**Health Literacy Centered Interventions in
Glaucoma Medication Adherence**

By

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Master's Paper Abstract

The influence of a patient's health literacy on his/her health has become a topic of increasing interest over the past decade. Many studies have examined the effect of health literacy on disease understanding and health outcomes in multiple chronic diseases. However, there is scarce literature exploring the role of health literacy in the field of ophthalmology, specifically glaucoma.

This paper includes systematic review of the current literature examining the effect of provider communication interventions on the rate of glaucoma medication adherence in patients with low health literacy. Of 89 titles identified for review, 86 were excluded based on population, intervention, outcome, or study design. The three included studies were assessed for study design, potential for selection bias, measurement bias, and confounding. All three studies were assigned an overall quality rating of fair based on these criteria. Comparison of results was difficult due to varying definitions of compliance and the use of multifaceted educational programs. However, the overall conclusion is that multifaceted interventions with both educational and behavioral aspects can improve glaucoma medication adherence by 9 to 19 percent. While statistically significant, the clinical importance of this improvement is still unclear.

Based on the above results, a preliminary qualitative study using focus groups was designed to explore provider communications with low health literacy African American patients with glaucoma. The goal of the study is to attempt to understand how African Americans perceive medical information related to their glaucoma care and to then use that information to develop a tool for improving provider patient communication about glaucoma.

Systematic Review Abstract

Purpose: This review was designed to synthesize the published studies that examine provider patient communication interventions designed to decrease the rate of non-adherence in glaucoma patients.

Methods: A systematic review of relevant qualitative and quantitative studies was conducted. Medline, Cochrane databases, CINAHL, EMBASE, and ISI health were searched from inception to March 2011 using MeSH and keyword terms. The search was restricted to the English language. Articles were selected based on the following criteria: glaucoma population, individual level educational intervention, and medication adherence outcome. Editorial and personal opinion articles were excluded. Studies were assigned a quality rating of poor, fair, or good. Data was abstracted by a single author based on criteria developed by the United States Preventive Services Task Force (USPSTF).

Results: Three studies, two randomized controlled trials (RCTs) and one survey, met the inclusion criteria. There was substantial heterogeneity of reported outcome analysis. Both RCTs showed an improvement in medication adherence in groups that received a multifaceted intervention. The survey found specific educational items but not total glaucoma knowledge to be associated with improved anti-glaucoma medication adherence. The authors concluded that multifaceted programs are likely to be more successful at improving adherence than education only interventions.

Conclusion: Although difficult to compare due to varied definitions of adherence, all three studies showed that multifaceted interventions at the provider patient level can improve adherence to topical ocular drop regimen in the glaucoma population.

Introduction

The effects of health literacy on disease management and outcomes have been the focus of study for over a decade. Health literacy centered interventions have been studied in multiple chronic diseases such as diabetes and human immunodeficiency virus (HIV) (1-4). However, interventions for people with low health literacy have been slow to permeate the field of ophthalmology, and the effects of health literacy centered interventions have not been well studied in ophthalmologic diseases. Primary open angle glaucoma (POAG) is a chronic disease that relies on patient understanding of the disease process for compliance to lifelong anti-glaucoma drop instillation. However, we lack literacy aids for glaucoma patients who have poor literacy skills and we lack tools to improve ophthalmologists' ability to communicate effectively with low health literacy patients. Additionally, the principles of chronic disease management that are important in the treatment of POAG are not widespread in the field of ophthalmology.

Similar trends with low treatment adherence rates have been found in ophthalmology as in other fields of medicine (5). The Glaucoma Adherence and Persistency Study (GAPS) examined medication adherence from the perspective of patient beliefs and experiences (5). GAPS identified several modifiable barriers at the provider-patient level including lack of concern over disease progression and passive dependence on the provider. Both of these barriers can be addressed by improving provider-patient communication.

The American Medical Association (AMA) defines functional health literacy as the ability to read and understand written health information, oral health information, and the ability to act on such information (6). Paasche-Orlow and Wolf proposed a basic conceptual model to describe the pathway between health literacy and health outcomes (7). This model incorporates both patient and system level factors that influence health outcomes. The model identifies several modifiable factors, specifically

at the patient-provider level.   Modifiable patient factors include knowledge and participation in decision making, while the provider factors are communication skills, teaching ability, time, and patient-centered care.

Patients with low health literacy have been shown to be less likely to ask their provider questions and seek additional services or information. In addition, patients with low health literacy are less likely to use preventive health services, more likely to have less knowledge about their chronic disease and have worse health outcomes (8). Hironaka and Paasche-Orlow offer strategies to improve provider-patient communication by improving the decision making process (8).   These strategies, focused on improving the provider's communication and teaching skills, instructed providers to use multiple forms of communication, such as written, graphic and oral; helped their patients ask questions; and confirmed that the patient actually understood the message (8).

While many studies have examined the rate and potential causes of medication non-adherence, very little is known about how to actually improve patient understanding and adherence in ophthalmological diseases such as glaucoma. Many of the current recommendations are based on other chronic diseases, such as diabetes or hypertension, but their effect on glaucoma is unknown. The aim of this systematic review is to identify provider communication interventions to mitigate poor glaucoma medication adherence in patients with low health literacy.

Methods

Search Strategy

In collaboration with a medical librarian, Medline, Cochrane databases, CINAHL, EMBASE, and ISI Health were searched for relevant articles from inception through March 2011. Both MeSH and keyword terms were used in literature searches with the search strategy listed in Appendix 1. The

PubMed search was conducted using the limits Humans, Clinical Trial, Meta-Analysis, Randomized Controlled Trial, Review, Case Reports, Classical Article, Clinical Trial, Phase I, Clinical Trial, Phase II, Clinical Trial, Phase III, Clinical Trial, Phase IV, Comparative Study, Controlled Clinical Trial, Evaluation Studies, and English. The reference lists of identified articles were searched for additional citations of interest.

