Patient Preference and Adherence

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CLINICAL TRIAL REPORT

The Effect of a Patient Decision Aid Developed for Chinese Primary Angle Closure Patients: A Randomized Control Trial

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Purpose: Patient decision aid (PDA) can help inform appropriate selection of laser peripheral iridotomy for primary angle closure suspect (PACS) or primary angle closure (PAC). This study assesses the impact of a PDA on the decision-making process of patients diagnosed with PACS or PAC when evaluating LPI treatment options.

Patients and Methods: All participants were randomly assigned 1:1 to either the control group (n = 53), with an informed consent form, or to the intervention group with a PDA (n = 54). The primary outcome investigated was decisional conflict, which was assessed at baseline and again immediately following the intervention. The secondary outcomes included knowledge scores, patient satisfaction with their participation in the decision making, and decision regret.

Results: A total of 107 participants with PACS or PAC were involved in this study. The post-intervention decisional conflict score of the intervention group was lower than that of the control group, and the difference in their scores was statistically significant ($P < 0.001$). Patients in the intervention group scored higher on the knowledge questionnaire than those in the control group after the intervention, showing a statistically significant difference ($P < 0.001$). Furthermore, no statistically significant differences were identified in the scores between the groups for patient satisfaction with participation in medical decision making ($P = 0.721$) or in decision regret ($P = 0.104$).

Conclusion: In comparison to the control group, the application of the PDA enabled patients with PACS or PAC to be more informed, to experience reduced decisional conflict.

Keywords: patient decision aid, primary angle closure suspect, primary angle closure, laser peripheral iridotomy, decisional conflict

Introduction

Glaucoma is the foremost cause of irreversible blindness worldwide.[1] Primary angle-closure glaucoma (PACG) is a more aggressive form than primary open-angle glaucoma, with a higher likelihood of resulting in severe bilateral visual impairment.[2] The International Society of Geographical and Epidemiological Ophthalmology (ISGEO) has delineated the natural progression of PACG into three stages: primary angle closure suspect (PACS), primary angle closure (PAC), and PACG.[3] Medical intervention to prevent the onset of PACG is most efficacious during the PACS and PAC stages, prior to any structural or functional damage to the optic nerve.[4] As a result of the ongoing global aging trend, glaucoma cases are increasing annually. Projections estimate an excess of 110 million glaucoma cases worldwide by the year 2040, 30 million of these accounted for by PACG.[1] The highest prevalence of PACG is observed in Asia, which accounts for 77% of PACG cases worldwide.[1] Data from China indicate that approximately 13.12% of its rural population already

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exhibits the risky anatomical status of either PACS or PAC,[5] highlighting the importance of early stage diagnosis and prevention of PACG.

Laser peripheral iridotomy (LPI) is currently regarded as the primary treatment for angle closure and is the most effective clinical method of preventing this condition.[6] This procedure involves using a laser to make a hole in the iris, thereby relieving the pupillary block, improving aqueous humor circulation in the eye, and decelerating the progression of PACG.[6] Although LPI is a demonstrably safe intervention, it has limited efficacy in reducing the risk of PAC progression or an acute attack, with a reported reduction of only 47%.[7] In certain instances, treatment with LPI is ineffective in preventing the progression of disease in some patients,[8] thereby necessitating additional pharmacological and surgical interventions. Complications can arise with any treatment modality; in the case of LPI, these include iris bleeding, temporary elevation of intraocular pressure, and visual dysphotopsias.[7–9] Despite numerous national and international studies, the exact effectiveness of laser therapy in preventing PACG has not been established conclusively, resulting in uncertainty in the forecasting of patient outcomes by healthcare providers. Consequently, patients are faced with a decision-making dilemma regarding laser therapy, having to weigh the associated risks and potential benefits of either accepting or declining the treatment.

