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Indian Journal of Clinical and Experimental Ophthalmology

Journal homepage: www.ijceo.org

Original Research Article

Trends and practices in the management of neovascular age-related macular degeneration (nAMD) amongst ophthalmologists across India: Findings of a cross-sectional survey

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ARTICLE INFO

Article history:

Received 23-04-2021

Accepted 27-05-2021

Available online 30-09-2021

Keywords:

Neovascular age-related macular degeneration
Ophthalmologists
Retinal disorders
Retinal fluid
Survey
Trends and practices

ABSTRACT

Background: To understand the clinical practice pattern of general ophthalmologists in the management of retinal diseases. Also, aimed to explore the ophthalmologist's perspective towards patient compliance and unmet need in the management of neovascular age-related macular degeneration (nAMD).

Materials and Methods: A total of 108 ophthalmologists participated in this cross-sectional questionnaire-based survey. A paper-based questionnaire with a tool of twelve questions, with response options ranging on a five-point Likert scale of 'strongly agree' to 'strongly disagree' was provided to participants.

Results: Out of 108, 95.4% ophthalmologists confirmed that they were commonly consulted for nAMD amongst the different retinal disorders (RDs). The majority of respondents (87%) confirmed that 60% or fewer patients continue the treatment for a year. About 81.5% of ophthalmologists stated that fluid (Intra-retinal fluid, Sub-retinal fluid) on optical coherence tomography (OCT) was an extremely important parameter for disease activity. The survey revealed that injection frequency was the factor for non-compliance in majority of (>50%) patients. More than 64% of respondents opined that improved efficacy (70.4%), reduced treatment burden (64.8%), and longer acting agents/sustained delivery (64.8%) are the most critical unmet needs for nAMD patients.

Conclusion: Based on the findings, it can be concluded that, in addition to functional outcomes i.e. visual acuity, ophthalmologists also considered retinal fluid and central retinal thickness as important parameters for treatment-related decisions. Ophthalmologists suggested that there is a need to develop longer-acting agents with improved efficacy which may help in reducing treatment burden in nAMD management.

Key Message: Longer acting anti-vascular endothelial growth factor (VGEF) agents with improved efficacy may help in reducing the treatment burden in nAMD management.

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1. Introduction

Age-related macular degeneration (AMD) is the leading cause of irreversible vision loss characterized by a progressive and chronic degeneration of the macula, responsible for high acuity vision. As the disease progresses

to the advanced stages, it can manifest as either geographic atrophy/ 'dry' or exudative/ 'wet' AMD.^{1,2} The prevalence rate of AMD ranges from 0.6 to 1.1% in developing countries.¹ As per a World Health Organization report published in 2019, 196 million people have AMD globally, including 10.4 million people with moderate to severe vision impairment or blindness. Due to an aging population, the global burden of AMD is expected to rise to more than

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243 million cases in 2030.³

A study by Kulkarni SR et al. (2013) reported that the proportion of patients with overall AMD in India was 1.38% (95% CI 1.21-1.55).⁴ AMD, a neurodegenerative disease, affects the macular region of the retina and causes irreversible destruction of vision. The disease is further categorized into two types, dry (geographic atrophy) or wet (neovascular).⁵ In case of neovascular AMD (nAMD), choroidal neovascularization (CNV) leads to the growth of abnormal blood vessels.⁶

The management of nAMD changed significantly in the last decade with introduction of anti-vascular endothelial growth factor (VEGF) therapy. For the management of nAMD, several treatment options were used. Pharmacotherapeutic agents (anti-VEGF agents) which are currently available for the treatment of nAMD block the biological effects of VEGF on neovascular endothelium by preventing VEGF to bind to its receptor on the cell surface. These agents include pegaptanib, ranibizumab, aflibercept, bevacizumab (off-label), brolucizumab, conbercept. Various treatment guidelines (European Society of Retina Specialists, American Academy of Ophthalmology, Vitreo Retina Society of India, Royal college of Ophthalmologist) across the globe recommend the use of anti-VEGF agents as first line therapy, while use of photodynamic therapy and laser therapy is limited to selected patients.^{7–10} Amongst the five anti-VEGF agents, pegaptanib is no longer used for the management of nAMD because it has shown less efficacy for vision improvement in clinical trials of nAMD compared with other agents while bevacizumab is used as 'off label'.¹¹ While selecting an optimal therapy to treat nAMD, a key factor is to consider the impact of treatment on the patients' quality of life. The disease management with intravitreal injections is associated with burdens of multiple monitoring/injection visits, continuous follow-ups of every month, and emotional factors, including frustration and needle phobia.¹²

