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Received: 15 August 2000 Accepted in revised form: 6 April 2001 Enucleation in a tertiary eye care centre in India: prevalence, current indications and clinicopathological correlation

Abstract

Purpose Enucleation is a standard surgical treatment modality for many end-stage eye diseases. Indications for enucleation vary with changing trends in disease management. Few studies have addressed the issue of the frequency and indications of enucleation of eyes in India. We aimed to determine the frequency and the current clinical indications for enucleation in patients at a tertiary eye care centre in India, and attempted a clinicopathological correlation.

Methods Medical records of patients undergoing enucleation at a tertiary eye care centre over a period of 3½ years (January 1995 to July 1998) were reviewed to obtain patients' demographic data and socio-economic status. The clinical indications and predisposing factors were assessed. The formalin-fixed, paraffin-embedded sections of all enucleated eyes were re-evaluated and histopathological findings were correlated with the clinical diagnosis. The prevalence of enucleation was calculated, and age adjustments were done using the Indian population data from 1998 mid-year statistics.

Results Enucleation of the eye was performed in 150 patients (151 eyes) out of 88 991 new ophthalmic cases, constituting 0.17% of the cases seen in the hospital, and amounting to a prevalence of 0.33% (95% CI, 0.27–0.40). Males outnumbered females in a ratio of 1.85:1 (98 males, 53 females). The median age was 8 years (mean 16.8 \pm 18.3 years). Children below 15 years of age constituted 85.2% (95% CI, 81.2-89.21%) of cases that underwent enucleation. Clinical indications for enucleation included tumours in 74 (49%); staphyloma in 38 (25%); acute injury in 20 (13%); absolute glaucoma in 9 (6%); painful blind eye in 5 (3%); phthisis bulbi in 1 (1%); and others in 4 (3%). Of the 74 cases with a clinical diagnosis of tumour, histopathology revealed retinoblastoma in 55 (74%) cases, melanoma in 6 (8%) and ocular surface tumours in 4 (6%). Clinico-pathological correlation was 100% in cases with a definite

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clinical diagnosis of retinoblastoma and melanoma. Nine blind eyes (6%) in which an intraocular tumour was one of the differential diagnoses, were negative for a tumour on histopathology. Staphyloma was more prevalent in the low socio-economic group (p = 0.0004), with a history of childhood trauma in 34% cases.

Conclusions The prevalence of enucleation in the population reporting to this tertiary eye care centre was 33 per 10 000 population over the study period of 31/2 years. Major indications for enucleation were tumours, staphyloma and trauma (88% of all cases). Increased frequency in the young was due to the high proportion of retinoblastoma and staphyloma. Childhood trauma, inflammation and malnutrition may together play a role in the pathogenesis of staphyloma. Awareness at the level of primary health care providers, paediatricians and general practitioners should be promoted to identify the disease process at an early stage and facilitate early intervention measures that could result in eye and vision salvage.

Key words Enucleation, Histopathology, Indications, Staphyloma, Retinoblastoma

Enucleation is an accepted modality of treatment for severely traumatised eyes, advanced stages of tumours, and cosmetically unacceptable or painful blind eyes.¹ The indications for enucleation have changed over the past few decades. Fewer eyes with tumours and severe trauma are enucleated²⁻⁴ now due to the availability of new eye-salvaging treatment modalities.⁵ In India, previously reported indications for enucleation and evisceration include trauma, endophthalmitis, uveitis, corneal ulcer, staphyloma, glaucoma, tumours and phthisis bulbi.^{6–8} This retrospective study was undertaken at a tertiary eye care centre to determine the frequency, prevalence and current indications for enucleation, to correlate

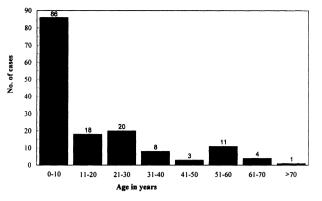


Fig. 1. The frequency of enucleation of eye in each decade of life.

clinical and pathological diagnosis, and to analyse the associated histological changes in the globe.

Materials and methods

A retrospective analysis was carried out of enucleated eyeballs received at the Ophthalmic Pathology Service of the L.V. Prasad Eye Institute over a period of 31/2 years (January 1995 and June 1998). Medical records of these patients were reviewed to obtain demographic data, history of consanguinity, family history of tumours, presenting symptoms and their duration, and laterality. The primary clinical indications for enucleation were divided into seven groups, namely anterior staphyloma, tumours, acute injury, absolute glaucoma, painful blind eye, phthisis bulbi and others. In the tumour group a further note of suspected or definite diagnosis of a particular tumour was made for correlation with the final histological diagnosis. The predisposing causes for the final clinical diagnosis were categorised as trauma, infection, tumour and others. All patients seen at the Institute were categorised by age (15 years or above, and below 15 years). The age adjustments were done based on the 1998 Indian mid-year population, which was 981 666 198 including 337 857 014 (34.4%) children under the age of 15 years.⁹ The socio-economic status was estimated by trained counsellors using a combination of direct and surrogate measures at the initial hospital visit to categorise patients into those who could afford to pay (paying patients) and those who had to be treated free (non-paying patients).

