Disease Burden in the Treatment of Age-Related Macular Degeneration: Findings From a Time-and-Motion Study

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• PURPOSE: To examine the time burden of managing neovascular age-related macular degeneration (AMD) imposed on physicians, staff, patients, and caregivers.
• DESIGN: Mixed-methods, prospective, observational time-and-motion study.
• METHODS: The multicenter study was conducted from March 2011 through August 2012. Retina specialists administering ≥50 vascular endothelial growth factor (VEGF)–inhibitor injections monthly were surveyed and completed records for ≥5 patients scheduled for office visits within 3 weeks for anti-VEGF injection or monitoring. A survey was administered to 75 neovascular AMD patients aged ≥50 years who received ≥1 anti-VEGF injection in the past 6 months. Telephone interviews were conducted with 13 neovascular AMD patient caregivers.
• RESULTS: Fifty-six physicians provided data for 221 patients with neovascular AMD. Patients accounted for 20% of the health care staff's time per week, with an average of 23 staff members. An average patient visit for neovascular AMD was 90 minutes (range: 13 minutes to > 4 hours). Patients reported an average time per visit of almost 12 hours, including preappointment preparation (16 minutes), travel (66 minutes), waiting time (37 minutes), treatment time (43 minutes), and postappointment recovery (9 hours). Patients stated that caregivers took time away from work (22%) and personal activities (28%) to provide transportation to appointments.
• CONCLUSIONS: Neovascular AMD management imposes a substantial time burden on physicians, staff, patients, and caregivers. There may be a need for additional support and/or reimbursement for services required by patients and caregivers and provided by physicians. (Am J Ophthalmol 2015;160(4): 725–731. © 2015 The Authors. Published by Elsevier Inc. This is an open access article under the CC BY-NC-ND license (http://creativecommons.org/licenses/by-nc-nd/4.0/).)

NEOVASCULAR AGE-RELATED MACULAR DEGENERATION (AMD) is a debilitating, progressive disease that has a profound impact on patients’ visual acuity and overall visual function.1 It is the third-leading cause of blindness worldwide, after cataracts and glaucoma, and the leading cause of blindness in industrialized countries.1 It is estimated that 1.75 million individuals aged ≥40 years in the United States (US) (prevalence 1.47%; 95% confidence interval [CI] 1.38–1.55) have advanced AMD, and an estimated 1.22 million (prevalence 1.02%; 95% CI 0.93–1.11) patients have neovascular AMD in at least 1 eye; these numbers are expected to increase with the aging population.7 As visual impairment progresses, independence and overall quality of life decline in parallel.3,4 As visual function declines, the negative impact on activities of daily living substantially increases.7 This has been shown to have a detrimental impact on cognitive functioning, with 1 in 7 patients with AMD showing cognitive decline.5 Patients with AMD have also shown an increased risk of depression compared with patients without AMD.7

As many as one-third of patients with AMD require caregiving services owing to their AMD.3 As AMD progresses, these indirect costs for caregiver services form a greater proportion of total costs,7 and caregiver burden can be substantial.10

AMD also results in substantial economic impact in terms of direct health care costs.8,9,11,12 Costs also increase in direct proportion to disease progression. Patients with AMD require more services (eg, rehabilitation, counseling), devices, and supplements (eg, approximately two-thirds of patients took vitamins with lutein) than patients without AMD.9 Patients with neovascular AMD incurred twice the annual costs per patient compared to individuals without AMD (2011 US$: $34 308 vs $17 473), based on a cohort of 241 patients.11 Physicians must attempt to continually improve patient...
outcomes in the face of more stringent budgetary constraints, and health care decision makers (ie, physicians and payers) struggle to balance quality of care with costs of care and reimbursement for time and services provided.

The current mainstay of treatment for neovascular AMD is anti–vascular endothelial growth factor agents (anti-VEGFs), intravitreal therapeutics with demonstrated efficacy in improving visual acuity in patients with neovascular AMD.¹³–¹⁸ The management of patients with neovascular AMD is costly and time consuming. The provision of high-quality care requires commitments of significant time and services from physicians, staff, patients, and caregivers.

The objective of this multicenter, mixed-methods, prospective, observational time-and-motion study was to understand the total physician and patient burden of the current standard of care for management of neovascular AMD in the US. This manuscript focuses on the quantitative results from surveys of retina specialists, patients, and associated patient records.

