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Original Research Article

Clinical validation of artificial intelligence-based cataract screening solution with smartphone images (Logy AI cataract screening module)

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ABSTRACT

Background: Purpose of the study was to clinically assess the accuracy of Logy AI cataract screening solution, an artificial intelligence-based module, which works through WhatsApp and also as a separate smart phone application, that can detect cataracts using images taken by a smartphone camera, by comparing with slit lamp based diagnoses made by ophthalmologists.
Methods: A prospective clinical study was conducted in an eye clinic of a tertiary care hospital in the southern part of India with 437 patients. Smartphone images taken were sent to the Logy AI cataract screening solution which predicted if the patient had cataract or not. It graded cataracts as immature and mature. Patients were examined by ophthalmologists with slit-lamp and diagnosis was documented. Both were compared.
Results: 794 eye images were included in the study. The overall accuracy of the AI screening solution for cataract detection was computed to be 90.08%. Further, the accuracy was 88.02% for immature cataract, 97.16% for mature cataract, and 90.08% normal category. The sensitivity was 90.38%, the specificity was 89.87%, and the F1 score was 87.98%. The positive predictive value was 85.71% and the negative predictive value was 93.29%. Logy AI cataract prediction module's AUC (0.8946) falls under the good category.
Conclusions: Logy AI cataract screening module could work as an effective cataract screening tool at the community level in remote areas where there is no expensive equipment and ophthalmic health care workers considering the accuracy and efficiency to work in low resource settings. It can also be a good home screening tool suitable for the post-COVID era.

Keywords: Cataract, Artificial intelligence, Smartphone, Deep learning

INTRODUCTION

Blindness caused by cataracts was a major global health problem in the last century but was not recognized as such. In today's world, it is a greater problem that is better understood.[1] Cataract-related blindness is a major public health problem, especially in rural areas where there is limited access to eye care services.[2] In 2020, an estimated 2.2 million people were blinded by cataracts in low and middle income countries.[3] This number is expected to increase to 3.6 million by 2050 if there is a delay in diagnosis.[4] Conventionally, the diagnosis of cataracts is done by an ophthalmologist using a slit lamp. Mass community screening in remote areas and door-to-door screening could potentially aid in early diagnosis and decrease the burden on existing healthcare systems. This would aid in decreasing blindness by creating awareness and prompt referral. These are difficult with the conventional diagnostic method. Other methods like handheld portable slit lamps, smartphone attachments, fundus photos, and slit lamp images are being tried for this purpose.[5] But these require additional equipment which are not only costly but also require additional skills for screeners. Thus, there is an imperative need for novel methods to overcome existing limitations and revolutionize cataract detection to address the growing health burden related to cataracts.[6]

With the advancement of technology in computing and artificial intelligence (AI), such as machine learning (ML) and deep learning (DL), digital ophthalmology is likely to grow and expand by making existing resources more accessible, available, and productive.[7] AI is already being applied in the diagnosis of various ophthalmic diseases like diabetic retinopathy, glaucoma, and macular degeneration.[8-12] AI analysis of images captured from smartphones that do not require any external hardware can be useful as they are not only readily available in remote areas but also a cheaper alternative. Some researchers have tried to build a solution that uses luminance-based eye image analysis to detect cataracts based on images captured from a smartphone.[13]

Similarly, Logy AI has developed an artificial intelligence (AI) based model to detect cataracts using images captured by a smartphone camera. It uses free-hand images captured with the flashlight using a smartphone and internally runs deep learning algorithms on the captured images. These algorithms try to find patterns similar to the cataract eye on which the models are trained.

