocznego i zdjęcia dna oczu cyfrową kamerą. Następnie wszystkie wykonane zdjęcia dna oczu zostały ocenione przez system RetinaLyze (algorytm sztucznej inteligencji) w celu wykrycia objawów AMD lub/i DR.

Wyniki: łącznie 13850 dorosłych pacjentów przeszło badanie narządu wzroku w pięćdziesięciu trzech poradniach Vision Express (VE) w piętnastu województwach pomiędzy 1 stycznia 2019 roku a 30 czerwca 2019 roku. W tym czasie system AI RetinaLyze wykrył AMD lub/i DR u 2475 (17.9%) zbadanych osób. Największy odsetek pacjentów z rozpoznaniem AMD lub/i DR był w południowo-wschodniej Polsce (31,8% w woj. lubelskim, 39,0% w woj. małopolskim i 40,1% w woj. podkarpackim). Najniższy odsetek (tylko 1.9%) pacjentów z rozpoznaniem AMD lub/i DR przez AI był w woj. podlaskim.

Wnioski: całkowity odsetek pacjentów z chorobami siatkówki w badanej populacji pacjentów wybranych poradni VE w Polsce jest wyższy niż w innych badaniach, które obejmowały populację dorosłych Polaków.

Słowa kluczowe: AMD, retinopatia cukrzycowa, sztuczna inteligencja.

The authors declare no conflict of interest/ Autorzy zgłaszają brak konfliktu interesów w związku z publikowaną pracą

ISSN 0023-2157 Index 362646

Introduction

According to the Vision Loss Expert Group of the Global Burden of Disease Study the leading causes of moderate and severe vision impairment among the global population in year 2015 were cataract, uncorrected refractive error, age-related macular degeneration (AMD), glaucoma and diabetic retinopathy (DR) (1). However, in high income countries AMD became the leading cause of blindness, in Central and Eastern Europe cataract remained the leading cause (2, 3). The recently published studies from the central region of Poland revealed that, in the urban population of the city of Lodz, age-related macular degeneration (AMD) followed by cataract, amblyopia, glaucoma and diabetic retinopathy (DR) was the principal cause of both unilateral and bilateral non-correctable visual impairment among subjects aged 35 years or older (4) and also showed low level of education about possible eye complications of systemic diseases (5). In year 2018, The Vision Express Company, which is the biggest chain of opticians and ophthalmic out-patients clinics in Poland, introduced the first commercially available screening programme aimed to detect all principal causes of vision impairment in Poland (6). This screening programme also introduced the first commercially available telemedicine system of automated detection of DR and AMD using the artificial intelligence in Poland (RetinaLyze software, RetinaLyze International, Kobenhavn, Denmark). This screening is currently performed in fifty three Vision Express (VE) clinics across whole country, which means it covers a nationwide population. Such artificial intelligence (AI) systems have been demonstrated to lower costs, improve diagnostic accuracy and increase patients access to the screening of eye diseases including DR, AMD, cataract and glaucoma (7–12). The aim of this pilot study was to evaluate the prevalence of age-related macular degeneration and diabetic retinopathy in patients undergoing screening in selected Vision Express out-patients clinics in Poland with the RetinaLyze software.

Materials and Methods

The study design was a retrospective, comparative case series. We included into the study 13850 adult subjects from fifteen regions of Poland. Initial examination included: intraocular pressure (IOP) measurements using pneumo-tonometry, distance and near visual acuity (VA) testing with standard charts, a cover test and binocular vision assessments. Then refraction data were obtained in all eyes using the computer autorefractometry. Based on this refraction, subjective refraction tests were performed to achieve best corrected visual acuity (BCVA). After achieving BCVA, the slit lamp evaluation of the anterior eye segment was performed. Finally the fundus photos of both eyes were taken with using of digital cameras either Canon CF1 (Canon Inc, Tokyo, Japan) or DRS fundus camera (Centervue S. p. A., Padova, Italy). All fundus photos were analyzed by RetinaLyze software which uses automated algorithm module (AI) to detect signs of eye diseases (13). The RetinaLyze software as other AI systems in ophthalmology had used supervised learning model from already human-labeled training data (fundus photos) to train to recognized diabetic retinopathy and age-related macular degeneration lesions in retina. However, the final diagnosis should always be confirmed by an ophthalmologist. Thus, all our patients with recognized DR or AMD lesions were referred to the retina specialists. Our study adhered to the provisions of the Declaration of Helsinki for research involving human subjects and all included subjects signed the written consent for eye examinations.

