

Group 4: Glaucoma care outcomes - clinical perspective

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Executive Summary

Background

To know whether we achieve the goal of glaucoma treatment, we need to reach consensus on key clinical outcome measures by which the healthcare system can be judged.

Objectives of the workshop

To achieve consensus on key clinical outcome measures in glaucoma which are relevant, measurable and practical. Also, to define methods of assessment and to suggest implementation plans for the EGS and national societies.

Methods

The workshop took place during the EGS Members' Meeting, 8-9 September 2017, in London, UK. Following an interactive web-based polling to exchange views, 5 key clinical outcomes in glaucoma were selected based on a structured workshop with approximately 30 participants (6 groups). For each of these key clinical outcomes, the groups were asked to provide methods of assessment and implementation plans.

Summary of data

Key clinical outcomes proposed

1. Visual Field Progression
2. IOP control
3. Quality of life
4. Treatment complications
5. Progression of combined structure/function index

Implementation plans

These were provided for each key clinical outcome as specific action points under 2018, 2019 and next 5 year milestones. Details on methods of measurements and milestones are presented in the workshop report. Developing self-assessment tools, improving software algorithms for data analysis, standardising data collection and establishing central data repositories were dominant concepts in most implementation plans.

Conclusions and recommendations

Out of the 5 key clinical outcomes proposed by the group, 3 were directly relevant to patients' vision (outcome 1), patients' quality of life (outcome 3) and patients' safety (outcome 4). IOP remains an important clinical index in glaucoma management and the group focused on the concept of achieving individualised targets (clinical outcome 2: IOP control). Structural indices would be most clinically relevant once combined with functional measures (clinical outcome 5: progression of combined structure/function). Feedback on the proposed outcomes received in the meeting indicated general agreement, but with a high level of reservations, suggesting that further work is required to refine the suggested outcome measures. We propose an EGS working group to address this.

Workshop report

Background/introduction

According to the European Glaucoma Society (EGS) guidelines, “the goal of glaucoma treatment is to maintain the patient’s visual function and related quality of life, at a sustainable cost”. Achieving this goal requires actions at the levels of society, patients and clinical healthcare. With regard to the latter, we need to ensure that vision loss under care is minimal and that clinical interventions are safe. For this purpose, we need consensus on key outcome measures from the perspective of the clinician by which the healthcare system can be judged.

Objectives of the workshop

To achieve consensus on key clinical outcome measures in glaucoma which are relevant, measurable and practical. Also, to define methods of assessment and to suggest implementation plans for the EGS and national societies.

Processes used to achieve the objectives

The workshop took place during the EGS Members’ Meeting, 8-9 September 2017, in London, UK. The workshop consisted of three parts: 1) interactive polling with open questions, 2) group workshop and 3) interactive polling on selected outcomes.

1. Interactive polling with open questions

During the first part of the workshop, all attendees participated in an active poll using a web-based audience interaction tool (<https://www.sli.do>). The attendees were asked to provide their views on a number of open questions, including what would be the best definition for glaucoma, and which would be the most relevant, measurable and practical societal, patient and clinical outcomes. With regard to the clinical outcomes, the following question was asked: “What would you measure to demonstrate that the activity in your clinic is doing your patients any good?”

2. Group workshop

All attendees were assigned to 24 allocated tables in total (5-6 attendees per table). Among these, 6 tables were assigned to the topic of “Clinical outcomes”. The process of identifying key clinical measures consisted of the following steps:

- a) All participants in the clinical outcome group were asked to review the polling data and write in grid cards their top 2 clinical outcomes
- b) Participants at each table were asked to share their measures and synthesize their top 4 outcome measures
- c) The workshop facilitators clustered similar outcome measures from all the tables in the clinical outcome group in columns on a board
- d) Each person in the clinical outcome group was asked to ‘dot vote’ the 3 top outcome measures among those presented in the board.
- e) For the top 5 (most voted) clinical outcomes each table was asked to draft an implementation plan covering
 - How the clinical outcome should be measured
 - 2017, 2018 and 2020 milestones

A synthesis of all implementation plans was conducted and presented the following day by the group facilitators.

3) Interactive polling on selected outcomes

Following the group workshop, all attendees participated in a second active poll to provide their views on the clinical outcomes and the methods of measurements selected during the workshop. For each clinical outcome the

attendees had to choose among 'fully agree', 'agree with question or reservation' or 'disagree with question or reservation'. Questions, comments or reservations were also provided by the attendees as free text after each one of the above questions. This was followed by open discussion in the audience.

