PREVALENCE OF KERATOCONUS IN PATIENTS WITH ALLERGIC CONJUNCTIVITIS ATTENDING KENYATTA NATIONAL HOSPITAL EYE CLINIC

DR STELLA N. MUGHO
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A DISSERTATION SUBMITTED IN PARTIAL FULFILLMENT FOR THE DEGREE OF MASTER OF MEDICINE, IN OPHTHALMOLOGY AT THE UNIVERSITY OF NAIROBI.

2016
DECLARATION

I declare that this dissertation is my original work and has never been published or presented for a degree in any other University.

SIGNATURE …………………………… DATE……………………

Dr. Stella Njeri Mugho

MBChB (University of Nairobi),

Registrar, Department of Ophthalmology,

University of Nairobi.

H58/69904/2013
APPROVAL

This dissertation has been submitted with our approval as Supervisors:

Prof. Dunera Ilako
MBChB (Nrb), M. Med. Ophthalmology (Nrb.), MBA-Health, FEACO, Associate Professor, Department of Ophthalmology, University of Nairobi.

Signature …………………………………………………Date ……………………………

Dr. Muindi Nyenze
MBChB, (Nrb.) M. Med. Ophth (Nrb.), F.E.A.C.O. Oculoplastics/orbit/ocular Oncology (LV Prasad Eye Institute and Aravind Eye Hospitals – India), Lecturer, Department of Ophthalmology, University of Nairobi.

Signature………………………………………Date …………………………………
DEDICATION

This work is dedicated to my family, for their unconditional support. They make it all worthwhile.
ACKNOWLEDGMENT

I wish to express my gratitude to the following for their support:

- To God for His grace and giving me strength.
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LIST OF ABBREVIATIONS

AC - Allergic conjunctivitis
D - Dioptres
IgE - Immunoglobulin E
KC - Keratoconus
KNH - Kenyatta National Hospital
L E - Left eye
PMMA - Polymethyl-methacrylate
R E - Right eye
VKC - Vernal keratoconjunctivitis
ABSTRACT

Objective: To determine the prevalence of keratoconus among patients with allergic conjunctivitis aged between 8 and 30 years, attending Kenyatta National Hospital eye clinic.

Methods: Patients already diagnosed with allergic conjunctivitis were requested to participate in the study. The patients were examined on the slit lamp, clinical signs of keratoconus were elicited, then keratometry and corneal topography was done on each of them. The social demographic and clinical data was captured in a questionnaire. The data collected was analysed using SPSS version 20.0. Descriptive analysis was done to determine means, frequencies and proportions of the various variables. The relationship between the demographic characteristics of the patients, the duration and severity of allergic conjunctivitis, with keratoconus was assessed.

Results: 246 eyes of 123 patients with allergic conjunctivitis were examined. Keratoconus prevalence was found to be 10.6% by clinical diagnosis, 14.6% by keratometry and 30.9% by topography. Majority of the patients with keratoconus were aged 10 to 14 years (42.1%). The male: female ratio of those with keratoconus was 1.9:1. Among those with keratoconus, 34.2% had moderate allergic conjunctivitis, and 42.1% had severe allergic conjunctivitis, which was statistically significant. Patients with allergy symptoms for more than 10 years had the highest proportion among those with keratoconus (42.1%).

Conclusion: Corneal topography diagnosed more patients, especially those with mild keratoconus despite having good vision. There was a strong association found between severe and long standing symptoms of allergic conjunctivitis with keratoconus. Corneal topography was highly recommended as part of the follow up investigations for all patients with allergic conjunctivitis, for early detection and management of keratoconus. This is especially so with newer forms of treatment like cross linking which has been shown to stop keratoconus progression, thus preserving vision.
1.0 INTRODUCTION

1.1 Allergic conjunctivitis

This is a type 1 hypersensitivity reaction due to exposure to allergens. It presents mainly with itching, tearing, redness of the eyes and photophobia. It occurs mostly in areas with high seasonal allergens.

Subtypes of allergic conjunctivitis are:

1. **Acute allergic conjunctivitis.**
   It is an acute conjunctival reaction to allergens, which presents with itching, watering and chemosis.

2. **Seasonal and perennial allergic conjunctivitis.**
   Seasonal allergic conjunctivitis (hay fever eyes) is worse during spring and summer. Perennial allergic conjunctivitis, symptoms are throughout the year. Symptoms are milder than seasonal allergic conjunctivitis. The symptoms usually resolve between the episodes.

3. **Atopic keratoconjunctivitis.**
   It develops in adulthood, after a long history of atopic conditions. Symptoms tend to be severe and throughout the year.

4. **Vernal keratoconjunctivitis.**
   It is IgE mediated and mainly affects boys from age of 5 years to late teens. It is predominant in the Mediterranean, Middle East, Africa and India. It is classified into: palpebral, limbal and mixed types. Exacerbation of the symptoms is seasonal and it is the most sight threatening of the subtypes of allergic conjunctivitis.
In this study, allergic conjunctivitis was graded according to severity as proposed by Bore et al., who did an evaluation of clinical approach and management of allergic conjunctivitis by ophthalmologists in Kenya\(^1\).

<table>
<thead>
<tr>
<th>Grade</th>
<th>Mild</th>
<th>Moderate</th>
<th>Severe</th>
</tr>
</thead>
<tbody>
<tr>
<td>Papillae</td>
<td>Micro: &lt;0.3mm</td>
<td>Cobblestone Papillae 0.3-&lt;0.5mm,</td>
<td>Giant: &gt;0.5mm</td>
</tr>
<tr>
<td></td>
<td></td>
<td>+/- fibrosis</td>
<td></td>
</tr>
<tr>
<td>Conjunctiva</td>
<td>Hyperaemia</td>
<td>Hyperaemia</td>
<td>Hyperaemia</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Diffuse thin chemosis</td>
<td>Cyst like chemosis/scar</td>
</tr>
<tr>
<td>Cornea</td>
<td>Sectoral SPK</td>
<td>Diffuse SPK</td>
<td>Shield Ulcer, Keratoconus +/- central leucoma</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Or epithelial erosion</td>
<td></td>
</tr>
<tr>
<td>Limbus</td>
<td>No manifestation</td>
<td>&lt;1/2 limbal circumference</td>
<td>½ or &gt; of limbal circumference</td>
</tr>
<tr>
<td>(Limbal oedema/trantas dots)</td>
<td></td>
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</tr>
</tbody>
</table>

The above signs are assessed and the grade is determined by the most severe sign present in the more severe eye.
1.2 Keratoconus.

This is a bilateral progressive disorder of the cornea, which is characterised by central or paracentral asymmetrical, non-inflammatory, thinning and corneal protrusion, assuming a conical shape. This induces irregular astigmatism, myopia and corneal scarring, which may cause mild to severe visual impairment. Onset is usually at puberty and the condition progresses up to the third or fourth decade. Progression may halt at any stage between mild to severe keratoconus.

1.2.1 Risk factors for keratoconus.

1. Genetics

There is a scientific view that keratoconus develops in genetically predisposed people, when subjected to certain triggers, however, no mutation of any gene has been identified. Keratoconus is associated with some genetic disorders, like Down’s syndrome with a reported prevalence of 0.5% to 15%, that is 10-30 fold of normal population\(^2\). Approximately 10% of patients with keratoconus have affected relatives\(^3\), with some studies showing a prevalence of 11-14% of keratoconus, among clinically unaffected relatives of patients with keratoconus\(^4,5\).

