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Interventions to Promote Follow-up After Trabeculectomy Surgery in Rural Southern China
A Randomized Clinical Trial

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IMPORTANCE Follow-up after trabeculectomy surgery is important to surgical success, but little is known about the effect of interventions on improving follow-up in low-resource areas.

OBJECTIVE To examine whether text message reminders and free eye medications improve follow-up after trabeculectomy in rural southern China.

DESIGN, SETTING, AND PARTICIPANTS This randomized clinical trial studied 222 consecutive patients undergoing trabeculectomy from October 1, 2014, through November 31, 2015, at 4 rural hospitals in Guangdong and Guangxi Provinces, China. Data from the intention-to-treat population were analyzed.

INTERVENTIONS Patients undergoing trabeculectomy were randomized (1:1) to receive text message reminders 3 days before appointments at 1 and 2 weeks and 1 month after surgery and free topical corticosteroid medication (US$5.30) at each visit or to standard follow-up without reminders or free medication.

MAIN OUTCOMES AND MEASURE Follow-up at 1 month postoperatively.

RESULTS Among 222 eligible patients, 13 (5.9%) refused and 209 (94.1%) were enrolled, with 106 (50.8%) randomized to the intervention group (mean [SD] age, 64.4 [12.7] years; 56 women [52.8%]) and 103 (49.3%) to the control group (mean [SD] age, 63.0 [12.7] years; 53 women [51.5%]). A total of 6 patients (2.9%) were unavailable for follow-up. Attendance at 1 month for the intervention group (59 of 102 [57.8%]) was significantly higher than for the control group (34 of 101 [33.7%]) (unadjusted relative risk [RR], 1.72; 95% CI, 1.13-2.63; P = .01). Factors associated with 1-month attendance in multiple regression models included intervention group membership (RR, 1.65; 95% CI, 1.08-2.53; P = .02) and being told to return for suture removal (RR, 1.80; 95% CI, 1.06-3.06; P = .03). One-month attendance among controls not told about suture removal was 3 of 31 (9.7%), whereas it was 44 of 68 (64.7%) among the intervention group with suture removal (unadjusted RR, 6.69; 95% CI, 2.08-21.6; P = .001).

CONCLUSIONS AND RELEVANCE In this setting, low-cost interventions may significantly improve postoperative follow-up after glaucoma surgery, a potential opportunity for interventions known to improve surgical success.

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Glaucoma is the third leading cause of blindness worldwide after cataract and uncorrected refractive error, and China is no exception, with 7.7% to 11% of blindness attributable to glaucoma. Although medical treatment for glaucoma remains a common first-line option in developed areas, lack of availability and cost of medications make this modality less practical in areas of limited resources. For these reasons, glaucoma surgery, such as trabeculectomy, may be preferred as initial treatment for glaucoma in rural areas of lower- and middle-income countries (LMICs). However, poor adherence to follow-up after trabeculectomy surgery may interfere with appropriate postoperative management. Previous work in rural southern China found that only a quarter of patients returned a month after glaucoma surgery, with other studies in China and India also documenting poor follow-up after trabeculectomy. There is an urgent need for strategies to increase adherence in LMICs to improve surgical outcomes.

Traditional reminder methods, such as telephone calls and posted letters, have high unit costs and require significant resources to administer. The number of Chinese cell phone users now exceeds 1.3 billion, giving China the largest cohort of users in the world. Short message service (SMS) text messaging has been suggested as a method to improve delivery of health services around the world, and randomized clinical trials of automated mobile health technology interventions have demonstrated increased adherence to eye care services in China.

However, to the best of our knowledge, no studies have evaluated whether SMS reminders could be combined with modest financial incentives, such as free postoperative medications, to improve low rates of follow-up after trabeculectomy surgery. Given the importance of early postoperative interventions, such as bleb needling and ocular massage, in determining success of surgery, there is a need to improve follow-up. We performed a randomized clinical trial to assess whether SMS reminders combined with the offer of free postoperative medications could improve follow-up after glaucoma surgery in rural China.

Methods

The protocol for this study was approved in full by the Ethics Committee of the Zhongshan Ophthalmic Center, Sun Yat-sen University (Guangzhou, China). Oral informed consent was obtained from all participants, and the tenets of the Declaration of Helsinki were followed throughout. The trial protocol appears in the Supplement.

