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2013-01-23
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PSEUDOEXFOLIATION SYNDROME IN A RURAL GLAUCOMA CLINIC IN THE EASTERN CAPE, SOUTH AFRICA.

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A research report submitted to the Faculty of Health Sciences, University of the Witwatersrand, Johannesburg, in partial fulfilment of the requirements for the degree of

Master of Public Health

January 2012

DECLARATION

I, Rasayi Rufaro Mdlankomo, declare that this research report is my own work. It is being submitted for the degree of Master of Public Health in the University of the Witwatersrand, Johannesburg. It has not been submitted before for any degree or examination at this or any other University.

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16 January 2012

To all the Glaucoma patients for whom our intervention was too late.

ABSTRACT

Introduction

Glaucoma presents an ever-increasing burden in Africa because of its asymptomatic nature. In South Africa, pseudoexfoliation syndrome (PXS) is particularly prevalent among black South Africans patients with glaucoma. The objective of the study was to determine the prevalence of PXS in a population of patients attending a glaucoma clinic; and to ascertain its clinical features.

Materials and methods

This was a cross-sectional survey of patients attending a glaucoma clinic in rural Eastern Cape. A sample of 100 patients were selected for the study and data was collected using a questionnaire and by doing a clinical examination. Data was analysed in Epi-info to determine prevalence, clinical features, and chi square test to determine association between PXS and socio-demographic factors and the severity of glaucoma.

Results

A total of 100 patients attending the clinic were included in the study. The majority of patients were male (59%); in their 60s; of rural origin (63%); and did not have any tertiary education (74%). Of note is that 84% of the patients had Primary Open Angle Glaucoma (POAG). The prevalence of pseudoexfoliation syndrome in these patients was 13%. All 13 PXS had the central round disc of PCE material on the lens capsule and a peripheral ban of PXS and a clear zone in between and PXS material was visible on the papillary margin in all cases.

Conclusion

This study shows a prevalence of 13% which is in keeping with other figures of previous South African studies which vary between 8.1% and 21.6%.

ACKNOWLEDGEMENTS

My husband's unwavering support and constant encouragement enabled me to finish this report. My children, Yoliswa, Rugare and Ungumangaliso were ever so generous with their time. Much gratitude and appreciation to my mother Mrs. Florence Pswarayi, and Ms Beauty Mulambo for being the best surrogate mothers ever to my children whilst I worked on this project. I thank them with all my heart.

I would also like to thank my supervisors Dr. Mary Kawonga and Professor Trevor Carmichael who were always accessible and patient. I am also so thankful to my research assistant Sr Thandokazi Mpolweni whose excellent Xhosa ensured me the cooperation and understanding of my study participants. My heartfelt gratitude goes to Mr. Gaylord Ndlovu who through his patience and kindness revealed the intricacies of the computer to me.

I thank God because of His strength, I can do all things.

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1. INTRODUCTION

1.1 Background

Blindness is an important public health problem that affects a significant number of people across the globe. In 1975 the first analysis of data on blindness estimated that there were 28 million blind people (acuity in the better eye less than 3/60) worldwide. (1) By 1984 this had risen to 31 million and in 1990 to 38 million. Projections based on increasing population and increased life expectancy suggest there were 50 million blind in the year 2000, and, if services do not improve, there will be 76 million blind people in 2020. (1)

Overall, cataract is responsible for approximately 50% of global blindness. (1) Glaucoma is second to cataracts as the most common cause of blindness. Glaucoma affects an estimated 70 million people and is a leading cause of irreversible blindness throughout the world. (2) World Health Organisation statistics, published in 1995, indicate that glaucoma accounts for blindness in 5.1 millions persons or 13.5% of global blindness (3), and Pseudoexfoliation Syndrome (PXS) has recently been recognized as the most common identifiable cause of glaucoma. (4)

Pseudoexfoliation Syndrome (PXS) is an age-related disease in which abnormal fibrillar extracellular material is produced and accumulates in many ocular tissues. Its ocular manifestations involve all of the structures of the anterior segment, as well as conjunctiva and orbital structures. (4) Glaucoma occurs more commonly in eyes with PXS than in those without it. (4)

The most fundamental fact concerning glaucoma is that it is not a single disease process. Rather it is a large group of disorders that are characterized by widely diverse clinical and histopathologic manifestations. (5) The common denominator of the glaucomas is a characteristic optic neuropathy, which derives from various risk factors including intraocular pressure (IOP). Glaucomatous optic neuropathy is associated with a progressive loss of the visual field which can lead to total irreversible blindness if the condition is not diagnosed and treated properly.

Most eye care programs in Africa focus on elimination of reversible blindness, hence the priority is cataract surgery. Following the inclusion of glaucoma in Vision 2020, some countries in Africa are now directing some of their attention to glaucoma. Vision 2020 is a global initiative to eliminate avoidable blindness. The initiative is a partnership between the World Health Organization (WHO) and the International Agency for prevention of Blindness (IAPB), which is the umbrella organization for eyecare professional groups and non-governmental organizations (NGOs) involved in eyecare. (1) The initial goal of Vision 2020 is to eliminate avoidable blindness by the year 2020. Long term goals are to ensure the best possible vision for all people and thereby improve quality of life. (1)

The control of glaucoma involves screening for early detection and appropriate treatment. The major difficulty with glaucoma and the blindness that it can lead to is the lack of a uniform case definition. (6) Glaucoma commonly refers not to a single disease, but to a group of disorders that have certain common features, in particular:

- Cupping and atrophy of the optic nerve head
- Characteristic visual field loss; and
- Often, but not invariably, increased intra-ocular pressure. (6)

Of these cardinal signs, visual field loss is diagnostically the most specific, since both cupping and intra-ocular pressure exhibit physiological variations in a given population. However visual field loss is a late manifestation of glaucoma, and therefore is not particularly suitable for early detection of the disease. In addition it is not easily investigated reliably in large –scale population screening in developing countries. (6) The major problem in developing appropriate screening techniques for glaucoma is its asymptomatic nature and that it needs specially trained personnel to measure the intraocular pressure and to do funduscopy. Therefore, in developing countries glaucoma is often detected at a late stage as early screening is not routinely practiced for the majority of the population.

