



Preliminary findings from the Implementation of a wet macular degeneration patient-reported outcome and experience measure

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Abstract

Aim: The aim of the study was to understand the perspectives, experiences, and concerns of patients with wet macular degeneration (MD).

Background: There are limited tools available with real-world applications to assess patient-reported outcomes and experiences in those with wet MD.

Methods: A prospective analysis of 143 (M:F 46:97) patients with wet MD utilizing a wet MD patient-reported outcome and experience measure (POEM).

Results: The perceived understanding of their diagnosis, management plan, side effect acceptability, as well as their health practitioner satisfaction was favorable. There was much variability observed related to the perception of deterioration, concerns surrounding the loss of visual function, and the effect on everyday living with high interquartile ranges. Patients with worse visual acuity, those receiving treatment for a greater duration, and currently having active treatment in at least one eye indicated a perception of greater diagnosis understanding. Worse vision resulted in more interference with daily living.

Conclusions: The MD POEM can identify concerns pertinent to the patient. Qualitative analysis can be applied to interpret these findings to deliver health-care aligned to patient expectations.

Clinical Significance: The establishment of patient-centered care and delivery of holistic outcomes.

Introduction

Age-related macular degeneration (AMD) can result in significantly decreased vision, subsequently impacting a patient's independence with activities of daily living, social relationships, financial security, and general mental well-being.^[1-4] A utility value study of MD found that patients with minor visual impairment would trade 11% of their remaining lifetime to restore their vision, while patients with severe impairment would trade 60%; highlighting the significant impact AMD can have on the individual.^[5]

An understanding of the concerns, experiences, and perspectives of patients with wet MD is critical in delivering patient-centered care and improving life quality over a long period. Examination of the patient's visual acuity in isolation is

inadequate in understanding the impact on everyday activities and results in disagreement between the doctor and the patient's perspectives and priorities. Despite the availability of numerous resources providing information on wet MD, patients continue to report poor understanding of their condition and dissatisfaction with the level of information provided by health-care services.^[4-7] There is a clear need to identify such shortcomings in patients' understanding of wet MD, its treatment, and its impact on the individual's quality of life.

The present study utilizes a patient-reported outcome and experience measure (POEM) [Figure 1] specific to patients with wet MD in a real-world clinical setting. The aims are to understand the experience and motivation of patients in relation to age, sex, level of vision, and management.

Macular Degeneration Questionnaire (POEM)		Response		
Please indicate to what extent you agree with the following statements at the moment	Strongly disagree	Please mark with a cross along the line	Strongly agree	Unable to rate
1. I understand my diagnosis	☹️	—————	😊️	
2. I understand how my condition is managed	☹️	—————	😊️	
3. My macular degeneration treatment (and any side-effects) are acceptable to me	☹️	—————	😊️	
4. I do <u>not</u> think my macular degeneration is getting worse	☹️	—————	😊️	
5. My macular degeneration does <u>not</u> interfere with my daily life	☹️	—————	😊️	
6. I am <u>not</u> worried about losing vision from macular degeneration	☹️	—————	😊️	
Answers to the following two questions will only be shared with your eye care team after anonymisation				
7. I feel safe under the care of my macular degeneration team	☹️	—————	😊️	
8. My macular degeneration care is well organised	☹️	—————	😊️	
Comments:				
Thank you for your participation!				

Figure 1: Macular degeneration patient-reported outcome and experience measure

Methods

This prospective study included 143 patients with wet MD recruited consecutively over a 4-month period from practice sites affiliated with City Eye Centre in Brisbane, Australia. All patients undertook informed consent. Following the Declaration of Helsinki tenets, the study was accepted by the Human Research Ethics Committee (University of Queensland) (#2015000530). Patients with a diagnosis of dry MD and other visually significant ocular diseases were excluded from the study. Data collected from patient records included sex, laterality of disease, previous treatments, ocular surgery, and current treatment regimen. Covariates included age, duration of treatment, and best-corrected visual acuity (BCVA) of the worse eye. BCVA was classified as normal logMAR -0.1 – 0.1 , mild 0.2 – 0.5 , moderate 0.6 – 0.9 , and severe ≥ 1.0 level of visual impairment.