Despite the World Health Organization encouraging the involvement of patients in their own safety, annual trends from public hospitals indicate a large population base and an increasing number of ophthalmology patients, limiting the time available for healthcare providers to interact with patients.[10–12] This presents a challenge for patients to engage fully in making decisions regarding their own healthcare during brief outpatient visits. Therefore, healthcare professionals should consider the individual characteristics of patients in clinical settings,[4] to evaluate the risks, benefits and financial implications encountered by patients, and to assess fully the implications of laser surgery treatments based on patient preferences and values. Shared decision making, which represents a strategy for integrating patient preferences, values, and requirements, is a promising approach to achieving this goal.[13] Patients are also empowered to make an informed decision by receiving detailed treatment information from healthcare professionals, outlining the advantages and disadvantages of the available options.[13] While patient decision aids (PDAs) offer an efficient approach to implementing shared decision making, they are often systematic, evidence-based, and personalized,[14] representing a marked difference from conventional tools such as promotional brochures and health education. Furthermore, PDAs clarify the patient's decision-making preferences and focus on the consistency between personal values and decisions.[15] In scenarios in which there is no optimal treatment, or when the benefits and drawbacks differ between individuals, PDAs facilitate the patient's comprehension of treatment options through the use of unbiased and readily comprehensible language or visuals.[16] This enhanced understanding enables patients to accurately perceive the risks and benefits of treatment options, enhance their knowledge level, and consequently reduce decisional conflict during treatment while improving decision satisfaction and reducing post-decision regret.[15] By addressing patients' decision-making challenges within the limited consultation time available, this approach enables medical staff to fulfill their duties more effectively in busy work environments. Nevertheless, there is a paucity of research examining the use of PDAs for patients with PACS or PAC when facing the decision of LPI treatment that merits deeper investigation.

In order to address this gap in existing clinical research, a randomized controlled trial was conducted in a specialist ophthalmology hospital. The objective was to evaluate the efficacy of an evidence-based PDA[17] developed by our research team for patients with PACS or PAC in making informed decisions and reducing decisional conflict. This study also quantified the levels of patient satisfaction with their participation in medical decision making and the degree of regret experienced by patients in both the intervention and control groups. These results can provide further evidence regarding the efficacy of PDAs in ophthalmology and lend support to the implementation of such aids in future clinical practice.

Material and Methods

Study Design and Participants

A population-based and parallel-group randomized controlled trial was conducted in a ophthalmic specialist hospital, involving 107 participants recruited at a tertiary ophthalmic specialist hospital between March 2023 and

June 2024. All participants were randomly assigned 1:1 to either the control group or the intervention group. Participants were included in the study based on the following criteria: (1) participants aged ≥18 years; (2) participants diagnosed with PACS or PAC who meet ISGEO criteria3; (3) participants who do not wish to undergo cataract surgery. Participants were excluded from the study if they had: (1) serious complications such as cardio-cerebral, pulmonary, or renal disease; (2) cognitive impairments, severe mental disorders, or hearing impairments that could hinder their use of the PDA; (3) urgent need of other ophthalmic treatments (such as severe vitreoretinopathy, ocular trauma).

The trial was conducted in accordance with the Declaration of Helsinki, approved by the ethics committee of of the Eye Hospital of Wenzhou Medical University (number: 2022–050-K-35-03) and registered on Chinese Clinical Trial Registry (number: ChiCTR2300077589). The trial was reported in accordance with the Consolidated Standards of Reporting Trials (CONSORT) statement, and written informed consent was obtained from all participants prior to enrollment.

Demographic data was gathered from the participants with a general questionnaire, including their age, gender, educational level, job status, place of residence, payment method of medical expenses, and family history of glaucoma. The participants' clinical information was obtained using the electronic medical record system, including data on intraocular pressure and anterior chamber depth in both eyes. Participants were also asked about their preference regarding consultation with their physicians before making decisions about clinical treatment options.

Randomization and Masking

A researcher not involved in this study created a table of random numbers using the 'RANDBETWEEN' function in Microsoft Excel. Another researcher used this random number table to provide opaque numbered sealed letters to the principal researcher, which were used to enclose cards marked as 1 (intervention group) or 2 (control group). Blinding procedures for participants were not implemented in this study, based on the principle of informed consent.

Interventions

The participants were evaluated in consulting rooms by a glaucoma team consisting of physicians who had undergone uniform training. The participants were examined by physicians to determine whether they exhibited characteristics consistent with PACS or PAC. Thereafter, the physicians discussed the condition with the patients and informed them about the risks associated with PACG. After obtaining informed consent, the physician referred the participants to the primary researcher. The participants were then sent to a quiet consulting room for further communication. A paper-based PDA,[17] developed by the research team and based on the Ottawa Decision Support Framework (ODSF)[18] and International Patient Decision Aid Standards (IPDAS),[19] was utilized by the participants in the intervention group (Supplementary Figure 1). This PDA has undergone preliminary evaluation and is comprised of the following seven components: (1) clarification of the decision; (2) assessment of decision needs; (3) provision of information; (4) risk-benefit analysis; (5) clarification of value; (6) decision-making guidance; (7) confirmation of the decision. In the control group, participants were provided with a standardized informed consent form for LPI, which is employed routinely in clinical practice. The form contained general information regarding surgical treatment, potential associated complications, post-operative follow-up recommendations, and protocols for managing surgical failure. The PDA employed in this study differed significantly from the preoperative informed consent form, with an emphasis not only on providing information about the disease and its treatment but also identifying the decision-making needs of participants via a methodical step-by-step approach. It supported patients in evaluating the risks and benefits associated with accepting or refusing LPI, clarified the importance of individual values and preferences, and ultimately aided the patient in finalizing their decision. Moreover, given the substantial number of middle-aged and elderly participants included in this study, the sections concerning the efficacy of LPI treatment and the rate of the progression of the disease were presented in graphical form. The PDA (or preoperative informed consent form) was provided to the patients in a uniform and standardized explanation.

