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Comparison of Manual Refraction Versus Autorefraction in 60 Diabetic Retinopathy Patients

Keyvan Shirzadi[1], Kourosh Shahraki[2], Emad Yahaghi[3], Ali Makateb[1], and Keivan Khosravifard[1*]

[1]Department of Ophthalmology, AJA University of Medical Sciences, Tehran, Iran
[2]Department of Ophthalmology, Alzahra Eye Hospital, Zahedan University of Medical Sciences, Zahedan, Iran
[3]Baqiyatallah University of Medical Sciences, Tehran, Iran

Corresponding author: Keivan Khosravifard, Department of Ophthalmology, AJA University of Medical Sciences, Tehran, Iran. Tel: 00989121998066. E-mail: khosravi.keivan@gmail.com

ABSTRACT

Aim: The purpose of the study was to evaluate the comparison of manual refraction versus autorefraction in diabetic retinopathy patients. **Material and Methods:** The study was conducted at the Be'sat Army Hospital from 2013-2015. In the present study differences between two common refractometry methods (manual refractometry and Auto refractometry) in diagnosis and follow up of retinopathy in patients affected with diabetes is investigated. **Results:** Our results showed that there is a significant difference in visual acuity score of patients between manual and auto refractometry. Despite this fact, spherical equivalent scores of two methods of refractometry did not show a significant statistical difference in the patients. **Conclusion:** Although use of manual refraction is comparable with autorefraction in evaluating spherical equivalent scores in diabetic patients affected with retinopathy, but in the case of visual acuity results from these two methods are not comparable.

Key words: Diabetes, Retinopathy, Autorefraction, Manual refraction, Patient.

1. INTRODUCTION

Civilization progress is associated with unfavorable changes in the lifestyle of the majority of human population. Improper diet, rich in fat and carbohydrates, and simultaneous limitation of physical activity can lead to the development of a severe metabolic disorder, diabetes. According to WHO estimates the worldwide population of patients with diabetes will reach 20 million by 2030 (1). Diabetes mellitus is a chronic metabolic disorder that can result in multiple long-term micro- and macro-vascular complications. Micro-vascular complications include retinopathy, nephropathy and neuropathy. Diabetes is well known as the leading cause of blindness, end-stage renal disease (ESRD) and limb amputation. In molecular level, diabetes is mainly characterized by defects in the metabolism of carbohydrates. This disease is the sixth leading cause of death in the world and developing countries. Based on various studies, diabetes can lower the life expectancy in humans by about 5 to 10 years (2).

Wide prevalence of diabetes, along with acute and chronic complications that are associated with this disorder has created many potential threats to the human race. Statistics show that 14 to 23 percent of the Iranian population over the age of 30 years has diabetes (3, 4). One of every twenty Iranian people is affected with diabetes and half of these numbers are not aware of their disease. Worldwide, one person dies in every 10 seconds because of diabetes. Every 30 seconds one person loses their feet in the world because of the diabetes (3, 5).

Vascular complications of diabetes are classically divided into mi-

cro-vascular (caused by damage to small blood vessels) and macro-vascular (caused by damage to larger blood vessels). Micro-vascular complications include retinopathy, nephropathy, and neuropathy. Diabetic retinopathy involves changes to retinal blood vessels that can cause them to bleed or leak fluid, distorting vision. Diabetic retinopathy is the most common cause of vision loss among people with diabetes and a leading cause of blindness among working-age adults. Incidence of retinopathy in diabetic patients is 25 times higher than unaffected population. It should also be noted that people with diabetes are at higher risk of developing glaucoma, cataracts and Age-related Macular degradation (AMD) (6, 7).

Diabetic retinopathy is a common cause of vision loss and blindness (25% of cases of blindness in Western countries). Patients with untreated diabetes have 25 times higher risk of blindness than unaffected people. The presence and severity of diabetic retinopathy mostly depends on the age of patient at the time of diagnosis and duration of diabetes other than severity of the disease and control of blood sugar. 100% of patients with type I diabetes and 60% to 80% of patients with Type II diabetes develop retinopathy in the first 20 years of disorder. With improvements in methods of treatment and diagnosis of both diabetes and retinopathy, only a small percentage of diabetic patients will develop serious vision problems, Provided that they undergo examinations in the proper time (8, 9).

There are two main types of diabetic retinopathy, including background diabetic retinopathy (small artery aneurysms, infarcts or interrupt blood flow to part of the retina) and proliferative retinopathy. Background retinopathy is usually not associated with loss of vision. However macular edema or proliferative retinopathy (especially new blood vessels near the optic disc) requires immediate treatment with laser photocoagulation in order to prevent loss of vision (10).

