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Original Article

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Comparing Ultrasound applanation Biometry and Partial Coherence Interferometry, for Axial length Measurement and Intra ocular lens Power Calculation: A Randomized Clinical Trial

Arun Kumar Sharma[1], Preeti Singh[2], Gaurav Kumar[3], Vishal Katiyar[4], Siddharth Agrawal[5], Sanjiv Kumar Gupta[6]

Abstract

Objectives: This study was done to evaluate and compare PCI and AUS measured axial lengths and accuracy of IOL power calculation using UBII IOL power calculation formula.

Methods: patients undergoing cataract surgery underwent ocular biometry and IOL power calculation using PCI and AUS using Universal Barrett II formula. The subjects were randomized into 2 groups PCI and AUS respectively to receive the IOL power accordingly. The post op refractive spherical equivalent was evaluated and the groups were compared using residual refractive error and absolute residual refractive error at 6 weeks post-op.Comparison of axial length, IOL power between the two groups was done using the Bland-Altman plot and the agreement between the predicted refraction and the final refraction in both groups was compared using paired student-T test or Mann-Whitney test.

Results: Total 119 subjects were analyzed with 61 and 58 subjects in the Group PCI and AUS respectively. The two groups (PCI and AUS) comparable with reports to age, gender and laterality. The average axial length, predicted IOL power, residual refractive error and absolute residual refractive errors were statistically similar between both the groups.

Conclusions: The PCI and AUS are similarin measuring ocular axial length and can be used interchangeably with UBII formula for reasonable post cataract surgery refractive accuracy.

Keywords: PCI (Partial Coherence Interferometry); AUS (Applanation Ultrasound biometry); IOL (Intra Ocular Lens), Universal Barrett II; IOL master 500; PSC ((Posterior Subcapsular Cataract); Mature Cataract; Immature Cataract; Keratometry; Axial Length.

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Introduction

Inaccuracies in ocular biometry, either arising from the measurements themselves or associated underlying assumptions, account for 27% of the refractive surprises.[1] Hence the accuracy of measurement of axial length is of pivotal importance to achieve the desired refractive outcome. Presently the two most popular methods of measuring the axial lengths are Optical biometry (Partial Coherence Interferometry; PCI) and Applanation Ultrasound biometry (AUS).[2] Though the literature has sided with PCI as the more accurate method,[3,4,5] the PCI fails to measure axial lengths with optimum signal to noise ratio in cases with significant media opacities and this can range from 10% to 36%.[6,7,8,9,10] When it comes to developing countries, the cataracts are denser and there is a higher prevalence of white cataracts, where the PCI fails to measure the axial length. Many centers are not equipped with the more expensive optical biometers and use AUS for biometry. Thus, for the above mentioned reasons, the role of ultrasound

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will remain there despite emerging technologies in optical biometry. The studies which have compared PCI to AUS for measuring the ocular parameters to calculate IOL power have used the older IOL power calculation formulas which can induce error in IOL power calculation in comparison to 4th generation formulas.[11,12] In this study we have compared the PCI and AUS in terms of axial lengths, IOL power, and post cataract surgery refraction using the 4th generation IOL power calculation formula (Universal Barrett II formula). To our knowledge, this comparison has not been done in the Indian population yet.

The study hypothesis is that the measurement of the axial length of the eye and the IOL power calculated for eyes undergoing cataract surgery using Partial Coherence Interferometry (PCI) and Applanation Ultrasound Biometry (AUS) are comparable when Intra Ocular Lens power is calculated using the Universal Barrett II formula.

Methods

This was a prospective double blind randomized clinical trial involving patients presenting in the department of ophthalmology at a tertiary care teaching hospital with visually significant senile cataract.Subjects were screened for inclusion and exclusion criteria (Table 1) and included in the study after taking informed consent. The study was approved by theInstitutional Ethics Committee and conducted following the tenets of the Declaration of Helsinki.

After the subjects were included in the study, they were randomized into two groups, Group PCI (partial coherence interferometry biometry using IOL master 500 (Carl Zeiss Meditec, Bengaluru, India)) and Group AUS (Applanation ultrasound biometry using A-scan Biometer (Echorule PRO Biomedix Optotechnik & Devices Private Limited, Bengaluru, India).

Intra Ocular Lens power was calculated using the Universal Barrett II formula (UB II)suiteavailable at the APACRS site[13] for all the subjects using axial lengths measured by PCI & AUS. The UB II formula allows the input of lens thickness as an optional parameter, which is not measured by PCI (IOL master 500) so the lens thickness was used only with axial length obtained AUS group when calculating the IOL powers. The first myopic IOL power was selected for implantation during the cataract surgery as per the UB II formula. The subjects allotted to the respective groups were implanted with the IOL power as per the designated group (PCI or AUS). A preloaded hydrophobic Monofocal IOL was implanted (Supraphob, Appasamy associates, Chennai, India) after 2.8 mm Clear corneal phacoemulsification as described by Sanjiv et al.[14] The final refractive status at 6 weeks after the surgery was evaluated in terms of spherical equivalent power in diopter, the residual refractive error (postop spherical equivalent power minus predicted spherical power), and absolute residual refractive error were compared between the two groups and analyzed.

A sample size of ~100 subjects was reached upon considering a confidence level of 95%, confidence interval of 10, and population of 4000 (the total number of patients operated in the hospital unit in a year). Thus, we planned to screen 150 subjects assuming a 20% dropout rate. As is known that PCI is unable to measure the axial length in mature cataracts and dense PSC (Posterior Subcapsular Cataract) we shifted these patients to Group B and used the axial length as measured by the AUS for the IOL power calculation.

The statistical analysis was done to compare the axial lengths between the two groups using the **Bland Altman** (B & A) **plot** and mountain plot. The agreement between the predicted refraction and the final refraction in both groups was compared using paired student T test or Mann Whitney test. The Chi square test was used to compare the grades of post op refractive errors between the groups.

