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Cluster Randomized Trial to Compare Spectacle Delivery Systems at Outreach Eye Camps in South India

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Abstract

Purpose—To study the optimal method for delivery of spectacles at eye camps to maximize procurement and use.

Methods—A cluster randomized controlled trial, undertaken in the catchment districts of Aravind Eye Hospital – Theni, in the state of Tamil Nadu, India. Community eye camps ($n = 21$) were allocated to offer one of three types of service for purchase of spectacles to correct refractive error: (1) Issuance of a prescription only; (2) booking orders for spectacles with subsequent delivery; (3) on-the-spot fitting and dispensing of spectacles. Follow-up questionnaires were administered 6 weeks after interventions to assess patient outcomes. The primary outcome measured was spectacle procurement at follow-up 6 weeks post-screening. Secondary outcomes included use of and satisfaction with spectacles. Reasons for purchase/non-purchase were also assessed.

Results—Compared to those who were issued only a prescription and adjusting for distance from base hospital, spectacle procurement was significantly higher for those allowed to book spectacles for subsequent delivery (odds ratio, OR, 8.79, 95% confidence interval, CI, 4.61–16.78) and for those receiving spectacles on the spot (OR 13.97, 95% CI 8.12–24.05). Among those with spectacles at 6 weeks, spectacle use was nearly universal and satisfaction with spectacles varied between 92 and 94% among the three different dispensing modalities.

Conclusion—Making spectacles available on the spot is important to ensure procurement in a context where availability and access to dispensing opticians is poor.

Keywords

Eye camp; India; outreach; refractive error; spectacle dispensing; spectacles

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Introduction

Across the globe, an estimated 153 million people are visually impaired due to uncorrected refractive error. It is the leading cause of correctable blindness and visual impairment worldwide.¹ With the World Health Organization reporting that upwards of 90% of those with visual impairment reside in developing countries,² it is imperative for eye care delivery mechanisms to address the unique challenges in this context. Correction of refractive error can be effected by means of spectacles, contact lenses, and keratorefractive surgery. Of these, spectacles are the most affordable and the easiest to dispense and distribute.³ Previous studies have shown that some reasons for low procurement of corrective services include inadequate access to refractive services and lack of affordable corrections.^{4,5}

In India, the most common means of receiving refractive services is to approach either a hospital that provides ophthalmic care or an individual optician who dispenses spectacles. Access to these services in rural areas is relatively limited. While outreach eye camps are now a well-accepted and widely adopted outreach strategy their main emphasis has been to provide cataract services, and for those in need of refractive correction only a prescription for spectacles is provided.^{4,6,7} The outreach program at Aravind Eye Care System (AECS) has evolved to include dispensing spectacles at the campsite with the aid of a spectacle sales person and a technician who fits the lenses.⁸ The cost of spectacles provided starts from a minimum of 150 Indian rupees (INR; US\$3.30).

Although comprehensive programs offering refractive screening and spectacle provision have been shown to be cost-effective compared to screening programs alone, the optimal method for delivering treatment services has not been assessed.^{9,10} The Aravind Eye Hospital – Theni, a 150-bed eye hospital serving a population of 1 million across three districts in two states (Kerala, Tamil Nadu),¹¹ is part of the broader AECS, which is the largest individual provider of eye care services in Southern India, performing 269,577 surgeries and seeing 2,455,948 out-patients in 2009.¹²

This paper reports the results of a randomized community intervention trial of outreach eye camps conducted by AECS to assess the effectiveness of three delivery models in the uptake of spectacles.

