

Diagnostic Accuracy of An Artificial Intelligence Based mHEALTH Intervention for Cataract Detection: A Multi-Center Prospective Study in Tamil Nadu, India

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ABSTRACT

Background: E-Paarvai is an AI-based mHealth initiative piloted in Tamil Nadu, which enables frontline health workers to screen for cataract using a smartphone camera. The study aims to evaluate the diagnostic accuracy and reliability of e-Paarvai for cataract detection in primary care settings.

Methodology: This prospective study was performed in 2022 in seven Upgraded Primary Health Centers across Tuticorin, India. Outpatients (age ≥ 50 years) without bilateral aphakia/pseudophakia, recruited by consecutive sampling, were each screened for cataract by e-Paarvai and an Ophthalmic assistant. Estimates of accuracy and reliability were reported along with their 95% confidence intervals (CI).

Results: Among 337 participants (674 eyes) included in the analysis, 55 (16%) had unilateral and 168 (50%) participants had bilateral cataract on clinical eye examination. E-paarvai had a sensitivity and specificity of 83% and 53% at the subject level and 73% and 70.3% at the eye level respectively. Assuming 65% prevalence for cataract, PPV was 76% and 82%, while NPV was 62% and 58% in the per-subject and per-eye analysis respectively. The test-retest agreement was substantial with Kappa of 0.63.

Conclusions: E-paarvai has an undeniable potential to improve detection and yield of cataract when implemented as a mass strategy in an eye care resource limited population.

Keywords: Accuracy, AI, artificial intelligence, cataract, e-Paarvai, mHealth

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INTRODUCTION

Blindness and visual impairment are increasing globally, alongside major non-communicable diseases, with over 2.2 billion people affected worldwide.¹ In India, the National Blindness and Visual Impairment Survey (2015–2019) reported a prevalence of blindness at 1.99% and visual impairment at 13.8% among individuals aged over 50 years, translating to more than 25 million people currently living with blindness.² Cataract remains the leading cause of avoidable blindness in this demographic, accounting for approximately 66% of cases.² Ophthalmologists and slit lamp cameras being very scarce resources in rural India, with the current ophthalmologist to population ratio in rural India at 1:250000,³ there is an enormous backlog in operable cataract.

Accessible and affordable low-cost innovations in tele-ophthalmology being the need of the hour, many AI based cataract screening systems are in the development and validation phase globally.^{4–8} However, most of these applications, notably the CC-Cruiser model used for childhood cataract detection in Chinese eye clinics,⁶ still rely on images from slit-lamps or fundus cameras; while other smartphone-camera based models require external device attachments,^{7,8} limiting their use in field settings. To fulfil this dire need for a scalable cataract detection model, the Tamil Nadu eGovernance Agency (TNeGA) in collaboration with National Health Mission in India has developed an AI-powered Android application called e-Paarvai in February 2021. E-Paarvai leverages artificial intelligence to equip frontline health workers to identify cataract in a person's eye using images captured from a smartphone camera. These free hand frontal eye images are analysed by the inbuilt AI model and results uploaded to a centralized dashboard at the district and state level which enables easy monitoring of the screening coverage and therapeutic follow up.^{3,9}

In keeping with the national campaign Rashtriya Netra Jyoti Abhiyan,¹⁰ which envisages to make India cataract surgery backlog-free, this telehealth initiative could potentially facilitate 100% screening of our above 50 population for cataract, especially in remote areas. The mHealth application is currently being piloted in more than 14 districts across the state.³ This study aims to estimate the diagnostic accuracy and test-retest reliability of e-Paarvai as a primary screening tool for cataract in the above 50 population in Tuticorin district of Tamil Nadu, India.

METHODOLOGY

Study design and Participant Recruitment: This is a multicenter, prospective cross-sectional study conducted in the district of Tuticorin in southern India in November 2022. The “Standards for Reporting Diagnostic accuracy studies” guidelines¹¹ have been followed in our study. The study was performed in

seven Upgraded Primary Health Centres (UPHC), which serve as the linkage between primary and specialist care. Outpatients reporting to above centers were considered potentially eligible for the study if they were more than 50 years of age. Bilateral aphakia/pseudophakia or a co-existing eye condition affecting anterior chamber visibility were the exclusion criteria.