Results

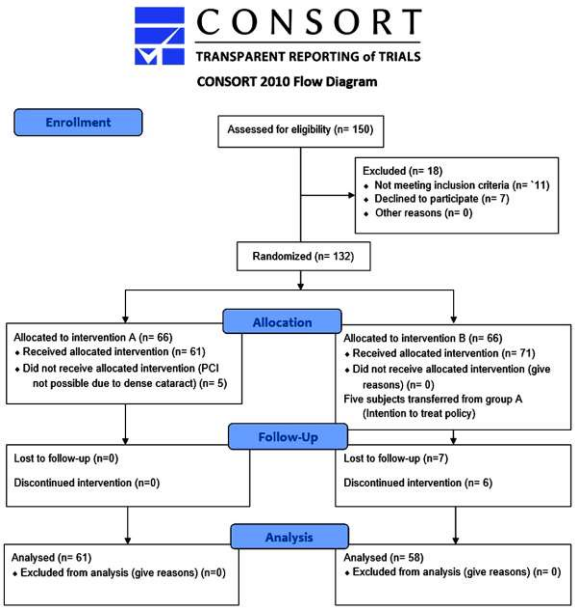
A total of 150 subjects were screened against the exclusion criteria (Table 1)

Table 1: Exclusion criteria for screening subjects.

Exclusion Criteria
Intraoperative and postoperative complications.
Pre-existing astigmatism >2.5D
History of previous ocular surgery.
Presence of associated ocular pathologies (such as uveitis, zonular dialysis, corneal disease or dystrophy, glaucoma).
Diabetic retinopathy.
Uncooperative for PCI (IOL master)
Uncooperative for phacoemulsification under topical anesthesia

and 132 subjects were randomized into Group PCI and group AUS. Five subjects had to be shifted from group PCI to group AUS due to a very dense cataract which precluded axial length measurement using PCI. Thirteen subjects were lost to follow up

due to various reasons and thus finally, 119 subjects were analyzed with 61 and 58 subjects in the Group PCI and AUS respectively (Figure 1. CONSORT flow chart).



The demographic features of the study group have been presented in Table 2.

Table 2: Demographic details of the study population and the groups. (PCI-Partial Coherence Interferometry, AUS-Applanation Ultrasound).

	Group PCI	Group AUS	Total	
Gender				
Females	31	30	61	P=0.93
Male	30	28	58	
Laterality				
Right	28	29	62	P=0.79
Left	33	29	57	
Age (Years) Median	58	58		P=0.64

The two groups (PCI and AUS) were symmetrical regarding the age, gender, and eye planned for the surgery. The clinical characteristics of the two groups are depicted in Table 3, which shows a significant difference in the pre-op visual acuity between the two study groups (p<0.0001). The frequency of the types of cataracts was also significantly different

Table 3: Preop clinical data of the subjects in the two groups.

	Visual aquity (Log MAR)		Cataract Type					Average Keratometry		Axial lengths (mm)			IOL power		
	Preop (Avg, SD, Range)	P value (Mann-Whitney test)	IMSC	Mature cataract	Posteri or polar cataract	PSC	P value (Chi-squared test)	Median (Average, Range)		Average (SD, Range)	Median	P value (Student t test)	Average (SD, Range)	Median	P value (Mann-Whitney test)
Group PCI (n=61)	1.0 (0.78, 0.18-1.0)	p<0.0001	55	0	1	5	p=0.0087	44.7 (44.47, 40.84-47.67)	p=0.60	23.27 (1.2, 19.59-27.16)	23.3	0.4	20.85 (2.95, 11.5-29.5)	21	0.59
Group AUS (n=58)	1.4 (1.51, 0.18-3.0)		44	10	1	3		44.29 (44.26, 33.02-48.88)		23.13 (1.25, 19.65-27.3)	23.2		21.0 (2.96, 12-29.5)	21	

between the groups (p=0.008). This difference in the visual acuity and the types of cataracts was different because of mature cataracts being exclusively allotted to the AUS group. Once we excluded mature cataracts (10, 8.4%), which were exclusively allotted the AUS group, the frequency of the types of cataracts between the groups was symmetrical (p=0.91).

Average keratometry was similar between the groups (p=0.6).The average axial length measured using PCI (107) and AUS (119) were statistically similar when compared using the studentt-test (p=0.4) (Table 3). The axial lengths as measured by PCI and AUS had a correlation coefficient of 0.99 (p<0.0001), indicating excellent agreement between the two methods (Figure 2).

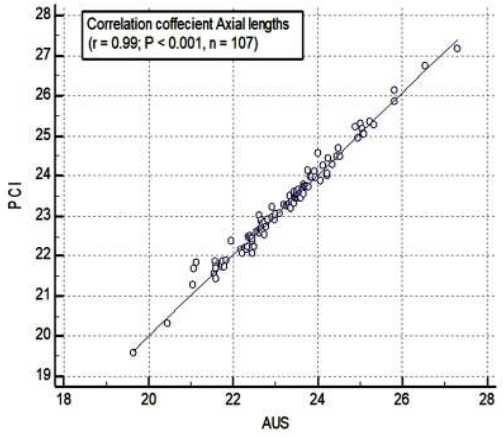


Fig. 2: Scatter diagrtam showing correlation between the axial lengths as measured using AUS (Applanation Ultrasound) Vs PCI (Partial Chorerence Interferometry).

We classified the eyes as short (<22mm) 22 eyes (18.5%), Medium (22.1-24mm) 83 eyes (69.7%), long (24.1-26) 12 eyes (10.1%), and very long (>26mm) 2 eyes (1.7%) based on AUS as there were few eyes where PCI failed to measure axial length. The distribution of these types of eyes was statistically similar between the groups (p=0.12).

The regression analysis showed the following relation between the axial lengths measured using AUS and PCI as per the givenequation for the range 19.65-26.3 mm (Figure 3).

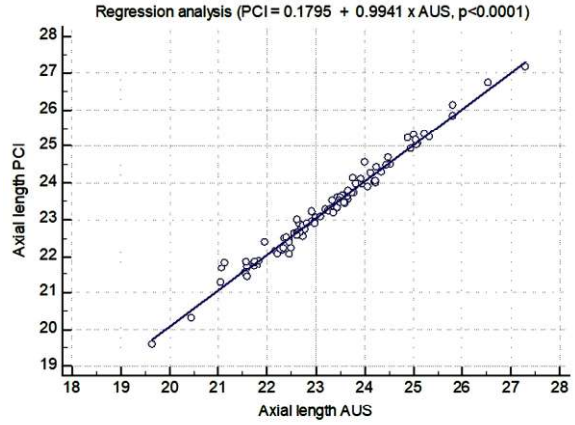


Fig. 3: Regression analysis showing relation between axial lengths as measured using PCI and AUS and equation repesenting the relationship.