METHODS

This multicenter, mixed-methods, prospective, observational time-and-motion study included 3 parts: (1) an ethnographic study, (2) qualitative interviews of patients with a diagnosis of neovascular AMD and their caregivers, and (3) quantitative surveys of retina specialists and patients with a diagnosis of neovascular AMD. There was no institutional review board (IRB) approval for the study, as it was initially conducted (not by RTI Health Solutions) as a market research project and patients were not consented to have their records included in the study. After conferring with the Journal, an exception to IRB approval was permitted in order to have these nonidentifiable data published.

Figure 1 presents an overall summary of the study.

First, an ethnographic study was conducted to gain a full understanding of the intravitreal anti-VEGF treatment process by means of observations and interviews conducted during site visits to 10 retina specialists’ offices in the US. This study consisted of 22 patients (17 established patients receiving a possible re injection of an anti-VEGF agent, and 5 new patients, receiving their first intravitreal injection of an anti-VEGF agent). Four elements were included in the ethnographic study design:

Patient shadowing: The observer shadowed the patient throughout the entire visit to observe, record, and time the activities that took place and to identify the staff performing each activity. Waiting time that was not directly associated with a particular procedure or test was recorded separately. However, waiting time directly associated with a test was included into the average time for that procedure.

Postobservation debrief with health care provider staff to collect information on office logistics and setting, standard operating procedures, decision to administer anti-VEGF therapy, steps in preparation and administration of anti-VEGF therapy, postinjection examination and discharge, delays in processing patients, challenges with current process, and staff education and training.

Postobservation debrief with retina specialists to collect information on delays in processing patients, injection scheduling, consideration of comorbidities and well-being, additional diagnostic procedures, use of as-needed vs monthly injections, consideration of anti-VEGF alternatives, and any limits on number of injections.

Postobservation debrief with office manager or the reimbursement specialists to collect information on the mix of payers involved, costs and reimbursement of diagnostic tests, requirements for prior authorization, how anti-VEGF therapy is obtained (ie, through the manufacturer/distributor or through a specialty pharmacy), cost and reimbursement for anti-VEGF therapy and the injection procedure, other costs and reimbursement associated with the injection, opinions on current process for anti-VEGF treatment, and the impact of caregivers and disabilities on the process.

Qualitative research also was conducted through 1-hour in-depth telephone interviews with 17 patients receiving anti-VEGF treatment and 13 caregivers of patients with neovascular AMD. A professional moderator trained in techniques to build rapport and elicit deeper insights conducted patient interviews. The aims were to assist in quantifying the burden of care for neovascular AMD, identify drivers and barriers to treatment, and understand the patient experience beyond the injection process in terms of the impact on patient/caregiver quality of life and the burden of time and effort involved. The results of this qualitative research helped in guiding the development of a quantitative survey instrument.

Quantitative research followed, consisting of 3 elements. The first was a telephone survey of 75 patients who had a diagnosis of neovascular AMD, aged 50 years or older, treated in the US by an ophthalmologist or retina specialist, and who received at least 2 injections of anti-VEGF treatment in the 6 months prior to the date of the survey.

Secondly, a paper-based survey was issued to 57 retina specialists in the US who had been recruited randomly and then screened for eligibility until the quota was filled. The recruiting, screening, and selection criteria followed guidelines established by the Council of American Survey Research Organizations. Eligibility criteria included the requirement to have administered 50 or more anti-VEGF inhibitor injections per month. The objective of this portion of the research was to capture each step of an office visit (including injection and monitoring) for the management of neovascular AMD among patients who received intravitreal injections of anti-VEGF agents. The specific information captured concerned preparation required prior
to patient arrival, time spent while the patient is in the office, and activities undertaken after the patient leaves, such as reimbursement and billing.

The quantitative research section of this study was conducted between July and November 2011; additional sampling of respondents from Midwest and Great Plains states was carried out from June through August 2012, as these regions were underrepresented in the original sample. A total of 20 states were sampled: Arizona, California, Colorado, Connecticut, Florida, Georgia, Hawaii, Illinois, Iowa, Missouri, Nebraska, New Jersey, New Hampshire, New York, North Carolina, Ohio, Pennsylvania, South Dakota, Texas, and Washington.