Study Selection and Data Extraction

Title and abstracts of all papers identified by electronic and hand searches were assessed for inclusion criteria. Full reports were obtained and assessed for all potentially eligible studies identified by title and abstract review. The reviewer was not masked to the names of the investigators or journal of publication during assessment. Results were evaluated for duplication from multiple databases. Papers were examined for education based interventions for glaucoma patients at the individual level. Studies were excluded based on population, intervention, outcome, or design. Studies were also excluded if the intervention was at the population instead of individual level. Papers that did not report on original research, such as editorials and reviews were excluded. Outcomes of interest were patient understanding of disease and medication adherence. Data were extracted from each paper by a single author (AB) onto data extraction forms.

Study quality assessment

A form modified from the US Preventive Services Task Force guidelines for critical analysis was used for assessment (Appendix 2). A single author (AB) evaluated each included paper for study design, sample size and outcomes. Studies were assessed for the potential for selection bias, measurement bias, and confounding. Study quality was assessed on the following criteria: adequacy of source and sample population description, similarity of cases and controls at baseline, adequacy of measurement tool description, appropriateness of analysis, adequacy of results description and external validity. Each

criterion was given a score of 1 for poor, 2 for fair, or 3 for good.   Overall study validity was rated as good, fair, or poor based on these criteria. Poor was defined as overall score of 6-10, fair as 11-14, and good as 15-18.

Results

The search identified eighty-nine titles for review (Figure 1). Using the selection criteria stated above seventy-four articles were excluded by citation and abstract review. Of the fifteen articles selected for full-text review, twelve were excluded. Seven papers, three reviews (9-11) and four editorials (12-15) were excluded on the basis of not reporting on original research. Two studies were excluded because they did not examine a population with glaucoma (16, 17), one did not contain a health literacy intervention (18), and two did not examine the effect on treatment adherence (19, 20). This resulted in three studies that examined the relationship between individual level education and compliance to glaucoma medication (21-23). Two RCTs (21, 22) and one survey (23) were included in this review (Table 1). All three studies were determined to be of fair quality (Table 2).

Okeke Study

Okeke et al performed a two phase randomized controlled trial to examine the effect of a multifaceted educational intervention on compliance to glaucoma medications (21). Glaucoma patients seen at the Scheie Eye Institute and the Wilmer Eye Institute between November 2006 and June 2007 were recruited to participate in the study. Phase one of the study consisted of a prospective cohort study of patient compliance to glaucoma medication for three months. After three months, patients with 75% compliance or less were included in phase two and randomized to the intervention or control group. Medication adherence was measured by a previously validated Dosing Aid. The intervention consisted of four parts: a ten minute educational video, an organized strategy discussion with the study coordinator, reminder telephone calls, and audio and visual alarms on the Dosing Aid.

Baseline adherence was similar between the intervention and control groups (54% in the intervention group versus 45% in the control group, P=0.10). While the two groups were similar in most demographic and ocular aspects, the control group was significantly more likely have used ocular drops for less than a year (5.71% of the intervention group versus 29.0% of the control group, P<0.01). The mean adherence rate significantly increased from 54% to 73% (P<0.01) for the intervention group while the change in mean adherence for the control group was not statistically significant (46% to 51%, P=0.19).

Study Design

This study was a two phase randomized controlled trial (RCT). External generalizability, often a limitation of RCTs due to the typical complexity of design and rigid exclusion criteria, was not an issue with this study which had a relatively pragmatic behavioral intervention. In addition, there were relatively few exclusion criteria, related primarily to the participant's ability to understand and use the Dosing Aid. Criteria for phase two was a baseline adherence rate of 75% or less during phase one. This design was used to maximize the chance of finding significant results.

Selection of Study Population

Patients were selected from major academic centers which are likely a different population from the general population in which there is a higher percentage of patients with more advanced disease than in the general population. Researchers specifically recruited patients shown to be of lower compliance for phase two of the study as that population is more likely to benefit from intervention. Although the authors state that participants were recruited from the Wilmer Eye Institute and the Scheie Eye Institute, they do not specify how the patients were recruited.   It is possible that there was some bias in selection of the recruited patients.   In addition, there was an unspecified number of

patients who were lost to follow up during phase two. Overall, there was a moderate potential for selection bias.

Measurements

The Dosing Aid is a valid measuring device that was used in a consistent fashion between the intervention and control groups. However, the participants were aware of the purpose of the Dosing Aid during the study which could have created a non-differential bias, artificially inflated the rate of compliance in both groups. This bias towards the null could have decreased the magnitude of effect between the two groups. In addition, it was determined that some patients actually took their drops without using the Dosing Aid but the study did not report the number of participants or which arm they were in. Overall, there was a moderately low potential that measurement bias threatens the study's validity.

Confounding

Several factors are potential confounders in this study. Factors such as education level, age, disease duration and severity, race, family history of glaucoma, and general health are all potential confounders. However, multivariate analysis showed only the intervention, a baseline compliance rate less than 50%, and white race to be associated with increased compliance. Overall, there is a low potential for confounding.

Statistical Analysis

Okeke et al was the only study in this review to clearly describe the process for sample size estimation. Based on an 80% power with 0.05 alpha to determine a 20% improvement in compliance rate they determined a sample size of forty-nine participants per arm for phase two (the intervention section) of the study. However, they had only thirty-five participants in the intervention arm and 31 in

the control arm. Although underpowered they still found a statistically significant increase in adherence in the treatment as compared to control group. Under sampling causes inherent difficulties in determining the reliability of the results. The sixty-six patients included in the phase two study might not adequately reflect the source population. It is also possible that the researchers would have found an even larger improvement in compliance if the study was fully powered. They did perform a univariate and multivariate analysis to determine factors associated with compliance rate.   The intervention, low baseline compliance rate, and white race were all associated with increased compliance.

