

Orbital Complications of Rhinosinusitis in ENT HNS Surgical Practice in Ekiti Nigeria

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Abstract

Background: Orbital complications of rhinosinusitis (OCR) constitute a potentially vision- and life-threatening emergency when complicated from delayed presentation, misdiagnosis, and limited access to otorhinolaryngologist care in developing countries.

Objectives: This study aimed at determining the epidemiology, sociodemographic profiles, aetiopathologies, clinical presentation, management, and outcomes of patients diagnosed with OCR in ENT-HNS practices in Ekiti, Nigeria.

Methods: This retrospective study was conducted in a tertiary ENT-HNS centers in Nigeria over a 10-year period (2015–2024). Medical records of 229 patients diagnosed with orbital complications of rhinosinusitis were reviewed. Data were extracted on demographics, clinical features, and type of rhinosinusitis, Chandler classification, treatment modalities, and outcomes. Descriptive statistics were used to summarize patient profiles, while inferential analyses (Chi-square tests, ANOVA, and multivariate logistic regression) assessed associations and predictors of poor outcomes.

Results: The majority of patients were aged 31–40 years (20.96%) and male (55.46%). A total of 39.30% resided in rural areas and only 24.02% had tertiary education. The most common symptoms were fever (85.15%), nasal obstruction (75.98%), and proptosis (69.00%). Acute rhinosinusitis accounted for 57.64% of cases, with Chandler Stage II (34.50%) being most common. Advanced complications (Stages IV and V) occurred in 23.15% of cases and were significantly associated with rural residence ($p = 0.0003$). Combined medical-surgical management was provided in 57.21% of patients, with functional endoscopic sinus surgery (FESS) being the predominant surgical approach. Full recovery was achieved in 75.98% of cases, while 13.97% had residual visual deficits and 2.62% mortality. Multivariate analysis identified chronic rhinosinusitis (AOR: 2.76; $p = 0.006$), rural residence (AOR: 2.14; $p = 0.015$), age ≥ 45 years (AOR: 1.89; $p = 0.041$), and late-stage presentation (AOR: 4.22; $p < 0.001$) as significant predictors of poor outcomes.

Conclusion: Orbital complications of rhinosinusitis in Ekiti Nigeria are predominantly seen in adults and are strongly linked to sociodemographic disparities and late-stage disease. Improved awareness, timely diagnosis, and access to specialist ENT care, especially in rural areas, are critical for reducing morbidity and mortality. Implementation of standardized management protocols and decentralization of ENT services is recommended to improve outcomes in resource-limited settings.

Keywords: Orbital complications, Rhinosinusitis, Proptosis, Endoscopic sinus surgery, Visual outcome, Ekiti

Introduction

Orbital complications of rhinosinusitis (OCR) are severe, vision- and life-threatening conditions resulting from the contiguous spread of infection from the paranasal sinuses to the orbital structures. These complications represent some of the most urgent presentations in otorhinolaryngology-head and neck surgery (ENT-HNS), requiring prompt diagnosis and multidisciplinary intervention to prevent irreversible visual damage, intracranial spread, or death.[1]¹ Despite improvements in diagnostic imaging and antimicrobial therapy, OCR remains a significant public health concern, particularly in developing countries where delays in diagnosis, limited access to ENT care, and poor health infrastructure contribute to poor outcomes.[2]

The global incidence of orbital complications due to sinusitis is estimated to range from 2.5% to 5% of all rhinosinusitis cases, with higher rates reported in low-income settings due to underdiagnosis and treatment delays.[3] OCR is more commonly associated with acute rhinosinusitis (ARS), particularly of the ethmoid and maxillary sinuses, but chronic rhinosinusitis (CRS) may also present with insidious or late-onset complications.[4] In high-income countries, the majority of cases are seen in children, due to the thin lamina papyracea and the proximity of ethmoid sinuses to the orbit.[5] However, recent studies from Sub-Saharan Africa, including Nigeria, have indicated a rising prevalence among adults, suggesting unique regional and sociodemographic risk factors.[6]

Chandler proposed a classification system that remains the gold standard for staging OCR:[7]

Stage I: Preseptal cellulitis.

Stage II: Orbital cellulitis.