Logy AI cataract screening model

The working model of the Logy AI cataract screening solution is depicted in a flowchart in Figure 1. The Logy AI screening solution uses an ensemble of deep learning models with Convolutional Neural Networks (CNN) and other image processing techniques such as computer vision. CNN is a type of artificial neural network that helps in image/object recognition. To learn spatial hierarchies of features of the images or objects, the CNN system is designed to automatically and adaptively learn low-level patterns to higher-level patterns.[14] With the features extracted from the CNN layer as inputs, these features are sent to the dense layer classifier. Based on the inputs, the classifier generates the corresponding output probability. The Logy AI system is already trained on thousands of eye images so that it finds patterns similar to cataract eyes. In essence, it uses an eye image as an input, finds the required eye area, and then predicts the diagnosis (normal lens vs cataract) based on the lens opacity, cloudiness, and iris shadow. The model is trained using pytorch, torchvision, and pytorch lightning.[15,16]

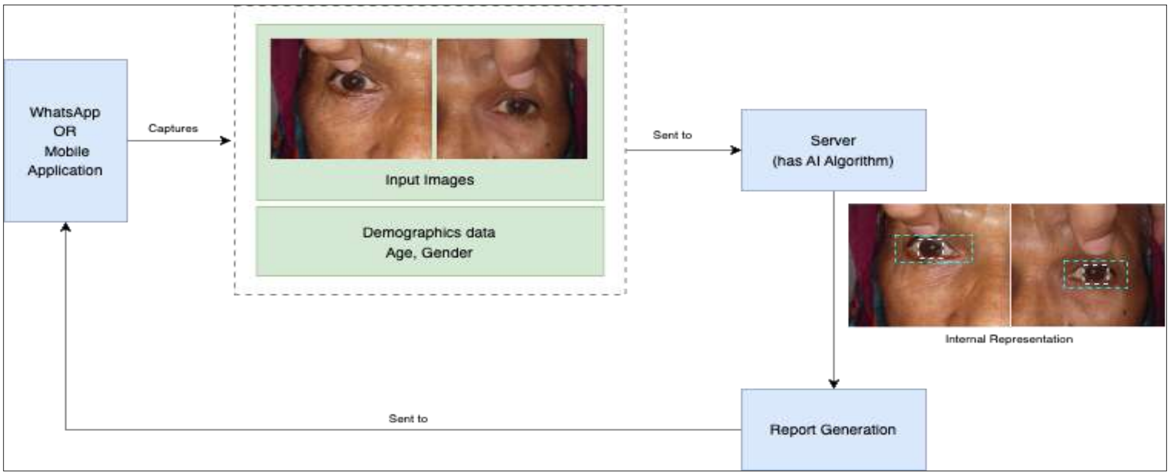

Figure 1: Logy AI cataract screening flow.

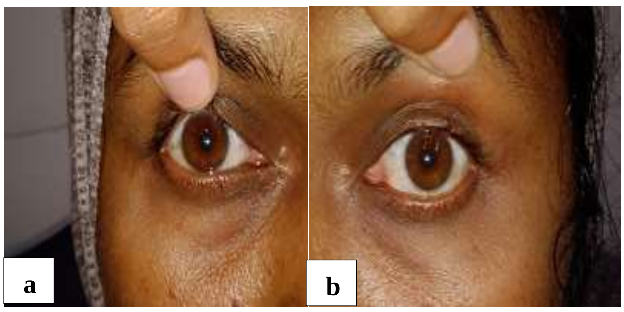

Figure 2: Sample (a) left and (b) right eye images sent to AI for cataract prediction.

The eye images are taken in such a way that they represent only the corresponding (left/right) eye and no other part.

Figure 2 shows sample images captured for both the left and right eye of a participant. To avoid any other type of reflection, the image is to be taken at 2X zoom and in a dimly lit room. AI suggests whether the image quality is optimal or not and then predicts whether the cataract is present or not only on optimal images. If the image is suboptimal, it can be retaken.

