

# Health-related quality of life on age-related macular degeneration patients

La calidad de vida relacionada con la salud en pacientes con degeneración macular asociada con la edad

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Received: 08-29-2016 / Accepted: 10-11-2016

## ABSTRACT

Age-related macular degeneration (AMD) is a disease of the retina that not only affects the visual function, but also influences the patient's general health and quality of life. For this reason, visual health assessment, which typically uses clinical indicators, should also include an evaluation that would allow to get a numerical value that represents the disease within the functional state of the patient. *Objective:* To establish statistically significant differences in health-related quality of life (HRQL) in participants diagnosed with AMD and in healthy patients. *Methodology:* Cross-sectional observational analytical study based on a sample of a total of 17 healthy participants and 13 participants with AMD for pilot tests. A specialist performed a retinal assessment and applied the HRQL questionnaire called the National Eye Institute Visual Functioning Questionnaire (NEI VFQ-25). Subsequently, a statistical analysis was developed to correlate data from the two groups. *Results:* Differences in HRQL were established among participants with AMD and healthy individuals; statistically significant differences ( $p \leq 0.05$ ) were found in the following subscales: general vision, near activities, distance activity, social functioning, difficulty in a role, visual dependency, color vision, and well-being and suffering. *Conclusions:* Participants with AMD presented with a decrease in HRQL, associated with lower scores on the NEI VFQ-25 subscales.

**Keywords:** macular degeneration, health-related quality of life, questionnaire.

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## RESUMEN

La degeneración macular asociada con la edad (DMAE) es una enfermedad de la retina que no solo afecta la función visual, sino que influye en la salud general del paciente y en su calidad de vida; por esta razón, la medición de la salud visual típicamente efectuada con los indicadores clínicos debe, además, abarcar una evaluación que permita obtener un valor numérico que represente la enfermedad dentro del estado funcional del paciente. *Objetivo:* establecer diferencias estadísticamente significativas de la calidad de vida relacionada con la salud (CVRS) en los participantes diagnosticados con DMAE y en pacientes sanos. *Metodología:* estudio observacional analítico de corte transversal; muestra para pruebas piloto con un total de diecisiete participantes sanos y trece participantes con DMAE. Un especialista efectuó una valoración de retina y aplicó el cuestionario de CVRS denominado National Eye Institute Visual Functioning Questionnaire (NEI VFQ-25); posteriormente, se desarrolló un análisis estadístico para correlacionar los datos entre los dos grupos. *Resultados:* se establecieron diferencias en la CVRS entre participantes con DMAE e individuos sanos; se encontró en las subescalas visión general, actividades de cerca, actividad a distancia, función social, dificultad en un rol, dependencia, visión del color y bienestar y sufrimiento diferencias estadísticamente significativas ( $p \leq 0,05$ ). *Conclusiones:* los participantes con DMAE presentaron una disminución de la CVRS, asociada a puntuaciones más bajas en las subescalas del NEI VFQ-25.

**Palabras clave:** degeneración macular, calidad de vida relacionada con la salud, cuestionario.

## INTRODUCTION

Age-Related Macular Degeneration (ARMD) is a progressive and chronic ocular condition that mostly affects people older than 50 years of age (1). It is the main cause of blindness in the western world for people older than 60 and the third most common cause in the world after cataract and glaucoma (2). In the study carried out in Colombia (3) in a group of 535 people with an average age of 67.1 years (55-95 range), the general prevalence of ARMD was 4.86%. The prevalence of early ARMD was 11.8%. The prevalence of early ARMD by age group was: 7.4% (55-59), 9.8% (60-69), 17.2% (70-79), and 13.6% (older than 80). The prevalence of advanced ARMD among the different groups is: 0.7% (55-59), 1.0% (60-69), 8.0% (70-79) and 22.7% (older than 80). ARMD is the main cause of loss of central vision, which is needed for activities that require detailed vision, thus producing alterations when reading, driving or recognizing faces, altering color vision, reducing contrast sensitivity, and metamorphopsias (1). With the progressive deterioration of the macula, patients with ARMD experience multiple visual problems that significantly affect their mental health and quality of life (4). It has been documented that patients with conditions that alter visual