Overall Quality

Overall quality rating was determined to be fair. Although the study was well designed and conducted, the potential for sampling error limited its internal validity.   Good internal validity is a prerequisite for external validity. The poor internal validity limits the ability to extrapolate the results to external populations. This study can be generalized with moderate confidence to glaucoma patients with a low baseline adherence rate.   The conclusions are congruent with the other RCT included in the review which increases the validity of the results.

Norell Study

Norell completed a randomized controlled trial of the effect of a tailored patient educational program on glaucoma drop compliance (22). Eighty-two patients with glaucomatous changes who were prescribed pilocarpine for chronic open angle glaucoma were recruited from Huddinge University Hospital Ophthalmology department between March 1977 and November 1978. Medication adherence was measured for both control and intervention groups using an electronic monitor connected to the drop bottle. The intervention, conducted at the second study visit, consisted of a slide show and

handout of glaucoma and treatment information followed by a session with an ophthalmic assistant to tailor drop schedule to daily routines.

The duration of dose intervals and proportion of missed doses were similar between both groups at baseline. There was a significant difference in change of missed doses after the intervention between the two groups (t=2.89, P=0.004). The percent of missed doses decreased from 10% to 6% in the intervention group, while it increased from 10% to 15% in the control group. The difference in the change of dose intervals between the two groups was also significant after the intervention (t=4.60, P≈0). The percent of time exceeding the 8 hour dosing period decreased from 22% to 13% in the intervention group and increased from 21% to 24% in the control group.

Study Design

This RCT examined the short term effect of a tailored educational intervention on the rate of glaucoma mediation adherence. The follow up period after the intervention in this study only lasted 20 days. Thus, while the study shows that education can improve compliance in the short term, the effect may not last over extended periods. Randomization of participants to intervention or control is mentioned but not described. One cannot assess the quality of the randomization but because the research occurred in 1977, it is safe to assume that it was not a computer generated randomization process.

Selection of Study Population

The participants were recruited from the Huddinge University Hospital Ophthalmology Clinic. The study population consisted of men and women age 56-90 with chronic simple glaucoma. The authors do not give any additional demographic information. However, the baseline compliance rate is similar between the intervention and control group which suggests some degree of comparability

between them. Nine patients were lost to follow-up after the intervention period. The authors did

describe the reasons for loss to follow-up (six of which were due to equipment malfunction and three to

unrelated health complications), but did not list which arm the patients were lost from. It is unlikely

that patients lost to follow-up because of equipment malfunction raises concern for selection bias.

However, the hospitalized patients could all have come from the same arm, indicating that the general

health of one group is different from the other. Overall, there is a moderate to high potential for

selection bias based on the minimal information provided by the authors.

Measurements

Compliance was measured by an electronic monitoring device. The participants were blinded to

the purpose of the monitoring device until the conclusion of the study, and it was used in the same

manner in the both the intervention and control groups. The patient education was performed in a

consistent fashion. An ophthalmology assistant assessed patient knowledge and performed individual

patient tailoring. Patient tailoring involved the discussion of individual habits, the inclusion of drop

instillation in habits, and a written list of medication instillation times. Neither the number of assistants

used nor their training was described in the article. Overall, there was a relatively low potential for

measurement bias.

Confounding

Patients were stratified by age before randomized to either intervention or control group. The

authors did not mention controlling for any other potential confounders. In particular, the issues of

gender, race, education level, disease duration, nor disease severity were controlled for in the analysis.

Overall, there was a moderate to high potential for bias due to confounding.

A t test was used to examine the difference in frequency distribution of missed doses between the two groups. However, as stated above, potential confounders were not taken into account in the analysis.

Overall Quality

The overall quality rating of the study was determined to be fair. The article did not state the sample size estimate or give demographic information about the study participants. While the researchers may have addressed some of the issues that would make this study good instead of fair quality, the absence of this information in the methods section prevents me from designating a higher rating.

Hoevenaars Study

Hoevenaars et al created a questionnaire to examine the correlation between glaucoma disease and treatment knowledge and medication compliance (23). Sixty ophthalmologists identified by their membership in the Dutch Ophthalmological Society were randomly selected to participate in the study. Each ophthalmologist administered the questionnaire to four consecutive patients. Information about age, gender, duration of glaucoma, and socioeconomic status was collected for all of the participants (24).

There was not a statistically significant correlation between compliance and total level of glaucoma knowledge (P=0.12) or total level of knowledge of glaucoma treatment (P=0.46) or total level of need for information (P=0.19). There was a statistically significant negative correlation between the statement "a patient should always tell the ophthalmologist which other medications (s)he is using" with an adjusted odds ratio (OR) of 0.1. This indicates that patients that answer correctly (yes) are

actually less compliant, which is surprising. There was also a statistically significant positive correlation

(OR 3.3) between a correct answer to the statement "eye drops can repair the damage caused by

glaucoma" and compliance, indicating that participants who answer correctly (No) are more compliant.

Three "need for information" statements had a statistically significant positive correlation with

compliance, indicating that more compliant patients felt they did not need additional information on

those items. These items include "how to function better with glaucoma" (OR 3.1), "experiences of

other glaucoma patients" (OR 3.3) and "heredity of glaucoma" (OR 4.1).

Study Design

The validity of questionnaire based studies is strongly related to the reliability and validity of the

questionnaire used. One of the strengths of this study is the systematic development of the

questionnaire. Formative research included focus groups, expert opinion and pilot testing.   However,

even if the questionnaire used is valid, non-response rates and missing data can decrease the internal

validity of the study. Hoevenaars, et al. had a physician response rate of 73%. Response rates of at least

40-70% do not challenge a study's internal validity (25).