There is limited data available from the clinician perspective in India. The present survey was aimed at understanding the clinical practice pattern of general ophthalmologists and management of retinal diseases along with the ophthalmologists' perspective towards patient compliance and the approach of patient and their caregivers towards the management of nAMD.

2. Materials and Methods

This cross-sectional questionnaire-based survey was conducted at the 28th Annual National Conference of All India Ophthalmological Society (AIOS) held at Gurgaon, Haryana, India, in February 2020. A total of 108 ophthalmologists participated in the survey. The survey questionnaire was administered to the ophthalmologists (after receiving consent) who visited the medical booth

of Novartis Healthcare Pvt Ltd. The content of the questionnaire was developed and verified by an expert panel to understand the treatment pattern and practices in the management of nAMD. A paper-based questionnaire with twelve questions, with response options ranging on a five-point Likert scale of 'strongly agree' to 'strongly disagree' was used. The survey was self-administered by the participants under the supervision of the survey team if required. Table 1 presents the parameters that contained questions on disease burden, diagnostic aspects, and management of nAMD.

In context of disease burden, the questionnaire mainly focused on proportion of patients with nAMD, types of patients treated and the dosing regimen generally followed in their clinical practice. In diagnostic aspect, the questionnaire focused on various tools/imaging modalities they generally use for nAMD diagnosis; diagnosis based on disease activity on OCT and fluid parameters along with frequency of OCT they performed throughout the treatment period.

In management, the questionnaire mainly covers ophthalmologists' experience on different criteria they consider while treating a patient with nAMD in their clinical practice, different parameters of disease activity, different parameters they consider when referring to vitreo-retinal surgeon, reasons for patients' non-compliance, impact of available anti-VEGF on fluid resolution, time period from treatment initiation to drop out, and unmet need in management of nAMD. The follow-up diagnostic modalities preferred by the ophthalmologists were recorded for new-onset choroidal neovascularization (CNV) in nAMD, and also the vital parameters to assess the recurrence of disease and its management.

For disease activity, the ophthalmologists were asked to rate the significance of factors for disease activity like fluid on OCT, sub-retinal fluid (SRF), intra-retinal fluid (IRF), sub-RPE (retinal pigment epithelium) fluid/hemorrhage, central retinal thickness (CRT) and visual deterioration.

The confidentiality and anonymity of study participants were maintained throughout the survey. All participants provided written consent before participating into the survey.

3. Results

A total of 108 ophthalmologists completed the survey. Table 2 presents that 95.4% (n=103) and 78.7% (n=85) ophthalmologists confirmed that they were consulted commonly for nAMD and diabetic macular edema (DME) amongst the different retinal disorders, respectively.

Total number (Mean $\pm$ SD) of RD patients treated by an ophthalmologist was approximately 45 per month ranging from 10 to 200 patients. Out of all RDs, 34% of ophthalmologists stated that 20% of their patient pool was suffering from nAMD while 31% of ophthalmologists stated

that 30% of their patients were suffering from nAMD. In conclusion majority of ophthalmologist (65%), reported that 20-30% of their patient pool was suffering from nAMD. For the treatment of nAMD patients, ophthalmologists treat 59% of their patients by themselves while another 29% of patients are referred to retina specialists and 12% of patients either did not get treatment or dropped-out (Table 3).

The survey revealed that about half of the ophthalmologists (51.9%) used PRN regimen from the beginning for their nAMD patients. However, 38.9% used three loading doses followed by PRN regimen and 6.5% used two loading doses followed by PRN regimen. In about 40-70% of nAMD patients, the ophthalmologists (60%) used loading doses (two/three) in India. The majority of ophthalmologists (87%) confirmed that 60% or fewer patients continue the same treatment for a year.

