Demographic and Clinical Characteristics of Patients with Corneal Ectasia at Multiple Medical Centers in Saudi Arabia: A Hospital-based Study

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Abstract

Objectives: To explore the clinical characteristics of corneal ectasia and provide insights on related factors, including demography, ocular health, and the trends of management in the Saudi population.

Methods: A retrospective hospital-based chart review of patients with corneal ectasia was conducted in multiple medical centers in Saudi Arabia between January 1, 2018, and December 31, 2018. Eye care professionals diagnosed these patients based on their medical history, physical examination, and the use of Pentacam. The severity of the condition was assessed using the k median index from Pentacam map following the modified Krumeich grading system.

Results: The medical records of 430 eyes of 215 patients with corneal ectasia were reviewed. The majority of patients had bilateral corneal ectasia (98.6%), with 202 (94.0%) had keratoconus and 13 (6.0%) had post-LASIK ectasia. Males and age groups between 14 and 45 years were more affected. Mean age of onset was 7.11, ranging from 2 to 32 years which was higher among patients from the Western region. Regarding severity, 230 (53.5%) presented in initial stages, while 36 (8.4%) were in severe stage with no significant difference between the regions studied. No significant differences in mean central corneal thickness and power between patients from Central and Western regions. Corneal RGP CL was most used in treatment 176 (40.9%), followed by glasses 155(36. 0%), while corneal cross-linking was the common surgical intervention (10.9%), followed by penetrating keratoplasty (3.0%).

Conclusion: Most of the Keratoconus patients had a bilateral mild stage of the disease in their third decade. This high rate of bilaterality of diseases during diagnosis may be due to the misdiagnosis in the initial stages which highlights the importance of community and eye care professionals' awareness about comprehensive eye examinations and regular follow-up, including corneal topography assessments of both eyes.

Keywords: Keratoconus, corneal ectasia, clinical characteristics, corneal cross-linking, penetrating keratoplasty, Saudi Arabia

Introduction

Keratoconus (KC) is an eye disorder that affects the structure of the cornea, resulting in irregular astigmatism, vision impairment, and corneal scarring, leading to poor quality of life.[1] This disorder is a consequence of non-inflammatory processes characterized by ectasia of the central or inferior portion of the cornea.[2] KC has its usual onset in adolescence, and the likely course of progression extends to the third or fourth decade of life, when it is usually arrested.[2,3] Although a large proportion of patients with KC can be managed with spectacles or contact lenses, an average of about 20% of all cases requires corneal transplant.[4-6] Globally, the incidence of KC ranges between 1 and 50 individuals per 100,000.[7,8]

The aetiology and pathogenesis of KC are not well understood; however, genetic, and environmental factors such as eye rubbing, atopy, and UV exposure might have a role in generating this disease.[9] This corneal ectasia can also be a possible complication of refractive surgeries, which occurs in around 0.04% to 0.6% of those who underwent the procedures.[10,11]

There are a limited number of studies that have investigated the prevalence and clinical characteristics of KC in Saudi Arabia, and their results have been variable. In 2005, it was estimated that KC could affect 20 cases per 100,000 in the Assir region.[8] Whereas in 2018, the prevalence of KC among patients seeking laser vision correction was reported to be 8.6% in Taif city, of Saudi Arabia.[12] However, a recent study reported that the prevalence of KC in Najran Province was 87.3 per 100,000 people, with an incidence rate of 28.47 per 100,000 cases.[13] A more recent study estimated that KC can affect up to 4.8% of Saudis aged between 6 and 21 years old.[14] While KC appears to be prevalent in Saudi Arabia, there is still a gap in knowledge about the clinical manifestation and management of KC in this population. Therefore, the aim of this study was to retrospectively investigate the clinical characteristics of corneal ectasia and to provide insights on related factors, including demography, ocular health, and the trends of the management among the Saudi population.

Methods

The study was a retrospective hospital-based chart review of patients with corneal ectasia which conducted in multiple medical centres across Saudi Arabia between January 1, 2018, and December 31, 2018. Four hundred and thirty eyes of 215 patients with KC were selected by a non-probability sampling technique, and their ages ranged from 14 to 68 years. The sample was included 127 males and 88 females from the Central and Western regions of Saudi Arabia.

The inclusion criteria for the study were patients with KC or corneal ectasia in one or both eyes. Patients with a previous history of intraocular surgery as well as other significant ophthalmic disease rather than KC were excluded. Additionally, the patient records with missing essential data were also excluded from the study.