Assuming sensitivity as 91%,³ prevalence of cataract as 48%,¹² absolute precision as 5% at 95% confidence level, after accounting for 20% indeterminate results, the required number of participants for analysis at the subject level was found to be 342; hence 350 was chosen as the study size. There are 12 Upgraded Primary Health Centres (UPHC) in Tuticorin, of which nine were considered feasible for the study based on the availability of qualified Ophthalmic Assistants in the centre. It was decided to choose as the study sites, seven UPHCs by simple random sampling out of the 9, and to recruit 50 study participants from each site to achieve the required sample size of 350. Outpatients fulfilling the eligibility criteria were recruited by consecutive sampling and a written informed consent was obtained at enrolment from each individual participant.

Application Development: The e-Paarvai application integrates a deep learning AI algorithm based on a 16-layer Convolutional Neural Network (CNN), optimized for image-based cataract detection. The training dataset was developed from scratch, comprising 700 frontal eye images, 540 with clinically diagnosed cataract and 160 with normal eyes. These images were acquired from hospitals across Tamil Nadu, and validated by Ophthalmologists. The application has three core components: the mobile app interface used for capturing images and screening, the AI model, and the web dashboard for real-time case tracking and management. The app has been designed to run on phones with Android 6 operating system and above. A trained health care worker can upload the captured image to a cloud database where it is analyzed using the pre-trained model, and results are made available instantly. The app allows uploading from the image gallery of the device; thereby facilitating screening in areas with poor Internet connectivity⁹.

Test methods: The investigative team at each centre comprised one qualified nurse (designated Mid-Level Healthcare Providers or MLHPs) and an Ophthalmic Assistant (OA) who held a two-year diploma with a minimum of 10 years of experience performing refractive and cataract screening cum referral services in primary and secondary care centres, schools and outreach camps, and assisting cataract surgeries. All team members were previously trained and involved in performing the study-related procedures as part of ongoing programmatic activities. In preparation for the study, the teams underwent a one-day standardized training session conducted by the Head, Department of Ophthalmology at the affiliated tertiary care center, who also served as the District Blindness

Control Officer, Tuticorin. The training combined lecture-based and hands-on demonstration components, reiterating the operational definitions (table 1), and standard protocols for performing the tests. At the conclusion of the training session, a small subset of participants (two from each cadre) was randomly assessed, to reinforce learning and ensure consistency in protocol implementation.

Outpatients more than 50 years were considered potentially eligible for the study; while, exclusion screening was integrated into the clinical examination phase. The index test, which is the e-Paarvai smartphone application, was used by the MLHPs to screen for cataract in both eyes of the participant and was repeated twice in each eye 5 mins apart. The test involved capturing an image of each eye separately using a smartphone camera with a flashlight, following which the app reported one of five pre-specified diagnoses for each eye: namely No cataract, Immature cataract, Mature cataract, Pseudophakia or Indeterminate. Pseudophakia and indeterminate test results were categorized as 'test negative' and included in the analysis. The outcome of the first trial was used for estimation of accuracy; however, it was discarded from app memory, before repeating the test for the second time. This ensured that the outcomes of the two trials were independent of each other and therefore, enabled estimation of test-retest reliability.

The reference standard involved a clinical eye examination by an Ophthalmic assistant to ascertain presence of lenticular opacity on torch examination and complete/part obliteration of red reflex on distant direct ophthalmoscopy. The presenting visual acuity with available correction and best corrected visual acuity were also recorded. The operational definitions used for classifying the cataract and visual impairment status of each eye, adapted from National Blindness and Visual Impairment Survey (2015-19)² and National Blindness Survey (2001-02)¹² is presented in Table 1. The performers of the index and reference tests were each masked to the outcome of the other test. This was operationalized by conducting the two tests in physically separate enclosures, such that there was no visual or verbal communication between test personnel. Additionally, the test results were disclosed to the participants only upon completion of both tests. Each test result was recorded independently on distinct proformas, and linked using unique participant IDs, for further analysis.

