

Humanistic Burden and Health Resource Utilization Among Neovascular Age-Related Macular Degeneration (AMD) Patients: Results from a Multi-Country Cross-Sectional Study

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INTRODUCTION

- Age-related macular degeneration (AMD) is an under-recognized major public health issue accounting for 8.7 million cases of blindness around the world in 2002.¹
- AMD is a chronic, progressive disease of the macula resulting in loss of central vision and leading to significant functional impairment of the patient.
 - The resulting visual impairment affects patient quality of life (QOL) as much as arthritis, asthma, diabetes, and stroke.²
 - As a consequence of rapid vision loss, this aged population group becomes significantly more restricted in their daily activities, experience a higher incidence of falls and fractures, have higher rates of depression, and rely greatly on caregivers for assistance.³⁻⁵
 - The economic burden ensuing from vision loss in AMD patients is presumed to be substantial; existing literature however, focuses primarily on direct medical and treatment costs.⁶
- The present study has taken a unique approach to evaluating the impact of AMD on patients in that it:
 - combined diagnostic, physiologic, humanistic, medical resource utilization, and economic measures stratified by visual acuity (VA)
 - included multiple QOL measures and patient-specific questions concerning medical resource utilization
 - was a collaborative international study with medical history data collected for 2 years
 - employed a case-control design to allow for direct comparison with a sample of the general population not affected by AMD

PURPOSE

To assess the humanistic and economic burdens of neovascular AMD using multiple measures

METHODS

Study Design

A cross-sectional survey was performed in subjects ≥50 years of age in Canada, France, Germany, Spain, and the United Kingdom (UK). Subjects with bilateral, subfoveal neovascular AMD were recruited from retinal specialists' offices/clinics. Control subjects, who were recruited from general practitioners' offices/clinics, had best-corrected VA of 20/40 or better and were free from any ocular pathology impairing VA. The enrollment per country is in Table 1.

Table 1. Enrollment Per Country*

Group	Canada	France	Germany	Spain	UK	Total
AMD	67	87	83	89	75	401
Control	99	92	93	96	91	471

*Includes subjects who provided informed consent, met study inclusion/exclusion criteria, and provided both telephone interview and clinical data.

References

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- Lee HI, Scudis RJ. *Age Ageing* 2003;32:643-9.
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Methods - Continued

Study Endpoints

Primary Endpoint: Difference between AMD subjects and controls in the humanistic burden of disease as measured by the National Eye Institute Visual Function Questionnaire (NEI VFQ-25) summary scale

Secondary Endpoints: Differences between AMD subjects and controls in:

- Overall health-related QOL measured by the EuroQol (EQ-5D) health valuation scale
- Anxiety and depression symptoms measured by the Hospital Anxiety and Depression Scale (HADS)
- Frequencies of falls, fractures, and related treatment
- Health resource utilization and the economic burden of AMD measured by requirements for assistance with activities of daily living