1.2 Statement of the problem

Overall, approximately 70% of the world's cases of Primary open angle glaucoma (POAG) are found in developing countries. (6) The burden of disease is substantially higher among younger people in the African population. Among people with glaucoma in developed countries, only half are likely to be known to the health care system.(2) The lack of a uniform definition of the disease in its different forms makes it difficult to assess its public health impact. (6) Although it is agreed that the burden of blindness due to different types of glaucoma is high, the problem has been that there have not been reliable ways of detecting these diseases or straight forward

ways of treating them. Once the blindness of glaucoma has occurred, there is no known treatment that will restore the lost vision. In nearly all cases, however, blindness from glaucoma is preventable. This prevention requires early detection and proper treatment. Detection depends on the ability to recognize the early clinical manifestations of the various glaucomas.

The high costs of present methods for glaucoma screening are a barrier to the identification of people at high risk for glaucoma blindness. The low rate of glaucoma detection also results from the frustration of health care providers with impractical screening methods and the perceived inability to offer effective therapy for glaucoma.

Pseudoexfoliation glaucoma may be easily detected and because it is often a precursor to the development of glaucoma, raising awareness of it and screening for it may lead to better control of the disease. However, despite its importance and public health relevance, limited information is available on the prevalence of primary open angle glaucoma (POAG) or other glaucomatous optic neuropathies in black people (who often seek treatment late when the disease is very advanced whereas white people are picked up earlier because they seek treatment or avail themselves for screening early) and even less is known about possible risk factors. (7) This study, thus seeks to determine the prevalence of PXS amongst a black population of patients attending a glaucoma clinic in South Africa.

1.3 Justification for the study

The social and economic impact of glaucoma is enormous but difficult to quantify. (5) Pseudoexfoliation Syndrome has a high prevalence among black South Africans and incurs a moderate increase in risk of glaucoma. (8) Therefore it is important to augment the research on prevalence of PXS to provide baseline data for eye care programme planning.

1.4 Literature review

Pseudo exfoliation Syndrome (PXS) is the most common identifiable cause of secondary open angle glaucoma worldwide. (5) PXS leads not only to severe chronic open angle glaucoma, but also to lens subluxation, angle closure and blood-aqueous barrier impairment. During cataract surgery serious complications may occur such as zonular dialysis, capsular rupture and vitreous loss. There is increasing evidence for an aetiologic association of PXS with cataract formation and retinal vein occlusion. (9) Exfoliation material has been found not only in the eye but also in the walls of the posterior ciliary arteries, vortex veins and central retinal vessels as they exit the optic nerve. PXS has also been found in autopsy specimens of the heart, lung, liver, kidney, gall bladder and cerebral meninges. (9) Recently systemic associations have also been reported and these include transient ischaemic attacks, Alzheimer's disease, and hearing loss. (9) PXS also has a strong correlation with hypertension, angina, myocardial infarction and stroke. (9) There is strong evidence that PXS is an ischaemic disorder. (9) Iris ischaemia can be detected both on iris angiography and histopathologically in fellow eyes of patients with clinically unilateral involvement. (9)

Genetics of PXS

PXS and PXG (Pseudoexfoliative glaucoma) have been shown to demonstrate strong familial aggregation that is consistent with inherited disorders. Thorleifsson et al demonstrated a strong association of PXS and PXG conferred by three single nucleotide polymorphisms (SNPs) in the lysyl oxidase-like 1 (LOXL 1) gene. (10) LOXL 1 and elastin are expressed in the cornea, iris, ciliary body, lens capsule, and optic nerve. (10) No association has been shown with POAG, pigmentary glaucoma, or angle closure glaucoma. The most striking feature of the LOXL 1 association is the very high prevalence of the SNPs in affected individuals. This shows that this gene is a major genetic risk factor for this disease conferring approximately 80 – 99% population attributable risk in various cohorts. (10) However there is also a relatively high prevalence among control groups with reported prevalences of up to 88%, which raises the possibility that there are protective genes or environmental factors that retard the development of PXS or PXG. Further studies are needed to distinguish how the LOXL 1 gene leads to PXS and PXG development. (10)

The first well-designed survey of glaucoma was carried out by Hollows and Graham in the Rhondda Valley, South Wales. (11) Since then there have been nearly 30 published glaucoma prevalence surveys on the prevalence of glaucoma with acceptable sampling techniques and definitions. (1) Prevalence estimates based on blindness surveys may underestimate glaucoma prevalence because POAG is asymptomatic, and visual acuity and fields are only affected in the late stages of the disease. (12) Quigley's review of glaucoma prevalence worldwide reported a prevalence of 2.42% of POAG in Caucasians. (2) In the United States, glaucoma is the second

leading cause of blindness and the most frequent cause of blindness among African-Americans (6). A recent population-based study in rural Tanzania reported an age-adjusted prevalence of primary glaucoma very close to that in African-Americans. (13) The prevalence study in Tanzania carried out by Burhmann et al, (13) found a crude prevalence of 3.1% and the proportion of those blind was 11%.

