Dissertation on

"A CLINICAL STUDY ON ROLE OF RADIOIMAGING LIKE CT/ MRI IN DIAGNOSIS AND MANAGEMENT OF ORBITAL LESIONS"

Submitted in partial fulfillment of requirements of

M. S. OPHTHALMOLOGY BRANCH III

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CHENNAI - 600 003



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APRIL - 2020

CERTIFICATE

This is to certify that the dissertation entitled "A CLINICAL STUDY ON ROLE OF RADIOIMAGING LIKE CT/ MRI IN DIAGNOSIS AND MANAGEMENT OF ORBITAL LESIONS" is a bonafide record of the research work done by Dr.NISHA C., Post graduate in Regional Institute of Ophthalmology, Madras Medical College and Research Institute, Government General Hospital, Chennai-03, in partial fulfillment of the regulations laid down by The Tamil Nadu Dr.M.G.R. Medical University for the award of M.S.Ophthalmology Branch III, under my guidance and supervision during the academic years 2017-2020.

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OF ORBITAL LESIONS" is a genuine work done by me under the

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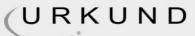
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INTRODUCTION

Imaging plays a vital role in characterization of orbital lesions in terms of site of lesion, extent and involvement of vital structures. Understanding of the imaging finding for various non traumatic orbital conditions like inflammation, infection, neoplasia is very crucial for the diagnosis and treatment of the condition in order to avoid visual loss¹. Imaging techniques like CT/ MRI has revolutionized the diagnosis of orbital lesions .CT SCAN is first line imaging tool for diagnosing orbital lesions in acute conditions, with MRI having an important role in diagnosis of soft tissue conditions. Although imaging studies can demonstrate tissue definition, pathological conditions can be assessed by tissue studies. Therefore a combined clinical, radiological and histology finding is essential for arriving at the diagnosis. Aim of our study is to find the role of radio imaging like CT/MRI in diagnosis of orbital lesions and to find clinical radiological and pathological correlation which aids in the management of orbital lesions.

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REVIEW OF LITERATURE

- Ralene Sim, Stephanie Ming Young et al² conducted a retrospective study among 83 patients undergoing biopsy or orbitotomy between September 2000 and August 2010 for orbital lesions and evaluated if there is any clinically, radiologically (CT) and histopathological correlation between the three modalities. There was less correlation between clinical diagnosis and radiology report, and more correlation in histopathology report and clinical diagnosis.
- Hind Manaa Alkatan et al³ conducted a retrospective study of all patients aged ≤18 years or younger who underwent orbital biopsy at King Khaled Eye Specialist Hospital (KKESH) from January 2000 to December 2013 and found that Clinically, the most common presenting complaints were eyelid or periocular swelling and proptosis.
- In 2006, Harsh kandpal et al⁴ cited in an article that dermoid was the most common congenital tumour of the orbit.

- In 2013, RB Dubey et al⁵ showed that Retinoblastoma was the most common intraocular malignant lesion.
- Imtiaz A.Chaudhry et al ⁶cited in an article that sinuses are the common source of infection in patients with orbital cellulitis.
- In 1997 Wright JE⁷- stated that orbital venous anomaly have features of both normal orbital veins and lymphatics and should be managed conservatively as possible.
- Chaudhry et al⁸ stated that pathological diagnosis remains the gold standard in diagnosis of orbital diseases when imaging reports are inconclusive.
- In 2015 **Porubanova M⁹**, et al cited that in case of orbital and peri-ocular capillary infantile haemangioma beta-blockers, both propranolol and metoprolol are very effective in reduction of the tumour size.

- In 2015, Bela S. Purohit¹⁰ stated that in patients with orbital masses, CT scanning is the modality of choice for evaluating calcification and osseous orbital lesions and metallic foreign body.
- In 2010, Williams MD et al¹¹ stated in an article that adenoid cystic carcinoma of the lacrimal gland is associated with bone invasion in almost all tumours and may warrant addressing the bony walls during surgery.

ANATOMY OF BONY ORBIT

The orbit is pear shaped cavity in the skull situated on either side. Posteriorly the cavity narrows to an apex of a triangular pyramid wherein the optic nerve and the muscles lie. The orbital rim is in the shape of a spiral, with its starting and end points at the anterior lacrimal crest and posterior lacrimal crests ¹²

EMBRYOLOGY OF THE ORBIT

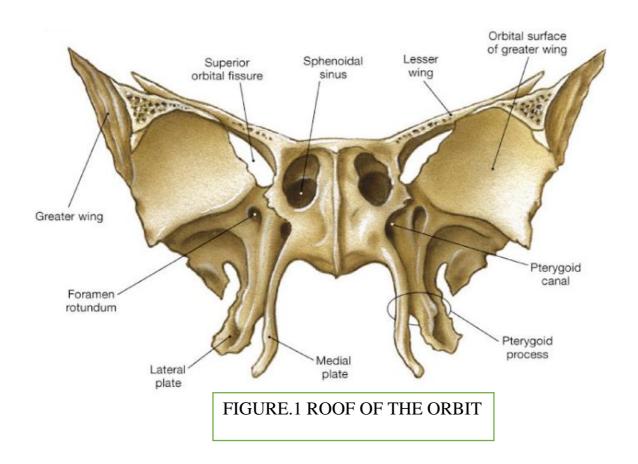
Bony walls of the orbit are formed from the mesoderm surrounding the eye. Visceral mesoderm of the maxillary process forms the floor and the lateral wall of orbit, paraxial mesoderm forms the roof while the lateral nasal process forms the medial wall. Paraxial mesoderm also forms the orbital contents, its muscles, fascia and vessels as well as the mesodermal stroma of the globe. Ossification centres for bones appear between 6th and 7th week of embryonic life.

ORBITAL WALLS

The orbital walls are made of seven bones.

- 1. Ethmoid
- 2. Frontal
- 3. maxillary
- 4. lacrimal
- 5.sphenoid
- 6. Palatine
- 7. Zygomatic

THE ROOF (Vault of the Orbit)



It is triangular in shape with the base placed anteriorly. The triangular plate of frontal bone forms the roof, and behind this by the lesser wing of the sphenoid. In the anterolateral aspect of the roof lies the fossa for the lacrimal gland. It contains the lacrimal gland and the orbital fat. In the anteromedial aspect of the roof above the frontolacrimal suture, 4 mm behind the orbital margin lies the trochlear fossa. Attached to this fossa is the fibrous pulley of superior oblique. The frontosphenoidal suture lies between the frontal bone and sphenoid¹³. The

orbital aspect of the roof consists of small apertures and are more marked in infants and children. The openings near the trochlear fossa transmit diploic veins. foramina in and around lesser wing of sphenoid transmit vessels connecting dural veins and ophthalmic veins. (**Fig.1**)

RELATIONS

In the anterior half lies the supraorbital artery, medially lies the trochlear nerve. The lacrimal gland adjoins the lacrimal fossa and the superior oblique the junction of roof and medial wall. Invading the roof are the frontal and ethmoidal sinuses. Frontal lobe of the cerebrum and its meninges are present above the roof.

THE MEDIAL WALL OF THE ORBIT

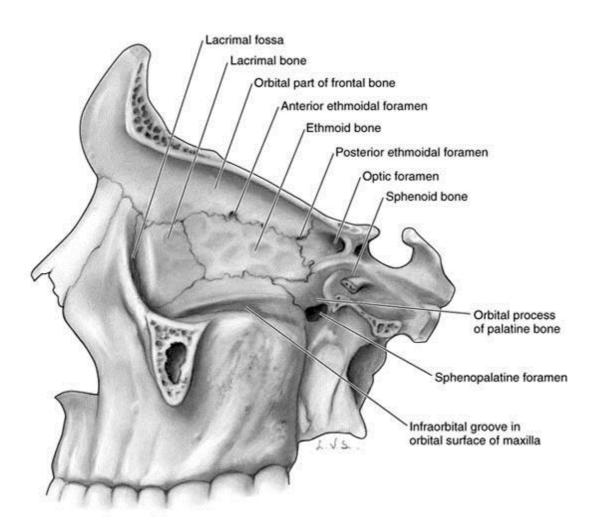


FIGURE.2. MEDIAL WALL OF THE ORBIT

Medial wall is the thinnest (0.2 to 0.4 mm) and it is formed by four bones : maxilla, lacrimal, ethmoid and sphenoid.

Anteriorly lies the lacrimal fossa, formed by the frontal process of the maxilla and the lacrimal bone¹⁴. Lacrimal fossa is bounded by the anterior and posterior lacrimal crests. About 20 mm behind anterior medial orbital margin is the anterior ethmoid foramen, and 12 mm behind this, is the posterior ethmoid foramen, which is 5-8 mm from the optic canal.(Fig.2)

RELATIONS

Medially lies the lateral nasal wall, infundibulum, ethmoidal sinuses and sphenoidal air sinus. optic foramen is located at posterior end of the medial wall. superior oblique muscle is in the angle between medial wall and the roof.