The survey inquired about the diagnostic tools used during the follow-up visits for nAMD patients. The majority of ophthalmologists [(41.7%) n=45] chose to perform initial fluorescein angiography (FA) and OCT, followed by OCT only while 39.8% (n=43) of ophthalmologists chose initial FA and OCT, followed by OCT; repeat FA only if new bleeding or no response. However, only 5.6% (n=6) of ophthalmologists chose initial FA and OCT, followed by OCT; repeat FA every three-six months in majority of patients (Table 4).

About 81.5% of ophthalmologists stated that fluid on OCT was an extremely important parameter for disease activity, followed by visual deterioration (11%) and CRT (4.6%). Figure 1 presents the parameters of disease activity rated by the ophthalmologists as per its importance.

The essential fluids on OCT, i.e. intra-retinal fluid (IRF), sub-retinal fluid (SRF), and sub-RPE fluid for disease activity, were reported as ‘important’ and ‘extremely important’ by 79.6%, 78.7%, and 18.5% ophthalmologists respectively (Figure 2).

The survey assessed that 85% of ophthalmologists agreed on the importance of ‘drying the retina.’ Similarly, approximately 82% agreed that ‘treating fluid in all pockets of the retina’ would be beneficial for nAMD patients, while about 17% of ophthalmologists agreed that leaving some sub-retinal fluid could be a useful measure while treating their patients. About 83% of ophthalmologists either strongly agreed or agreed to the fact that reducing fluid in the retina would increase the VA. Also, 40% of ophthalmologists strongly disagreed to ‘treat IRF only’ and 68% to ‘treat only SRF’ (Figure 3).

Sixty percent (60%) of ophthalmologists confirmed that OCT was performed on a patient during the injection-only visit if unexpected changes such as new symptoms or vision change develop. However, 16.7% of ophthalmologists always performed OCT during the injection-visit. 27.8% ophthalmologists did not schedule an injection-only visit for their nAMD patients.

The survey urged the doctors about the vital parameters of disease recurrence. Eleven (10.2%), four (3.7%), three (2.8%), six (5.6%), four (3.7%) ophthalmologists considered loss of vision, recurrence of SRF, recurrence of IRF, macular hemorrhage, and sub-RPE fluid as extremely important parameters, respectively. Table 6 presents the details about the parameters, where an ophthalmologist referred the patient to a vitreoretinal (VR) surgeon.

The factors for patients’ non-compliance were stated as injection frequency, caregiver burden, old age, and co-morbidities. The majority of ophthalmologists opined injection frequency was the factor for non-compliance in most (>50%) patients (Table 7).

More than 64% of ophthalmologists opined that improved efficacy (70.4%; n=76), reduced treatment burden (64.8%; n=70), and long-acting/sustained delivery (64.8%; n=70) are the most critical unmet needs for nAMD patients (Table 8).

Fig. 1: Parameters of disease activity

Fig. 2: Parameters for retinal fluid

4. Discussion

The present survey was a cross-sectional study, conducted to understand the current practice pattern amongst ophthalmologists for the management of nAMD in India. It was also aimed at evaluating patient compliance and reason for discontinuation of treatment. The survey aids in

