

Development of A Novel Decision Aid for Informed Decision-Making of Intraocular Lens Types in Patients Undergoing Cataract Surgery

Sabite Emine Gökce¹, Zaina Al-Mohtaseb²

¹ Dr. Abdurrahman Yurtaslan Oncology Research and Training Hospital, Department of Ophthalmology, Ankara, Turkey

² Baylor College of Medicine, Alkek Eye Center, Department of Ophthalmology, Houston, Texas

Abstract

Objective

Surgery is the main treatment of visual loss related to cataracts. There are multiple intraocular lens (IOL) options with certain advantages. Patient education on IOL types is necessary to achieve a successful shared decision making process and meet the expectations of the individual patient. Decision aids (DAs) are used for patient education and we developed a novel DA to assist patients during IOL type selection for their cataract surgery.

Methods

The Ottawa Personal Decision Guide and the 'Workbook on Developing and Evaluating Patient Decision Aids' were used in the development of this DA. General characteristics of cataracts, surgical treatment, and details including advantages and disadvantages of varying IOLs were included in the content of the DA. The DA was further evaluated by 3 physicians (Delphi assessment- International Patient Decision Aid Standards (IPDAS) Collaboration standards) and 25 patients (questionnaire of 6 questions with Five-point Likert scale).

Results

The DA was finalized with feedbacks from the experts. A total score of 50/54 was achieved in Delphi group assessment. Patient perception of the DA was favorable and patients also recommended its use by other patients.

Conclusions

This novel DA to assist IOL selection for cataract surgery was well accepted by the patients. There is a potential to improve patients' level of knowledge and diminish decisional conflicts. This potential can also increase patients' contribution on the shared decision making process. A further prospective randomized trial to compare with the standard patient informing process is also planned.

What is already known about this topic?

DAs have been used for patient education and for supporting the informed decision making process in many fields of medicine for over two decades. DAs improve the level of the patients' role in decision making process. Despite the prevalence of cataract surgery, currently the number of DAs reported to help cataract patients with their decision making process is scarce and they mainly focus on risk and benefits of undergoing cataract surgery.

What does this article add?

This article was designed to develop a novel DA focusing on IOL options for patients undergoing cataract surgery. Apart from other reported DAs for cataract surgery, our DA is unique to its content that it focuses on explaining pros and cons of the different types of IOLs. We believe that this DA will have a positive impact on patients' level of knowledge concerning different IOL options and will aid in patients' contribution towards a shared decision-making process.

Introduction

Cataracts are the most important cause of visual impairment and the leading cause of blindness worldwide [1, 2]. According to the National Eye Institute, the number of people in the U.S. with cataracts is expected to double from 24.4 million to about 50 million by 2050 [3]. Given its huge impact on quality of life and visual function, appropriate management of cataracts is vital. Cataract surgery is the main treatment of this condition and also the most commonly performed ophthalmologic procedure [4].

Patients today are increasingly interested in reducing their dependence on spectacles across a full range of vision after cataract surgery. Continued advances in intraocular lens (IOL) technology have resulted in various surgical options available for reducing corneal astigmatism and/or dependence on glasses for distance and reading. Patient satisfaction requires a personalized approach during cataract surgery planning and shared decision making between the surgeon and patient is essential for this process.

The practice of healthcare delivery has been largely changing to a more patient centered perspective which brings new attention to active collaboration and shared decision-making with patients. Shared decision making emphasizes patient autonomy, informed consent and patient empowerment. A decision aid (DA) is a tool to promote shared decision making and solve decisional conflict. DAs are designed for patient education on treatment alternatives and to assist the informed decision making process via improving the level of knowledge about the treatment options [5]. The International Patient Decision Aid Standards (IPDAS) Collaboration has developed criteria to judge the quality of DAs [6]. This includes a systematic development, provision of evidence-based information about treatment options and probabilities, clarification of patients' values, balanced presentation of options and using plain language. A Cochrane review of more than 80 studies shows that DAs have several benefits: better knowledge, more accurate risk and benefit perceptions, greater comfort with decisions and greater participation in decision making among patients [7].