FLOOR OF THE ORBIT

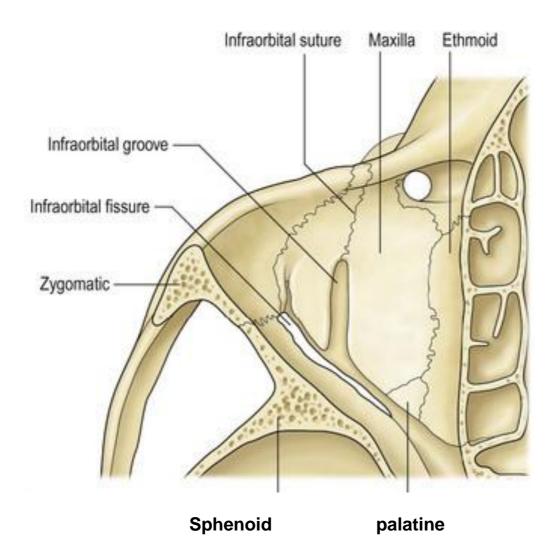


FIGURE. 3 FLOOR OF THE ORBIT

The infraorbital canal lies in orbital floor to open at infraorbital foramen about 4 mm below the orbital margin¹⁵. Posteriorly the lateral wall is separated from the floor by inferior orbital fissure .The floor is traversed by infraorbital sulcus (Fig.3)

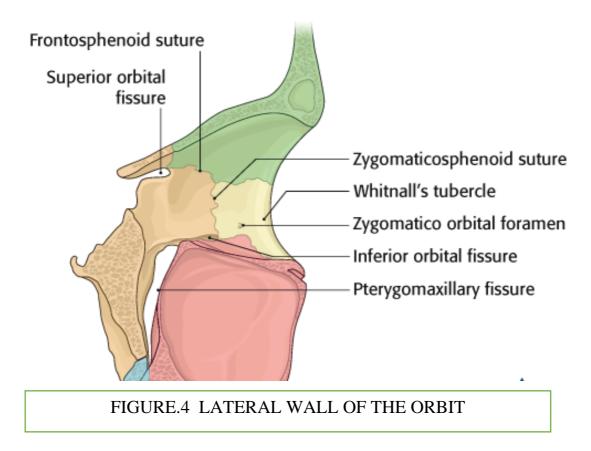
RELATIONS

Below the floor of the orbit is the maxillary sinus. The inferior rectus adjoins the floor of the orbit near the apex. At the lateral edge of the inferior rectus, is the nerve to inferior oblique. The infraorbital vessels and nerve occupy the sulcus canal.

INFERIOR ORBITAL FISSURE

It is located at the junction of the lateral wall and floor. It is bounded by maxilla and orbital process of palatine bone anteromedially and greater wing of the sphenoid posterolaterally . Before entering the cavernous sinus , the inferior ophthalmic vein passes through its lower portion

LATERAL WALL OF THE ORBIT



lateral wall is the thickest and forms an angle of about 45° with the median sagittal plane 16. formed by

- (i) Zygomatic bone
- (ii) greater wing of the sphenoid.

SUPERIOR ORBITAL FISSURE

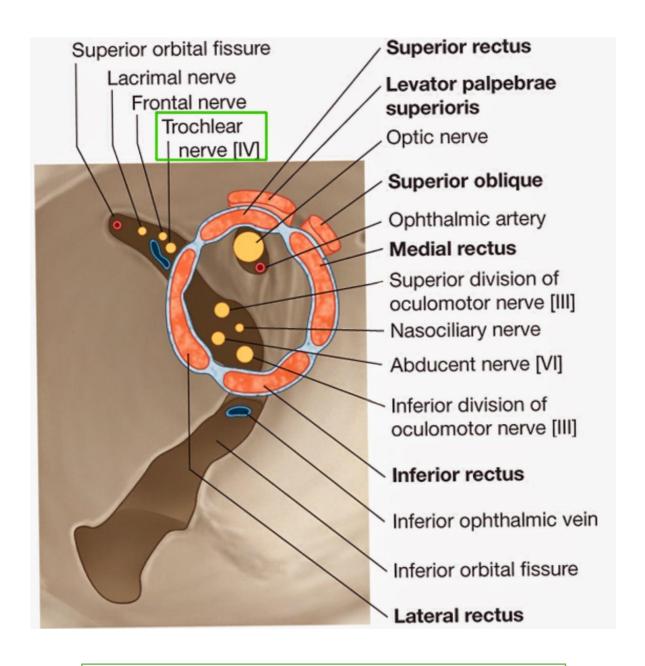


FIGURE.5 SUPERIOR ORBITAL FISSURE

It lies between the lesser wing of sphenoid and greater wings of the sphenoid and measures 22 mm in length¹⁷. The common tendinous ring of Zinn divides the fissure. (i)superior part lateral to the ring transmits lacrimal, frontal, trochlear nerves and superior ophthalmic vein (ii) The intermediate part is called oculomotor foramen which transmits superior division of oculomotor nerve, nasociliary, and sympathetic twig to ciliary ganglion. (iii) The part below and medial to the ring transmits inferior ophthalmic vein. (**Fig.5**)

Muscles Of The Orbit

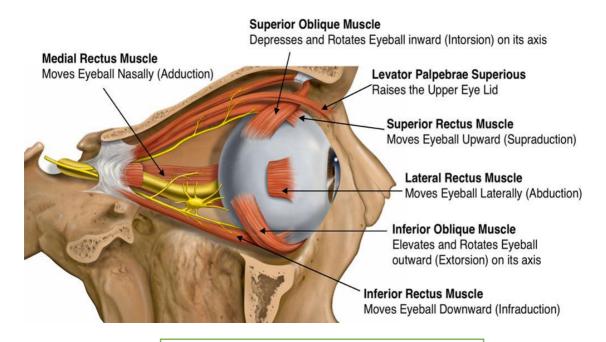
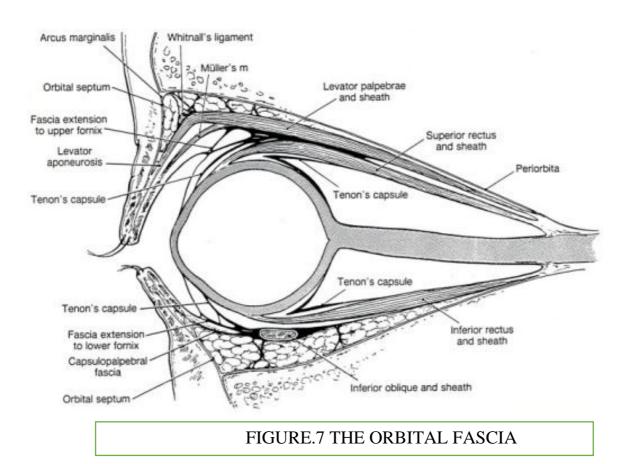


FIGURE.6 MUSCLES OF THE ORBIT

i. Extrinsic muscles

- four Recti namely superior , inferior , medial and lateral
- •two Obliques : superior and inferior
- ii. Muscles of the lids, levator palperbrae superioris
- iii. muscles of the orbit
 - muller muscle Periorbital muscle

1. The Orbital Fascia



orbital fascia comprises (Fig.7)

- 1. fascia bulbi (Tenons capsule)
- 2.fascial sheaths of the muscles
- 3. connective tissue supporting the orbital fat
- 4. check ligaments of the muscles
- 5. periorbital membrane (periosteum which lines the orbital cavity)
- 6. orbital septum.

Surgical spaces of the orbit

- i. Episcleral space lies between globe and tenons space
- ii. central space within the muscle cone
- iii. peripheral space between the muscles and the periosteum
- iv. subperiosteal space between the periosteum and the bone

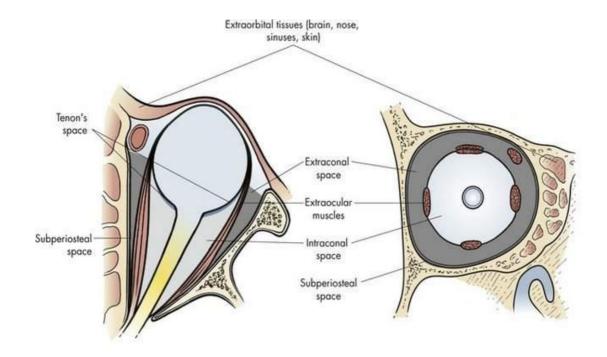


FIGURE 8 SURGICAL SPACES OF ORBIT

Blood vessels

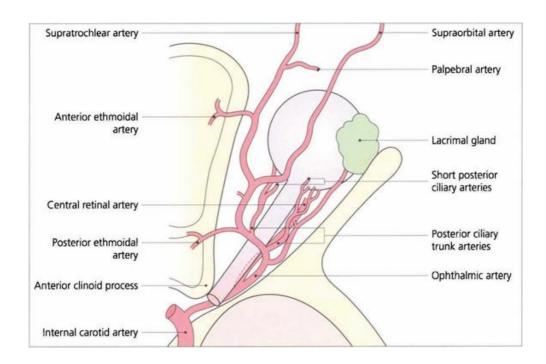


FIGURE.9 BLOOD SUPPLY

Blood supply

- Internal Carotid artery ¹⁸
- External Carotid

Venous supply

three main veins within the orbit

- (i) Superior ophthalmic vein
- (ii) Inferior ophthalmic vein

(iii) Central retinal vein. (Fig.9)

Lymphatics

In the orbit, there are no lymph nodes.