Patients and Randomization

From October 1, 2014, through November 31, 2015, consecutive eligible patients undergoing trabeculectomy were enrolled at the inpatient units of 4 rural county-level hospitals (2 in Guangdong Province and 2 in neighboring Guangxi, both in southern China) by ophthalmic nurses before surgery. Eligibility criteria included a medical record that indicated trabeculectomy surgery (concurrent cataract extraction was permitted but not other ocular operations) and the ability to comply with the study protocol. The patients were required to own a cell phone capable of receiving SMS text messages. Illiterate patients were eligible if assisted by a literate spouse, family member, or other person.

Participants were assigned by simple randomization (1:1) to receive both SMS reminders 3 days before appointments at 1 and 2 weeks and 1 month after surgery and free topical corticosteroid medication at each visit (intervention group) or to standard follow-up without reminders or free medication (control group) (Figure). The randomization codes were generated online (http://www.randomization.com). Written allocation assignments were sealed in individual opaque envelopes marked only with study identification numbers, with an equal number of control and intervention patients at each hospital. Regular ocular examinations and analyses were performed by investigators and clinical staff masked to group allocation. However, study participants and study personnel responsible for sending SMS text messages and distributing free eye drops could not be masked because the intervention required overt participation.

Interventions and Outcome Assessment

In the intervention group were informed that their cell phone would receive SMS reminders 3 days before their scheduled appointments but that they should attend their appointments even if the reminders were not received. The Chinese message text read, “This is a reminder of your appointment for ophthalmic examination at [name] Hospital on [date]. Please make preparations in advance to be on time.” The SMS reminders were sent by nurses at a cost to the sender of 0.1 RMB ($0.02) per message. (Chinese Telecom companies do not charge customers for receipt of SMS messages.)

Intervention group patients were told that they would receive 1 bottle of prednisolone acetate ophthalmic suspension, 1%, on returning for each scheduled postoperative examination (total value for 3 bottles was 99 RMB [$US$15.90]). Personnel costs per patient in the intervention group were calculated as 50 RMB ($US$7.90) based on time spent performing the intervention (sending the SMS, dispensing eye drops, and documenting attempted SMS contacts).

Trabeculectomy surgery was performed as an inpatient procedure at participating facilities, as is typical in rural China, and the initial postoperative examination was performed and questionnaires administered during this 3-day hospital stay. Either
The primary outcome was attendance at the scheduled 1-month postoperative examination. The study was designed to enroll 174 participants, resulting in 80% power with an error of .05 to detect a difference in adherence rates of 30% vs 55%, with an estimated 80% participation rate. Results were presented as mean (SD) for continuous data with normal distribution and number (percentage) for categorical data. The unadjusted proportions of completed 1-month follow-up examinations, with 95% CIs, were presented separately by study group, stratified by need for suture removal, which previous work had found to be strongly associated with follow-up. The differences between study groups in proportion of patients followed up at different times were calculated and 95% CIs constructed using the 2-proportion $z$ test. The unadjusted relative risks (RRs) and 95% CIs were calculated, using control group patients not needing suture removal as the reference.

Study group and all variables significant at the $P < .20$ level in simple regression models were included in multiple regression models, with attendance at the 1-month visit as outcome. We used generalized linear models with Poisson regression to estimate the RR associated with intervention group membership and other potential determinants. All statistical analyses were performed using STATA statistical software, version 13.1 (StataCorp).

To satisfy the requirement of intention-to-treat analysis to include all randomized participants in analyses, we used STATA software to perform multiple imputation of missing data with logistic regression models, selecting the independent variables based on predictive value and availability of data. The multiple imputation approach created 20 copies of the data, in which missing values were imputed by chained equations. Final results were obtained by averaging these 20 data sets using the Rubin rules, which ensured that the SEs for all regression coefficients took into account uncertainty in the imputations and in the estimation.

Results

Among 222 consecutive eligible patients undergoing trabeculectomy at the 4 hospitals, 13 (5.9%) declined participation and...
209 (94.1%) were enrolled. Among these, 103 (49.7%) were randomly assigned to the intervention group and 106 (50.3%) to the control group (Figure).

There was no significant difference in the age (intervention group vs control group: mean [SD], 64.4 [12.7] vs 63.0 [12.7] years; \( P = .43 \)), sex (56 women vs 53; \( P = .84 \)), educational level (52 individuals vs 64 who had received no schooling or only an elementary school education; \( P = .06 \)), family annual income (52 individuals vs 57 earning <US$800 per year; \( P = .44 \)), or other potential determinants of postoperative follow-up between the 2 groups at baseline (Table 1 and Table 2). All patients in both groups received the allocated intervention, and information on the main trial outcome (follow-up at 1 month) was available for 102 patients (96.2%) in the intervention group and 101 (98.1%) in the control group (Figure).

