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ORIGINAL RESEARCH

Italian Patient Satisfaction with wAMD Management: SWAN Study Results

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Purpose: Limited data is available on treatment satisfaction with the management of wet age-related macular degeneration (wAMD) among patients in Italy. In this cross-sectional real-world study, treatment satisfaction with anti-vascular endothelial growth factor (anti-VEGFs) was assessed in patients with wAMD in Italy.

Patients and Methods: This was a non-interventional, cross-sectional survey involving patients with wAMD receiving anti-VEGFs. The survey was administered through a virtual assistant via phone. Patients' treatment satisfaction was assessed using a newly developed Novartis Tailored Treatment Satisfaction Questionnaire (NVS TTSQ) and the validated Macular Disease Treatment Satisfaction Questionnaire (MacTSQ).

Results: Overall, 154 evaluable patients were enrolled in 5 centers across Italy. The mean (SD) age of the patients was 76.8 years (7.01). Overall treatment satisfaction score assessed by NVS TTSQ was 40.50 (7.11), with a mean of 9.97 (1.84) on the information domain and 22.98 (4.57) on the unmet need domain. Patients were satisfied with diagnosis communication (4.99 [1.30]), information provided on treatment administration (4.58 [1.49], range 0–6), the waiting room (4.40 [1.43]), and management of visits and injections at the center (5.14 [1.12]), general management of maculopathy at the center (5.22 [1.01]). Patients were not satisfied with their independence in terms of disease management (2.56 [2.45]); they would like additional information about the disease (5.38 [1.03]) and to discuss the injection procedures (4.02 [1.94]) with already-treated patients. The overall treatment satisfaction score on MacTSQ scale was 55.84 (10.13).

Conclusion: Patients with wAMD are satisfied with the overall management of their disease in Italy. However, patients would like to have more information on prognosis and management of the disease.

Keywords: anti-VEGF, patient-reported outcomes, real-world study, treatment satisfaction, treatment satisfaction questionnaire, wAMD

Introduction

Neovascular or wet age-related macular degeneration (wAMD) is a leading cause of visual impairment and severe visual loss.[1] Globally, new cases of early and late AMD have been estimated to be 39.05 million by 2050.[2] wAMD is characterized by the presence of choroidal neovascularization (CNV), a pathologic form of angiogenesis whereby new abnormal blood vessels spread beneath the retina into the sub-retinal or below the sub-retinal pigment epithelium space from the subjacent choroid.[1] It has a major impact on the quality of life (QoL) and social functioning of patients.[1,3] Anti-vascular endothelial growth factor (anti-VEGF) treatments have improved visual outcomes and vision stabilization in 30% and 95% of patients, respectively.[4] Due to their remarkable clinical efficacy, anti-VEGFs have become the standard of care for the management of wAMD.[5] However, anti-VEGFs require frequent injections and visits to a healthcare center, which places a substantial burden on patients, caregivers, and physicians.[4,6] They may lead to poor compliance and clinical outcomes, resulting in poor patient satisfaction with disease management and decreased QoL.[7] Recent real-world studies

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indicate that undertreatment of wAMD is frequent and is associated with suboptimal outcomes.[8,9] Thus, further efforts are needed to address unmet medical needs in the management of wAMD to increase patient compliance.

Patient-reported outcome (PRO) measures are now widely accepted tools to assess the perspectives of patients regarding their conditions and treatments.[10] These outcomes help in evaluating both the effect of treatment on patients' QoL and experience with the clinical care received.[4] Thus, PROs can be used to assess the impact of disease management on QoL.[4] Assessment of PROs such as patient satisfaction has now become an integral part of therapy that can impact adherence to treatment and follow-up visits, which are important for long-term treatment outcomes.[11]

The Macular Disease Treatment Satisfaction Questionnaire (MacTSQ) is a validated tool to assess treatment satisfaction with therapies for macular disease. It has been used in randomized clinical trials and real-life studies to evaluate the treatment satisfaction of patients with wAMD. A few studies have reported patient satisfaction with the management of wAMD in the literature using MacTSQ. In a cross-sectional survey of 250 patient–caregiver pairs from 3 public ophthalmic treatment facilities in the United Kingdom, treatment satisfaction was assessed.[4] Patient satisfaction with wAMD management was found to be only partially dependent on functional visual outcome (visual acuity). The most important determinants were service provided at the clinic, health-related QoL and duration of wAMD.[4] Furthermore, in another cross-sectional global survey, patients reported symptom awareness, disease information and support, and management of follow-up visits for injections as areas for improvement in the management of wAMD.[12] Thus, treatment satisfaction is far more important for patients than clinical outcomes. However, limited real-world data are available on patient satisfaction with the management of wAMD in Italian patients and the factors affecting treatment burden. Thus, patients' overall experience with the management of wAMD needs to be explored and understood.[9] A greater understanding of the impact of satisfaction with disease management from a patient perspective will help to gain insights to improve both clinical practice and long-term management of wAMD.