Nerves supply

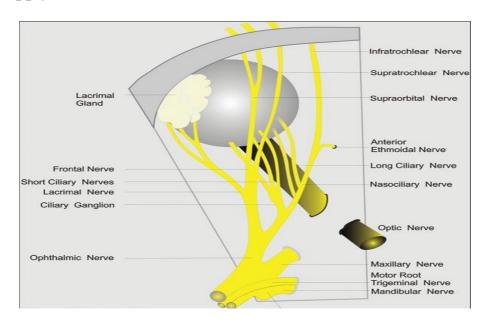


FIGURE.10 NERVES SUPPLY

- i. Optic nerve
- ii. III, IV, VI: supply extra ocular muscles and LPS
- iii. V: supply eye ball, lacrimal gland, conjunctiva, lids (Fig.10)
- iv. VII: supply lacrimal gland.
- v. Sympathetic supply: eye ball, lacrimal gland

CLINICAL EXAMINATION

SYSTEMIC EXAMINATION

- 1. Vital pulse rate, respiratory rate, blood pressure
- 2. Lymphadenopathy
- 3. Hepatosplenomegaly
- 4. Any other mass palpable
- 5. neck examination for thyroid swelling
- 6. Finger tremors
- 7. Nasopharyngeal examination/ tooth examination
- 8. musculoskeletal disorders
- 9. Dermatological examination
- 10. CNS examination/ CVS/ Respiratory / GIT Examination

GENERAL OPHTHALMIC

- 1. Visual acuity and refraction: Patient may be hypermetropic because retina may be pushed forwards, or myopic in case of pseudoproptosis.
- 2. Colour vision
- 3. visual field charting
- 4. Diplopia and Hess charting

- 5. Squint examination
- 6. Slit lamp biomicroscopy of anterior segment
- 7. Pupillary examination
- 8. Intraocular pressure by applanation tonometry. It increases in orbital inflammatory diseases. Differential tonometry should be done.
- 9. posterior segment Fundus to rule out papilloedema/ papillitis/ optic atrophy/ opticociliary shunt/ retinal folds, choroidal folds.

SPECIFIC EXAMINATION

- 1. Facial symmetry.
- 2. Position of eye lids
- 3.ptosis examination
- 4. extraocular movements
- 5. signs of thyroid orbitopathy

PROPTOSIS EXAMINATION

- Check for axial or eccentric proptosis
- unilateral or bilateral.
- Down and out proptosis in ethmoidal mucocles.
- Down and in displacement occurs in lacrimal gland tumours
- Up ward displaced in maxillary involvement.
- Downward displacement in subperiosteal hematomas

HERTEL'S EXOPHTHALMOMETER

It is most commonly used . Resting on the lateral orbital margin, distance between the apex of the cornea and the temporal rim of the orbit is measured when the red and white line are superimposed .

ON INSPECTION

Naffziger's sign: While looking tangentially over the forehead, the apex of the cornea is seen.

Look for

- mass lesion in orbit
- visible pulsation/ engorged veins
- Lagophthalmos
- Conjunctival congestion at muscle insertion indicates thyroid orbitopathy while diffuse congestion means vascular anomaly.

ON PALPATION

Palpate the orbital margin for any irregularity, mass lesion, finger insinuation is done between globe and orbital bones. Size, shape, surface, skin over swelling, consistency, signs of inflammation, tenderness, resistance to retropulsion, reducibility, compressibility must be noted. Variability of the swelling with valsalva maneouvre should be looked for.

ON AUSCULTATION

bruit over the mass lesion positive for A-V malformations.

INVESTIGATIONS:

COMPUTED TOMOGRAPHY

CT scan is useful to evaluate location, extent of lesion and to decide the surgical approach .Slice thickness are available in the range of 1-10mm .Generally slice width for orbital CT scanning is 2 mm .Disadvantage of thin slice include high radiation, more number of slices and longer examination duration. Current CT scan administers a dose of radiation exposure of approximately 1-2 cGy per orbit scan. CT scan has resolution to allow imaging of soft tissue, bones, contrastcontaining blood vessels, and foreign bodies. Coronal CT scanning is especially useful in evaluating orbital floor and extra ocular muscle size in Grave's ophthalmopathy. Axial cuts are taken parallel to rhese line and coronal cuts are taken 75 degree to the rheese line. In case of suspected vascular lesions like varices scan is done while the patient does valsalva maneuver. The spiral CT scanning moves the scanner in a spiral fashion around the patient, generating data set. Three dimensional CT scan allows reformatting of CT information in three dimensional projection of the bony orbital walls.

MAGNETIC RESONANCE IMAGING (MRI)

MRI has revolutionalised for soft tissue lesions. It is a non-invasive imaging, no exposure to ionizing radiation. T1 weighted scans gives anatomical details and T2 weighted scans gives pathological details. In case of lesions involving optic nerve, fat suppression is done Angiography using MRI (MRA) can be done on diagnosis of vascular lesions - ophthalmic artery aneurysm, AV malformation and vascular tumours.

Contraindication to MRI:

- ❖ Suspected magnetic FB,
- ❖ Metallic clips,
- ❖ Cardiac pace makers,
- ❖ Cochlear implant and
- ❖ Pregnancy.

LESIONS IN THE ORBIT:

CONGENITAL:

EPIDERMOID AND DERMOID TUMORS:

These are the most common cystic tumours in the orbit commonly occurring at the fronto zygomatic suture¹⁹.

CT SCAN may show bone remodeling and erosion.

MRI can detect subtle lipoid changes in the lesions . Dermoid may also demonstrate internal fluid signal and appear low on T1 weighted and high on T2 weighted images and show rim enhancement .

TREATMENT: complete removal of the cyst.



FIGURE 11- DERMOID CYST



FIGURE 12 - CT SCAN SHOWING DERMOID CYST

INFLAMMATORY:

NONSPECIFIC IDIOPATHIC ORBITAL INFLAMMATION:

It is a non specific, idiopathic, benign inflammatory process characterized by polymorphous lymphoid infiltrates and varying degree of fibrosis.

Histologically its composed of polymorphous infiltrates like mature lymphocyte, plasma cells, macrophages

RADIOLOGICAL FINDING:

CECT shows ragged infiltrates in anterior orbit, scleral enhancement and thickening. In cases of myositis, thickening of the entire muscle belly and tendon is seen

TREATMENT:

The primary treatment is the suppression of inflammation by giving corticosteroids

Thyroid-associated orbitopathy /

Graves' Orbitopathy:

It is an immune-mediated inflammatory disorder causing muscle and fat enlargement^{20,21} .it can present as eyelid retraction, proptosis, soft tissue swelling

, extraocular movement restriction, and loss of vision from compressive optic neuropathy

Pathogenesis

Orbital fibroblasts have increased numbers of TSH-Receptors, which bind to circulating autoantibodies (TRAb) and stimulates adipogenesis and stimulate the deposition of hyaluronic acid within orbital muscle and fat.

plot of orbital disease severity against time is called Rundle's curve^{22,23} The steepness of the graph in the active phase reflects the acuity of progression, with a steeper slope means more serious sequellae

IMAGING:

Muscle belly is enlarged with sparing of tendon is typically seen . Coronal scans are most useful to assess the degree of crowding of the apex .

TREATMENT:

In mild cases of proptosis, management is conservative with reassurance, cool compresses, head elevation, and nonsteroidal anti-inflammatory agents.

In cases where there is optic neuropathy, high dose corticosteroids by intravenous route is given .Surgical decompression of the medial wall is done (through a Lynch, transcaruncular approach / endoscopic transethmoidal approach) in order to relieve pressure on the optic nerve



FIGURE 13- PROPTOSIS WITH EXPOSURE KERATOPATHY

FIGURE 14 MRI SCAN SHOWING EXTRAOCULAR
MUSCLE ENLARGEMENT

ORBITAL INFECTIONS

Orbital infections can be either preseptal cellulitis, in which infection is located anterior to the orbital septum and orbital cellulitis, in which there is infection of orbital tissues posterior to the orbital septum²⁴.

