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Detection of Posterior Segment Eye Disease in Rural Eye Camps in South India: A Non-Randomized Cluster Trial

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Abstract

Purpose: Rural screening camps in India have historically focused on detection of cataract and uncorrected refractive error. This study aimed to increase detection, referral, and follow-up for posterior segment diseases (PSD) in rural eye camps using a novel technology-driven eye camp model.

Design: A clustered non-randomized trial in the catchment area of Aravind Eye Care System (AECS) —Pondicherry to compare two eye camp models, the traditional AECS eye camp and the novel, technology-driven, eye camp models.

Participants: Patients aged 40–75 years who attended free camps conducted by AECS– Pondicherry. Those with corneal pathology were excluded since this precluded an adequate view to the posterior segment to screen for PSD.

Methods: The clinical protocols in the two arms were standardized and the same study team was used in both study arms. The unit of allocation to the two study arms was at the level of the eye camp rather than the level of the individual study participant.

Main Outcome Measures: The primary study outcome was detection of suspected PSD (glaucoma, diabetic retinopathy, age-related macular degeneration, other PSDs). Secondary outcomes included: i) the proportion of referred participants who received an exam at the base hospital and ii) the proportion with confirmed PSD upon exam at the base hospital.

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Results: The study included 11 traditional and 18 novel eye camps with a total of 3,048 participants (50% in each study arm). The mean age of all participants was 58.4±9.1 years and 1434 (47%) were male. The proportion receiving a referral for PSD was significantly greater in the novel (8.3%) compared to the traditional (3.6%) eye camps (p<.001; RR=2.31 [95% CI 2.30–2.34]). Among the 183 participants referred from the camps for PSD, 73 (39.9%) followed-up for further evaluation at the base hospital.

Conclusions: In a resource-constrained setting, use of digital fundus photography in novel eye camps resulted in increased detection and referral of PSD. Follow-up rates at the base-hospital remained low and future interventions may be undertaken in an effort to address this. Further research is needed to determine whether this intervention is cost-effective and may contribute to prevention of avoidable blindness and visual impairment in south India. Further research is also needed to improve follow-up of patients referred from camps for suspicion of PSD.

Precis

In a resource-constrained setting in South India, the use of digital fundus photography, an electronic medical record, handheld slit lamps, and rebound tonometry in a novel eye camp model resulted in increased detection and referral of posterior segment disease.

Introduction

The Aravind Eye Care System (AECS) is one of the largest non-governmental eye care service providers in the world with a catchment area that includes the Indian states of Tamil Nadu and Kerala, the bordering districts of Andhra Pradesh and Karnataka, and the Union Territory of Pondicherry. Among adults age 50 and older in India, the prevalence of moderate to severe vision impairment is 22.2% and the prevalence of blindness is 2.9%.¹ To address the high prevalence of eye disease in India, Aravind's hub-and-spoke model of care allows for expansion of eye care services from the base hospital through screening camps, city center clinics, and community-based vision centers.²

ACES performs eye camps on a regular basis to provide free screening examinations and to identify patients who would benefit from further specialized eye care. Many individuals, especially those living in rural areas, may only access eye care through these camps and are deeply reliant on the hospital's outreach efforts to meet their eye care needs. Those who are identified as needing surgery are brought to the base hospital with little or no cost to the patient through the National Programme for Control of Blindness in India.^{3,4} Aravind Pondicherry typically conducts 300 eye camps per year, 25–30% of which have been novel eye camps in recent years. Most camps occur from February to September, while during the other months, monsoons and festivals limit the number of camps. The locations of Aravind Pondicherry's eye camps are depicted in Figure 1.