PCI = 0.1795 + 0.9941xAUS (p<0.0001)

The Bland-Altman plot and the mountain plot to compare the agreement between the PCI and AUS in measuring the axial length is shown in Figure 4a & 4b, where it is showingthat 95.8% cases were within the limits of agreement which is considered an adequate agreement between the two diagnostic modalities.[15]

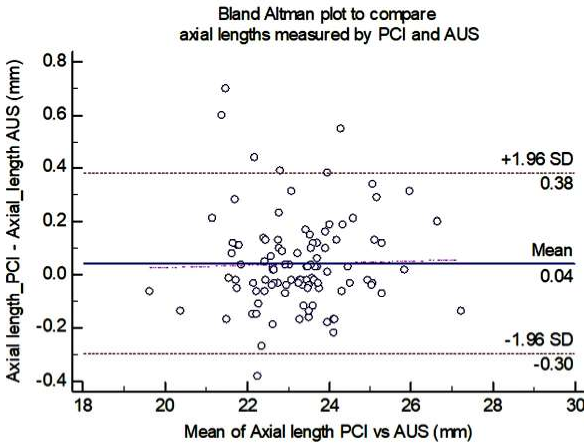


Fig. 4a: Bland Altman Plot comparing axial length as measured by PCI & AUS.

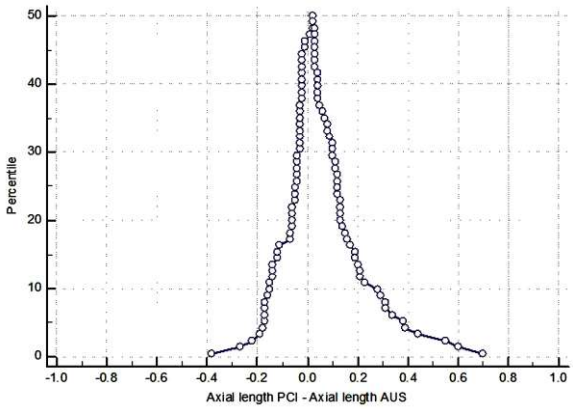


Fig. 4b: Mountain plot comparing axial length measured by PCI & AUS.

The average IOL power as calculated using axial lengths measured using PCI and AUS were 20.85D (SD 2.95, range 11.5-29.5D) and 21.0 D (SD 2.96, range 12.0-29.5 D)respectively (Table 3). This was statistically similar in both the groups with a pvalue of 0.59 (Mann-Whitney test). There was a statistically significant correlation (Correlation coefficient 0.98, p<0.0001) between the IOL power calculated by using axial lengths measured using PCI and AUS.

As is known, a change of 1 mm in the axial length may result in a change of 2.5 diopters in the IOL power calculation. When the IOL power-induced error is translated to the error in the refraction it is known that half of this error is reflected as the change in the refraction of the eye. Thus, an error of 1 mm in the measurement of axial length will result in induced refraction of ~1.25 D.[17] Considering that the residual refractive error of more than 0.75 may not be an acceptable outcome, we identified the cases where the disagreement between PCI and AUS was more than 0.5mm.

There were 6 such cases, 3 cases in each of the two groups. Bland-Altman plot to compare the two diagnostic techniques also revealed that there were 6 (4.2%) cases out of 119 cases that lay outside the limits of agreement (0.68 mm) when comparing the axial lengths measured by PCI and AUS (Bland Altman plot, Figure 4a). when comparing the IOL power calculated using the axial lengths measured using PCI and AUS there were 6 (5.0%) cases that lay outside the limits of agreement (Bland Altman plot, Figure 5).

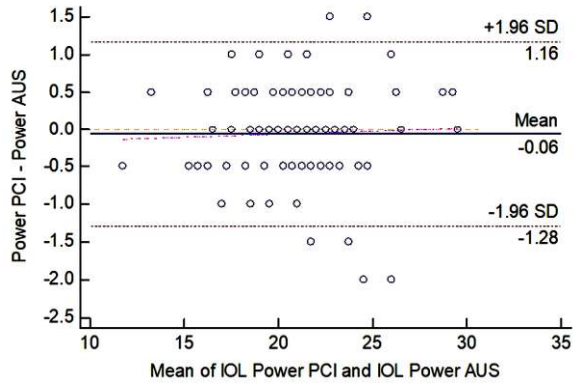


Fig. 5: Bland-Altman plot comparing the IOL power calculated using PCI & AUS.

The refractive outcomes at 6 weeks after the surgery is presented in Table 4.

Theaverage target post op refraction was -0.26 D as the target refraction was minimum myopia among all the subjects. For subjects having preexisting myopia since an early age,it was 2nd or 3rd myopic IOL power as it is desirable to leave them myopic as per their convenience and habit.[18] The average refraction at the end of 6 weeks was -0.51 D for all the subjects and -0.59 D and -0.43 D for the groups PCI and AUS respectively (P=0.44). It may be worth mentioning that though the post-op refraction was targeted to be myopic in all the subjects, however, there were 3 (4%) and 9 (15%) subjects in the PCI group and AUS group who ended up with hypermetropic refraction more than 1.0 D. Residual refractive error (Post-op refraction minus Target refraction) was similar in both the groups and the difference was statistically insignificant (p=0.68).

Table 4: Post-op refractive outcomes and comparison between the group PCI and Group AUS `showing statistical similarity between the two groups.

	Average All subjects (119) (SD, Range)	Average PCI (61) Group (SD, range)	Average AUS group (58) (SD, Range)	p value
Target refraction	-0.26 (0.36, -1.2 to 0.8)	-0.3 (0.33, -1.0 to 0.7 D)	-0.22 (0.39, -1.2 to 0.8 D)	0.27
Post-op refraction	-0.51 (1.09, -3.5 to 2.0)	-0.59 (1.01, -3.5 to 1.5 D)	-0.43 (1.17, -2.75 to 2.0 D)	0.44
Residual refractive error	-0.24 (1.13, -2.7 to 2.3)	-0.28 (1.07, -2.7 to 2.1 D)	-0.20 (1.20, -2.3 to 2.3)	0.68
Absolute residual refractive error	0.93 (0.68, 0 to 2.7)	0.84 (0.71, 0.0 to 2.7)	1.03 (0.63, 0.1 to 2.35)	0.12

	Number of subjects (%)	n (%)	n (%)	
Absolute residual refractive error <1.0	72 (60.5%)	41 (67.2%)	31 (53.4%)	0.17
Absolute residual refractive error>1.0	47 (39.5%)	20 (32.8%)	27 (46.6%)	

The absolute residual refractive error was greater in the AUS group when compared to the PCI group but this difference was statistically insignificant (p=0.12). The data distribution comparing the absolute residual refractive errors is presented in figure 6.