METHODS

Sample size calculation

Using the equation 1, a sample size of at least 284 patients/ 568 eyes was required to measure the diagnostic accuracy between Logy AI and senior ophthalmologists with no of diseased being 136 (272 eyes) and no of non-diseased being 150 (300 eyes); based on the expected accuracy of 90% in the AI arm and 95% in the senior consultant's arm, an 80% statistical power, and a 5% statistical significance level. The sensitivity of the study was 96.7%, while the precision was 3%. The estimated values of sensitivity and specificity are based on the findings of the pilot study that was conducted at the Sharp Sight Hospital on 100 patients (50 in each category). The pilot study aimed to validate the results between ophthalmologists and the Logy AI app. Assuming the confidence interval to be 95% and the prevalence of cataracts 47.5%, the sample size was calculated.[17]

$$N = \frac{Z^2_{\left(1-\frac{\alpha}{2}\right)} S_e (1 - S_e)}{d^2} \qquad (1)$$

Where N=sample size number, $Z_{(1-\alpha/2)}$ =Z score for given confidence interval, S_e=sensitivity, d=precision

Study design

A prospective, observational clinical trial was conducted to evaluate the accuracy of the Logy AI eye screening solution for cataract detection. The clinical trial was performed in an eye clinic of one of the leading hospitals in India. The consolidated standards for reporting trials (CONSORT) guidelines have been followed throughout the study.[18] The centre for this trial was Aster Speciality Hospital, located in Wayanad, Kerala in southern India. The trial took place for six months between May 2023 and September 2023. The study protocol was approved by the ethics committee and the institutional review board of Aster Hospital, Wayanad.[19] This trial is registered with ClinicalTrials.gov CTRI/2023/09/057602.

Method

A total of 437 patients were recruited from the eye clinic in India. All patients, attending the eye clinic, who were more than 45 years, were included in the study. First, written consent was obtained from the patients to capture their eye images for the AI prediction. Demographic details like name, age, gender, and images of the left and right eye were taken from the Redmi 9A smart phone with main camera (13 megapixel) by the two trained optometrists and sent to the WhatsApp-based Logy AI screening solution software that generates a unique identification number (ID) for each participant. Investigators and clinical staff at the hospital received standardized training before the study began. This data and the predictions given by AI for each eye were automatically stored in Google Sheets. AI predicted whether the eye image had a cataract or a normal lens. Intraocular lens (IOL) was also predicted as normal. Cataract was further graded as immature and mature cataracts. With a unique ID, the patient was then examined by three principal investigators of the study, who were all ophthalmologists. All three ophthalmologists have experience of 4-5 years in ophthalmology and examined each patient separately. Cataracts were manually examined by them using slit lamps with proper illumination and normal eye position. Whether the patient had cataract or not was noted down with their respective unique IDs. Cataracts were also graded by ophthalmologists as immature and mature. This data was later digitized. Once the data had been digitized, the diagnostic results of the AI and ophthalmologist were compared. Then the outcome measures were calculated.

Outcome measures

The primary outcome measure was the accuracy of the eye screening solution for normal vs cataracts. The secondary outcome measures were the sensitivity, specificity, precision, and F1 score of the eye screening solution and also to estimate the accuracy of grading provided by the AI solution.

These metrics are often used in machine learning to evaluate the performance of classification models. The choice of metric depends on the specific problem being solved. For example, if it is important to minimize false negatives (e.g., in medical diagnosis), then sensitivity may be a more important metric than accuracy. On the other hand, if it is important to minimize false positives (e.g., in fraud detection), then specificity may be a more important metric.

Statistical analysis

Descriptive statistics like mean, standard deviation, and frequency were used for analyzing the demographic data like age and gender. Interquartile range (IQR) was computed for continuous variables. The computed lower and upper bounds using IQR were used to detect outliers in the data. Statistics such as accuracy, sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV), and other similar stats were calculated along with their Clopper–Pearson 95% confidence intervals. Receiver operating characteristic (ROC) curves and area under the curve (AUC) were used to assess the model's predictive ability for different thresholds. Pandas, Scikit-learn, SciPy, and Numpy packages in the Python programming language were used to compare the results of AI predictions with those of the ophthalmologists' diagnoses.[20-22] For drawing histograms, curves, and other figures Seaborn and Matplotlib were used.[23,24]