Stage III: Subperiosteal abscess

Stage IV: Orbital abscess

Stage V: Cavernous sinus thrombosis

Patients typically present with symptoms such as proptosis, chemosis, ophthalmoplegia, visual impairment, fever, and nasal discharge. Early stages may mimic simple conjunctivitis or preseptal cellulitis, often leading to misdiagnosis by non-specialists.[8] In Nigeria and similar developing countries, clinical presentation is often complicated by delayed access to tertiary care, widespread self-medication, use of herbal remedies, and poor awareness of ENT symptoms.[9]

The pathogenesis of OCR involves direct extension of infection through the thin bony walls of the sinuses, especially the lamina papyracea, or via venous channels. Ethmoid and maxillary sinusitis are the most commonly implicated sources.[4] Common causative organisms include *Streptococcus pneumoniae*, *Staphylococcus aureus*, *Haemophilus influenzae*, and anaerobes in chronic cases.[10] Resistance to first-line antibiotics is increasingly reported in Nigeria, largely due to irrational antimicrobial use.[11] Several comorbidities increase the risk and severity of OCR, including diabetes mellitus, HIV/AIDS, immunosuppressive conditions, and poorly controlled chronic rhinosinusitis.

Sociodemographic factors—such as rural residency, low educational attainment, and socioeconomic disadvantage—play a central role in the epidemiology and outcome of OCR. In Nigeria, rural dwellers often rely on primary health centers with limited diagnostic capabilities, leading to mismanagement or delayed referrals.[12]¹³ Studies have also highlighted how limited ENT workforce distribution in Nigeria disproportionately affects rural populations.[13] A study found that rural patients were more likely to present at advanced Chandler stages and had poorer functional outcomes compared to their urban

counterparts.[14] Health literacy, cultural beliefs, and economic constraints are compounding factors that must be addressed to improve OCR outcomes in the region.

Management of OCR involves medical therapy with broad-spectrum intravenous antibiotics, nasal decongestants, corticosteroids, and analgesics. Surgical interventions, especially for stages III to V, including functional endoscopic sinus surgery (FESS), external drainage of abscesses, and orbital decompression. While FESS is the gold standard in high-resource settings, its availability in Nigeria remains limited to a few tertiary centers.[15] A study in southwestern Nigeria reported that lack of endoscopic equipment and trained personnel limited timely surgical intervention in 30% of OCR patients.[15] The delay in intervention correlates directly with complications such as vision loss, recurrence, intracranial extension, and death. Mortality rates for stage V with cavernous sinus thrombosis are reported as high as 20% in Nigeria, compared to <5% in developed countries.[15]

Timely intervention leads to favorable outcomes in most cases. However, vision loss, prolonged hospitalization, and functional disability remain common in resource-constrained settings. Prognostic factors linked with poor outcomes include delayed presentation (>7 days), rural residence, advanced Chandler stage (IV/V), age ≥ 45 years, chronic rhinosinusitis and comorbidities such as diabetes and HIV. There is urgent need for standardized protocols, better ENT service distribution, and community-level education to reduce OCR-related morbidity and mortality.

OCR remains a serious ENT-HNS challenge in Nigeria and similar developing countries, with distinct clinical, demographic, and systemic factors contributing to poor outcomes. There is an urgent need for localized data to guide context-sensitive prevention, early detection, and management strategies. This study aims to bridge this knowledge gap by providing detailed epidemiological, clinical, and outcome data on OCR in Nigerian tertiary ENT centers. This study aimed at determining the epidemiology, sociodemographic profiles, aetiopathologies, clinical presentation, management, and outcomes of patients diagnosed with OCR in ENT-HNS practices in Ekiti, Nigeria.

Materials And Methods

This retrospective cross-sectional study was conducted in the Department of Ear, Nose and Throat of Ekiti State University Teaching Hospital Ado Ekiti a tertiary hospital in Nigeria, a developing country. The study was carried out over a 10-year period from January 2010 to December 2019. This center serve as major referral center for patients with complex ENT-HNS conditions across neighbouring states.

The study population comprised all conservative patients diagnosed with orbital complications of rhinosinusitis, managed within ENT-HNS department during the study period. Orbital complications were classified according to the Chandler classification system (Stages I–V).

Inclusion Criteria: Patients of any age and gender with clinical and/or radiological confirmed diagnosis of orbital complications of rhinosinusitis. Patients who received treatment and follow-up in ENT-HNS departments. Patient with complete medical records including clinical presentation, demographic data, imaging results, management modalities, and outcomes.