Summary of findings

1. Polling data on the open question

The open question "What would you measure to demonstrate that the activity in your clinic is doing your patients any good?" generated a large amount of responses. The ones which are most relevant to clinical outcomes can be grouped conceptually as follows:

Functional damage

- Visual acuity
- Binocular visual field
- Proportion of patients with visual impairment and blindness
- Proportion of patients meeting driving standards
- Proportion of patients having falls
- Contrast sensitivity
- Progression
 - Visual field index (VFI) at baseline and last visit
 - Rate of progression in the visual field
 - Level of visual field progression significant to patient
 - Proportion of patients with visual field stability or slow progression in the visual fields
 - Proportion of patients with progression to advanced glaucoma
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- Easier perimetry tests (which correlate better with quality of life)

Structural damage

- Optic disc changes
- OCT parameters
- Loss of neuroretinal rim/year

Intraocular pressure - related outcomes

- Intraocular pressure
- Percentage of patients achieving target IOP

Quality of life and patient experience

- Vision-related QoL
- Questionnaires on quality of care
- Patient reported outcomes
- Questionnaire exploring fear of blindness
- Rates of patient satisfaction
- Decreased need of follow-up visits

Treatment-related outcomes

- Side effects of treatment

- Unplanned visits due to side effects of treatment
- Compliance with treatment
- Satisfaction with treatment
- Cost/benefit of treatment

2. Key clinical outcomes and method of measurement (synthesis of data)

Clinical outcome	Selected by (groups)	Method of measurement
1. Visual Field Progression	6/6	<ul style="list-style-type: none"> • Mean deviation (HFA or Octopus) / Visual field index • Global indices trend analysis • Pointwise trend analysis • Regional visual field analysis
2. IOP control	5/6	<ul style="list-style-type: none"> • Reaching target IOP using applanation tonometry • More than 1 measurement
3. Quality of life	4/6	<ul style="list-style-type: none"> • Validated questionnaires • NEI VFQ 25 • EGS-QoL questionnaire
4. Treatment complications	3/6	<ul style="list-style-type: none"> • Surgical complications • Rate of reoperations • Permanent visual loss • Comfort • Function • Morphology
5. Progression of combined structure/function index	2/6	<ul style="list-style-type: none"> • Statistical significant reduction using validated software for imaging/visual field modalities • Ganglion cell/retinal nerve fibre layer loss/year + visual field pointwise loss

3. Polling data on the clinical outcomes and method of measurement

- Clinical Outcomes 1 - Visual Field Progression: Measuring this outcome: a) MD (HFA or Octopus) / VFI, b) Global indices trend analysis, c) Pointwise trend analysis d) Regional VF analysis
 - Fully agree 68%
 - Agree with question or reservation 27%
 - Disagree with question or reservation 5%
- Questions, comments or reservations:
 - Should consider both eyes
 - Using VF only or a combined function/structure criterion should depend on stage of glaucoma
 - Rate is less important than risk of blindness or loss of driving license
 - The interpretation of progression needs to be clinically relevant to patients

- Consensus needed on which techniques to use
 - Indirect and too difficult to measure
 - For simplicity, we should focus on global analysis
 - Must develop VFI for octopus
 - Measurement variability issues
 - Must standardise measurements
- Clinical Outcomes 2 - IOP control: Measuring this outcome: a) Reaching target IOP using applanation tonometry, b) More than 1 measurement
 - Fully agree 53%
 - Agree with question or reservation 34%
 - Disagree with question or reservation 13%
 - Questions, comments or reservations:
 - Why focus on IOP? The latter is not included in the definition of glaucoma
 - IOP target concept should be clearly defined by the EGS
 - Target IOP is difficult to define
 - Target IOP is not a validated concept
 - Target IOP should be defined on electronic medical record for each patient
 - We should not use only applanation tonometry
 - One should consider IOP fluctuations
 - Which IOP? Day, night, 4hour?
- Clinical Outcomes 3 - Quality of life: Measuring this outcome: a) Validated questionnaires, b) NEI VFQ 25, c) EGS-QoL questionnaire
 - Fully agree 54%
 - Agree with question or reservation 39%
 - Disagree with question or reservation 7%
 - Questions, comments or reservations:
 - Not practical for the real world setting
 - Due to cultural differences throughout Europe, such a questionnaire will be difficult to validate
 - There are a lot of confounders to consider
 - We need a longitudinal assessment of quality of care, which is not provided by these questionnaires
 - Requires Rasch analysis
- Clinical Outcomes 4 – Treatment complications: Measuring this outcome: a) Surgical complications, b) Rate of reoperations, c) Permanent visual loss, d) Comfort, e) Function, f) Morphology
 - Fully agree 30%
 - Agree with question or reservation 58%
 - Disagree with question or reservation 12%
 - Questions, comments or reservations:
 - Most patients are treated medically, not surgically
 - We need to adjust for covariates
 - Analysis should be done by type of procedure, type of glaucoma and patient associated risk factors
 - Not all complications are of same weight and severity