Ethical permission for the study was obtained from the regional ethics committee of the Saudi Ministry of Health (Qassim Office). The study was conducted according to the Declaration of Helsinki guidelines. The need for consent was waived by the ethics committee due to the retrospective nature of the study. Efforts were made by the principal investigator to ensure that patient privacy and confidentiality were assured.

De-identified data were extracted from patients' records at three medical centres in three different Saudi cities: two from Central region (Riyadh and Qassim) and one from the Western region (Jeddah). Data extracted were as follows: demographic data (age, gender, and residential area), onset of KC, dry eye assessment, stage of KC, and best corrected visual acuity (BCVA, decimal notation). The assessment of central corneal thickness (in microns) and anterior corneal curvature (in dioptre) was carried out by Pentacam. Additionally, the type of treatment, either optical correction (glasses or contact lenses) or surgical intervention, was determined in this study. Many scales were used for classification of KC. In this study classification was based on the modified Krumeich grading system.[15]

Descriptive and inferential statistical analyses were performed using SPSS for Windows version 24 (SPPS Inc., Chicago, IL, USA). Data were reported as frequency and mean ± standard deviation (SD). An independent sample t test was used to compare the means of variables between different study groups. Pearson's correlation was used to find the relationship between dependent and independent variables among the study population. A P value of < 0.05 was considered to be statistically significant with a 95% confidence level (CL).

Results

A total of 430 eyes from 215 patients who had corneal ectasia in one or both eyes were enrolled in this study. The mean age of patients was 30.63 ± 8.31years (range: 14-68 years), while mean age of onset was 7.11± 6.53 years (range: 2-32 years). Men, women distribution was 127 (59.1%) and 88 (40.9%) respectively, however, no significant difference in age was found between both gender (P = 0.45). From the total number of subjects, 112 (98.6%) had bilateral KC and 3 (1.4%) were diagnosed as unilateral KC. Two-thirds of the KC patients, 139 (64.7%), were from the Western region, and 76 (35.3%) were from the Central region. Regarding corneal ectasia, the majority of patients, 202 (94.0%), were diagnosed with KC while 13 (6.0%) were diagnosed with post-LASIK corneal ectasia. Furthermore, 44 (20.5%) of KCs patients complained of dryness, as shown in Table 1.

Analysis showed no significant differences in age between males and females (P = 0.451). The mean age in the Central region and Western region was 29.26 ± 6.05 years (range: 19 – 44 years) and 31.30 ± 9.16 (range: 14–68) years, respectively. Among them, 212 (98.6%) had bilateral KC, and only 3 (1.4%) had unilateral KC. More than half, 127 (59.1%) were males and 88 (40.9%) were females, with a mean age of 30.63±8.32 years (range: 14–68 years). Two-thirds of the KC patients, 139 (64.7%), were from the Western region, and 76 (35.3%) were from the Central region. Regarding corneal ectasia, 202 (94.0%) patients had KC, and 13 (6.0%) patients had post-LASIK corneal ectasia. Furthermore, 44 (20.5%) KC patients complained of dryness, as shown in Table 1.

Table 1: Demographic data of the total number of patients.

Demographic data (n-215)		Frequency (%)
Gender	Male	127 (59.1)
	Female	88 (40.9)
Age	14 – 30 years	102 (47.4)
	31 – 45 years	101 (47.0)
	46– 60 years	11 (5.3)
	61– 70 years	1(0.5)
Residential area	Central region	76 (35.3)
	Western region	139 (64.7)
Laterality	Bilateral	212 (98.6)
	Unilateral	3 (1.4)
Corneal ectasia	KC	202 (94.0)
	Post LASIK corneal ectasia	13 (6.0)
Dryness	Yes	44 (20.5)
	No	171 (79.5)

The distribution of corneal ectasia among the study sample is illustrated in Table 2, which showed that 410 (95.3%) of eyes had KC, 7 (1.7%) had no corneal irregularities, and 13 (3.0%) had post-LASIK corneal ectasia. In the Western region, 268 (62.3%) of eyes had KC, 4 (1.0%) of eyes had no corneal irregularities, and 6 (1.4%) had post-LASIK corneal ectasia. Whereas in the Central region, 144 (33.0%) of eyes had KC and 7 eyes (1.6%) had post-LASIK corneal ectasia. Using Chi-squire test, the association between corneal ectasia and regions was found not statistically significant (X^2=3.294, df=2, P=0.193)

Table 2: Distribution of corneal ectasia among study population.