Regarding the use of DAs in ophthalmology, the National Health Service has developed a DA for patients with cataract [8]. Shum et al. also developed an open-angle glaucoma DA for Chinese population. [9]. Recently, Zheng et al. published a DA focusing on the risks and benefits of undergoing cataract surgery [10]. In this present study we aim to develop a novel DA for educating patients on IOL options and assisting in the shared decision-making process in the surgical treatment of visually symptomatic cataract patients.

Materials and methods

The Ottawa Personal Decision Guide and the 'Workbook on Developing and Evaluating Patient Decision Aids' were used in the development of this DA [11,12]. The established DA was further evaluated according to the criteria of International Patient Decision Aid Standards (IPDAS) Collaboration, which is a multinational collaboration that developed the standards for DAs [6].

The content of the DA discussed:

1. General characteristics of cataracts and their surgical treatment
2. Details including advantages and disadvantages of varying IOLs

This DA is in the form of a booklet. Initially, it was evaluated by 3 different ophthalmologists experienced in cataract surgery and IOLs. They commented on the information provided by the DA and its structure and linguistic properties. The DA was further revised in accordance with this feedback.

Next, the DA was sent to three different ophthalmologists for the Delphi group assessment and was further evaluated with the guidance of the IPDAS instrument checklist. This checklist provides objective evaluation of a DA in three distinct parts:

content, process development, and overall effectiveness. Initial assessment was performed individually and final scores were established after evaluation as a group.

The last step was to get responses from the patients. For this purpose, the DA was provided to 25 patients with visually significant cataracts. All of these patients had an education level of at least elementary school and were able to read and write in the Turkish language. After reading the DA the patients were asked to complete a questionnaire. A Five-point Likert scale was used to answer these questions:

1. Was the amount of information sufficient?
2. Was the information provided clear?
3. Do you think this DA is useful?
4. Did this DA improve your knowledge?
5. Would you recommend this DA to others?
6. Can you score the design of this DA?

In addition to these questions, patients were also required to make suggestions for improvement of the DA. Further revisions based on this feedback was used to improve the understandability of the DA especially concerning the language content and medical terms used.

The final version of the DA consisted of three main parts. The first part began with the aim of the DA and provided brief general information about characteristics and surgical treatment of cataracts. The second part focused on the different types of IOLs including their advantages and disadvantages. The third part involved a summary graph of the IOL types and iconic explanation of near, intermediate and distance daily visual activities. The DA was presented as a supplemental file.

The results of the IPDAS instrument checklist and the patient questionnaires were all provided as descriptive data and no statistical analysis was performed.

Results

Three ophthalmologists initially evaluated the DA and revised its scientific information and linguistic structure. In the second step, the Delphi group assessment was performed and revealed favorable scores. For the first part (content scale), a score of 25/27, for the second part (development process) a score of 19/21, for the third part (effectiveness) a score of 6/6, and in total a score of 50/54 was established. The scores provided by each expert and the total scores are summarized in Table 1.

The results of the patient evaluation of the DA were as follows: The mean age of the patients was 66 ± 6.6 and 15 (60%) of the patients were male. Educational status showed that: 10 (40%) patients had an elementary school degree, 12 (48%) had a high school degree, and 3 (12%) patients had a college degree. For occupational status, 8 (32%) patients were employed, 13 (52%) patients were retired and 4 (16%) were housewives. The mean score for each question is summarized in Table 2.

Discussion

Shared decision making is a key component of patient-centered health care. Although the concept is not new, it is increasingly being implemented in today's health care systems. Shared decision making concept can be easily confused with the standard informed consent mode of patient-physician communication. It is well known that informed consents are critical to every field in medicine and they are necessary for invasive procedures to clarify the advantages and limitations of various treatment options. Shared decision making differs from informed consents in that a decision is informed by best evidence, not only about advantages and limitations of treatment options, but also patients' values and preferences. Indeed, in patient-centered healthcare, shared decision making should be considered as part of the informed consent process.