Smith and Spencer classification of orbital infections into 5 tiers were later modified by Chandler .^{25,26}

- Preseptal cellulitis
- Orbital cellulitis
- Subperiosteal abscess
- Orbital abscess

• Cavernous sinus thrombosis.

Etiology:

- Bacteria, most commonly Streptococcus ,Staphylococcus aureus,
 Hemophilus influenzae, and anaerobes
- Fungal infections are less common than bacterial and occur in immunocompromised patients .
- Complications of orbital cellulitis includes
- Cavernous sinus thrombosis
- Brain abscess or meningitis
- Permanent vision loss.

Imaging Studies

- Computed Tomography (CT) scan CT scan axial and coronal view (2mm cuts) of the orbit, sinuses and frontal lobe is essential
- Magnetic Resonance Imaging (MRI) improve visualization of cavernous sinus thrombosis.

TREATMENT:

Adults with preseptal cellulitis are treated by oral antibiotics with close follow-up. Those with orbital signs need admission and IV antibiotics or antifungals under close supervision. Surgical intervention should be performed in cases where CT shows evidence of subperiosteal or orbital abscess. In case if fever persists or patient fails to respond, surgery is performed after 48 hours



FIGURE 15- SHOWING ORBITAL CELLULITIS LEFT EYE

MUCOCELE:

Any inflammation, trauma or mucosal disease affecting the ostium can lead to mucocele formation which can slowly expand to involve the orbital cavity most commonly seen in (40-70) years in the fronto ethmoidal sinus.

CT scan findings are bowing of the sinus wall into the orbit, with attenuation or even erosion of bone with a cystic cavity. Mucocele is treated surgically by removal of the lining of the cyst.

VASCULAR LESIONS:

Lymphangioma.

Superficial lymphangiomas are seen as multiple serous or blood filled cysts

Deep Lymphangiomas cause proptosis. They increase in size during upper respiratory infection and also causes acute proptosis due to bleeding into the cyst causing a chocolate cyst.

MRI is diagnostic²⁷, useful to delineate the lesions well and is also helpful in identifying the timing the chocolate cyst as acute, subacute or chronic.

MANAGEMENT:

Most cyst show spontaneous regression hence managed conservatively Picibanil (OK-432) percutaneous ethanol and bleomycin,5% sodium morrhuate and sodium tetradecyl sulfate are used for management of low flow vascular lesions.

Cavernous Hemangioma

Cavernous hemangiomas are the most common benign orbital tumor in adults .most commonly occurs in middle aged females in the intraconal space²⁸. they present as slowly progressing unilateral proptosis. Other features are hyperopia, optic nerve compression, optic disc edema, choroidal folds, gaze-evoked amarousis, raised intraocular pressure and strabismus.

IMAGING FINDING:

CT scan shows a well defined intraconal mass with smooth margins that enhances homogenously with intravenous contrast. Small areas of calcification may be seen.

In MRI the lesion is isointense and hyper intense to the muscle on T1 and T2 weighted respectively.

Lateral orbitotomy is the most common approach in intraconal lesions

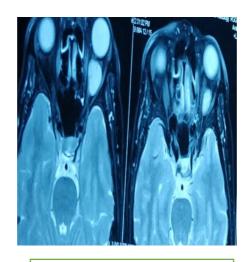


FIGURE 16 SHOWING
CAVERNOUS HEMANGIOMA

Orbital Varices

Orbital varices are weakened, dilated tortuous segments of orbital venous system. Mostly unilateral and frequently seen in the upper nasal quadrant. It presents as a non pulsatile reversible proptosis ²⁹ which increases in size by increasing venous pressure like straining, or by a valsalva maneuver.

IMAGING FINGING

Doppler shows the flow of blood. Spiral CT during valsalva maneuver shows characteristic enlargement of the varix .Angiography shows connection of the lesion to venous system and completely fills following injection. Management is conservative. But in cases of optic nerve compression, surgical removal is done .Complete removal is usually not possible as the lesions are friable, not encapsulated. Embolization using coils through a distal vein can also be done



FIGURE 17 SHOWING ORBITAL VARICES LEFT EYE

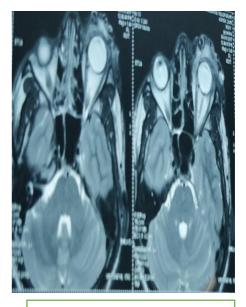


FIGURE 18 – MRI SCAN SHOWING VARICES LEFT EYE

Carotid-Cavernous Fistula

It is an abnormal communication between the carotid artery and the cavernous sinus. The blood in the cavernous sinus becomes arterialized thereby raising the venous pressure and at the same time the arterial perfusion suffers. It can be classified as 'direct or indirect', 'high flow or low flow ' and 'spontaneous or traumatic'.

Trauma is the most common cause of direct fistulas seen in basal skull fractures. Indirect or type C, D, E are due to congenital anomalies or spontaneous rupture of the aneurysm, atherosclerosis and hypertension.

Clinical features include classical triad of conjunctival hemorrhagic chemosis, pulsatile proptosis and bruit.³⁰

CT scan shows enlarged superior ophthalmic vein, enlarged extraocular muscles³¹ and the cavernous sinus. selective internal or external carotid angiography which will demonstrate the fistula and its hemodynamics. Surgical occlusion of the fistula by balloons /coil (by arterial / venous route is recommended for the Type A.

Treated when vision is threatened by amblyopia as a result of anisometropia, ptosis or strabismus. Intralesional steroids usually 40-80 mg of triamcinolone with 25 mg of methylprednisolone is injected into the lesion. Systemic steroids are indicated for visceral involvement. In case of failure of medical management surgical resection is carried out.

Capillary Hemangioma

Common benign primary tumors of the orbit in children in the first or second week after birth and enlarges during the first year of life, after which they involute. It usually regresses by 7 years of age. It can present as a strawberry naevus when the hemangioma involves the lid. Anterior and superior quadrant of

the orbit is a favoured site in the orbit. They present as a progressive non-pulsatile proptosis³². It may be associated with high output failure, 'Kasabach-Meritt Syndrome' (Anemia + thrombocytopenia + low coagulant factors) and 'Maffuci Syndrome' (Hemangiomas + enchondromatosis). Treatment is indicated in amblyopia as a result of anisometropia, ptosis or strabismus. Intralesional steroids 40-80 mg of triamcinolone with 25 mg of methylprednisolone is injected into the lesion. Complications include skin depigmentation, fat atrophy, eyelid necrosis and rarely central retinal artery occlusion. Systemic steroids are indicated for extensive lesions with visceral involvement. Recommended dosage used is 1.5 to 2.5 mg/kg prednisolone daily over a few weeks .



FIGURE 19 SHOWING CAPILLARY HEMANGIOMA





FIGURE 20 SHOWING RIGHT EYE CAPILLARY HEMANGIOMA

FIGURE 21 SHOWING REGRESSION OF CAPILLARY HEMANGIOMA AFTER BETA BLOCKERS

HEMANGIOPERICYTOMA

This is a tumour of the pericyte which occupies a position outside of the endothelial cells but in close apposition to them in capillaries and post capillary venular channels. Usually presents with proptosis of 6 months to 2 years duration. Tumour is usually situated within or outside the muscle cone and usually does not involve bone at the onset. Eyelid swelling, diplopia, a palpable mass in 60% of patients are present.

MALIGNANT HEMANGIOENDOTHELIOMA

Malignant tumour of the endothelial cells of the blood vessels. These are uncommon. These tumours are infiltrative and locally aggressive and have a high metastatic potential.

NEUROGENIC LESIONS

NEUROFIBROMATOSIS

Ocular manifestation occur in the first decade of life, transmitted in an autosomal dominant fashion. Orbital involvement is invariably unilateral. One characteristic finding is absence of orbital bones usually the sphenoid bone and orbital roof posteriorly.

OPTIC NERVE GLIOMAS

Account for 65% of optic nerve tumors. The mean age of presentation is 8.8 years Most lesions are sporadic although there is an association with neurofibromatosis (NF 1). Benign optic nerve gliomas are typically pilocytic astrocytomas originating from astrocytic glia^{33,34} and can involve the visual pathways anywhere from the optic nerve to the visual cortex.

Histologically they are composed of delicate, hair-like elongated eosinophilic cells in an interwoven pattern. The nuclei may be round or oval. The proliferating astrocytes in an optic glioma may be associated with worm-like densely eosiniophilic bodies, known as Rosenthal fibers

Fusiform swelling of the optic nerve is typically seen in patients without NF 1, whereas those with NF 1 tend to have more irregular nerves with areas of kinking or buckling.