A population-based cross sectional survey done in Hlabisa, South Africa in 2002 (14) found that glaucoma prevalence is generally higher in those of African origin than in other racial groups and that it is principally POAG in type. The crude prevalence rate was 2.8% (adjusted 3.2%). The other glaucoma prevalence study done in Temba, South Africa in 2003, found a prevalence of 5.3% of all glaucomas. (15) A population study in Ghana carried out by Ntim-Amponsah et al found an overall prevalence of Glaucoma of 8.4% (8.2% females and 8.6% males) with a 95% confidence interval of 7.74% - 9.06%. The standardized age-specific prevalence was 7.7% for ages 30years and above and 8.5% for ages 40years and above. (12)

The Barbados Eye Study is the largest glaucoma study ever conducted in a black population and identified more people with POAG than did any previous population study. The observed overall prevalence was 6.8% (95% CI, 6.1 to 7.6) and varied significantly by age and sex. It increased steeply with age, reaching 14.8% at ages 70 through 79years and 23.2% at older ages. In every age group, prevalence was higher in men than in women, with an age-adjusted prevalence ratio of 1.4. (7) The National Survey of the prevalence of Glaucoma conducted in St. Lucia, West Indies identified by stringent criteria an overall prevalence rate of POAG of 8.8%.

The prevalence rate increased sharply with increasing age and was higher in women in all age groups younger than 70 years of age. Using secondary criteria, they found an overall prevalence rate of 16.0%. (16)

The Baltimore Eye Survey compared the prevalence of POAG between black and white Americans and found that age-adjusted prevalence rates were four to five times higher in blacks as compared to whites. Rates among blacks ranged form 1.2% in those aged 40 through 49 years to 11.3% in those 80 years or older, whereas rates for whites ranged from 0.9% to 2.2% respectively. There was no difference in rates of POAG between men and women for either blacks or whites for this population. (17)

The prevalence of pseudo exfoliation increases dramatically with age and varies considerably from country to country and from region to region. Geographic and ethnic differences appear to be important with PXS prevalences world wide. It appears to be particularly common in Norway and in the Eastern European and Mediterranean countries. It is rare in the African-Americans and blacks in the West Indies, but is seen commonly in the black South Africans. (18) The influence of race differs among geographic populations. The percentage of PXS patients with glaucoma is different for every population.

Overall studies indicated about 40% of PXS patients will develop glaucoma. (4) Glaucoma in PXS has a more serious clinical course and worse prognosis than Chronic open angle glaucoma (COAG). There is a significantly higher frequency and severity of optic nerve damage at the time

of diagnosis, worse visual field damage, poorer response to medications, more severe clinical course, and more frequent necessity for surgical intervention. (4) In South Africa, PXS was found in 20% of black patients with open angle glaucoma, compared with 1.4% in whites in South Africa. (19) Pseudo exfoliation accounted for 16% of all glaucoma cases in the Temba glaucoma study (15) and 21.6% of all glaucoma in the Hlabisa survey. (14)

Studies specifically done to find the prevalence of PXS in South Africa are very few. Luntz (19) looked at patients attending a glaucoma clinic in Johannesburg and found that in black patients, PXS was present in 50% of the glaucoma patients and in whites about 17%. Bartholomew noted a similarly high prevalence of PXS in population study of a rural black community in the Eastern Cape, South Africa, of 8.1%. (18) More recent studies done in Hlabisa (14) and Temba (15), South Africa, found an age-adjusted prevalence of PXS of 7.7% and 6.0% respectively.

Elsewhere, in the Framingham Eye Study conducted in the United Kingdom the prevalence of PXS was found to be 1.8% (20), and in the Blue Mountains Eye Study done in Australia it was 0.4%. (21) A study carried out in Australia by McCarty and Taylor found PXS to be a relatively common condition, affecting 6% of people in their eighties and the overall rate of PXS was 0.98%. They also found a higher, although not significant, prevalence of pseudoexfoliation syndrome in men. They also found two strong correlates of pseudoexfoliation syndrome in their population-based sample of Victorians aged 40 years and older: age and glaucoma. They did not find a significant correlation between PXS and intra-ocular pressure. (22)

1.5 Aim and objectives of the study

1.5.1 Overall aim

To determine the prevalence of PXS and to describe its clinical features amongst patients attending a glaucoma clinic in the Eastern Cape for the period September 2008 to November 2009.

1.5.2 Specific objectives

1. To ascertain the socio-demographic profile of patients attending the glaucoma clinic
2. To identify and describe the relative frequencies of different types of glaucoma in the glaucoma clinic
3. To determine the prevalence of PXS among patients attending the glaucoma clinic
4. To describe the clinical features of PXS
5. To determine the prevalence of visual loss associated with glaucoma amongst patients attending the glaucoma clinic
6. To determine the association between socio-demographic factors and the presence of PXS
7. To determine the association between the severity of glaucoma and the presence of PXS

2: MATERIALS AND METHODS

This chapter details the study design, the study population and the sampling techniques. It also outlines the method of data collection, and the variables that were measured to fulfil the study objectives. The end of the chapter deals with the data processing the data analysis methods used, as well as the ethical considerations.

2.1 Study design

The study was a cross-sectional analytical survey of patients attending the glaucoma clinic at Frontier Hospital in the Eastern Cape.

2.2 Study population

Black, male and female adult patients (greater than 40years old) attending the glaucoma clinic from the Queenstown catchment area during the period September 2008 to November 2009 at Frontier Hospital, Eastern Cape, South Africa**,** were the study population for the study.

2.3 Study sample

A sample of 100 patients was selected for the study. Thus number was based on feasibility. Patients were selected from amongst those booked in the Glaucoma Clinic Appointment book as well as those that were not booked. All patients attending the clinic on that day were asked to participate in the study and the first 3 to 5 patients in the queue that agreed were recruited per clinic which runs twice a month. 100 patients represent 25% of the clinic population that were in the Glaucoma clinic in that same period. Realistically it takes about 45minutes to

examine one patient, and so only three to four patients were done per day since I had to see other patients in the clinic as well and so the recruitment period was longer than initially anticipated. Over a period of fifteen months (September 2008 till November 2009), I recruited one hundred patients: from September 2008 to June 2009 I recruited seven patients per month and then from July to November 2009 I recruited six patients per month.