DAs are valuable tools for the proper education of the patient which is the first step to shared decision-making. With developments in IOL technology and risen expectations of patients for perfect outcomes, the DAs and proper patient education tools play a

larger role in ophthalmology. The number of medico-legal claims regarding ophthalmology has been increasing [13]. Doctors are deemed liable in 42% of medical litigations related to cataract surgery and more than half of these cases result from a violation of informed consent, which means that perioperative explanations related to surgery were not fully provided [14]. Providing patients with as much information as possible in both verbal and written form is the best defense against a patient's claim of being uninformed and underinformed. It is known that using DAs also increases satisfaction by helping patients feel more engaged in their healthcare decisions. Therefore, we believe that records of DAs are valuable tools for documentation of patient education and informed consent during preoperative cataract surgery planning. In this study, we developed a novel DA to help shared decision-making of patients concerning their selection of the IOL that will be implanted during cataract surgery.

DAs have been used for patient education and for supporting the informed decision making process in many fields of medicine for over two decades [15-17]. A Cochrane review about DAs was published in 2014 stating that DAs successfully improve patients' level of knowledge concerning treatment options and reduce the amount of decisional conflict related to feeling uninformed and unclear about their personal values. Also, DAs improve the level of the patients' role in the decision making process [7]. Despite the prevalence of cataract surgery, currently the number of DAs reported to help cataract patients with their decision making process is scarce [8,10]. Given the crowded health care system and the high patient workload of ophthalmologists, proper patient counseling may be difficult. Some patients may not be aware of the different IOL choices and expect clinicians to tell them what lens to use. Our DA can inform patients undergoing cataract surgery about the different IOL options and help them reach an informed choice.

Production of DAs requires a systematic process and has been published previously [5]. We developed a printed DA booklet because of its cost-effectiveness and availability in diverse eye clinic settings. Therefore, standardization of the patient informed process

can be achieved even in crowded eye care centers. We followed the recommended guide [12] to develop our DA and further evaluated the DA (Delphi group assessment) in accordance with the IPDAS criteria [6]. This evaluation provided a favorable result of a total score of 50/54. The patient evaluation stage also yielded great results since most of the patients recommended the DA to other patients that required cataract surgery. The visual graph was found to be helpful in explaining near, intermediate and far vision concepts. It might not be possible to adequately portrait the halo-glare side effects and visual performances of different IOL types in a printed booklet. Further studies involving virtual reality devices and simulator googles might provide better simulation of vision with different IOL types. Most patients felt that the information included in the booklet empowered their decisions and the length of the DA was ideal. Our DA is designed be used on patients who already decided on having their cataracts removed which helped us to mainly focus on IOL types and limit the length of the DA.

Zheng et al. recently developed a DA in the form of a booklet explaining the risks and benefits of cataract surgery for cataract patients[10]. Their DA was well received and appreciated by patients. As a continuation of their first article, the same group designed a randomized controlled study to determine the effectiveness of their DA and published their favorable results recently [18]. We also plan to design a prospective randomized comparison of our DA with the standard verbal patient informing process for the future.

Our DA is unique to its content that it focuses on explaining the pros and cons of the different types of IOLs. We discuss monofocals, multifocals, extended depth of focus (EDOF) and toric IOLs. We believe that selection of an IOL should be individualized to meet the visual expectations for each patient as related to their lifestyle. While clear near vision is important for an avid reader, intermediate vision may be mandatory for someone who works on a computer all day. In addition, financial issues and insurance policies also play a role in the IOL selection process. Preoperative patient counseling concerning out of pocket costs is necessary to avoid unhappy patients. Most importantly, the patient should make the ultimate choice of the IOL type.