We conducted a cross-sectional survey to assess the satisfaction of wAMD patients treated with currently available anti-VEGFs in Italy using both the standardized MacTSQ and the new Novartis Tailored Treatment Satisfaction Questionnaire (NVS TTSQ). NVS TTSQ was developed using the focus group methodology and patient feedback by Novartis to evaluate broader aspects of treatment satisfaction. It is structured to cover aspects of patient management other than treatment, which are not covered in MacTSQ. It includes questions to obtain patient perspectives on and satisfaction with care and the healthcare system, diagnosis management, unmet needs, information received regarding disease, and caregiver burden. The aim of this study was to identify gaps underlying poor disease management satisfaction among patients with wAMD in Italy. Real-world evidence obtained in this study will help to better understand unmet needs in wAMD from a patient perspective in order to design and develop new therapeutic programs to improve patient engagement and adherence, treatment satisfaction, and clinical outcomes.

Material and Methods

Study Population

Consecutive patients who attended the retina center for a follow-up visit were screened according to inclusion and exclusion criteria and enrolled. Male or female patients aged ≥50 years with wAMD treated with any anti-VEGFs at time of inclusion in the study were enrolled. Patients must have completed an anti-VEGFs loading phase defined as 3 doses within 90 days from the first dose and a period of follow-up of at least 9 months (including the loading phase). Patients receiving treatment with an anti-VEGF for a period of less than 9 months and/or patients who did not complete the loading phase were excluded from the study.

Study Design

This was a non-interventional cross-sectional survey conducted at some of the largest retina centers in Italy. The data were collected from 24 September 2021 to 21 May 2022. The survey was conducted using an innovative digital system, Confirmo (Openview s.r.l). After the patient provided written informed consent, the data was entered into the Confirmo back-office web application by the investigators. The Confirmo virtual assistant contacted the patient by phone at a suitable time. Patients were asked to confirm their identity by entering their year of birth. Once patient identity was

confirmed, the survey began administering the MacTSQ and NVS TTSQ questionnaires. The survey took approximately 20 minutes to complete. Data collected through the Confirmo system were translated directly into e-CRF.

This procedure was chosen to facilitate visually impaired patients' completion of the questionnaires orally rather than manually and to limit bias to answers to satisfaction questionnaires in front of doctors.

This was a non-interventional study, which did not impose a therapy protocol, diagnostic/therapeutic procedure, or a visit schedule. Patients were treated according to local prescribing information, and routine medical practice in terms of visits, frequency, and types of assessments performed, and only these data were collected as part of the study. Informed consent was collected for all participants. The study was conducted following Declaration of Helsinki guidelines. The final study protocol, informed patient consent forms, and accompanying materials were reviewed and approved by the following ethics committees: Comitato Etico Indipendente Dell'azienda Ospedaliera Universitaria Di Cagliari, Cagliari (Canada), Comitato Etico Dell'irccs Ospedale San Raffaele Di Milano Via Olgettina, Milano (MI), Comitato Etico Interaziendale Milano Area 1 C/O Asst Sacco Fatebenefratelli Via Giovanni Battista Grassi, Milano (MI), Comitato Etico Centrale Irccs Lazio - Sezione Ifo-Bietti C/O Irccs Istituti Fisioterapici Ospitalieri Di Roma, Via Elio Chianesi, Roma (RM), and Comitato Etico Dell'aou Consorziale Policlinico Di Bari Piazzale Giulio Cesare, Bari (BA).

Outcome Measures

Demographic and baseline characteristics were collected at screening. Patients' perspectives on current wAMD management (diagnosis, treatment, and follow-up) were evaluated by phone survey among patients using the NVS TTSQ and MacTSQ, along with a few additional questions.