Most optic nerve gliomas have an indolent growth pattern ,spontaneously regressing.



FIGURE 22- SHOWING RIGHT EYE PROPTOSIS

FIGURE 23 SHOWING OPTIC NERVE GLIOMA

OPTIC NERVE MENINGIOMA

Optic nerve meningiomas account for one third of primary optic nerve tumors. Primary optic nerve meningiomas originate from the cap cells of the arachnoid surrounding the intraorbital or intracanalicular portion of the optic nerve. The typical age at presentation is 40 years of age^{35,36}

The classical triad (HOYT SPENSOR TRIAD) of clinical findings in optic nerve meningioma are visual loss, optic atrophy and optociliary shunt vessels 35

Typically the lesions show 'tram-tracking' in which a thickened optic nerve sheath surrounds a central lucent optic nerve. MRI with gadolinium enhancement is particularly sensitive in detecting meningiomas

Treatment options include surgery and radiotherapy

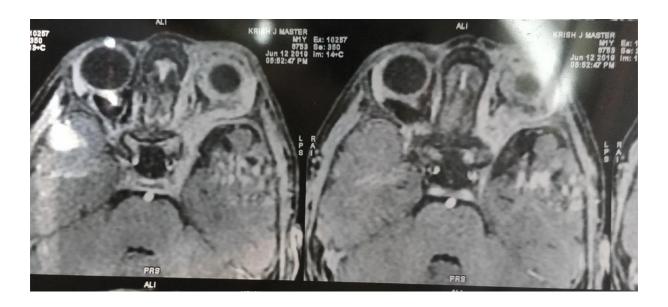


FIGURE 24 SHOWING LEFT EYE OPTIC NERVE MENINGIOMA

ORBITAL SCHWANNOMA (NEURILEMMOMA)

Schwannomas also known as neurilemmomas account for approximately 1-4% of orbital tumors, occurring most commonly in men between the second and fifth decades 37.38.

Histologically schwannomas show two growth patterns: Antoni A where densely packed spindle shaped cells are arranged with palisaded nuclei sometimes forming Verocay bodies, and Antoni B where cells are separated by an abundant myxoid stroma with no alignment of nuclei. Mitoses are usually absent.

Surgery is the treatment of choice

MESENCHYMAL SOFT TISSUE TUMORS

STRIATED MUSCLE TUMORS

RHABDOMYOSARCOMA

Rhabdomyosarcoma is the most common soft tissue sarcoma in children^{39,40} occurring in the head and neck region. Orbit is the second most common site in the head and neck. It presents as a rapidly developing exophthalmos over weeks with conjunctival and eyelid swelling.

CT scan shows a well-defined, homogeneous, hyperdense extraconal mass in the superomedial orbit displacing the eye and medial rectus muscle downward.

MRI typically shows isointensity to skeletal muscle and hypointensity to orbital fat on T1, hyperintensity on T2 to orbital fat and muscle. pleomorphic type caries the best prognosis and alveolar caries the worst prognosis.



FIGURE 25 SHOWING RHABDOMYOSARCOMA

SECONDARY ORBITAL INVOLVEMENT

FROM THE GLOBE

RETINOBLASTOMA

most common intraocular tumour of Childhood. Rb 1 gene, on the long arm of chromosome 13 is implicated. Clinical presentation includes leucocoria, strabismus, secondary glaucoma, pseudo-hypopyon, orbital cellulitis.



FIGURE 26 SHOWING RETINOBLASTOMA

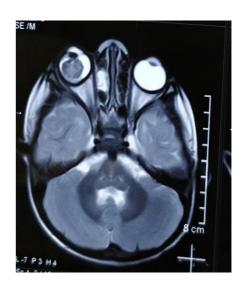


FIGURE 27 SHWOING MRI SCAN OF RIGHT EYE RETINOBLASTOMA

METASTASIS

NEUROBLASTOMA

It is a neoplasm of embryonic neuroblastic tissue. Clinical features includes proptosis, flushing, diarrhoea and hypertension.



FIGURE 28 SHOWING BOTH EYE ECCHYMOSIS OF A CASE OF NEUROBLASTOMA

LYMPHORETICULAR MALIGNANCY

The acute leukemias cause orbital metastasis . Orbital involvement occurs in 2% of patients 41

ORBITAL EXTENSION OF MEDULLOEPITHELIOMA

These are rare tumour in the first decade. These tumors arises from the neuroepithelium of the ciliary body.

ORBITAL EXTENSION OF LACRIMAL SAC TUMORS

Lacrimal sac tumours are rare, they are usually epithelial in origin and include squamous and transitional cell papilloma, oncocytic adenoma.

ORBITAL EXTENSION FROM NASAL AND PARANASAL SINUS

Patients usually presents with nasal obstructive symtoms and epistaxis . if orbit is involved then proptosis and EOM restriction can be seen .

ORBITAL FRACTURES:

Orbital fractures can be either with or without rim involvement .blow out fractures present with diplopia in downward gaze , enopthalmos , orbital anaesthesia . In case of muscle entrapment , persistent diplopia surgery can be done .

AIM OF THE STUDY

- 1. To study the role of CT, MRI in the diagnosis of orbital lesions
- 2. To correlate the imaging with histopathological features

MATERIALS AND METHOD

- ✓ This prospective study was done at Orbit and Oculoplasty department ,
 RIOGOH Chennai for one year period from January 2018- December 2018.
 50 patients who came to Orbit department were evaluated and followed up .
- ✓ A history of the patient in relation to the mode of onset, progression, laterality, associated symptoms like proptosis, diplopia, defective vision and palpable mass.
- ✓ Complete general and ocular examinations including visual acuity, examination of orbit, lids, anterior and posterior segments were done.
- ✓ Slit lamp biomicroscopy, ophthalmoscopy, Hertel's exophthalmometry, perimetry, colour vision, refraction, intra ocular pressure and examination of proptosis were done.
- ✓ Radiological investigations like CT, MRI were done to aid in the etiological diagnosis and to plan the management.

✓ Patients were also referred to other departments like ENT, Haematology, Neurology, paediatrics ,Oncology and Radiology to get expert opinion regarding diagnosis and for treatment whenever indicated.

INCLUSION CRITERIA:

- Patients with proptosis with or without extraocular movement restriction , palpable mass.
- Patients with isolated orbital trauma were also included.

EXCLUSION CRITERIA:

1. Patients with polytrauma and poor general condition

STATISTICAL ANALYSIS:

Analysis done by pearson chi square test

RESULTS

1. AGE DISTRIBUTION

AGE GROUP	FREQUENCY	PERCENTAGE(%)
<1 YEAR	3	6
1-18 YEARS	14	28
19-38YEARS	11	22
39-58 YEARS	17	34
ABOVE 58YEARS	5	10
TOTAL	50	100

TABLE 1 SHOWING THE AGE DISTRIBUTION

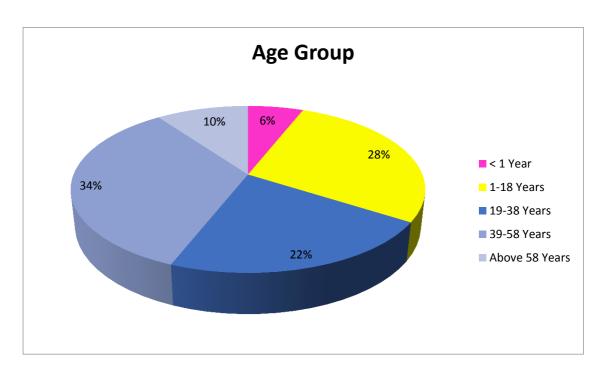


CHART 1 SHOWING AGE DISTRIBUTION

In our study, majority (34%) were in the age group of 39-58 years followed by 1-18 years.