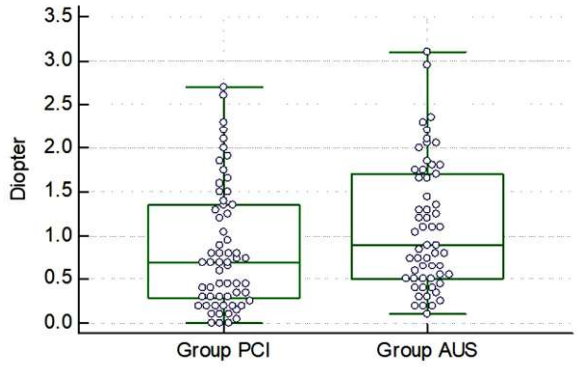


Fig. 6: Box & Whisker plot comparing Absolute residual refractive errors between the two groups. (Mann-Whitney test, p=0.05).

The number of subjects within 1 Diopter of absolute residual refractive error was 41 (67.2%) and 31 (53.4%) within the PCI and AUS groups respectively (p=0.08). There were 47 subjects with absolute residual refractive error >1.0D (20 (32.7%) in PCI group and 27 (46.5%) in AUS group, p=0.41). Thus,the PCI group had a greater percentage of subjects within +/- 1.0 D of the desired refraction butit was statistically insignificant.There were 2 cases with absolute residual refractive error of more than 2.5 D, both the cases in the PCI group.

Discussion

The subjects in the groups PCI and AUS were comparable in terms of gender, age, and laterality establishing the congruency between the two study groups. The distribution of the types and maturity of the cataracts were not comparable as the subjects with mature and dense cataracts were shifted to the ultrasound group because of the inability of the IOL Master 500 to measure the axial lengths in eyes with dense media opacity. This also caused lower pre-operative visual acuity in the AUS groups when compared to the PCI group.

Axial lengths measured using PCI and AUS were comparable with reasonable agreeability in our study (p=0.4). This has been seen in other studies as well.[19,20,21,22] A study by Nakhli FR[21] has estimated a linear equation establishing a relation between axial lengths measured using PCI and AUS, which is very similar to the relation derived in our study. The mountain plot and Bland-Altman plot are used to compare diagnostic tests against each other to visualize the agreement between the measurements done by two different methods. Agreement of more than 95% of the readings within 2 standard deviations from the mean of the differences measured by the methods in question validates the compared methods when tested by the Bland-Altman plot.[15] In our study we had 95% of the axial lengths falling between the defined limits demonstrating good agreement between PCI and AUS techniquesand this has been seen in the studies by other authors as well.[5, 21,23]

The IOL power calculation was done for all the patients using both the techniques except for the subjects in which PCI failed to measure the axial lengths due to media opacity(Group PCI =107, Group AUS =119). The average IOL power calculated for the subjects using axial lengths measured using PCI and AUS was 20.85D and 21.0D respectively and was statistically similar (P=0.59). The IOL power calculation was done using the UB II formula and the parameters as provided by the IOL master 500 except for the axial length and ACD which was derived using PCI or AUS. As the axial lengths were in good agreement between the two groups hence it was reasonable that the IOL power between the two groups will also in agreement as seen in other studies as well.[9,24] The similarity between the IOL powers between the two groups was also tested using the Bland Altman plot which also confirmed the good agreement between the two groups (95% cases between the limits of agreement).

The post op refractive status of the patients can be considered to be the litmus test for the accuracy of biometry done by the two techniques. The post op refractive status is illustrated in table 4.As mentioned, the target refraction was not emmetropia so we did our analysis on the residual refractive error (post op refraction target refraction) and absolute residual refractive error. The results showed that the average residual refractive errors in both the groups PCI and AUS were comparable with the average being -0.28D and -0.20 respectively (p=0.68). The absolute residual refractive error was 0.84D and 1.03D in the respective groups (p=0.12). Table 4 illustrates the absolute residual refractive error in the two groups as per the categories of <1.0D and more than 1D. It can be seen that the subjects with absolute residual refractive error with >1D were more in the group AUS but this difference was statistically insignificant (p=0.17). Thisindicates that the PCI provides better accuracy in IOL power calculation but the difference is statistically insignificant when compared to AUS. It has been observed and recommended in various studies that nearly 70% to 85% of cases fall within +/- 1.0D of refraction after cataract surgery.[25,26,27] In our study we had 60.5% of cases within +/-1.0D of refraction at the end of the observation period.

Conclusion

The PCI and AUS are comparable for the measurement of axial lengths and can be used interchangeably without inducing significant error. The axial lengths measured by AUS are marginally smaller when compared to PCI and this can be corrected by using the given equation.

The IOL powers predicted for a given target post-op refraction using axial lengths provided by PCI and AUS using the UBII formula are in good agreement for the axial lengths between 19.5-27.16 mm as seen in the study.

The post op residual refractive error (Post op refraction-target refraction) and absolute residual refractive error are statistically similar when comparing the PCI and AUS provided axial lengths.

Thus, the AUS and PCI can be considered as a reliable replacement for each other and considering the cost difference between the two techniques the health care provider can invest in any of the technique looking at the other relevant issues like cost, convenience, patient turnover, and sterilization without compromising the clinical and refractive outcomes.

We thanks for the Acknowledgement: Syed Meesam Abbas, Research Assistant, King George's Medical University, Lucknow, Email - meesam704@gmail.com

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Original Article

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Efficacy of Citicoline as an Adjuvant to Patching in Unilateral Amblyopia

Salil Kumar[1], Poorva Shrivastava[2], Lalit Shrivastava[3]

Abstract

***Background*:** The present study aimed to study the role of citicoline as an adjuvant to patching in unilateral Amblyopia.