Exclusion Criteria: Patients with orbital disorder like trauma, malignancy, thyroid orbitopathy. Incomplete records or lost to follow-up before outcome determination. Immunocompromised patients like diabetes mellitus, HIV/AIDS) to minimize confounding.

In this study a structured data collection form was designed to retrieve relevant information from hospital electronic and physical medical records, surgical record books, radiological archives, and follow-up notes. The data extracted included sociodemographic characteristics on age, sex, residence, educational level and occupation. Clinical presentations involving duration and nature of symptoms like fever, proptosis, visual loss, nasal discharge, pain, diplopia and chemosis. Aetiopathological data on type of rhinosinusitis (acute, chronic), causative pathogens (when cultured), comorbidities like diabetes mellitus and HIV. Classification of orbital complications using Chandler stages (I to V). Patient management modalities included medical using antibiotics, nasal decongestants, and corticosteroids or surgical included functional endoscopic sinus surgery (FESS), external drainage and orbital decompression). Treatment

outcomes of the patients in resolution of symptoms, duration of hospital stay, recurrence, complications and mortality.

Ethical approval was sought for and obtained from the Ekiti State University Teaching Hospital Ado Ekiti Nigeria ethical committee. All patient data were anonymized and handled with strict confidentiality in compliance with the Declaration of Helsinki.

Data collected were entered into Microsoft Excel and exported into IBM SPSS Statistics version 29.0 for analysis. Double data entry was used to minimize input errors.

Descriptive statistics were employed to summarize and present the data for continuous variables like age, duration of symptoms and hospital stay were described using means and standard deviations depending on the distribution. Categorical variables like sex, type of rhinosinusitis, orbital complication stage and treatment type were summarized using frequencies table and percentages. The prevalence rate of orbital complications among all rhinosinusitis cases was calculated.

Inferential statistical methods were applied to explore associations between key variables this included Chi-square Test (χ^2) or Fisher's Exact Test (where cell count <5) was used to assess associations between categorical variables such as age groups vs orbital complication type, type of rhinosinusitis vs Chandler classification and management modality vs outcome. Student's t-test or Mann-Whitney U-test was applied to compare means between two groups like hospital stay duration in medical vs surgical management. One-way ANOVA or Kruskal-Wallis Test for comparing more than two groups such as Chandler stages vs duration of symptoms. Binary Logistic Regression Analysis was used to identify predictors of poor outcome, including delayed presentation (>7 days), Chandler stage IV or V, presence of comorbidities and rural residence.

Results were reported as Adjusted Odds Ratios (AORs) with 95% Confidence Intervals (CIs) and p-values. Multivariate Logistic Regression model included variables with $p < 0.20$ in bivariate analysis to control for confounders.

A p-value < 0.05 was considered statistically significant.

Records with missing critical data points were excluded from analysis. Where minor data were missing, pairwise deletion or imputation methods were employed based on the nature and pattern of missingness.

Results

There were rhinosinusitis in 6691 patients and orbital complicated rhinosinusitis accounted for 229 (3.42%). The patients ranged in age from 1 to 67 years. The most represented age group was 31–40 years, accounting for 20.96% of the study, followed by 51–60 years and 21–30 years, both contributing 17.47% each. The least represented age group was 11–20 years (6.11%). The mean age was 32.32 ± 15.93 years. Males constituted a slight majority of the patient population with 127 (55.46%), compared to 102 (44.54%) females. A higher proportion of the patients resided in urban areas (60.70%) compared to rural areas (39.30%). Regarding educational attainment, secondary education was the most common level, reported in 37.55% of patients, followed by primary education (26.64%) and tertiary education (24.02%). Patients identified as farmers formed the largest occupational group (31.44%), followed by civil servants (27.95%), students (21.83%), and the unemployed (18.78%). This is shown in table 1.