Materials and Methods

Camp and Patient Eligibility Criteria

The study took place at outreach eye camps organized and run by the Aravind Eye Hospital, Theni within the Theni district. Camps were excluded on the basis of the following criteria: (1) if the expected attendance of outpatients exceeded 500 persons; (2) if free spectacle distribution was being offered by a third party sponsor; or (3) if it was a specialty eye camp (such as camps specifically focusing on refractive services, pediatric services or diabetes screening, which are targeted towards different population groups). Using permuted-block randomization, the eye camps were assigned to one of three methods of delivering spectacles to patients diagnosed with refractive error:

- **Arm 1, prescription only:** Patient received a prescription for spectacles, no spectacle dispensing services were offered.
- **Arm 2, booking order (with subsequent delivery):** Patient received a prescription and placed an order for spectacles, choosing from a range of frames at the campsite. Delivery was made typically within a week, either through the mail (which cost an additional 50INR) or delivered to the closest Aravind Vision Centre (primary eye care centers).
- **Arm 3, on-the-spot delivery:** Patient received the prescription and could place an order for spectacles by choosing from a range of frames at the campsite. The lenses were fitted and delivered on the spot.

Individuals between the ages of 20 and 70 years, who were diagnosed with refractive error and issued spectacle prescriptions, were considered eligible for the study.

Ethics approval for the protocol was obtained from the AECS Institutional Review Board. Written consent was obtained from the patients before enrolling them in the study.

Intervention

All eye camps followed AECS standardized eye camp protocols for patient flow, diagnostic techniques, general patient assessment, and estimation of refractive error. In brief, patient intake and registration was handled by a camp volunteer, measurement of visual acuity was performed by a paramedic, and a preliminary examination was conducted by a post-graduate or fellow. Following this, refraction using a Snellen chart, intraocular pressure measurement, and duct examination were performed by a paramedic. For patients aged 40 years and older, the paramedic also took a blood pressure measurement. Thereafter a final examination was performed by a medical officer. All patients at each camp proceeded through these checkpoints in the same order. At final evaluation, a medical officer issued spectacle prescriptions for patients found to have refractive error starting from ± 0.5 diopter (D) sphere or ± 0.5 D cylinder for both eyes.

All patients receiving prescriptions were administered a baseline questionnaire by the field staff who were trained in questionnaire administration and familiar in its usage. Six weeks after the camp, field staff visited patients who received a prescription, in their homes and administered a follow-up questionnaire to assess procurement of spectacles, compliance and factors mediating the decision to obtain spectacles (or not). The same staff administered the questionnaires at all the camps and the follow-up visits.

All outcomes were assessed at the individual patient level. The primary outcome was defined as procurement of spectacles (either through these camps, where available, or on their own) within 6 weeks. Secondary outcomes (assessed by questionnaire at follow-up) were use of spectacles at follow-up, satisfaction with spectacles ("Are you satisfied about your vision after wearing the spectacles?"), and total out-of-pocket expenses for purchasing spectacles.

Sample size

Based on an initial pilot study, we estimated purchase rates of 52% among patients receiving prescriptions only and 72% among patients receiving on-the-spot delivery. In the absence of comparable benchmarks for an expected intra-cluster correlation coefficient (ICC), we assumed a conservative ICC of $\rho = 0.02$. We assumed an average of 20 patients with refractive error per eye camp. Under these assumptions, we anticipated a power of 80% to detect a difference of 20% between the control and intervention arms at $\alpha = 0.05$ with seven eye camps randomized for each intervention arm. Figure 1 explains the enrollment of camps in each arm and the subsequent patient enrollment.

Statistical Analysis

Generalized linear mixed models with 2-level hierarchy (patient and eye camp) were used to assess variability in baseline characteristics across intervention arms. Separate models were run for each baseline characteristic. Random effects logistic regression models were used for dichotomous variables. Continuous variables were evaluated with linear mixed models, and categorical variables were assessed using random effects multinomial logistic regression. In each model, the intervention group was included as a fixed effect. For the analysis of spectacle procurement, use, and satisfaction, population-level odds ratios (ORs) were determined with general estimating equations using an exchangeable correlation matrix. We conducted an adjusted analysis in which a baseline covariate for working status was included.

