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Taurine Could Affect the Progression of Age-related Cataract: A Single-arm Pre-post Intervention Study

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ABSTRACT

Background: Oxidative stress is the principal contributor to the pathogenesis and progression of age-related cataract (ARC), the most prevalent type of cataract.
Objectives: The current study was designed to evaluate the therapeutic potential of taurine to prevent the progression of the nuclear subtype of ARC.
Materials and methods: In total, 61 participants, 115 eyes with the grade I or II nuclear subtype of ARC, were included in this single-arm, open-label, pre-post intervention clinical trial. Participants were instructed to apply taurine-containing eye drops four times a day for one year. Ophthalmological examinations, including best corrected visual acuity (BCVA), were performed at the baseline visit and subsequent follow-up visits at 3-month intervals for one year. The trial was registered at https://clinicaltrials.gov/study/NCT06639711.
Results: The study cohort comprised 15 males (24.6%) and 46 females (75.4%). The median age of the participants was 62 years (IQRs 58-68). At the baseline visit, the mean logMAR BCVA was 0.2 ± 0.19. In this study, BCVA was stable throughout the study (Wald Chi-square = 1.254, P-value = 0.534). Additionally, age and female sex were found to have significant deteriorating effects on BCVA (P-value < 0.001 and P-value = 0.028, respectively).
Conclusion: This interventional study demonstrated that taurine-containing eye drops can serve as an effective therapeutic option to prevent further deterioration of BCVA and potentially inhibit the progression of nuclear ARC. In addition, age and sex were key factors that influenced the progression of ARC. Further studies incorporating randomized controlled designs, extended follow-up, and multiple centers are recommended.
Keywords: Age-related Cataract; Nuclear; Best-corrected visual acuity; Progression; Taurine.

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INTRODUCTION

Cataracts can significantly affect human quality of life. Cataracts are the leading cause of reversible blindness worldwide. In developing countries, particularly those with high levels of ultraviolet radiation, such as Iraq, the prevalence of cataracts in the visually impaired population approaches 2% [1]. This could impose a high burden on healthcare systems. Indeed, the waiting list for cataract surgery, the gold standard for cataract treatment in Iraqi hospitals, is very long [2].

The human eye lens is naturally transparent. The transparency of the lens is maintained by highly arranged crystallin proteins [3]. Age-related factors are major predisposing factors for lens opacity and, hence, cataracts. Other risk factors include diabetes, ultraviolet radiation, trace element deficiency, and smoking [4]. Age-related cataract (ARC), also called senile cataract, is the most predominant type of cataract and its prevalence increases with age [5].

As mentioned earlier, surgery is the most effective treatment option for cataract. However, in developing countries, people may avoid cataract surgery due to social and cultural factors, economic status, or fear of surgery and its outcomes [6]. Pharmacological strategies to prevent the progression of

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ARC, particularly antioxidants, have been the focus of research over the past few decades [4]. It should be noted that oxidative stress plays a central role in the pathogenesis of ARC [7]. Grey *et al.* [8] demonstrated that there is a region-specific and aging-related decrease in the distribution of the essential antioxidant glutathione in the human eye lens, where the nuclear region always has lower concentrations than the cortical region. Therefore, the nuclear region is vulnerable to oxidative stress [9]. In light of this, it was estimated that the nuclear subtype of ARC has a higher (42%) one-year opacity progression rate than the cortical (32%) and posterior subcapsular (10%) subtypes [10].

Among the multiple antioxidants that have been extensively investigated to inhibit the ARC progression, taurine, an amino acid that is naturally abundant in the lenticular structure, has been suggested to decrease the progression of cataracts *in vitro* [11] and *in vivo* [12]. In 1981, a clinical trial by Vodovozov and Glotova [13] revealed that taurine instillation in 50 ARC participants significantly improved their visual acuity and prevented cataract progression. However, these results have not been verified by additional clinical trials or implemented as an approved treatment option to prevent ARC progression. Therefore, the aim of the current interventional study was to determine the effectiveness of taurine-containing eye drops as a preventive strategy for ARC progression, particularly the nuclear subtype.