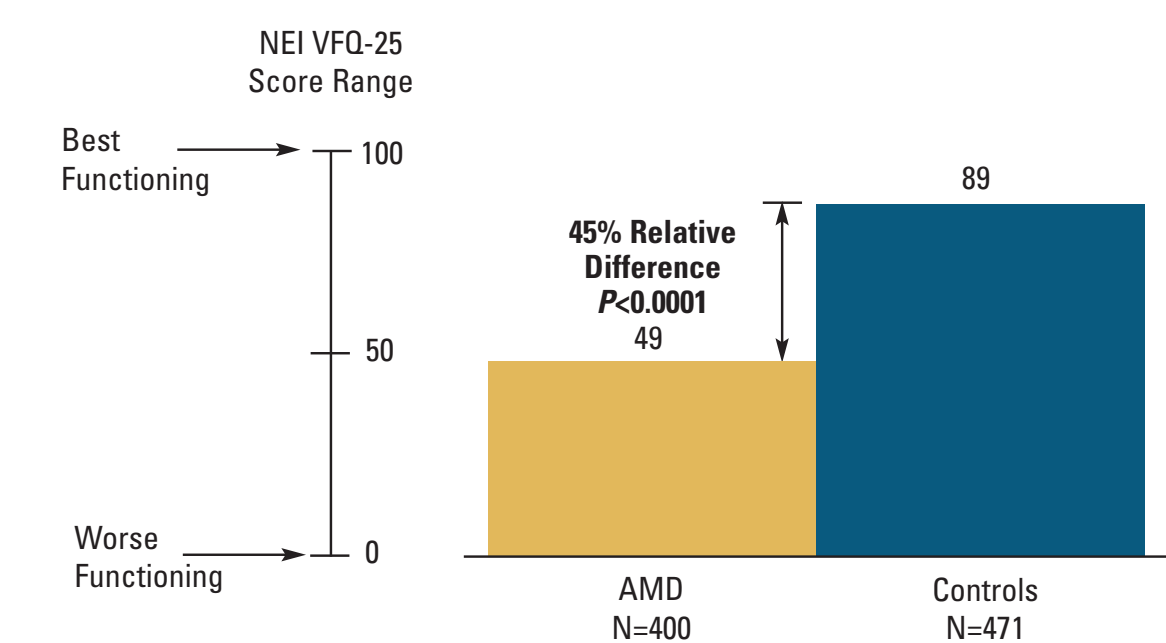
Analysis Methods

- Descriptive statistics were calculated for each measure.
- Study endpoints were compared between AMD and control subjects using standard bivariate methods (chi-square tests and 1-way analysis of variance models) and multivariate methods.
- Additional analyses were performed with endpoints stratified by VA in the better-seeing eye: normal acuity (better than 20/40 or 6/12); mild vision loss (20/40 to better than 20/80 or 6/12 to better than 6/24); moderate vision loss (20/80 to better than 20/200 or 6/24 to better than 6/60); severe vision loss (20/200 to better than 20/400 or 6/60 to better than 6/120); and near blindness (20/400 or worse or 6/120 or worse).

RESULTS

- Compared to controls, AMD subjects were older (mean age: 63.8 vs. 78.1 years, respectively) and had worse VA in the better-seeing eye (mean VA: 20/20 vs. 20/80, respectively); the AMD group included larger percentages of females (57% vs. 65%, respectively) and Caucasians (90% vs. 99%, respectively).
 - Given the between-group difference in the distribution of patient ages, all analyses were replicated in an age-matched subgroup; results paralleled those for the overall population demonstrating that the difference did not significantly impact findings.
- The humanistic burden of AMD was substantial. The adjusted mean NEI VFQ-25 summary score for AMD subjects was 40 points lower (worse) than that for controls (45% relative difference; $P<0.0001$; Figure 1).

Figure 1. NEI-VFQ Summary Scores* (Primary Endpoint)

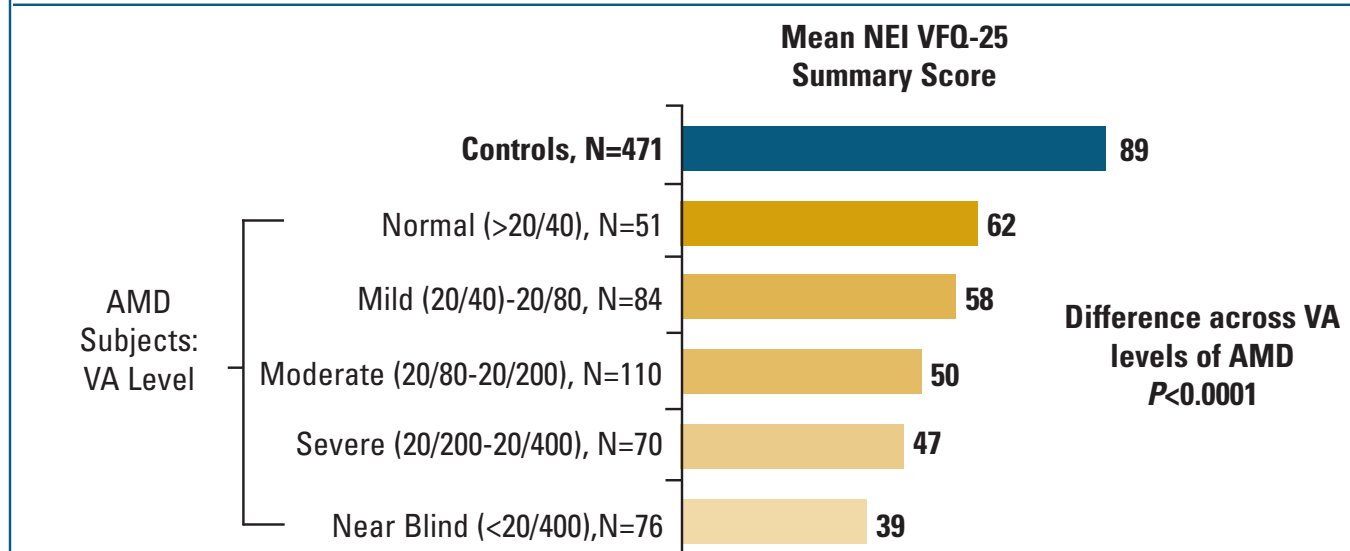


*Adjusted for age, gender, race, comorbidities and country.