The MD POEM [Figure 1] is an eight-item questionnaire designed for self-administration and printed in Calibri font size 14. It was developed with input from five specialist ophthalmologists, a clinical optometrist, a biostatistician, and a pilot group of 25 patients. The questionnaire took between 2 and 4 min to complete. Consecutive patients who presented to the clinic for review or treatment were asked to complete the POEM and return completed surveys to clinic staff. Patients responded to each question by placing a mark along a 100 mm horizontal visual analog scale (VAS), from “strongly disagree” on the left (0) to “strongly agree” on the right (100). Each VAS response (measured in millimeters) was recorded as a score between 0 and 100 for each question. Participants’ with reduced visual acuity who could not independently complete the survey and wished to participate were provided with help from the trained clinical staff (i.e., patients were read each question and provided a verbal response on a scale from 0 to 100). The first six

questions of the POEM survey focused on patients’ perception of their understanding of the diagnosis, management, treatment acceptability, and side effects, perception of disease progression, interference with everyday activities, and concern levels regarding worsening of the MD. The last two questions focused on patient satisfaction of health-care provision.

Statistical analysis

The minimum, maximum, median, and quartile ranges for each question were reported and represented in a box and whisker plot [Figure 2]. IBM SPSS Statistics Software (Version 22; SPSS Inc., Chicago, IL, USA) was used for the analysis. A linear multivariate model with the response to each question as the dependent variable was used for analysis with outcomes described as B coefficients with a 95% confidence interval (CI). The continuous predictors were described as a variation in the VAS score number. If the B coefficient had $P \leq 0.05$, it was considered significant.

Results

There was a total of 143 (F:M 97:46) wet MD patients in the study. The mean \pm SD age of patients was 79 ± 11 years. One hundred and thirty-six patients (95.1%) were presently undergoing active intravitreal treatment, whereas the remaining patients had previously received anti-vascular endothelial growth factor treatment. Sixty-five patients (45.5%) had severe visual impairment (logMAR mean visual acuity ≥ 1.0) in the worse eye. Patient demographics and disease-specific clinical data are provided in Table 1. The box and whisker plot in Figure 2, demonstrates minimum and maximum scores, median scores, and interquartile ranges for each question. The results from the multivariate linear analysis of the eight POEM statements are summarized in Table 2.

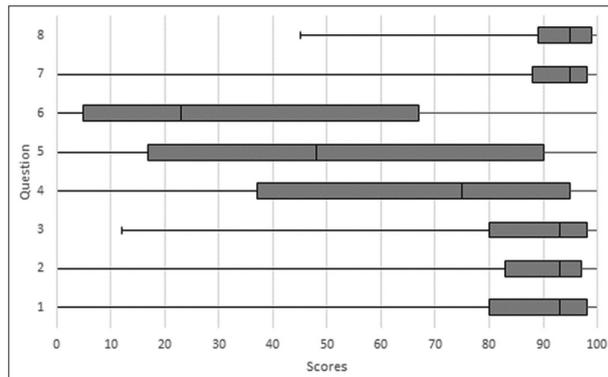


Figure 2: Box and whisker plot demonstrating minimum/maximum/median values and interquartile ranges for each patient-reported outcome and experience measure question

Perception of diagnosis and management understanding

Patients had a high level of perceived understanding of their diagnosis with a median score of 93 points and an interquartile range of 18 in Question 1. The multivariate model for Question 1 [Table 2] indicated that a worse visual acuity (B coefficient -4 , 95% CI -8 – -1 , $P < 0.02$), at least one eye undergoing current treatment (B coefficient -17 , CI 95% -33 – -1 , $P < 0.04$), and for longer treatment duration (B coefficient 2 , 95% CI 1 – 3 , $P < 0.001$) were associated with a greater perception of understanding the diagnosis.

Question 2 indicated that the majority of patients perceived their understanding of the management plan to be favorable, with a median score of 93 points and an interquartile range of 14. The multivariate model for Question 2 [Table 2] demonstrated no connection between predictor variables and perceived understanding of the management plan. Of note, older patients did not have a lower perceived understanding of their diagnosis and management nor were there any sex-related differences.

Acceptability of treatment and side effects

Question 3 demonstrated that patients were very accepting of the treatment with a median score of 93 and an interquartile range of 18. There were no statistically significant associations between the predictor variables and treatment acceptability found on the multivariate analysis. It was found that being younger or having a longer duration of treatment did not adversely affect patients' perceptions.