MATERIALS AND METHODS

Study design

The current study was designed as a single-arm, open-label, pre-post, intervention clinical trial to evaluate the potential therapeutic effect of taurine-containing eye drops in preventing the progression of the nuclear subtype of ARC. The study was conducted in accordance with the principles of the Declaration of Helsinki and the guidelines for good clinical practice. Ethical approval was obtained from the Ethical Approval Committee of the University of Anbar (Ref: 170). Furthermore, this intervention study was registered at https://clinicaltrials.gov/study/NCT06639711.

Patients and intervention

Participants with grade I or II nuclear ARC subtypes were recruited from July 10, 2023, to November 1, 2023, at Al-Nahrain Eye Clinics, Ramadi, Iraq. Informed consent was obtained from all the participants.

The recruited participants underwent detailed ophthalmological examination. This included the assessment of visual acuity and best-corrected visual acuity (BCVA) using the Snellen chart, objective and subjective refraction, and intra ocular pressure (IOP) using a tonometer (iCare IC100, Icare, Finland). In addition, slit-lamp examination of the anterior segment of the eye and dilated fundoscopy with volk lens wide field following the application of tropicamide 1% were performed by an ophthalmologist to determine the degree of opacification in eye lenses based on lens opacity classification system II (LOCS II).

Patients with ARC from both sexes with grade I and II nuclear subtypes according to the LOCS-II were included. The exclusion criteria were grade III and IV nuclear subtypes of ARC, cortical and posterior subcapsular subtypes of ARC, corneal lesions, uveitis, glaucoma, a history of ocular trauma or surgery, age-related macular degeneration, and retinal dystrophy. Individuals with systemic diseases that might affect ocular function, such as diabetes mellitus and metabolic disorders, as well as those with systemic steroids, were also excluded. Following the baseline assessment visit, the participants were instructed to apply taurine-containing eye drops (Viziloton®, Farmak IJC, Ukrain) as one drop in the eye 4-times daily. The Viziloton® contained 0.5% taurine (w/v). Participants were scheduled for follow-up visits every 3 months for a total period of 12 months (4 visits following the baseline visit). The same ophthalmologist performed all examinations during the follow-up visits.

Sample size

The sample size was estimated using G Power software (version 3.1.9.4, Heinrich Heine University, Düsseldorf, Germany), assuming an effect size of f = 0.25, significance level of $\alpha = 0.05$, and power of 0.80. Based on these assumptions, the sample size that provided a meaningful effect was 45 participants.

Statistical analysis

The effect of taurine-containing eye drops on ARC progression over time was analyzed using the Generalized Estimating Equation (GEE) with Wald Chi-square tests. This model accounted for multiple measurements over time. Age, sex, IOP, and time were included as covariates in GEE model. Data were also analyzed using the Bayesian Hierarchical Generalized Linear Model (GLM) to detect minor effects of intervention, time, age, sex, and IOP on ARC progression. For the purpose of analysis, the right and left eyes were considered separate entries. Results are expressed as median (interquartile range; IQR), mean ± standard deviation (SD), or number of participants (%). Analyses were performed using Statistical Package for the Social Sciences (SPSS) software (version 27, IBM Corp., NY, USA) and the brms package of R software (version 4.4.1, R Foundation for Statistical Computing, Vienna, Austria) as appropriate. P-value < 0.05 was considered statistically significant difference.

RESULTS

Between July 10, 2023, and November 1, 2023, 103 individuals were screened for eligibility, of whom 61 were enrolled in the study (115 eyes). All participants had a grade I or II nuclear ARC subtype in one or both eyes. Eight (13.1%) and two (3.2%) participants were lost to follow-up at the 6 months and 9 months visits, respectively. Those participants were included in the analysis (Figure 1). No participant was enrolled after November 1, 2023, as determined by the study protocol. Baseline characteristics of the study participants are presented in Table 1.