Refraction, the determination of the refractive error of an eye, is an essential part of eye care. Refraction is used clinically to determine the spectacle prescription so that the best possible acuity can be achieved. One of the most important methods of examination for vision defects is refractometry. This method is used to measure the visual acuity (VA) in diabetic patients. There are two types of refractorymetry. In the manual refractometry, patient perception of quality and resolution of vision determines the status of the eye, while in the second type, Autorefractometer, as the name suggests, an automatic instrument determines the patient's eye number. For many years, clinical research studies have utilized the Manual refrectometry testing method for standardizing refraction and subsequent measurement of VA. However, this method requires substantial investment in training and certification of refractionists, and the procedure itself can be time consuming. Thus, an acceptable, less time intensive alternative to the rigorous manual refrectometry procedure might result in substantial savings of cost and time for clinical trials in diabetic retinopathy. It might also improve clinical trial subject recruitment and retention because of shorter and less technically burdensome clinic visits.

One potential alternative to manual refraction is autorefraction. This technique utilizes a computer-controlled device to provide an objective measure of an individual's refractive error without the need for a skilled refractionist. Since first being described and validated against manual refraction in the early 1970 (11), autorefractors have come into widespread clinical use due to the ease and speed of the semi-automated autorefraction procedure, the lack of need for a trained refractionist, and commercial availability.

In clinical trials, the role of autorefraction has been limited to providing starting information for subsequent manual refraction. However, results from a recent single site study sponsored by the Diabetic Retinopathy Clinical Research Network (DRCR.net) suggest that autorefraction using certain devices may be an acceptable substitute for the manual refraction in obtaining best corrected VA in eyes of patients with diabetes (12).

The purpose of the study was to evaluate the comparison of manual refraction versus autorefraction in diabetic retinopathy patients.

2. MATERIALS AND METHODS

Number of samples was determined according to available sources and sample size calculation formula ($N=2(Z1-\alpha/2+Z1-\beta)\ 2\sigma 2d2$) which is based on comparison of average sample size. According to these preconceptions in period of three months, 60 patients were randomly selected and enrolled in the research.

The study was conducted at the Be'sat Army Hospital and consists of two phases. Study of manual refraction and automatic refraction and comparison of results from these two methods.

In manual refraction, patient perception of quality and resolution of pictures was questioned and based on this perceptions the status of the patient's eye was determined.

In auto refraction, patient were sat in front of automatic refractometer and at any moment an image was displayed in front of one eye, subsequently the device determined status of patient's eye and therefor the whole process is completely objective. Also in this study age, sex, marital status, location, diet, amount of daily exercise, weight and disease history of all participants was recorded.

All patients with diabetic retinopathy who had a blood sugar below 200 were included in the study and patients with history of trauma, ocular surgery, cataract, glaucoma, uveitis and other eye diseases were excluded.

All patients have signed consent forms before entering the study.

3. RESULTS

The average age of the participants in this study was 47.3 years with standard deviation of 13.58 years, the youngest participants was 30 years old and the oldest one was 68 years old. Of the 60 patients, 20 patients (33.3%) were affected with grade 1, 26 patients (43.3%)

with grade 2 and 14 patients (23.3%) with grade 3 retinopathy, respectively (Figure 1).

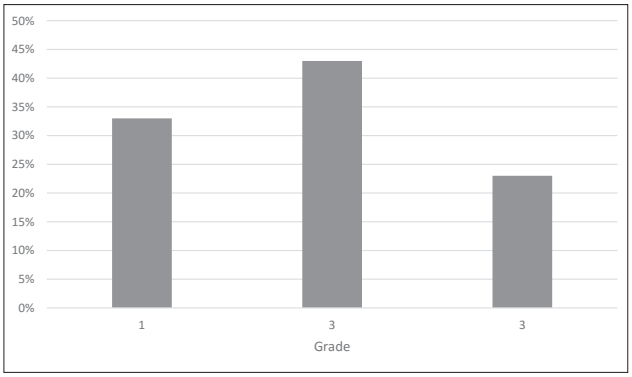

Figure 1. Distribution of patients in three different grades of diabetic retinopthy.

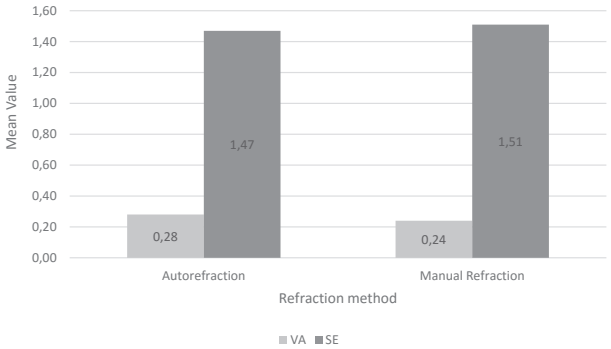

Figure 2. Comparison of mean of VA and SE values for Auto versus Manual refraction method in diabetic retinopathy patients. SE: spherical equivalent, VA: visual acuity.