2.4 Measurement

Data collection started in September 2008 after ethics approval and continued until 100 patients had been recruited. Patients were recruited if already on treatment for glaucoma or patients newly diagnosed during the survey. The major inclusion criteria for selection of study patients were: evidence of glaucomatous optic nerve damage, visual field defect and /or raised IOP. Patients who met these criteria were asked to participate in the study and to sign the consent form (Annexure A). The data collected were entered onto a data sheet (Annexure B) which was de-identified. Data were only accessed by the principal investigator (R R Mdlankomo).

2.4.1 Variables and data collection

A questionnaire was completed by the research assistant for socio-demographic variables including age, sex, residence, level of education and occupation. A rural area was defined as any area outside of Queenstown. Queenstown is semi-rural in that it is a designated nodal town.

Clinical ophthalmological assessment was done to measure the following variables:

- Visual acuity: assessment was done with a Snellen chart projector and patients were categorized according to the new revised WHO definition of blindness (23) as shown below:

Mild or no visual impairment	(0)	>6/18
Moderate visual impairment	(1)	<6/18 – 6/60
Severe visual impairment	(2)	<6/60 – 3/60
Blindness	(3)	<3/60 – 1/60
Blindness	(4)	<1/60 – Light perception
Blindness	(5)	no light perception
	(9)	undetermined or unspecified

- Visual field: testing was done in eyes with a visual acuity of 6/60 or better. Testing of central 30 degrees visual field was done using the Optopol PTS910 Field Analyzer. Patients were classified as having normal visual field, minimal, moderate and severe glaucomatous visual field changes as follows:
    - Normal - no visual field damage
    - Minimal – generalised peripheral constriction, a scotoma between 10 and 20 degrees of fixation, a nasal step and or a wedge defect
    - Moderate – arcuate-shaped scotoma, double arcuate scotoma

- Severe – small central island of vision plus a temporal island, only a central island of vision (tunnel vision).

- Presence of pseudoexfoliatrive material: slit-lamp biomicroscopy before pupil dilatation was done to look for pseudoexfoliative material. There were two categories for the presence of PXS; present or absent. The pseudoexfoliative material was classified as present if it was noted in any of the following areas: granular deposits at the pupillary margin, on the anterior lens capsule and in the angle of the anterior chamber. The examination also included looking for pigment deposition on the corneal endothelium, and iris illumination defects but these were not part of the classification for the presence or absence of PXS.
- Intra-ocular Pressure (IOP): this was measured using both a calibrated Goldmann and i-care tonometer and the patients were grouped into four categories:
  Low IOP <10; Normal 10 – 21; borderline 22 – 25; High >25.

- The type of glaucoma was determined as follows: Firstly, gonioscopy was performed using a Goldmann 3-mirror lens to grade the angle of the anterior chamber. The Shaffer grading system was used to assign a numerical grade to each angle as follows (24):
  - Grade 4 (35-45degrees) – very wide angle
  - Grade 3 (20-35degrees) – open angle incapable of closure
  - Grade 2 (20degrees) – narrow angle with closure possible but unlikely
  - Grade 1 (10degrees) – narrow angle with high risk of closure
  - Grade 0 (0degrees) – closed angle

Then using these data and the data from the assessment of intraocular pressure, patients were classified as having:

- Primary Open Angle Glaucoma (POAG) for angles Grade 4 to 1
- Primary Closed Angle Glaucoma (PCAG) for angle of Grade 0
- Normal tension Glaucoma (NTG) open angles with IOP <10
- Pseudoexfoliative Glaucoma (PXG) for glaucoma associated with PXS
- Other – glaucoma due to inflammation or trauma

- Severity of glaucoma: pupillary dilatation was initially conducted if the angle was judged not to be occludable to allow examination of the lens and to facilitate binocular funduscopy. Binocular funduscopy was then done to ascertain the cup-disc ratio (CDR) of the optic nerve head (disc). The optic cup is a pale depression in the centre of the optic nerve head. The size of the cup is related to the diameter of the disc. Pathological cupping occurs in adult glaucomas because of a decrease in the number of nerve fibres in the optic nerve head (24). The normal CDR is 0.3 in the horizontal meridian in most eyes. For this study, the CDR was categorised as follows to determine optic nerve damage or severity of glaucoma:

    - normal - CDR 3/10 or less
    - minimal glaucomatous damage – CDR 4/10 – 5/10
    - moderate glaucomatous damage – CDR 6/10 – 7/10
    - severe glaucomatous damage - CDR 8/10 – 10/10

2.5 Data processing and data analysis

Data were first entered onto the data sheets during the clinical assessments. Data were then entered onto an MS Excel spreadsheet, and cleaned and analysed using the Epi-info statistical package (version 3.5.1). To describe the socio-demographic profile, mean and standard deviation were used to summarise age; and proportions were used to summarise categorical data (sex, residence, level of education and occupation).

Summary statistics (proportions) were also used to classify patients, and determine frequency distributions of patients for the following clinical variables: visual acuity, visual field damage, presence of PXS, type of glaucoma and severity of glaucoma.

Statistical analysis was done using the chi square test to determine the association between the socio-demographic variables (age, sex, geographical location, level of education and occupation) and the occurrence of PXS, as well as the severity of glaucoma. Statistical significance was set at a p value of 0.05.

2.6 Ethical considerations

This research protocol was submitted to the University of The Witwatersrand Committee for Research on Human Subjects (Medical) as well as to the Walter Sisulu University Ethics Committee. The study commenced after approval from the Wits Ethics Committee Ethics No M080457 (Annexure C) was obtained and official authorization from the Eastern Cape Department of Health was given.