Statistical Analysis: Baseline demographic and clinical characteristics were analysed descriptively with estimation of frequency (percentages rounded off to 2 significant digits) and/or mean (SD) as appropriate. The primary outcome measured was the diagnostic accuracy of the index test, while the secondary outcome was test-retest reliability between two trials of the index test. Two approaches to analysis were used namely, per-subject and per-eye analyses with each participant or eye as the unit of analysis

respectively. For the per-subject analysis, we define 'cataract present' in a subject if cataract is present in either eye, and 'test positive' in a subject if the test is positive in either eye. For the per-eye analysis, both eyes of eligible participants are included and inter-eye correlation, if any, is ignored while performing analysis at the eye level.

Measures of diagnostic accuracy such as Sensitivity, Specificity, False positivity and negativity rates were estimated by cross tabulation of outcome of trial 1 of the index test, and reference standard. Using sensitivity and specificity estimates, likelihood ratios for positive (LR+) and negative (LR-) tests were estimated; and applying anticipated cataract prevalence rates to sensitivity and specificity estimates yielded the positive and negative predictive values. Test-retest reliability was assessed by percentage agreement between two trials of the index test and Kappa statistics. All estimates are reported with their 95% confidence intervals calculated by relevant approaches.^{13,14} Normal approximation method was used for arriving at CIs for sensitivity, specificity, false positivity and negativity rates and reliability estimates; CIs were obtained by log method for likelihood ratios, while standard logit confidence intervals were reported for predictive values. All statistical analyses were performed with SPSS (version 23; SPSS, Inc., Chicago, IL, USA) with the exception of estimation of likelihood ratios and predictive values, for which MedCalc (version 22; MedCalc Software, Ostend, Belgium) was used.

Ethical Approval: The study was approved by the Institutional Ethics Committee, Directorate of Public Health and Preventive Medicine, Chennai (DPHPM/IEC/2022/044, Date of Approval: 15.10.2022)

Table 1: Operational Definitions

Variable	Operational definition
Cataract	Presence of a visible lenticular opacity partially or completely obliterating the red reflex
No Visual Impairment	Presenting visual acuity $\geq 6/12$ in the better eye with available correction
Early Visual Impairment (EVI)	Presenting visual acuity $< 6/12$ but $\geq 6/18$ in the better eye with available correction
Moderate/Severe Visual Impairment (MSVI)	Presenting visual acuity $< 6/18$ but $\geq 3/60$ in the better eye with available correction
Blindness	Presenting visual acuity $< 3/60$ in the better eye with available correction
Immature cataract	Greyish white lens with partial obliteration of red reflex on distant direct ophthalmoscope
Mature cataract	Pearly white lens with complete obliteration of red reflex on distant direct ophthalmoscope and associated with MSVI or blindness in same eye
Operable cataract	Cataract associated with MSVI/Blindness in same eye

*Adapted from National Blindness and Visual Impairment Survey (2015-19)² and National Blindness Survey (2001-02)¹²