Table 1: Parameters collected in the survey

Parameters	Elements
Clinical Practice Patterns	<p>Average number (per month) of patients the ophthalmologists' encounter having retinal disorders including both new and follow-up patients.</p> <p>Three most common retinal disorders the ophthalmologists come across in their practice</p> <p>Average proportion of nAMD patients in their clinical practice</p> <p>Average number of nAMD patients treated by them and dosing regimen they follow.</p> <p>Proportion of patients who take loading dose for first three months and continue with the same treatment that was initiated for at least a year for the management of nAMD.</p>
Diagnostic Measures	<p>Initial fluorescein angiography (FA) and OCT, followed by OCT only</p> <p>Initial FA and OCT, followed by OCT; repeat FA every three-six months</p> <p>Initial FA and OCT, followed by OCT; repeat FA only if new bleeding or no response</p> <p>Initial OCT only, followed by OCT</p> <p>Any other</p>
Parameters for disease activity	<p>Fluid on OCT</p> <p>Central Retinal Thickness (CRT)</p> <p>Visual deterioration</p>
Parameters for retinal fluid	<p>Intra-retinal fluid (IRF)</p> <p>Sub-retinal fluid (SRF)</p> <p>Sub-retinal pigment epithelium (Sub-RPE) fluid</p> <p>IRF, SRF, and Sub-RPE</p>
Frequency of OCT in an established patient during an injection-only visit	<p>Never</p> <p>Unexpected change such as new symptoms or vision change</p> <p>Always</p> <p>Do not schedule patients for injection only visits</p> <p>Other, please specify</p>
nAMD management considerations	<p>Dry the Retina</p> <p>Treat every fluid in all pockets of the Retina (IRF, SRF, and sub-RPE)</p> <p>Treat only IRF, Treat only SRF</p> <p>Beneficial effect of leaving some sub-retinal fluid</p> <p>Under-treatment in nAMD patients</p> <p>Reducing fluid in the retina leading to increase in the visual acuity</p>
Parameters for Re-treatment decisions	<p>Loss of vision</p> <p>Recurrence of SRF, Recurrence of IRF</p> <p>Macular Hemorrhage</p> <p>Sub RPE fluid</p>
Parameters for a referral to vitreo-retinal surgeon	<p>Visual acuity</p> <p>Retinal fluid</p> <p>Structural parameters</p> <p>Visual acuity, Retinal fluid & structural parameters</p>
Reasons for non-compliance	<p>Old age and comorbidities</p> <p>Injection frequency</p> <p>Caregiver burden</p> <p>Travel considerations</p> <p>Treatment-related anxiety</p> <p>Any other</p>
nAMD patients stop taking treatment	<p>After three months, After six months</p> <p>After nine months, After 12 months</p>
Unmet need	<p>Improved efficacy</p> <p>Reduced treatment burden</p> <p>Improved safety</p> <p>Long-acting/sustained delivery</p> <p>New treatment mechanism of action</p>

Fig. 3: Management considerations for AMD

Table 2: Consultation for common retinal diseases

Disease	Ophthalmologist n (%)
Age-related Macular Degeneration	103 (95.4)
Diabetic Macular Edema	85 (78.7)
Retinal Vein Occlusion	15 (13.9)
Diabetic Retinopathy	21 (19.4)
Others	94 (87)

Table 3: Clinical practice patterns

Parameters	Mean (SD)
Total number of RD patients in a month	44.91 (25.56)
Proportion of patients suffering from nAMD (%)	24.95 (10.49)%
nAMD patients treated by ophthalmologists (%)	58.98 (29.82)%
nAMD patients referred to retina specialist (%)	28.89 (25.92)%
nAMD patients do not get treated (or treatment)/ drop out (%)	12.13 (11.58)%
Proportion of patients on loading dose for the first three months (%)	46.71 (23.71)%
Proportion of patients continuing the same treatment (%)	48.66 (16.97)%

SD - Standard Deviation; RD- Retinal Diseases; nAMD- neovascular Age-related Macular Degeneration

Table 4: Diagnosis of CNV in the proportion of nAMD patients by FA and OCT

Proportion of Patients	Initial FA and OCT, followed by OCT only	Initial FA and OCT, followed by OCT; repeat FA every three-six months	Initial FA and OCT, followed by OCT; repeat FA only if new bleeding or no response
	Ophthalmologists n(%)		
None	55 (50.9)	97 (89.8)	56 (51.9)
10 - 50%	8 (7.4)	5 (4.6)	9 (8.3)
60 - 100%	45 (41.7)	6 (5.6)	43 (39.8)

Table 5: Frequency of OCT during Injection-only visit

Frequency of OCT	Ophthalmologists n(%)*
Never	0
Unexpected Changes	65 (60.2)
Always	18 (16.7)
No Injection-only visits	30 (27.8)
Other (6 weeks)	1 (0.9)

* Some of the ophthalmologists preferred to choose two options

Table 6: Parameters leading to referral to VR surgeon

Parameters	Ophthalmologists referring to VR surgeon n (%)*
Visual Acuity	31 (28.7)
Retinal Fluid	44 (40.7)
Structural parameter	42 (38.9)
Visual acuity, Retinal fluid & structural parameter	28 (25.9)