Results

Between 1st of January 2019 to 30th of June 2019 the screening programme was available in fifty three Vision Express (VE) out-patients clinics in fifteen regions of Poland (except Opolskie province) (Fig. 1). The biggest number of VE clinics was in Mazowieckie province with the biggest number of VE clinics in capital city of Warsaw. In total, 13850 of adult subjects have underwent the eye screening programme during study period (Table I) and 2475 (17.9%) of them have been recognized by RetinaLyze software to have either DR or AMD lesions in the retina.

The number of patients screened as well as recognized to have DR or AMD varied between VE clinics. The biggest number of patients screened by RetinaLyze software was in Mazowieckie province and in capital city of Warsaw. The smallest number of patients screened was in Lubuskie province and in the city of Zielona Góra. The highest rates of patients recognized by RetinaLyze software to have either DR or AMD were in south-east regions of Poland (Lubelskie, Małopolskie and Podkarpackie province as calculated by 31.8%, 39.0% and 40.1%, respectively). The lowest rate of patients (only 1.9%) recognized by AI to have DR or AMD was in Podlaskie province at North-East of Poland. In other regions the rate of patients with positive DR or AMD diagnoses by RetinaLyze software ranged from 8.0% in Warmińsko-Mazurskie province to 26.6% in Zachodniopomosrkie province. The only region of Poland which did not have any patients screened for eye diseases by AI was Opolskie province.

Discussion

This study evaluates for the first time the automated detection of DR and AMD with AI system (RetinaLyze software) on such a big scale in Poland. The study reported the rate of patients recognized by AI to have either DR or AMD in entire study population on the level of about 17.9% which ranged from 1.9% in Podlaskie province to 40.1% in Podkarpacke province, respectively. However, it might be overestimated, because many people with eye problems seek help in opticians due to limited accessibility to ophthalmologists in public health care system in Poland. Direct comparison of our results to the findings obtained in other prevalence studies of DR and AMD from Poland and other countries (with or without using of AI systems) is limited due to differences in the study design. The major limitation is the fact that our DR and AMD diagnoses made by AI system were not confirmed by retina specialists. Other limitations included the differences between study populations. We enrolled into our study subjects solely from VE clinics, thus the prevalence of ocular disorders might be overestimated. In Poland, Nowak et. al. showed that the prevalence of all retinal disorders among subjects aged 35 years or older in the urban population of the city of Lodz was 9.1% (14). In the same population, the prevalence of DR and AMD was 1.7% and 4.3% respectively (15). In 2018, Grzybowski and Brona fo-

BIAŁYSTOK	1
BIELSKO-BIAŁA	1
BYDGOSZCZ	2
CZĘSTOCHOWA	1
ELBLĄG	1
EŁK	1
GDAŃSK	2
GDYNIA	2
GLIWICE	1
KATOWICE	2
KIELCE	1
KONIN	1
KOSZALIN	1
KRAKÓW	3
LUBLIN	1
ŁÓDŹ	3
OLSZTYN	2
OSTROŁĘKA	1
PŁOCK	1
POZNAŃ	1
RADOM	1
RUMIA	1
RYBNIK	1
RZESZÓW	1
SŁUPSK	1
SZCZECIN	3
TARNOWO GÓRNE	1
TORUŃ	2
WARSZAWA	8
WROCŁAW	4
ZIELONA-GÓRA	1

Fig. 1. The number of Vision Express out-patient clinics offering automated DR and AMD detection with AI system (RetinaLyze software) in particular regions and cities of Poland.