While for many years, refractive and cataract-related vision impairment have been efficiently identified and managed through AECS screening camps, other causes of vision loss, especially in earlier stages, may not have been detected as consistently in this setting. In fact, a situational analysis in 2017 suggested that only 1% of patients seen at eye camps were referred for diseases of the posterior segment (unpublished internal data). However,

Schehlein et al.

prior studies have reported that the prevalence of glaucoma is 2.6–2.7% in adults living in rural communities and 3.23% in urban communities in India. In 2016, the prevalence of diabetes among adults in Tamil Nadu (the state surrounding the Union Territory of Pondicherry) was 13.1%.⁵ The prevalence of diabetic retinopathy (DR) among people with diabetes in south India is 20%⁶, though only about 7% of those with diabetes have had an eye exam.^{6,7,8,9} Posterior segment diseases (PSD) like glaucoma and DR are common causes of irreversible blindness in India and globally.¹⁰ The importance of detecting these largely chronic, non-communicable diseases is likely to increase further as the population ages and cataract and refractive coverage continues to improve.

Traditionally, AECS eye camps have utilized basic instrumentation to examine the anterior segment of the eye and measure intraocular pressure, with paper medical records used in an effort to maximize throughput of patients². Camps have been organized in this way due to constraints in time, rural outreach facilities, limited clinical providers, transportation, and environmental constraints. However, new methods of diagnostic technology may provide the opportunity to more effectively screen individuals for disease. Digital fundus photography has been successfully utilized in the large healthcare organizations in the US, such as the Veterans Administration for ophthalmic screening¹¹ and is gaining traction in other countries¹². In order to address the problem of under-detection of PSD in eye camps, this trial was designed to test a novel eye camp model that incorporated the use of rebound tonometry, portable slit lamps, digital fundus photography, and an electronic medical record (EMR) in an effort to increase PSD case detection and follow-up rates.

Methods

Trial Design

We conducted a non-randomized cluster trial to compare two models of eye care delivery, referred to as the *traditional* and the *novel* eye camp models. The unit of allocation to the two study arms was at the level of the eye camp rather than the level of the individual study participant. Cluster allocation was used to avoid ethical problems associated with offering different interventions at the same camp, to streamline eye camp efficiency, and to avoid confusion among patients and study coordinators about study protocol and data entry. The protocol was approved by the institutional review board of AECS–Pondicherry and was prospectively registered in the Indian Clinical Trials Registry (CTRI/2019/05/019422). Results of this study are reported in accordance with Consolidated Standards of Reporting Trials (CONSORT) guidelines.

The clinical protocols in the two arms were standardized and same study team was used in both arms. Appendix 1 presents the screening protocol used in each arm. Eligible participants in both groups were given or read a form in the local language which explained the purpose of the study. Written consent was obtained from all participants (thumb prints for illiterate patients). Participants did not receive any compensation. The study was conducted over a period of four months from June to September 2019. There was a window of one month after a referral was made to determine whether a participant had followed-up at the eye hospital. This time frame was chosen since internal data indicated that the rate of follow-up was very low after 1 month.

Participants

Participants were included if they were aged 40–75 years and attending free camps conducted by AECS–Pondicherry. Those with corneal pathology were excluded since this precluded an adequate view to the posterior segment to screen for PSD.

Interventions

The protocol for the two study arms is depicted in Appendix 1. In the traditional eye camp study arm, patients were registered at the start of the camp and informed consent was obtained from all who agreed to participate. Registration consisted of questions (Appendix 2) about any ocular complaints, past medical history, and past ocular history, in addition to demographic information. Participants then passed through different stations of the camp. First, visual acuity was measured with a wall-mounted Snellen visual acuity chart. Intraocular pressure was then measured with a Schiotz tonometer. If an individual complained of epiphora, they underwent dilation and irrigation of the puncta. An ophthalmologist then performed an anterior segment examination with a penlight. Those who had diabetes underwent pupillary dilation prior to seeing a trained ophthalmologist who performed direct ophthalmoscopy. Dilation was also performed in cases where the ophthalmologist did not find that anterior segment findings (e.g., cataract) accounted for the measured visual acuity. Those who required refraction were refracted using retinoscopy and provided with spectacles assembled at the campsite. Participants who required surgery were transported to the main hospital. When the physician suspected PSD based on a dilated fundus examination, the patient was provided verbal and written instructions to follow-up at the main hospital. If the patient did not present to the hospital within one week of their referral, study coordinators contacted them by phone once in the first week and once in the second week after the referral.