2.GENDER DISTRIBUTION:

GENDER	FREQUENCY	PERCENTAGE(%)
MALE	25	50
FEMALE	25	50
TOTAL	50	100

TABLE 2 SHOWING GENDER DISTRIBUTION

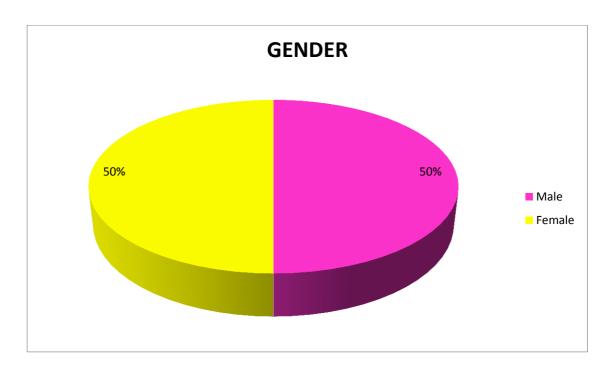


CHART 2 SHOWING GENDER DISTRIBUTION:

Both male and female were equally distributed

3.NATURE OF LESION:

NATURE	FREQUENCY	PERCENTAGE(%)
CONGENITAL	8	16
INFLAMMATORY	18	36
NEOPLASTIC	10	20
TRAUMATIC	10	20
VASCULAR	4	8
TOTAL	50	100

TABLE 3 SHOWING NATURE OF THE LESION

53

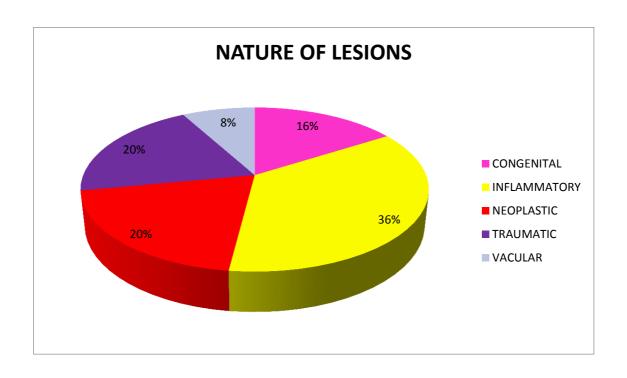


CHART3 SHOWING NATURE OF LESION:

Inflammatory lesions were the maximum (36%) followed by neoplastic and traumatic

4.CLINICAL PRESENTATION:

PRESENTATION	FREQUENCY	PERCENTAGE(%)
DEFECTIVE VISION	7	14
EOM RESTRICTION	3	6
PROPTOSIS	23	46
PALPABLE MASS	15	30
OTHERS(WHITE	2	4
REFLEX)		
TOTAL	50	100

TABLE 4 SHOWING CLINICAL PRESENTATION

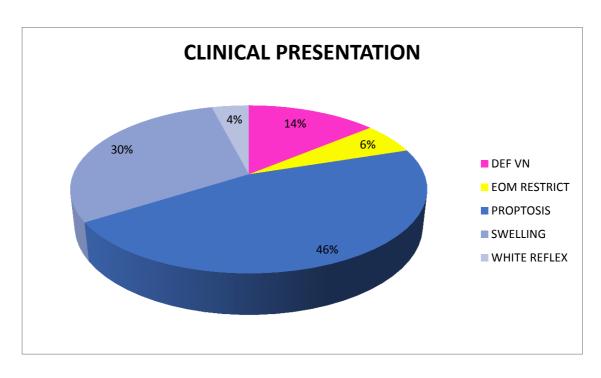


CHART 4 SHOWING CLINICAL PRESENTATION

Majority presented with proptosis (46%) followed by palpable mass .

5.BENIGN CONDITIONS

Nature of lesion	Congenital	Inflammatory	Neoplastic	Traumatic	Vascular
BLOW OUT				5(11.9%)	
CAPILLARY HEMANGIOMA					1(2.4%)
CAVERNOUS HEMANGIOMA					2(4.8%)
CONJUNCTIVAL GRANULOMA		1(2.4%)			
DACYROADENITIS		3(7.1%)			
DERMOID	8(19%)				
FUNGAL GRANULOMA		2(4.8%)			
GRAVES		2(4.8%)			
MENINGIOMA			1(2.4%)		
MUCOPYOCELE		1(2.4%)			
OPTIC NEUROPATHY				5(11.9%)	
ORBITAL ABCESS		3(7.1%)			
ORBITAL VARICES					1(2.4%)
ORBITAL CELLULITIS		4(9.5%)			
PRESEPTAL CELLULITIS		2(4.8%)			
RHABDOMYOMA			1(2.4%)		
TOTAL	8	18	2	10	4

TABLE 5 SHOWING BENIGN LESIONS

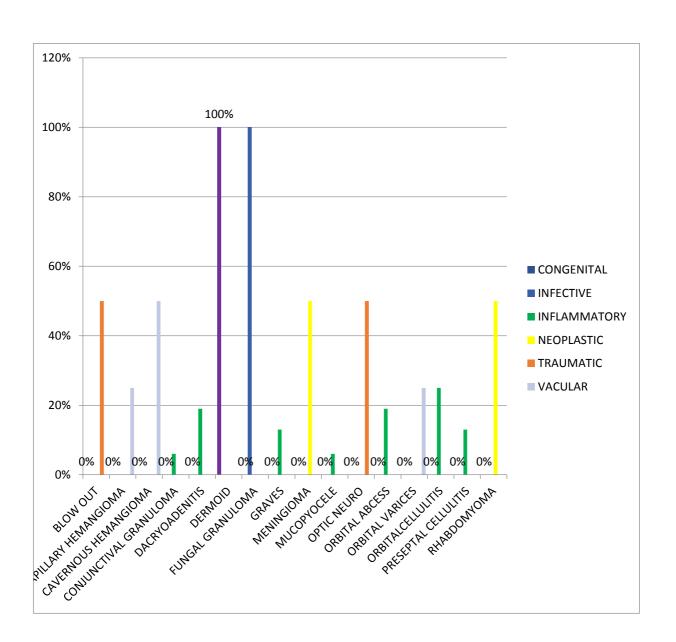


CHART 5 SHOWING BENIGN LESIONS:

Out of the benign lesions, majority were diagnosed to have dermoid (19%) followed by blow out fracture and traumatic optic neuropathy.(11.9%)

6. MALIGNANT CONDITIONS:

MALIGNANT	FREQUENCY(%)
ADENOID CYSTIC CA	2(25%)
NEUROBLASTOMA	1(12.5%)
RETINOBLASTOMA	3(37.5%)
RHABDOMYOSARCOMA	1(12.5%)
SQUAMOUS CELL CARCINOMA	1(12.5%)
TOTAL	8(100%)

TABLE 6 SHOWING MALIGNANT LESIONS:

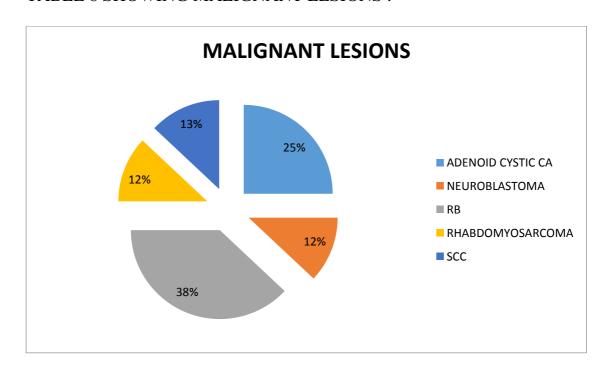


CHART 6 SHOWING MALIGNANT LESIONS:

Retinoblastoma (37.5%) was the most common malignant lesion which presented to us followed by adenoid cystic carcinoma

7.INFLAMMATORY CONDITIONS WITH THE CHARACTERISTIC IMAGING FINDING:

Inflammatory	Paranasal	Peri	Extra	Lacrimal	Optic
Conditions	Sinus	Orbital	Ocular	Gland	nerve
		Tissue	Movement		
CONJUNCTIVAL	-	-	-	-	-
GRANULOMA(1)					
DACRYOADENITIS(3)	-	3	2	3	-
	_		_		
FUNGAL	2	1	2	-	-
GRANULOMA(2)					
GRAVES(2)	-	2	2	-	-
		4			
MUCOPYOCELE(1)	1	1	1	-	-
ORBITAL ABCESS(3)	1	3	3	_	
ORBITAL	1	4	4	-	-
CELLULITIS(4)					
PRESEPTAL	2	2	-	-	_
CELLULITIS(2)					

TABLE 7 SHOWING THE INFLAMMATORY LESION WITH THE CHARACTERISTIC IMAGING FINDING :

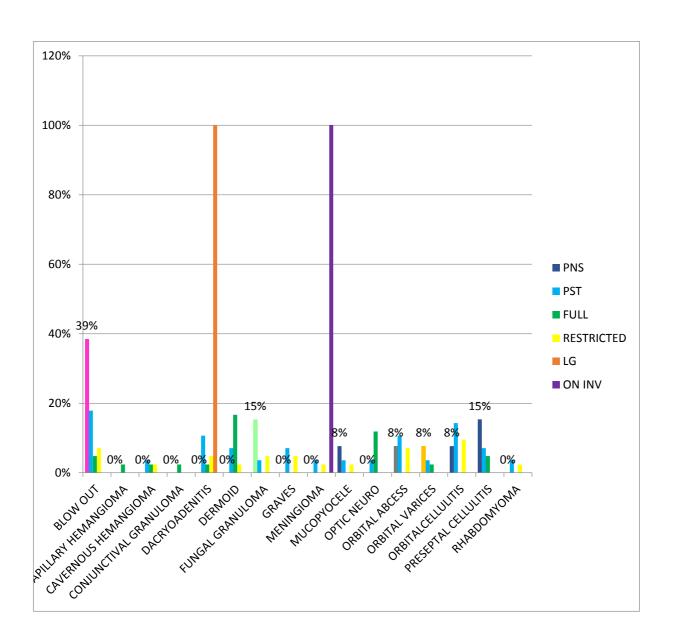


CHART 7 SHOWING INFLAMMATORY CONDITION WITH CHARACTERISTIC IMAGING FINDING

Out of inflammatory conditions, orbital cellulitis was the most common. out of 4 cases of orbital cellulitis, 1 case had associated para nasal sinus involvement. Two patient presented with fungal granuloma and preseptal

cellulitis and both of them had associated paranasal sinus involvement. Out of 18 inflammatory condition presented, 7 cases had paranasal sinus involvement.