Ryc. 1. Liczba poradni Vision Express w Polsce oferujących ocenę przesiewową narządu wzroku z wykorzystaniem systemu sztucznej inteligencji (RetinaLyze software) z podziałem na regiony i miasta.

Region/ Województwo	No. of patients screened/ Liczba przebadanych pacjentów n (100%)	No. of DR or AMD detections/ Liczba rozpoznań DR lub AMD n: %
Dolnośląskie	1251	240 (19.2%)
Kujawsko-Pomorskie	841	87 (10.3%)
Lubelskie	512	163 (31.8%)
Lubuskie	72	10 (13.9%)
Łódzkie	787	120 (15.2%)
Małopolskie	1053	411 (39.0%)
Mazowieckie	3712	500 (13.5%)
Opolskie	0	0
Podkarpackie	227	91 (40.1%)
Podlaskie	105	2 (1.9%)
Pomorskie	1312	208 (15.8%)
Śląskie	1402	214 (15.3%)
Świętokrzyskie	486	46 (9.5%)
Warmińsko-Mazurskie	671	54 (8.0%)
Wielkopolskie	560	100 (17.8%)
Zachodniopomorskie	859	229 (26.6%)
Totally/ Razem	13850	2475 (17.9%)

Tab. I. The total number of patients screened and number of DR or AMD detections with AI system (RetinaLyze software) in selected Vision Express out-patients clinics by regions of Poland.

Tab. I. Całkowita liczba pacjentów poddanych ocenie przesiewowej przez system sztucznej inteligencji (RetinaLyze software) w wybranych poradniach Vision Express w Polsce oraz liczba pacjentów z rozpoznaniem DR lub AMD z podziałem na regiony.

ISSN 0023-2157 Index 362646

und that the rate of DR recognized by AI system (IDx-DR, IDx Technologies Inc., Coralville, IA, USA) among DM patients in Poznan was 21.5% with the values of sensitivity and specificity of this system of 94% and 95%, respectively (9). However, the results of other studies outside Poland showed the sensitivity and specificity of RetinaLyze software to detect DR as high as 97.0% and 96.7% (8, 16, 17). In our study the rates of patients recognized to have either DR or AMD varied between regions of Poland. The total rate of 17.9% was much higher than found in hospital based population in Lodz, but lower than found in Poznan among DM patients. The lowest rate was observed in Podlaskie province. According to the Maps of Healthcare Needs published by Polish Ministry of Health the morbidity of AMD and other retinal diseases in this region is one of the lowest in Poland (Fig. 2) (18).

However, it is difficult to explain why the highest rates were observed in our study in the south-east part of Poland. The VE patients are not obliged to inform us back whether the diagnosis of retinal disease was confirmed or not. But the sensitivity and specificity of RetinaLyze software is good enough to provide reliable findings. The AI systems are widely used in many countries for screening of retinal diseases. Those systems are based of machine deep learning (DL) or deep convolutional neural networks (DCNN) which are explicitly trained for performing automated grading of DR or AMD lesions and often outperform human graders (8, 11, 12, 19). In China, 19,904 fundus images from 6013 diabetic patients were acquired during Shanghai Diabetic Eye Study (SDES) and analyzed by SmartEye AI software with high diagnostics accuracy (20). In Singapore Eye Research Institute (SERI) 494,661 retinal images were analyzed by deep learning system (DLS) with the sensitivity and specificity of DLS in a multiethnic population around 90.5% and 91.6% for DR, 100% and 91.1% for sight threatening DR, and 93.2% and 88.7% for AMD (10). In the USA, the diagnostic accuracy of DCNN system in an AREDS population (more than 130,000 fundus images from 4613 patients) ranged between 88.4% and 91.6% for AMD (18). The next step in developing AI systems for the diagnosis of retinal diseases is introducing of the optical coherence tomography (OCT) images. The first results of the pilot studies are very promising (21–23).