In the novel eye camp study arm, participants were registered using the EMR system and informed consent was obtained. The EMR system was a modified version of the EMR used in AECS hospitals and vision centers. The EMR collected the same demographic, medical, and ocular history data as the paper charts in the traditional study arm. At the beginning of each camp, provisional local Wi-Fi networks were established to facilitate the use of mobile devices (e.g., laptops and tablets) needed to implement the electronic system.

After registration, visual acuity was measured with a wall-mounted Snellen visual acuity chart. Punctal dilation and irrigation was performed for those with epiphora. Intraocular pressure was measured with iCare rebound tonometry (iCare USA, Raleigh, NC), and participants had their eyes dilated and fundus photographs were obtained with a handheld fundus camera (Fundus Imaging Module, Bosch Eye Care solutions, Bangalore, India). All participants underwent pupillary dilation except in cases where an advanced cataract precluded a view of the fundus. Next, the physician examined each participant with a handheld slit lamp (Model AIA, Appasamy Associates, Chennai, India) and reviewed the fundus photographs in the EMR. The physician at the campsite determined if the participants had findings suspicious for PSD. Refractive errors and the need for surgery were handled in the same manner as in the traditional camps.

Referable PSDs were identical for both study arms and included age-related macular degeneration (AMD), DR, glaucoma, optic neuropathies, retinal vascular occlusions, and other miscellaneous PSD. If the individual had many macular drusen or evidence of a choroidal neovascular membrane, they were referred for AMD. Those with DR were referred if they had proliferative DR or moderate to severe non-proliferative DR. Referral criteria for suspicion of glaucoma were based on The International Society of Geographical and Epidemiologic Ophthalmology (ISGEO) criteria¹³: cup to disc ratio (CDR) 97.5% of the population distribution (CDR 0.7), or focal notching of the neuroretinal rim (width reduced 0.1 CDR), in addition to disc hemorrhage. Patients with anatomically narrow angles and those suspected of having had vascular occlusions and other optic neuropathies were also referred. All examination, diagnosis, and treatment recommendations were recorded in the EMR. Distance to each camp was determined by measuring the most common route to each location (e.g., the route taken by the camp teams).

Outcomes

The primary study outcome was the proportion of participants receiving a referral for suspected PSD. Secondary outcomes included: i) the proportion of referred participants who received an exam at the base hospital and ii) the proportion with confirmed PSD upon exam at the base hospital.

Sample size

Sample size was calculated using pilot data collected at AECS Pondicherry eye camps prior to initiation of this study. In these pilot data, 5% of participants in novel camps were referred for PSD compared to 1% in traditional camps (mean number of participants was 264 in each pilot camp). Sample size was calculated to detect a difference in PSD prevalence of this magnitude between study arms with 80% power and two-tailed error (α =0.05), while assuming an intraclass correlation coefficient of 0.1. Based on these inputs, the clusterPower package in R version 3.5.3 (Vienna, Austria) determined a target of 29 clusters.

Study Arm Allocation

All individuals attending a selected cluster who enrolled in the study were included. Nonrandomized allocation of camps to the two study arms was undertaken for two reasons. First, some camps did not have facilities that would allow for set-up of a mobile WiFi network, a necessity in the novel camps. Second, since a larger number of participants were enrolled in each traditional camp, additional camps were allocated to the novel arm in order to recruit an equivalent number of participants into each study arm. Recruitment ceased once the target number of eye camps was reached.