2. Hormones

The hypothesis of hormonal involvement in keratoconus is supported by the fact that it generally begins at puberty and has also been shown to progress more during pregnancy\(^2\).

3. Allergy and eye rubbing

Most patients with keratoconus have ocular allergy which leads to vigorous eye rubbing. A case control study done by Bawazeer in Australia showed significantly higher level of allergy and eye rubbing in patients with keratoconus\(^6\). This implies that there is need for management
of itching, whether due to allergy or ametropia. Higher prevalence of asthma, eczema and hay fever has also been reported in patients with keratoconus. In the Dundee University Scottish keratoconus study, it was found to be 23%, 14% and 30% respectively.\(^7\)

### 1.2.2 Pathogenesis of Keratoconus

Increased lysosomal and proteolytic enzymes in tears lead to altered collagen configuration causing progressive stromal thinning.\(^8\) A study by Balasubramanian showed that allergens react with allergen specific IgE on mast cells releasing inflammatory molecules like histamine, proteases, tumour necrosis factor and interleukin. Eye rubbing also causes an increase in inflammatory molecules in tears.\(^9\)

Some studies have also indicated that keratoconus corneas lack the ability to self-repair. This exposes the cornea to oxidative stress due to abnormal processing of superoxide radicals.\(^10\)

Induced corneal trauma from constant rubbing by knuckles or ill fitted contact lenses has also been implicated in inducing the conical change in keratoconus.\(^11\)

### 1.2.3 Features of Keratoconus

Patients present with history of progressive loss of vision with ghost images, frequent changing of spectacle correction with unsatisfactory results, and ocular allergies with frequent eye rubbing.

The characteristic clinical signs are Munson’s sign, i.e. indentation of the lower eyelid by the conical cornea in down gaze. Rizzuti’s sign, i.e. Conical reflection of nasal cornea when a penlight is shone from the temporal side.

On slit lamp, one may see central or paracentral stromal thinning, corneal scarring, Vogt’s striae (fine vertical striations that disappear with firm pressure over the eyeball), or Fleischer
ring (brown iron deposits within the epithelium around the base of the cone). Some patients present with acute hydrops, which is a break in the descemets membrane allowing aqueous into the stroma causing corneal thickening.

Irregular astigmatism which is demonstrated by scissoring reflex is seen on retinoscopy.

<table>
<thead>
<tr>
<th>Keratometry grading</th>
<th>K-readings</th>
<th>Pachymetry grading</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mild keratoconus</td>
<td>K&lt;48D</td>
<td>&gt;400 micrometres</td>
</tr>
<tr>
<td>Moderate keratoconus</td>
<td>K48-54D</td>
<td>200-400 micrometres</td>
</tr>
<tr>
<td>Severe keratoconus</td>
<td>K&gt;54D</td>
<td>&lt;200 micrometres</td>
</tr>
</tbody>
</table>

**Corneal topography**

The topography diagnosis takes into account the inferior-superior steepening of >1.4, central corneal power of >47.2D, skewed radial axis, or significant displacement of the thinnest area of cornea form the centre.\(^\text{12}\).
2.0 LITERATURE REVIEW

2.1 History of keratoconus

Ramez Babara did a review of the history of the development and advances of keratoconus treatment, and highlighted that keratoconus was first described by Burchard David Mauchart in 1748. He was a professor in Anatomy and Surgery, and called the condition ‘staphyloma diaphanum’, meaning bulging of the cornea. Barbara also stated that in 1854, John Nottingham distinguished keratoconus from other forms of corneal ectasia. Nottingham also wrote a book called Practical Observations on Conical Cornea where he described the signs and symptoms. In 1859, William Bowman, a British ophthalmologist was the first to diagnose keratoconus using an ophthalmoscope. He angled the ophthalmoscope mirrors to be able to visualise the conical cornea. The disorder acquired the name keratoconus in 1869, when a thesis on the treatment of keratoconus was done by Johann Horner, a Swiss ophthalmologist.13

2.2 Prevalence of keratoconus

The prevalence of keratoconus varies widely depending on geographical location, cohort of selected patients, diagnostic criteria used and ethnicity of patients.

In the general population, it ranges from 0.3 per 100000 as reported by Gorskova and Sevost’ianov in Russia, to 2300 per 100000 as reported in Central India by Jonas et al.14

In the USA, keratoconus is estimated to affect 1 in every 2000 people.10 A 48 year clinical study done in Minnesota showed the average incidence rate of keratoconus as 2 per 100000 populations. By the end of the study, that is December 31st 1982, the prevalence was 54.5 per 100000. It was greatest in younger people, but there was no sexual predominance demonstrated.15
Nielsen et al reported the incidence of keratoconus of 1.3 per 100000 per year, and a prevalence of 86 per 100000, in Denmark\textsuperscript{16}.

In Asia and the Middle East, the prevalence of keratoconus is higher than in the west. A study in rural Maharashtra in India, by Jonas et al, demonstrated a prevalence of 2.3\%. They defined Keratoconus as corneal refractive power $>48$ dioptres\textsuperscript{17}. Agarwal evaluated the characteristics of keratoconus in patients presenting at Clear vision eye centre in India, and noticed that they presented at a younger age and with more severe keratoconus, compared to western countries\textsuperscript{18}. Xu et al, also defined keratoconus as central corneal power $>48$ dioptres and found a prevalence of 0.9\% among Chinese in Beijing, aged 50 years and above\textsuperscript{19}.

In Asir province, Saudi Arabia, Assiri et al found a prevalence of 0.02\%. Just like in India, the patients had more severe disease and an early mean age of presentation. They attributed this to environmental and/or genetic factors, after finding that 16\% of the patients with keratoconus, had a positive family history\textsuperscript{20}. Millodot in Jerusalem demonstrated a KC prevalence of 2.34\%, also with significant positive family history\textsuperscript{21}.

In a collaborative Longitudinal Evaluation of Keratoconus study, Wagner found that 14\% of the patients had positive family history of the disease\textsuperscript{22}. After evaluating relatives of patients with keratoconus, Karimian also found a family history prevalence of 14\%\textsuperscript{4}. Besharati et al examined the corneal topography of healthy siblings of patients with keratoconus and diagnosed 12.3\% with keratoconus, while 6.6\% were classified as keratoconus suspects\textsuperscript{5}. This emphasises on the importance of doing topography on relatives of patients with keratoconus, and careful evaluation of those considering keratorefractive surgery. However, Szczotka et al demonstrated that family history is not associated with more severe disease\textsuperscript{23}.

Ethnicity has also been shown to influence the incidence and prevalence of keratoconus. In Bradford Royal Infirmary, Cozma et al found an incidence rate of 32.3 per 100000 per year
among Asians, and 3.5 per 100,000 per year among whites. It was also noted that the Asian patients were significantly younger at time of diagnosis than whites\textsuperscript{24}. This is similar to Georgiou’s earlier findings at Dewsbury district general hospital, where he found a higher incidence of atopy among the whites compared to the Asians, suggestive of different aetiologies of keratoconus in the two groups\textsuperscript{25}.