Fever was the most frequently reported symptom, present in 195 patients (85.15%), highlighting the systemic inflammatory nature of orbital involvement secondary to rhinosinusitis. Nasal symptoms were also highly prevalent in nasal obstruction occurred in 174 patients (75.98%) and purulent nasal discharge in 167 patients (72.93%). Orbital and Ocular Signs included proptosis which was observed in 158 patients (69.00%), making it the most common orbital manifestation. Visual impairment was documented in 97 patients (42.36%), indicating that nearly half of the patients experienced functional ocular compromise. Painful eye movement, present in 101 patients (44.10%), likely reflects extraocular muscle involvement or orbital inflammation. Chemosis in 65 patients (28.38%), suggests conjunctival edema due to increased orbital pressure or venous congestion. Diplopia was the least common but still notable, occurring in 38 patients (16.59%) from extraocular muscle dysfunction, nerve involvement and orbital abscess or cavernous sinus involvement. This is demonstrated in table 2.

Majority of patients, 132 (57.64%), were diagnosed with acute rhinosinusitis, while 97 (42.36%) had chronic rhinosinusitis. Chandler classification of orbital complications revealed orbital cellulitis (Stage II) was the most frequent presentation, affecting 79 patients (34.50%), subperiosteal abscesses (Stage III) were also significantly prevalent, occurring in 24.45%, a finding that supports the rapid progression of untreated or inadequately managed orbital cellulitis, orbital abscess (Stage IV) and cavernous sinus thrombosis (Stage V) were recorded in 14.85% and 8.30% of patients, respectively, indicating a substantial burden of advanced orbital and intracranial complications. This is illustrated in table 3.

Out of the 229 patients, 131 (57.21%) received a combination of surgical and medical therapy, while 98 (42.79%) were managed with medical therapy alone. The high surgical intervention (over half of all cases) reflects the advanced stage of presentation. Among the 131 patients who underwent surgery Functional Endoscopic Sinus Surgery (FESS) was the most frequently performed procedure, used in 78 cases (59.54%), standard minimally invasive approach. External drainage procedures were employed in 37 patients (28.24%). Orbital decompression, a more aggressive surgical approach, was required in 16 patients (12.21%), reflecting severe orbital involvement. The majority of patients, 174 (75.98%), achieved full recovery, demonstrating that timely and appropriate intervention. 32 patients (13.97%) experienced residual visual deficits. Recurrence occurred in 17 patients (7.42%), potentially reflecting underlying chronic rhinosinusitis. Mortality, though low, was recorded in 6 cases (2.62%), underscoring the life-threatening nature of orbital and intracranial complications arising from rhinosinusitis. This is revealed in table 4.

Among the 53 patients classified as having late-stage disease, 32 (60.38%) were from rural areas, 21

(39.62%) were from urban areas. In contrast, among the 176 patients with early-stage disease, 118 (67.05%) were from urban settings, 58 (32.95%) were from rural areas. A chi-square test of independence revealed a statistically significant association between residence and stage of disease presentation ($\chi^2 = 12.93$, $p = 0.0003$). This indicate rural residence is significantly associated with a higher likelihood of presenting with late-stage orbital complications. This is shown in table 5.

Patients aged 41 years and above had a significantly higher likelihood (89% increased odds) of experiencing poor outcomes compared to younger patients. Age-related physiological decline, delayed immune response, and possible comorbidities may contribute to worse prognosis. Rural residents had more than twice the odds of poor outcomes compared to urban counterparts. This reinforces the earlier findings of late-stage presentation and highlights systemic healthcare access inequalities. The presence of chronic rhinosinusitis significantly increased the odds of poor outcome by 176%. Chronic inflammation may facilitate deeper infection spread and complicate management. Late-stage disease (i.e., Chandler IV and V) was the strongest predictor of poor outcome, with more than fourfold increased odds. This highlights the critical need for early detection and intervention to prevent severe morbidity and mortality. Although not statistically significant, surgical intervention showed a trend toward being protective, with a 46% reduction in the odds of poor outcome. Larger sample sizes may further validate the role of timely surgery in improving outcomes. This is illustrated in table 6.

The ANOVA test yielded an F-value of 19.56 with a p-value < 0.001 , indicating a statistically significant difference in the duration of hospitalization across the different Chandler stages. This is demonstrated in table 7.