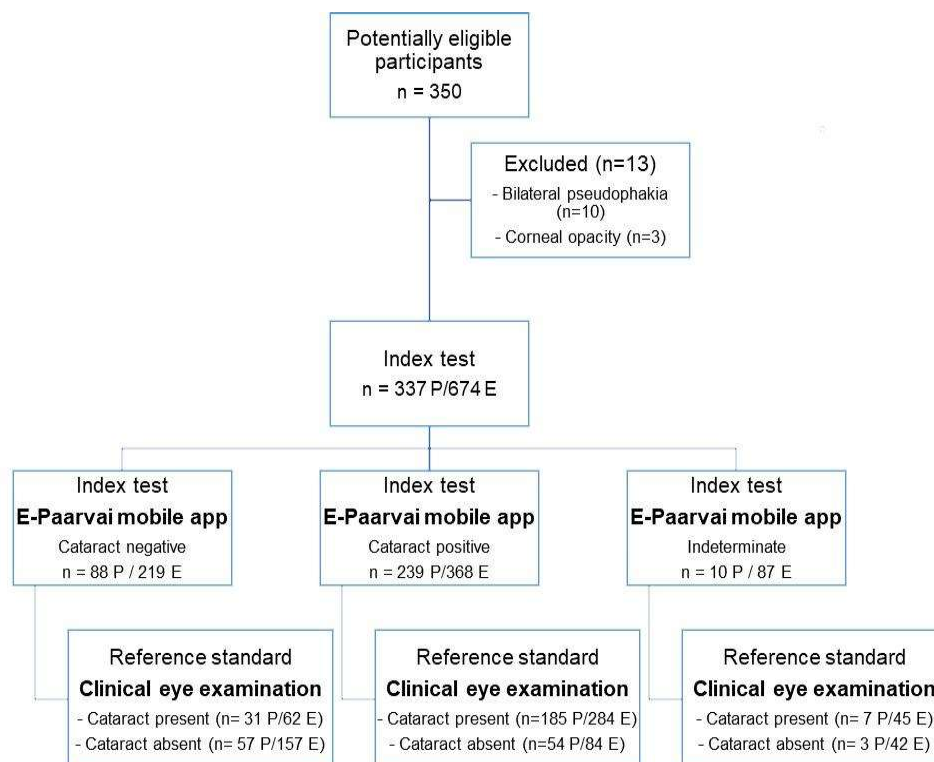


Figure 1: Flow of Study Participants

RESULTS

Between November 1 and November 30, 2022, 350 participants were screened for eligibility, out of whom 13 were excluded and 337 participants (674 eyes) were included in the analysis. The flow of study participants is shown in Figure 1. Baseline demographic and clinical characteristics of the 337 subjects including age, sex, cataract status, history of co-existing eye condition or previous eye surgery is reported in Table 2. The age of the study participants ranged from 50 to 90 years with a mean \pm SD of 60.4 ± 8.4 years. The male to female ratio in the study population was 1:2. Among the 337 subjects, 223 patients (66%) had cataract in either eye based on clinical eye examination, including 55 (16%) unilateral and 168 (50%) bilateral cataracts.

The cataract and visual impairment classification of the diagnosed participants/eyes is reported in Table 3. Among the 674 eyes tested, a total of 360 (53%) immature and 31 (4.6%) mature cataracts were identified. In case of bilateral cataract, the subject was assigned the cataract classification of the worse eye, whereas for visual impairment, by definition, the visual acuity of the better eye is considered at the subject level. In 62/223 (28%) participants and 165/391 (42%) eyes, cataract was associated with moderate to severe impairment or blindness, falling under the category of 'operable cataract'.

The agreement in cataract status from e-Paarvai mobile application and clinical eye examination is shown in Table 4 for subject level comparison and Table 5 for an eye level comparison. Clinical eye examination achieved a definitive diagnosis as per the

operational definition for all subjects. Unilateral pseudophakia was identified in 47 subjects/eyes and these eyes were categorized as 'cataract absent' for the purpose of estimation of accuracy. Similarly, the first trial of e-Paarvai reported pseudophakia in 54 (8%) eyes and indeterminate results in 87 (13%) eyes; they were included for analysis as 'cataract negative'. The frequency of indeterminate results, when considering both trials of the index test, reduced to 38 (5.6%) eyes.

Table 2: Baseline demographic and clinical characteristics of study participants (n=337)

Variables	Participants(%)
Age in years	
50 – 59	163 (48)
60 – 69	118 (35)
70 – 79	46 (14)
≥ 80	10 (3)
Sex	
Male	107 (32)
Female	230 (68)
Comorbidity	
Hypertension	99 (29)
Diabetes mellitus	84 (25)
Ischemic Heart Disease	11 (3)
Presence of cataract	
Yes	223 (66)
No	114 (34)
Coexisting eye condition	
Glaucoma	3 (0.9)
Retinal detachment	1 (0.3)
Pterygium	1 (0.3)
History of previous eye surgery	
Unilateral lens removal with IOL implantation	47 (14)
Pterygium excision	1 (0.3)

Table 3. Clinical profile of the study participants/eyes with cataract as assessed by the reference standard (n=223 P/391 E)

Variables	Per-subject analysis (n=223) (%)	Per-eye analysis (n=391) (%)
Presence of cataract		
Unilateral	55 (16)	391 (58)
Bilateral	168 (50)	
Severity classification		
Immature	195 (58)	360 (53)
Mature	28 (8.3)	31 (4.6)
Visual impairment (VI) classification		
No VI	133 (60)	175 (45)
Early VI	28 (13)	51 (13)
Moderate / severe VI	55 (25)	124 (32)
Blind	7 (3.1)	41 (10.5)