*Some of the ophthalmologists preferred to choose two factors

Table 7: Factors of non-compliance

Proportion of Patients	Old age and co-morbidities	Injection frequency	Caregiver burden	Travel considerations	Treatment-related anxiety
Ophthalmologists n (%)					
None	16 (14.8)	1 (0.9)	13 (12)	52 (48.1)	87 (80.6)
<5-25%	75 (69.4)	15 (14)	81 (75)	52 (48.1)	18 (16.7)
30-50%	13 (12.1)	24 (22.2)	13 (12.1)	4 (3.7)	3 (2.7)
>50%	4 (3.7)	68 (63)	1 (0.9)	0	0

Table 8: Unmet need

Unmet needs	Most Important n(%)	Moderately Important n(%)	Important n(%)	Slightly Important n(%)	Least Important n(%)
Improved efficacy (108)	76 (70.4)	14 (13.0)	8 (7.4)	4 (3.7)	6 (5.6)
Reduced treatment burden (108)	70 (64.8)	15 (13.9)	7 (6.5)	5 (4.6)	11 (10.2)
Improved safety (108)	4 (3.7)	5 (4.6)	7 (6.5)	25 (23.1)	67 (62)
Long acting/sustained delivery (107)	70 (64.8)	16 (14.8)	7 (6.5)	2 (1.9)	12 (11.1)
New treatment mechanism of action (108)	3 (2.8)	4 (3.7)	5 (4.6)	34 (31.5)	62 (57.4)

understanding the unmet needs and supports the strategies to develop an effective treatment option for nAMD. The present survey describes the disease activity parameters, treatment outcome, and burden of disease in Indian patients.

As per survey findings, ophthalmologists were being consulted on average by 45 patients with nAMD every month. nAMD was the most commonly consulted disease for 95.4% of ophthalmologists, followed by DME (78.7%) and diabetic retinopathy (DR) (19.4%).

The survey focused on certain factors that were considered vital by ophthalmologists to understand the activity of the disease and to manage the same in patients. OCT is the established diagnostic tool used to describe and measure the cross-sectional architecture of the retina.

The present survey demonstrated that the ophthalmologists considered IRF (79.6%), SRF (78.7%), and sub-RPE (18.5%) fluid on OCT as ‘extremely important’ and ‘important’ disease activity parameters. The current practice states that fluid on an OCT is considered as an indication of active disease.¹³ The guidelines also suggest that treating physician need to keep certain factors, such as drying the retina, a priority while managing the disease; treating fluid in all pockets of the retina were essential parameters to be considered.¹⁴ American Society of Retina Specialists practice and trend survey (2018) conducted with retina specialists (N=1028) revealed that the recurrence of both SRF (reported by 49.9% United States and 54.0% international specialists) and IRF (reported by 32.2% united

states and 24.4% international specialist) were indicated as the most important factor in nAMD disease activity during the maintenance phase.¹⁵ This evidence indicates that both SRF and IRF are important disease activity parameters in patients with nAMD.¹⁶

In this survey, majority of ophthalmologists (41.7%) chose to perform initial fluorescein angiography (FA) and OCT, followed by OCT only, while 39.8% of ophthalmologists chose initial FA and OCT, followed by OCT; repeat FA only if new bleeding or no response. However, only 5.6% of ophthalmologists chose initial FA and OCT, followed by OCT; repeat FA every three-six months in majority of patients. Similar findings were observed in Preferences and Trends (PAT) survey conducted by the American Society of Retina Specialists (ASRS) in 2014, where most of the retina specialists from Central and South America (80%) reported FA and OCT as most commonly used tests for the initial examination of patient with nAMD followed by the United States (69%), Europe (67%), Africa/Middle East (66%) and Asia-Pacific (41%).¹⁵