Corneal ectasia	Western region N (%)	Central region N (%)	Total N (%)	Chi-Square Tests
KC	268(62.3)	142(33.0)	410(95.3)	$X^2 = 3.294$
No corneal irregularities	4(1.0)	3(0.70)	7(1.6)	Df = 2
Post LASIK corneal ectasia	6(1.4)	7(1.6)	13(3.0)	$p = 0.193$
Total	**278(64.7)**	**152(35.3)**	**430(100)**	

Further analysis using an independent sample t test was conducted to compare the means of variables among study groups, and the results are displayed in Table 3. Significant mean difference was detected in age and KC onset between patients in the Central and Western region with P values of 0.018 and <0.001 respectively. With regard to clinical findings, unaided visual acuity and BCVA were found significantly difference between both study groups with p values of < 0.001. However, no significant difference was found between the Central and Western region patients in terms of mean corneal power, mean spherical equivalent of refraction (SE) and mean corneal astigmatism with P values of 0.79, 0.63 and 0.133 respectively. Additionally, no significant mean difference was also found between the study groups in terms of central corneal thickness (CCT) and Intraocular pressure (IOP) with P values of 0.49 and 0.44 respectively (refer to table 3).

Table 3: Comparison of variables among study populations.

Variable	Total (N= 416)	Central region (N = 138)	Western region (N = 278)	P value
Age (years)	30.62±8.31	29.26±6.04	31.30±9.16	0.018
KC onset (years)	7.11±6.53	3.43±3.77	8.88±6.84	< 0.001
CCT (micron)	465.24±53.25	462.50±43.14	466.49±57.65	0.499
IOP (mmHg)	14.76±2.52	14.91±2.72	14.55±2.22	0.444
CP (diopter)	47.46±5.18	47.56±5.60	47.41±4.96	0.788
Unaided vision (decimal)	0.28±0.22	0.21±0.19	0.31±0.23	<0.001
BCVA (decimal)	0.61±0.25	0.51±0.20	0.66±0.25	<0.001
SE (diopter)	5.14±4.35	4.97±4.59	5.37±4.03	0.625
Ocular astigmatism (diopter)	3.25±2.03	3.01±2.05	3.58±1.97	0.133
BCVA (decimal)	0.61±0.25	0.51±0.20	0.66±0.25	<0.001

KC = keratoconus, CCT = central corneal thickness, IOP = intraocular pressure, CP = corneal power, SE = sphere equivalent, BCVA = best corrected visual acuity.

According to Krumeich scale, stage 1 and 2 of KC are commonly found among the patients, which were 230 (53.5%) and 100 (23.3%), respectively. In addition, a cross-tabulation test was used to find the distribution of KC stages among the study population, The Chi square test showed no significant differences in KC stages between study groups (p > 0.05) (refer to table 4).

Table 4: Distribution of the Kc stage among the study population.

Kc stage	Total		Central region		Western region		*p*-value
	Freq.	%	Freq.	%	Freq.	%	
Stage 1	230	53.5	108	25.9	122	29.4	0.330
Stage 2	100	23.3	25	6.1	75	18.0	0.681
Stage 3	46	10.7	9	0.5	37	8.9	0.787
Stage 4	36	8.4	7	0.0	29	7.0	0.524
No keratoconus	8	1.9	3	0.7	5	1.2	
No reading	10	2.4	0	0.0	10	2.4	
Total	**430**	**100.0**	**152**	**35.3**	**278**	**64.9**	

Stage 1 = early Kc= 7.8 – 6.7mm, ≤48D, CCT >400 µm.
Stage 2 = moderate Kc= 7.5 – 6.5mm, ≤53D, CCT >400 µm.
Stage 3 = advance Kc= 6.9 – 5.3mm, 53-55D, CCT 200 - 400 µm.
Stage 4 = severe Kc= 6.6 – 4.8mm, >55D, CCT <200 µm.

A cross-tabulation test was used to determine the distribution of several types of optical correction used among study groups. Corneal RGP CL was the most common treatment method used, accounting for 176 (40.9%), followed by glasses 155 (36.0%). In the Central region, glasses were commonly used at 101 (23.5%), whereas in the Western region, Corneal RGP CL 143 (33.3%) was the most common optical appliance used in the treatment of keratoconus patients. Almost 40 (9.3%) eyes remain without any form of optical correction, as shown in Table 5.