The slides from formalin-fixed, paraffin-processed tissues were retrieved from the Ophthalmic Pathology Service of our institute. The haematoxylin and eosin (H&E) stained sections of all the specimens were reevaluated by an experienced ophthalmic pathologist with special attention to histopathological diagnosis and associated pathological changes in the eye. Anterior segment disorganisation, neovascularisation of the iris, peripheral anterior synechiae, evidence of inflammation and drusen were specifically noted. In tumours, further details such as type of tumour and differentiation pattern were noted. The clinical diagnosis in the tumour group was correlated with the final histopathological diagnosis. The data were analysed using Fisher's exact test, chisquare test and ANOVA.

Table 1. Mean age, duration of symptoms and clinical indications of enucleation

Clinical diagnosis	No. of cases	Mean age (years)	Mean duration of symptoms (months)
Tumours	74 (49%)	8	8
Anterior staphyloma	38 (25%)	21	27
Acute injury	20 (13%)	28	0.2
Absolute glaucoma	9 (6%)	37	44
Painful blind eye	5 (3%)	31	10
Phthisis bulbi	1 (1%)	18	16
Others	4 (3%)	9	52

Results

There were 151 eyes (150 patients) enucleated during the study period of 31/2 years. During this period, 88 991 new ophthalmic patients were registered in the outpatient clinics of the hospital. Therefore, the frequency of enucleation was 0.17% of all new cases with a prevalence of 0.33% (95% CI, 0.27-0.40). The enucleated eyes constituted 8% (151 of 1977) of all surgical specimens received at the pathology centre during the period of study. The patients attending this institution were mainly from the states of Andhra Pradesh, Madhya Pradesh, Maharashtra, West Bengal and Orissa. The age of these patients ranged from 45 days to 72 years (mean $16.8, \pm 18.3$ years, median 8.0 years), with 61.3% (92/150)below 15 years of age and 87% (132/150) below 40 years of age. Of all patients attending our institute during the same period of study, 12.5% were below 15 years and 87.5% were above 16 years. Age-adjusted values based on the 1998 mid-year population showed that 85.2% of the enucleations were in patients below the age of 15 years (95% CI 81.2-89.2%) and 14.8% were in patients above the age of 15 years (95% CI 10.8-18.8%). Fig. 1 shows the age distribution of these patients in each decade of life. There were 98 male and 53 female patients with a male to female ratio of 1.85:1. Non-paying patients constituted 62% of those undergoing enucleation, while in the general outpatient population attending our institute during the same study period, this group constituted 31% of patients.

The clinical indications for enucleation are given in Table 1. Tumours (74, 49%) comprised the commonest factor indicating enucleation, while phthisis bulbi (1, 2%) was the rarest indication. Patients with a clinical diagnosis of tumour were further categorised into five groups, as shown in Table 2. The clinicohistopathological correlation was 100% in the group with a clinical diagnosis of retinoblastoma, melanoma or other

Table 2. Age distribution and clinico-pathological correlation for patients with tumours

	No. of	Mean age		HP
Clinical diagnosis	cases	(years)	HP	correlation
Retinoblastoma	48	2.1	48	100%
Suspected retinoblastoma	16	5.8	7	44%
Melanoma	4	48.2	4	100%
Suspected melanoma	2	50.5	2	100%
Other tumours	4	34.0	4	100%

HP, histopathology.

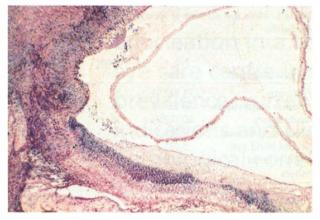


Fig. 2. Section of an eyeball with an abscess within the vitreous cavity, in the centre of which is seen a degenerating cysticercosus. The surrounding tissues elicited a granulomatous inflammation. (Haematoxylin and eosin, $\times 250$.)

tumour. In the suspected retinoblastoma group, retinoblastoma was histologically confirmed in 7 cases (44%), while no tumour was identified in 9 cases (56%). The histopathological diagnosis in 9 cases (6.3%) where a tumour was suspected included proliferative vitreoretinopathy with gliosis (3), retinal dysplasia (1), granulomatous inflammation (1), intraocular cysticercosis (1) (Fig. 2) and choroidal haemangioma (1) (Fig. 3). All these patients had undergone a complete investigation by imaging modalities with equivocal findings and were all blind and symptomatic, prompting the decision in favour of enucleation for histopathological confirmation of the diagnosis, and to provide symptomatic relief.