There has been no study done in our set up, to determine the prevalence of keratoconus in the general population and among those with allergy. The data that is currently available is from the western and Asian countries, which are very different environmentally and also in terms of race. It is important to have data on prevalence of keratoconus, and to determine the predisposing and aggravating factors in our set up.

2.3 **Prevalence of allergic conjunctivitis.**

Allergic conjunctivitis affects 15-20\% of the general population, with some newer studies showing a prevalence of up to 40\%\textsuperscript{26}. In Gambia, Wade PD et al found the prevalence of allergic conjunctivitis to be 7.9\%, more predominant in children\textsuperscript{27}. In Jos-Nigeria, the prevalence was found to be 32\%, and was highest in age group 1 to 16 years\textsuperscript{28}. De Smedt SK reported 3.98\% prevalence of VKC among school children in Rwanda\textsuperscript{29}.

2.4 **Association between allergy conjunctivitis and keratoconus**

Studies have proven a definite association between allergy and keratoconus. In a case control study in Australia, Bawazeer demonstrated that eye rubbing due to allergy was a major cause of keratoconus\textsuperscript{6}. In Israel Rosen et al compared corneal topography of children with VKC and those without, and found patterns consistent with keratoconus in 15\% of those with VKC but none in those without\textsuperscript{30}.
Several studies done on patients with ocular allergy, for example, the study by Dantas et al in Sao Paulo, have found a higher prevalence of keratoconus than in the general population\textsuperscript{31}. Totan et al found incidence of keratoconus among patients with VKC to be 26.8\%. The high incidence was associated with male gender and mixed and palpebral forms of VKC\textsuperscript{32}. Similar findings were demonstrated by Shonja and Besharati who found an incidence of 28\% in Iran\textsuperscript{33}. Agarwal did a retrospective analysis of keratoconus patients and found that 24.5\% of them had ocular allergy\textsuperscript{18}. Cingu et al also associated VKC with more severe keratoconus and younger age of the patients at presentation in southern Turkey\textsuperscript{34}.

Few studies in Africa have reported the prevalence of keratoconus. In Gambia, Wade et al found a prevalence of 0.9\% of keratoconus, among patients with ocular allergy\textsuperscript{27}. In Lusaka, Thengil found a strong association between keratoconus and VKC, and the younger age group of 10-20 years was the most affected\textsuperscript{35}. In Rwanda, De Smedt found 1.7\% of the children had corneal astigmatism or keratoconus\textsuperscript{29}. Waweru et al did a study on vernal keratoconjunctivitis as seen at KNH, and he found 3\% of the patients had keratoconus\textsuperscript{36}. The lower prevalence reported in Africa, compared to the West and Asia, could be attributed to the different methods of diagnosis, because in the studies in Africa keratoconus was diagnosed by clinical signs.

### 2.5 Role of corneal topography

Ocular allergy has been associated with early onset keratoconus, and corneal topography is important in detecting early keratoconus, which would otherwise be missed clinically. This has been demonstrated in a few studies where the prevalence of clinically diagnosed keratoconus was found to be lower than when corneal topography was used\textsuperscript{31,32}. Different authors have also recommended that topography should be performed routinely in young children with history of allergy and eye rubbing, especially those with corneal astigmatism\textsuperscript{8}.  


Topography and clinical signs should be considered together in the diagnosis of keratoconus. In our set up, keratoconus is mainly diagnosed clinically, which is not as sensitive as topography in detecting early disease. Keratoconus is best managed in the early stage for good visual prognosis. It is therefore necessary to have data demonstrating the importance of adopting corneal topography as a diagnostic tool.

In this study, the Pentacam derived Amsler-Krumreich staging of keratoconus was used, and it has been shown to have more sensitive and specific indices for keratoconus diagnosis\textsuperscript{37}.

2.6 Treatment options for keratoconus

Management of keratoconus depends on the disease progression stage. In an article by Prof. Vajpayee from centre of eye research Australia, he stated that in early stages, spectacle correction is an option for those patients who can achieve 6/12 or better vision. However spectacles do not correct irregular astigmatism, which is why contact lenses are used by more than 90\% of keratoconus patients. Soft contact lenses may be used in early disease to correct myopia and regular astigmatism, but as the disease progresses, rigid gas permeable contact lenses may be used. Scleral contact lenses have been used in patients with irregular anterior corneal surface.

He also mentions intracorneal ring segments which are PMMA implants, inserted via channels made mechanically or with help of femtosecond laser. This does not eliminate progression of keratoconus but, it delays the need for corneal transplant\textsuperscript{38}.

The use of toric and phakic intraocular lenses has also been reported to be successful especially in none progressive keratoconus. However, these patients would need another procedure if they develop cataract.
Lamella keratoplasty has been the management for advanced keratoconus in cases without significant corneal scaring or corneal hydrops. It reduces the risk of graft rejection because the descemets membrane and endothelium are preserved\(^{38}\).

Corneal collagen crosslinking is a technique that was first developed in Dresden University, Germany in 1998. The first clinical trial on patients was in 2003 by Professor Sieler T. et al. who found that it halted the progression of keratoconus, therefore reducing the need for keratoplasty\(^{39}\). Conventional corneal collagen crosslinking involves, epithelial debridement, use of 0.1% riboflavin drops and ultraviolet-A (360-375\(\mu\)m) exposure for about 30 minutes. In accelerated corneal collagen crosslinking, the UVA exposure is 3 minutes\(^{40}\).

Crosslinking is indicated in patients with progressive keratoconus, whereby progression is considered to be change in refractive status and astigmatism more than 10 degrees in 12 months, change in corneal thickness, and change in corneal shape. It is contraindicated in patients with, corneal thickness less than 400\(\mu\)m, keratometry of more than 60 dioptres, those who have had prior herpetic infection or severe corneal scarring\(^{41}\).

Penetrating keratoplasty has been the mainstay of treatment for keratoconus for many decades. In Australia, graft survival is reported to be 95% and 89% at 5 and 10 years respectively after corneal transplant in cases with keratoconus\(^{38}\). Abba et al did a review of indications and outcomes of penetrating keratoplasty in Kenya, and found that keratoconus was the leading indication for corneal grafts. He also reported that at 24 months, 90% of keratoconus grafts survived\(^{42}\).
3.0 JUSTIFICATION

Keratoconus is a condition that leads to visual impairment, but the cause is not well understood. Patients with allergic conjunctivitis are known to be at a greater risk of developing keratoconus. In our set up patients tend to be diagnosed with keratoconus when the disease is at an advanced stage. Corneal topography on the other hand has been shown to detect early keratoconus changes. This study will evaluate patients for early keratoconus, who can benefit from newer treatment options like cross linking, which has been shown to halt progression of the disease. This is important because obtaining donor corneas for patients with advanced disease is difficult in Africa.

The study will help to determine the importance of doing corneal topography on patients with allergic conjunctivitis as part of follow up.

This is the only study on prevalence of keratoconus in our set up and the findings will provide baseline information for the policy makers in setting up proper diagnostic and treatment measures.
4.0 OBJECTIVES

4.1 MAIN OBJECTIVE

1. To study the prevalence of keratoconus by topography, keratometry and clinical diagnosis and to assess the clinical characteristics of allergic conjunctivitis associated with keratoconus.

