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RESEARCH

QUALITY OF LIFE IN THE ELDERLY POPULATION: EFFECTS OF AGE RELATED MACULAR DEGENERATION ON NEI-VFQ 25 SCORES

ABSTRACT

Introduction: To investigate and to evaluate the quality of life of the patients with exudative age-related macular degeneration (AMD) by using National Eye Institute Visual Function Questionnaire 25 (NEI-VFQ 25) before and after the photodynamic therapy (PDT) .

Materials and Method: Forty-five patients with exudative AMD who were candidate for PDT were enrolled in the study. Main outcome measures were visual acuity, lesion size on fundus fluorescein angiography (FFA) and central foveal thickness on optical coherence tomography (OCT), and the quality of life scores by using NEI-VFQ 25.

Results: The mean age of the patients was 72.2±7.1 years. The mean follow-up duration was 9.1±4.5 months. The visual acuity was maintained within +3 lines in 71% of the patients. The treatment caused no significant change on the quality of life scores.

Conclusions: PDT was one of the most effective treatment strategies of exudative AMD before the era of vascular endothelial growth factor antibodies. PDT was found to be safe and effective in preservation of vision and in reducing the probability of severe vision loss due to exudative AMD, but it was found to be inadequate to provide an increase in vision, and in life quality.

Key Words: Macular Degeneration; Quality of Life; Photochemotherapy

ARAŞTIRMA

YAŞLI NÜFUSTA YAŞAM KALİTESİ: YAŞA BAĞLI MAKULA DEJENERASYONUNUN NEI-VFQ 25 SKORLARINA ETKİSİ

ÖZ

Giriş: Eksudatif tip yaşa bağlı makula dejenerasyonu (YBMD) için fotodinamik tedavi (FDT) uygulanan hastaların tedavi öncesi ve tedavi sonrası National Eye Institute Visual Function Questionnaire 25 (NEI-VFQ 25) ile ölçülen yaşam kalitelerini değerlendirmek ve tartışmak.

Gereç ve Yöntem: Eksudatif tip YBMD'si olup FDT uygulanması planlanan 45 hasta çalışmaya dahil edildi. Temel sonuç kriterleri görme keskinliği, fundus floresein anjiyografide (FFA) lezyon boyutu, optik koherans tomografide (OKT) merkezi makula kalınlığı ve NEI-VFQ 25 yaşam kalitesi skorları idi.

Bulgular: Hastaların ortalama yaşı 72.2±7.1 yıl idi. Ortalama takip süresi 9.1±4.5 ay idi. Görme keskinliği hastaların %71'inde +3 sıra içinde korundu. FDT'nin yaşam kalitesini skorlarına anlamlı etkisi olmadı.

Sonuç: FDT vasküler endotelyal büyüme faktörü antikorlarından önce eksudatif tip YBMD'de en etkili tedavi idi. Güvenli bir tedavi yöntemi olan FDT eksudatif tip YBMD'ye bağlı ciddi görme kaybı riskini azaltmada ve görme keskinliğini korumada etkili, ancak görmenin ve yaşam kalitesinin artırılmasında yetersiz bulundu.

Anahtar Sözcükler: Yaşa Bağlı Makula Dejenerasyonu; Yaşam Kalitesi; NEI-VFQ, Fotodinamik Tedavi.

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Introduction

Age-related macular degeneration (AMD), especially exudative type, is the leading cause of blindness especially in people who are older than 65 years of age (1). This condition increases significantly with ageing. Its prevalence increases to 30% over the age of 70. There are many risk factors believed to play a role in AMD development such as age, gender, race, smoking, socioeconomic factors, refractive errors, iris color, cataract surgery, cup-disc ratio, vitamins, minerals, antioxidants, obesity, sunlight exposure, drugs, systemic diseases and genetic factors (2). The detachment and the tear of the retina pigment epithelium, subretinal hemorrhage, disciform scar, vitreous hemorrhage and especially the choroidal neovascularization (CNV) are the main causes of the severe visual loss in exudative AMD. Photodynamic therapy (PDT) has been shown to be effective alone or as a complementary method for exudative AMD. Combination therapies including combination of PDT with vascular endothelial growth factor antibodies (antiVEGF agents) are being developed and can provide stabilization or improvement of vision (3).