Table 5: Distribution of optical correction among the study population.

Variable	Total		Central region		Western region	
	Freq.	%	Freq.	%	Freq.	%
No correction	40	9.3	14	3.3	26	6.0
Glasses	155	36.0	101	23.5	54	12.6
Corneal RGP	176	40.9	33	7.7	143	33.3
Hybrid lenses	26	6.0	4	1.0	22	5.1
Soft spherical CL	16	3.7	0	0.0	16	3.7
Scleral/ mini scleral	11	2.6	0	0.0	11	2.6
Soft toric CL	6	1.4	0	0.0	6	1.4
Total	**430**	**100.0**	**152**	**35.3**	**278**	**64.7**

RGP = rigid gas permeable, CL= contact lens.

A cross-tabulation test was used to assess the distribution of several types of surgical interventions used among study groups. Corneal cross-linking (CXL) was the most common surgical intervention used, accounting for 47 (10.9%), followed by penetrating keratoplasty (PKP) at 13 (3.0%). In the western region, CXL was the most used surgical intervention at 31 (7.5%), followed by PKP at 13 (3.1%), as shown in Table 6.

Table 6: Distribution of surgical interventions among the study population.

Variable	Total		Central region		Western region	
	Freq.	%	Freq.	%	Freq.	%
No surgery	**336**	**78.1**	**126**	**29.3**	**210**	**50.4**
CXL	47	10.9	16	3.8	31	7.5
CXL/Intacs	2	0.5	0	0.0	2	0.5
PKP	13	3.0	0	0.0	13	3.1
ICRS	1	0.2	0	0.0	1	0.2
correcting laser	4	1.0	0	0.0	4	1.0
Intacs	11	2.6	10	2.4	1	0.2
ICL	7	1.7	0	0.0	7	1.7
Corneal graft	2	0.5	0	0.0	2	0.5
PKP/refractive surgery	1	0.2	0	0.0	1	0.2
laser/CXL	1	0.2	0	0.0	1	0.2
laser/CXL/PKP	1	0.2	0	0.0	1	0.2
PKP/LKP	1	0.2	0	0.0	1	0.2
ICRS/ICL/PKP	1	0.2	0	0.0	1	0.2
CXL/ICL	2	0.5	0	0.0	2	0.5
Total	**430**	**100.0**	**152**	**35.3**	**278**	**64.7**

CXL = corneal cross linking. PKP = penetrating keratoplasty. ICRS = intra corneal ring segment. ICL = implantable collamer lens. LKP = lamellar keratoplasty.

Discussion

Describing the distribution proportion characteristics of the disease and its management is crucial for predicting current and future clinical needs in different geographical locations. Given the high prevalence of KC among Saudi population, thus, the study was conducted to assess the clinical characteristics of corneal ectasia and to offer insights

on related factors, including demography, ocular health, and the trends of the management of the KC among the Saudi population.

Our study found that the most common type of corneal ectasia was KC and about 6.0% had post-LASIK corneal ectasia. The mean age of the patients with KC at the time of our study was 30.62 ± 8.31 years, these findings higher-than-recent studies[16-18] of KC in Middle Eastern people have reported mean ages ranging from 23 to 29.3 years. Conversely, previous studies[8-19] has reported significantly lower mean ages at the time of diagnosis 18.5–22.5 years and anticipated an early age of onset of KC among Middle Eastern people. However, in the current study, the mean age of KC onset was 7.11, ranging from 2 to 32 years, which shows significant difference between the regions ($P < 0.001$). These are consistent with an early study showing that KC commonly manifests during the late teenage years, with a gradual development for approximately 15 years from diagnosis.[20] Due to several factors such as climate, environment, race, demography, and geography, the epidemiology of diseases can vary significantly between regions. For example, environmental or geographic factors, including a warm, sunny, and dusty climate, might affect the risk of KC and cause eye allergies and dryness. A previous study reported that the interaction between eye rubbing, and allergies can lead to the rapid development of KC.[21] Earlier studies[12-23] reported that KC typically starts in one eye but can later progress to the other eye and sometimes it takes years after the initial diagnosis. This was consistent with our findings; most of the cases were bilateral (98.6%). The high rates of bilaterality in our study upon diagnosis may be due to misdiagnosis in the initial stages of the KC. This highlights the importance of comprehensive eye examinations and regular follow-up, including Pentacam assessments of both eyes, to prevent missing the disease in the unaffected eye.