function experience a significant reduction on the health-related quality of life (HRQL), which is expressed as a greater social dependency, daily life difficulties, higher rates of clinical depression, higher risk of falling, premature admission to adult living facilities, and suicide (4). Because of this, the measure of visual health must cover a mental and social evaluation of the well-being, which can be achieved with the HRQL (5), gaining strength as a way to evaluate the population's health and its conditions, since it takes into account the importance of the functional state of the patient (including physical, social, and mental state). On the other hand, because health care evolves from an illness-based model (6) to a patient-centered model, the importance of evaluating the results of health care from the patient's perspective is now known. Therefore, aside from the clinical measures, a number of measuring instruments have appeared, allowing patients to express their own concepts that evaluate their quality of life, their functional state, and their own perception experiences (7). Usually, quality of life is measured with questionnaires that contain instructions for application, and the purpose of those questionnaires is to measure areas or domains such as: pain, mobility, and achievement of specific activities, among others (6,8,9).

## AGE-RELATED MACULAR DEGENERATION

ARMD is a degenerative condition of the photoreceptors and the pigment epithelium of the retina in human macula. It is characterized by the presence of drusens, retinal pigment epithelium (RPE) abnormalities, hypo or hyperpigmentation, choriocapillaris-RPE geographic atrophy compromising or not the center of the fovea and, in some occasions, generating choroidal neovascularization (CNV). It is the most common cause of visual disability in patients older than 55 years in developed countries (10). The ARMD classification criteria include the one established by the AREDS (Age-Related Eye Disease Study) (11), a classification system applied to patients diagnosed with ARMD (Table 1).

TABLE 1. Age-Related Macular Degeneration (ARMD) classification

CLASSIFICATION	CHARACTERISTICS
No ARMD (AREDS Category 1)	No drusen or very few and small with < 63 microns.
Early ARMD (AREDS Category 2)	Combination of multiple small drusen, few intermediate drusen (63 to 124 microns of diameter), or RPE abnormalities.
Intermediate ARMD (AREDS Category 3)	Extensive intermediate drusen, with at least one large drusen ( $\geq 125$ microns of diameter), or geographic atrophy without compromising the center of the fovea.
Advanced ARMD (AREDS Category 4)	Presence of one or more of the following alterations: RPE-choriocapillaris geographic atrophy compromising the center of the fovea, neovascular maculopathy (choroidal neovascularization, RPE or neurosensory retinal hemorrhagic or serous detachment, exudates, sub-retinal and sub-RPE fibrovascular proliferation and disciform scarring)

Source: AREDS (11).

The main symptoms of macular degeneration are: lines and objects distortion, evident visual acuity reduction, blurry vision, increasing light sensitivity, the sensation of having a permanent dark spot in the center of the eye (12). Symptoms can be nonspecific in early stages of the dry type condition and it can even progress so slowly that people are unable to notice any change in their vision and, in some cases, particularly when the neovascular or wet type is present, the condition

progresses rapidly and can cause vision loss in both eyes (10).

## HEALTH-RELATED QUALITY OF LIFE

The demographical and epidemiological changes, the illnesses spreading, and the increased life expectancy, have led to a growing interest for quality of life and the Health-Related Quality of Life (HRQL). According to the World Health Organization (WHO) (5), quality of life is the result of the perception that people have about situations of their everyday life, determined by the cultural context in which they live and related to the objectives, expectations, regulations, and concerns, while the HRQL is the subjective perception of well-being, health, and individual functionality on different areas of their lives and on diverse dimensions of the human being, such as the physical, psychological, independence level, social relations and the relationship with the environment (13). The concept of quality of life is the social well-being index focused on the life situation of an individual regarding their emotional development (happiness, satisfaction, ability to function in society, normal functioning of their social roles and interpersonal relations) trying to measure the positive sensation of their life (14).