Methodology: The study was conducted at atertiary care centred ,during the study period of 1 year on 50 patients presenting with mild to moderate amblyopia. Patients were subjected to detailed history and ocular examination using a slit lamp.

Results: 24% patients belonged to the age group of 7-8 years of age. About 52% cases were females. Citicholine with patching therapy was used in 25 cases (36% strabismus cases, 32% anisometropia and 32% combined) and patching therapy was used in 25 cases (32% strabismus , 40% anisometropia and 28% combined).

Conclusion: Though this study has its limitations nonetheless it shows that adding citicoline in addition to patching therapy can significantly influence the visual acuity in amblyopia patients.

Keywords: Amblyopia; Occlusion therapy; Citicholine.

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Introduction

Amblyopia or lazy eye is commonly known as unilateral or bilateral reduction of BCVA without visible organic cause. Patching /occlusion is the gold standard in the management of amblyopia. Other modalities of management has been a subject of intense clinical research.

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Citicoline has been suggested as a adjuvant to patching therapy for a rapid improvement in unilateral amblyopia.

Methodology

The study was conducted at the Department of Ophthalmology, of a tertiary care centre of central India during the study period of 1 year. The inclusion criteria was patients in the age group of 3 to 10 years ,mild to moderate unilateral amblyopia, patients with strict compliance for patching, showing compliance for oral medications. Patients with previous history of ocular surgery, known case of blindness or previous central corneal opacity were excluded from the study.

The study was approved by Institutional ethical committee. Written consent was obtained from parents/ guardians in case of minors. All the cases fulfilling inclusion criteria and presenting to

study area during the study period were enrolled. Patient's name, age, sex, occupation, address, and other socio demographic data was obtained from all the study participants and entered in questionnaire. Detailed history was noted. Further, the patients were subjected to detailed clinical and ocular examination. Ocular examination included best corrected VA, anterior segment examination, slit lamp biomicroscopy, intra ocular pressure, fundus examination. All the cases were also subjected to B scan ultrasonography for ruling out posterior segment pathology.

Patients were divided into 2 groups and study was conducted in 2 phases.

Phase 1

- Patching
- Patching

Phase 2

- Patching +citicholine
- Patching

Statistical Analysis

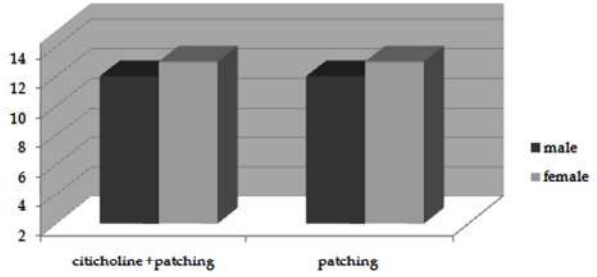
The data was compiled using MsExcel and analysed using IBM SPSS software version 20. Data was expressed as frequency and percentage.

Results

24% patients belonged to the age group of 7-8 years of age. About 52% cases were females. Citicholine with patching therapy was used in 25 cases (36% strabismus cases, 32% anisometropia and 32% combined) and patching therapy was used in another 25 cases (32% strabismus, 40% amblyopia and 28 % combined).

- **Distribution of patients according to gender.**

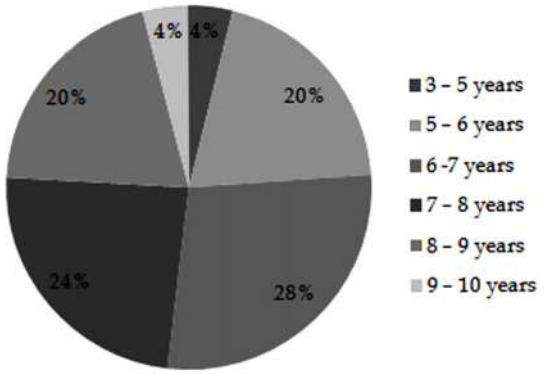
Gender	Citicoline with patching		Patching	
	No of Patients	Percentage	No of Patients	Percentage
Male	12	48%	12	48%
Female	13	52%	13	52%
Total	25	100%	25	100%



- **Distribution of patients according to age group.**

Age Group	Citicoline with patching		Patching	
	No of patients	Percentage		
3 – 5	1	4%	1	4%
5 – 6	5	20%	5	20%
6 - 7	7	28%	9	36%
7 – 8	6	24%	5	20%
8 – 9	5	20%	3	12%
9 – 10	1	4%	2	8%
Total	25	100%	25	100%

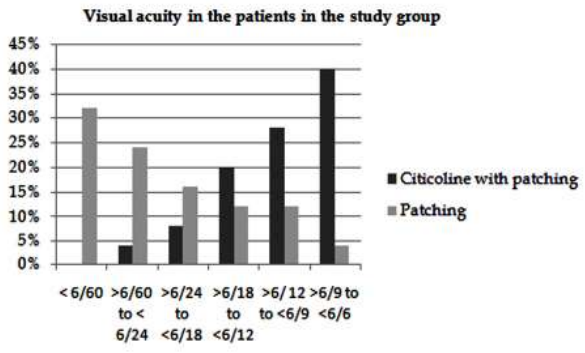
Distribution of patients according to the age group.



- **Visual acuity of the patients in the Study group.**

Visual Acuity	Citicoline with patching		Patching	
	No of patients	Percentage	No of patients	Percentage
< 6/60	0	0%	8	32%
>6/60 to < 6/24	1	4%	6	24%
>6/24 to <6/18	2	8%	4	16%
>6/18 to <6/12	5	20%	3	12%
>6/ 12 to <6/9	7	28%	3	12%
>6/9 to <6/6	10	40%	1	4%
Total	25	100%	25	100%

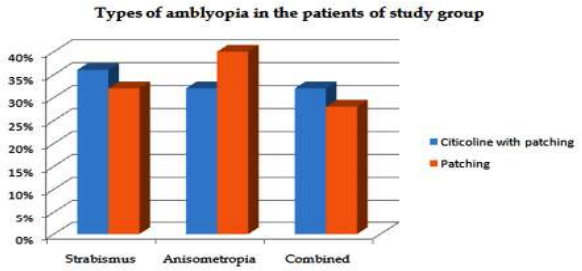
Visual acuity in the patients in the study group.