Males and age groups 14–45 was more affected by KC and the majority (55.3%) of patients presented with an early stage, whereas only 7.0% had a severe stage. In this study, the number of male patients exceeded the number of female patients, which aligns with the global trend of a slightly higher number of males are affected by KC in comparison to females.[13,16,22] The majority of the patients in the present study, as well as those in the Palestine,[18] Macedonian,[23] and Malaysian[24] studies, were in the mild KC stage at the time of diagnosis. For instance, in the current study, 53.3% had mild KC, 23.3% had moderate KC, and only 8.4% had severe KC. Furthermore, in Palestine, 62% were in the mild stage, 28.1% had a moderate stage, and 9.9% were in the severe stage.[18] In Macedonia, 52.08% of cases were mild, 36.45% were moderate, and 11.57% were late stage.[23] Most patients, as mentioned above, had a mild to moderate form of the KC at diagnosis, with some variation. There are several reasons for these findings, as cited in previous studies.[18,23,24] Firstly, eye care professionals are more aware of KC and actively investigate to identify patients in the preliminary stages. Secondly, KC may be unintentionally detected during comprehensive eye exams or when changing spectacles, especially since KC patients often have myopia and astigmatism and require frequent prescription updates. Lastly, the growing popularity of refractive surgeries for myopia increases the chances of detecting KC, as preoperative assessments using technologies.

The mean central corneal thickness and anterior corneal power of KC patients were 465.24±53.25µm and 47.46±5.18D, respectively. The clinical findings, in the present study such as cornel thickness, and corneal power, were consistent with previous reports in the Saudi population.[8,12,13] In the present study, complaints of dryness were found in 20.5%. Corneal RGP CL was the most used treatment method, 40.9% followed by glasses 36.0%. Whereas CXL was the most frequently performed surgical intervention at 10.9%, followed by PKP at 3.0%. The Mean BCVA was 0.61±0.25, while the mean unaided visual acuity was 0.28±0.22. This difference was statistically significant ($p < 0.001$). Even so, a sizable portion of patients arrive without any optical correction, while the majority of patients with KC wore spectacles as their primary optical correction even though their BCVA mean was only 6/10.This result was comparable to those in Palestine[18] and Malaysia,[24] where most of the patients have a BCVA of 0.5. Additionally, previous studies conducted among Saudi Arabians with KC showed comparable results.[8] Most optometrists are prescribing corneal RGP, and only 2.6% of KC patients were wearing scleral lenses. This could be due to the limited availability of scleral lenses as well as the lack of qualified optometrists to deal with this exceptional design of CL. Thus, the training of eye care professionals on fitting and assessment of different types of scleral CL needs to be expanded, especially since 1 of every 5 patients reported having dry eye in the present study. Furthermore, CXL is only found in 10.9% of the eyes, even though it is covered by free public hospital care as well as private insurance. This method of treatment is essential because most of the KC patients are still in mild form, and it is beneficial at this stage. In our study, corneal ectasia after refractive surgery affects up to 6% of those visiting eye clinics, which indicates that a considerable number of patients who underwent refractive surgery may be affected.

The limitations of the present study include: First, retrospective nature of the study, patient records were sometimes incomplete, and there was a loss of information. The second concerns generalizability, while the information was only drawn from three centres in two regions. Nevertheless, despite the limitations mentioned, our study provides useful information about the clinical characteristics of corneal ectasia and offers insights on related factors, including demography, general, ocular health, and the trends of the treatment of the KC among the Saudi population.

Conclusion

Most of the KC patients had a bilateral mild stage of the disease in their third decade. Males are more commonly presented with disease than females, with a higher proportion in the western region. Post-LASIK corneal ectasia and dryness complaints were found among patients. Corneal RGP CL was the most used optical treatment, followed by glasses, and corneal cross-linking (CXL) was the most common surgical intervention used, followed by penetrating keratoplasty (PKP). Thus, the high rates of bilaterality of diseases during diagnosis may be due to misdiagnosis in the initial stages. This highlights the importance of community and eye care professionals' awareness about comprehensive eye examinations and regular follow-up, including corneal topography assessments of both eyes.

Disclosure

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