Informed consent to participate in the study was obtained from all patients (by the research assistant) and confidentiality was maintained. The patients were informed that they had the right to withdraw and any benefits and risks were outlined (Annexure D).

3: RESULTS

This chapter presents the result of the study. The data are presented in five sections. The first section presents the socio-demographic profile of the study participants; the second section describes the types of glaucoma; the third section describes the clinical features of PXS; the fourth section presents the prevalence of visual loss associated with glaucoma; and the fifth section describes the results of the analysis to evaluate associations between PXS and socio-demographic variables and between PXS and severity of glaucoma.

3.1 Socio-demographic profile of study participants

A total of 100 patients participated in this study, 59 of who were male, and 41 female. Out of the 100 patients in the sample, the age range was 40 to 98 years. The age variable was normally distributed, and the mean age was 67.4 (SD: 2). Just over 70% of participants were 60 years and older (Table 1).

All patients were black and Xhosa-speaking except for three Caucasians (one white female and two white males). The majority of the participants (64%) were from a rural area. Just over half of the participants had no formal education or had primary education (56%). Only 7% were professional i.e. nurses or teachers. (Table 1)

Table 1: Socio-demographic profile of patients attending the glaucoma clinic during September 2008 to March 2009

Variable	No	%
AGE		
40 – 49	7	7
50 – 59	22	22
60 – 69	31	31
70 – 79	23	23
80+	17	17
SEX		
Female	41	41
Male	59	59
EDUCATION		
None	16	16
Primary	40`	40
Secondary	37	37
Tertiary	7	7
OCCUPATION		
Unskilled	46	46
Semiskilled	26	26
Professional	19	19
Pensioner	9	9
RESIDENCE		
Rural	64	64
Semi-rural	36	36

3.2 Types of Glaucoma and prevalence of PXS

There was a preponderance of the primary open angle type glaucoma (84%). Fifteen patients had secondary glaucoma. Of these 13 were due to PXS and the other was a female who had bilateral panuveitis and the one was a male patient with angle recession glaucoma following trauma. There was only one case of normal tension glaucoma (Table 2).

Table 2: Types of Glaucoma

Types of Glaucoma	**No**	**%**
Primary Open Angle Glaucoma	84	84
Primary Closed Angle Glaucoma	0	0
Normal Tension Glaucoma	1	1
Pseudoexfoliative Glaucoma	13	13
Other	2	2
TOTAL	**100**	**100**

3.3 Clinical Features of PXS

As presented in table 2 13% of the 100 patients attending the glaucoma clinic had PXS. All cases of PXS were bilateral; amongst these PXS cases, only one was female and the other 12 were males. All but one of these PXS subjects was less than 60 years old.

Eight PXS cases had IOP less than 21mmHg and 5 had IOPs greater than 21mmHg. All 13 PXS patients had vertical CDR greater than 5/10. One patient out of the 13 was pseudophakic, two had cataracts and the rest had their normal lenses.

All 13 PXS patients had the central round disc of PCE material on the lens capsule. This was seen easily in the dilated pupil where the characteristic pattern of a central disc and a peripheral band of PXS, with a clear zone in between (24). PXS material was visible on the pupillary margin of the iris in all 13 cases. There were no iris illumination defects. Deposits of pigment on the inferior third of the endothelium were seen in 9 out of 13 cases.

On gonioscopic examination, all the 13 pairs of eyes with PXS were heavily pigmented. No exfoliative material was seen in the angle and all 13 pairs of eyes had a band of pigment anterior to the Schwalbe line (Sampaolesi line). The angles were all grade IV. Eleven eyes out of 26 eyes with PXS were blind i.e. they had a visual acuity less than 3/60.

3.4 Prevalence of Visual Loss associated with Glaucoma

Table 3 depicts the proportion of patients with visual loss and shows that 32.5% of the 200 eyes were blind and of these 15 eyes (7.5%) had no light perception. Blindness prevalence increased with age. In patients older than 60 years, blindness prevalence was 45% and in those older than 80 years it was 56%.

Table 3: Visual loss associated with Glaucoma

Visual Acuity	**No of eyes**	**%**
Mild or no visual impairment 0 6/18 or more	70	35
Moderate visual impairment 1 <6/18 – 6/60	45	22.5
Severe visual impairment 2 <6/60 – 3/60	20	10
Blindness 3 <3/60 – 1/60(CF)	25	12.5
Blindness 4 <1/60 – LP	25	12.5
Blindness 5 No light perception	15	7.5
9 Undetermined or unspecified	0	0
TOTAL	**200**	**100**

3.5 Factors associated with PXS

Statistical analysis showed there was an association between sex and the presence of PXS and men were more likely than women to have PXS. There was no association between any of the other socio-demographic variables and the presence of PXS (Table 4). There was also no association between the severity of visual loss and the presence of PXS (Table 5).

Analysis of the association between severity of glaucoma and PXS showed a statistically significant association between optic nerve damage in the left eye and presence of PXS. Having optic nerve damage in the right eye however was not associated with the presence of PXS. There was a statistically significant association between visual loss in the right eye and the presence of PXS (Table 6).