All p values and 95% confidence intervals (CIs) were calculated with 2-tailed tests at an $\alpha = 0.05$ significance level. Statistical analyses were conducted using SAS statistical software version 9.2 (SAS Institute Inc, Cary, North Carolina).¹³

Results

Participants

From June 2009 to September 2009 (the defined study period), Aravind Eye Hospital, Theni conducted 35 outreach eye camps in Theni district. Of these, 21 eye camps fit our inclusion criteria and were randomized to one of three intervention arms (two camps were excluded because subsidized reading glasses were offered at the request of the camp sponsor; 12 eye camps were excluded as they offered specialty services.) Among the 21 eye camps (seven camps randomized to each arm), 568 participants were found to have correctable refractive error, of whom, 455 participants fell within the predefined age range of 20–70 years (197 in Arm 1, 132 in Arm 2, and 126 in Arm 3). Adjusting for clustering effects, most baseline characteristics did not differ significantly among the three allocation arms (Table 1), although differences in working status approached borderline significance ($p = 0.063$) and mean distance from base hospital was significant ($p < 0.001$). Some patients already wore glasses (13.2% in Arm 1, 14.4% in Arm 2 and 13.5% in Arm 3), and were only offered a new prescription if their presenting visual acuity at distance or at near had changed. At the time of the 6-week follow-up visit, four patients (0.9% of total) could not be located and were considered lost to follow-up (three patients in Arm 2, and one patient in Arm 3).

Spectacle Procurement

Spectacles were purchased by 243 patients; 49 (24.9%) in camps offering prescription only, 95 (73.6%) in camps booking orders, and 99 (79.2%) in camps offering on-the-spot delivery (Table 2). The crude analysis indicated that the booking order arm and on-the-spot delivery arm, relative to the prescription-only arm, had increased odds of spectacle purchasing (OR 8.30, 95% CI 4.39–15.70, and OR 11.51, 95% CI 7.87–16.86, respectively). Adjustment for mean distance from base hospital strengthened these results (OR 8.79, 95% CI 4.61–16.78 and OR 13.97, 95% CI 8.12–24.05, respectively; Table 2). Presenting distance visual acuity did not affect procurement of spectacles (Table 3).

Use and Satisfaction

Among the 243 camp patients who purchased spectacles, at follow-up, 239 reported wearing spectacles. These included 100% of those who procured spectacles in Arm 1, 99% of those in Arm 2 and, 97% of those in Arm 3 (Table 4).

Among purchasers, 93.9% of prescription-only patients, 94.6% of booking order patients, and 92.7% of on-the-spot delivery patients reported being “completely satisfied” with their spectacles. No significant difference in satisfaction across the arms was noted (Table 4).

Tables 5(A and B) present, by allocation arm, reasons why spectacles were not purchased within 6 weeks post-screening for those who were working and those who were not working, respectively. The primary reason for non-purchase, for each of the three delivery models, was financial.

Discussion

When patients proactively seek care at hospitals and are willing to pay for screening, they are usually willing and prepared to procure prescribed spectacles. The uptake of such patients at hospitals with an in-house optical shop may be considered to be the highest. The procurement of spectacles in the hospital based spectacle shop at Aravind Eye Hospital, Theni is 97%. In comparison to this, the on-the-spot delivery arm showed good procurement at 79.2%.

While all of Aravind's outreach camps regularly offer on-the-spot delivery of spectacles, for the purpose of this study, camps were organized into one of three delivery methods. Our exclusion criteria aimed to include a study population typical of those served by eye camps served by AECS and by other eye care outreach programs globally.

Patients found to have correctable refractive error and advised to acquire spectacle correction at eye screening camps were found to be more likely to procure spectacles if spectacle dispensing services were provided as part of the outreach services, either as on-site spectacle fitting or subsequent delivery, and were available at a reasonable price. This immediate access to spectacles enables patients to comply with the prescribed refractive correction, which could otherwise be postponed due to poor access to dispensing opticians and the additional cost involved.

In the on-the-spot delivery arm, of those who had purchased spectacles within the 6 weeks follow-up, 85% had purchased at the campsite. In this arm, 75% of the spectacles ordered were dispensed on the spot, the remaining were delivered subsequently by mail or through the local primary eye care center. This was either because the patient did not have enough money to pay the full cost of the spectacles or the prescription was not available in the inventory of lenses and had to be made to order.