Selection of Study Population

Sixty ophthalmologists were randomly selected from the Dutch Ophthalmology Society. It is

unclear if other ophthalmological societies exist in the Netherlands or if all certified ophthalmologist are

members of this society. Selection bias could be present both in the form of the selection of the

ophthalmologists included in the study and in their selection of the patient participants which were

selected in a consecutive fashion. Of the sixty ophthalmologists who were recruited, 73% responded to

the invitation for a total of 166 patients completing the questionnaire. The demographics of neither the

ophthalmologists nor the patients were described in the article, however it was stated that both

glaucoma specialists and general ophthalmologists were included. It is likely that the patient

populations of the specialists and general ophthalmologists were very different. The overall potential for selection bias was high.

Measurements

The questionnaire was systematically developed using focus groups, expert opinion and pilot tests. Cronbach's alpha was 0.83 which indicated good internal consistency of the questionnaire. Compliance was self-reported on the questionnaire. Researchers minimized recall bias by limiting the compliance time period to the previous four weeks. Potential reporting bias of compliance rates was minimized by using a strict noncompliance definition of missing one or more drops in the previous four weeks. The overall potential for measurement bias was low to moderate.

Confounding

The authors calculated adjusted odds ratios (OR) taking age, gender, duration of disease, educational level, glaucoma medications and history of prior glaucoma surgical treatment into consideration. However, disease severity, race, nor family history of glaucoma was explicitly controlled for in the analysis. Overall, the potential for confounding bias was low to moderate.

Statistical Analysis

Significance was appropriately tested for using a Pearson chi-squared test. Logistic regression was performed for each item on the questionnaire to calculate the OR for being compliant. Due to the high number of testing (fifty-nine total items on the questionnaire), it is highly likely that some of their results are due to chance.

Any missing data were categorized as "don't know/no opinion." However, the researchers do not state how many time items were classified in this manner. In addition, for the eleven participants

who did not answer how often they had missed their eye drops, the researchers classified the participant as noncompliant or compliant based on their answers to other questions.

Overall Quality

The Hoevenaars study received an overall quality grading of fair. The potential biases in the selection of both ophthalmologist and participants strongly affect its internal validity. Although the questionnaire itself appears to be reliable, the overall conclusions of the study do not agree with the conclusions of other studies, calling their results in question. The Netherlands are very ethnically homogenous which limits this study's applicability to the very heterogeneous US population.

Discussion

Both RCTs found an educational intervention to statistically improve compliance to medications in glaucoma patients. Although the results were statistically significant, the clinical significance remains unclear. Additionally, both trials involved multifaceted educational programs. It is difficult to determine the extent to which each component contributed to the increased compliance. Each study defined compliance differently, making it challenging to compare them directly. All studies received an overall quality grading of fair due to multiple potentials biases and limitations of external validity.

Despite these limitations both RCTs found the intervention to improve compliance. The interventions in the two trials included both knowledge and behavioral modifications. Hoevenaars et al conclude that education only based programs are unlikely to improve compliance, but that more complex interventions combining patient education, behavior modification, and patient belief systems would be more effective (23).

Both RCTs examined the effect of the intervention in the short term, from twenty days (22) to three months (21). Although we see a short term improvement in adherence, there are many

unanswered questions about long term effect. Both the frequency and composition of the intervention

are important factors to consider and may change throughout the duration of disease management.

This is especially important in regards to glaucoma which is a chronic disease often requiring lifelong

medical therapy.

Additionally, all three studies used medication adherence to measure intervention success.

However, adherence is an intermediate outcome and may not accurately reflect patient centered health

outcomes such as vision and quality of life (QoL). Glaucoma progression is correlated with a decrease in

both disease specific and general QoL (26). Future research should focus on the long term effects of

multifaceted behavioral and education based interventions on the prevention of glaucomatous visual

field loss and preservation of QoL. No published studies to date have examined the effect of this type of

intervention on long term disease progression or QoL.

Although this was a systematic and fairly thorough review, it was not completely

comprehensive. Thus, it is possible that literature on this topic was not captured in this search. The

review was limited to studies in the English language but there may be studies published in other

languages that address the topic of this review.   Additionally the review was limited to published

literature. Ongoing studies and unpublished articles were not included which limited the completeness

of the review.

Conclusion

Although a few studies have examined the effect of education on glaucoma medication

compliance, many of the recommendations are extrapolated from other chronic diseases such as

hypertension and diabetes. While it is likely that many of the concepts are also applicable to glaucoma

patients, the use of eye drops as opposed to oral medications could create different issues not

addressed in other chronic diseases. As of May 2011 there are three studies with specific

behavioral/educational interventions listed on the National Institutes of Health (NIH) website (27).

Although it is most likely that a multifaceted approach will be the most efficacious, it would be

worthwhile to examine which specific components of an educational program are most beneficial.

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Table 1. Evidence Summary Table

Citation	Study design	population	Intervention	outcomes	results	Strengths/weaknesses	Quality grading
Okeke, et al. Interventions Improve Poor Adherence with Once Daily Glaucoma Medications in Electronically Monitored patients. Ophthalmology.2009; 116: 2286-2293.	RCT	Glaucoma patients treated with a prostaglandin analog at Scheie Eye Institute or Wilmer Eye Institute between 11/06-6/07	Educational video & session with study coordinator, reminder phone calls, audio and visual dose reminders	Change in drop compliance	Intervention group had a 19% increase in adherence (P<0.0001); control group had 6% increase in adherence (P=0.19)	Study was well designed but underpowered; study was 3 month duration so we don't know long term effect	fair
Hoevenaars, et al. Will improvement of knowledge lead to improvement of compliance with glaucoma medication? Acta Ophthalmol. 2008; 86: 849-855.	Questionnaire	Patients of members or the Dutch Ophthalmological Society	NA	Correlation between compliance and glaucoma knowledge	No statistically significant correlation between compliance and total glaucoma knowledge (P=0.12), total glaucoma treatment knowledge (P=0.46), OR total need for information (P=0.19)	Questionnaire was systematically developed and has a Cronbach's alpha coefficient of 0.83	Fair
Norell, S.E. Improving medication compliance: a randomized clinical trial. British Medical Journal. 1972; 2, 1031-1033.	RCT	Patients treated for simple chronic glaucoma with pilocarpine at Huddinge University Hospital	Patient tailored educational program	Change in drop compliance	Proportion of missed doses was significantly few in the intervention group compared to the control group (P=.004)	Study does not describe demographics of study population so uncertain of external generalizability	fair