The NVS TTSQ is derived from 2 dedicated focus groups comprising a heterogeneous group of Italian patients with wAMD and caregivers for each meeting and an "expert patient" who helped supervise the discussion along with a qualified agency. The aims of the focus groups were to identify and agree on the most important domains to focus on in the questionnaire from a patient perspective. The patients/caregivers in the dedicated focus groups were from different regions of Italy: Lombardia (5 patients/caregivers), Piemonte (1), Lazio (1), and Basilicata (1). Based on the outputs of the focus groups, NVS TTSQ was developed, which included 9 questions, with each question scored on a 7-point Likert scale ranging from "not at all satisfied" (0) to "extremely satisfied" (6), generating a range of possible total scores from zero to 54. The questionnaire comprised questions regarding: patients' satisfaction with wAMD diagnosis and management (item 1), patients' satisfaction with the amount and quality of information received about their disease and its management (items 2 and 4), patients' unmet needs in the whole current management of wAMD (items 3, 5, 6, 7, and 8), and caregivers' treatment burden (item 9).

The MacTSQ includes 14 questions, with each item scored on a 7-point Likert scale ranging from "not at all satisfied" (0) to "completely satisfied" (6) except for some items that range from zero to 7, generating a range of possible total scores from zero to 72.[7] It provides 2 subscale (domain) scores: impact of treatment (range: 0–36) and information provision and convenience (range: 0–36). Higher scores for the total scale and the subscales represent increased satisfaction with treatment.[4]

Two additional questions regarding distance traveled and means of transport were asked at the end of the patient survey.

Statistical Methods

The sample size calculation was performed using Cochrane's formula for categorical data considering finite overall population and correcting by an estimated response rate. Assuming a proportion of expected events equal to 50%, a margin of error equal to 5% and a 95% confidence level, the estimated number of patients to be enrolled was 177. Considering an expected patient response rate equal to 70% (including valid interviews), approximately 254 patients were required to be screened.[13] Approximately, 330 patients with wAMD (ie, overall population size) were expected to have a follow-up visit during an enrollment period of approximately 6 months according to a formal feasibility assessment performed at the participant sites. The patients were balanced according to the capacity of the center. Continuous data were summarized by mean, standard deviation (SD), median, minimum, and maximum, while categorical data were presented by absolute and relative frequencies (n and %) and a 95% confidence interval (CI).

Results

Patient Disposition

Of the 181 patients enrolled in the study, 154 (85.08%) were included in the population of evaluable patients, which included those who did not violate the protocol and did complete the NVS TTSQ (Figure 1).

Patient Demographics and Baseline Characteristics

Mean (SD) age of the patients was 76.8 years (7.01) and most were female (61%) (Table 1). Almost half of patients (48.7%) received treatment for 1 to 3 years and 39% for over 3 years; 68% of patients received more than 10 injections of anti-VEGF treatment.

Treatment Satisfaction in Patients according to NVS TTSQ

Patients' treatment satisfaction was evaluated using a newly developed questionnaire, the NVS TTSQ. Patients were satisfied with disease management; in fact, the overall satisfaction score was 40.50 (7.11), mean (SD). The information domain had a mean (SD) score of 9.97 (1.84), and the unmet need domain, 22.98 (4.57). Patients' responses to all individual items in the questionnaire are presented in Table 2 and Figure 2. Notably, patients expressed willingness to receive additional information on the disease (5.38 [1.03]; range, 1–6) and to discuss the injection procedure with patients who had received similar treatment (4.02 [1.94]; range, 0–6]. Treatment satisfaction score by treatment period (ie, patients who have been receiving injections for less than a year, between 1 and 3 years, and more than 3 years) is presented in Table 3. Treatment satisfaction score was also described by number of anti-VEGF injections (3–5, 6–10, and >10 injections) received, and is presented in Table 3.

The average overall satisfaction score assessed by MacTSQ is 55.84 (10.13), considering a range of 26–74, with an impact of treatment domain equal to 28.48 and an information provision and convenience score of 27.37. No new or unexpected trends compared to the literature were observed in the responses of Italian patients with wAMD to the items of the MacTSQ.

Patients' Satisfaction on the Basis of Means of Transport and Location

Most patients use their own vehicle (car) to go to the center (Table 4). The majority of patients reported residing in the same city or district where the healthcare center is located (Table 4).