4.2 SPECIFIC OBJECTIVES

1. To determine the prevalence of keratoconus among patients with allergic conjunctivitis at KNH eye clinic.

2. To compare prevalence of keratoconus by different diagnostic methods (clinical, keratometry and topography).

3. To determine the association between characteristics of allergic conjunctivitis with keratoconus.
5.0 METHODS

Study design

The study design was a cross sectional.

Study area

The study was conducted at Kenyatta National Hospital eye clinic 35. This is a national referral and teaching hospital located in Nairobi Kenya. The catchment area is mainly the Eastern, Central and Nairobi regions of Kenya. The eye clinic serves an average of 2500 patients per year, of which about 800 patients are on follow up for allergic conjunctivitis.
Figure 1: Map of Kenya showing KNH location

Study population

Patients aged between 8 to 30 years, diagnosed with allergic conjunctivitis, presenting to Kenyatta National Hospital eye clinic. This is because it has shown that keratoconus mostly develops between puberty and the 3\textsuperscript{rd} decade of life\textsuperscript{43}.

Sampling method and sample size

Consecutive patients presenting to the eye clinic, for management of allergic conjunctivitis were recruited into the study, upon giving consent and assent for those less than 18 years old. The recruitment was done on a daily basis at the eye clinic until the sample size was attained.

According to records, the average number of patients with allergic conjunctivitis attending Kenyatta National Hospital eye clinic is 804 per year. The sample size was thus determined using the formula;
n = \frac{N Z^2 P (1-P)}{d^2 (N-1) + Z^2 P (1-P)}

Where:

n = sample size with finite population correction.

N = population size (the study will use 804).

Z = Z score. The study used 1.96 for a 95% confidence level.

P = expected proportion. The study used 0.28 (M.R. Shonja and Besharati 2006)\textsuperscript{33}.

d = precision in proportion of 1 i.e. 0.075.

The calculation gave a sample size of 118

**Inclusion criteria**

- All the patients with allergic conjunctivitis between the ages of 8-30 years.
- Willing to give informed consent and assent for those less than 18 years.

**Exclusion criteria**

- Patients with corneal scarring from causes other than hydrops.
- Patients with corneal ulcers.
- Patients who did not complete the study.

**Study period**

March 2014 to May 2016
Ethical consideration

Ethical approval was obtained from Kenyatta National Hospital/ University of Nairobi ethics and research board to conduct the study in KNH eye clinic.

Informed consent was obtained from all the adult patients participating in the study. For those under the age of 18 years, consent was given by the parent/guardian and the child assented to the study.

All investigations carried out on the patients were non-invasive.

Patients diagnosed with keratoconus were referred to the anterior segment clinic. Those with refractive errors that were corrected to 6/12 or better with spectacle correction were given the appropriate prescription. The ones who required contact lenses, and those requiring surgical intervention were referred accordingly. Eye drops were prescribed for all the patients with active allergy.

Confidentiality was maintained throughout the study while handling the patients and the data collected.

Recruitment of patients

As patients presented to the eye clinic, those who met the inclusion criteria were requested to participate in the study and the details of the study were explained to them in order to obtain informed consent. A study explanation was given to them to read through and any questions or concerns raised were addressed. Once the patient understood the study explanation and was willing to participate, they signed the consent form. The guardians gave consent for those under 18 years, and the child also gave assent to participate. Those who declined consent were not discriminated in any way but were left to undergo routine clinic evaluation and management.
Data collection procedure

Upon giving consent, relevant history from each patient was taken. Presenting visual acuity was also taken and recorded.

Clinical signs were demonstrated, that is Munson’s sign and Rizzuti’s sign.

Placido disc was used to demonstrate mires on the cornea.

Slit lamp exam was performed on each patient to grade the severity of allergic conjunctivitis, and look for central or paracentral stromal thinning, vogt’s striae, Fleischer ring or stromal thickening due to acute hydrops.

Retinoscopy was done to demonstrate presence or lack of a scissoring reflex and to objectively measure the refractive error.

Corneal topography was done on all patients and each of them was given the topography results for their personal records.

The information for each patient, that is the history, slit exam, clinical signs and topography findings was captured in a structured questionnaire.

Clinical diagnosis of keratoconus was made if a patient had stromal corneal thinning by slit lamp evaluation accompanied by 1 or more of: Munson sign, irregular or crowded mires on placido disc, scissoring on retinoscopy, or if they had stromal thickening due to hydrops.

Diagnosis and grading of keratoconus using keratometry was done.

A topographic diagnosis of keratoconus was made using the Pentacam derived Amsler-Krumeich staging. The indices measured were keratometry, surface variance, vertical asymmetry, height asymmetry, index of height descentration and keratoconus index.
Data storage

The questionnaires were stored in a locked cabinet, with the principal researcher having the key. Computer data was stored with passwords.

Data statistical analysis

Questionnaires were coded and entered in Microsoft Excel 2013. Statistical analysis was done using the Statistical Package for Social Scientists (SPSS) version 20.0. Study population was described using socio-demographic and clinical characteristics by summarizing categorical and continuous variables into percentages and means or medians respectively. Prevalence of keratoconus in allergic conjunctivitis was calculated as a percentage number of patients with 95% confidence interval (CI). Grade of keratoconus was correlated with the severity of allergic conjunctivitis using chi square test. Furthermore, presence of keratoconus was correlated with other variables such as age, sex, duration and severity of allergic conjunctivitis using chi square test for categorical variables and student’s t test for comparison of means. All statistical tests were conducted at 5% level of significance (p value less or equal to 0.05). The findings were presented in tables and graphs.
6.0 RESULTS

Figure 1: Flow chart of patients’ recruitment

The study had a response rate of 88%. Results from 123 patients were used in the study. We examined 246 eyes.
Figure 2: Distribution of patients by sex

Male: Female ratio 1.05:1

Figure 3: Distribution by age.

n=123

Age in years

<table>
<thead>
<tr>
<th>Percentage</th>
<th>&lt;10</th>
<th>10-14</th>
<th>15-19</th>
<th>20-24</th>
<th>&gt;24</th>
</tr>
</thead>
<tbody>
<tr>
<td>17.1%</td>
<td></td>
<td>33.3%</td>
<td>18.7%</td>
<td>14.6%</td>
<td>16.3%</td>
</tr>
</tbody>
</table>
Most patients were aged 10 to 14 years (33.3%). The mean age of the patients was 16 years (SD +/- 7), the range was 8-30 years. The median age was 14 years, and the mode 16 years.

**Figure 4: Duration of allergic conjunctivitis symptoms**

Majority of the patients (58.5%) had symptoms of allergy for duration of 1 to 4 years. The mean duration of allergy was 4.1 years with SD of 3.2.
Most of the patients had mild allergic conjunctivitis, followed by moderate and severe allergy.

Figure 6: Prevalence of keratoconus
The highest prevalence of keratoconus was diagnosed with topography, and it was statistically significant in comparison to clinical diagnosis and keratometry with p value <0.001.