- **Types of amblyopia in the study group.**

Type of Amblyopia	Citicoline with patching		Patching	
	No of patients	Percen tage	No of patients	Percen tage
Strabismus	9	36%	8	32%
Anisometropia	8	32%	10	40%
Combined	8	32%	7	28%
Total	25	100%	25	100%

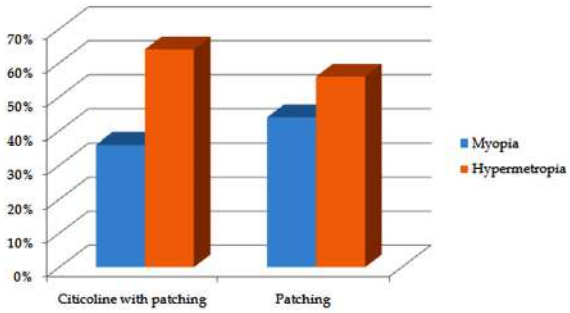
Types of amblyopia in the patients of study group.



- **Types of refractive error in the patients of study group.**

Refractive error	Citicoline with patching		Patching	
	No of patients	Percen tage	No of patients	Percen tage
Myopia	9	36%	11	44%
Hypermetropia	16	64%	14	56%
Total	25	100%	25	100%

Types of refractive error in the patients of study group.



Discussions

Amblyopia or lazy eye is commonly known as unilateral or bilateral reduction of BCVA without visible organic cause. Patching/occlusion is the gold standard in the management of amblyopia. Other modalities of management has been a subject of intense clinical research. Citicholine has been suggested as a adjuvant to patching therapy for a rapid improvement in unilateral amblyopia.

The present study aimed to study the role of citicholine as an adjuvant to patching in unilateral Amblyopia.

Our study included a total of 50 patients of unilateral amblyopia. Majority of patients belonged to 7-8 years of age (45.2%). About 52% cases were females. Citicholine with patching therapy was used in 25 cases (36% strabismus cases, 32% anisometropia and 32% combined) and patching therapy was used in another 25 cases (32% strabismus, 40% amblyopia and 28 % combined).

A similar outcome was observed in the study conducted by Pawar PV et al1, they observed no significant difference in the mean visual acuities in the two groups in phase 1 till plateau was reached. In phase 2, for the initial four months, there was no significant difference in the visual acuities in the two groups, at the respective intervals. however, five months onward, upto 12 months, there was a significant difference in the visual acuities in these groups. the result was the same in younger patients (<seven years of age) as well as in older patients (>seven years of age). In phase 2, the mean proportional improvement in group I was significantly more than that I group II, at two months and onward , at the respective intervals.

A similar outcome was observed in a study conducted by Anurag et al 2. They observed no ignificant difference in the mean visual acuities in the two groups in first 6 months or till plateau was reached. After starting citicoline in one group for the initial two months, there was no significant difference in the visual acuities in these two groups , at the respective intervals, However four months onward, upto 12 months, there was a significant difference in the visual acuities in these groups. The result was the same in younger patients (<eight years of age) as well as older patients (> eight years of age). After starting citicoline the improvement in group I was significantly more than that in group II, at two months and onward, at the respective intervals.

Conclusion

Though this study has its limitations nonetheless it shows that adding citicoline in addition to patching therapy can significantly influence the visual acuity in amblyopia patients.

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Review Article

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Prevalence and Associated Factors of Dry Eye in Patients Above 40 Years of Age at a Tertiary Centre

Sharavan G Masurkar[1], Ramesh C Hulakund[2], Anupama C Shetkar[3], Jay Singh B N[4], Salma Sultana[5], Shishir K N[6]

Abstract

Purpose: To determine the prevalence of dry eye in ophthalmology out patients At a tertiary carehospital and its possible association with various clinico epidemiological factors.

Patients and Methods: This was a hospital based cross sectional study involving 390 patients who visited ophthalmology OPD in a tertiary care hospital. Patients who are aged more than 40 years irrespective of their dry eye related complaints. Tear film break up time was used as an indicator for the diagnosis of Dry eye disease. The study span was of 10 months.

Results: Overall prevalence of DED was 51.6% among the patients. The prevalence of DED was more among elderly population as well as among patients who are having diabetes and hypertension with prevalence of 59% and 49% respectively. Females constituted more in number as well as they had higher prevalence of DED 55.8%. Burning sensation and watering was present in 39% and 32% of DED patients respectively.

Conclusion: This study reflects a major burden of DED among the routine out patients. We observed various contributing factors for dry eye such as age, female gender, outdoor jobs, Tobacco consumption, Diabetes Mellitus, Hypertension, Meibomian gland disease, antiglaucoma medications and contact lens use to name a few. There is need to educate general public regarding the awareness and sensitivity toward the symptoms of DED. Further studies need to be undertaken to establish a universal diagnostic criterion, concrete etiologic association and options to deal with the same.

Keywords: Dry Eye Disease; Diabetes Mellitus; Tear Film Breakup Time.

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Overview

Dry eye disease (DED) is one of the most common clinical disease encountered in all the regular OPD patients. Most of patients who visit ophthalmic clinics report symptoms of dry eye directly or indirectly making it a growing public health problem and one of the most common conditions seen by ophthalmologists in general.[1]

Dry eye is a disorder of the tear film which occurs due to tear deficiency or excessive tear evaporation; it causes damage to the interpalpebral ocular surface and is associated with a variety of symptoms reflecting ocular discomfort.[2]

In 2007, the International Dry Eye Workshop (DEWS) revised the original definition and classification scheme of DED and developed a new definition, as well as a three-part classification of DED based on etiology, mechanism, and severity of thedisease.[3] Because the tear film in dry eye patients is unstable andincapable of mentaining theprotective qualities that arenecessary for its structure and function, patients experiencethe discomfort symptoms associated with dry eye, which are burning, stinging, grittiness, foreignbody

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sensation, tearing,ocular fatigue, and dryness etc.[4]

Aim

Aims of this study were to determine the prevalence of dry eye in ophthalmology out patients at a tertiary care hospital and its possible association with various clinico epidemiological factors.

Patients and methods

This prospective hospitalbased study was done during the period of 10 months from November 2020 to August 2021 at Department of Ophthalmology, S.N. Medical College & HSK Hospital, Bagalkot.

Prior to start of the study clearance from institutional ethical committee was obtained.