Quality of life is recently considered as an important criteria for the success of the treatment of many eye diseases (4). Visual acuity measurement, optical coherence tomography (OCT) and fundus fluorescein angiography (FFA) findings alone are insufficient to identify the impairment in the elderly (5-7), since AMD has been shown to cause disability and emotional distress (8). Many types of questionnaires have been developed to demonstrate the quality of life quantitatively (9,10). Recently, quality of life scores have been used in the evaluation of success of the treatment. In our study, we used National Eye Institute Visual Function Questionnaire 25 (NEI-VFQ 25) which had been previously cross-validated in Turkish population (11). NEI-VFQ 25 was shown to provide an appropriate measurement of the quality of life and to be strongly and independently associated with an objective measurement of visual impairment in the elderly (12). It differentiates well between various levels of visual impairment (13). Before the era of antiVEGF agents, PDT with verteporfin was the only proven and available option for CNV secondary to AMD. Therefore, the aim of this study was to review the results of PDT for AMD, and its effects on life quality.

Methods

The study was designed as a prospective study undertaken at a single university based hospital between December 2005- April 2007. Written informed consent was obtained from all patients, and the study was carried out with the approval of the Institutional Review Board.

A total of 45 patients were enrolled in the study. The study group was composed of the patients with CNV secondary to exudative AMD who were suitable for PDT. All patients underwent complete ophthalmologic examination including best corrected visual acuity with Early Treatment of Diabetic Retinopathy Study (ETDRS) chart, Goldmann applanation tonometry, slit-lamp examination, fundus examination. FFA, OCT and NEI-VFQ 25 were applied. Patients included in the study were required to fulfill the folllowing inclusion criteria; having CNV secondary to AMD which was confirmed on FFA and on OCT, eligibility for undergoing one or more PDT with verteporfin, and having no obstacle for follow-up. Patients who had geographic atrophy on the study eye, visual loss due to another retinal pathology, corneal disease or cataract, another cause of choroidal neovascularization, fibrosis occupying at least 50% of the lesion, fluorescein hypersensitivity, medical problems blocking the follow-up, previous intraocular surgery in the past three months, and renal diseases were excluded from the study.

Visual acuity measurement with ETDRS chart, OCT and FFA were performed before PDT, and at the last visit. FFA images were assessed for lesion size, composition, activity and for presence of any leakage. OCT images were assessed for central macular thickness and presence of any sub-or intraretinal fluid indicating lesion activity. Quality of life was evaluated by using NEI-VFQ 25 before PDT and at the last visit. The questionnaire was administered to all patients by the same author (HTS).

Patient selection and PDT practice were done according to Verteporfin guidelines. (14) Primary outcome measures were visual acuity with ETDRS chart, central foveal thickness measured on OCT, lesion size on FFA and the quality of life scores. Severe vision loss was defined as a loss of 15 letters or more on ETDRS chart.

SPSS version 14.0 for Windows (Chicago, IL, USA) software was used for statistical analysis. Data from 45 patients were analysed using descriptive statistics for age and frequency statistics for distribution of gender, laterality, membrane type, the number of photodynamic therapy and for the follow-up duration. Paired Samples Statistics were used to com-

pare the initial and the final visual acuities. Independent Samples Test was used to compare the mean age of both genders. The correlation between laterality of the disease and quality of life scores was evaluated by using Mann Whitney U Test and Wilcoxon Test. The effect of visual acuity on quality of life scores was analysed by Spearman's Rho Test. The inital and final scores of quality of life were compared by Friedman Test.

RESULTS

Of the 45 patients, 24 (53%) were males and 21 (47%) were females. The mean age of the study group was 72.2±7.1 (53-85) years (71.8±6.9 years for men, 72.6±7.4 years for women, p=0.75) . The mean follow-up duration was 9.1±4.5 (1-18) months. Twenty-four (53%) of 45 patients had predominantly classic lesions, 16 (36%) had occult lesions and 5 (11%) had minimally classic lesions. Choroidal neovascularization was subfoveal in 37 eyes (82.2%) and juxtafoveal in 8 (17.8%) eyes. CNV was bilateral in 31 (69%) eyes and unilateral in 14 (31%) eyes.