Primary Outcome

The primary outcome assessed was the patient decisional conflict regarding LPI treatment, based on the Decisional Conflict Scale (DCS).[20] Prior to, and directly following, the intervention, participants completed the evaluation in person under the guidance of the researcher in a quiet consulting room. The 16-item DCS, in statement format, was based on a 5-point Likert scale measurement, covering five dimensions (uncertainty, information, clarity of values, support, and effective decision), and was employed to assess the degree of uncertainty experienced by participants when confronted with the available treatment options in this study.[21,22] Each item was scored from 0 (strongly agree) to 4 (strongly disagree). Scores below 25 were associated with the implementation of decisions, and scores above 37.5 indicated delayed decision making.[23] The total score was calculated by multiplying the mean score of the item by 25, resulting in a range from 0 to 100, with higher scores indicating higher levels of decisional conflict (Cronbach's alpha: 0.963).[23]

Secondary Outcomes

The secondary outcomes of the assessment included scores regarding the patients' knowledge, satisfaction with their participation in medical decision-making, and the degree of decision regret. The Knowledge Questionnaire, comprising 12 true-or-false questions, was devised by the research team based on the content of the PDA. The total score ranged from 0 to 12, with higher scores indicating greater knowledge. It was assessed by conducting face-to-face assessments with the participants, both before and immediately after the intervention. The 16-item Patients Satisfaction with Participation in Medical Decision Making Scale covered four dimensions (information, deliberation, decision, and global satisfaction and confidence). Each item was rated on a 5-point Likert scale, ranging from 1 (strongly disagree) to 5 (strongly agree).[24] The standardized item scores were calculated by subtracting the raw scores from 1 and then multiplying the result by 25, covering a range from 0 to 100, with higher scores indicating greater patient satisfaction (Cronbach's alpha: 0.899). This score was obtained during a follow-up visit via a telephone call, which occurred seven days following the patient's clinical visit. The Decision Regret Scale was utilized to assess the level of regret among patients regarding health-related decisions.[25] Five items were assessed on a 5-point Likert scale, with each item ranging from 1 (strongly agree) to 5 (strongly disagree). Items 2 and 4 were reverse scored, and the total score ranged from 0 to 20, with higher scores indicating greater levels of regret (Cronbach's alpha: 0.826).[26] This data was also gathered during a telephone follow-up, occurring either one month after the patient's visit to the clinic or one month after the completion of LPI treatment. Participants were also asked during this call whether they had experienced any ocular discomfort. The collection timepoints for each scale were shown in Table 1.

Sample Size Determination

The findings of the randomized controlled trial, entitled "The Impact of Patient Decision Aids Developed for Chinese Primary Open-Angle Glaucoma Patients", revealed that the decisional conflict score of the intervention group following

Table 1 Data Collection Timepoints

Measures		**Intervention Group**	**Control Group**
Location		Eye Hospital of Wenzhou Medical University	
Format		Laser Therapy Patient Decision Aid for Patients with Primary Angle Closure	Informed Consent Form for Laser Peripheral Iridotomy
Time points	T0 (Baseline): Day of visit T0′ (Post-intervention): Day of visit T1: 1 week after visit T2: 1 month after visit /1 month after laser surgery	Face-to-face collection of patient baseline data (demographic and clinical data, DCS, and knowledge questionnaire). Face-to-face collection of DCS and knowledge questionnaire. Telephone follow-up survey on Patients Satisfaction with Participation in Medical Decision Making Scale. Telephone follow-up survey on Decision Regret Scale.	

the intervention was (25.6 ± 13.3), while that of the control group was (37.4 ± 17.5).[27] Based on these findings, the present study was conducted using PASS 15. The alternative hypothesis was set as two-sided, with $\alpha = 0.05$. The power was set at 0.9, with the group allocation designated as equal (N1 = N2), and the input type was designated as the mean values. The means $\mu 1$ and $\mu 2$ were 25.6 and 37.4, respectively, while the standard deviations $\sigma 1$ and $\sigma 2$ were set to 13.3 and 17.5, respectively. The calculated sample size was N1 = N2 = 38, for a total of 76 cases. Considering the 20% rate of loss to follow-up, a final sample size of 96 cases was set, with a total of 107 patients ultimately enrolled in this study.