The study adhered to the declaration of Helsinki. study involving 390 patients who visited ophthalmology OPD in a tertiary care hospital. Patients who are aged more than 40 years irrespective of their dry eye related complaints were considered for study.

All the willing subjects after obtaining valid consent were administered a structured questionnaire.[5]

Questionnaire was administered by single trained resident in local language and examination was done by an experienced ophthalmologist.

Inclusion Criteria

- Patients who are more than 40 years are older
- Patients who are willing to participate in the study.

Exclusion Criteria:

- Patients with ocular surface/lid infections
- Patients with extensive ocular surface pathologies
- Patients who have undergone any ocular surgery within last 2 months.

Data of all patients including sex, age, demographic details such as occupation and duration of diabetes, as well as a history of other diseases wereobtained by reviewing medical records and throughdirect patient interviews.Dry eyes were suspected on the basis of a history ofocular discomfort, including soreness, gritty sensation,itchiness, redness, blurred vision that improves withblinking, and excessive tearing which was evident after scoring in questionnaire.

Dry eye was confirmed by tear film break up time(TBUT) and Schirmer's I test. Diagnosis wasfinalised by positivity of one or both the tests (TBUT or Schirmer's test). Structures of the eye were assessed with slit lamp biomicroscopy examination. Retinal status was evaluated by indirect ophthalmoscopy after dilation with tropicamide drops, and diabetic retinopathy was gradedaccording to Early Treatment Diabetic Retinopathy Study.

Tear film break up time:

Moistened with non preservative saline fluorescein strips (Fluro Touch; Ophthalmic Strips by Medicare surgical Delhi.) were introduced into the conjunctival sac with minimal stimulation, undetected by the patients. The individuals were then instructed to blink several times for a few seconds to ensure adequate mixing of fluorescein. The tear film was examined with a broad beam and a cobalt blue filter.

The interval between the last complete blink and the appearance of the first corneal blackspot or line in the stained tear film was measured using a stopwatch.

A TFBUT value more than 10 s was considered normal, a value of 8–10 s was considered mild dryness, a value of 5–7 s was considered moderate dryness, and a value less than 5 s was considered severe dryness.

Schirmer's test

This test measures tear secretion over a specified time. Schirmer test I without topical anaesthesia (total tear secretion) was carried out with standardized strips. The strip was folded at the notch and placed at the junction of the middle and lateral thirds of the lower eyelids and allowed to stay in place for 5 min with patient's eyes gently closed.

The filter paper was removed, and the amount ofwetting was measured.

More than 10mm of wetting after 5 min was consideredrnormal, 8–10mm of wetting was considered mild dryness, 5–7mm of wetting was considered moderatedryness, and less than5mm of wetting was consideredsevere dryness at the end of 5 min.

Statistical analysis

We obtained the data and entered the data in XL sheets.Data are expressed as Mean±SD. Parameters

between groups were analysed by the Student's t-test, and analysis of variance was performed withthe χ2-test. A P value of less than 0.05 wasconsidered statistically significant.

SPSS for windows 10 (version 14.0; SPSS, Inc., Chicago, Illinois, USA) was) was used for statistical studies.

Various univariate and multivariate observations were noted and subjected to appropriate tests like chi-squared tests etc.With 95% Confidence interval odds ratio were calculated.Tests were done to see the correlation between DED and various socio demographic findings as well as systemic illnesses.

Results

Of the 420 consecutive patients, 390 patients agreed to participate in the study (7% drop out rate). Mean age group of the study population was 60.3 years Figure I.

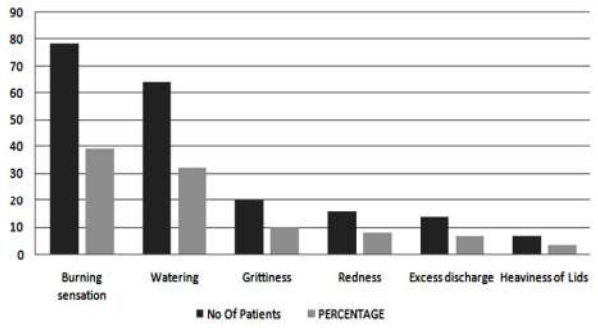

Fig. I: Presenting symptoms of DED in patients.

Sample consisted of 55 % females, and the majority of them were home makers.12% of study population was consuming Tobacco in various forms, hence making it the most prevalent addiction.

Table I: Represents the baseline characteristics of study population (n=390).

Variable	No of subjects	Percentage of total
Age wise distribution		
40-50	101	26%
51-60	129	33%
61-70	121	31%
70-80	35	9%
>80	4	1%
SEX		
Male	175	45.8 %
Female	215	55.12 %
Occupation		
Home makers	170	43.5%
Office worker without AC	83	21.2%
Farmer/Labour/ Outdoor worker	105	27%
Office worker with AC	32	8.2%
Systemic diseases		
Diabetes	117	30%
Hypertension	49	12.5%
Arthritis	46	11.7%
Addictions		
Tobacco chewing	14	7%
Smoking	08	4%
Smoking/chewing/ others	02	1%

The overall prevalence of DED was 51.6% among the of the sample size of 390 participants of age 40 years and above. The prevalence of dry eye was found to be maximum in the elderly. It was 65% in participants aged 71 years and above. 55.8% of females had dry eye disease which was more compared males.We assessed the prevalence of dry eye among various occupation groups

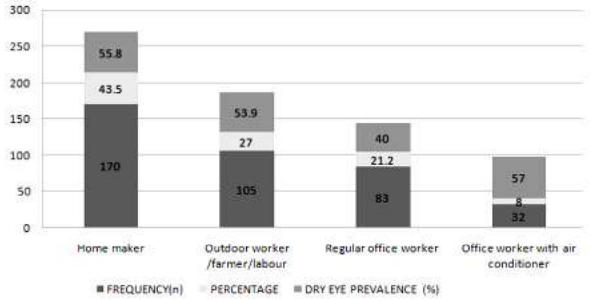

Fig. II: Prevalence of DED among various occupation groups.

Figure II, Home makers had the highest prevalence of dry eye 55.8%, Farmers and those doing outdoor jobs have prevalence of dry eye, which is 53.9%. while those doing indoor jobs without the use of air conditioners have the least prevalence of dry eye 40%. Tobacco consumption in the form of chewing and smoking is frequently seen in this study area hence 12% of study population in our study showed Tobacco consumption in some or the other formTable1.