Conclusions

In summary, our study showed the total rate of patients with AMD and DR lesions in population screened by RetinaLyze software in selected VE out-patients clinics in Poland is higher than in general population.

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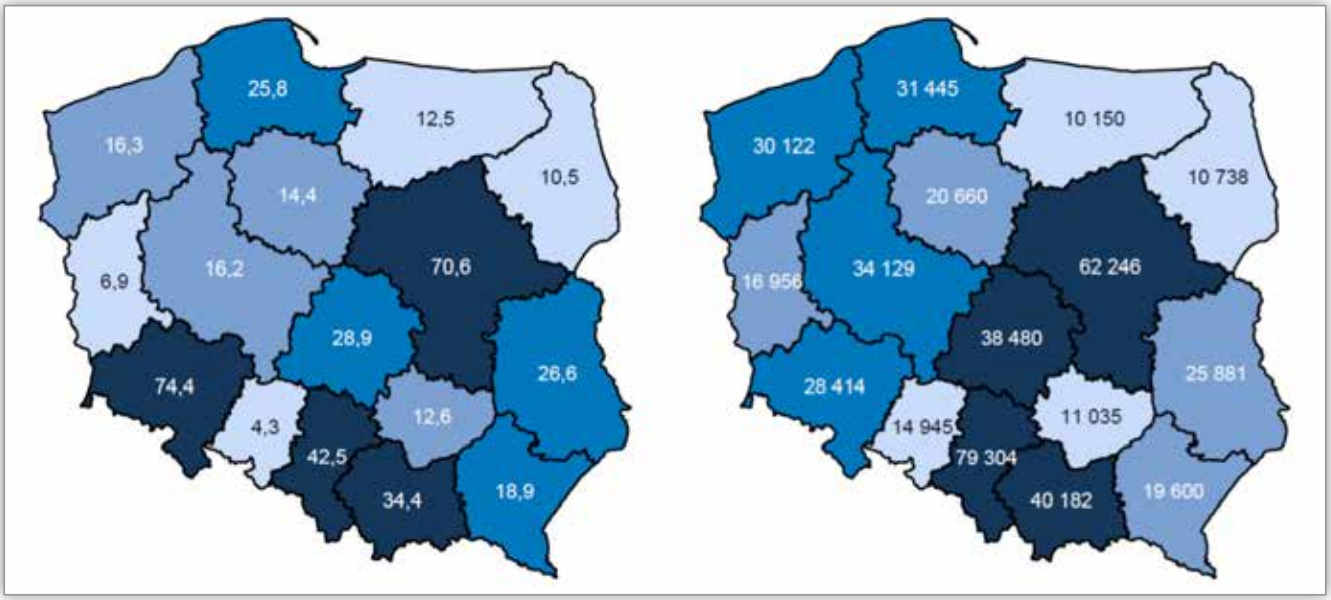

Fig. 2. Registered morbiditiy of AMD (left – in thousands of cases) and other retinal diseases (right – including DR) in Poland on 31st of December 2016, according to Maps of Healthcare Needs – Database of Systemic and Implementation Analyses.

Ryc. 2. Rejestrowa chorobowość AMD (po lewej – w tysiącach przypadków) oraz innych chorób siatkówki (po prawej – w tym DR) w Polsce na dzień 31 grudnia 2016 r. według Map Potrzeb Zdrowotnych – Baza Analiz Systemowych i Wdrożeniowych.

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The paper was originally received 07.11.2019 (KO-00222-2019)/
Praca wpłynęła do Redakcji 07.11.2019 (KO-00222-2019)
Accepted for publication 08.12.2019/
Zakwalifikowano do druku 08.12.2019

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ISSN 0023-2157 Index 362646