Results - Continued

- When stratified by VA severity level, AMD subjects demonstrated clear, consistent trends toward worse QOL as VA progressed toward blindness (Figure 2).

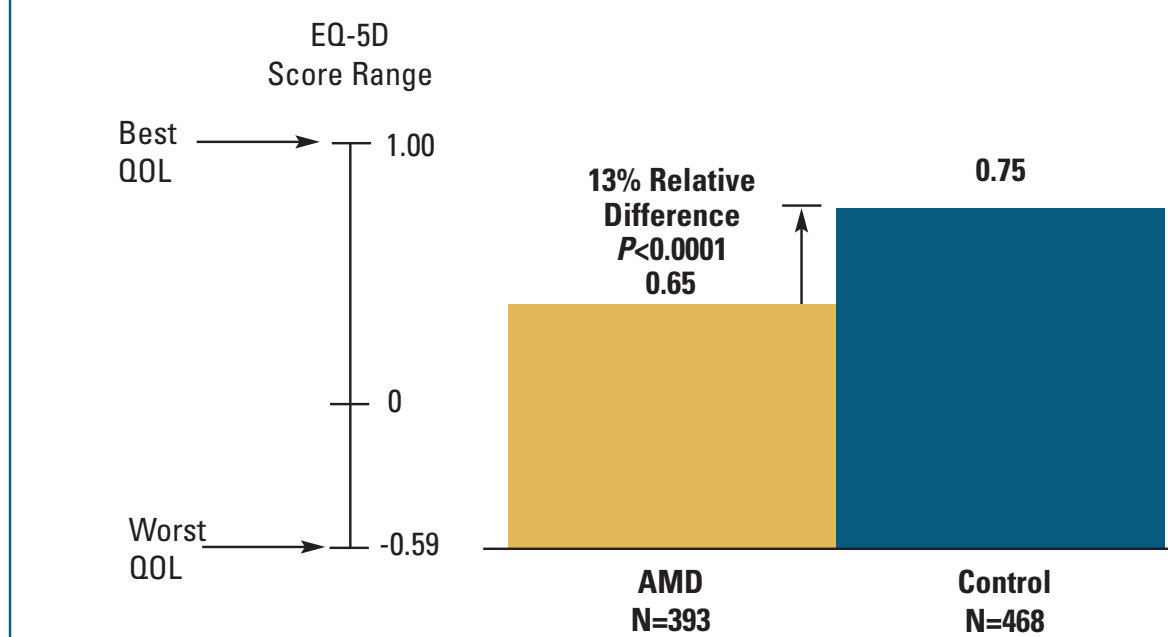
Figure 2. NEI VFQ-25 Summary Scores* by VA Severity Level in the Better-seeing Eye



*Adjusted for age, gender, race, comorbidities and country.

- AMD negatively impacted overall health-related QOL. The adjusted mean score on the EQ-5D health state valuation scale was significantly lower in AMD subjects (13% relative difference; $P<0.0001$; Figure 3).