**Figure 7: Keratoconus laterality**

![Pie chart showing laterality of keratoconus](Image)
Most of the patients with keratoconus were between 10-14 years, followed by those aged 15-19 years.

The mean age of the patients diagnosed with keratoconus was 14.9 SD 5.9.
Figure 9: Distribution of keratoconus laterality by age

The proportion of patients with bilateral keratoconus increased with increase in age.

Table 1: Presenting visual acuity of all the eyes (246 eyes)

<table>
<thead>
<tr>
<th>Presenting visual acuity</th>
<th>Keratoconus n (%)</th>
<th>No keratoconus n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>6/6-6/18</td>
<td>39 (17.5)</td>
<td>184 (82.5)</td>
</tr>
<tr>
<td>&lt;6/18-6/60</td>
<td>9 (69.2)</td>
<td></td>
</tr>
<tr>
<td>&lt;6/60-3/60</td>
<td>2 (100)</td>
<td></td>
</tr>
<tr>
<td>&lt;3/60</td>
<td>8 (100)</td>
<td></td>
</tr>
</tbody>
</table>
13 eyes were diagnosed with keratoconus clinically, 3 of which had hydrops. 4 of the eyes that were diagnosed clinically were found to have moderate keratoconus by keratometry, and 6 had severe keratoconus by keratometry. All the eyes that had keratoconus by clinical diagnosis, had severe keratoconus by corneal topography.

Table 3: Presenting visual acuity of the eyes with keratoconus (54eyes)

<table>
<thead>
<tr>
<th>Visual acuity</th>
<th>Mild keratoconus n (%)</th>
<th>Moderate keratoconus n (%)</th>
<th>Severe keratoconus n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>6/6-6/18</td>
<td>15(38.5)</td>
<td>14(35.9)</td>
<td>10(25.6)</td>
</tr>
<tr>
<td>&lt;6/18-6/60</td>
<td>2(22.2)</td>
<td>3(33.3)</td>
<td>4(44.4)</td>
</tr>
<tr>
<td>&lt;6/60-3/60</td>
<td>-</td>
<td>-</td>
<td>2(100)</td>
</tr>
<tr>
<td>&lt;3/60</td>
<td>-</td>
<td>-</td>
<td>8(100)</td>
</tr>
</tbody>
</table>

All the patients with visual acuity less than 6/60 had severe keratoconus by topography.
Table 4: Factors associated with keratoconus

<table>
<thead>
<tr>
<th>Variable</th>
<th>Corneal topography</th>
<th>OR (95% CI)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Keratoconus</td>
<td>No keratoconus</td>
<td></td>
</tr>
<tr>
<td>Sex</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>25 (65.8%)</td>
<td>38 (44.7%)</td>
<td>2.4 (1.1-5.3)</td>
</tr>
<tr>
<td>Female</td>
<td>13 (34.2%)</td>
<td>47 (55.3%)</td>
<td>1.0</td>
</tr>
<tr>
<td>Severity of AC</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mild</td>
<td>9 (23.7%)</td>
<td>60 (70.6%)</td>
<td>1.0</td>
</tr>
<tr>
<td>Moderate</td>
<td>13 (34.2%)</td>
<td>17 (20.0%)</td>
<td>5.1 (1.9-13.9)</td>
</tr>
<tr>
<td>Severe</td>
<td>16 (42.1%)</td>
<td>8 (9.4%)</td>
<td>13.3 (4.4-40.1)</td>
</tr>
<tr>
<td>Allergies/asthma</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>6 (15.8%)</td>
<td>11 (12.9%)</td>
<td>1.3 (0.4-3.7)</td>
</tr>
<tr>
<td>No</td>
<td>32 (84.2%)</td>
<td>74 (87.1%)</td>
<td>1.0</td>
</tr>
<tr>
<td>Chronic illnesses</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>3 (7.9%)</td>
<td>7 (8.2%)</td>
<td>1.0 (0.2-3.9)</td>
</tr>
<tr>
<td>No</td>
<td>35 (92.1%)</td>
<td>78 (91.8%)</td>
<td>1.0</td>
</tr>
</tbody>
</table>

Table 5: Association of duration of allergy with keratoconus

<table>
<thead>
<tr>
<th>Duration of allergic conjunctivitis</th>
<th>Keratoconus</th>
<th>No keratoconus</th>
<th>OR (95% CI)</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Median (IQR)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Category, n (%)</td>
<td>5 (4-8)</td>
<td>2 (1-5)</td>
<td>-</td>
<td>0.001</td>
</tr>
<tr>
<td>1-4 years</td>
<td>16 (22.2)</td>
<td>56 (77.8)</td>
<td>1.0</td>
<td>0.088</td>
</tr>
<tr>
<td>5-9 years</td>
<td>13 (38.2)</td>
<td>21 (61.7)</td>
<td>2.2 (0.9-5.3)</td>
<td>0.006</td>
</tr>
<tr>
<td>&gt;10</td>
<td>9 (53)</td>
<td>8 (47)</td>
<td>5.3 (1.6-17.0)</td>
<td></td>
</tr>
</tbody>
</table>

The mean duration of allergy symptoms in patients with keratoconus was 5.8 years, SD 3.8
7.0 DISCUSSION

Demographic characteristics.

In this study, 246 eyes of 123 patients were examined (fig 1). The male to female ratio was almost equal 1.05:1 (fig 2), unlike in other similar studies where the male: female ratio was higher. Shoja et al found a Male : female ratio of 1.7:1 and Totan et al found a ratio of 3:1. This could be attributed to the fact that all types of allergic conjunctivitis were examined in this study unlike in the other studies where they looked at patients with VKC, which has been found to affect males more than females.

The patients’ ages ranged from 8 to 30 years with the majority aged between 10 to 14 years (33.3%). The mean age was 16 years SD 7(fig 3). This is comparable to the study by Totan et al and Shoja et al whereby the mean age (SD) in their studies was 15.04 (6.11) and 13.07 (4.71) respectively. This can be attributed to the fact that allergic conjunctivitis mainly affects patients between the ages of 5-20 years with a peak at 11 to 15 years. A similar age distribution has been demonstrated in several studies including that done by Waweru at KNH.

Severity and duration of allergic conjunctivitis.

Most of the respondents had symptoms of allergic conjunctivitis for duration of 1 to 4 years, with a mean duration of 4.1(SD 3.2) years (fig 4). This duration is shorter by 1 year compared to what was found by Totan et al of 5.52 +/- 4.16 years and Shoja et al. who found 5.12 +/- 4.29 years. Allergic conjunctivitis was graded according to the criteria proposed by Bore et al. which takes into consideration conjunctiva signs, cornea and limbal involvement. Majority of the patients had mild allergic conjunctivitis (56.1%), whereas 24.4% had moderate allergy and 19.5% had severe allergy (Fig 5).
Prevalence of keratoconus

The prevalence of keratoconus was found to be 10.6% by clinical diagnosis, 14.4% by keratometry and 30.9% of the patients had keratoconus by topographic criteria (fig 6). The difference in the prevalence found by corneal topography was statistically significant when compared to keratometry and clinical diagnosis, with a p value <0.001. This is because topography diagnosed eyes with early signs of keratoconus, which did not have evident clinical and keratometry changes. This difference in prevalence depending on the diagnosis method compares to what Totan et al found; 8.5% by slit lamp biomicroscopy, 18.4% by keratometry and 26.2% by corneal topography. It is also similar to what Dantas et al found in Brazil where the prevalence was 9.85% by clinical diagnosis and a higher prevalence of 22.5% by topographic diagnosis. Shoja et al. found a comparable prevalence of 28% in Iran after using topography to diagnose keratoconus.