Interference with daily living, disease progression, and concerns about vision loss

Questions 4 through 6 demonstrated the highest variability in responses in this study. Question 4 had a predominant right shift of values with a median score of 70, indicating that patients mostly did not believe their condition to be worsening but with high variability in responses with an interquartile range of 58. The multivariate model for Question 4 [Table 2] indicated that a worse level of acuity was associated with a higher perception of

Table 1: MD patient characteristics

Variable	Mean±SD (range) or n (%)
Age (years)	79±11 (36–99)
Gender	Female 97 (68) Male 46 (32)
Laterality of disease	Unilateral 89 (62) Bilateral 54 (38)
Current treatment regime	Review only 12 (8) Unilateral IVI 87 (61) Bilateral IVI 44 (31)
Previous related treatment	IVI 135 (94) PDT 50 (35) Antioxidant supplements 83 (58) Any combination of above 89 (62) One treatment type only 54 (38)
Other ocular surgery	None 52 (36) Phaco and IOL only 65 (46) Anterior segment surgery ± phaco and IOL 2 (1) Vitreoretinal surgery ± phaco and IOL 24 (17)
Duration of treatment (years)	5.8±3.6, range 0.00–13.75
Mean visual acuity (logMAR)	Worse eye: 1.27±1.15 (0.00–3.51) Better eye: 0.33±0.49 (–0.10–2.90)
Worse eye acuity	Normal 13 (9) Mild loss 42 (29) Moderate loss 23 (16) Severe loss 65 (46)

MD: Macular degeneration, IVI: Impact of vision impairment

the condition getting worse (B coefficient -6 , CI 95% -11 – -1 , $P < 0.02$).

Question 5 assessed the patient's perceived interference on daily living secondary to their diagnosis. This question had a median score of 48 and the highest interquartile range of all questions at 73. Question 5, represented in the model in Table 2, showed that greater visual acuity loss was associated with a greater impact on everyday life (B coefficient -8 , CI -14 – -2 , $P < 0.01$). Question 6 addressed patient concerns about losing vision. This question had the lowest median score of 23 and an interquartile range of 62, showing that patients strongly disagree with this statement and have continued concerns regarding vision loss. There were no significant associations found for Question 6 pertaining to predictor variables and concerns about vision loss [Table 2]. More specifically, younger patients and

Table 2: Results of multivariate analysis

Variable	β (95% CI)							
	Q1	Q2	Q3	Q4	Q5	Q6	Q7	Q8
Age	-0.04 (-0.43,0.36)	-0.06 (-0.44,0.32)	0.16 (-0.20,0.51)	-0.44 (-1.01,0.12)	0.32 (-0.34,0.97)	0.23 (-0.44,0.90)	-0.20 (-0.45,0.05)	-0.05 (-0.23,0.13)
Duration of treatment (years)	2.14 (0.97,3.30)*	1.08 (-0.04,2.20)	0.33 (-0.73,1.38)	0.11 (-1.55,1.77)	-1.46 (-3.38,0.46)	0.20 (-1.77,2.17)	0.22 (-0.51,0.95)	0.12 (-0.42,0.66)
VA worse eye	-4.41 (-7.99,-0.84)*	-1.31 (-4.75,2.13)	0.07 (-3.17,3.32)	-6.25 (-11.33,-1.17)*	-7.82 (-13.71,-1.93)*	-2.41 (-8.46,3.64)	-0.07 (-2.32,2.18)	0.65 (-1.01,2.31)
Gender (Male)								
Female	3.92 (-3.66,11.49)	4.71 (-2.58,12.00)	2.50 (-4.38,9.37)	10.16 (-0.61,20.92)	0.08 (-12.41,12.56)	-0.66 (-13.48,12.16)	0.09 (-4.67,4.85)	-0.96 (-4.47,2.55)
Eyes affected (Unilateral)								
Bilateral	-2.20 (-18.68,14.29)	2.10 (-13.77,17.97)	6.13 (-8.83,21.09)	18.62 (-4.82,42.05)	11.89 (-15.28,39.06)	-3.90 (-31.80,24.01)	3.79 (-6.57,14.16)	1.39 (-6.25,9.02)
Previous MD treatments (Single)								
Combination	-4.97 (-12.94,3.00)	-3.51 (-11.18,4.16)	-2.33 (-9.56,4.90)	-9.27 (-20.59,2.06)	-6.44 (-19.56,6.69)	6.85 (-6.63,20.34)	-0.86 (-5.86,4.15)	-0.70 (-4.38,2.99)
Previous ocular surgery (None)								
Phaco and IOL only	-2.17 (-10.50,6.16)	-3.04 (-11.06,4.98)	-1.95 (-9.51,5.61)	1.35 (-10.49,13.19)	-1.83 (-15.56,11.89)	1.02 (-13.08,15.12)	1.61 (-3.62,6.85)	-0.42 (-4.27,3.44)
Anterior segment	16.00 (-13.30,45.30)	13.83 (-14.38,42.04)	-27.85 (-54.43,-1.27)*	21.74 (-19.90,63.39)	13.89 (-34.39,62.17)	-25.91 (-75.49,26.37)	5.61 (-12.81,24.02)	2.64 (-10.93,16.20)
Vitreo-retinal	-4.18 (-14.22,5.87)	-6.52 (-16.19,3.15)	-0.86 (-9.97,8.25)	-6.13 (-20.41,8.14)	10.20 (-6.35,26.75)	0.12 (-16.88,17.12)	-0.16 (-6.48,6.15)	-2.20 (-6.86,2.45)
Current regime (Review only)								
Unilateral IVI	-17.17 (-33.39,-0.95)*	1.06 (-14.56,16.67)	-11.81 (-26.52,2.91)	15.34 (-7.71,38.40)	9.52 (-17.20,36.25)	-5.70 (-33.15,21.75)	0.08 (-10.19,10.20)	-4.19 (-11.70,3.32)
Bilateral IVI	-15.87 (-38.72,6.98)	-1.02 (-23.02,20.99)	-15.90 (-36.63,4.84)	-11.13 (-43.62,21.36)	-13.91 (-51.58,23.75)	-5.98 (-44.66,32.70)	-4.42 (-18.79,9.95)	-7.52 (-18.10,3.07)