The HRQL is about a concept that is influenced by the physical health of the subject, their psychological state, level of independence, social relations, and their relationship with the environment. It is not only influenced by the nature and magnitude of the deterioration, but also by the impact on how to function in its environment. Therefore, the HRQL evaluation must cover more than the performance of activities, including spiritual well-being, emotional and social aspects, areas that could have been affected by consequence of the illness onset. It is a way to study the population's health and conditions, and to analyze the effectiveness and efficiency of a treatment or a health system, because it takes into account the importance of the functional (as well as the physical, social and

mental) state of a patient within the multidimensional context in which it takes place, considering quality of life as a subjective phenomenon that makes it possible to obtain a numeric value that represents the condition and state of health of the patient (6).

One of the more used instruments in HRQL, specifically in visual health, is the National Eye Institute Visual Functioning Questionnaire-25 (NEI VFQ-25), designed to evaluate the impact that ocular diseases have on visual functioning and the HRQL. The NEI VFQ-25 is the short version of the NEI VFQ-51, equally validated and reliable, with psychometric properties for the ocular conditions. It has been translated into nine languages. The NEI VFQ-25 measures the everyday life visual function, as well as the social and emotional impact of vision opposite to the patient's health (15). Mangione et al. (16) developed the NEI VFQ-25 questionnaire with the purpose of creating a survey that can subjectively measure the perception of the visual health state with a content of specific conditions for patients with age-related ocular chronic diseases. The questionnaire's questions were designed with the purpose of measuring the influence of the visual disability and the visual symptoms related to the everyday life social and emotional well-being, daily activities and visual functioning (17-24). The NEI VFQ-25 is a reliable questionnaire, psychometrically valid and sensitive to be used on the visual health with the purpose of measuring the quality of life of patients with different diseases (17). The NEI VFQ-25 is a short version of the original 51-items that was designed to reduce the load of the original and to increase its appropriateness and validity; it was planned since the first phase of the long version development, despite the success of its results (17).

## METHODS

Cross-sectional, analytical and observational study of the health-related quality of life of participants with ARMD (n = 13) as compared to healthy par-

ticipants (n = 17) according to the methods posed by Hertzog (19), in order to calculate the sample of the pilot study, which was performed in Bogotá, specifically at the Colombian Ophthalmology Center. Each one of the study participants signed the informed consent. The study complies with the ethical protocols given by the Helsinki declaration for human beings.

In order to conduct the present study, the following activities were defined:

1. ARMD diagnosis given by an ophthalmology professional with a retina supra-specialty. The degree of severity of ARMD was established according to the AREDS classification (11).
2. The healthy participants group was equally evaluated by a retina supra-specialist to confirm the absence of retinal or posterior segment conditions.
3. A medical record previously established was used for the study, where aspects such as general background and visual functional state were evaluated.
4. A validated Spanish version of the NEI VFQ-25 questionnaire was applied.
5. Data analysis.

Participants were selected accordingly to the following criteria:

1. Participants with Age-Related Macular Degeneration:
  - 1.1. Inclusion:
    - Females and males between the ages of 50 and 90 years old.
    - Participants are capable of speaking and reading Spanish fluently, without any mental or physical disability.
  - 1.2. Exclusion:
    - Participants with any illness or condition that affects visual function, not due to age-related macular degeneration, or with any disability or mental retardation.

## 2. Healthy participants.

### 2.1. Inclusion:

- Participants with no illness or condition that affects visual function, capable of speaking and reading Spanish fluently.
- Females and males between the ages of 50 and 90 years old.

### 2.2. Exclusion:

- Participants with any mental retardation or disability.

## FUNDUS EXAMINATION

The examination was performed by a retina supra-specialist. Each one of the participants was examined, establishing the absence of posterior segment conditions on the healthy patients and, according to characteristics, was classified according to the criteria established by the study (11).

## HEALTH-RELATED QUALITY OF LIFE EVALUATED WITH THE NEI VFQ-25

The previously validated translated version of the NEI VFQ-25 was used for this study (25). The NEI VFQ-25 consists of 25 questions related to visual health, social and emotional well-being and visual functioning subscales. This questionnaire has been used in patients with ocular conditions (17-26) and it contains an item that describes the general health of the patient, which has shown to be a solid predictor of future health and mortality in population-based studies (17).