Statistical Analyses

SPSS 25.0 software was used for data analysis in this study. The normal distribution variables provided were the mean and standard deviation in the measurement data, while those of the skewed distribution were the median and interquartile range. Count data were shown as a frequency and a percentage. Chi-square test, Fisher's exact test, Two-sample *t*-test and Mann–Whitney *U*-test were used to analyze the baseline data, post-intervention knowledge, post-intervention DCS, patient satisfaction with participation in medical decision making, and decision regret in the intervention and control groups. Paired sample *t*-test and Wilcoxon signed-rank test were used to compare pre- and post-intervention decisional conflict and knowledge scores within the intervention group and control group. Spearman rank correlation was conducted on all post-intervention scales. The level of statistical significance was set at $P < 0.05$.

Results

Study Flow and Patient Characteristics

A total of 142 patients were recruited in the study between March 2023 and June 2024. Of these, 21 either declined to participate at the time of initial contact or asserted that they could not be reached in a timely manner. Six patients were excluded from the study based on findings from further ophthalmological examinations that were inconsistent with the inclusion criteria. Four patients were unable to attend the subsequent follow-up visits. A further 4 patients withdrew from the trial prior to randomization. The remaining 107 patients who had met the eligibility criteria and provided written informed consent were randomly assigned to either the intervention group (n=54) or the control group (n=53) at a ratio of 1:1 (Figure 1). The two groups of participants exhibited comparable baseline characteristics. The majority of patients (55%) had completed at least junior high school. Furthermore, more than 75% of participants in both groups were covered by health insurance. Despite these factors, most participants were responsible for the majority of the costs associated with the LPI treatment. Moreover, over 55% of patients in both groups indicated a preference for discussing the options available with their physicians before making decisions regarding medical intervention (Table 2).

At the time of the follow-up study, 8 patients (7.5%, comprising 3 from the intervention group and 5 from the control group) did not complete all the questions. Four (3.7%) of these declined to answer, 3 patients (2.8%) were unable to undergo the follow-up procedure, likely due to their underlying disease, and 1 patient (0.9%) underwent alternative surgical treatments due to a rapid disease progression during the waiting period for the LPI treatment. The remaining 99 patients completed the follow-up portion of the study, comprising 51 individuals in the intervention group and 48 in the control group. No statistically significant difference was found between the patients who withdrew from the study at random and the remaining patients (Supplementary Table 1).

Primary Outcome

The primary outcome was assessed for both groups. Following the intervention, the DCS score in the intervention group decreased to (24.68 ± 7.92) from (49.25 ± 11.10) in the pre-intervention period, representing a statistically significant difference ($t = 21.48$, $P < 0.001$). This score was lower than that of the control group, and the difference in the post-intervention DCS scores of the two groups was statistically significant ($t = -4.30$, $P < 0.001$) (Table 3). The distribution of DCS scores showed that 31 patients (57.4%) in the intervention group achieved scores lower than 25, compared to 12 patients (22.6%) in the control group. The difference in DCS score distribution between the two groups was statistically significant ($\chi^2 = 13.624$, $P = 0.001$) (Table 4).