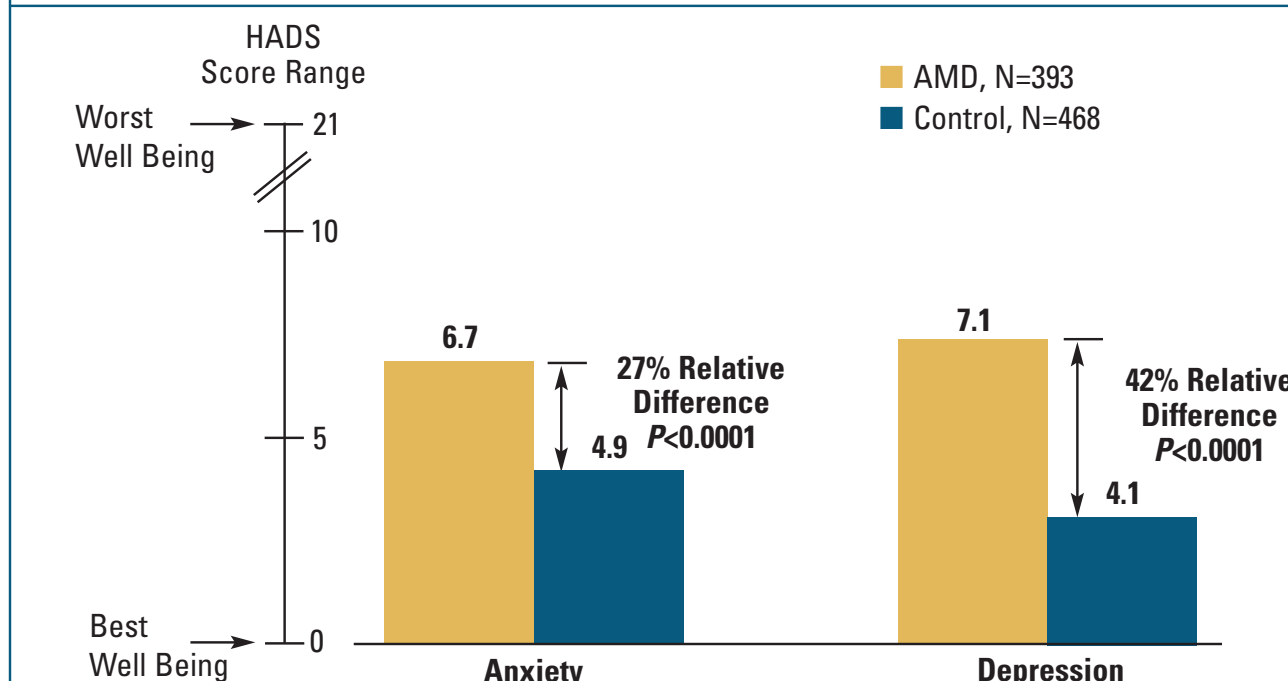
Figure 3. Health State Valuation (EQ-5D Scores)*



*Adjusted for age, gender, race, comorbidities and country.

- AMD subjects reported significantly poorer emotional well being compared to controls (Figure 4).

Figure 4. Anxiety and Depression Symptoms (HADS Scores)*

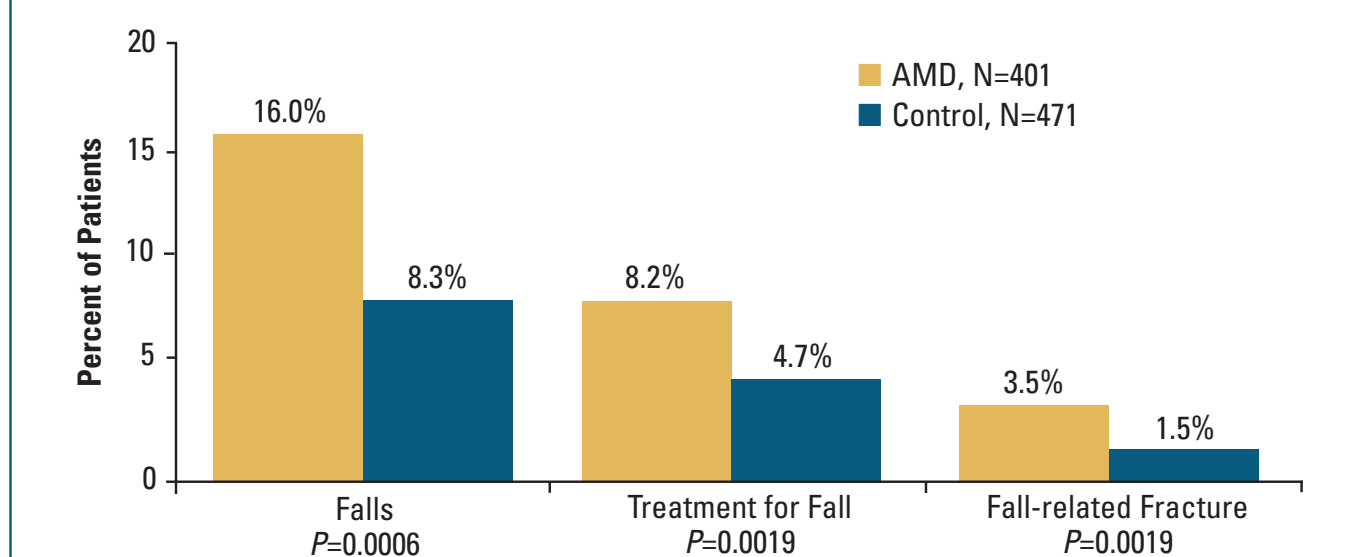


*Adjusted for age, gender, race, comorbidities and country.