8.NEOPLASTIC CONDITIONS WITH CHARACTERISTIC RADIOLOGICAL FEATURE :

Neoplastic	Enhancement	Calcification	Optic nerve invasion	Bone destruction
ADENOID	2	-	1	2
CYSTIC				
CARCINOMA(2)				
NEUROBLASTOMA(1)	1	-	-	1
RETINOBLASTOMA(3)	-	3	2	-
RHABDOMYOSARCOMA	1	-	1	-
(1)				
SQUAMOUS CELL	1	-	-	-
CARCINOMA(1)				

TABLE 8 SHOWING NEOPLASTIC CONDITION WITH

CHARACTERISTIC RADIOLOGICAL FEATURE: Out of 3 cases of retinoblastoma, all of them had calcification, 2 of them had optic nerve involvement. 2 cases of adenoid cystic carcinoma had evidence of bone destruction.

9.TYPE OF IMAGING:

TYPE	FREQUENCY	PERCENTAGE(%)
PLAIN	42	84
CONTRAST	4	8
ВОТН	4	8
TOTAL	50	100

TABLE 9 SHOWING TYPE OF IMAGING DONE

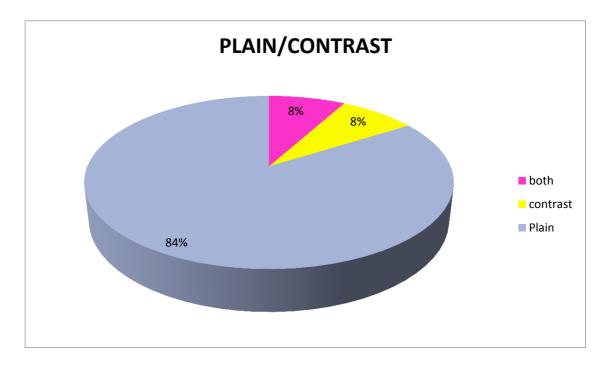


CHART 8 SHOWING TYPE OF IMAGING DONE

Majority of the patients (42%) had undergone plain study without use of contrast

10.IMAGING DONE:

IMAGING	FREQUENCY	PERCENTAGE(%)
СТ	34	68
MRI	13	26
ВОТН	3	6
	3	U
TOTAL	50	100

TABLE 10 SHOWING IMAGING DONE

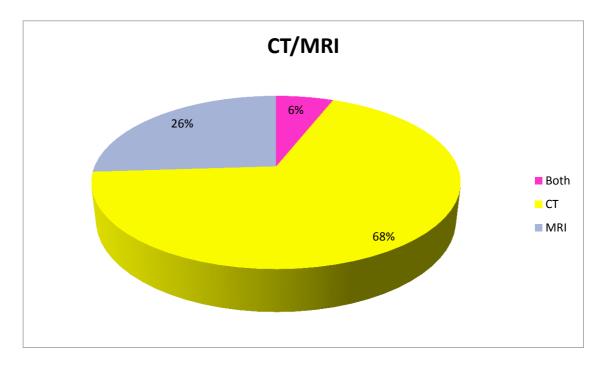


CHART 9 SHOWING IMAGING DONE

CT Scan was done in 68% of the patients followed by MRI in 26% patients

11.MANAGEMENT OPTIONS

MANAGEMENT	FREQUENCY	PERCENTAGE (%)
MEDICAL	27	54
SURGICAL	23	46
TOTAL	50	100

TABLE 11 SHOWING MANAGEMENT OPTIONS

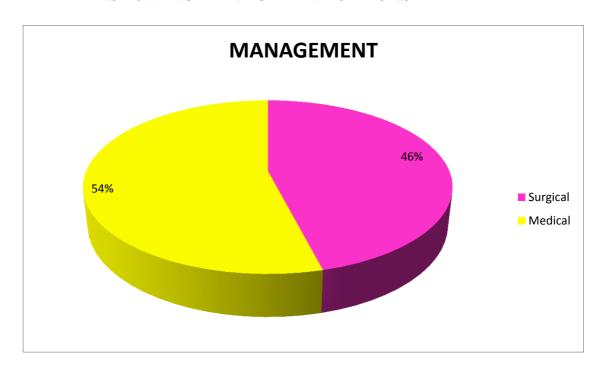


CHART 10 SHOWING MANAGEMENT OPTIONS:

54% of patients were managed medically and 46% were treated surgically .

12.CLINICO PATHOLOGICAL CORRELATION

	FREQUENCY	PERCENTAGE(%)
YES	17	34
NO	1	2
NOT APPLICABLE	32	64
TOTAL	50	100

TABLE 12 SHOWING CLINICO PATHOLOGICAL CORRELATION

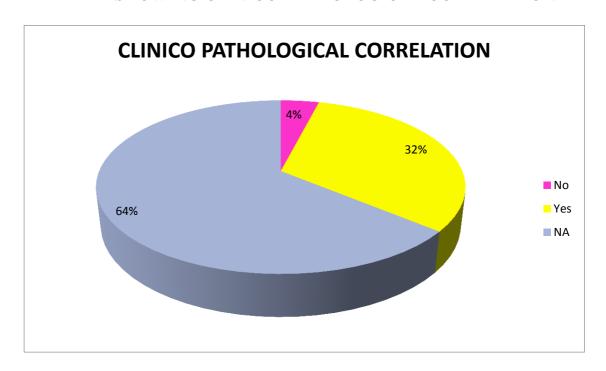


CHART 11 SHOWING CLINICO PATHOLOGICAL CORRELATION

Out of 18 cases which were subjected to biopsy, 17 patients had clinical pathological correlation . only 1 patient of angular dermoid was diagnosed histopathologically as lipoma .

13. CLINICO RADIOLOGICAL CORRELATION:

	FREQUENCY	PERCENTAGE(%)
YES	44	88
NO	6	12
TOTAL	50	100

TABLE 13 SHOWING CLINICO RADIOLOGICAL CORRELATION

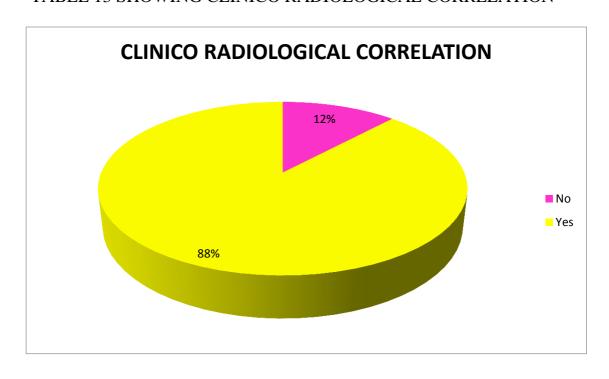


CHART 12 SHOWING CLINICO RADIOLOGICAL CORRELATION 88% HAD CLINICO RADIOLOGICAL CORRELATION.

14.SIGNIFICANCE BETWEEN RAPD AND RADIOLOGICALLY OPTIC NERVE INVOLVEMENT:

	RA	APD	Total
	No	Yes	
OPTIC No	37	8	45
OPTIC No NERVE	94.9%	72.7%	90.0%
	2	3	5
IN MRI Yes	5.1%	27.3%	10.0%
Total	39	11	50
Total	100.0%	100.0%	100.0%

Pearson chi square =4.675* p=0.031

TABLE 14 SHOWING SIGNIFICANCE BETWEEN RAPD AND RADIOLOGICALLY OPTIC NERVE INVOLVEMENT

There exist a statistical significance between rapd and radiologically optic nerve involvement.

15.CALCIFICATION IN RETINOBLASTOMA:

	CALCI	FICATION	Total
	No	Yes	
NO	44	3	47
RB	100.0%	50.0%	94.0%
YES	0	3	3
1123	0.0%	50.0%	6.0%
Total	44	6	50
Total	100.0%	100.0%	100.0%

Pearson Chi-Square=23.404** P<0.001

TABLE 15 SHOWING CALCIFICATION IN RETINOBLASTOMA:

There exist a statistical significance between calcification and retinoblastoma

DISCUSSION

In our study , 50 patients who presented to the orbit and oculoplasty department were analysed.

