Psychometric Evaluation of the Allergan Satisfaction with Treatment Experience Questionnaire (ASTEQ) Using Data from a Phase 3b Study of an Intraocular Implant for Open-Angle Glaucoma (OAG) and Ocular Hypertension (OHT)

Rupali Naik,[1] William Christie,[2] Dana Wallace,[3] Miriam Kolko,[4,5] Kim Cai,[6] Joelle Hallak,[6] Joice T. Huang,[6] Jyotsna Maram,[5] Ashley Nguyen,[6] James S. McGinley,[7] Carrie R. Houts,[7] Fawn Thomas,[2] James Paauw[8]

[1]Noesis Healthcare Technologies, Inc., Redwood City, CA, USA; [2]Scott & Christie and Associates, Cranberry Township, PA, USA; [3]Thomas Eye Group, Sandy Springs, GA, USA; [4]Copenhagen University Rigshospitalet-Glostrup, Glostrup, Denmark; [5]University of Copenhagen, Copenhagen, Denmark; [6]Allergan, an AbbVie company, Irvine, CA, USA; [7]Vector Psychometric Group, Chapel Hill, NC, USA; [8]Piedmont Eye Center, Lynchburg, VA, USA

OBJECTIVE

To evaluate psychometric properties and establish a scoring algorithm for ASTEQ, a 9-item patient-reported outcome measure designed to quantify patient satisfaction with sustained-release bimatoprost implant treatment in open-angle glaucoma (OAG) and ocular hypertension (OHT)

CONCLUSIONS

The ASTEQ items are reliable and valid for evaluating satisfaction, bother, and physical discomfort in patients with OAG/OHT receiving bimatoprost implant

While a summary score from the ASTEQ items was not empirically supported, individual items are face-valid assessments and can be used as stand-alone measures, especially for satisfaction and short- and long-term side effects, in implant-treated patients with OAG or OHT

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INTRODUCTION

- Efforts to manage OAG are complicated by the poor adherence that exists among patients using conventional, self-administered, topical intraocular pressure (IOP)–lowering medication[1,2]
- The intracameral bimatoprost sustained-release implant (Durysta®; AbbVie, North Chicago, IL) provides a therapeutic option for patients with OAG and OHT who are non-adherent or have difficulty using eyedrops[3]
- The implant consists of 10-µg bimatoprost in a sustained-release drug delivery system, and was approved by the US Food and Drug Administration in March 2020 for single administration per eye to lower IOP in OAG and OHT[4,5]
- To quantify patient satisfaction with sustained-release bimatoprost implant, a de novo 9-item patient-reported outcome instrument, the Allergan Satisfaction with Treatment Experiences Questionnaire (ASTEQ), was developed[6]

ASTEQ Instrument Items

1. Overall satisfaction with the implant experience
2. Satisfaction with frequency of implant administration
3. Satisfaction with how implant administration fits with routine/schedule
4. Bother due to immediate side effects
5. Bother due to long-term side effects
6. Worry about implant administration
7. Worry about potential side effects of the implant
8. Physical discomfort during preparation for the implant procedure
9. Physical discomfort during the implant procedure

- This study focuses on the results of the psychometric assessment and establishing a scoring algorithm for ASTEQ to quantify patient satisfaction with the sustained-release bimatoprost implant treatment in OAG and OHT

METHODS

- In a multicenter, open-label, phase 3b trial of bimatoprost 10-µg implant (NCT 03850782), patients with OAG/OHT received ≤3 (pro re nata) bimatoprost implant injections in the study eye at ≥16-week intervals over 36 months
- ASTEQ and the Treatment Satisfaction Questionnaire for Medication (TSQM) version 1.4, a 14-item patient-reported outcome measure to assess satisfaction with a clinical trial medication, were administered
  - TSQM was used to define a stable sample for assessing test-retest reliability and as a reference variable in validation analyses
- ASTEQ and TSQM data at 12 weeks and 8 months after the first injection were included in an interim analysis of study outcomes
- ASTEQ items 2 and 3, pertaining to repeat administration, were excluded from analyses; data were evaluated for patients receiving a single implant
- Dimensionality assessments (exploratory and confirmatory item factor analyses) at week 12 focused on the satisfaction items (items 1, 4, 5, 8, and 9) and applied a unidimensional model to the items
- Internal consistency assessed for ASTEQ composite and test-retest reliability was examined for the composite scores and individual items between week 12 and month 8 using a subsample of patients identified as stable (no change in overall TSQM response from week 12 to month 8)
- Convergent/discriminant correlations were used to examine the relationships between the ASTEQ items and reference variables at both week 12 and month 8
- Known-groups analyses (item responses/scores reflecting differences that are expected to be present in groups defined by relevant/clinically meaningful reference variables), and responsiveness to change (change scores representing the difference between week 12 and month 8 scores) were assessed