Table 4: Socio-demographic variables and presence of PXS

Socio-demographic variable	**Presence of PXS No (%)**			***p-value**
AGE	**Yes**	**No**	**Total**	**0.16**
40 -49	0(0.0)	7(100)	**7(100)**	
50 -59	1(4.5)	21(95-5)		
60 – 69	3(9.7)	28(90.3)		
70 – 79	6(26.1)	17(73-9)		
80+	3(17.6)	14(82.4)	17(100)	
SEX				**0.0088**
Female	1(2.4)	40(97.6)	**41(100)**	
Male	12(20.3)	47(79.7)	**59(100)**	
Level of education				**0.37**
None	3(18.8)	13(81.3)	**16(100)**	
Primary	7(17.5)	33(82.5)	**40(100)**	
Secondary	2(5.4)	35(94.6)	**37(100)**	
Tertiary	1(14.30	6(85.7)	**7(100)**	
Occupation				**0.80**
Unskilled	5(10.9)	41(89.1)	**46(100)**	
Semi-skilled	5(18.5)	22(81.5)	**27(100)**	
Professional	2(11.1)	16(88.9)	**18(100)**	
Pensioner	1(11.1)	8(88.9)	**9(100)**	
Residence	**Yes**	**No**	**Total**	
Rural	11(17.2)	53(82.8)	**64(100)**	
Semi-rural	2(5.7)	34(94.3)	**35(100)**	

***p-value:** a p value of 0.05 is statistically significant

Table 5: Prevalence of Visual loss and presence of PXS

Visual Acuity	**Presence of PXS No (%)**			***p-value**
	Yes	**No**	**Total**	
Visual Acuity Left Eye				**0.1447**
Mild or no visual impairment 0 6/18 or more	3(8.3)	33(91.7)	**36(100)**	
Moderate visual impairment 1 <6/18 – 6/60	2(11.8)	22(88.2)	**17(100)**	
Severe visual impairment 2 <6/60 – 3/60	2(14.3)	3(85.1)	**14(100)**	
Blindness 3 <3/60 – 1/60(CF)	6(6.3)	29(93.8)	**16(100)**	
Blindness 4 <1/60 – Light Perception(LP)	5(35.7)	9(64.3)	**14(100)**	
Blindness 5 No Light Perception (NLP)	0	3(100)	**3(100)**	
TOTAL	**13(13.0)**	**87(87.0)**	**100(100)**	
Visual Acuity Right eye				**0.0403**
Mild or no visual impairment 0 6/18 or more	3(8.8)	31(91.2)	**34(100)**	
Moderate visual impairment 1	6(21.4)	22(78.6)	**28(100)**	

<6/18 – 6/60				
Severe visual impairment 2 <6/60 – 3/60	0(0.0)	6(100.0)	**6(100)**	
Blindness 3 <3/60 – 1/60(CF)	0(0.0)	9(100.0)	**9(100)**	
Blindness 4 <1/60 – Light Perception(LP)	4(36.4)	7(63.6)	**11(100)**	
Blindness 5 No Light Perception (NLP)	0(0.0)	12(100)	**12(100)**	
TOTAL	**13(13.0)**	**87(87.0)**	**100(100)**	

***p-value:** a p value of 0.05 is statistically significant

Table 6: Severity of glaucoma and presence of PXS

Optic nerve damage	**Presence of PXS No (%)**			***p-value**
	Yes	**No**	**Total**	
Optic nerve damage left eye				0.0098
Normal CDR 3/10	0(0.00)	3(100)	**100(100)**	
Minimal CDR 4/10 – 5/10	1(9.1)	10(90.9)	**100(100)**	
Moderate CDR 6/10 – 7/10	6(28.6)	15(71.4)	**21(100)**	
Severe CDR 8/10 – 10/10	6(7.8)	59(92.2)	**64(100)**	
Total	**13(13.0)**	**87(87.0)**	**100(100)**	
Optic nerve damage right eye	**Yes**	**No**	**Total**	0.28
Normal CDR 3/10	1(33.3)	2(66.6)	**3(100)**	
Minimal 4/10 – 5/10	2(13.3)	13(86.70	**15(100)**	
Moderate 6/10 – 7/10	5(25.0)	15(75.0)	**20(100)**	
Severe 8/10 – 10/10	5(8.2)	57(91.8)	**61(100)**	
Total	**13(13.0)**	**87(87.0)**	**100(100)**	

***P-value**: a p value less than 0.05 is statistically significant.

Chapter 4: DISCUSSION

This cross-sectional study confirms the high prevalence of PXS (13%) reported amongst blacks in South Africa; and particularly in this study, it showed the high prevalence amongst Xhosa-speaking people. The study further shows that PXS is more common in males than in females and that there is a high rate of visual loss associated with PXS.

Although PXS has a worldwide distribution, there is a well-recognised tendency for the syndrome to cluster both geographically and within racial and ethnic subgroups. (25) The prevalence of pseudoexfoliation syndrome depends on the ethnic background of the population studied. Information on the prevalence of PXS among the African population is scarce and in the few available reports, the prevalence of PXS is reported to vary widely. (26)

Several South African studies have found the prevalence of PXS to be high: 16%, 21.6%, 20%, 8.1% (17,15,21,20). The Hlabisa (14) and Temba (15) studies are particularly important because these were population-based surveys. Similarly in other parts of Africa, the prevalence of PXS was found to vary between 7 and 40%. The prevalence was found to be 7.4% in a clinic in Zimbabwe; while in Ethiopia the prevalence of PXS in a glaucoma clinic population was found to be 25%. (27, 28) Further in another study in Ethiopia a PXS prevalence of 39.3% was found among patients scheduled for cataract surgery. (26) In Tanzania, however, a population-based survey found no PXS among a sample of 3268 people. (13) Low prevalences have also been reported among African-Americans. (13)

In Asia the prevalence of PXS was found to vary between 1.1% and 6.5%. The Kandy Eye Study was carried out in central, rural Sri Lanka and it demonstrated the prevalence of PXS to be 1.1%. (25) The Aravind Comprehensive Eye Survey was conducted in a rural population of southern India and the prevalence of PXS was found to be 6.0%. (29) In Pakistan, a prevalence survey was carried out in an eye clinic in Bahawalpur Victoria Hospital and the prevalence of PXS was found to be 6.5%. (30) The Meiktila Eye Study was carried out in a rural Burmese population and the prevalence of PXS was 3.4%. (31)

Prevalence of PXS was particularly low in the Chinese people, 0.4% (32) and in the Malay persons, 0.5%. (33)