The estimates of diagnostic accuracy and their corresponding 95% CIs are reported in Table 6. Sensitivity and specificity of e-Paarvai for cataract diagnosis are 83% and 53% at the subject level, and 73% and 70.3% at the eye level respectively. Among eyes with

immature and mature cataract, e-Paarvai identified presence of cataract in 261/360 (72%) eyes and 23/31 (74%) eyes respectively. However, e-Paarvai was more likely to assign a diagnosis of immature cataract to both categories; 260/261 (99.6%) immature and 20/23 (87%) mature cataracts identified by clinical examination were classified as immature cataract by e-Paarvai. Of the 124 and 41 cataractous eyes with associated moderate to severe visual impairment (MSVI) or blindness, e-Paarvai diagnosed cataract in 94 (76%) and 33 (80%) eyes respectively. Pseudophakia was correctly identified by e-Paarvai in 29/47 (62%) eyes. The diagnostic accuracy at the eye level with and without inclusion of indeterminate results was (483/674) 71% and (483/587) 82% respectively.

Table 7 gives the predictive values for a positive and negative test at the subject and eye level for various anticipated prevalence. In Table 8, it is seen that the two trials of the index test were in agreement in the assigned outcome in 520/674 (77%) eyes, with Kappa of 0.63 (95% CI: 0.58 – 0.68, $P < 0.001$).

Table 4. Cross tabulation of cataract status from e-Paarvai app and Clinical eye examination: Per-subject analysis (n=337)

E-Paarvai - Cataract status in left eye/right eye	Clinical eye examination - Cataract status in left eye/right eye				Total
	Present/Present	Present/Absent	Absent/Present	Absent/Absent	
Positive/Positive	100	3	1	25	129
Positive/Negative	30	19	0	19	68
Negative/Positive	17	1	14	10	42
Negative/Negative	21	10	7	60	98
Total	168	33	22	114	337

Table 5: Cross tabulation of cataract status from e-Paarvai app and Clinical eye examination: Per-eye analysis (n=674 eyes)

E-Paarvai app - cataract status	Clinical eye examination - cataract status		
	Present (%)	Absent (%)	Total (%)
Positive	284 (73)	84 (30)	368
Negative	107 (27)	199 (70)	306
Total	391	283	674

Table 6: Diagnostic accuracy of e-Paarvai mobile application for cataract detection

Test parameter (%)	Per-subject analysis (n=337)			Per-eye analysis (n=674)		
	N	Estimate	95% CI	N	Estimate	95% CI
Sensitivity	223	83	78 - 88	391	73	68 - 77
Specificity	114	53	43 - 62	283	70.3	65 - 76
False positivity rate	114	47	38 - 57	283	30	24 - 35
False negativity rate	223	17	12 - 22	391	27	23 - 32
Positive Likelihood Ratio	337	1.75	1.43 - 2.14	674	2.45	2.02-2.96
Negative likelihood Ratio	337	0.32	0.23 - 0.45	674	0.39	0.33-0.47

Table 7. Predictive Values of e-Paarvai mobile application for detection of cataract at various prevalence

Assumed Prevalence of cataract	Per-subject analysis (n=337)		Per-eye analysis (n=674)	
	Positive predictive value (95% CI)	Negative predictive value (95% CI)	Positive predictive Value (95% CI)	Negative predictive Value (95% CI)
45%	59 (52 - 65)	79 (70 - 87)	67 (62 - 72)	76 (71 - 80)
50%	64 (57 - 70)	76 (66 - 84)	71 (66 - 76)	72 (67 - 77)
55%	68 (62 - 74)	72 (62 - 80.3)	75 (70 - 79)	68 (62 - 73)
60%	72 (66 - 78)	67 (57 - 76)	79 (74 - 83)	63 (58 - 68)
65%	76 (71 - 82)	62 (52 - 72)	82 (78 - 86)	58 (52 - 64)

Table 8. Percentage agreement of outcomes of two trials of index test at eye level (n=674)

Trial 1 of index test	Trial 2 of index test, n (%)					Total
	No cataract	Immature cataract	Mature cataract	Pseudo-phakia	Indeterminate	
No cataract	129 (78%)	26	0	2	8	165
Immature cataract	20	310 (85%)	2	7	25	364
Mature cataract	0	1	3(75%)	0	0	4
Pseudophakia	5	5	0	40 (74%)	4	54
Indeterminate	13	34	1	1	38 (44%)	87
Total	167	376	6	50	75	674