RESULTS

- Included were 313 participants who had received 1 bimatoprost 10-µg implant: 54.3% were female, 80.2% were White, 16.6% were Black, and 95.2% non-Hispanic; mean (standard deviation) age was 63.2 (10.9) years
- Dimensionality assessment and internal consistency analyses did not support creation of an overall satisfaction summary score; unidimensional model fit was poor and overall satisfaction item (ASTEQ1) had the lowest loading of all 5 items
- Individual ASTEQ satisfaction items displayed test-retest correlations from 0.63 (worry about the implant) to 1.00 (long-term side effects) indicating the ASTEQ items, except the worry items, produced reliable scores over time

Test-Retest Values Among ASTEQ Items Between Week 12 and Month 8 in a Stable Patient Subset

ASTEQ Item	Item Content	n	Polychoric r
ASTEQ1	Overall satisfaction	66	0.75
ASTEQ4	Short-term side effects	66	0.87
ASTEQ5	Long-term side effects	62	1.00
ASTEQ6	Worry – implantation	66	0.63
ASTEQ7	Worry – side effects	66	0.70
ASTEQ8	Physical discomfort during prep for implant	66	0.84
ASTEQ9	Physical discomfort during implantation	66	0.83

ASTEQ, Allergan Satisfaction with Treatment Experience Questionnaire; r, correlation coefficient

- Observed correlations with reference variables at both week 12 and month 8 demonstrated that the ASTEQ item scores performed as expected
  - Discriminant correlations were all near zero (eg, visual acuity [r range = –0.11 to 0.10], not tabled) for all items, meeting expectations stated a priori
  - Convergent correlations at week 12 and month 8 varied in magnitude based on item content and supported that ASTEQ items scores performed as expected (eg, ASTEQ1 [overall satisfaction] met the expectation of highest correlation with the TSQM global score, also showing the strongest correlation among all ASTEQ items)

Convergent and Discriminant Correlations Among ASTEQ Satisfaction Items and TSQM Reference Variables at Month 8

	TSQM Global		TSQM Effectiveness		TSQM Convenience		TSQM Side Effects	
ASTEQ Item	N	r	N	r	N	r	N	r
ASTEQ1	151	–0.49***	151	–0.41***	150	–0.37***	151	–0.23**
ASTEQ4	151	–0.01	151	0.04	150	0.11	151	–0.21*
ASTEQ5	147	–0.24**	147	–0.11	146	–0.18*	147	–0.49***
ASTEQ6	151	–0.20*	151	–0.21**	150	–0.16*	151	0.03
ASTEQ7	151	–0.23**	151	–0.22**	150	–0.15	151	–0.06
ASTEQ8	151	–0.25**	151	–0.16*	150	–0.12	151	–0.04
ASTEQ9	151	–0.24**	151	–0.15	150	–0.22**	151	–0.19*

ASTEQ, Allergan Satisfaction with Treatment Experience Questionnaire; r, correlation coefficient; TSQM, Treatment Satisfaction Questionnaire for Medication Version 1
*P<.05. **P<.01. ***P<.001

- Known-groups validity analyses and correlations of change scores also produced results supporting the ASTEQ items 1, 4, and 5 as stand-alone measures
  - At week 12 for ASTEQ4, there were statistically significant differences in the response distributions for groups defined by reported side effects via TSQM item 4 and the adverse event indicator variable (P=.0002 each)
  - A similar pattern was seen in the month 8 results, but these differences were only statistically significant for the group defined by reported side effects via TSQM item 4 (P=.0472)
  - Results for ASTEQ5 mirrored those for ASTEQ4
- Responsiveness to change analyses were somewhat hampered by the limited variability in ASTEQ responses over time; the large majority of participants were satisfied at week 12 and remained that way through month 8
  - The sensitivity to change analyses for ASTEQ1 were supportive of it being able to detect change over time; correlations of ASTEQ1 change scores with change score for all TSQM subscale scores were small to moderate conforming to expectations
- With exception of the correlation between ASTEQ5 and TSQM side effect subscale score, remaining change score correlations tended to be near zero or small

Correlations Between Change in ASTEQ Scores and Change in Reference Variables (Month 8 to Week 12)

	TSQM Global		TSQM Effectiveness		TSQM Convenience		TSQM Side Effects	
ASTEQ Item	N	r	N	r	N	r	N	r
ASTEQ1	147	–0.33***	147	–0.27***	146	–0.15	147	–0.13
ASTEQ4	147	0.04	147	–0.03	146	–0.01	147	–0.10
ASTEQ5	140	–0.06	140	–0.06	139	–0.03	140	–0.36***
ASTEQ6	147	–0.10	147	–0.21*	146	–0.16	147	–0.12
ASTEQ7	147	–0.08	147	–0.17*	146	–0.07	147	–0.18*
ASTEQ8	147	–0.15	147	–0.12	146	0.02	147	–0.05
ASTEQ9	147	–0.02	147	0.16	146	–0.18*	147	–0.10

ASTEQ, Allergan Satisfaction with Treatment Experience Questionnaire; r, correlation coefficient; TSQM, Treatment Satisfaction Questionnaire for Medication Version 1
*P<.05. ***P<.001

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