The prevalence of PXS in various populations was reported to be: England (4%), Germany (4.7%), Norway (6.3%), Eskimos (0.3%), Russia (12%), Finland (22%), Iceland (29%), Greece (16.1%), Australia (0.98%) and Iran (9.6%). (34) In Icelanders the prevalence of PXS was 10.7%. (31) The glaucoma clinic population in this study reflects a high prevalence of PXS. The colour of the iris, being dark brown in black patients may have made detection of the PXS easier in this study. (30)

Age is an important determinant of PXS. Patients with PXS who have glaucoma tend to be older than those who do not. (4) This study also reflects that PXS is a disease of the elderly where the mean age of patients with PXS was 74 years compared to the mean age of 67 years for all patients in this study; 10 out of the 13 patients with PXS were older than 70 years; and the youngest patient with PXS was 59 years. In this study however, though the prevalence of PXS increased with increasing age, this association was not statistically significant. However, early

onset of PXS has been found in certain population subgroups. Bartholomew described what he termed a pre-granular stage at about age 40 in a black South African tribe of whom 6.4% in the 30-39 age group were already affected. (18) Several other studies around the world also demonstrated an increase in prevalence with age (25, 29, 30).

All cases of PXS in this study were bilateral. A review of the literature comparing the frequency of monocular versus binocular involvement in various series is particularly confusing. (4) Binocular involvement is more common in the European literature than elsewhere with ratios as high as 3:1. Other series, including most American ones, have reported unilateral involvement to predominate again with ratios as high as 3:1. (4)

All our cases presented with open angle glaucoma which is in agreement with the literature. Pseudoexfoliative glaucoma was the next most prevalent form after POAG. This is similar to the findings of the Hlabisa study. (14) There were no cases of ACG in this study and the one case of ocular hypertension did not have PXS. A study conducted in Cape Town did not identify PXS as a risk factor for ACG, risk factors related mainly to the configuration of the eye itself. (35)

PXS is known to be a definite risk factor for the development of elevated IOP and glaucoma.
The mean IOP in the PXS patients was 15.4 and the mean IOP in the rest of the glaucoma patients was 19.1. All the PXS patients were already on glaucoma treatment and this could account for the low IOPs. Contrary to other published reports (30,31) this study did not find

significant differences in the mean IOP of eyes with PXS and those without PXS. The high rate of IOP could be due to the design of the study which was hospital-based.

The conversion of ocular hypertensives with PXS to glaucoma has been found to be more common than conversion of ocular hypertensives without PXS. (34) The cumulative risk of glaucoma in eyes with PXS is 5% at 5 years and 15% at 10 years. (34) A patient with unilateral PXS glaucoma and only PXS in the fellow eye is at a high risk (50% in 5 years) of developing glaucoma in the fellow eye. (24)

Glaucoma in PXS has a more serious clinical course and worse prognosis than POAG. There is a significantly higher frequency and severity of optic nerve damage at the time of diagnosis, worse visual field damage, poorer response to medications, more severe clinical course, and more frequent necessity for surgical intervention. (4) It is difficult to assess severity and prognosis of POAG due to PXS from this study because it is a clinic based population undergoing treatment, but all the 13 cases of PXS had a CDR greater than 5/10 plus there was a statistically significant correlation between optic nerve damage of the left eye and PXS. It is also unclear from the literature whether the risk of glaucoma in association with PXS is dependent upon the IOP. Rotchford et al, found that the relationship between PXS and OAG appears to be dependent on IOP, in that the effect of PXS on the risk of glaucoma is almost restricted to those with raised IOP. (8)

This study demonstrates a high rate of glaucoma blindness and this begs the question, is POAG

more aggressive in this population? The study by Rotchford et al also demonstrated a higher rate of visual loss in the untreated subjects with PXS than that found among subjects with OAG not associated with PXS. (8)

The finding of PXS in a developing country with many visually disabled or blind from cataract is potentially important for two reasons. The first is that both PXS and cataracts are age-related, and in a country with cataract as a major cause of treatable blindness, the identification of PXS is critical because pseudoexfoliation is associated with weak zonules and an increased risk for complications during cataract surgery. (29) Additionally, both PXS and glaucoma are age-related and PXS is known to be a major risk factor in modern extracapsular cataract extraction (ECCE) and phacoemulsification. (36) The risk of intraoperative problems (eg, poorly dilating pupil, zonule rupture, capsule break, vitreous loss) and post-operative complications (eg, fibrinoid reaction, posterior synechiae, cell deposits, capsule contraction) is higher in eyes with PXS that have had ECCE or phacoemulsification. (36) Further, the slit-lamp observation of PXS may become a marker to identify some of those who currently have or might later develop glaucoma. (29) Pseudoexfoliation may also serve as a marker for glaucoma in this population; early detection of glaucoma may help reduce the burden of preventable blindness resulting from glaucoma. (29)

A convenience sample as used in this study places limitations on interpretation of the results. Another flaw is that it was hospital-based and so the glaucoma clinic population may reflect a higher prevalence of PXS than could be found in population-based study. Another limitation is that the diagnosis of glaucoma was made by one Ophthalmologist.

Chapter 5: CONCLUSION AND RECOMMENDATIONS

5.1 Conclusion

This study confirms a high prevalence of PXS amongst Black South African people attending a hospital-based glaucoma clinic and that glaucoma is a significant public health problem. The study also shows a high prevalence of visual impairment associated with glaucoma and that there is an association between the presence of PXS and optic nerve damage of the left eye and visual impairment in the right eye.

5.2 Recommendations

A high degree of suspicion should be maintained for the presence of PXS during routine ophthalmic examination, particularly in the elderly with high IOPs. Also mechanisms need to be put in place to allow for screening of persons above the age of 30 years for the presence of PXS which is easily detectable on slit lamp biomicroscopy. Since case finding remains a challenge, the approach could be one of increasing awareness of the need to seek treatment when the vision in one or both eyes is reduced.