Of the 55 cases of histologically diagnosed retinoblastoma, bilateral involvement was seen in 34.5% and unilateral involvement in 65.5%. Family history of consanguinity was present in 11 of 55 retinoblastoma cases (25%), of which 6 were bilateral and 8 were unilateral. The differentiation based on rosette formation in the bilateral and unilateral cases and its relation to the

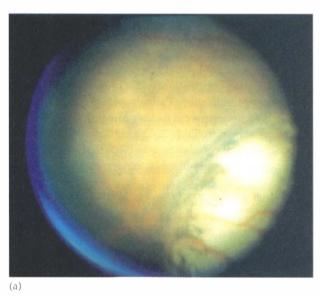


Table 3. Socio-economic status of patients in all groups

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Clinical diagnosis	Total	Paying	Non-paying
Anterior staphyloma	38	3 (13%)	35 (87%)
Tumours	74	33 (45%)	41 (55%)
Injury	20	13 (65%)	7 (35%)
Glaucoma	9	4 (45%)	5 (55%)
Blind eye	5	2 (40%)	3 (60%)
Phthisis bulbi	1	-	1 (100%)

Table 4. Retinoblastoma cases: rosette differentiation in tumour versus bilaterality and age of the children

	Laterality			
Differentiation	Unilateral	Bilateral	Mean age (years)	
Well differentiated	5	9	0.9	
Moderately differentiated	6	5	1.9	
Poorly differentiated	25	5	3.1	

age of the patients is given in Tables 3 and 4. The diagnosed cases of choroidal melanoma included 4 cases of mixed cell type and 2 of the spindle cell variety. All these cases were choroidal melanomas. Ocular surface tumours included 2 cases each of squamous cell carcinoma and sebaceous cell carcinoma with invasion of ocular coats. A diagnostic biopsy for histological confirmation was performed in all these ocular surface tumours before surgery.

Anterior staphyloma (Fig. 4) constituted 25% (38 of 151) of all cases, with a mean age of 21.2 years (\pm SD 17 years, range 2–55 years) and a mean latent period of 27 months (\pm SD 45 months, range 1–168 months) from the onset of symptoms. History of trauma was elicited in 15 cases (40%) cases, sustained at an average of 21 months before enucleation. In this group, non-paying patients constituted 92% (35 of 38), while paying patients constituted 8% (p = 0.0004). The main reasons for enucleation of symptoms. The histological changes observed were corneal scarring, stromal degeneration, secondary angle closure with anterior synechiae, neovascularisation, inflammation, and deep optic cup.

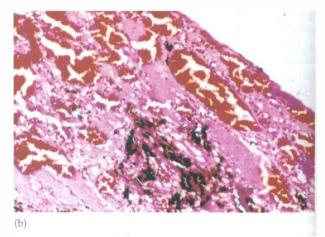


Fig. 3. (*a*) The fundus picture of a 10-year-old girl with a clinical diagnosis of retinoblastoma showing a retinal detachment and a subretinal mass. (*b*) Section of the eyeball from the same patient revealed a vascular tumour in the choroid, consisting of dilated cavernous spaces filled with blood, lined by flattened endothelial cells, confirming the diagnosis of choroidal haemangioma. (Haematoxylin and eosin, ×250.)







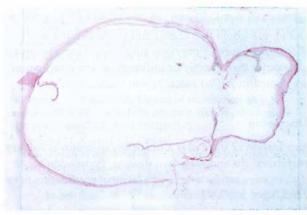




Fig. 4. (a) The clinical picture of a patient diagnosed with staphyloma, showing raised yellowish nodules on the corneal surface denoting secondary degenerative changes. Note the thinning of sclera and limbus with bluish discoloration caused by prolapse of uveal tissue. (b) The gross photograph of an enucleated eye from another patient with anterior staphyloma. (c) Whole mount section of the same eyeball depicting the anterior pouch lined internally by thinned uveal tissue.