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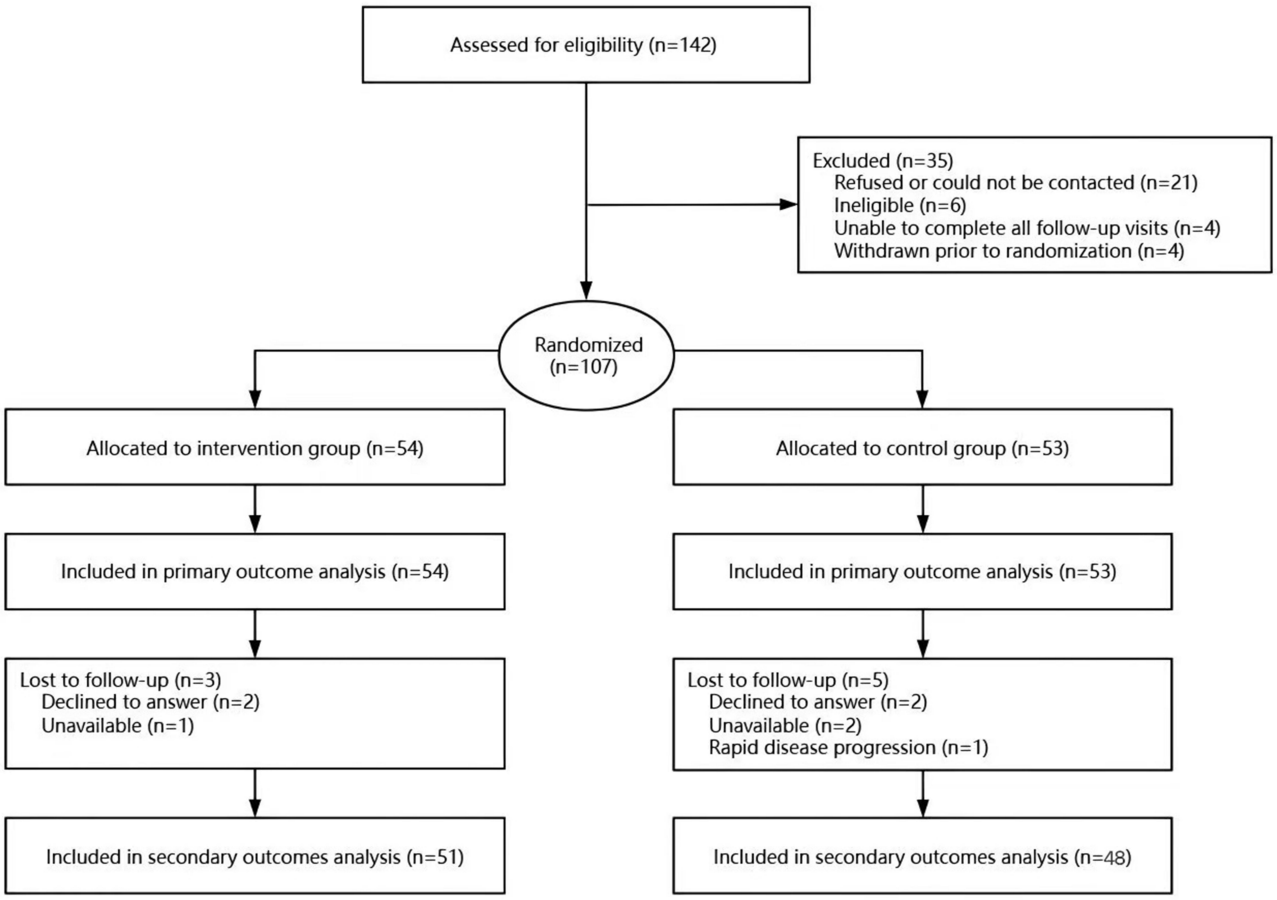

Figure 1 Flow chart.

Secondary Outcomes

The post-intervention score on the knowledge questionnaire was higher for patients in the intervention group than in the control group, showing a statistically significant difference (8 (4) vs 4 (2), 95% CI 3.00 (3.00–4.00), $P < 0.001$). No statistically significant difference was observed between the groups in the post-intervention scores on the Patients Satisfaction with Participation in Medical Decision-Making scale (95.83 (16.04) vs 94.53 (10.55), 95% CI 0.21 (−1.88–2.50), $P = 0.721$). There was also no statistically significant difference in decision regret between the two groups (4 (4) vs 4 (2), 95% CI −1.00 (−2.00–0.00), $P = 0.104$). Item 3 ("I would make the same choice if I had to do it again") revealed a statistically significant difference between the groups (2.00 (1.00) vs 2.00 (1.00), 95% CI 0.00 (−1.00–0.00), $P = 0.045$) (Table 5). Furthermore, five patients in each group reported ocular discomfort. Given the similarity of the results of item 3 between the two groups, the specific percentages of the population are presented (Supplementary Table 2).

Correlations

The correlation analyses indicated negative correlations between decisional conflict and knowledge level ($r = -0.399$, $P < 0.001$) and between decisional conflict and patients satisfaction with participation in medical decision-making ($r = -0.203$, $P = 0.044$) (Table 6).