Table 1: Sociodemographic Characteristics of the Patients

Variable Category	Frequency (n) Percentage (%)
Age Group (years)	
1–10	28 (12.23)
11–20	14 (6.11)
21–30	40 (17.47)

31–40	48 (20.96)
41–50	32 (13.97)
51–60	40 (17.47)
≥61	27 (11.79)
Total	229 (100.0)
Sex	
Male	127 (55.46)
Female	102 (44.54)
Residence	
Urban	139 (60.70)
Rural	90 (39.30)
Education Level	
No formal	27 (11.79)
Primary	61 (26.64)
Secondary	86 (37.55)
Tertiary	55 (24.02)
Occupation	
Student	50 (21.83)
Farmer	72 (31.44)
Civil Servant	64 (27.95)
Unemployed	43 (18.78)

(n = 229) Mean Age: 32.32 years SD: 15.93 years

Table 2: Clinical Presentation of Patients

Symptom/Sign	Frequency (n) Percentage (%)
Fever	195 (85.15)
Nasal obstruction	174 (75.98)
Purulent nasal discharge	167 (72.93)
Proptosis	158 (69.00)
Visual impairment	97 (42.36)
Painful eye movement	101 (44.10)
Chemosis	65 (28.38)
Diplopia	38 (16.59)

(n = 229)

Table 3: Types of Rhinosinusitis and Chandler Classification

Parameter Category	Frequency (n) Percentage (%)
Type of Rhinosinusitis	
Acute	132 (57.64)
Chronic	97 (42.36)
Chandler	
Stage I (Preseptal Cellulitis)	41 (17.90)
II (Orbital Cellulitis)	79 (34.50)
III (Subperiosteal Abscess)	56 (24.45)
IV (Orbital Abscess)	34 (14.85)
V (Cavernous Sinus Thrombosis)	19 (8.30)

Table 4: Management Modalities and Outcomes

Variable Category	Frequency (n) Percentage (%)
Treatment Type	
Medical Only	98 (42.79)
Surgical + Medical	131 (57.21)
Type of Surgery (of surgical cases)	
FESS	78 (59.54)
External Drainage	37 (28.24)
Orbital Decompression	16 (12.21)
Outcome	
Full Recovery	174 (75.98)
Residual Visual Deficit	32 (13.97)
Recurrence	17 (7.42)
Mortality	6 (2.62)

Table 5: Association between Residence and Late Chandler Stage (IV & V)

Variable	Late Stage (n=53)	Early Stage (n=176)
Urban	21 (15.11%)	118 (84.89%)
Rural	32 (35.56%)	58 (64.44%)

$$\chi^2 = 12.93 \text{ p-value } 0.0003$$

Table 6: Logistic Regression Predicting Poor Outcome (Residual Visual Deficit / Death)

Predictor	AOR	95% CI	p-value
Age ≥ 41 years	1.89	1.02 – 3.51	0.041
Rural residence	2.14	1.16 – 4.00	0.015
Chronic rhinosinusitis	2.76	1.34 – 5.68	0.006
Chandler Stage IV/V	4.22	2.01 – 8.87	<0.001
Surgical intervention	0.54	0.27 – 1.09	0.084

Table 7: Mean Duration of Hospital Stay by Chandler Stage

Chandler Stage	Mean $\pm$ SD (days)
Stage I	4.12 $\pm$ 1.45
Stage II	5.28 $\pm$ 2.13
Stage III	7.41 $\pm$ 2.66
Stage IV	9.62 $\pm$ 3.14
Stage V	11.88 $\pm$ 3.77

ANOVA F = 19.56 p-value <0.001

Discussion

In this recent study involving 6,691 patients with rhinosinusitis, the prevalence of orbital complications was identified as 3.42%, with 229 patients exhibiting such complications. This prevalence rate is consistent with existing literature, which reports orbital complications in rhinosinusitis cases typically ranging from 1% to 5%.[4] The prevalence rate in this study may reflect a cohort with better healthcare access, as rates can be higher (up to 20%) in developing countries, where delayed treatment is common.[16] Lower prevalence rate in this study may indicate under reported cases in our study population. The documented 3.42% prevalence of orbital complications emphasizes the importance of vigilance in managing rhinosinusitis. This finding contributes to a broader understanding of morbidity associated with this condition and underscores the need for effective healthcare strategies to mitigate risks, particularly in vulnerable populations. This study provides a large-scale overview of the clinical presentation, sociodemographic patterns, aetiopathology, management, and outcomes of 229 patients diagnosed with orbital complications of rhinosinusitis (OCR) in ENT-HNS practices across Nigeria. It is one of the

most extensive reviews of OCR in Sub-Saharan Africa to date.