Once spectacles were acquired, the mode of delivery did not affect secondary outcomes of follow-up use and satisfaction with spectacles.

At Aravind, it has become routine practice to offer on-the-spot spectacle dispensing services at its outreach camps. AECS conducts a significant number of camps in the state (1334 eye camps were conducted between January and December 2011, 316,718 patients were screened and 59,152 spectacles dispensed), and routinely announces the availability of affordably priced glasses for sale at eye camps as part of the prescreening camp publicity. Thus, patients often come to these camps prepared to purchase eye glasses if they are needed. For this reason, procurement rates in our camps may be higher than they would be for providers offering spectacle delivery for the first time at screening camps in their region.

In our experience, for every 25 spectacles dispensed at a screening camp, the team required two additional staff. One staff member provided the patient with necessary details and answered questions, helped the patient choose a frame, and booked the spectacle order. The second staff member served as a dispensing technician who edged and fitted the lenses in the chosen frame. The dispensing team was expected to carry a sufficient selection of frames to satisfy local tastes and an adequate inventory of lenses appropriate for the frames. As a rule of thumb, a reasonable inventory to accommodate between 80% and 85% of prescriptions, was approximately 10 times the number of expected orders (e.g. for 25 orders, it would be 250 pairs of lenses). Orders requiring lenses for rarer prescription powers needed to be made to order and therefore required booking with subsequent delivery at a later time (approximately 1 week).

To our knowledge, this is the first randomized trial to assess the effectiveness of various spectacle delivery modalities in resource-constrained settings. Previous research on cataract eye camps showed treatment costs as well as indirect costs to be significant predictors of treatment.^{14–17} Indirect costs include barriers such as time, lost income, and limitations in daily activities. Our study findings are consistent with these results in that ~60% of non-compliers cited either monetary or time-related issues as the primary reason for not purchasing spectacles (Tables 5A and 5B).

The strength of our study was limited by the inclusion of a relatively small number of camps and the inability to individually randomize study subjects to the type of spectacle delivery system. Because groups of participants attend a given eye camp on the same day, individual allocation offering different spectacle services was not feasible. The inclusion/exclusion criteria used for eye camps and individual patients were specified in an attempt to maintain comparability with comprehensive outreach eye camps in other developing world countries. Of note, the geographic districts analyzed in this study were all within proximity of Theni

Hospital and AECS freestanding primary eye care centers which also offered comprehensive vision services.

In conclusion, our study results indicate that provision of spectacle dispensing services as part of outreach eye care screening services in resource limited settings can result in dramatic improvements in spectacle procurement. Where on-the-spot spectacle fitting may not be feasible, booking order with subsequent delivery may be introduced with similar procurement levels. Other methods beyond delivery of prescription only services can also be explored to deliver basic ophthalmic services in settings where the human and financial resources necessary to establish vision centers are currently unavailable. We recommend additional studies to further elucidate the patient-specific factors motivating improved procurement and use.

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Figure 1.
 Allocation of eye care outreach camps to the study arms, Theni district, India.

Table 1

Baseline characteristics of participants by three types of spectacle delivery method at outreach camps, Theni district, India.

Variable	Prescription only Camps=7, n=197	Booking order Camps=7, n=132	On-the-spot delivery Camps=7, n=126	p value
Mean no. of people screened per camp (range)	166.4 (128–227)	149.1 (91–234)	129.0 (49–183)	0.257
Mean distance from base hospital, km (range)	63.4 (12–104)	54.6 (20–90)	33.4 (10–60)	<0.001
Mean age (SD), years	49.1 (10.5)	50.0 (10.0)	49.0 (11.2)	0.743
Sex, %				
Male	53.3	57.6	56.4	0.756
Female	46.7	42.4	43.6	
Residence, %				
Rural	54.3	74.2	58.7	0.376
Urban	45.7	25.8	41.3	
Education, %				
No schooling	24.9	18.2	23.8	
Primary (1–5 years)	21.8	27.3	27.8	0.793
Secondary (6–10 years)	44.2	41.7	37.3	
Higher studies (10+ years)	9.1	12.8	11.1	
Marital status, %				0.339
Married	79.7	84.1	87.3	
Unmarried	4.6	1.5	3.2	
Other	15.7	14.4	9.5	
Working status, %				
Worker	57.4	70.5	68.2	0.063
Non-worker	42.6	29.5	31.8	
Mean (SD) family income, INR	28112.08 (30379.75)	37502.29 (45783.87)	25485.71 (26000.95)	0.390
Presenting distance visual acuity – better eye, n (%)				
6/6>6/18	159 (80.7)	113 (85.6)	107 (84.9)	0.821
6/18>6/60	35 (17.8)	18 (13.6)	18 (14.3)	
6/60	3 (1.5)	1 (0.8)	1 (0.8)	