This study found a higher prevalence of keratoconus by topography as compared to other studies, which could mean that the allergic conjunctivitis patients in our set up have a slightly higher prevalence of keratoconus than in other geographical regions, especially since Africa is considered as one of the regions with a higher prevalence of VKC. The topography diagnostic criteria should also be taken into account, and in this case the Pentacam derived Amsler staging which was used, has been shown to have highly sensitive measures for detecting early ectatic corneal disorders.

The prevalence of keratoconus by clinical diagnosis in other studies is lower compared to what our study found. In Rwanda, De Smedt, evaluated children with VKC, and found 1.7% had keratoconus. Waweru et al. also did an evaluation of patients with VKC at Kenyatta National Hospital and found 3% had keratoconus by clinical diagnosis. This can be attributed to the difference in clinical diagnostic criteria used, or the fact that the other two studies were
generally evaluating all the clinical features in patients with VKC while this study concentrated on diagnosing keratoconus in patients with allergy, therefore picking more signs of keratoconus.

Of note is that, only two patients in this study had been diagnosed with keratoconus previously while for the others this was the first time the diagnosis was made. This implies that most clinicians don’t concentrate in looking for signs of keratoconus in patients with allergic conjunctivitis. It could also be attributed to limited resources for diagnosing keratoconus especially topography which was found to be more effective in diagnosing early keratoconus in this study.

In the USA, the prevalence of keratoconus in the general population was found to be 0.05%³ whereas in Saudi Arabia it was 0.02%, diagnosed clinically and by keratometry²⁰. In India and China, the prevalence of keratoconus in the general population has been reported as 2.3% and 0.9% respectively¹⁷,¹⁹. Both in India and China keratoconus was defined as keratometry >48D. There are no population based studies on the prevalence of keratoconus in Africa. The higher prevalence of KC among the allergic conjunctivitis patients implies that they are at a higher risk of developing keratoconus as compared to the general population. This has been demonstrated in several cohort studies³⁰,³¹. It has been attributed to the increased levels of inflammatory mediators produced in allergic conjunctivitis and the repeated corneal trauma from rubbing of the eyes resulting in cornea stromal thinning⁸,⁴⁴.

**Characteristics of patients diagnosed with keratoconus**

Among the patients who were diagnosed with keratoconus in this study, majority were aged 10 to 14 years followed by those 15 to 19 years and the reported mean age 14.9 ± 5.9 (fig 8). The age distribution is similar to what Thengil found in Lusaka where most of the patients with keratoconus were 10 to 20 years old ³⁵. The mean age of patients with keratoconus in
this study is also comparable to the mean age found in other studies; Dantas found 13.9,\(^\pm\)4.3\(^\text{31}\), Totan et al found 15.78,\(^\pm\)4.72\(^\text{32}\), and Shoja found 14.5,\(^\pm\)5.34\(^\text{33}\). This is the same age group that forms the highest proportion of patients with allergic conjunctivitis, therefore the most likely to have keratoconus. Hormonal changes have also been postulated to have a role in pathogens on keratoconus which could also be one of the reasons why the incidence of keratoconus is high in the teenage years.

There was male predominance in those with keratoconus, a male: female ratio of 1.9:1 (table 4). This has also been the case in the studies done by Totan et al, M:F=2.7:1\(^\text{32}\), and Shoja et al M:F=1.8:1\(^\text{33}\). Keratoconus has been associated with male sex in some studies, although the reasons are not well understood\(^\text{21,45}\). However, not all studies are in consensus with the male predominance theory, as some have found equal sex distribution while others have found female predominance, as highlighted by Gorgdon-Shaag et al\(^\text{46}\).

Among the patients diagnosed with keratoconus, 47% had unilateral, whereas 53% had bilateral keratoconus (fig 7). The proportion of those with bilateral keratoconus increased with increasing age. This can be explained by the natural course of keratoconus where by KC has been found to be a bilateral but asymmetrical condition. It therefore means that if a patient is diagnosed with keratoconus in one eye they are likely to develop similar signs in the other eye at a later period.

In terms of keratoconus diagnosis and severity, clinical diagnosis picked 13 eyes, of which 3 presented with hydrops. The number of eyes diagnosed with keratoconus by keratometry was 34 and by topography 54 (table 2). All the eyes diagnosed clinically were also picked by keratometry and topography. By keratometry, 6 of the clinically diagnosed eyes were graded as moderate and the rest as severe whereas by topography, they were all graded as severe keratoconus. Clinical criteria picked the more advanced keratoconus in contrast to
topography which picked more eyes with mild keratoconus (31%). This is not surprising because it has been proven that corneas with keratoconus exhibit topographic, tomographic and pachymetry changes way before slit lamp and clinically detectable signs. In this study, most of the eyes presented with a visual acuity better than 6/18 followed in proportion by those who presented with visual acuity worse than 6/18 but better than 6/60 (table 1). Most of the patients with keratoconus presented with visual acuity better than 6/18 (72%). Majority of them had mild to moderate keratoconus. All the patients who had visual acuity worse than 6/60, had severe keratoconus (table 3). This shows that visual acuity is not a suitable parameter for diagnosing keratoconus. Visual performance is not clearly predictable in keratoconus and can present with wide variation. It also emphasises on the importance of diagnosing keratoconus in its early stages in order to intervene before the vision is severely impaired especially in our set up where corneas for PKP are not readily available.

In this Study, 23.7% of the patient with keratoconus had mild allergy, 34.2% had moderate allergy which was statistically significant, with a p value=0.002, and 42.1% had severe allergy, which was also statistically significant with a p value<0.001 (table 4). This could be attributed to the fact that patients with severe allergies are like to rub their eyes more therefore causing more trauma to their corneas and release more immune mediators into the tears, which has been postulated to have a role the pathogenesis of keratoconus.

The mean duration of allergy symptoms among those with keratoconus was 5.8, +/ 3.6 (table 5). This is slightly lower than that found by Totan et al. 6.65,+/−4.75 and Shoja et al. 7.65,+/−4.32. This implies that the patients in our set up may develop keratoconus much earlier than those of Turkey and Iran. Among the patients in this study, 53% of those who had allergy symptoms for >10 years had keratoconus compared to, 22.2% with symptoms for 1to 5 years,
and 38.2% with symptoms for 5 to 9 years, implying that the longer the duration of allergic conjunctivitis symptoms, the higher the proportion of those with keratoconus. This was statistically significant with a p value of 0.006 (table 5). Patients with allergic conjunctivitis for more than 10 years were found to have a higher chance of developing KC. This is comparable to the study in Lusaka where they also found association between long standing symptoms of allergic conjunctivitis and keratoconus.\(^{35}\) Emphasis should be put on the follow up allergic conjunctivitis patients, to reduce both the severity and duration of the symptoms as they seem to have an impact on keratoconus.