MD: Macular degeneration, CI: Confidence interval, IVI: Impact of vision impairment

those with longer duration of disease did not have any more concerns than older patients regarding vision loss.

Perceived confidence in treatment plan and health-care providers

Questions 7 and 8 assessed patient's perceived confidence in the treatment plan and their health-care providers. It indicated that patients were highly satisfied with their treatment plan and health-care providers with the highest median scores and the lowest interquartile ranges. Questions 7 and 8 both had a median score of 95 and interquartile ranges of 10. There were no statistically significant associations found for Question 7 and Question 8 [Table 2] with the predictor variables.

Discussion

A number of instruments have been developed and validated for assessing outcomes and experience for a variety of diseases.^[8-10] Patient-reported outcome measures (PROMs) are available that assess outcomes from the patient's perspective.^[10] PROMs are frequently utilized in outpatient clinical settings and highlight the increasing focus on the patient-based evaluation of healthcare.^[11] In wet MD, PROMs have mostly focused on the experience of living with the disease, the experience of receiving intravitreal treatment, and treatment choice.^[12,13] Other generic questionnaires that have application in all causes of visual impairment, such as the impact of vision impairment questionnaire, have also been used in MD.^[14]

Few studies have investigated a patient's perceived level of understanding, fear of disease progression, and acceptability of treatment and side effects, in conjunction with the impact on daily living. Somner *et al.* devised a POEM for glaucoma and suggested as an alternative tool to the PROM to address the above shortcomings.^[15] This measure is a six item questionnaire arising from the "First National Glaucoma Think-Tank" event in the United Kingdom in 2012. This novel instrument proposed to address three aspects of outcome (fear of blindness, acceptability of treatment/side effects, and impact on daily life) and three aspects of experience (safety, respect, and understanding) that was not previously addressed in conventional tools. However, the validity and reliability of such a tool needed further research. The use of a glaucoma POEM adapted for a private clinic case mix has been recently described by Fraenkel *et al.*^[16] This study demonstrated the feasibility of employing a POEM in a clinical care setting and successfully captured the concerns of a practice's glaucoma cohort with the view to use the obtained information to enhance the quality of glaucoma care delivered.

This POEM has been formulated in a "patient-generated" way with the use of focus groups that addressed the concerns most relevant to the patient cohort. This POEM can also be customized based on the characteristics of the cohort, such as cultural differences. The patients involved in the POEM's development, demonstrated an enthusiasm to participate, and perceived the POEM as a means of heightened patient

empowerment and improved health-care delivery. From the clinician's perspective, the simplistic nature of this POEM ensures practicality for real-world, everyday use. Unlike other tools that required trained personnel and consist of lengthy questionnaires, this POEM has been optimized for routine clinical application in wet MD patients.^[15-18] It is extremely important to move from the patient being the "object" of patient-centered care to being the "subject." The quantitative data output obtained from the modified POEM, will aid in health care and research agendas being realigned according to the patients' experiences and priorities.