Results - Continued

- The negative impact of AMD also was seen in the prevalence of falls and fall-related injuries (Figure 5). The percent of AMD subjects who fell in the preceding 12 months was nearly twice that of controls (16.0% vs. 8.3%, respectively; $P=0.0006$); approximately half of subjects in each group who fell required treatment.

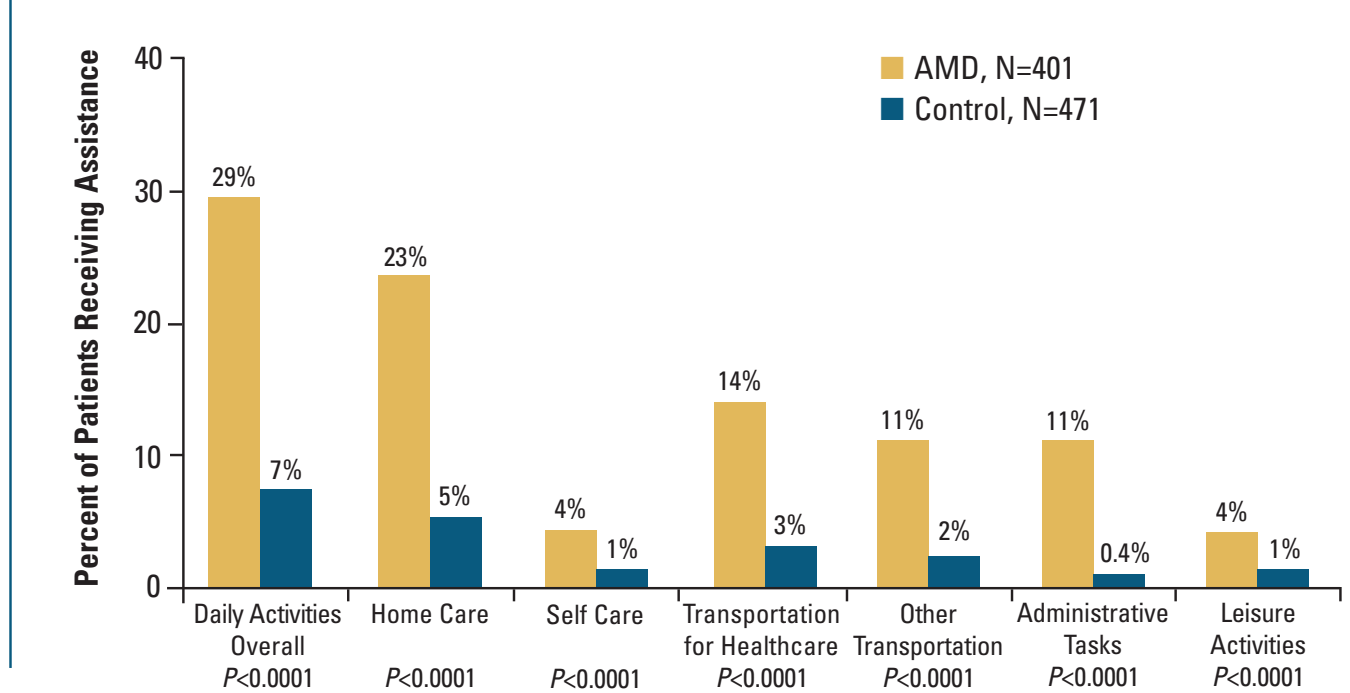
Figure 5. Falls and Fall-Related Injuries*



*Falls within the preceding 12 months. Percentages in the Figure are unadjusted. After adjusting for covariates, the odds of falling in AMD subjects remained 2-fold higher than in controls (OR [95% CI]: 2.0 [1.1, 3.6], $P=0.02$).

- AMD patients were significantly more likely to receive assistance with daily activities in a variety of areas (Figure 6). The need for assistance among AMD subjects was particularly great in the areas of home care, transportation, and administrative tasks.

Figure 6. Assistance With Daily Activities



CONCLUSIONS

- This is the first major international study to assess simultaneously the clinical, personal, and economic consequences of neovascular AMD at the patient level.
- The visual impairment associated with AMD negatively affected patient QOL, and these effects increased as VA progressed toward blindness.
- AMD was associated with anxiety, depression, falls and fractures, dependency on caregivers, and increased medical resource utilization.
- The study confirms that large amounts of resources are required to support individuals progressing to blindness due to AMD. The magnitude of this problem remains generally unrecognized by health care decision makers.
- These findings highlight the importance and value of effective and early management of neovascular AMD.