Discussion

The exceptionally high level of decisional conflict among patients in this study at baseline reinforces the importance of conducting this research program. The knowledge of the patients was improved by using the PDA, and a reduced level of

Table 2 Descriptive Statistics of Patient Demographics and Clinical Characteristics by Study Group (n=107)

Measures	Intervention (n=54)	Control (n=53)	*P*
Age (year), mean (SD)	53.65 (10.24)	55.13 (6.99)	0.383
Gender, n (%)			0.541
Male	6 (11.1)	8 (15.1)	
Female	48 (88.9)	45 (84.9)	
Education level, n (%)			0.732
Primary school or below	22 (40.7)	23 (43.4)	
Junior high school	14 (25.9)	16 (30.2)	
High school/Technical secondary school	9 (16.7)	5 (9.4)	
Junior college/bachelor's degree or above	9 (16.7)	9 (17.0)	
Job status, n (%)			0.370
Not working currently#	25 (46.3)	20 (37.7)	
Working	29 (53.7)	33 (62.3)	
Place of residence, n (%)			0.603
Urban area	32 (59.3)	34 (64.2)	
Rural area	22 (40.7)	19 (35.8)	
Payment method of medical expenses, n (%)			0.263
Medicare	29 (53.7)	31 (58.5)	
Rural insurance	17 (31.5)	10 (18.9)	
Self-pay	8 (14.8)	12 (22.6)	
Family history of glaucoma, n (%)			0.063
No	45 (83.3)	36 (67.9)	
Yes	9 (16.7)	17 (32.1)	
Whether want to discuss treatment options with physicians, n (%)			0.384
No	19 (35.2)	23 (43.4)	
Yes	35 (64.8)	30 (56.6)	
Intraocular pressure in the right eye (mmHg), median (IQR)	14.8 (4.2)	15.7 (3.5)	0.497
Intraocular pressure in the left eye (mmHg), median (IQR)	14.9 (3.4)	15.4 (3.7)	0.945
Anterior chamber depth in the right eye (mm), mean (SD)	2.149 (0.235)	2.157 (0.230)	0.921
Anterior chamber depth in the left eye (mm), mean (SD)	2.148 (0.227)	2.150 (0.245)	0.928

Notes. #: Not employed, on-leave, leave without salary, or housewife.
Abbreviations: SD, standard deviation; IQR, interquartile range.

Table 3 Comparison of DCS Scores Between the Two Groups of Patients Before and After the Intervention (n=107)

Measures	Pre-Intervention (Mean±SD)	Post-Intervention (Mean±SD)	t-Test	
			t	*P*
Intervention group (n=54)	49.25±11.10	24.68±7.92	21.483	<0.001
Control group (n=53)	46.31±9.01	31.13±7.59	15.707	<0.001
t	1.499	−4.300		
P	0.137	<0.001		

Table 4 The Distribution of DCS Scores for Two Groups (n=107)

Scores	Intervention (n=54)	Control (n=53)	χ^2	*P*
<25	31 (57.4)	12 (22.6)	13.624	0.001
≥25 and ≤37.5	19 (35.2)	32 (60.4)		
>37.5	4 (7.4)	9 (17.0)		

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Table 5 Comparison of Secondary Outcomes Between the Two Groups (n=99)

Measures	Intervention (n=51) Median (IQR)	Control (n=48) Median (IQR)	Estimated difference* (95% CI)	z	*P*
Knowledge questionnaire (baseline)	0.00 (1.00)	0.00 (1.00)	0.00 (0.00–0.00)	−1.328	0.184
Knowledge questionnaire (post-intervention)	8.00 (4.00)	4.00 (2.00)	3.00 (3.00–4.00)	−5.775	<0.001
Patients satisfaction with participation in medical decision-making	95.83 (16.04)	94.53 (10.55)	0.21 (−1.88–2.50)	−0.358	0.721
Information	93.75 (18.75)	100 (18.75)	0.00 (0.00–0.00)	−0.506	0.613
Deliberation	100.00 (18.75)	100 (10.94)	0.00 (0.00–0.00)	−0.266	0.790
Decision	91.67 (25.00)	91.67 (22.92)	0.00 (−0.00–8.33)	−0.069	0.945
Global satisfaction and confidence	95.00 (20.00)	95.00 (13.75)	0.00 (0.00–0.00)	−0.292	0.770
Decision regret	4.00 (4.00)	4.00 (2.00)	−1.00 (−2.00–0.00)	−1.624	0.104
Item1	2.00 (1.00)	2.00 (0.00)	0.00 (0.00–0.00)	−1.729	0.084
Item2	2.00 (1.00)	2.00 (0.00)	0.00 (0.00–0.00)	−1.436	0.151
Item3	2.00 (1.00)	2.00 (1.00)	0.00 (−1.00–0.00)	−2.006	0.045
Item4	1.00 (1.00)	1.00 (1.00)	0.00 (0.00–0.00)	−0.606	0.545
Item5	2.00 (1.00)	2.00 (0.00)	0.00 (0.00–0.00)	−0.802	0.423

Note. *: Hodges-Lehmann estimation; In the absence of follow-up data, 8 cases were excluded from the analysis, comprising 6 cases for the knowledge questionnaire and 2 cases for decision regret.