INR, Indian rupees; SD, standard deviation

Table 2

Primary outcome – procurement of spectacles as noted during follow-up 6 weeks after attending eye outreach camp, Theni district, India.

	<i>N</i>	Spectacles procured, <i>n</i> (%)	Crude OR (95% CI)	<i>p</i> value	Adjusted OR (95% CI) ^a	<i>p</i> value
Arm 1 – prescription only	197	49 (24.9)	1	1	1	1
Arm 2 – booking order	132	95 (73.6)	8.30 (4.39–15.70)	<0.0001	8.79 (4.61–16.78)	<0.0001
Arm 3 – on-the-spot delivery	126	99 (79.2)	11.51 (7.87–16.86)	<0.0001	13.97 (8.12–24.05)	<0.0001

^a Adjusted for mean distance from base hospital

OR, odds ratio; CI, confidence interval

Table 3

Presenting visual acuity and procurement of spectacles across the different study arms, Theni district, India.

Presenting visual acuity	Patients who procured spectacles, <i>n</i> (%)			<i>p</i> value
	Prescription only	Booking order	On-the-spot delivery	
6/6–6/12	40 (81.6)	82 (86.3)	86 (86.9)	0.672
6/18–6/36	8 (16.3)	12 (12.6)	13 (13.1)	
6/60	1 (2.0)	1 (1.0)	–	
Total	49	95	99	

Table 4

Secondary outcomes – use and satisfaction with spectacles as noted during follow-up 6 weeks after eye outreach camp, Theni district, India.

	Spectacles used (among purchasers) <i>n</i> (%)	Satisfaction with spectacles (among purchasers) <i>n</i> (%)	OR (95% CI)
Arm 1 – prescription only	49 (100.0)	46 (93.88)	1.00
Arm 2 – booking order	94 (98.95)	88 (94.62)	1.06 (0.26–4.27)
Arm 3 – on-the-spot delivery	96 (96.97)	89 (92.71)	0.74 (0.17–3.33)

OR, odds ratio; CI, confidence interval

A. Patient-cited reasons for not purchasing spectacles stratified by patients who were working (multiple reasons were allowed), Theni district, India.

Table 5

	Prescription only			Mail order			Immediate delivery			Total		
	n	%		n	%		n	%		n	%	
Did not have enough money	34	38.6	9	30.0	4	25.0	47	35.1				
Did not have the time	21	23.9	9	30.0	3	18.8	33	24.6				
Was using old spectacles	12	13.6	4	13.3	2	12.5	18	13.4				
Was away from home	5	5.7	4	13.3	3	18.8	12	9.0				
Other reasons	16	18.2	4	13.3	4	25.0	24	17.9				

B. Patient-cited reasons for not purchasing spectacles stratified by patients who were not working (multiple reasons were allowed), Theni district, India.

	Prescription only			Mail order			Immediate delivery			Total		
	n	%		n	%		n	%		n	%	
Did not have enough money	29	43.3	1	25.0	5	41.7	35	42.2				
Did not have the time	13	19.4	-	-	-	-	13	15.7				
Was using old spectacles	5	7.5	-	-	3	25.0	8	9.6				
Was away from home	4	6.0	1	25.0	-	-	5	6.0				
Other reasons	16	23.9	2	50.0	4	33.3	22	26.5				