Table 2. Quality Scoring

1st author, Year	Source and sample population adequately described	Cases and controls similar at baseline	Adequate description of measurement tool	Appropriate analysis	Adequately reported results	External validity	Overall quality score (x/18)
Okeke, 2009	3	2	3	2	2	1	13/18
Hoevenaars, 2008	1	NA	3	2	3	1	10/15
Norell, 1979	1	2	2	2	2	2	11/18

Poor=1, fair=2, good=3

Figure 1. Article Selection Flow Diagram
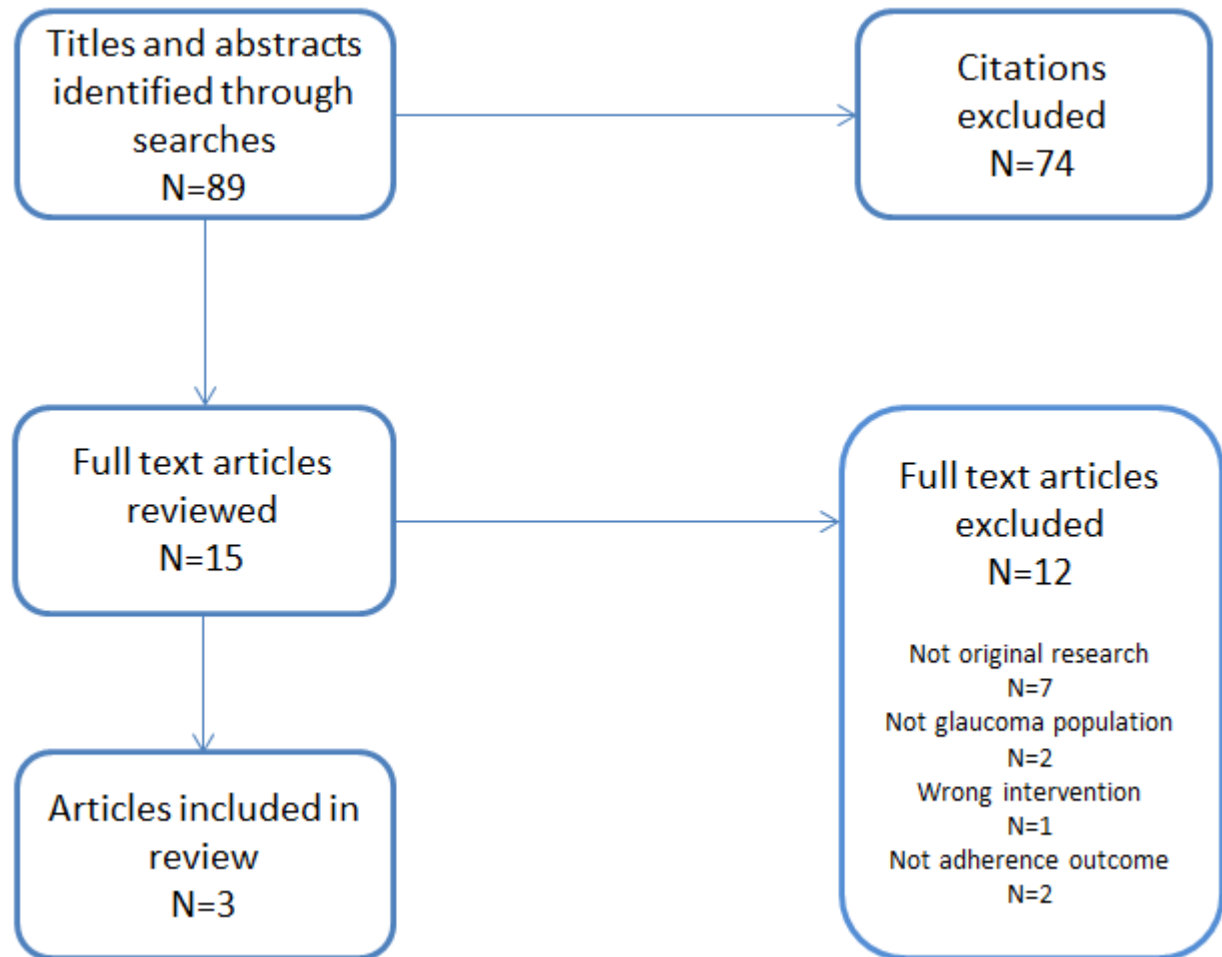
Appendix 1: Search Strategy

PubMed:

1. Communications

2. Health education

3. Health status

4. Patient compliance

5. Physician patient relations

6. Patient compliance AND physician patient relations AND glaucoma

7. Communications OR health education AND physician patient relations AND patient compliance AND glaucoma

CINAHL:

1. Patient compliance AND health education AND physician patient relations

EMBASE:

1. Communications OR health education AND physician patient relations AND patient compliance AND glaucoma

ISI:

1. Communication AND patient compliance AND physician patient relations

Cochrane:

1. Patient provider communication

2. Health literacy

3. Adherence AND intervention

4. Provider communication AND literacy

Appendix 2: Critical Appraisal Form

Citation (JAMA style)	
Study Question and Research Design	
Source Population	
Study Population (descriptive: demographics, eligibility criteria) and how chosen (volunteers, recruitment, tertiary care clinics, population-based, etc.)	
Initial Comparability of groups (i.e., randomization or group composition; concealment of allocation)	
Drop outs (no endpoint data), adherence, crossovers (attrition, loss to follow up)	
Potential for selection bias (+ to +++) and explain	
Measurement of exposure, intervention, potential confounders, and outcomes; reliability and validity of measurement; how performed, blinding	
Potential for measurement bias (+ to +++)	
Potential confounders (name and describe how each was controlled for)	
Potential for confounding (+ to +++)	
Analysis (intention to treat or other adjustment)	
Results: magnitude and direction (point estimate; random error or precision (confidence interval); statistical significance	
Clinical and Public Health importance for the source population; for a wider population	
Overall judgment of internal validity (good, fair, poor)	
External validity: applicability to other populations	
Comments and overall conclusions/interpretation (include consistency with other studies; biologic plausibility; conflicts of interest; selective endpoint reporting)	

Study Abstract

Purpose: Glaucoma, a chronic progressive disease is initially asymptomatic. Vision loss, which typically begins in the periphery of the visual field, is irreversible once it has occurred. Adherence to ocular anti-glaucoma drops is important to prevent the progression of vision loss and ultimately blindness. The purpose of the described study is to examine how African Americans perceive medical information related to glaucoma care from their providers. The ultimate goal is to use this information to develop a tool for improving provider patient communication about glaucoma and its treatment.

Methods: A qualitative study using focus groups was designed to explore the interactions between provider and patient used to impart disease related information. Low health literacy African American patients recruited from the eye clinic at UNC Chapel Hill will attend one of three focus groups of six to eight individuals each. Qualitative and quantitative data will be analyzed using Atlas.ti.60 and STATA 10.1, respectively.

Anticipated Results: Several major themes are expected to emerge from the focus groups. The first is education using multiple media formats (verbal, written, and graphic) appropriate to health literacy level. It is expected that provider patient relationship can be improved through the exploration of patient beliefs and attitudes towards disease. Multiple communication skills such as motivational interviewing, ask-tell-ask dialogue, and assessing readiness for change, likely can be used to identify and address patient adherence.

Conclusion: Improving patient adherence is likely to need a multifaceted, individualized approach. However, the identification of patient beliefs, values and learning style are an important first step in determining an individualized educational plan.

Introduction

Primary open-angle glaucoma (POAG), a chronic progressive optic neuropathy, affects approximately 2.22 million adults in the United States (1). POAG affects a disproportionally higher percentage of African-Americans with as much as a six fold increase in prevalence in some age groups when compared to their White counterparts (2, 3). The onset of POAG occurs on average ten years earlier and progresses more rapidly in African Americans than other races (2).

In one study, lack of knowledge about glaucoma was found to be the most important barrier to care in predominately African American populations (4). Lack of knowledge about one's medical condition has been linked to lower health literacy. Health literacy is the ability to read and understand written health information, oral health information, and the ability to act on such information (5).   The concept of health literacy in disease management is beginning to permeate the field of ophthalmology. Not only is low health literacy correlated with poorer understanding of disease, but it is also associated with lower compliance to medical treatment and worse health outcomes (6-10).

A cross-sectional patient survey of 197 patients with open angle glaucoma found that 52% read at or below eighth grade level and 11.7% were at or below third grade reading skills (11). In addition, the researchers found a correlation between poorer literacy skills and lower medication adherence, measured by the number of prescription refills (11). Lower health literacy is more prevalent among the lower socioeconomic urban population, which is predominately African-American (11). A review of educational material produced by the American Academy of Ophthalmology (AAO) in 1997 found that only 32% of the material was written at or below an eighth grade reading level (12). The overall mean Flesch-Kincaid score of the material was 9.6 (12). In contrast, AAO educational material published in 2008 improved to a mean score of 8.0 on the Flesch-Kincaid Grade Level Scale (13).

Barriers to effective patient care can be grouped into four basic categories: medication regimen, patient factors, provider factors, and situational factors (14) (15). While multiple studies have addressed the issue from the perspective of medication adherence, additional studies are needed to explore these basic categories in order to tailor interventions to patients' needs. Specifically, tools to improve ophthalmologists' ability to communicate effectively with low literacy patients are lacking.

Although it is unknown whether poor health literacy is a causal mechanism for worse disease outcomes or a marker for presently unknown factors, the provider-patient interaction has been identified as a modifiable step along the causal pathway to improved disease outcomes (10). Therefore, the goals of the planned study are to understand how African Americans perceive medical information related to glaucoma care. The information will then be used to develop a tool for improving provider-patient communication about glaucoma.

Methods

Approach

This qualitative study will use grounded theory to explore provider and patient interactions that are used to impart disease information.   Focus groups will be used to extract patient perspectives on the form and content of information their ophthalmologists could better provide to help them understand glaucoma and their role in glaucoma management.   There will be a series of three focus groups consisting of six to eight participants with a goal of twenty-four total participants. All three groups will be asked a series of scripted questions, including several open ended questions (Appendix 1). The moderator can use probe questions at his/her discretion to explore participant responses. Probe questions are expected to vary across the groups, according to individual situations.   A retrospective chart review will be used to determine disease severity and demographic information of each participant. A validated questionnaire (16), along with a confirmation letter, mailed to participants prior

to the focus group will be used to collect data on perceived glaucoma education and compliance (Appendix 2).   The study will be approved by the Institutional Review Board prior to study initiation and informed consent will be obtained from all participants.

Setting

The participants will consist of African Americans previously seen at the glaucoma or resident clinic at Kittner Eye Center of UNC Chapel Hill. Clinic schedules will be reviewed daily to identify potential participants by age and disease status. Participants will be recruited and screened by UNC School of Medicine (SOM) medical students at the time of their regularly scheduled glaucoma appointment using a predetermined script (Appendix 3).   It is estimated to take approximately two weeks per focus group to enroll the six to eight participants. Participants will be told that researchers seek to hear from patients on "physician-patient communication issues." Due to the sensitive nature of the term "low literacy," participants will not be explicitly told about the literacy component of the study. One African American trained focus group moderator will facilitate open and interactive dialogue amongst the group members and monitor the participation of each group member. One trained medical student will serve as note taker for each focus group to capture major themes and group dynamic information. The groups will be held in a neutral location on the campus of UNC-Chapel Hill.