Questions 1 and 2 demonstrated that the perception of their diagnosis and management understanding was high, with a general right skew with high median scores and lower interquartile ranges. It was found that patients with worse visual acuity, active management with intravitreal injections in at least one eye, and for longer treatment duration, were associated with a greater perceived understanding of the diagnosis. Conversely, it can be deduced that those with better visual acuity, no previous treatment or treatment for a shorter duration, had a poorer understanding of their diagnosis. Studies such as that conducted by Kandula *et al.* have suggested that knowledge of the disease process and its treatment in MD patients is limited and influences disease progression or prevention.^[19] Better comprehension is linked with improved adherence to treatment, higher patient satisfaction, and less anxiety.^[9,10,18]

Our study has helped identify particular patient characteristics associated with a poorer understanding of the disease process and can help with targeted education initiatives on an individual and collective scale. A study by Slota *et al.* identified that patients often felt more comfortable expressing treatment concerns to research assistants (at 41% of the cohort), rather than their treating ophthalmologist (at 10%).^[20] A POEM can be a useful tool in providing transparency and in helping a team of clinicians to adapt their practice by highlighting any deficiencies that can be addressed in the consultation.

Question 3 demonstrated that patients were very accepting of the treatment and possible side effects. It is notable that patients independent of age, gender, and the severity of vision found the treatment and side effects acceptable. Intravitreal injections are an invasive technique with visually threatening risks, including endophthalmitis.^[21] Injections are often performed often on a regular and frequent basis, requiring patients to invest a substantial amount of time traveling, in clinics, and recovering. Patients during the survey often remarked that if it was possible to save their vision, they would gladly undertake intravitreal injections or any other treatment. Despite patients undergoing months to years of treatment and potentially many more in the future, they still found the treatment acceptable.

Questions 4 through 6 demonstrated that patients had a higher degree of variability in their views regarding disease progression, interference on daily living, and concerns about vision loss with high interquartile ranges. It was found that a large proportion of patients do not feel that their MD is getting worse. This may reflect that patients received sufficient education about

the expectations of treatment before commencement. Patients may understand that the intention is to suppress and stabilize the MD, and thus, the patients feel that their vision is neither worsening nor improving. Despite a dominant right skew in responses to most questions in this POEM, patients continue to have concerns regarding vision loss with the lowest median value for Question 6.

Poorer level of visual acuity was associated with a greater perception of the MD progressing and interfering with daily living. The strong and significant relationship between reduction in visual acuity and decrease in quality of life has been previously validated in other studies such as The National Eye Institute visual functioning Questionnaire.^[22-24] The fact that patients with poorer visual acuity have a greater perception of their condition worsening may simply represent a subgroup with poor prognostic indicators and reduced responsiveness to therapy.^[25] Studies have also highlighted a correlation between depressive symptoms and a loss of activity in those with increasing MD severity.^[26,27] This could impact the patient's optimism about their prognosis and subsequently perceived worsening of the condition in those with poorer visual acuity.

Patients were very satisfied with their treatment plan and health-care providers with the highest median scores and lowest interquartile ranges for questions 7 and 8. There were no statistically significant associations between predictor variables and treatment plan acceptability and satisfaction with the health-care providers. This is in keeping with a large number of studies that have been inconclusive in assessing the determinants of patient satisfaction. It is likely that patient satisfaction is heavily influenced by other cultural, behavioral, and socio-demographic differences,^[28] and potentially by other significant concomitant health issues. Patient satisfaction is challenging to assess as there is inherent bias if the study is conducted within a clinic by staff directly associated with the treating clinician.

The MD POEM in the current format requires completion of a paper survey and data entry of the responses. To ensure consecutive recruitment and avoid selection bias in the study, staff assistance to complete the survey was provided to patients with visual, cognitive, and motor limitations. This survey required manual measurements of VAS scores and manual input of data into a database for analysis. This can be both time and resource consuming. By adapting the paper survey to devices such as tablets or smartphones, it would enable automatic data collection and streamline data analysis. With the application on a larger scale, the use of electronic input systems would ensure consistency and reliability in data collection. This study was limited to a private practice patient group, consisting of a predominantly Caucasian, higher educated, and socio-economic cohort. This population expressed appreciation to participate, and they understood the importance of collaborative care in improving their own outcomes. Future investigations using this POEM could encompass a wider demographic, such as in an outpatient non-private hospital clinic.

Conclusion

The MD POEM is the first of its kind worldwide and allows the patient to be the "subject" of patient-centered care, as opposed to the "object." Traditional clinical measures of MD, such as visual acuity, are important but inadequate in the holistic assessment of a patient. This POEM has application in everyday real-world clinical practice and provides additional information about the patient's perceived understanding, experience, and acceptance of their disease and its management. It has indicated that patients have an overall positive response to perceived wet MD outcomes and experience. It also enables the collation of big data that enable a macroscopic view on common themes among patient subgroups. This can subsequently be used in optimizing health initiatives that are aligned to the patients' experience and priorities.

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