The questionnaire's questions are divided into eleven scales, where items are grouped according to the pre-established classification. The questionnaire includes the following sub-scales: global vision rating, difficulty with near vision activities, difficulty with distance vision activities, limitations in social functioning due to vision, role limitations due to vision, dependency on others due to vision, well-being and distress, driving difficulties due to vision, peripheral vision limitations, ocular pain

and color vision difficulties (17). According to Vargas (20), it takes an average of approximately ten minutes to apply the NEI VFQ-25 questionnaire (25).

## NEI VFQ-25 SCORE CALCULATION

For the total calculation of the NEI VFQ-25, it was necessary to obtain an average of the recoding of the subscales, oriented to the visual function results. By conducting an average of every subscale qualification, the weight of every one of them is given (17).

## STATISTICAL METHODS

The statistical data analysis was performed using the Graph Pad 6,0 program for Windows. The variables were analyzed by descriptive statistical methods. The analysis of the quantitative variables included mean and standard deviation calculations. In order to correlate the related variables with the questionnaire, the Spearman correlation test was performed. A significance level of  $p \leq 0.05$  was considered.

## RESULTS

A total of 26 eyes with the condition classified as shown in Figure 1 were evaluated.

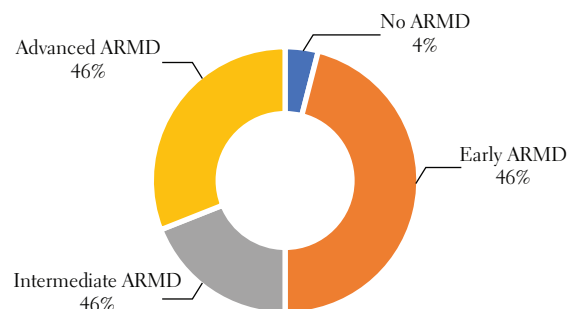


FIGURE 1. Percentage distribution of eyes with classified condition according to AREDS

Source: Own production.

The final average of each of the healthy participants and the ones with ARMD was determined

by grouping each one of the questions on the correspondent subscale (Tables 2 and 3, respectively). The maximum score obtained for every subscale was 100 points and the minimum was 0. On the healthy participants' results, the subscales with the highest average were color vision, dependency, social function, and the lowest were ocular pain, well-being and distress, and role difficulties. On the other hand, the highest average subscales for ARMD participants were color vision, peripheral vision, and dependency, while the lowest average subscales were role difficulties, difficulty with near vision activities and global vision rating, respectively.

Differences were established regarding the health-related quality of life between ARMD and healthy participants, finding a significant statistical difference of  $p \leq 0.05$  for the corresponding subscales of: global vision rating; difficulty with near vision activities; difficulty with distance vision activities; social function; role difficulties; dependency; color vision; and well-being and distress. No significant statistical differences were found in the ocular pain, peripheral vision and driving subscales (0.23, 0.14 and 0.22, respectively).

## DISCUSSION

It is generally recognized that ARMD is a condition that not only affects visual function, but also the patient's general health and quality of life, for which a measure of the visual health typically evaluated with clinical indicators (visual acuity and contrast sensitivity) must also cover an evaluation that makes it possible to obtain a numeric value that represents the condition within the patient's functional state, as well as their physical, mental or social state (27).

The NEI VFQ-25 is a questionnaire designed to evaluate multiple dimensions of vision related to the quality of life, and it has been evaluated in diverse populations that also include patients with conditions such as ARMD. Some authors

TABLE 2. NEI VFQ-25 results in healthy participants, showing the highest average on the color vision subscale and the lowest on the ocular pain subscale.

SCALE	PARTICIPANTS	AVERAGE	STANDARD DEVIATION
NEI VFQ-25 Total	17	89.4	± 8.139
Global vision rating	17	85.6	± 18.530
Ocular pain	17	72.1	± 20.506
Near vision activities	17	90.2	± 11.500
Distance vision activities	17	89.7	± 12.335
Social function	17	97.8	± 6.607
Role difficulties	17	85.3	± 18.872
Dependency	17	98.0	± 6.270
Driving	13	92.3	± 18.069
Color vision	17	100	± 0.000
Peripheral vision	17	91.2	± 15.158
Well-being and distress	17	81.6	± 12.396

Source: own production.