Follow-up remained higher in the intervention group (59 of 102 [57.8%]) compared with the control group (34 of 101 [33.7%]) throughout the study, with the difference most prominent at 1 month (unadjusted RR, 1.72; 95% CI, 1.13-2.63; \( P = .01 \)). Attendance at 1 month among controls not told to return for scleral flap suture removal was 3 of 31 (9.7%) and 44 of 68 (64.7%) among intervention patients who were told about suture removal (unadjusted RR, 6.69; 95% CI, 2.08-21.6; \( P = .001 \)) (Table 3).

Factors associated with 1-month attendance in multiple regression models included membership in the intervention group (RR, 1.65; 95% CI, 1.08-2.53; \( P = .02 \)) and being directed to return for removal of scleral flap sutures at 1 month (RR, 1.80; 95% CI, 1.06-3.06; \( P = .03 \)). Age, sex, income, transportation costs, travel distance, waiting time, and cost of the follow-up examination were not significantly associated with follow-up (Table 4). Inclusion of baseline intraocular pressure and visual acuity at 2 weeks as indicators of disease severity and rate of recovery, respectively, did not alter the results of the model.

Discussion

This intervention combining SMS reminders and the offer of free postoperative medication significantly increased adherence to follow-up of patients after glaucoma surgery in rural southern China. The American Academy of Ophthalmology’s Preferred Practice Pattern for Open-Angle Glaucoma,23 which has been adopted for use in China, recommends postoperative follow-up continue for at least 6 weeks, during which time the patient should be evaluated for complications, and a variety of treatments, including repair of bleb leaks, bleb massage, suture lysis, and bleb needling, should be used as needed to maximize the chances of long-term pressure control. Without the SMS and free drug intervention in our current study, barely a third of patients returned at 1 month after surgery (34 of 101 [33.7%]), a time when these important postoperative interventions would commonly still be performed. We did not attempt to extend follow-up beyond 4 weeks in view of previously published work in this population,24 which found very low rates of follow-up already at this point.

Of interest, simply telling patients to return for removal of scleral flap sutures after surgery had an even greater effect on improving adherence and without the costs associated with free medications or sending SMS reminders. In the setting of this project, scleral flap sutures were only routinely removed, and patients were told to return for this procedure when releasable sutures had been used during surgery. However, conjunctival sutures may need to be removed because of the frequent lack of absorbable material in this setting, and it is not uncommon for nonreleasable scleral flap sutures to loosen and become exposed, also requiring removal. Thus, although expanding training in the use of releasable sutures remains a priority, until this substantial task is completed, requesting that all patients return for possible suture removal after glaucoma surgery in rural China is ethical and potentially beneficial to their care. Combining all these simple interventions succeeded in motivating nearly two-thirds of patients to return at 1 month (44 of 68 [64.7%]). This result has significant implications for programs that perform glaucoma surgery in rural China and potentially in similar low-resource areas in other LMICs.

The total cost of providing 3 bottles of medication was only US$15.90 per patient, which may be compared to the mean surgical fee for trabeculectomy at these 4 facilities of 4250 RMB (US$680). Presumably, this cost could be reduced further through bulk purchase of medication across several rural
Table 2. Additional Factors Potentially Associated With Postoperative Follow-up in a Randomized Clinical Trial of Follow-up After Glaucoma Surgery