Statistical methods

All continuous variables were described as means and standard deviations or medians and interquartile ranges (IQR), while categorical variables were described as counts and percentages. Visual acuity was converted to logarithm of minimal angle of resolution (logMAR) for statistical analyses. The better eye was determined based on the presenting visual acuity and the right eye was used for analyses if both eyes had the same visual acuity.

Schehlein et al.

The cluster sampling was accounted for using the type of eye camp as the primary sampling unit and using specialized survey statistics (*svy* command) in STATA 12.1 (StataCorp, Fort Worth, Texas, USA). Generalized linear models were used to compare referrals for overall PSD and for specific PSDs between the traditional and the novel camps and the risk ratio (RR) and 95% confidence interval (CI) in unadjusted analysis were reported. Group differences in means and proportions between the two types of eye camps were also calculated using the survey specific statistics. P = 0.05 was considered statistically significant and all statistical tests were two-tailed.

Results

A total of 3048 patients were included in the study. On average, 139 participants were enrolled in each traditional camp and 85 in each novel camp. The final sample included 18 camps in the novel camp arm and 11 camps in the traditional arm, with 1,524 participants enrolled in each arm. Figure 2 provides complete details on recruitment of the study sample. The mean age of all participants was 58.4 ± 9.1 years and 1434 (47%) were men.

A comparison of baseline demographic and clinical characteristics between individuals in the two study arms is shown in Table 1. A greater proportion of participants in the traditional camps reported having been diagnosed with an eye problem in the past (34% vs 11%, p<0.001), which was predominantly cataract (n=668, 97%). Significantly more participants in the novel camp had a history of diabetes (18% vs 15%, p=0.03), hypertension (18% vs 14%, p=0.007), using spectacles (18% vs 14%, p=0.003), and lived further from the base hospital in Pondicherry (98.2 \pm 27.4 km vs. 78.3 \pm 19.4 km, p=0.002).

Table 2 shows a comparison of anterior segment characteristics from the better-seeing eye in participants in each study arm. Participants were more likely to receive a referral for anterior segment disease in the traditional compared to novel (57% vs 51%, p<0.001). Presenting visual acuity was about three letters worse on the eye chart in the traditional camps (0.56 [0.41] vs 0.50 [0.40], p=0.01). Abnormal lens findings, including cataract, aphakia, decentered intraocular lenses, and posterior capsular opacification were also slightly more common in the traditional compared to novel camps (76% vs 74%, p=0.04).

Overall, across both study arms, suspected PSD was detected in 183 participants (6.0%). A significantly greater proportion of participants in the novel (n=128 [8.3%]) compared to traditional camps (n=55, [3.6%], p<0.001) received a referral for suspected PSD, which resulted in a RR of referral for PSD in the novel camp of 2.31 (95% CI 2.30–2.34). Additionally, glaucoma, AMD, and other PSDs were identified significantly more frequently in the novel camps, though there was no significant difference in the proportion of study participants referred for DR (0.9% vs 1.1%, p=0.72) (Table 3).

Among the 183 participants referred from the camps for PSD, 73 (39.9%) followed-up for further evaluation at the base hospital. Though a slightly greater proportion of participants from novel camps (n=56 [44%]) arrived at the base hospital compared to the traditional camps (n=17 [31%]), this difference was not statistically significant (p=0.42). However, after adjustment for distance of eye camps from the base hospital, participants referred

from the novel eye camps for suspected PSD were 74% more likely to arrive at the base hospital for evaluation (RR=1.74, 95% CI=1.73–1.76). Greater than 90% of those who were referred from the eye camps and evaluated at the base hospital for suspected PSD received a confirmatory diagnosis of at least one PSD; this finding was similar across both study arms (traditional camp 94% vs novel camp 91%, p=0.52). Since the number of participants who followed up at the base hospital after a referral for PSD was too small to adjust for study design factors, a secondary protocol analysis including only those who adhered with referrals was not performed.