RESULTS

Demographic data

Amongst the 437 patients recruited, 29 patients were not screened by ophthalmologists and 11 patients had suboptimal image quality. 397 patients were included of which 233 were females and 164 were males. The mean age of males and females combined is 61.2 years, and the respective means of age are 63.04 and 59.96 years. The

IQR on the combined age data is 17.0 [52.0-69.0], on male age data it is 15.0 [56.0-71.0] and on the female age data, it is 18.0 [50.0-68.0] with no outliers. The demographic distribution of age by gender is shown in Figure 3.

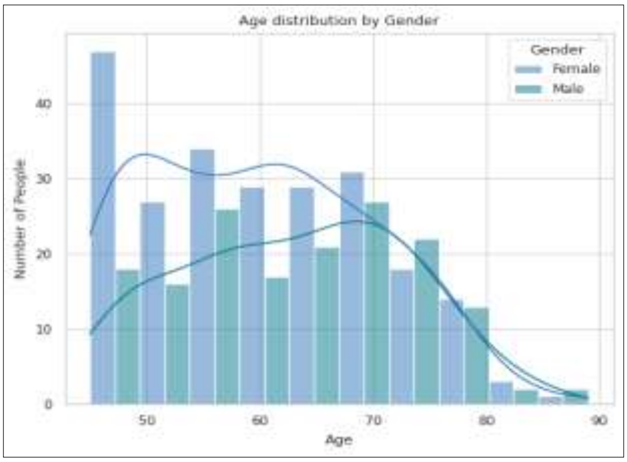

Figure 3: Histogram showing age distribution by gender.

Diagnostic data

18 of the 794 images the module said final verdict as can't say and hence were left out. 776 eye images were included in the final study analysis after exclusions. Of these, ophthalmologists diagnosed 312 eyes (40.20%) to have cataracts and 464 eyes (59.79%) to have either clear lens or intraocular lens (IOL). AI predicted 329 eyes (42.39%) to have cataract and 447 eyes (57.60%) to be normal. The module can only classify cataracts into immature and mature cataracts. It also predicts clear lens and IOL as normal. Further grading of cataracts to be immature and mature is as shown in Table 1.

Figure 4 shows how age increases the chance of getting a cataract. In the 45 to 55 years age group there are some cataract cases but their number is very low. However, as we progress towards age of 60 years, the frequency of cataract cases increases.

Accuracy

The overall accuracy of the AI screening solution for cataract detection was computed to be 90.08% [95% confidence interval (CI) 87.98-92.18%]. For grading, the accuracy was 87.63%. Further, the accuracy of the screening solution was 88.02% [95% CI 85.74-90.3%] for immature cataract, 97.16% [95% CI 95.99-98.33%] for mature cataract, and 90.08% [95% CI 87.98-92.18%] for normal category (clear lens and IOL). The accuracy of mature cataract is high but the sample size is very less compared to other classes. When accuracy was determined at the patient level for diagnosis of cataract it was 91.94% (397 patients).

Table 1: Data showing predictions of AI module and ophthalmologists' diagnoses by slit lamp.

Class type	AI predictions (%)	Ophthalmologist diagnosis (%)
Immature cataract	296 (38.14)	289 (37.24)
Mature cataract	33 (4.35)	23 (2.96)
Total cataracts	329 (42.39)	312 (40.20)
Normal and intraocular lens	447 (57.60)	464 (59.79)
Total	776 (100)	776 (100)