Out of those diagnosed with keratoconus, 15% had other atopies (table 4), but this association was not statistically significant in this study probably due to the sample size. However, the association between keratoconus with other atopic conditions cannot be ruled out and more studies with larger sample size should to be done to determine this.
8.0 CONCLUSIONS

1. The prevalence of keratoconus in patients with allergic conjunctivitis was found to be high.

2. Corneal topography diagnosed more patients, especially those with mild keratoconus with good vision, compared to keratometry and clinical diagnosis.

3. There was a male predominance in patients with keratoconus despite having an almost equal sex distribution in the study population.

4. Long standing symptoms of allergic conjunctivitis were associated with a higher proportion of patients with keratoconus.

5. Most patients diagnosed with keratoconus had moderate or severe allergic conjunctivitis.
9.0 RECOMMENDATIONS

Corneal topography should be part of the investigations for patients with allergic conjunctivitis, especially between the ages of 10 to 19 years. This will ensure early detection and management of keratoconus. These patients can benefit from crosslinking which is known to stop keratoconus progression, and reduce the need for keratoplasty. This is of great importance especially in our setup where corneal tissues are not readily available.

In areas with limited resources, all the patients on follow up for moderate or severe allergic conjunctivitis, or visual acuity of 6/18 or worse, should be referred to an ophthalmologist and for corneal topography. This will ensure prompt diagnosis of keratoconus, before severe visual impairment.

Emphasis should be put on improving awareness on the risks factors and diagnosis of keratoconus among the clinicians and patients, for better and timely management.
10.0 REFERENCES


3. Global keratoconus foundation website. Available from: http://kcglobal.org/content/view/14/26/


44. Asymmetric Keratoconus Attributed to Eye Rubbing : Cornea [Internet]. LWW. [cited 2014 Nov 26]. Available from:


11.0 APPENDICES

Appendix 1: Consent information and consent form

Introduction

I am Dr Stella Njeri Mugho, a postgraduate student in the department of Ophthalmology at the University Of Nairobi. I am conducting a study on clinical and topographic evaluation of keratoconus in patients with allergic conjunctivitis attending KNH eye clinic.

Purpose of the study

This study aims to find out the prevalence of patients with keratoconus among those with allergic conjunctivitis and to diagnose early keratoconus using corneal topography.

Basis of participation

Your participation will be purely voluntary. You are free to withdraw at any time during the course of the study period. Your refusal to participate or withdrawal at any time during the study period will not in any way affect the quality of your treatment.

Study procedure

Upon reading understanding and giving consent, you will be recruited into the study. You will be asked questions about your allergic conjunctivitis, the allergy medication you have been using and any other allergies you may be having. A slit lamp examination will be done, some clinical signs, i.e munson’s, placido disc, abnormal mires will be elicited. You will then have a corneal topography done. The information will be entered into a structured questionnaire, and used to make a diagnosis of keratoconus.
Confidentiality

All information obtained in the study will be treated with utmost confidentiality.

I shall NOT use your name in any of my reports.

Benefits

The results of this study may be published in a medical book or journal or for teaching purposes and will be given to the community for better understanding of this topic. You will be given a copy of your topography result for your medical records.

Risks and discomfort

The examination process and topography are none invasive, and no pain will be experienced. Some of the questions asked may be personal but privacy and confidentiality will be assured at all time.

Request for information

You may ask more questions about the study at any time or at this moment. You will be informed of any significant findings discovered during or after the study.

Contact information

You may contact Dr Stella N Mugho on 0722585493 or Prof Dunera Ilako (UON department of Ophthalmology) or Dr Muindi Nyenze (UON department of Ophthalmology) or KNH/UoN Ethical Review Committee Secretariat P.O Box 20723-00202 Nairobi, telephone number. +25427276300 Ext 44102 and email address uonknh_erc@uonbi.ac.ke.
Consent

Having read this consent form, all my questions have been answered, my signature below indicates my willingness to participate in this study and my authorization to use and share with others.

I…………………………………………………………………….the(Patient/Guardian)
of……………………………………………after reading and having the study purpose explained to me by Dr Stella N Mugho, do hereby give informed consent to participate in the study: Clinical and topographic evaluation of keratoconus among patients with allergic conjunctivitis attending Kenyatta National Hospital Eye clinic.

Signed……………………………………………..            Date………………………….

Thumb Print………………………………………...        Date………………………..

I confirm that I have explained to the patient the above statement.

Signature of questionnaire Investigator (Dr Stella Njeri Mugho)……………………………………...

Dr. Stella Njeri Mugho

Phone No. 0722 585493
**Assent form (age 8-17)**

**Introduction**

My name is Dr Stella Njeri Mugho. I am a post graduate student in the department of ophthalmology at the University of Nairobi.

I am conducting a study on: Clinical and topographical evaluation of keratocous among patients with allergic conjunctivitis attending Kenyatta National Hospital eye clinic.

**Purpose of the study**

The study aims to find out the prevalence of patients with keratoconus among those with allergic conjunctivitis and to diagnose early keratoconus using corneal topography.

**Basis of participation**

Your participation will be purely voluntary. You are free to withdraw at any time during the course of the study period. Your refusal to participate or withdrawal at any time during the study period will not in any way affect the quality of your treatment.

**Confidentiality**

All information obtained in the study will be treated with utmost confidentiality.

I shall NOT use your name in any of my reports.

**Benefits**

The results of this study may be published in a medical book or journal or for teaching purposes and will be given to the community for better understanding of this topic. You will be given a copy of your topography result for your medical records.
Risks and discomfort

The examination process and topography are none invasive, and no pain will be experienced. Some of the questions asked may be personal but privacy and confidentiality will be assured at all time.

Request for information

You may ask more questions about the study at any time or at this moment. You will be informed of any significant findings discovered during or after the study.

Voluntary Participation

You do not have to be in the study if you do not want to be in it. After we begin the study and you do not want to take part in it any further it is fine. We have informed your parents/guardian about the study.

If you agree to take part in the study, please sign your name.

Name of the Participant__________________ Date______________________

Sign your name ____________________________

Thumb Print………………………… Date………………………..

I confirm that I have explained the details of the research to the participant.

Researcher’s Name ___________________________ Date______________________

Signature of Researcher____________________

Principal Investigator

Dr. Stella Njeri Mugho

Phone No. 0722585493
Fomu ya ridhaa

Kuanzishwa

Jina langu ni Daktari Stella Njeri Mugho, mwanafunzi katika idara ya Oftalmologia katika Chuo Kikuu cha Nairobi. Mimi ninafanya utafiti juu ya ugonjwa wa keratoconus kwa wagonjwa walio na mizio wa ngozi inayofunika ndani ya jicho, ambao huenda klininki ya macho katika hospitali kuu ya Kenyatta.

Madhumuni ya utafiti

Maudhui ya utafiti huu ni kujua kiwango cha wagonjwa walio na keratoconus miongoni mwa wale walio na mizio wa ngozi inayofunika ndani ya jicho. Pia ni muhimu kutambua wagonja walio na keratoconus kabla ugonjwa huu hujaenea zaidi, kwa kupiga picha ya maumbile ya sehemu ya mbele ya jicho.