Sampling

Convenience sampling will be used to identify potential participants who receive care at UNC Kittner Eye Center. Ophthalmology clinic schedulers will be blinded to the nature of the study to decrease bias in scheduling patients for their regular clinic appointments. Patients will be eligible if they are age 18 years or older, have a diagnosis of primary open angle glaucoma for at least six months, or have inadequate or marginal level functional health literacy. Functional health literacy will be determined at screening using the Short Test of Functional Literacy in Adults (STOFHLA), a validated and

reliable measure of health literacy. Patients will be excluded if their best corrected vision is worse than 20/50 in their better eye, a Mini Mental Status Exam (MMSE) worse than 25 or a documented psychiatric disorder, or a significant hearing disability. Decreased vision, low level score on MMSE , psychiatric disorders or hearing disabilities could interfere with a person's ability to complete the literacy test or to interact with participants during the focus groups. Interested participants will be seen by a researcher to screen for eligibility criteria.   The general consensus in qualitative research is that expected information saturation occurs by the third focus group. This theory was used as the rationale for a sample size of three focus groups.

Information Collection and Analysis

Data will be collected from chart reviews, a questionnaire administered via mail prior to the focus group, field notes collected by the assistant moderator, and transcription from the group audio recording.   Quantitative data collected from the chart review and questionnaire will be analyzed using STATA 10.1. Qualitative data collected from the field notes and audio transcription is to be analyzed using Atlas.ti 6.0 for emerging themes used to describe and explore provider and patient interactions. Computer assisted analysis is used to increase standardization and efficiency of analysis. Dependability of data will be established by the use of transcribed audio recordings of focus group sessions. Interobserver reliability will be established through the use of a debriefing session at the end of each focus group between the moderator and assistant moderator. This debriefing session will be audio recorded and included in data analysis. Data will be coded based on the identified themes and ideas. Data sets will be coded independently by two different analysts and resultant codes compared. After completing analysis, the two coders will meet to discuss the results and address any discrepancies which will be resolved by consensus reached by the two analysts.

Expected Results

Although scarce literature exists examining the effects of patient education on adherence in glaucoma, several ophthalmologists have written editorials presenting guidelines for both the detection and management of adherence issues based on researched gathered from other chronic diseases such as hypertension and diabetes (17, 18) . The use of verbal, written and graphic instructions can enhance understanding (19)(20). Health literacy should be a major consideration while constructing the written information as over ninety million Americans have limited literacy skills (5). The reading grade level of current American Academy of Ophthalmology (AAO) patient education material ranges from 4.9 to 11.1 with a mean of 8.0 (13) but 44 million American read at only the 5th grade level (21).

Provider patient relationship is an important part of the path to adherence (22). Motivational interviewing has been used successfully in other fields of medicine and has been suggested to be useful in nonadherent glaucoma patients. Although physicians assess for nonadherence, many factors cause patients to underreport medication adherence (23). Reported education centered barriers to adherence include insufficient understanding of drop installation, drop regimen, the consequences of poor drop adherence and inadequate education (24-26).

Several communication based strategies have been suggested, such as using an "Ask-Tell-Ask" dialog (13, 23, 27, 28), motivational interviewing (28), assessing for readiness for change (28), and "Ask Me 3" (27). More passive learners are less likely to ask questions (15), so a communication strategy forcing patients to interact with their physicians such as "Ask Me 3" or "Ask-Tell-Ask" could encourage greater disease comprehension and more open dialogue between the physician and patient.

In addition, valuable information can be gathered from examining the health beliefs and values of African Americans concerning other diseases. Lack of concern over vision loss is associated with decreased adherence to glaucoma medications and medical appointments in both white and nonwhite

patients (15). African American patients state that trust, empathy, and good communication is important in their interactions with physicians (22).

Potential Difficulties

Targeting recruitment to low literacy patients could cause enrollment to be slower than initially estimated. Unfortunately, a stigma still exists around the issue of low literacy. Patients with low literacy might be less willing to participate due to embarrassment of literacy skills. The presentation of the study will be very important to avoid a negative depiction of the low literacy demographic we are seeking to enroll. If slow enrollment continues to be a problem, we can choose to also include patients at Duke Ophthalmology Clinic or private practices in the area.

Although we plan to send out a confirmation letter with directions and a reminder phone call, committed participants may not actually show up for the focus group. This can be due to a number of factors and is a known phenomenon.   Over recruitment is a common solution to this problem. We aim to have six to eight participants for each focus group so we will enroll ten participants to ensure that we have enough participants to run the focus group. We will offer monetary incentive of fifteen dollars per participant to encourage confirmed individuals to attend the session. In addition, we will be sure to hold the focus group in a location that is convenient to most participants and near a form of public transportation.

Discussion

Improving patient adherence is likely to need a multifaceted approach, with patient centered education as only one part of the puzzle. Additional approaches, such as lowering costs and simplifying treatment regimens are also important. The Glaucoma Adherence and Persistency Study (GAPS) identified different types of learners: doctor dependent, who learn all their information from physicians;

collaborative, who learn most of their information from physicians; and doctor independent, who learn very little from his/her doctor. These three types of learners report their physician encounters differently, with doctor dependent learners less likely to report their physicians confirming their understanding (15). In addition, doctor dependent learners had lower adherence rates. These patients would likely benefit from a more aggressive approach to patient education from their physicians.

Findings from GAPS support the theoretical models of adherence behaviors showing doctor-patient communications, doctor-patient relationship, and health related beliefs to be important predictors of adherence (15). Identifying patient beliefs and attitudes along with their style of learning is an important first step in the patient encounters. Physicians must also be appropriately trained to modify their interactions depending on patient preference. This individualized approach makes one uniform communication tool difficult to construct. A potentially more useful tool would be a general guideline based on the assessment of patient learning style and health beliefs.