We also calculated prevalence of DED in systemic illnesses Table 1 like Type 2 diabetes mellitus, hypertension and arthritis with dry eye was evaluated, 62% of the diabetic patients suffered from dry eye. This is quite high as compared to the dry eye prevalence in osteoarthritis (49%) and those suffering from hypertensive patients

(50%). Cataract extraction was the most common intraocular surgery undergone by study group 35%, of that 55% of patients had dry eye disease. Patients who had undergone surgery within the last 2 months were excluded from the study.We also studied the prevalence of dry eye among patients with meibomian gland disease. Twelve percent of the study population had blockage in meibomian glands, which were diagnosed on slit lamp examination. 92% of these patients had dry eye disease.

Sample also consisted of 5 % glaucoma patients who were on various topical antiglaucoma medications, out of which 70 % had dry eye.

We asked the patients regarding dry eye symptoms like burning sensation, watering in eye, excessive discharge etc burning sensation in the eye was the most common complaint 39%followed by watering 32%. Figure 1. A multivariable logistic regression analysis showed an association between dry eye prevalence and outdoor workers, participants working indoor using air conditioner, housewives, diabetics, patients who have undergone cataract surgery and those with meibomian gland dysfunction (MGD), Table II.

Table II: Multivariable logistic regression analysis showing association of dry eye.

Variable	P	OR	CI	
			Lower	Upper
Occupation				
Regular office worker	0.071	Reference category	-	-
Farmer/labour/ outdoor worker	0.036	2.13	1.13	4.029
Indoor worker with air conditioner	0.25	1.985	0.680	4.935
House wife	0.021	1.99	1.132	3.214
Previous ocular surgery				
(no/yes)*	0.090	1.589	0.992	2.667
Meibomian gland dysfunction (no/yes)*	0.00	18.283	4.589	89.91
Diabetes mellitus (no/ yes)*	0.002	2.182	1.467	3.999
Constant	0.002	0.446		

*First variable in parenthesis refers to the reference category.

OR : Odds ratio, CI : Confidence interval.

Discussion

Dry eye prevalence as estimated in this study is around 51.5 % in patients aged more than 40 years visiting the Outpatient Department at a Tertiary Care Center.in recent years there has been a substantial increase in the knowledge and understanding of dry eye disease. One major advance in the understanding of DED is the recognition of the two distinct parts of the disease tear evaporation and insufficient tear production and their roles individually or concomitantly in DED.[6] One more important realization that the thickness of the lipid layer might determine the stabilityof the tear film. As tear film instability is invariably seen in various stages of DED.[7,8]

Various epidemiological studies over the years have thrown light over many risk factors associated with DED such as increase in age and female gender particularly post menopause groups.DED in menopausal and postmenopausal can be attributed to the significantdecrease of tear production around the 6thdecade of lifein women.[9,10]

A study by Guillon et al.[11] have shown in Britain that the tear film evaporation is significantly higher in people aged more than 45 years.

The prevalence of dry eye disorder varies considerably as evident from the previous hospital as well as population- based studies. Studies have reported the prevalence of dry eye to be anywhere between 5% to as high as 73.5%.[12,13]

The International DEWS on its update stated that the global prevalence of dry eye is about 17% while several other studies show a higher prevalence of approximately 30% in people of Asian descent.[14] One study done by Miami and Broward Veterans Affairs eye clinics showed a prevalence of 22% DED in females compared to 12% in males.[15] A study done by Shah s et all showed prevalence of DED in patients aged more than 40 years of age to be 54.3%.[16] According to a study conducted in Korea, 33.2 percent of people are affected by DED.[17] The overall prevalence of dry eye in our study sample of patients aged 40 and over is 51.6% percent, which is significantly greater than that seen in other similar studies.This could be due to the impact of tropical weather in our study area, as well as other population features in the sample group. Daily wage workers and farmers and also outdoor labours showed high degree of DED in them (53.9%), it could be due to over exposure to sunlight and dry weather and it could also be due to lack of awareness regarding usage of protective goggles etc while working.Among diabetes patients, we observed a prevalence of 62% DED. This matches a research by Manaviatet al.[18] in Iran, which found that 54.3 percent of type 2 diabetic

patients had dry eye syndrome.The possible cause behind this could be the autonomic and sensory neuropathy occurring due to diabetes in lacrimal gland.[19] 70% of glaucoma patients had DED in our study, which could be attributed to harmful effects of preservatives like benzalkonium chloride etc epithelium of cornea.[3] 92% of patients who had meibomian gland disease had DED.According tothe definition of the International Workshop on MGD, MGD is a chronic and diffuse anomaly of the meibomian glands, generally characterized by terminal duct obstruction and/or qualitative/ quantitative changes in glandular secretion. This can lead to changes in the tear film, symptoms of eye irritation, clinically evident inflammation and disease of the surface of the eye.[20] Dry eyes have been observed in asymptomatic patients or in those with very few symptoms. We found that the prevalence of dry eye in asymptomatic patients is 24.1%.

There are many limitations to our study first and the foremost is the usage of fluorescein stain for TBUT instead of noninvasive BUT. As fluorescein is an irritant which can trigger the reflex watering in patients which testing for TBUT. Since our study was done in a tertiary care hospital it doesn't represent the overall community which might have different prevalence of DED.This study emphasizes the burden of Dry eye disease among routine OPD patients and need for careful evaluation and treatment irrespective of presence of symptoms. Very few studies are available in our region regarding DED. Although a similar study was conducted in the state of Rajasthan,using univariate analysis which on itself was a major drawback.[21] This reiterates the need for gathering more data regarding the extent of dry eye disease in our country. Millions of dollars are spent annually by Americans for DED as reported by a population based study done by LempMA[22] Le et al.[23] in a study done in Republic of china highlighted the various psychological effects as well as adverse effects on vision related quality of life in various DED patients.

Conclusion

A careful history taking and through clinical evaluation are the key factors in diagnosing this under reported disease. We need more extensive research and standard diagnostic criterion which are universally applicable for effective treatment and reduction in the disease burden in susceptible groups.

Financial Support and Sponsorship:Nil.

Conflicts of Interest: There are no conflicts of interest.

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