DISCUSSION

In this study, we showed that e-Paarvai mobile health application exhibits 83% sensitivity and 53% specificity for cataract detection in routine primary care settings. The subject-level sensitivity was higher (83% vs 73%) and the specificity lower (53% vs 70%) than when the test accuracy was assessed per eye. This can be reasoned bearing in mind that a subject is assigned 'cataract present/positive' status if he/she is diagnosed with or tested positive for cataract in either eye, as would occur in real world practice settings, where referral would be warranted irrespective of whether a test is positive in one or both eyes. As cataract is frequently a bilateral phenomenon, with 82% subjects showing inter-eye agreement in cataract status from clinical eye examination (Table 4) in this study, the subject-level approach is entirely appropriate. The per-subject approach results in pragmatic estimates of accuracy, while the eye-level analysis reflects the true diagnostic efficacy of e-Paarvai in identifying cataract from an image of the eye. For the purposes of this study, to infer the effectiveness of e-Paarvai as a public health intervention for improving cataract detection at the field level, accuracy estimates at the subject level may be considered.

The frequency of a diagnosis of cataract among participants in the study was 66%. This may not reflect the true prevalence in the above 50 population in the community, as a cohort of outpatients are more likely to have multiple comorbidities. As estimates of PPV and NPV depend on the prevalence of the underlying condition in addition to intrinsic accuracy of the test, estimates of prevalence sourced from other studies were used to calculate the predictive values. The prevalence of cataract in Tamil Nadu varied across studies, ranging from 48% to 62.8%.^{12,15,16} Hence, we calculated the PPV and NPV and their 95% CIs under the assumption of prevalence of cataract ranging from 45% to 65%.

When the prevalence was 45%, the PPV was low (59%) and NPV was relatively higher (79%) at the subject level. However, when the prevalence was 65%, estimates of PPV (76%), and NPV (62%) showed an absolute increase or decrease of 17% respectively. When the same prevalence of cataract ranging from 45% to 65% and the eye-level sensitivity and specificity were used to calculate eye-level PPV and NPV, PPV showed a modest increase, whereas the NPV values were only marginally less

than those from subject-level analysis. Likelihood ratios for e-Paarvai, calculated using both approaches, were modest at best, with a positive or negative test increasing or decreasing the odds of someone having cataract by approximately 2:1 or 1:3 respectively. The test-retest reliability was substantial with a Kappa of 0.63, which was statistically significant at $p < 0.001$. However, utility of e-Paarvai as a sole detection tool for cataract in remote settings is limited by the high proportion of indeterminate results (13%) and modest accuracy estimates observed.

It is observed that the diagnostic accuracy in field conditions is less (82% vs 91%) compared to that reported with eye image datasets by the developer.³ This may be due to various reasons, including uncontrolled lighting conditions, camera resolution or orientation, distance of the camera from the eye, interference from eyelids/eyelashes. Some of these are expected limitations of free hand eye images taken at the field level, without providing a chin rest as in eye clinics.⁵ Recent state-of-the-art studies conducted elsewhere utilize a portable slit lamp device attached to the smartphone camera to produce high quality images with accuracy estimates above 95%.^{7,8} Studies using the smart phone camera without any external device, similar to the current study, were found to be less accurate, with estimates ranging from 85% to 90%.^{5,17} During analysis, we found that, excluding the indeterminate results produced better accuracy estimates. In the real-world context, since having an indeterminate result translated to 'no further action', we decided to retain them as 'test-negative'; this needs to be considered, when comparing accuracy estimates across studies.

Since the completion of this study, two relevant publications have emerged. The first assessed Logy AI, a smartphone-based cataract detection tool using a similar AI algorithm, which demonstrated 90% sensitivity and specificity. However, it was tested in a private tertiary eye clinic in Kerala, limiting its comparability to primary care contexts.¹⁷ The second study independently evaluated e-Paarvai but was conducted at a specialist eye care centre among patients over 40 years old with best corrected visual acuity $< 20/40$. This created a disease-enriched sample with a 90% cataract prevalence, resulting in inflated sensitivity (96%) and PPV (92%) estimates.¹⁸ These figures are potentially misleading and not generalizable to primary care or outreach settings.