The average number of PDT was 1.27±0.4 (1-3). Mean recurrence time was 3.2±3.45 months in 19 eyes (42.4%) after the first PDT, 2.2±2.9 months in 5 eyes (11.1%) after the second PDT. The visual acuity was initially 45.4±15 (36-54) letters before PDT and declined to 40.9±17.8 (35-51) letters at the last follow-up visit (p= 0.008). Mean lesion size measured on FFA was 3520±1156mm before the first PDT and 3737±1440m at the last visit (p>0.05). The influence of treatment on central foveal thickness on OCT was also investigated, and no significant change was found after PDT (448±162m before PDT and 445±189m after PDT). No adverse reaction were encountered during and after PDT. Thirty-two (71.1%) patients maintained their visual acuity within ±3 lines were defined as Group 1. Thirteen patients (28.9%) who had severe vision loss (as described vision loss of more than 3 lines) were defined as Group 2. All of the patients in Group 2 were referred for intravitreal injections after the final visit. Those patients in Group 2 had initial larger membranes compared to others, and two of them required more than one PDT sessions, and did not respond well to treatment. The mean initial visual acuities of Group 1 and Group 2 were similar (46.15±14.74 and 45.16±15.51, respectively). The final visual acuity of Group 2 was significantly lower compared to Group 1 (29.23±13.18 and 45.59±17.38, respectively with p=0.004). The mean final lesion size and the mean central macular thickness were higher for Group 2 compared to Group 1, but the difference was statistically insignificant (3802.31±1079.13 µ and 3152.81±1071.13 µ with p=0.07, and 440.08±199.23 µ and 405.91±193.21 µ with p=0.59, respectively).

The influence of the treatment on the quality of life was investigated by using NEI-VFQ 25 (Table 1). Driving score was not included in the statistical analysis because only one patient answered this question. There was no overall significant change on any of the scores of the questionnaire. However, the scales and subscales of NEI-VFQ-25 were evaluated and compared for unilateral and bilateral disease. The initial

Table 1— Mean Scores of NEI-VFQ 25of 45 Patients at the Initial and Final Visits

	Scores		
NEI-VFQ 25 Subscales	**Initial**	**Final**	**P**
General Health	77.5	72.5	0.289
General Vision	50.0	50.0	0.773
Ocular Pain	100.0	100.0	0.773
Near Activity	58.3	66.7	0.965
Distance Activity	58.3	66.7	0.264
Social Function	75.0	75.0	0.311
Mental Health	56.2	62.5	0.804
Role Difficulties	62.5	68.7	0.102
Dependency	75.0	75.0	0.165
Color Vision	75.0	75.0	0.223
Peripheral Vision	75.0	75.0	0.849
General	68.8	68.3	0.088

Table 2— The Quality of Life Scores of Patients Who Had Unilateral and Bilateral Disease

	NEI-VFQ Scores Median (Minimum-Maximum)		
Subscales of NEI-VFQ-25	**Unilateral**	**Bilateral**	**p**
Initial			
General Health	77.50 (40.00-100.00)	65.00 (40.00-87.00)	0.47
General Vision	50.00 (28.00-83.00)	50.00 (28.00-65.00)	0.26
Ocular Pain	100.00 (50.00-100.00)	100.00 (50.00-100.00)	0.53
Near Activity	66.70 (25.00-100.00)	50.00 (25.00-75.00)	0.18
Distance Activity	75.00 (33.00-100.00)	54.15 (25.00-75.00)	**0.02**
Social Function	75.00 (25.00-100.00)	50.00 (25.00-75.00)	**0.02**
Mental Health	62.50 (38.00-100.00)	56.20 (25.00-75.00)	0.23
Role Difficulties	75.00 (50.00-100.00)	50.00 (25.00-100.00)	0.07
Dependency	75.00 (33.00-100.00)	50.00 (25.00-100.00)	**0.02**
Color Vision	75.00 (25.00-100.00)	50.00 (25.00-100.00)	0.17
Peripheral Vision	75.00 (25.00-100.00)	50.00 (25.00-100.00)	**0.04**
General	69.80 (41.00-95.00)	56.95 (33.00-81.00)	0.05
Final			
General Health	72.50 (40.00-100.00)	65.00 (40.00-87.00)	0.32
General Vision	55.00 (40.00-83.00)	50.00 (28.00-65.00)	0.12
Ocular Pain	100.00 (50.00-100.00)	100.00 (50.00-100.00)	0.65
Near Activity	66.70 (25.00-100.00)	50.00 (25.00-83.00)	0.23
Distance Activity	66.70 (33.00-100.00)	54.15 (25.00-75.00)	0.05
Social Function	75.00 (25.00-100.00)	50.00 (25.00-75.00)	**0.01**
Mental Health	68.70 (31.00-100.00)	56.20 (25.00-75.00)	0.16
Role Difficulties	75.00 (50.00-100.00)	62.50 (25.00-100.00)	0.22
Dependency	75.00 (42.00-100.00)	54.15 (25.00-100.00)	**0.03**
Color Vision	75.00 (25.00-100.00)	50.00 (25.00-100.00)	0.29
Peripheral Vision	75.00 (25.00-100.00)	75.00 (25.00-100.00)	0.15
General	69.60 (46.10-95.00)	57.85 (32.70-81.50)	**0.04**