Finally, the same physicians also completed paper-based forms for up to 5 neovascular AMD patients scheduled for an office visit within the next 3 weeks (either for follow-up evaluation or for treatment with an additional anti-VEGF injection). The patients were required to be aged 50 years and older and to have received at least 1 injection of anti-VEGF therapy during the 6 months prior to the survey. The form included a patient history section for the physician to complete before the visit, and a patient diary in which the physician recorded activities of the patient visit, materials used, time taken for each step, and staff involvement. The physicians were instructed to complete the patient diary on the same day as the patients’ visit.
RESULTS

THE PHYSICIANS WERE RANDOMLY RECRUITED FROM A US-based list of retina specialists. Every physician who passed screening for qualification agreed to participate. There were 57 retina specialists involved in the survey, 68% (39 of 57) were in a group practice, 14% (8 of 57) practiced in an academic setting, and 18% (10 of 57) were solo practitioners. The average total number of patients treated per month in these 3 settings was 556, and the average number of neovascular AMD patients treated per month was 201. Fifty-six of the 57 retina specialists completed records on upcoming visits, for a total of 221 patients with neovascular AMD.

The results of the retina specialist survey showed that on average, 23 staff members were involved in the management of neovascular AMD patients, including the receptionist, the office manager, the billing manager, technicians, and other physicians or staff (Table). The management of patients with neovascular AMD accounted for an average of 20% of the staff’s time per work week: most technicians (68%) spent more than 20% of their time, one-quarter of office managers spent more than 10% of their time, and more than one-third (37%) of billing managers spent more than 20% of their time managing patients with neovascular AMD (Figure 2).

Figure 3 summarizes the series of steps involved in the management of a patient with neovascular AMD. According to the patient records, the time spent on 1 office visit by a patient with neovascular AMD during 1 visit averaged 90 minutes, but ranged from 13 minutes to over 4 hours. The average time for new and established patients was similar; however, how their time was spent differed. New patients spent more time with the technician during the initial examination and with the photographer, and they had a longer examination time with the retina specialist. Established patients spent more of their clinic visit time waiting.

As shown in Figure 4, 8 preparatory steps were conducted ahead of patient visits, with each step taking 4–8 minutes. Although these preparatory steps were typically performed concurrently, the average total staff time spent on all preparation steps was 43 minutes.

When asked about the impact of activities for monitoring and injection administration on staff time, the majority of the surveyed retina specialists (62%, 35 of 57) felt that frequency of patient monitoring placed a significant burden on staff time. A large percentage of retina specialists (58%, 33 of 57) felt that billing and filing for reimbursement was also a significant burden on staff resources. In addition, 42% (24 of 57) of retina specialists considered monitoring frequency to be very impactful on material resources such as drugs and other supplies. Forty-nine percent (28 of 57) of retina specialists reported that the frequency of injections was an impactful burden on office space, including waiting rooms and examination rooms. Over one-third of physicians (35%, 20 of 57) considered frequency of patient monitoring to be an important motivator in choosing a treatment to prescribe. Two-thirds of physicians (38 of 57) stated they would find it very desirable to reduce office visits.
A total of 75 patients were surveyed. The average age was 79 years (range 55–98 years) and 89% (67 of 75) of patients had a concomitant medical condition. The average income was $40,000. The majority of patients (62%, 46 of 75) reported an income of less than or equal to $50,000. Seventeen percent (13 of 75) reported an income between $50,001 and $75,000 while 10% (8 of 75) had an income greater than $75,000. Eleven percent (8 of 75) of patients chose not to answer this survey question.

The patient survey elicited information on patient and caregiver burden. Patients reported that the average time commitment per visit for their neovascular AMD management was 11.7 hours, including preappointment preparation (16 minutes), travel (66 minutes), waiting time (37 minutes), treatment time (43 minutes), and an average of 9 hours of postappointment recovery. More than one-third (36%, 27 of 75) of patients reported that their most recent visit took 90 minutes or more, and 79% (59 of 75) reported spending at least 3 hours recovering following injections.

The majority of patients (72%, 54 of 75) were driven to their appointment by a caregiver. Their caregiver was a spouse or partner (65%, 35 of 54), an adult child or grandchild (22%, 12 of 54), a friend (7%, 4 of 54), or another person (6%, 3 of 54). Patients stated that the caregiver driving them had to take time off from work (22%, 12 of 54) or personal activities (28%, 15 of 54) to accompany them to their appointment. Twenty percent (15 of 75) of patients drove themselves, while 8% (6 of 75) took a car service or public or government transportation.

Few patients experienced direct out-of-pocket transportation costs. Eighty-nine percent (67 of 75) reported that they did not pay any transportation costs for their latest clinic visit. Among those who had out-of-pocket transportation cost, 12% (8 of 67) paid for parking, 6% (4 of 67) paid tolls, and 3% (2 of 67) paid bus fare.

**DISCUSSION**

**FIGURE 3.** Treatment of neovascular age-related macular degeneration: steps of patient flow and average times per step.