Discussion

In this real-world, Italian study, disease management satisfaction was assessed to identify factors that influence satisfaction in patients with wAMD treated with available anti-VEGFs using a newly developed questionnaire, the NVS TTSQ, and the validated MacTSQ. Patients reported high levels of satisfaction with disease management, resulting in an overall mean (SD) satisfaction score of 40.50 (7.11). These results were confirmed by MacTSQ, with an average

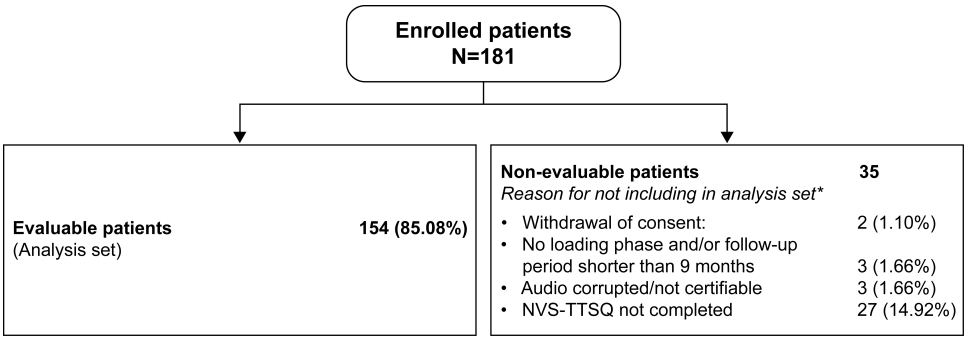

Figure 1 Patient disposition.
*Patients may have more than one reason for not being qualified for inclusion in the analysis set.

Table 1 Patient Demographic and Baseline Characteristics (N = 154)

Age (years), mean (SD)	76.79 (7.01)
Gender, n (%) Male Female	 60 (38.96) 94 (61.04)
Time from first treatment, n (%) <1 year ≥1 to <3 years ≥3 years	 18 (11.69) 75 (48.70) 61 (39.61)
Number of injections, n (%) 3–5 6–10 >10	 11 (7.14) 39 (25.32) 104 (67.53)

Abbreviations: N, total number of patients; n, number of patients in a group; SD, standard deviation.

Table 2 Patient Treatment Satisfaction Scores According to the NVS TTSQ (N = 154)

Overall total score, mean (SD)	40.50 (7.11)
Information domain, mean (SD)	9.97 (1.84)
Unmet need domain, mean (SD)	22.98 (4.57)
Items in the questionnaire	
1. How satisfied are you with "how your diagnosis was communicated to you"? Try to rethink the information you have been given and the way the diagnosis was communicated.	4.99 (1.30)
2. How useful would it be for you to have access to additional information about your maculopathy?	5.38 (1.03)
3. To what extent would it have been useful to have a discussion with a patient who was already being treated, for reassurance, and to receive an explanation of the intravitreal injection procedure after diagnosis?	4.02 (1.94)
4. How satisfied are you with the information you received regarding the duration and frequency of administration of the treatment?	4.58 (1.49)
5. How satisfied are you with "how the waiting room at your referral center is set up and organized"?	4.40 (1.43)
6. How satisfied are you with "how appointments for visits and injections are scheduled by your referral center"?	5.14 (1.12)
7. Overall, how satisfied are you with "how your referral center is treating your maculopathy"?	5.22 (1.01)
8. If your pathology provided an exemption, how likely is it that you would go to the center more often?	4.21 (2.02)
9. To what extent do you think you are dependent on another person (for example, a family member, a carer) in managing your daily routine since you started therapy?	2.56 (2.45)

overall satisfaction score of 55.84 (10.13). Similarly, Gohil et al reported a mean satisfaction score of 52.7 (8.9) using MacTSQ with 250 patients with wAMD receiving ranibizumab in the UK.[4] Similar treatment satisfaction scores were also reported by Amoaku et al and Calles-Monar et al.[11,14] Thus, our results are in line with previous treatment satisfaction scores reported by patients receiving anti-VEGF treatment.

In a cross-sectional survey conducted in 9 countries in 2012, Varano et al evaluated the physical and emotional impact of wAMD on a global cohort of patients who were receiving (or had previously received) anti-VEGF injections and caregivers (paid and unpaid) using an ophthalmologist-devised questionnaire.[12] Patients and caregivers reported that