The group with acute injury included 20 eyes with trauma of recent onset (<1 month) leading to enucleation. The mean age was 27.8 years (\pm SD 17 years, range 5–73 years). The types of injury included road traffic accidents, perforating injury with a sharp object and firecracker burst injury. The distribution of cases in paying and non-paying categories was equal. Enucleation was performed either because the eye could not be salvaged or because of significant concern for sympathetic ophthalmia. Histological changes included evidence of corneo-scleral repair, corneal scarring, choroidal and vitreous haemorrhage and retinal detachment. Other indications for enucleation included absolute glaucoma (9 of 151), painful blind eye (5 of 151) and phthisis bulbi (1 of 151). Two cases of sympathetic

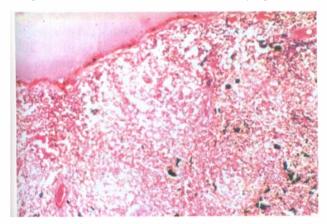


Fig. 5. Section from an enucleated eyeball of a patient diagnosed with sympathetic ophthalmia showing granulomatous inflammation in the choroid. (Haematoxylin and eosin, \times 500.)

ophthalmitis (Fig. 5) were identified on histopathology in 2 eyes with a history of trauma 6 months and 3 years prior to enucleation.

The general histological changes in these eyes included retinal detachment (76%, 104 of 151), neovascularisation (53%, 80 of 151), angle closure (46%, 69 of 151), inflammation (21%, 31 of 151) and drusen (15%, 23 of 151). Other histological changes observed in these eyes were ossification (5%, 7 of 151) (Fig. 6), spheroidal degeneration (4%, 6 of 151), iris cyst (3.5%, 5 of 151), sympathetic ophthalmitis (1.3%, 2 of 151) and specific infections (1.3%, 2 of 151).

The most common predisposing factor leading to the clinical condition prompting enucleation was tumour (49%, 74 of 151), followed by trauma in 30% of cases (45

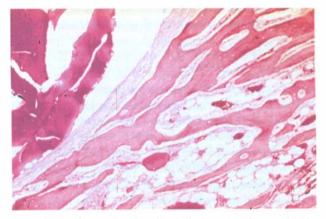


Fig. 6. Section from an enucleated eyeball of a patient diagnosed with phthisis bulbi, revealing osseous metaplasia within the choroid. (Haematoxylin and eosin, ×125.)

of 151), staphyloma in 15 (10%), painful blind eye in 5 (3.3%), glaucoma in 3 (2.6%) and phthisis bulbi in 1 (0.6%). A history of previous surgery (for cataract and glaucoma) that directly or indirectly led to enucleation was noted in 7 (5%) cases.

Discussion

Enucleation of the eye is a major organ-removal surgery performed for end-stage eye disease. Population-based studies have estimated the incidence of enucleation to be 2.6–5.0 per 100 000 population.^{10,11} Indications of enucleation vary across different centres in the world and also denote a changing trend.^{12–14} While some workers report an increase in the relative proportion of enucleation in tumours,^{13–15} others report a decline.² Though no population-based study has been reported from India, the indications for enucleation and evisceration together have been studied in adults and children.^{6–8} This study aimed to evaluate the frequency, prevalence and current indications for enucleation in patients presenting at a tertiary referral centre. In addition, the correlation between the clinical and histopathological diagnosis was determined.

In the absence of a population-based study, the prevalence of enucleation we arrived at - 33 per 10 000 population – is only an estimate. This is almost 100 times the incidence in Iceland of 2.66 per 100 000 population.¹⁰ As in other series, there was a predominance of males undergoing enucleation.^{16–18} 61.3% of the patients in our series were children below 15 years of age. This is in itself significantly higher since children less than 15 years of age comprised only 12% of patients who attended the general outpatient clinic during the same time. The ageadjusted prevalence would be 85.2% of patients below 15 years of age (95% CI, 81.2-89.2). The high predilection for young age in this series contrasted with findings in other series, which quote an increasing incidence of enucleation with age.¹⁹ The high percentage of enucleation in children in this series is due to retinoblastoma as well as staphyloma. However, our results were similar to a report from Turkey, in which 54% of enucleations occurred in patients below 30 years of age.¹³

Tumours and suspected tumours in our study constituted 49% of enucleated eyes, comparable to the 42% reported by Poriccha and Aurora⁷ in children. However, it was higher than the incidence of 20–34% reported by others.^{12–26} It is possible that advanced retinoblastoma, which is one of the major indications for enucleation in children, necessitates enucleation of the eye. This also highlights the fact that though the incidence of enucleation is changing in other parts of the world, there has not been much change in India over the past two decades. Schultz et al.20 have documented an actual increase in the number of retinoblastomas. Early diagnosis and timely intervention could help reduce this incidence. The ratio of retinoblastoma to melanoma in this series was 9:1, as compared with 1:2¹² reported in tumours of the oculo-adenexal region and 1:13¹⁶ in intraocular tumours. This ratio reflects the low incidence of melanoma in the pigmented races and the relatively high incidence of retinoblastoma in India.