scores of distance activity, social function, dependency, peripheral vision and general scores were significantly higher in unilateral disease compared to bilateral disease. The final scores of distance activity, social function, dependency, and general score were also significantly higher in unilateral disease compared to bilateral (Table 2).

The NEI-VFQ 25 scores of the patients who experienced severe vision loss (Group 1) were compared with other patients whose visual acuity maintained within ± 3 lines (Group 2) which is widely accepted a favorable visual outcome for wet AMD (Table 3). There was no siginificant difference betwee Group 1 and Group 2 in any of the scores of NEI-VFQ 25.

The correlation between the initial visual acuity and initial quality of life scores, and between the final visual acuity and final quality of life scores were analysed. No significant correlation was found for either variable, and the details were given in Table 4.

There was significant correlation between age and initial distance activity (p=0.03), initial role difficulties (p=0.05), initial general (p=0.04), final near activity (p=0.03), final distance activity (p=0.02), final role difficulties (p=0.02), final peripheral vision (p=0.03) and final general scores (p=0.02) (Table 5). However, when the cut off point for age was accepted as 65 years old, no statistically significant difference between any of the quality of life scores of patients younger and older than 65 years was found. All of the scores except ocular pain score were higher for patients younger than 65 years, but the difference for all these scores were statistically insignificant.

Table 3— The Comparison of NEI-VFQ 25 Scores of Group 1 and Group 2

	NEI-VFQ Scores		
NEI-VFQ 25 Subscales	**Group 1**	**Group 2**	**p**
Initial			
General Health	70.55±14.93	71.73±17.27	0.82
General Vision	54.31±14.21	49.81±12.56	0.33
Ocular Pain	89.84±17.80	90.38±19.20	0.93
Near Activity	61.07±18.56	56.41±25.03	0.49
Distance Activity	68.48±18.30	66.35±21.28	0.04
Social Function	67.58±19.54	66.35±21.28	0.85
Mental Health	62.88±17.17	64.42±20.15	0.79
Role Difficulties	65.82±17.11	67.31±20.75	0.81
Dependency	70.57±22.69	70.02±20.75	0.94
Color Vision	66.41±20.68	67.31±21.37	0.89
Peripheral Vision	67.97±21.05	75.01±22.82	0.33
General	67.24±13.81	66.37±15.36	0.85
Final			
General Health	68.98±16.12	71.15±17.99	0.69
General Vision	55.16±11.88	53.46±7.18	0.63
Ocular Pain	90.63±17.68	92.31±15.71	0.77
Near Activity	63.15±19.66	53.85±23.72	0.18
Distance Activity	66.33±17.22	57.03±16.97	0.11
Social Function	67.71±17.52	67.31±21.37	0.95
Mental Health	63.73±17.41	62.82±19.58	0.95
Role Difficulties	68.16±15.51	72.12±23.47	0.81
Dependency	69.79±19.81	70.66±19.63	0.89
Color Vision	64.84±20.93	67.31±21.37	0.72
Peripheral Vision	71.48±18.32	67.31±21.37	0.51
General	68.32±13.12	66.43±14.42	0.67

Discussion

CNV due to AMD is the major cause of severe visual impairment in the elderly. The primary outcome of the present study was to assess PDT effect on visual acuity, FFA and OCT findings and the quality of life.

Sahni et al., showed that in eyes treated with PDT, neuroretina and nerve fiber layer were better preserved and visual acuity was better in treated eyes compared to untreated. (15) PDT was demonstrated to reduce the risk of vision loss in predominantly subfoveal and minimally classic CNV in TAP study (16). The visual acuity was maintained in ± 3 lines in 32 of 45 eyes (71.1%) in the present study. PDT provided the preservation of the vision in more than half of our study group but was remained inadequate in increasing the visual acuity. All types of CNV were treated in the present study, but no significant effect of the treatment was found on visual acuity, lesion size and central macular thickness.