<table>
<thead>
<tr>
<th>Factor</th>
<th>Intervention Group</th>
<th>Control Group</th>
<th>Significance</th>
<th>Significance</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>No. (%) of Patients</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>All (n = 106)</td>
<td>GD (n = 56)</td>
<td>GD (n = 50)</td>
<td>GX (n = 50)</td>
</tr>
<tr>
<td>Residential status</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Rural</td>
<td>70 (66.0)</td>
<td>28 (56.0)</td>
<td>42 (75.0)</td>
<td>66 (64.1)</td>
</tr>
<tr>
<td>Urban</td>
<td>36 (34.0)</td>
<td>22 (44.0)</td>
<td>14 (25.0)</td>
<td>37 (35.9)</td>
</tr>
<tr>
<td>Travel time from home to hospital, h</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt;1</td>
<td>53 (50.0)</td>
<td>27 (54.0)</td>
<td>26 (46.4)</td>
<td>44 (42.7)</td>
</tr>
<tr>
<td>≥1</td>
<td>53 (50.0)</td>
<td>23 (46.0)</td>
<td>30 (53.6)</td>
<td>59 (57.3)</td>
</tr>
<tr>
<td>Travel cost, US$*</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>≤8</td>
<td>53 (50.5)</td>
<td>24 (49.0)</td>
<td>29 (51.8)</td>
<td>51 (49.5)</td>
</tr>
<tr>
<td>&gt;8</td>
<td>52 (49.5)</td>
<td>25 (51.0)</td>
<td>27 (48.2)</td>
<td>52 (50.5)</td>
</tr>
<tr>
<td>Accompanying friend or family member present*</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>85 (82.5)</td>
<td>40 (80.0)</td>
<td>45 (84.9)</td>
<td>74 (73.3)</td>
</tr>
<tr>
<td>No</td>
<td>18 (17.5)</td>
<td>10 (20.0)</td>
<td>8 (15.1)</td>
<td>27 (26.7)</td>
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<tr>
<td>Outpatient waiting time*</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Half hour or less</td>
<td>35 (34.0)</td>
<td>22 (44.0)</td>
<td>13 (24.5)</td>
<td>25 (24.8)</td>
</tr>
<tr>
<td>More than half hour</td>
<td>68 (66.0)</td>
<td>28 (56.0)</td>
<td>40 (75.5)</td>
<td>76 (75.2)</td>
</tr>
<tr>
<td>Surgery type</td>
<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Trabeculectomy only</td>
<td>80 (75.5)</td>
<td>34 (68.0)</td>
<td>46 (82.1)</td>
<td>69 (67.0)</td>
</tr>
<tr>
<td>Trabeculectomy and extracapsular extraction</td>
<td>26 (24.5)</td>
<td>16 (32.0)</td>
<td>10 (17.9)</td>
<td>34 (33.0)</td>
</tr>
<tr>
<td>Fee for follow-up visit, US$*</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>≤20</td>
<td>50 (48.5)</td>
<td>25 (50.0)</td>
<td>25 (47.2)</td>
<td>36 (35.6)</td>
</tr>
<tr>
<td>&gt;20</td>
<td>53 (51.5)</td>
<td>25 (50.0)</td>
<td>28 (52.8)</td>
<td>65 (64.4)</td>
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<tr>
<td>Satisfaction with surgery*</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Satisfied</td>
<td>96 (93.2)</td>
<td>46 (92.0)</td>
<td>50 (94.3)</td>
<td>96 (95.1)</td>
</tr>
<tr>
<td>Not satisfied</td>
<td>7 (6.80)</td>
<td>4 (8.00)</td>
<td>3 (5.66)</td>
<td>5 (4.95)</td>
</tr>
<tr>
<td>Need to remove suture postoperatively*</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>68 (66.7)</td>
<td>31 (63.3)</td>
<td>37 (69.8)</td>
<td>70 (69.3)</td>
</tr>
<tr>
<td>No</td>
<td>34 (33.3)</td>
<td>18 (36.7)</td>
<td>16 (30.2)</td>
<td>31 (30.7)</td>
</tr>
<tr>
<td>Knowledge about importance of follow-up</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>after glaucoma surgery*</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Important</td>
<td>74 (71.2)</td>
<td>34 (68.0)</td>
<td>40 (74.1)</td>
<td>74 (73.3)</td>
</tr>
<tr>
<td>Not important</td>
<td>30 (28.8)</td>
<td>16 (32.0)</td>
<td>14 (25.9)</td>
<td>27 (26.7)</td>
</tr>
</tbody>
</table>

Abbreviations: GD, Guangdong Province; GX, Guangxi Province.
*a One missing value.
*b Five missing values.

Table 3. Observed Proportion of Patients Followed up at Study Time Points After Surgery

<table>
<thead>
<tr>
<th>Time Point After Surgery</th>
<th>No./Total No. (%) of Patients</th>
<th>Difference Between Intervention and Control Patients, % (95% CI)</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 wk</td>
<td>73/101 (72.3)</td>
<td>9.15 (~5.40 to 21.2)</td>
<td>.24</td>
</tr>
<tr>
<td>2 wk</td>
<td>81/101 (80.2)</td>
<td>6.21 (~5.01 to 17.4)</td>
<td>.28</td>
</tr>
<tr>
<td>1 mo</td>
<td>34/101 (33.7)</td>
<td>24.1 (3.91 to 44.5)</td>
<td>.02</td>
</tr>
</tbody>
</table>

a Two patients were unavailable for follow-up across 3 time points.
b Three patients were unavailable for follow-up at 2 weeks and 4 patients were unavailable for follow-up at 1 mo after surgery.

facilities (for reference, there are 120 county hospitals in Guangdong and 109 in Guangxi).