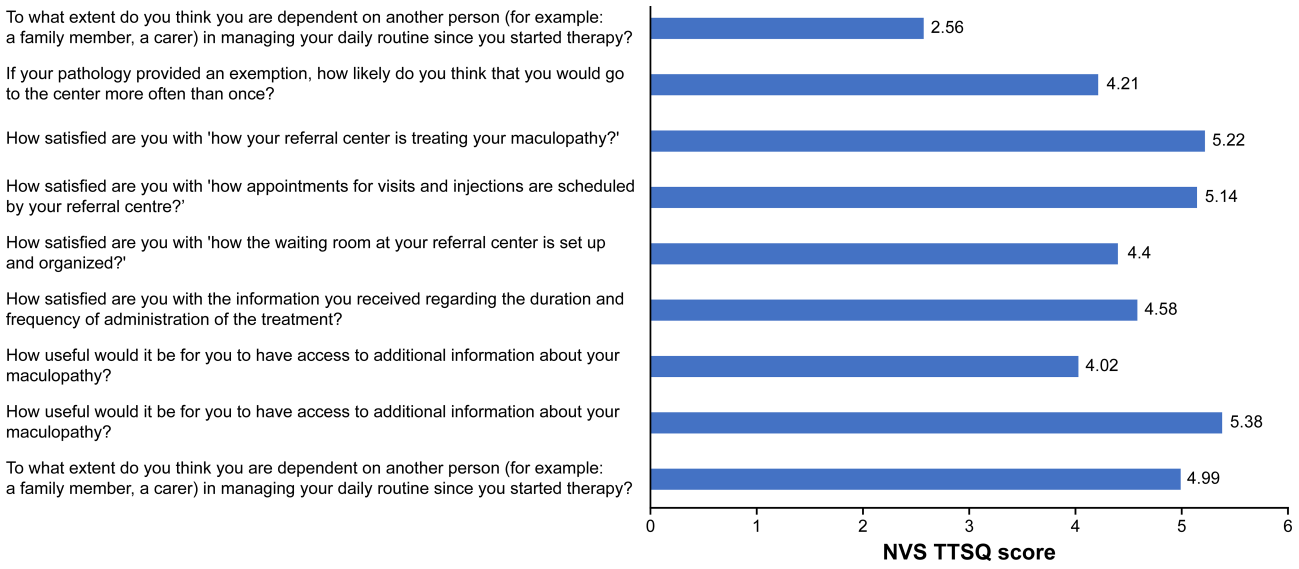

Figure 2 Patient treatment satisfaction scores according to the NVS TTSQ (N = 154).

elements of the treatment of wAMD (anti-VEGF injections, frequency of injections, and possible injection-related side effects) were obstacles in the management of the condition. In our study, patients reported a higher level of satisfaction with the management of wAMD treatment, underlining recent improvements in treatment approaches. Patients were satisfied with services at healthcare centers, waiting room facilities, handling of visits and injections, and management of maculopathy. Moreover, patients reported good satisfaction scores with diagnostic procedures and information provided about such procedures before treatment administration. As this study was conducted in well-known retina centers across Italy, this observation can be attributed to improvements in healthcare infrastructure and high quality patient-centered services provided by healthcare centers.

Of note, patients treated for more than 1 year and who received more than 6 injections expressed the need for additional information on their treatment and disease outcomes. Patients also desired additional information on their disease and a chance to talk with already treated patients about injection procedures. These results suggest that patients

Table 3 Patient Treatment Satisfaction (NVS TTSQ) in Relation to Duration and Number of Anti-VEGF Injections

NVS TTSQ scores by duration of anti-VEGF injection (N = 154)			
	<1 year (n=18)	**≥1 year and ≤3 years (n = 75)**	**>3 years (n = 61)**
Overall total score, mean (SD)	39.94 (4.12)	40.97 (7.43)	40.08 (7.36)
Information domain, mean (SD)	10.33 (1.29)	9.97 (1.99)	9.85 (1.76)
Unmet need domain, mean (SD)	22.33 (3.62)	23.41 (4.73)	22.64 (4.58)
NVS TTSQ scores by number of anti-VEGF injection (N = 154)			
	3–5 (n = 11)	**6–10 (n = 39)**	**>10 (n = 104)**
Overall total score, mean (SD)	40.36 (4.07)	41.05 (6.75)	40.31 (7.47)
Information domain, mean (SD)	10.45 (1.44)	10.38 (1.37)	9.76 (1.98)
Unmet need domain, mean (SD)	22.64 (2.96)	23.05 (5.01)	22.99 (4.54)

Abbreviations: N, total number of patients; n, number of patients in a group; SD, standard deviation.