The total average time from set-up to breakdown of a traditional camp was 5 hours and 11 minutes, as compared to 6 hours and 53 minutes for a novel camp.

Discussion

In a resource-constrained setting in south India, use of digital fundus photography, rebound tonometry, portable slit lamps, and EMR increased referral for suspected PSD compared to traditional methods of screening for eye disease. Specifically, glaucoma, AMD, and other PSDs (e.g., retinal vascular occlusions, non-glaucomatous optic neuropathies) were identified and referred more frequently in the novel eye camps. There was no difference in the rate of referral for DR, likely because all individuals with diabetes underwent dilated fundus examination regardless of study arm.

This study used digital fundus photography to detect suspected PSD, which may have significant value particularly in underserved settings, where access to high-quality eye care is otherwise scarce¹⁴. Applying these findings to high-income countries, there may be a role for similar approaches to detect undiagnosed PSD, including in rural and underserved communities.¹⁵ For example, in the United States, more than 50% of glaucoma may be undiagnosed,^{16, 17} a public health problem that could benefit from innovative and technologically-driven solutions. Some pilot programs at the United States Veterans Administration have already shown promise in this area.¹¹

It is important to recognize the added costs in the novel eye camp study arm, including the digital fundus cameras, rebound tonometers, internet enabled devices, and internet connection. Additionally, the novel camps lasted about 1.5 hours longer than the traditional camps. This was likely due to the extra time needed for dilation, fundus photography, and any delays caused by loss of electricity or wireless internet that may have temporarily precluded access the EMR. Ongoing work is being conducted to determine the value – that is, the incremental benefit relative to the added costs – of the novel eye camp model.

We anticipated a significant difference in the proportion of participants adhering to referrals between study arms, a secondary outcome of the study. However, such a difference was only detected after adjusting for the distance of eye camps from the base hospital. Since patients attending novel camps traveled, on average, farther to reach the base hospital this may have acted as a barrier to adherence with referrals for some participants. After adjustment for the distance of camps from the base hospital, participants in the novel camp arm were in fact 74% more likely to follow-up for care. Due to use of the EMR in this

study arm, we were readily able to track adherence with referrals. Still, follow-up after referral for PSD remained low in both study arms (<50%), possibly because of the lack of perceived visual symptoms early in the course of some of these ocular conditions.¹⁸ Future investigations may consider whether additional interventions, for example, showing patients ocular pathology on their retinal photographs could result in improved follow-up.

It is important to note that participants with diabetes were only referred if they were noted to have moderate to severe non-proliferative or proliferative DR. Those with mild disease were counseled at the camp and advised to return to an AECS camp or vision center at a specified follow-up interval (for example, one year for mild non-proliferative diabetic retinopathy). In the future, artificial intelligence may provide a means for high-throughput and accurate screening for DR using digital retinal photographs like those acquired in our study.¹⁹

There were several limitations to this study. First, the study was conducted in south India by a very experienced eye care team and these factors may limit the generalizability of the study to other settings or eye care delivery systems. Additionally, if participants in one study arm had more experience accessing the healthcare or eye care system, this could have biased results. This study was designed as a pragmatic clinical trial wherein referrals for suspected PSD were made based on the judgement of the treating ophthalmologist. However, the aforementioned criteria for referable PSD were used to guide referrals at all camps in this study. Importantly, the same team of ophthalmic assistants and physicians staffed the traditional and novel eye camps. Of note, there was no significant difference detected in the proportion of study participants referred for DR (0.9% vs 1.1%, p=0.72) (Table 3). This is likely due to the existence of specific DR camps – patients who have attended a DR camp in the past may be less likely to attend a general eye camp.