The mean of VA score for autorefraction and manual refraction was 0.28 and 0.24 with standard deviations of 0.23 and 0.22 respectively. Mean of SE score for autorefraction and manual refraction was 1.47 and 1.51 with standard deviations of 2.73 and 2.3 respectively (Figure 2). Results of independent t-test on these two variables (mean of VA and SE) showed that, although differences in VA between the two groups of patients was significant (P=0.001), no statistically meaningful difference exists in spherical equivalent (SE) score of the patients (P=0.539). In addition, the numbers for these two variables were very close to each other.

4. DISCUSSION

Chronic diseases such as diabetes mellitus and its complications has now become one of the most important health problems in society. Diabetic retinopathy is one of the microvascular complications of diabetes which is under influence of many factors (6).

Comparison of retinopathy in different countries is quite complicated because of differences in the types of diabetes in each country, the number of patients studied in different investigations and differences in examination methods (13). Diabetic retinopathy is a common cause of vision loss and blindness (25% of cases of blindness in Western countries). Those who have untreated diabetes, are 25 times more at risk of blindness than other people (10).

The presence and severity of diabetic retinopathy is mostly related to age of the patient at the time of diagnosis and duration of diabetes, rather than severity of the disease and control of blood sugar. After 20 years, retinopathy occurs in 100% of patients with type I diabetes and 60% to 80% of patients with Type II diabetes (14).

On the other hand, the training and certification of examiners to accurately refract study participants for the determination of best corrected VA is both time-consuming and expensive. The rigorous manual refraction protocol currently in use also is time consuming to perform and lengthens visits for study participants. Thus, the ability to substitute an automated refraction for manual refraction could streamline study visits and result in substantial savings of time and cost for clinical staff.

There are a huge body of literature regarding diabetic retinopathy, its prevalence and diagnosis.

In a study by Funatsu et al to assess retinopathy patients awareness of their disorder, 1333 patients with type II diabetes were measured by a questionnaire. Results of this study showed that although more than 98 percent of patients were aware of their disease, about 30.5% of them refuse to undergo periodic ocular examination because they were not familiar with visual complications of diabetes (15).

In 2001 Orr et al studied 29 patients affected with sub Foveal Choroidal Neovascularization (CNV). On average, manual refraction was reported to be one spherical (equivalent to 1.04 Diopter) more than auto refraction. Moreover, Average score of Perspicuity in manual refraction was 1.5 times higher than auto refraction (2).

Rein et al studied costs of treatment of over 10 million diabetic patients in the age of 30 to 48 years. Patients in this study had no or minor retinopathy. Results of this work indicate that one-year treatment and examinations of the patients are more affordable than those of two-year, Because in the one year excess period, patients may become affected with microaneurysms (16).

The aim of this study was to compare manual refraction with automatic refraction in patients suffering from diabetic retinopathy. Our results showed that, despite significant differences in VA between the two groups (P=0.001), there was no statistically significant difference in SE score of the patients (P=0.539). In addition, the numbers for these two variables were very close to each other.

These findings are in contrast with Orr's study which was concluded that amount of SE in autorefraction is considerably higher than manual refraction. Other studies are mostly in support of Peggy et al and in contrast to ours (2, 12).

The most probable explanation for this difference could be variation in the type of underlying disease. For example, Peggy et al studied patients with Subfoveal Choroidal Neovascularization. Studies by Canon et al and Lake Success et al are also done on the same subtype of disorder and are in favor of Peggy's study.

In 2006 Chung et al studied the accuracy of autorefraction in comparison with manual refraction in diagnosis of children with refractive error. In this study, total

number of 117 children was examined by three types of autorefraction machine and manual refraction instrument with and without cycloplegia. Results of this study showed that in non-cycloplasia condition, all three types of instruments have more false positive diagnosis for myopia, but with inclusion of cycloplasia diagnosis was associated with more accuracy and hence less false positive results (17).

In a prospective study by Pesudovs et al in 2004 on 190 patients, differences in using auto versus manual refraction methods were investigated. This study showed that results of diagnosis by both types of autorefraction instruments, Nidek ARK-700A (Fremont, CA) and Topcon KR-8000 (Paramus, NJ), are completely comparable with results from manual refraction methods. Despite a significant difference in the average amount of aspherical (0.14 diopters), almost the same limitations of the proposed clinical similarities was present in both methods (18).

5. CONCLUSION

For conclusion, results of this study show that although use of autorefraction is comparable with manual refraction in evaluating SE scores in diabetic patients affected with retinopathy but in the case of VA results from these two methods are not close to each other. Moreover, with exception of grade II, there was no significant difference between VA scores in different retinopathy grades. Although in general autorefraction may not be an acceptable substitute for manual refraction, specific elements of study design including increased sample size may allow limited substitution of autorefraction for manual refraction in some studies and even in the clinical practice.

• Conflict of interest: none declared.

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