Table 4 Patient Satisfaction Based on the Mode of Travel to Center and Place of Residence

NVS TTSQ mode of travel to center (N = 154)				
	Public transport (n = 23)	**Private car (n = 107)**	**Taxi (n = 14)**	**Other (n = 10)**
Overall total score, mean (SD)	40.52 (6.47)	39.97 (7.22)	41.86 (5.66)	44.20 (7.72)
Information domain, mean (SD)	9.52 (2.22)	9.90 (1.83)	10.79 (1.01)	10.60 (1.11)
Unmet need domain, mean (SD)	23.87 (4.15)	22.63 (4.69)	23.14 (3.89)	24.50 (4.54)
NVS TTSQ place of residence (with respect to healthcare center) (N = 154)				
	Same city (n = 57)	**Same district (n = 55)**	**Out of district (n = 33)**	**Out of region (n = 9)**
Overall total score, mean (SD)	40.04 (6.93)	39.36 (7.37)	41.70 (6.62)	46.00 (4.74)
Information domain, mean (SD)	10.33 (1.36)	9.58 (2.03)	9.67 (2.07)	11.11 (1.29)
Unmet need domain, mean (SD)	22.67 (4.71)	22.64 (4.73)	23.61 (4.20)	24.78 (3.15)

Abbreviations: N, total number of patients; n, number of patients in a group; SD, standard deviation.

who have started treatment are concerned with the treatment and its outcomes after a period of time. This may be attributable to the lack of information and follow-up on the progress of treatment after some time and also to a need to improve communication regarding disease chronicity. Patients enrolled in other similar studies have also reported the lack of adequate information regarding treatment as an obstacle in the management of wAMD.[12] This highlights the importance and need for improvement of patient physician communication regarding diagnosis and disease management of patients with wAMD.

Patients were not satisfied with their dependence on caregivers and mentioned less satisfaction regarding "independence toward family members in the management of their disease". In earlier studies considering the age of patients with wAMD, patients are often dependent on caregivers for traveling to healthcare centers.[15] Treatment with wAMD requires frequent visits to the healthcare center, which is not convenient for patients and their caregivers. Thus, reducing the treatment burden of anti-VEGF injection is an unmet medical need, which impacts patients' treatment satisfaction significantly.[9]

This is the first real-world survey involving patients with wAMD in Italy assessing patients' satisfaction with wAMD management. In addition, we used a newly developed questionnaire, the NVS TTSQ, collecting data on patients' needs and opinions, which includes questions regarding patient perspective and satisfaction with care and the healthcare system, diagnosis management, unmet needs, information received regarding disease, and caregiver burden. The commonly used treatment satisfaction survey, MacTSQ, does not contain such a wide variety of questions and, according to available literature, this study was the first time it was used to assess patient satisfaction with the whole course of treatment in addition to focusing on treatment satisfaction. Thus, our survey provides deeper insights into patient treatment satisfaction compared with commonly used MacTSQ. In addition, the survey used an innovative digital method (Confirmo). It ensured the recording of response to all the questions of the questionnaire. It collected patients' insights and was tailored to patient with visual impairment, which could be useful in further research. As physicians were not able to receive/read the single answers from patients, it contained sincere responses from those patients.

However, there were a few limitations of this study, including a selection bias for patients and the centers. The centers selected for this study were renowned and well-established. Patient population and the standard of care in these centers may not represent the patient population and centers across Italy. These centers may have higher standards of care compared to other small healthcare centers. Thus, patients receiving treatment in these centers may generally have higher treatment satisfaction. Moreover, patient populations in these centers may also not be a true representation of the entire patient population spread across Italy. Of note, it is difficult to access a large number of patients in other centers. Thus,

these centers were selected for this study. The enrolled patients completed a loading phase of at least 3 doses within 90 days from the first dose and a period of follow-up of at least 9 months (including the loading phase). A few of the data points were missing or incomplete. However, this is real-world data, which is more representative of both the study population of interest and the outcomes of interest. Patients were selected consecutively to minimize patient selection bias.

Conclusions

Results from this study provide insights into factors affecting patient satisfaction with management of wAMD in Italy, which will help retina centers in terms of updating services and treatment approaches. Ten years after the introduction of intravitreal anti-VEGFs, patients with wAMD are more satisfied with the management of the disease as reported in earlier studies conducted globally. Improvement in patient–physician communication regarding disease management and prognosis is warranted, which may further increase patient satisfaction with the treatment of wAMD and could improve future patient adherence.

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Author Contributions

All authors made a significant contribution to the work reported, whether that is in the conception, study design, execution, acquisition of data, analysis and interpretation, or in all these areas; took part in drafting, revising or critically reviewing the article; gave final approval of the version to be published; have agreed on the journal to which the article has been submitted; and agree to be accountable for all aspects of the work.

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Disclosure

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