Quality of life scores were also evaluated. It is known that the influence of exudative changes is not limited with decrease in visual acuity. It causes a visual impairment which affects daily activities and social life, and leads to reading difficulties and creates dependency (17).

NEI-VFQ-25 is a reliable and valid tool for AMD patients (17,18).

Cahill et al., showed that age, visual acuity, period of visual loss and reading speed were the major factors influencing the quality of life of AMD patients and they demonstrated the profound impact of central vision loss on a person's life. (19) The quality of life has been accepted as a key in the definiti-

Table 4— Correlation Between Visual Acuity and NEI-VFQ Scores

NEI-VFQ 25 Subscales	Initial Visual Acuity Correlation Coefficient p	Final Visual Acuity Correlation Coefficient p
General Health	0.12	0.05
	0.42	0.75
General Vision	0.05	0.07
	0.77	0.63
Ocular Pain	0.03	**0.01**
	0.84	0.94
Near Activity	0.02	0.05
	0.88	0.94
Distance Activity	0.008	0.13
	0.96	0.39
Social Function	0.03	**0.002**
	0.84	0.99
Mental Health	0.11	**0.04**
	0.49	0.78
Role Difficulties	0.01	**0.073**
	0.91	0.63
Dependency	0.02	**0.03**
	0.92	0.85
Color Vision	0.001	**0.02**
	0.99	0.88
Peripheral Vision	0.02	0.21
	0.87	0.17
General	0.003	0.09
	0.98	0.52

on of rehabilition of AMD patients (10). Changes of the scores of NEI-VFQ during follow-up were statistically related to visual acuity changes (20). Bilateral diseases and lower initial visual acuity were shown to have a significant relationship with the quality of life (21). These results can be helpful for ophthalmologists, low-vision specialists and optometrists to make detailed assessment of the quality of vision and to choose appropriate rehabilitation method (22).

Kim et al., found that PDT improved both general health and vision related quality of life (23).

Reeves and associates reported that clinically significant deterioriation in clinical measures of vision is associated with small decreases in generic and vision specific quality of life (24). Physiological and functional ability is reduced in people with AMD, so it should be recognized and treated early to maintain the quality of life (25).

In the present study, we found that PDT had no effect on any of the scores of NEI-VFQ 25. This may be evaluated as the maintenance of the life quality during follow-up after PDT. The success criteria during follow-up of the age related macular degeneration is not only the increament of visual acuity, but also the maintenance of vision, and the prevention of complication related severe vision loss.

The patients who had unilateral disease seemed to be less affected in regard of life quality compared to bilateral ones as expected. However, patients who had severe vision loss during follow-up had quality of life scores similar to others. This finding supports the fact that the visual acuity is not the sole factor which affects quality of life. There are many others such as social, physical, psychological factors which contribute to quality of life, which could not be taken under control and have not been measured.

Table 5— The Correlation Between the Age and the Quality of Life Scores

NEI-VFQ 25 Subscales	Age Correlation Coefficient (p value)
İnitial	
General Health	0.18 (0.23)
General Vision	0.13 (0.42)
Ocular Pain	0.04 (0.78)
Near Activity	0.25 (0.09)
Distance Activity	0.32 **(0.032)**
Social Function	0.23 (0.12)
Mental Health	0.28 (0.06)
Role Difficulties	0.29 **(0.05)**
Dependency	0.27 (0.07)
Color Vision	0.21 (0.18)
Peripheral Vision	0.21 (0.18)
General	0.31 **(0.04)**
Final	
General Health	0.22 (0.13)
General Vision	0.08 (0.61)
Ocular Pain	0.08 (0.61)
Near Activity	0.32 **(0.03)**
Distance Activity	0.35 **(0.02)**
Social Function	0.29 (0.05)
Mental Health	0.21 (0.15)
Role Difficulties	0.45 **(0.02)**
Dependency	0.28 (0.06)
Color Vision	0.22 (0.15)
Peripheral Vision	0.32 **(0.03)**
General	0.34 **(0.02)**

The potential limitations of the present study were the small number of patients, short follow-up period and absence of a control group.

In conclusion, PDT seemed to have no significant effect on visual acuity and on quality of life in the elderly. The findings of the present study were compatible with the current literature, and highlight the unsatisfying and inadequate visual outcomes of PDT, may shed light for further prospective randomized studies which will be needed to compare the effects of PDT and antiVEGF agents on quality of life.

Conflict of Interest

The authors have no financial interest related with this study.

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