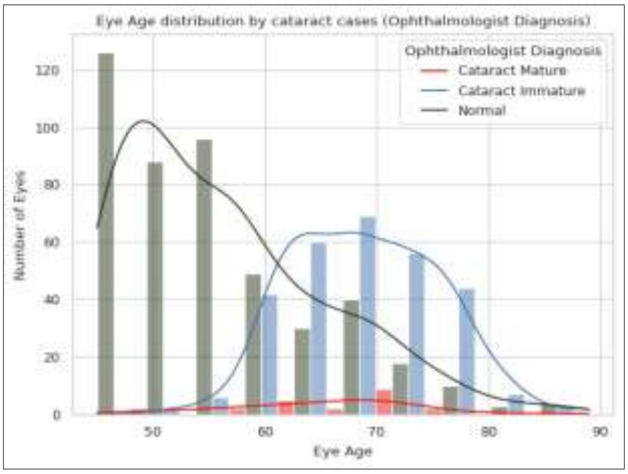

Figure 4: Eye age distribution by cataract cases (ophthalmologist diagnosis).

Other metrics

The sensitivity was 90.38% [95% CI 87.11-93.65%], the specificity was 89.87% [95% CI 87.12-92.62%], and the F1 score was 87.98%. The ophthalmologists and AI solution had an agreement in cataract diagnosis for 282 images and in the normal category, it was 417. Hence the positive predictive value was 85.71% [95% CI 81.93-89.49%] and the negative predictive value was 93.29% [95% CI 90.97-95.61%].

Figure 5 shows the confusion matrix in which 47 were falsely positive and 30 images were false negative. There was a mismatch in the verdict of 77 images between the ophthalmologist diagnosis and AI prediction.

Figure 6 shows the receiver operating characteristic (ROC) curve of the AI module which has an area under the curve (AUC) of 0.8946. The ROC curve is used to visually see the trade-off between sensitivity and specificity. If the curve is convex it means the model is performing well and if the curve is very near to the diagonal line (less convex) then the model is probably not good. For a diagnostic test to be meaningful, the AUC must be greater than 0.5. Generally, an AUC ≥0.8 is considered good while AUC ≥0.9 is considered excellent.[25] Logy AI cataract prediction module's AUC falls under the good category.

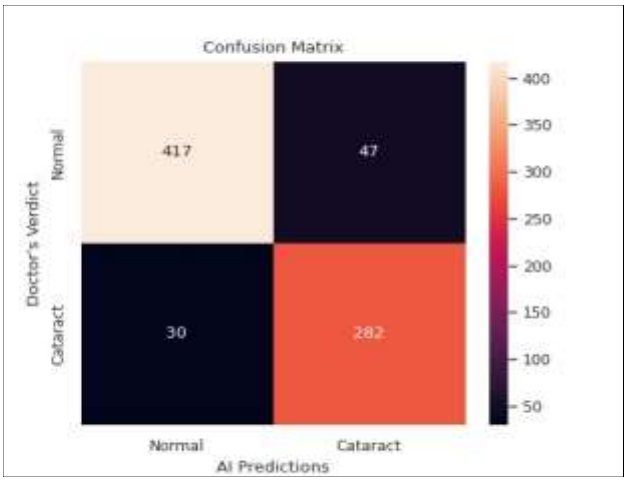

Figure 5: Confusion matrix with AI predictions and ophthalmologists' diagnoses.

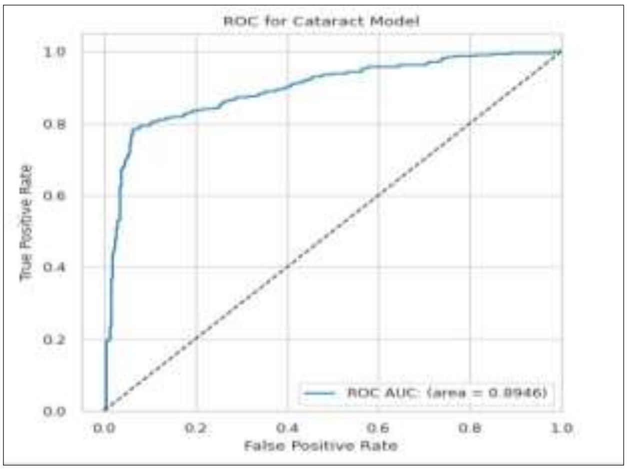

Figure 6: ROC curve of Logy AI cataract screening module.