The predominant age group was 30–44 years (29.70%), followed closely by those aged ≥ 45 years (28.38%), contrasting with studies from high-income settings where OCR is more common in pediatric populations, especially under 15 years of age.[3] This age shift may reflect differing immune status, healthcare-seeking behavior, and late presentation in adults in Nigeria. The male preponderance (55.46%) aligns with findings from other study that reported male dominance in sinonasal infections and complications.[17] Rural residency (39.30%) was significantly associated with late-stage presentation (Chandler stages IV and V, $p = 0.0003$). This suggests critical disparities in healthcare access and awareness between urban and rural communities, echoing observations by study that emphasized geographic and infrastructural limitations in ENT service delivery in rural Nigeria.[18] Educational levels in this study were predominantly secondary or lower, with only 24.02% attaining tertiary education, reinforcing previous evidence that lower educational attainment correlates with poor health literacy and delayed care-seeking behavior.[19]

Fever (85.15%), nasal obstruction (75.98%), and proptosis (69.00%) were the most frequently reported symptoms. This aligns with classical symptomatology in orbital cellulitis and abscess formation as reported by Chandler and reiterated by recent African studies.[20] Visual impairment (42.36%) was notably higher than in similar studies in Kenya (28.6%) and South Africa (30.2%), possibly due to delayed presentation or mismanagement in peripheral healthcare centers.[21] Acute rhinosinusitis (57.64%) was more prevalent than chronic forms, similar to global trends where acute infections more often lead to aggressive orbital extension.[22] However, patients with chronic rhinosinusitis had , as reported by other study.[23] Chandler Stage II (orbital cellulitis) was the most frequent presentation (34.50%), but stages IV and V together constituted 23.15%—an alarmingly high rate compared to developed countries (typically <5%).[1] This reflects the diagnostic delays and therapeutic gaps still prevalent in Nigeria's health system.

A combination of surgical and medical treatment was adopted in 57.21% of cases, demonstrating increased preference for early surgical drainage and sinus surgery in more advanced presentations. Functional Endoscopic Sinus Surgery (FESS) was the most common surgical intervention (59.54% of surgical cases), in line with global ENT guidelines recommending minimally invasive drainage and sinus ventilation.[24] Orbital decompression was performed in 12.21%, primarily in stages IV/V cases—similar to reports from Egypt and India.[25] The overall recovery rate of 75.98% is comparable to the 73–85% success rates seen in tertiary ENT centers globally.[26] However, residual visual deficits in 13.97% and mortality in 2.62% of patients raise serious public health concerns. These outcomes were significantly associated with age ≥ 45 , rural residency, chronic rhinosinusitis, and late-stage disease ($p < 0.05$), consistent with findings from a large cohort in South Africa.[27] The length of hospital stay increased significantly with disease severity (mean 4.12 days for Stage I vs 11.88 for Stage V, $p < 0.001$), suggesting that advanced stages consume more resources and cause higher socioeconomic burden—echoing the conclusions of a Tanzanian cost-of-care study.[28]

Early detection and referral systems to strengthen primary care awareness and prompt referral pathways for rhinosinusitis complications, especially in rural

communities. Community ENT outreach to implement community-based ENT health education and periodic screening programs in underserved areas Training and infrastructure to expand training of general practitioners in early diagnosis of orbital complications and ensure availability of CT imaging and FESS capabilities at secondary-level hospitals. Policy and resource allocation to targeted funding for rhinosinusitis and its complications within Nigeria's non-communicable disease programs. Future research on multicenter prospective studies are needed to evaluate the impact of standardized management protocols on OCR outcomes in low-resource settings.

Conclusion

Orbital complications of rhinosinusitis remain a significant clinical challenge in ENT-HNS practices in Nigeria. Adults in their third to fifth decades, males, rural dwellers, and those with low educational attainment are disproportionately affected. Proptosis, fever, and visual impairment are key clinical indicators. Chronic rhinosinusitis, delayed care, and rural residency are strong predictors of poor outcomes, including vision loss and death. Although the combination of FESS and antibiotics is effective, outcomes are suboptimal in advanced stages, emphasizing the importance of early diagnosis and intervention.

Ethical approval

Approval for the study was obtained from the Ethics and Research Committee. The study was conducted according to the guidelines of the Declaration of Helsinki.

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