The clinical presentation of retinoblastoma mimics many non-tumorous conditions including Coats' disease, endophthalmitis and proliferative vitreoretinopathy. The false positive clinical diagnosis in our series was 6% (9 of 151), slightly higher than the 2.3% reported by Gottrau et *al*.²¹ It is of interest to note that when the clinical diagnosis of retinoblastoma was certain, the histopathological correlation was 100%. It is also interesting to note that the mean age of true positive retinoblastoma was 2.13 years (\pm SD 1.6 years) while that of suspected retinoblastoma was 5.8 years (± SD 3.9 years; p = 0.002). Another interesting feature relating to these tumours is that the differentiation appears to decrease with increasing age (p < 0.0001). Long-standing tumours could possibly become less differentiated with time, which might explain the advanced disease at presentation and the poor outcome. Bilateral retinoblastoma was seen in 34.5% of our cases, similar to the findings in a series by Sahu et al.²² Poor differentiation, which may have a bearing on clinical outcome, correlated with unilateral involvement (p = 0.002) and with increasing age (p = 0.0004). There was no significant difference in the socio-economic status of patients in the tumour group, leading us to consider factors such as delay in diagnosis due to lack of awareness of this entity in parents, general ophthalmologists and general medical practitioners.

In the non-tumour group, anterior staphyloma was the most common indication for enucleation, contributing 25.2% of all cases. While this is a rare indication of the Western literature, the numbers in our series compare with those reported from India (12–33%),^{6–8} Ethiopia (11%)¹⁹ and West Africa.²³ In this series, 92% (35/38) of cases of staphyloma were from the non-paying group, which in our study represents the low socio-economic group. This is a significant observation, compared with the 31.2% of non-paying patients attending the general outpatient care in our hospital during the same period of study. We therefore suggest the possible role of nutritional factors, hygiene and infections predisposing to the pathogenesis of staphyloma. Another important feature was the high incidence of staphyloma (87%) in young patients below 30 years of age. A history of trauma was elicited in 34% of cases; in many patients this trauma dated back to childhood. An anatomically disorganised anterior segment with high intraocular pressure, contributed by the intact secretory function of the ciliary body, is probably required for causation of staphyloma. The possible factors implicated in its pathogenesis include trauma, chicken pox, measles,²⁴ malnutrition,^{6,7} pathological myopia,²⁴ congenital factors²⁵ and a postoperative state.²⁶ The high incidence of this condition in our series could possibly be due to nutritional factors, childhood trauma, infections and inflammations, which predispose the patient to staphyloma. It could also be compounded by other factors such as ignorance on the

part of the patient, increased tolerance of glaucoma symptoms and improper or inadequate treatment at the onset of the disease process. The role of environmental factors such as ultraviolet radiation, inflammatory mediators and free-radical-induced damage should be investigated as a propagating stimulus to the pre-existing malnutrition, since this entity occurs more in tropical countries and with childhood infections and inflammation.^{19,23}

Histological evidence of neovascularisation of the iris (53%) was comparable to the 48% reported by Gottrau *et al.*²¹ The histological evidence of angle closure (46%) in our series is, however, less than 60% as reported in the same series; yet the incidence of staphyloma is high. The percentage of inflammatory changes (21%) is also significant in our series. This lends credit to our suggestions that factors other than neovascularisation and angle closure are implicated in the pathogenesis of staphyloma.

A history of acute trauma was seen in 12.2% cases, which is comparable to the findings of other series (7–18%),^{12,14,15} though much less than the 33–41% reported by Spraul *et al.*,¹⁵ and Haile and Alemayehu.¹⁹ The mode of injury included a sharp object, blunt injury and firecracker injury. Infections requiring enucleation were not very common in this series despite the increase of 2% of infectious keratitis attending the outpatient department at our institute (unpublished data). The possible reason for this is that in such situations evisceration is more commonly employed than enucleation.

In summary, the age-adjusted prevalence of enucleation at a tertiary eye care centre was 0.33% over a study period of 3½ years. A majority of eyes (88%) were enucleated due to tumours, staphyloma and trauma. Enucleation in children and for tumours is high in our series, which is in contrast to the declining trends reported from other parts of the world. This could have an immense impact on the loss of productivity and unnecessary loss of vision in this age group. Timely intervention may avoid enucleation. It requires awareness, and early diagnosis of the disease by primary eye care centres, general practitioners and paediatricians.

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