TABLE 3. NEI VFQ-25 results in ARMD participants, showing the highest average on the color vision subscale and the lowest on the role difficulties subscale.

SCALE	PARTICIPANTS	AVERAGE	STANDARD DEVIATION
NEI VFQ-25 Total	13	72.3	± 10.617
Global vision rating	13	63.1	± 13.774
Ocular pain	13	63.5	± 18.014
Near vision activities	13	60.9	± 32.522
Distance vision activities	13	64.1	± 31.802
Social function	13	78.8	± 29.040
Role difficulties	13	59.6	± 30.683
Dependency	13	81.4	± 27.670
Driving	4	81.3	± 12.500
Color vision	13	90.4	± 12.659
Peripheral vision	13	80.8	± 20.801
Well-being and distress	13	71.2	± 15.633

Source: own production.

(4,17,21,22,28,29) have evaluated the internal reliability of the NEI VFQ-25 in ARMD patients, where all the subscales reliability was over 0.70. In this study, each of the 11 sub-scales that evaluate the questionnaire was analyzed, obtaining

significant statistical differences when comparing both groups in the study on the following sub-scales: global vision rating, near vision activities, distance vision activities, social function, role difficulties, dependency, color vision and well-being and distress.

In this research, the low scores obtained by the ARMD participants, particularly in the sub-scales of global vision rating, distance vision activities and near vision activities, show the real issues that ARMD patients have in accomplishing everyday activities that depend on central vision, including newspaper reading, good near vision, and the interaction with their environment, specifically at home, and the environment where they perform their daily activities. The estimates are consistent with previous studies on ARMD patients (28,30), since those dimensions significantly affect ARMD during its natural course. From this study, we can determine that, in ARMD patients, the NEI VFQ-25 subscales that are more sensitive to visual compromise and to the severity of the disease are global vision rating, distance vision activities and near vision activities. This may indicate that patients with visual compromise have more difficulties to perform most of the daily life activities in which vision intervenes.

It is interesting to find that, despite the central visual compromise in ARMD participants, they showed normal values on color vision, which was unexpected. This aspect is related to the fact that only one question about picking out clothing difficulties does not show the real color perception limitations that the condition generates; these conclusions are similar to those reached by Cahill and collaborators in 2003 (26).

The low NEI VFQ-25 scores of ARMD participants in social function, role difficulties, dependency, well-being and distress sub-scales compared to the healthy participants show the isolation effect that the condition produces on patients. It is shown as a loss of independence, increasing problems with social interactions and increase anxiety as a

result of not being able to adapt to the relatively recent visual loss (17,26).

As far as the driving sub-scale is concerned, very few of the ARMD participants (23%) still drive, compared to healthy participants (76%). No significant statistical differences were found between the two groups, since the ARMD participants that still drive have a minimal visual compromise, which is similar to what happened in the study by Brody and collaborators (25).

It is particularly note-worthy that ARMD participants and healthy ones showed similar average values in the ocular pain sub-scale; this possibly happens because this dimension can capture symptoms associated to visual fatigue and visual demands for prolonged tasks that consequently cause great visual strain and discomfort. As far as the peripheral vision sub-scale is concerned, no significant statistical differences were found in either group, possibly due to the little or almost null compromise of the peripheral retina in ARMD.

## CONCLUSIONS

It is established that ARMD participants showed a reduced quality of life related to vision associated to low scores in the near vision activities, distance vision activities, social function, role difficulty, dependency, color vision, well-being and distress subscales of the NEI VFQ-25.

This study of quality of life in ARMD patients shows the profound impact of central vision loss and the ability of a person to perform vision-related activities. It prevents or restricts the development of daily tasks in the patient's daily life. This research confirms the ability of the NEI VFQ-25 to capture visual acuity changes and its use on ARMD patients, providing evidences that make it possible to infer that the questionnaire is a sensitive measure at the time of evaluating quality of life related with vision in ARMD patients.

This research represents a pilot test to evaluate the HRQL in ARMD and healthy patients that cannot be extrapolated to the study's population. It reveals limitations regarding the participants' population, since it was selected from a unique installation and it has the potential to limit how the conclusions are generalized.

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