DISCUSSION

Artificial intelligence is a reforming data-driven technology of modern times. AI is revolutionizing every field, from space, and science to healthcare. The use of AI in healthcare bridges the gap between doctors and patients. In the present work, the clinical study is done for the implementation of AI in the field of ophthalmology for cataract detection.[26] Cataract is the leading cause of blindness in the world, accounting for two-thirds of all cases. The main reason for cataract-related blindness is the delay in diagnosis.[27] Conventional means of detecting cataracts is by using slit lamps or fundus cameras, which are expensive and require a trained professional to operate.[28] Typically, these are used in hospital settings and are not portable. Since cataract is a growing health burden globally, novel approaches to cataract detection are needed to address existing limitations.[6] With the advent of AI technology to detect cataracts, it is possible to analyze digital images from the smartphone.[29] AI-based smartphone applications are an emerging research area with huge potential.

The above study evaluated the diagnostic efficacy of Logy AI smartphone-based AI application to detect cataracts without the need for ophthalmologists. It is a Whatsapp-based application that can be easily used on any smartphone. Additionally, it does not require any other installation. The accuracy of the Logy AI application is 90.08% with a sensitivity of 90.38% and a specificity of 89.87%. The area under the ROC curve was also good which makes it a good screening tool for cataract detection.

There is one other published literature on the e-parvai app which is a similar cataract detection application that has a higher sensitivity and lower specificity (25%) compared to Logy AI module.[29] It also showed a low performance in the normal category and mature cataracts. It also requires an additional installation of an application on the smartphone. Logy AI module has done away with the former's major drawbacks by having a better specificity (89.87%) and negative predictive value (93.29%) so that it can minimize the visits of patients to tertiary care centres thereby decreasing the burden. It also has a high accuracy in screening mature cataracts but the sample size was less in this study. Further studies with larger samples might be needed to address the screening of mature cataracts.

Several other studies have reported AI-based cataract screening solutions but they were all with slit-lamp and fundus images rather than with smart phones.[5] Hence this model which does not require any additional installation and also has good accuracy is a better model than the existing AI-based applications. Digital tele-screening solutions have the potential to address diagnostic, logistic, and operational challenges of healthcare facilities. Logy AI is a smartphone application that can be installed on most of the smartphones. Whatsapp is usually the preferred medium as it does not require any other external app installation. Logy AI Whatsapp-based model screens patients in less than two minutes and sends a report via Whatsapp. This technology is easily adaptable to low-resource settings such as community screening camps and healthcare facilities, such as primary healthcare centres and vision centres. With the help of the Logy AI solution, the initial screening can be done effectively at the primary level. The patients who are reported to be at high risk can further be transferred to higher tertiary care centres for evaluation and checkup by an ophthalmologist. Thus it is an easily accessible and cost-effective solution.

Furthermore, the Logy AI solution can be used as a home screening method to detect cataracts at an early stage. This home screening solution has even been adopted by some big hospitals across India such as Dr. Agarwals and Sharp Sight Hospital. This will decrease the primary delay in the detection and screening of cataracts. In the post-COVID era where we tend to reduce the number of hospital visits, this tool can serve as an ideal alternative for screening cataracts at home. Moreover, it will enable tele-ophthalmology and create a vista of opportunity for educational and research activities.

Limitations

Lesser samples in mature cataracts. Adequate zoom and lighting conditions were not followed for every image. Clear lens and intraocular lens were predicted as normal.

CONCLUSION

Logy AI cataract screening module could work as an effective cataract screening tool at the community level in remote areas where there is no expensive equipment and ophthalmic health care workers considering the accuracy and efficiency to work in low resource settings. It can also be a good home screening tool suitable for the post COVID era.

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Conflict of interest: None declared
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