Our DA is designed to be used in a diverse population of patients with different literacy levels. However, our preliminary results do not provide sufficient power to detect the recognition of the delivered information by the lower literacy group. Further clinical trials would help to determine if patients' decision of IOL type differ after the cataract surgery concerning their literacy status. Although the study population is small and the participants may not be representative of the general population; our study is strong in its design. Development of the DA followed the guidelines of international Patients Decision Aid Standards (IDPAS). Interaction with both ophthalmologists and patients enabled us to modify the DA to its current version. Twenty-five patients favorably perceived this DA and were willing to refer it to other patients. Our next step is to perform a prospective randomized trial to compare our DA with the standard verbal patient informed process with valid tools measuring the level of decisional conflict. We will directly compare increasing patients' level of knowledge and the level of decisional conflict by a previously defined decisional conflict scale [19].

Conclusion

This novel DA for patients undergoing cataract surgery, which was established through previously defined systematic steps, was well received by patients. We believe that this DA will have a positive impact on patients' level of knowledge concerning different IOL options and will aid in patients' contribution towards a shared decision-making process. A prospective randomized comparison with the standard verbal patient informing process is planned for the future.

Compliance with Ethical Standards: All of the investigations performed in this study are compliant with ethical standards and Declaration of Helsinki.

Funding: None

Ethical approval: All procedures performed in this study were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

References

1. Jonas JB, George R, Asokan R, Flaxman SR, Keeffe J, Leasher J, Naidoo K, Pesudovs K, Price H, Vijaya L *et al*: Prevalence and causes of vision loss in Central and South Asia: 1990-2010. *Br J Ophthalmol* 2014, 98(5):592-598. DOI: [10.1136/bjophthalmol-2013-303998](https://doi.org/10.1136/bjophthalmol-2013-303998)
2. Khairallah M, Kahloun R, Bourne R, Limburg H, Flaxman SR, Jonas JB, Keeffe J, Leasher J, Naidoo K, Pesudovs K *et al*: Number of People Blind or Visually Impaired by Cataract Worldwide and in World Regions, 1990 to 2010. *Invest Ophthalmol Vis Sci* 2015, 56(11):6762-6769. DOI: [10.1167/iovs.15-17201](https://doi.org/10.1167/iovs.15-17201)
3. National Eye Institute Cataract Data and Statistics. <http://www.nei.nih.gov>. Accessed 12 December 2020
4. Usmani B, Iftikhar M, Latif A, Shah SMA: Epidemiology of primary ophthalmic procedures performed in the United States. *Can J Ophthalmol* 2019, 54(6):727-734. DOI: [10.1016/j.cjco.2019.03.006](https://doi.org/10.1016/j.cjco.2019.03.006)
5. Elwyn G, O'Connor A, Stacey D, Volk R, Edwards A, Coulter A, Thomson R, Barratt A, Barry M, Bernstein S *et al*: Developing a quality criteria framework for patient decision aids: online international Delphi consensus process. *BMJ* 2006, 333(7565):417. DOI: [10.1136/bmj.38926.629329.AE](https://doi.org/10.1136/bmj.38926.629329.AE)
6. Holmes-Rovner M, Nelson WL, Pignone M, Elwyn G, Rovner DR, O'Connor AM, Coulter A, Correa-de-Araujo R: **Are patient decision aids the best way to improve clinical decision making? Report of the IPDAS Symposium**. *Med Decis Making* 2007, 27(5):599-608. DOI: [10.1177/0272989X07307272](https://doi.org/10.1177/0272989X07307272)
7. Stacey D, Legare F, Col NF, Bennett CL, Barry MJ, Eden KB, Holmes-Rovner M, Llewellyn-Thomas H, Lyddiatt A, Thomson R *et al*: **Decision aids for people facing health treatment or screening decisions**. *Cochrane Database Syst Rev* 2014(1):CD001431. DOI: [10.1002/14651858.CD001431.pub4](https://doi.org/10.1002/14651858.CD001431.pub4)
8. National Health Service Cataract Surgery Decision Aid. <https://bmjophth.bmj.com/content/bmjophth/2/1/e000100/DC2/embed/inline-supplementary-material-2.pdf?download=true> (Accessed 18 March 2021)
9. Shum JWH, Lam WWT, Choy BNK, Chan JCH, Ho WL, LAI JSM. Development and pilot-testing of patient decision aid for use among Chinese patients with primary open-angle glaucoma. *BMJ Open Ophthalmology* 2017;2:e000100. .doi:[10.1136/bmjophth-2017-000100](https://doi.org/10.1136/bmjophth-2017-000100)