- Clinical Outcomes 5 - Progression of combined structure/function index: Measuring this outcome: a) Statistical significant reduction using Validated software for imaging/VF modalities, b) Ganglion cell/RNFL loss/year and VF pointwise loss
 - Fully agree 29%
 - Agree with question or reservation 49%
 - Disagree with question or reservation 22%
- Questions, comments or reservations:
 - Unrealistic for the near future
 - Too complicated
 - Too difficult to standardize
 - Problematic due to ever evolving imaging techniques
 - Problematic due to fact that there are various imaging techniques
 - Little relevance to our treatment goals for glaucoma
 - May be relevant only for early/moderate glaucoma

4. Implementation plans (synthesis of data)

Clinical outcome 1: Visual Field Progression

- 2018 milestones
 - Analyse current practices in Europe
 - Ensure availability of resources and visual field testing for every patient
 - Standardise data collection from automated perimetry
 - Define minimal logistic requirements
 - Implement visual field trend analysis
 - Aim for advances in visual field analysis
- 2019 milestones
 - Achieve European consensus on the definition of visual field progression
 - Develop tool for self-assessment of visual field (home perimetry)
 - Improve software and algorithm for visual field analysis (to allow automated extraction of data, cluster analysis etc)
- Next 5 years milestones
 - Implement the agreed definition of visual field progression in Europe
 - Spread self-assessment of visual field in clinical practice
 - Establish tele-monitoring and develop central repository of visual field data (to allow for analysis and feedback)
 - Integrate visual field measures with structural measures
 - Introduce objective perimetry or alternative to visual field testing

Clinical outcome 2: IOP control

- 2018 milestones
 - Develop task force on target-IOP
 - Develop tool for the calculation of target IOP
 - Develop self-tonometry
- 2019 milestones
 - Implement the recommendation of the task force in Europe
 - Implement self-tonometry in clinical practice
 - Develop method for continuous measurement of IOP
 - Develop tool for automated extraction of IOP data

- Achieve EMA approval for new therapies
- Next 5 years milestones
 - Validate concept of target-IOP
 - Spread self-tonometry in clinical practice
 - Develop central repository of IOP data
 - Incorporate ocular biomechanics in IOP measurements

Clinical outcome 3: Quality of life

- 2018 milestones
 - Develop and standardise a glaucoma specific questionnaire (EGS initiative)
 - Test quality of life annually in all patients
- 2019 milestones
 - Validate the glaucoma specific questionnaire
 - Develop automated tool for assessment of quality of life
- Next 5 years milestones
 - Annual self-assessment of quality of life
 - Develop algorithms for data analysis
 - Incorporate quality of life data in electronic patient records

Clinical outcome 4: Treatment complications

- 2018 milestones
 - Develop grading system for various side effects
 - Standardise definitions for vision loss and reoperation
 - Define 'acceptable' complication rates
- 2019 milestones
 - Validate the grading system
 - Develop tool for automated extraction of relevant data
 - Training of centres across Europe above the benchmark
- Next 5 years milestones
 - Implement strategies to minimise the risk of complications
 - Develop a central repository of data
 - Study outcomes/trends for complications

Clinical outcome 5: Progression of combined structure/function index

- 2018 milestones
 - Increase accuracy of OCT imaging and progression analysis with validation studies
 - Define the best strategy for combined assessment of structure and function
- 2019 milestones
 - Standardise the OCT modality and define criteria for progression
 - Validate the strategy for combined assessment of structure and function
- Next 5 years milestones
 - Define and standardise an index for structural progression
 - Develop other technologies

Recommendations for (1) refinement, (2) implementation

Feedback from in the plenary session on the proposed clinical outcome measures indicated general agreement, but a high level of reservations. This suggests that further work needs to be done to refine the proposed outcome measures. We suggest an EGS working group to address this.

The group highlighted the need for developing self-assessment tools, improving software algorithms for data analysis, standardising data collection and establishing central data repositories.