Table 6 Correlation Analysis of Post-Intervention DCS with Post-Intervention Knowledge, Patients Satisfaction with Participation in Medical Decision-Making and Decision Regret (n=99)

Measures	*r*	*P*
Knowledge	−0.399	<0.001
Patients satisfaction with participation in medical decision-making	−0.203	0.044
Decision regret	0.099	0.330

decisional conflict was also exhibited. However, the impact on patient satisfaction with participation in medical decision-making and decision regret was not statistically significant. Furthermore, patient knowledge and decision-making satisfaction were found to be negatively correlated with decisional conflict. Thus, the implementation of the PDA has the potential to bridge the gap in communication between physicians and patients, leading to an improvement in the quality of healthcare services. This could prove beneficial to all parties involved, including patients, healthcare providers, and the healthcare system as a whole. Ultimately, this can contribute to the realization of patient-centered healthcare.

Enabling patients to make decisions that are in line with their individual preferences is a common goal towards which healthcare providers are currently working. Our study demonstrated that the PDA intervention significantly reduced decisional conflict among patients considering LPI treatment, with 57.4% of intervention group patients achieving clinically meaningful low decisional conflict (DCS < 25) compared to only 22.6% in the control group. This approximately 25-point reduction in DCS represents a substantially greater improvement than reported in previous long-term follow-up studies,[27,28] achieved within a relatively brief intervention timeframe. The substantial reduction in decisional conflict may be attributed to the binary nature of the treatment decision faced by PACS and PAC patients—whether or not to undergo prophylactic LPI. Unlike patients with diagnosed or end-stage disease who must choose among multiple treatment alternatives under time pressure and heightened psychological vulnerability,[29] our patients dealt with a direct and preventive decision (treat or not treat). The PDA was particularly effective in this context because it could comprehensively address the core uncertainty of a binary choice, systematically presenting the single intervention option versus no treatment, enabling more substantial conflict reduction than typically achieved in studies involving complex multi-alternative treatment decisions. Additionally, it is noteworthy that almost half of the remaining patients with relatively high levels of decisional conflict had a low level of education, indicating that the decline in DCS may be associated with educational attainment.[30] This finding suggests that while PDAs are effective tools for shared decision-making, their impact may be enhanced through targeted educational interventions. For assisting patients with a limited

educational background, healthcare professionals could benefit from prior decision-making training, including repetitive exercises and feedback virtual patient simulations.[31] Furthermore, PDAs are currently employed primarily in the diagnostic phase of disease, with minimal application to decision making in the context of preventive health programs. A promising future avenue of research could be to focus on this area.

Providing patients with information about their disease and treatment is both a prerequisite for informed decision making and an important aspect of protecting the rights of patients. At the outset of the study, patients exhibited significant misunderstandings regarding the inevitability of the progression of the disease and the necessity of LPI treatment. Considerable deficiencies in patient knowledge were observed at the baseline. The results of this study demonstrate that the use of the PDA led to a significant improvement in the knowledge base of the patients, accompanied by a correction of their previous misconceptions. The most recent synthesis of the 209 randomized controlled trials published on Cochrane reached the same conclusion: PDAs can facilitate improvements in patient knowledge and enhance the capacity to perceive risk accurately.[15] Furthermore, the findings of this study indicated that there was a negative correlation between knowledge and decisional conflict; an increase in patient knowledge was accompanied by a reduction in decisional conflict. This further highlights the significance of ensuring that patients have access to sufficient information,[32,33] as it enables them to make well-informed decisions that align with their personal values and preferences. A recommendation suggested by this study is for governments, medical and healthcare institutions, as well as science popularization bases and similar organizations, to consider the widespread dissemination of scientific knowledge on the prevention and treatment of PACG. Advanced decision-making simulation systems could also be integrated with electronic medical records systems. Transparent and comprehensive messaging can enable patients to gain earlier access to more detailed information, which could facilitate a more nuanced understanding of the information presented by their healthcare providers.