Clinical evidences have reported better visual outcomes with the T&E approach than with the PRN regimen in a real-world setting. But some patients prefer a regular 12-week injection with ongoing T&E while many are keen to avoid any long-term injection treatments but are happy to remain under monitoring. So patient choice should be taken into account when attempting a change from Treat & Extend to PRN monitoring.¹⁷ A number of studies were conducted to understand the treatment burden on patients and the outcome of different treatment regimens.¹⁸ The treatment regimen is difficult to maintain due to the financial and psychological burden on patients. The present survey reported that about half of the ophthalmologists (51.9%) used PRN regimen from the beginning for their nAMD patients. However, 38.9% used three loading doses followed by PRN regimen and 6.5% used two loading doses followed by PRN regimen. The ophthalmologists treated approximately 46.7% of patients on loading dose for the first three months, and about 48% of patients remained on the treatment regimen for a year as per the present survey results. In the PAT survey conducted by ASRS (2019), the majority of retina specialists agreed to initiate therapy with loading dose schedule of ≥ 3 before monthly injection, 'T&E' and 'PRN'.¹⁹ Results from the BeMOc Trial concluded that loading dose leads to slightly better visual stability in terms of proportions of patients experiencing moderate visual loss.²⁰ With increasing experience of using anti-VEGF therapy, ophthalmologists have shifted away from a "one size fits all" to an "individualized" approach based on disease activity with the aim of achieving a fluid-free retina for the treatment of nAMD.¹⁶ The PAT survey showed that fluid recurrence is the most important factor indicating recurrent nAMD disease activity in the maintenance phase.²¹

Re-treatment decisions were usually taken by the majority of treating ophthalmologists based on VA, retinal fluid, and structural parameters, as revealed in the present survey. In the present survey, more than 64% of ophthalmologists opined that improved efficacy, reduced treatment burden, and long-acting/sustained delivery are the most critical unmet needs for nAMD patients. For disease management, it was interpreted from the study data that treatment burden may be reduced by adding either a long-acting agent or a sustained release formulation with better efficacy. Similar findings were observed in PAT survey conducted by ASRS (2018) where most of the retina specialists reported 'reduced treatment burden' (69.1% from Asia/Pacific; 73.2% from US) and 'long-acting/sustained delivery' (66.8% from Asia/Pacific; 56.3% from US) as unmet needs.²² In two other surveys, ophthalmologists reported that there is a need to reduce the burden of treatment on patients and develop a longer-acting anti-VEGF therapy for effective nAMD management.^{23,24}

The limitations of the present study were that the number of participants enrolled in the study may not be representative of all the practitioners in the country. The enrollment bias may affect the evaluation; for example, the standard number of patients treated for nAMD introduced variability in the dataset. However, the variability in the number of patients treated by the ophthalmologist did not affect the results of the survey as the findings are in line with previously published studies. The WAVE and AURA studies have shown that first-year treatment may require an average of seven to eight injections, but only four to five were actually administered in real world due to the burden of monthly visit/s and intravitreal injections over a long period of time.²⁵ According to a survey conducted by VRSI in 2017, the average number of Anti VEGF injections per patient was five during the first year of therapy in patient with nAMD.²⁶ The survey results are consistent as compared with other data from across the globe, including the adequacy of treatment, disease burden, or population size. The scope and criteria included in this survey would be helpful for the application of unmet medical needs.²⁷

5. Conclusion

The present survey revealed important aspects of current trends and practice pattern of ophthalmologists in the management of nAMD in India. In addition to functional outcomes i.e. visual acuity, retinal fluid and CRT were also considered as important parameters by participants in making treatment-related decisions. For majority of patients, Injection frequency was identified as main reason for non-compliance to treatment. Ophthalmologists suggested that to overcome this challenge there is a need to develop longer-acting agents with improved efficacy which may help in reducing the treatment burden in nAMD management.

6. Source of Funding

This survey was funded by Novartis Healthcare Pvt. Ltd.

7. Conflicting Interest

The authors declare no conflict of interest.

Acknowledgements

Medical writing support in the development of this paper was provided by Tech Observer India Pvt. Ltd. and was funded by Novartis Healthcare Pvt Ltd.

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Cite this article: Bhavsar M, Maksane N, Shah U, Madhavan A, Dhar P, Thaker M. Trends and practices in the management of neovascular age-related macular degeneration (nAMD) amongst ophthalmologists across India: Findings of a cross-sectional survey. *Indian J Clin Exp Ophthalmol* 2021;7(3):515–522.