A multicenter RCT in Chinese eye clinics (2017–18)

evaluated an AI platform for pediatric cataract detection using slit lamp images, reporting sensitivity, specificity, PPV, and NPV of 90%, 86%, 74%, and 95%, respectively. The AI also provided faster diagnoses than human doctors (2.8 vs 8.5 minutes), with higher patient satisfaction.⁶ Most earlier studies only classified eyes as having or not having cataracts. A 2020 study went further, reporting classification accuracies of 60% for normal eyes, 95% for immature cataracts, and 63% for mature cataracts, similar to trends observed in the current study, where immature cataracts were most accurately identified.⁵

Tamil Nadu faces a significant cataract surgery backlog, with only 2.5 lakh cataract surgeries performed annually, against a target of 5 lakh.⁹ To screen the estimated 1 crore individuals aged 50 and above, the 10000+ non-specialist frontline healthworkers, including Mid-level healthcare providers and Women Health Volunteers engaged under the Universal Health Coverage scheme, can be mobilized, for achieving near-total coverage in a year's time. Aside from modest costs for server hosting and maintenance, the system requires no recurring expenditure; and significantly reduces the time and travel burden on patients and eye-care providers in existing programmatic settings. Future research should focus on refining AI algorithms to improve detection of cataracts in uncontrolled illumination settings, where pupil size may vary. Data from the dashboard on referral completion and surgical uptake rates can be leveraged to assess the impact of AI-enabled screening pathways on blindness prevention.

STRENGTH AND LIMITATIONS

To our knowledge, this is the first evaluation of the e-Paarvai application in a primary care field setting. The strengths of the study include the index test being tested in its intended setting, in the hands of its intended users, thereby appropriately evaluating the real-world diagnostic performance of e-Paarvai. The study setting and large sample size ensured adequate representativeness of the target population, across the disease spectrum. Further, complete verification of all subjects by the reference standard, with masking, precludes other intrinsic biases, namely verification and review bias.

However, this study has some limitations. The clinical eye examination performed by an experienced ophthalmologist using a slit lamp biomicroscope remains the gold standard for diagnosing cataract. In our study, the reference standard used was suboptimal, and this may have led to missed diagnoses. As with most accuracy studies relying on imperfect reference standards, the accuracy estimates of the index test may be negatively biased. Misclassification of diseased subjects, correctly identified by the AI-based app but missed by ophthalmic assistants, as 'false positives' could result in an underestimation of the app's specificity. Using the Staquet et al correc-

tion method, the degree of this potential bias in specificity can be estimated based on the assumed sensitivity of the reference standard.¹⁹ Assuming a high but imperfect sensitivity of the reference standard, ranging from 95% to 100%, the corrected specificity of the index test would range from approximately 57% (at 95%) to 53% (at 100%), indicating a maximum potential negative bias of about 4 percentage points. These adjusted values account for the likely misclassification introduced by the suboptimal reference and provide a more accurate reflection of the AI system's true diagnostic performance. Furthermore, in the eye-level analysis, the correlation between the two eyes of the same individual was not accounted for, potentially resulting in narrower confidence intervals, as has been previously observed.^{20,21}

CONCLUSION

e-Paarvai represents a low-cost, technology-enabled, and scalable solution for population-based cataract screening. It is particularly relevant in developing countries like India, where a shortage of eye care specialists and slit lamps, especially in rural areas, hamper timely diagnosis. At its current stage of development, e-Paarvai can effectively support the efforts of Ophthalmic Assistants by enabling large-scale, time-sensitive screening. With ongoing refinements to its algorithm and more robust field level validation, e-Paarvai could evolve into an 'appropriate technology' for primary eye care in resource-limited settings.

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Authors' Contributions: SSG was involved in all stages of the study design, data acquisition, analysis, manuscript preparation, editing and final approval. DV, KR and PS contributed to the conceptual design and planning of the study, manuscript editing and approval. DV and KR also contributed to the training and supervision of study teams.

Availability of Data: Data is not available in the public domain. Available on request to the corresponding author.

No use of generative AI tools This article was prepared without the use of generative AI tools for content creation, analysis, or data generation. All findings and interpretations are based solely on the authors' independent work and expertise.

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