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ANNEXURE A

INFORMED CONSENT

I hereby confirm that I have been informed by the study investigator, Dr R Mdlankomo, about the nature, conduct, benefits and risks of the study. I have also received, read and understood the above written participant information sheet regarding the study.

I am aware that the results of the study will be anonymously processed in to a study report and may, at any stage without prejudice withdraw my consent and participation in the study. I have had sufficient opportunity to ask questions and (of my own free will) declare myself prepared to participate in the study.

PARTICIPANT (patient):

---------- ---------- ----------

Printed name Signature Date and Time

I, Dr R Mdlankomo herewith confirm that the above participant has been fully informed about the nature and conduct of the above study.

ANNEXURE B

DATA SHEET

1. Patient No
2. Age
3. sex
4. residence
5. Level of education
6. Occupation

7. full ophthalmic examination
    - visual acuity
    - conjunctiva
    - corneas
    - sclera
    - pupil
    - anterior chamber
    - iris
    - lens
    - vitreous
    - fundus

- cup/disc ratio
- IOP
- Gonioscopy

8. Type of glaucoma
    - POAG
    - PACG
    - NTG
    - Other

8. Presence of pseudoexfoliative material
    - Papillary margin
    - Anterior lens capsule
    - Angle of anterior chamber

9. Visual Field
    - Normal
    - Minimal glaucoma changes
    - Moderate glaucoma changes
    - Severe glaucoma changes

10. Visual acuity

- Mid or no visual impairment (0) >6/18
- Moderate visual impairment (1) <6/18 – 6/60
- Severe visual impairment (2) <6/60 – 3/60
- Blindness (3) <3/60 – 1/60
- Blindness (4) <1/60 – Light perception
- Blindness (5) No Light perception
- (9) undetermined or undefined

ANNEXURE C

Ethics Clearance Certificate

UNIVERSITY OF THE WITWATERSRAND, JOHANNESBURG

Division of the Deputy Registrar (Research)

HUMAN RESEARCH ETHICS COMMITTEE (MEDICAL)
R14/49 Mdlankomo

CLEARANCE CERTIFICATE	PROTOCOL NUMBER M080457
PROJECT	Pseudoexfoliation syndrome in a rural glaucoma clinic in Eastern Cape South Africa
INVESTIGATORS	Dr R Mdlankomo
DEPARTMENT	School of Public Health
DATE CONSIDERED	08.04.25
DECISION OF THE COMMITTEE*	Approved unconditionally

Unless otherwise specified this ethical clearance is valid for 5 years and may be renewed upon application.

DATE 08.09.29 CHAIRPERSON .....
(Professor P E Cleaton Jones)

*Guidelines for written 'informed consent' attached where applicable

cc: Supervisor : Dr M Kawonga

DECLARATION OF INVESTIGATOR(S)

To be completed in duplicate and **ONE COPY** returned to the Secretary at Room 10004, 10th Floor, Senate House, University.
I/We fully understand the conditions under which I am/we are authorized to carry out the abovementioned research and I/we guarantee to ensure compliance with these conditions. Should any departure to be contemplated from the research procedure as approved I/we undertake to resubmit the protocol to the Committee. **I agree to a completion of a yearly progress report.**

PLEASE QUOTE THE PROTOCOL NUMBER IN ALL ENQUIRIES

ANNEXURE D: PARTICIPANT INFORMATION SHEET

Study title

Pseudoexfoliation Syndrome in a rural glaucoma clinic in Eastern Cape, South Africa

Good day, my name is Rasayi Mdlankomo. I am an Ophthalmologist working at Frontier Hospital, Queenstown. I am undertaking a study investigating the problem of glaucoma.

Why am I doing this?

Glaucoma is a major cause of blindness worldwide and here in South Africa. It is an important health problem for the population, and we need to learn more about it so that we can find ways of detecting it early, so that it can be treated to avoid loss of sight.

Invitation to participate

I think you will be able to help me and I am inviting you to take part in this research study which is trying to find out more about glaucoma. Please read the rest of this document (or I can read it to you), and if you agree to participate in the study, please kindly give me permission

What is expected of the participants?

If you agree to participate, you will be examined as usual for your condition and a few additional tests may be performed to test your eyes. We will need about 45 minutes of your time. I will also be asking a few questions about your background. I will examine 100 patients in this clinic from May to October 2008.

Risks of being involved in the study?

There are no risks because it will be just like your usual glaucoma check up.

Benefits of being in the study?

You will be helping me to stop more people from getting blind.

Participation is voluntary

Please know that your participation in this study is completely voluntary (this means you, and only you, can choose whether you like to join the study). If you decide you don't want to be part of the study, or if you no longer want to continue, this is okay, it will not be held against you.

Reimbursements for "out of pocket" expenses

You will not be paid for participating in the study. You will be seen here at the clinic as per your usual appointment.

What about confidentiality?

Anonymity and confidentiality will be maintained at all times. The results will be presented in group format and there will be no names on the forms, so that no individual can be identified and the results may be made available to you after the study. Organizations that may inspect and /or copy your research records for quality assurance and data analysis include groups such as the Research Ethics Committee.

Contact details of researcher:

If you need any more information, or are not happy about the study, please contact me at:

Dr Rasayi Mdlankomo

Frontier Hospital

Kingsway Street

Queenstown

5320

Tel: 045 808 4254

Cell: 083 277 0759

Contact details of the ethics committee

If you would like to report any complaints about the study or if you experience any problems you may contact the administrator and chairman of the University Research Ethics Committee (the people who allowed us to do this study).

The secretary

Human Research Ethics Committee

Wits University research Office Tel: 011 717 1234