There were, however, several significant differences at baseline between the traditional and novel eye camps. There was a significant difference in history of ocular disease - more participants in the traditional camp had prior disease than the novel camp (34% vs 11%, p<0.001). We anticipate that there may have been additional PSD in both study arms that was not detected due to cataracts obscuring the view of the fundus, however this may have been reflected to a greater degree in the traditional arm where cataract was more commonly seen. Additionally, only those with diabetes or those with anterior segment findings (e.g., cataract) that did not account for the measured visual acuity were dilated in the traditional camp. All participants were dilated in the novel eye camp, and it is possible that dilation alone could contribute to the detection of additional PSD. We acknowledge that the novel camp model had multiple differences from the traditional camp (rebound tonometry, EMR, portable slit lamp, and fundus photography). However, fundus photography likely had the largest impact on the study outcome since referral criteria were almost entirely based on fundus features. Finally, the 29 clusters included in this trial yielded a smaller number of patients than projected based on preliminary data; as a result, the study may have been somewhat underpowered even though we detected a highly significant difference between study arms for the primary outcome.

In conclusion, this study evaluated the use of technologies such as an EMR, digital fundus photography, rebound tonometry, and portable slit lamps to increase detection of PSD

in eye camps in rural south India. This non-randomized cluster trial demonstrated that, compared to traditional eye camps that are largely focused on the detection of cataract and uncorrected refractive errors, a novel, technologically-enabled eye camp can increase the detection of PSD. India is home to more people with vision impairment and blindness than any country in the world.¹ Given population growth and aging, the number affected by vision problems in India is projected to grow considerably over the coming decades, while non-communicable, chronic PSDs are expected to account for a growing proportion of the burden of vision impairment and blindness.¹⁰ Solutions to improve the detection of PSD in India and in other resource-constrained settings are needed in order to reach populations that may be at risk for under-diagnosis of potentially blinding and visually impairing eye diseases.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

Acknowledgments

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Schehlein et al.

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Schehlein et al.

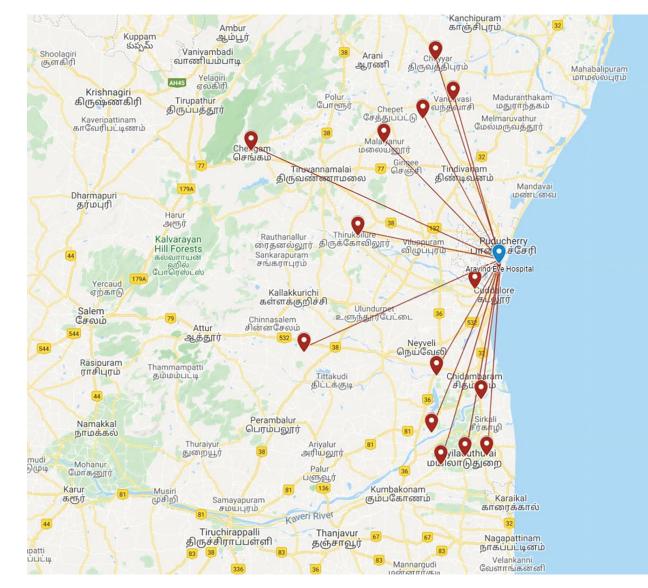


Figure 1: Aravind Pondicherry Eye Camp Locations

Schehlein et al.

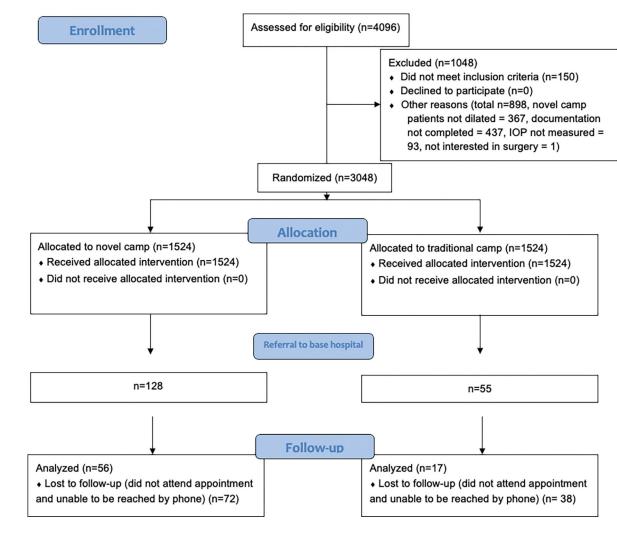


Figure 2: CONSORT Flow Diagram

Table 1:

Comparison of demographics and self-reported ocular and systemic illness between participants in the traditional and novel camps

Characteristic	Traditional camp (n=1524)	Novel camp (n=1524)	P value
Age (years)	58.3 ± 9.1	58.4 ± 9.2	0.71
Women	793 (52%)	821 (54%)	0.31
History of ocular disease	517 (34%)	171 (11%)	<0.001
History of glaucoma	3 (0.2%)	3 (0.2%)	0.99
History of diabetic retinopathy	9 (0.6%)	6 (0.4%)	0.44
History of AMD	1	1	0.99
History of cataract	505 (33%)	163 (11%)	<0.001
History of systemic illness ^a	407 (27%)	435 (28%)	0.26
History of diabetes ^b	234 (15%)	278 (18%)	0.03
Duration of diabetes	5.15 ± 4.2	4.63 ± 4.5	0.14
History of hypertension ^b	217 (14%)	272 (18%)	0.007
Duration of hypertension	3.84 ± 3.4	3.78 ± 3.3	0.76
History of cardiac illness ^b	16(1%)	20 (1.3%)	0.50
History of asthma ^b	31 (2%)	21 (1.4%)	0.21
History of wearing glasses	220 (14%)	281 (18%)	0.003
Using glasses for near	83 (38%)	74 (26%)	0.01
Using glasses for distance	51 (23%)	64 (23%)	
Using glasses for both	86 (39%)	142 (51%)	
Distance from base hospital (km)	78.3 ± 19.4	98.2 ± 27.4	0.002

 a Chronic illnesses such as diabetes, hypertension, cardiac disease, lung disease

b Includes patients with multiple illnesses

Table 2:

Comparison of anterior segment characteristics in the better eye between participants in the traditional and novel camps

Variable	Traditional camp (n=1524)	Novel camp (n=1524)	P value
% Right eye	1056 (69%)	1025 (67%)	0.23
Presenting visual acuity (logMAR)	0.56 ± 0.41	0.50 ± 0.40	0.01
Intraocular pressure	12.1 ± 3.8	12.4 ± 3.7	0.07
Abnormal Lids	10 (0.6%)	7 (0.5%)	0.46
Abnormal conjunctiva	50 (3%)	46 (3%)	0.68
Abnormal cornea	21 (1.3%)	23 (1.5%)	0.76
Abnormal pupil	53 (3.5%)	44 (3%)	0.35
Abnormal lens	1160 (76%)	1110 (74%)	0.04
Dilated exam	101 (6.6%)	808 (53%)	<0.001
Referral for anterior segment pathology	876 (57%)	775 (51%)	<0.001

Table 3:

Comparison of posterior segment pathologies detected in the traditional vs. novel campsites. N(%)

Diagnosis at campsite	Traditional camp	Novel camp	P value
PSD ^a	55 (3.6%)	128 (8.3%)	<0.001
Glaucoma	17 (1.1%)	46 (3%)	<0.001
Diabetic retinopathy	14 (0.9%)	17 (1.1%)	0.72
AMD ^b	1 (0.1%)	15 (0.9%)	0.001
Others	24 (1.6%)	53 (3.5%)	0.001
Arrival at base hospital	17 (31%)	56 (44%)	0.42
Pathology confirmed at base hospital	16 (94%)	51 (91%)	0.52

^aPSD: posterior segment disease.

^bAMD: age-related macular degeneration