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Table1: Participant Demographics

Demographic	Group 1	Group 2	Group 3
Age			

Gender
  Female
  Male			

Educational Attainment
   High School or less
   Some College
   College Graduate			

Duration of Disease			
Number of Glaucoma Medications			

Table 2: Questionnaire Results

Question	Percent answering correctly
Glaucoma is a disease that affects your eyes and no other part of the body	
Most glaucoma is painful	
Raised eye pressure can cause glaucoma	
Glaucoma affects central vision before side vision	
Vision loss in glaucoma usually occurs very quickly	
Glaucoma can be cured	
The most common treatment for glaucoma is surgery	
Lost eyesight from glaucoma can be restored	
Most people with glaucoma go blind	
Treatment for glaucoma is life long	
Regular check-ups are not necessary for glaucoma patients	
Glaucoma can run in families	
Glaucoma is more common as you get older	
Most people will have symptoms that warn them their glaucoma is getting worse	
Stress can make glaucoma worse	
A healthy diet slows the progression of glaucoma	
Using a computer will make glaucoma worse	
Fluorescent lights will make glaucoma worse	
Eye drops can have side-effects that affect other parts of the body	
Watering eyes indicates that there is a build-up of fluid inside the eyes	
A lot of reading may make glaucoma worse	
Lower the eye pressure is a treatment that slows the worsening of glaucoma	

Appendix 1: Focus Group Question Guide

1. Opening question/icebreaker

2. Where have you learned the most about glaucoma?

3. What is it like when you ask your glaucoma doctor questions about your medical care?

4. What questions do you have about your care after you leave your doctor's office?

5. What would help you follow the doctor's directions after you leave the office?

6. How do you learn best? Think of hearing versus reading versus seeing a picture.

7. What is the most important thing you learned about your disease from your doctor?

8. Is there anything else that we haven't talked about yet that you think we should have addressed?

Appendix 2: Glaucoma knowledge questionnaire (43)

1   Glaucoma is a disease that affects the eyes and no other part of the body
2   Most glaucoma is painful
3   Raised eye pressure can cause glaucoma
4   Glaucoma affects central vision before side vision
5   Vision loss in glaucoma usually occurs very quickly
6   Glaucoma can be cured
7   The most common treatment for glaucoma is surgery
8   Lost eyesight from glaucoma can be restored
9   Most people with glaucoma go blind
10   Treatment for glaucoma is life long
11   Regular check-ups are not necessary for glaucoma patients
12   Glaucoma can run in families
13   Glaucoma is more common as you get older
14   Most people will have symptoms that warn them their glaucoma is getting worse
15   Stress can make glaucoma worse
16   A healthy diet slows the progression of glaucoma
17   Using a computer will make glaucoma worse
18   Fluorescent lights will make glaucoma worse
19   Eye drops can have side-effects that affect other parts of the body
20   Watering eyes indicate that there is a build-up of fluid inside the eyes
21   A lot of reading may make glaucoma worse
22   Lowering the eye pressure is a treatment that slows the worsening of glaucoma

Appendix 3: Recruitment Script

Eligibility Criteria:

- ICD-9 diagnosis of primary open angle glaucoma for ≥6 months
- ≥18 years old
- Gender balance (no fewer than 3 men or women in each group)
- Inadequate or marginal functional health literacy as determined by the Short Test of Functional Literacy in Adults (STOFHLA)

Exclusion Criteria:

- Adequate functional health literacy as determined by STOFHLA
- Best corrected vision worse than 20/50 in better eye
- Mini Mental Status Exam (MMSE) worse than 25
- Documented psychiatric disorder
- Significant hearing disability

Script:

Hello Mr./Mrs. _____.   My name is [your full name] and I am working on a research project here at UNC. We are holding focus groups to talk about issues in physician patient communication in patients with glaucoma and would like you to be a part of that. This is a group interview that would last about two hours, and we would pay you $25 for your time.

You would get together with other African American patients with glaucoma to talk together and answer some questions for us. There will be just this one meeting.

Is this something that interests you?

The session we are trying to set up is one [day] at [time]. Is this something that could fit into your schedule?

If the participant is available, continue with background information:

We are putting together a group of people who are willing to discuss their opinions and experiences with physician communication. We are especially interested in finding what people in the African American community think about the topic. Does this sound like something that would work for you?

Scheduling:

The session would be at [location] on [date]. We will start at [time] and end by [time].   It is very important that everyone that signs up actually shows up. Do you think that you can come? It is also important that you will be there by [start time]. Will you have any trouble getting there on time?

The group itself will consist of 6-8 people, all African Americans with glaucoma. Most of the time will be spent talking amongst yourselves in a group discussion. The group session will be audio recorded to

make sure that we have a good idea of what was said. The recording and all that was is said during the session will be kept confidential. Attending this session is completely voluntary and you will be free to leave at any time for any reason.

I'd like to mail you a letter confirming your participation in this focus group, along with a map to the group location, and a survey to complete and bring along with you to the focus group session. What is the best address to send that to?

We will be starting the session right on time at [time] on [date]. If you get to the session late we may not be able to include you. So, it is very important that you get there on time.

So that everyone remembers, we will be calling you the evening before the group session to remind you about it. What is the best number to call you at?

Thank you very much. We are looking forward to seeing you on [date].

If the patient is unsure whether to participate:

First, make sure that the time is workable for that person. Do not waste time trying to recruit someone who won't be able to attend. If person is potentially available, offer to call them in a few days if you still have an opening in the group. It is very important that all participants show up to the focus group session. Only accept people who make a solid commitment to attend. If the person would like to participate but the group has filled up, you can offer the role of an alternate. An alternate can be called the evening before the group if a participant cancels at the last minute.