10. Zheng Y, Qu B, Shi W, Wang C, Chen S, Zhong Y, He M, Liu Y: Development and preliminary evaluation of a decision aid to support informed choice among patients with age-related cataract. *Int Ophthalmol* 2020 Jun;40(6):1487-1499. DOI: [10.1007/s10792-020-01318-3](https://doi.org/10.1007/s10792-020-01318-3)
11. **Ottawa Personal Decision Guide.** Ottawa personal decision guide. <http://www.iri.ca/ceu/ohdec>. Accessed 19 September 2019 .
12. **Ottawa Health Decision Center.** Workbook on developing and evaluating patient decision aids. http://decisionaid.ohri.ca/docs/develop/Develop_DA.pdf. Accessed 19 September 2019.
13. Patrick W Commiskey JK, Ahmed Kashkoush, Nitin Agarwal, Arpan Vaikunth Prabhu, John Nguyen: **Medical Malpractice Claims Related to Ophthalmology: A WestLawNext Database Analysis.** In: *American Academy of Ophthalmology*. San Francisco; 2019.
14. Kwak JY, Choi KR, Jun RM, Han KE: **Medical Litigations Associated with Cataract Surgery in Korea.** *J Korean Med Sci* 2018, **33**(27):e180. DOI: [10.3346/jkms.2018.33.e180](https://doi.org/10.3346/jkms.2018.33.e180)
15. Gokce MI, Esen B, Sanci A, Akpınar C, Suer E, Gulpınar O: **A novel decision aid to support informed decision making process in patients with a symptomatic non-lower pole renal stone <20 mm in diameter.** *J Endourol* 2017; 31(7):725-728. DOI: [10.1089/end.2017.0077](https://doi.org/10.1089/end.2017.0077)
16. Gokce MI, Wang X, Frost J, Roberson P, Volk RJ, Brooks D, Canfield SE, Pettaway CA: **Informed decision making before prostate-specific antigen screening: Initial results using the American Cancer Society (ACS) Decision Aid (DA) among medically underserved men.** *Cancer* 2017 ;123(4):583-591 DOI: [10.1002/cncr.30367](https://doi.org/10.1002/cncr.30367)
17. Volk RJ, Hawley ST, Kneuper S, Holden EW, Stroud LA, Cooper CP, Berkowitz JM, Scholl LE, Saraykar SS, Pavlik VN: **Trials of decision aids for prostate cancer screening: a systematic review.** *Am J Prev Med* 2007, **33**(5):428-434. DOI: [10.1016/j.amepre.2007.07.030](https://doi.org/10.1016/j.amepre.2007.07.030)
- ____18. Ye G, Qu B, Tham YC, Zhong Y, Jin L, Lamoureux E, Congdon N, Zheng Y, Liu Y: **A decision aid to facilitate informed choices among cataract patients: A randomized controlled trial.** *Patient Educ Couns.* 2020 Nov 9:S0738-3991(20)30597-8. DOI: [10.1016/j.pec.2020.10.036](https://doi.org/10.1016/j.pec.2020.10.036).

19. O'Connor AM: **Validation of a decisional conflict scale.** *Med Decis Making* 1995, **15**(1):25-30. DOI: [10.1177/0272989X9501500105](https://doi.org/10.1177/0272989X9501500105)