In the current study, GEE analysis of the data revealed a non-significant effect of time on BCVA over the time course of the study (Wald Chi-square = 1.254, P-value = 0.534). This indicates that ARC in participants taking taurine-containing eye drops did not progress over the 12 months. To determine subtle changes in BCVA over the study period, data were analyzed using Bayesian Hierarchical Generalized Linear Model. Similarly, the time coefficient estimate was close to zero, indicating stabilization of ARC progression over the study period. IOP had no significant effect on BCVA (Wald Chi-square=0.009, P-value = 0.904). However, age appeared to have a substantial deteriorating effect on BCVA (Wald Chi-square = 18.547, P-value < 0.001). As age increased, there is

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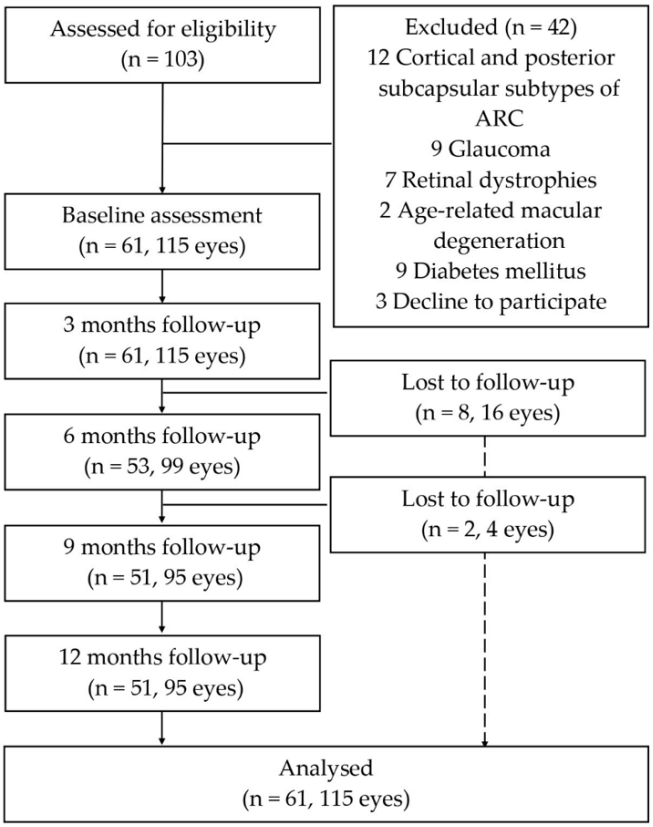

Figure 1. Study flow diagram. ARC, age-related cataract.

Table 1. Baseline characteristics of participants with age-related cataract (ARC)*.

Characteristic	Participants (n = 61)
Age, years	62 (IQR 58-68)
Sex	
Male	15 (24.6%)
Female	46 (75.4%)
Eyes	
Total	115
OD	57 (49.6%)
OS	58 (50.4%)
Visual acuity, logMAR	0.4 ± 0.18
BCVA, logMAR	0.2 ± 0.19
IOP, mmHg	13.7 ± 2.5
LOCS II	
Grade I	66 eyes (57.4%)
Grade II	49 eyes (42.6%)

* *OD*, right eye; *OS*, left eye; BCVA, best-corrected visual acuity; IOP, intra ocular pressure; LOCS II, lens opacity classification system II.

a decline in BCVA of the current study cohort. In addition, sex seems to have a mild but statistically significant effect on BCVA (Wald Chi-square = 4.837, P-value = 0.028), implying that female sex, in general, is associated with poor BCVA compared to male sex in the cohort of this study.

DISCUSSION

Cataracts are the most prevalent visual dysfunctions worldwide. ARC is, by far, the predominant type of cataracts. The pathogenesis of lens opacification in the ARC has yet to be completely clarified. Age-related oxidative stress is thought to be the principal contributor to lens opacity in ARC [7]. Antioxidants have recently received considerable attention as a treatment option to prevent ARC progression. Among these antioxidants, taurine is of particular interest. The current study was designed as a pre-post interventional trial to explore the effect of taurine on the progression of ARC nuclear subtype by assessing BCVA, the primary outcome, over one-year.