Msingi wa kushiriki

Kushiriki katika utafiti huu ni kwa hiari yako. Unaweza kuwacha kushiriki wakati wowote wa kipindi cha utafiti huu. Kutoziriki ama kutoka kwa utafiti huu, hakutadhuru matibabu yako katika hospitali ya Kenyatta kwa njia yoyote.

Utaratibu wa utafiti

Baada ya kupeana idhini, ya kushiriki katika utafiti huu, utaulizwa maswali kuhusu shida yako ya uazio wa ngozi ya mbele ya jicho, kisha utaangaliwa macho kutumia darubini ya macho. Baadaye utapigwa picha ya sehemu ya mbele ya macho, ili kuchunguza kama unaugonjwa wa keratoconus.

Usiri
Chochote utakachochangia katika utafiti huu kitawekwa siri.

Sitatumia majina yako katika ripoti zozote.

**Faida ya utafiti huu.**

Matokeo ya utafiti huu yanaweza kuchapishwa katika vitabu vya matibabu au jarida au kwa madhumuni ya kufundisha. Pia mtokeo haya yatachagia katika kuelewa zaidi ugonjwa huu, katika jamii yetu.

Utapewa nakala ya picha ya maumbile ya sehemu ya mbele ya jicho, utakayopigwa, ili kuweka kwa rekodi zako za matibabu.

**Hatari na usumbufu**

Katika harakati za uchunguzi na picha ya jicho hakuna uvamizi, wala maumivu yoyote.

Baadhi ya maswali utakayoulizwa yanaweza kuwa ya kibinafsi lakini faragha na uaminifu zitazingatiwa wakati wote.

**Ombi la taarifa**

Unaweza kuuliza maswali zaidi kuhusu utafiti huu wakati wowote. Utahamishwa kuhusu matokeo ama jambo lolote muhumu kwa afya hayo, litakalogunduliwa katika utafiti huu.

**Mawasiliano**

Unaweza kuwasiliana na Daktari Stella N Mugho, namba ya simu 0722585493 au Prof Dunera Ilako (UON idara ya Ofthalmologia) au Dk Muindi Nyenze (UON idara ya ofthalmologia) au KNH / UON Kamati ya maadili S.L.P. 20723-00202 Nairobi, namba ya simu. +2542726300 Ext 44102 na barua pepe uonknh_erc@uonbi.ac.ke
Ridhaa

Baada ya kusoma na kuelewa fomu hii ya ridhaa, maswali yangu yote yamejibiwa, sahihi yangu hapa chini inaonyesha nia yangu ya kushiriki katika utafiti huu na idhini yangu kutumia matokeo na kushirikiana na wengine.

Mimi ............................................................ (Mgonjwa/mzazi) wa
............................................................ minesoma na nikaelezwa lengo la utafiti huu na Dt Stella N Mugho. Ninatoa ridhaa ya kushiriki katika utafiti katika hospitali kuu ya Kenyatta kliniki ya macho.

Sahihi ................................................... .. Tarehe .................................

Gumba ..................................................... .. Tarehe ...............................

Ninathibitisha ya kwamba nimemueleza mgonjwa na kujibu maswali yake kuhusu utafiti huu.

Sahihi ya mpelelezi (Dt Stella Njeri Mugho) ...... ............................................

Dk Stella Njeri Mugho

Simu 0722 585493
Idhini ya walio na miaka 8-17

Ushiriki kwa hiari

Kushiriki katika utafiti huu ni kwa hiari yako, na sio kwa lazima. Unaweza kuwacha kushiriki wakati wowote, bila faini. Tumempa taarifa, mzazi / mlezi wako kuhusu utafiti huu.

Kama unakubali kushiriki katika utafiti, tafadhali tia sahihi yako.

Sahihi .................................................. .. Tarehe ..............................

Gumba .................................................. .. Tarehe .............................. ..

Ninathibitisha ya kwamba nimemueleza mgonjwa na kujibu maswali yake kuhusu utafiti huu.

Sahihi ya mpelelezi (Dt Stella Njeri Mugho) ...... ..............................................

Dk Stella Njeri Mugho

Simu 0722585493
Appendix II: Questionnaire

Participant’s number ____________________

Age __________     a) male           b) Female

Part A

1. How long have you had the symptoms of allergy (itching, tearing, conjunctiva discolouration, mucoid discharge)? ☐

2. a) Are you on treatment/follow up for allergy? i) Yes ☐  ii) No ☐
   b) If yes for how long?

3. Which medication are you on?
   a) Oral antihistamine ☐
   b) Topical antihistamine ☐
   c) Topical mast cell stabilizer ☐
   d) Topical steroid ☐
   e) Topical lubricant ☐

4. I) Severity of AC

<table>
<thead>
<tr>
<th>Papillae</th>
<th>&lt;0.3 mm</th>
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<tr>
<td></td>
<td>0.3-0.5 mm</td>
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<tr>
<td></td>
<td>Cobblestones &gt;0.5 mm</td>
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<thead>
<tr>
<th>Conjunctiva</th>
<th>Hyperemia</th>
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<td></td>
<td>Chemosis</td>
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<td>Cyst like chemosis</td>
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<td>Scar</td>
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<tr>
<th>Cornea</th>
<th>Sectoral SPKs</th>
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<tr>
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<td>Diffuse SPKs</td>
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<td>Epithelial erosion</td>
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<td>Shield ulcer</td>
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<td></td>
<td>Central leucoma</td>
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<tr>
<th>Limbus</th>
<th>No manifestation</th>
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<td>&lt;1/2 limbal circumference affected</td>
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<td>½ or &gt; of limbal circumference affected</td>
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a)mild        b) moderate        c)severe
i) Do you have other allergies or asthma?  a) Yes □  b) No □

If yes, specify (list)?

ii) Have you been diagnosed with other chronic illnesses?  a) Yes □ b) No □

If yes, which condition? (List)

iii) Do you use spectacles?  a) Yes □  b) No □

c) If yes, for how long have you used spectacles?

iv) How many times have you changed your prescription in the last 1 year?

Part B (examination)

1. Visual acuity (without correction)  RE _________  LE _________

2. Visual acuity (with correction)  RE _________  LE _________

3. Refraction (do retinoscopy, last retinoscopy findings or lensometer readings depending on the patient)

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<thead>
<tr>
<th>Type of error</th>
<th>Retinoscopy findings/Power of lenses</th>
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<tbody>
<tr>
<td>a) Myopia</td>
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<td>b) Hyperopia</td>
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<td>c) Astigmatism</td>
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<td>d) Scissoring reflex</td>
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4. Signs elicited and slit lamp examination. Put + if positive, - if negative

| a) Munson’s sign    |                                      |
| b) Placido disc     |                                      |
| c) Stromal thinning |                                      |
| d) Vogt’s striae    |                                      |
| e) Fleischer’s ring |                                      |
| f) Corneal scarring |                                      |

a) Has clinical keratoconus □

b) No clinical keratoconus □
5. **Keratometry**

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<th>K1</th>
<th>K2</th>
<th>Km</th>
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a) Mild  
b) Moderate 
c) Severe

6. **Pachymetry**

Pachymetry reading in micrometres _____________

**Part C: Corneal topography**

Topographic keratoconus classification (TKC)  
a) RE _____________  
b) LE _____________
## Appendix III: Study timeline

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