In this study, the models of shared decision making and informed consent were employed. However, there were no differences in decision satisfaction and regret between the two groups, a finding that warrants explanation. The majority of patients previously diagnosed with chronic eye disease expressed a desire to be involved in decisions regarding their medical care.[34,35] Nevertheless, traditional paternalistic decision making tends to be a dominant factor in time-sensitive situations or in the absence of viable treatment alternatives, often preventing the full involvement of patients in the decision-making process.[36] Despite these potential barriers to patient involvement, both groups demonstrated high satisfaction level, creating a ceiling effect. This can be attributed to the fact that patients typically demonstrate high levels of trust in and acceptance of physician recommendations, a Chinese cultural characteristic that predisposes patients to exhibit over-reliance on physicians. When lacking comprehensive knowledge about medical conditions and treatments, patients commonly perceive authoritative medical recommendations as the optimal decisions, leading them to express high satisfaction with medical decisions regardless of whether they experience conflict during the decision-making process. Consequently, there was no statistically significant difference in decision satisfaction between the two groups. Additionally, the lack of significant differences in decision regret may relate to the sample characteristics and follow-up duration.[37,38] For lifelong conditions such as PACS or PAC, the progression rate following LPI treatment is 0% to 0.3% per year (PAC 0–4%).[8] Only five patients (5.1%) in each group experienced ocular discomfort, including disease progression or short-term complications. Given the low complication rates and relatively short follow-up period, most patients had not experienced negative outcomes that typically trigger regret. Decision regret usually emerges with adverse consequences or poor long-term outcomes, which were infrequent within our study timeframe and will require evaluation in long-term follow-up studies. Furthermore, patients who utilized the PDA exhibited heightened confidence in making the same choice again. Collectively, these results emphasize the importance of patient involvement in healthcare decision making, not merely as an entitlement of the patient, but also as a crucial assurance of patient security. Medical professionals are responsible for the promotion of the shared decision-making model, the cultivation of effective communication channels, the facilitation of patient involvement in the decision-making process, and the support of patients in making well-informed decisions. The probability of patients experiencing regret can thereby be diminished, even in the presence of symptoms or disease progression.

The strengths of this study can be enumerated as follows: firstly, the PDA for PACS or PAC patients was developed by a team of experts with a scientific approach in strict adherence to the ODSF and in accordance with the IPDAS,

enabling its implementation in other hospitals. Secondly, the trial was randomized and controlled, with comparable baseline characteristics of the two groups of patients and a low rate of loss to follow-up. However, the findings of this study may be limited in their generalizability, as the study was conducted in a single hospital. Expanding the study to cover multiple centers would provide a more reliable result. Furthermore, the PDA employed in this study was in the form of a booklet, which may not be the optimal format to all patients, particularly those with limited education. The adaptation of the PDA into a variety of formats, including audio, video, software, and web pages, may prove beneficial in enhancing its usability for patients.

Conclusions

This is the inaugural randomized controlled trial in China of the implementation of a PDA for patients with PACS or PAC. The results demonstrated that the usage of the PDA resulted in enhanced patient knowledge, empowered patients to make well-informed decisions, and reduced their decisional conflict regarding the treatment. While neither a significant increase in patient satisfaction with participation in medical decision-making, nor a significant decrease in regret about their decisions due to the use of the PDA was observed, the overall effect nevertheless demonstrates the effectiveness of the PDA in this setting. This provides valuable insight for future optimization and dissemination of similar PDAs, which are anticipated to play a pivotal role in clinical practice, supporting patients in making optimal healthcare decisions.

Abbreviations

PDA, patient decision aid; PACS, primary angle closure suspect; PAC, primary angle closure; PACG, primary angle-closure glaucoma; DCS, Decisional Conflict Scale; ISGEO, International Society of Geographical and Epidemiological Ophthalmology; ODSF, Ottawa Decision Support Framework; IPDAS, International Patient Decision Aid Standards.

Data Sharing Statement

The datasets used and analyzed during the current study are available from the corresponding author Yanyan Chen on reasonable request.

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Author Contributions

All authors made a significant contribution to the work reported, whether that is in the conception, study design, execution, acquisition of data, analysis and interpretation, or in all these areas; took part in drafting, revising or critically reviewing the article; gave final approval of the version to be published; have agreed on the journal to which the article has been submitted; and agree to be accountable for all aspects of the work.

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Disclosure

The authors report no conflicts of interest in this work.

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