This interventional study demonstrated that BCVA did not change significantly during the study period (P-value = 0.534). This, in turn, could indicate that BCVA had stabilized for 12 months in participants taking taurine-containing eye drops. Therefore, taurine may have prevented ARC progression in this cohort. This proposition is supported by the fact that taurine has a well-documented antioxidant effect, which can counteract the modification of lens proteins *in vitro* [14]. Notably, a controlled clinical trial by Vodovozov and Glotova concluded that the ocular administration of taurine can improve visual acuity [13]. However, in our study, no improvement in BCVA was observed. The discrepancy between our results and those reported by Vodovozov and Glotova [13] could be related to the fact that visual acuity rather than BCVA was used for the assessment of ARC progression in that study, which is often nonspecific in terms of vision impairment related to lens opacity [15]. It is essential to highlight the results of a clinical study by Magno *et al.* [16], which revealed that nuclear ARC could progress by at least one LOCS II grade in 38% of participants over 6 months from baseline. The progressive nature of ARC correlates well with the deterioration of BCVA [17]. However, in the current study, BCVA was stable over the study period. This suggests that taurine therapy may be an effective strategy to prevent the progression of nuclear ARC. Nevertheless, it is essential to acknowledge the diversity of factors that could affect the progression of nuclear ARC, [18, 19] and the lack of a control arm in the current study. Therefore, the inherent absence of nuclear ARC progression in our study cohort cannot be entirely excluded.

The predominance of female participants, with a female-to-male ratio of 3:1, in the population of the current study seems to be consistent with the proposition that ARC is more prevalent in older females, often due to post-menopausal changes in estrogen levels [20]. Our results also suggest that females exhibit a weaker BCVA than males. Similar sex-based disparities have been reported by other investigators [21]. Considering the median age of participants in our study (62 years), the disparity in ARC intensity between females and males could also be linked to the depletion of estrogen levels in females. Notably, estrogen has been suggested to exert a protective effect against oxidative stress in the human eye [22].

In the present study, age was found to be a determinant factor for BCVA deterioration (P-value < 0.001). As individuals age, their visual function declines substantially. This concept has been widely accepted and well-documented in rigorous studies [23, 24].

Although the findings of this study provide invaluable insights into the therapeutic applications of taurine in the prevention of ARC, several limitations must be considered.

These include the lack of a control group and relatively short follow-up period, which restrict the ability to differentiate taurine-related effects from those of natural ARC progression. In addition, the current study was conducted at a single center, and participants were examined by a single ophthalmologist. Although this design allowed for consistency in measurements, subjective variability remains a possibility.

CONCLUSION

This interventional study demonstrated that taurine-containing eye drops may serve as an effective therapeutic option to prevent further BCVA deterioration and potentially inhibit nuclear ARC progression. Furthermore, the findings highlight the significance of age and sex as key factors influencing ARC progression. Although the findings presented in this study are promising, further studies incorporating randomized controlled designs, extended follow-up, and multiple centers are recommended.

ETHICAL DECLARATIONS

Acknowledgments

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Ethics Approval and Consent to Participate

The study was approved by the Ethical Approval Committee of the University of Anbar, Iraq. Informed consent was obtained from all participants.

Consent for Publication

Not applicable.

Availability of Data and Material

The datasets produced and/or analysed during the present study can be obtained from the corresponding author upon reasonable request.

Competing Interests

The authors declare that there is no conflict of interest.

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Authors' Contributions

Conceptualization, A.Z., Z.A. and T.M.; methodology, A.Z. and Z.A.; formal analysis, A.Z.; investigation, Z.A. and T.M.; data curation, A.Z. and Z.A.; writing—original draft preparation, A.Z.; writing—review and editing, A.Z., Z.A. and T.M.; project administration, T.M. All authors have read and agreed to the published version of the manuscript.

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