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**DISCUSSION**

THIS ARTICLE PRESENTS A COMPREHENSIVE ASSESSMENT OF the burden of managing patients with neovascular AMD in the US. Previous studies have described the economic burden of neovascular AMD but have not specifically focused on the time and workforce burden associated with the management of patients with the disease. The present study demonstrated that practices are highly invested in the management of patients with neovascular AMD, with an average retina practice consisting of 23 staff members involved in the disease management for every 1 treating retina specialist. Correspondingly, there is a substantial time commitment required for each patient visit as a result of the numerous
steps and range of expertise involved. In total, the management of patients with neovascular AMD accounts for one-fifth of the staff’s working week, and this estimate may likely underestimate the true workflow based on less structured communications with retina specialists. In light of pressures to reduce health care spending in the US, devoting such time can be a challenging commitment in a rapidly changing, cost-constrained environment while trying to balance quality of care with costs.

In the current study, the majority of retina specialists felt that injection frequency and the frequency of patient visits placed a heavy burden on staff time; around half added that it accounted for a disproportionate use of resources in terms of materials and office space. As such, most physicians felt that it would be very desirable to reduce injection frequency, and almost half felt that it is an important motivator in prescribing a particular treatment. It follows that a treatment that requires fewer injections would be desirable, would be more likely to be prescribed, and would ultimately reduce the burden on health care staff time and the use of resources such as materials and office space. Such reductions in physician and health care staff time and the overhead involved in managing patients with neovascular AMD may ultimately lead to a reduction in the overall burden of neovascular AMD.

This study provides important neovascular AMD burden information in the US; few time-and-motion studies have been conducted in the area of neovascular AMD. One other study, published in 1998, assessed time spent managing a range of ophthalmology conditions in the US, including glaucoma, cataracts, myopia, macular edema, and macular degeneration. The study did not separate macular degeneration into the dry and wet forms. The study reported that an initial visit to a retina specialist for macular degeneration took around 25 minutes, with a follow-up visit taking 40 minutes. These lengths of time were similar to visits for other retinal conditions, but were shorter than the visit times reported in our study. The increased time committed to treating neovascular AMD is most likely due to the fact that clinical evaluation, treatment options, and health care coverage and management for patients with AMD have changed significantly since 1998.

The strength of this study is its comprehensive methodology, which includes both physician and patient perspectives on neovascular AMD. It is based on responses of retina specialists from a wide variety of locations and practice types around the US, and focuses on physicians who regularly perform injection of anti-VEGF agents. However, selection bias may have been present in terms of which physicians chose to participate. These retina specialists may have been more comfortable participating in clinical research and therefore may not represent other segments of the retina community accurately. Regarding patient enrollment, the study includes a broad demographic range (50 years and older) and range of income levels. The current study was a US-only study; it may be useful to conduct similar studies in other markets of interest. As with all similar survey studies, the study is limited by the reliability of the physician and patient responses, and by the potential for inaccurate reporting of actual patient behavior and physician practices.

In conclusion, management of neovascular AMD carries a substantial burden to patients, caregivers, physicians, and their staff. The impact on staff time and health care resources to diagnose, clinically evaluate, treat, and schedule and process payments for patients with neovascular AMD equates to a significant commitment of resources. Coupled with the quality-of-life burden to the patients and their caregivers, the management of neovascular AMD has a significant societal impact.

![FIGURE 4. Preparatory steps for neovascular age-related macular degeneration patients and average time. Question on retina specialist survey was as follows: “In the following table, please identify the amount of time spent PREPARING for a typical Wet AMD patient before the patient’s arrival. Indicate the activities done in preparation for each Wet AMD patient visit, including the person(s) involved in the activity and the amount of time it takes to complete the activity (in minutes). If there is a PRE-PATIENT activity that is missing, please write in the space provided at “OTHER.” EMR = electronic medical record; ICG = indocyanine green chorioangiography; IVFA = intravenous fluorescein angiography; OCT = optical coherence tomography; VEGF = vascular endothelial growth factor.](image)
REFERENCES


Biosketch

Dr. Jonathan L. Prenner is a vitreoretinal surgeon and partner at NJ Retina, and an associate clinical professor of ophthalmology at Rutgers Robert Wood Johnson Medical School in New Brunswick, NJ. Dr. Prenner serves on the board of directors of the American Society of Retina Specialists and as a section and associate editor of the journal RETINA. He is an active clinician scientist and publishes and presents his clinical research routinely.