Although the personnel costs of sending the SMS reminders (US$7.90 total per patient) must also be considered, we have previously described an automated system for sending SMS reminders that could largely eliminate the unit costs of sending reminder messages manually, after the initial investment in setting up the system. The modest fees associated with the SMS messages themselves (US$0.02 per message per patient) added little to the overall cost of this intervention. An important point regarding the practicality of cell phone interventions in this setting is the finding in the study by Lin et al17 that more than 90% of prospective patients in a similar study in China owned a cell phone capable of receiving SMS messages. This finding is consistent with the current study in which only 1 patient (0.45%) did not own a cell phone and was excluded on this basis.
The result of the current study, in which adherence was nearly doubled with an intervention costing less than US$25 per patient, may be compared with other reports on interventions to enhance uptake of or adherence with eye care in rural China. Multimedia educational interventions, when used alone, have been unsuccessful in increasing acceptance of low-cost comprehensive eye examinations or cataract surgery, or in promoting purchase of children’s spectacles. Although a focus group study indicated that patients in rural China may not be comfortable with direct cash payments to encourage medical compliance, Ma et al have reported that the offer of free spectacles doubled spectacle wear at a later unannounced examination, which is consistent with improved adherence observed in the present study. It appears that the offer of free medical goods, such as medication and spectacles, may be particularly effective in this setting in changing behavior and gives the added advantage of direct clinical benefit to patients. This finding is also consistent with a finding in a previous trial where offering comprehensive examinations for free led to significantly higher uptake compared with even low-cost (US$3) examinations. It is possible that providing postoperative examinations without cost would have resulted in even higher follow-up in the current study, but unfortunately partner hospitals were unwilling to make such arrangements.

Our maximum effect in enhancing follow-up in the current study was achieved with what may effectively be seen as 3 interventions in combination: SMS reminders, offer of free medications, and directing patients to return for scleral flap suture removal. This finding is consistent with a review of interventions to promote adherence with medication use, which concluded that complex interventions, including several components, were most likely to be successful. Thus, this study was not designed to distinguish the separate effects of SMS reminders and free medication on follow-up because we did not think that either intervention alone would be as effective and both interventions were inexpensive, meaning there was little practical disadvantage to aggregating them.

The findings in the current study were not consistent with previous reports that poor adherence to follow-up visits may be significantly associated with transportation costs, financial barriers, and the lack of an escort. None of these factors was significantly associated with attendance at the 1-month visit in this setting, even in univariate analyses. The finding regarding transportation costs is consistent with an earlier study in which transport was not reported as an important barrier in a population study of access to cataract surgery in rural China. This finding may reflect a relatively robust transportation infrastructure in this setting. It is encouraging that adherence in this setting can be improved by relatively simple and inexpensive interventions, such as free medications and instructions to return for suture removal. Barriers such as low income and lack of an escort would be more challenging to overcome.

Strengths of the study include its randomized, controlled design, with intervention and control groups being similar at baseline. Losses to follow-up were minimal, and fidelity to the interventions assigned per protocol was good. Finally, the subject of adherence to follow-up after glaucoma surgery in LMICs is little studied and of significance given glaucoma’s status as the world’s leading cause of uncorrectable vision loss. The importance of adherence in achieving good surgical outcomes for this disease, and documented low follow-up in this setting, Weaknesses of the study must also be acknowledged. All patients were operated on and followed up at 4 centers. The results may thus only be applied to other settings with caution. As noted above, the study was not designed to distinguish between separate effects on adherence of the provision of free medications and the use of SMS messaging. Moreover,
the current study did not attempt to link postoperative adherence with surgical outcomes. Because many patients in the control group were unavailable for follow-up at 1 month, it is not possible to state whether the intervention significantly improved outcomes, including central visual acuity or peripheral vision, significantly. Finally, the practicality of replicating this intervention in other settings will depend on the willingness of hospitals and local health officials to commit resources to improving outcomes of glaucoma care. This goal may well be realistic and sustainable in at least parts of rural China but may not be so elsewhere in other LMICS.

Conclusions

Despite these limitations, it is hoped that these results may be applied more widely in low-resource areas, where poor acceptance of and adherence to glaucoma care may add to the burden of visual disability.

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Study concept and design: Jin, Li, Li, Congdon.

Acquisition, analysis, or interpretation of data: Yang, Jin, Zeng, Wei, G. Li, Man, Congdon.

Drafting of the manuscript: Yang, Zeng, Wei, G. Li, Man, Congdon.

Critical revision of the manuscript for important intellectual content: Jin, L. Li, Congdon.

Statistical analysis: Jin, Congdon.

Obtained funding: Congdon.

Administrative, technical, or material support: Man, Congdon.

Obtained funding: Man, Congdon.

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Study supervision: Jin, Congdon.

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REFERENCES