The analysis of age distribution in our study showed that majority(34%) were in the age group of 39-58 years of age .Both male and female were equally distributed .

Proptosis (46%) and eye swelling were the most common presenting illness by the patient. This was similar to a study done by hind manaa alkatan et al ³ And inflammatory lesion was the most common presenting condition . and among the inflammatory condition , orbital cellulitis was the most common . Out of 18 inflammatory condition presented , 7 cases had associated paranasal sinus involvement . according to a study done by Imtiaz A.Chaudhry et al , paranasal sinus infections are the common predisposing factor for orbital cellulitis .

• 2 Cases had fungal granuloma and presented as proptosis and were treated with parenteral antifungal treatment.

- 2 cases had graves orbitopathy with corneal exposure and treated with steroids.
- 1 case of conjunctival granuloma was excised surgically
- 2 cases of preseptal cellulitis and 4 cases of orbital cellulitis was treated medically and 3 cases of orbital abcess required incision and drainage.

Dermoid cyst was the most common benign lesion and also most common congenital condition presented according to a study done by harsh kandpal et al 4 dermoid was the most common congenital tumour of the orbit which was similar to our study .

5 patients presented with blow out fracture and 3 patients needed orbital floor reconstruction with titanium mesh and remaining two were managed conservatively.

5 cases were diagnosed to have traumatic optic neuropathy and out of these two cases which presented within 6 hours were treated with intravenous methylprednisolone and showed significant visual outcome.

Out of 4 vascular lesion which presented , two patients had cavernous hemangioma and out of these , one patient was managed surgically and the other

was treated conservatively as it was small lesion and didn't cause any visual impairment.

One patient had capillary hemangioma and treated with topical and systemic beta blockers and showed significant improvement . One case of orbital varices was referred to vascular surgery .

Retinoblastoma was the most common intraocular malignant lesion presented which was similar to a study done by **RB Dubey et al** ⁵

Three cases of retinoblastoma was reported and two cases had evidence of optic nerve invasion and managed with enucleation and chemoradiation therapy.

All the retinoblastoma cases presented had calcification as a radiological feature and two of them had optic nerve involvement. Adenoid cystic carcinoma had associated bone destruction which is similar to a study done by **williams MD** et al^{11} .

• CT was the most common imaging to be done similar to a study done by **Bela S.Purohit et al**¹⁰ who stated that in patients with orbital masses, CT scanning is the modality of choice for evaluating calcification and osseous orbital lesions and metallic foreign body and plain study was done in most of them

54% of patients were managed medically and 46% were treated surgically . Out of 18 cases which were subjected to biopsy ,17 patients had clinical pathological correlation . 1 patient of angular dermoid was diagnosed histopathologically as lipoma .

88% had clinico radiological correlation. It was noted that there was significant disparity between clinical and radiological report and , relatively less disparity between histopathological and clinical diagnosis which was similar to a study done by ${\bf ralene}$ sim et al 2

Out of 11 cases which had RAPD clinically 5 cases had optic nerve involvement radiologically and the association was found to be statistically significant. There also exist a statistical significance between calcification and retinoblastoma

SUMMARY

50 patients who came to Orbit department were evaluated and analysed.

The analysis includes role of radioimaging like CT/MRI in diagnosis of orbital lesions and to see whether any clinical , histopathological / radiological correlation.

The following results were obtained:

- majority(34%) were in the age group of 39-58 years of age.
- Both male and female were equally distributed.
- Proptosis (46%) and palpable mass were the most common presenting illness by the patient
- inflammatory lesion was the most common presenting condition and among the inflammatory condition, orbital cellulitis was the most common
- 2 Cases had fungal granuloma and presented as proptosis and were treated with parenteral antifungal treatment.
- 2 cases had graves orbitopathy with corneal exposure and treated with steroids.
- 1 case of conjunctival granuloma was excised surgically

- 2 cases of preseptal cellulitis and 4 cases of orbital cellulitis was treated medically and 3 cases of orbital abscess required incision and drainage.
- Dermoid cyst was the most common benign lesion and also most common congenital condition presented
- 5 patients presented with blow out fracture and 3 patients needed orbital floor reconstruction with titanium mesh and remaining two were managed conservatively.
- 5 cases were diagnosed to have traumatic optic neuropathy and out of these two cases which presented within 6 hours were treated with intravenous methylprednisolone and showed significant visual outcome.
- Out of 4 vascular lesion which presented, two patients had cavernous hemangioma and out of these one patient was managed surgically and the other was treated conservatively as it was small lesion and didn't cause any visual impairment.
- One patient had capillary hemangioma and treated with topical and systemic beta blockers and showed significant improvement.
- One case of orbital varices was referred to vascular surgery
- Retinoblastoma was the most common intraocular malignant lesion.
- And there was a statistical significant association found between presence of calcification and retinoblastoma

- Adenoid cystic carcinoma was associated with bone destruction .
- 54% of patients were managed medically and 46% were treated surgically.
- Out of 18 cases which were subjected to biopsy ,17 patients had clinical pathological correlation . 1 patient of angular dermoid was diagnosed histopathologically as lipoma .
- 88% had clinico radiological correlation.
- Out of 11 cases which had RAPD clinically 5 cases had optic nerve involvement radiologically and the association was found to be statistically significant.

CONCLUSION

CT imaging is an excellent tool in diagnosing fractures in the orbit, graves disease and to differentiate orbital cellulitis from idiopathic orbital inflammatory disease. CT scan is better to evaluate the bone involvement and calcification in orbital tumours. This study highlights the role of comprehensive history taking, and appropriate imaging technique to decide treatment option. It was noted that there was significant disparity between clinical and radiological report and, relatively less disparity between histopathological and clinical diagnosis. Clinical diagnosis and imaging report can narrow down the differential diagnosis but diagnosis of orbital lesions ultimately requires the histological confirmation

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PROFORMA FOR THE STUDY

Name of the pati	ient :	
Age of the patie	nt / Sex :	
O.P no		
Chief Complaint	s:	
History of prese	nt illness:	
Past History:		
Personal History	<i>y</i> :	
Family History:		
General Examina	ation:	
Vitals:		
RIGHT EYE	EXAMINATION	LEFT EYE
	Vision	
	lids	
	lashes	
	EOM	

Vision	
lids	
lashes	
EOM	
Conjunctiva	
Cornea	
Ac	
Iris	
Pupil	
Lens	

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Diagnosis:

Lab tests:

 $\ensuremath{\mathsf{CBC}}$, $\ensuremath{\mathsf{ESR}}$, $\ensuremath{\mathsf{TC}}$ DC Serum free T3, T4, TSH

Peripheral smear

Radiological studies:

MRI scan /CT scan orbit

Involvement of paranasal sinus involvement

Optic nerve invasion

Calcification

Bony destruction

Bone remodeling

Periorbital soft tissue involvement

Lacrimal gland involvement

Any enhancement seen

Intracranial spread

Biopsy: FNAC/ Incisional/ Excisional

HPE Report

Final Diagnosis:

Clinical radiological correlation

Clinical pathological correlation:

Treatment: Medical/ Surgical/ Chemotherapy/ Radiotherapy/ Others

Followup:

INSTITUTIONAL ETHICS COMMITTEE MADRAS MEDICAL COLLEGE, CHENNAI 600 003

EC Reg.No.ECR/270/Inst./TN/2013 Telephone No.044 25305301 Fax: 011 25363970

CERTIFICATE OF APPROVAL

To
Dr.C.Nisha
I Year Post Graduate in MS Ophthalmology
Regional Institute of Ophthalmology & GOH/
Madras Medical College
Chennai

Dear Dr.C. Nisha,

The Institutional Ethics Committee has considered your request and approved your study titled "A CLINICAL STUDY ON ROLE OF RADIOIMAGING LIKE CT, MRI IN DIAGNOSIS AND MANAGEMENT OF ORBITAL LESIONS " -

The following members of Ethics Committee were present in the meeting hold on 09.01.2018 conducted at Madras Medical College, Chennai 3

3. Prof.Sudha Seshayyan,MD., Vice Principal,MMC,Ch-3 : Mem 4. Prof.N.Gopalakrishnan,MD,Director,Inst. of Nephrology,MMC,Ch 5. Prof.S.Mayilvahanan,MD,Director,Inst. of Int.Med,MMC, Ch-3 6. Prof.A.Pandiya Raj,Director, Inst. of Gen.Surgery,MMC 7. Prof.Shanthy Gunasingh, Director, Inst. of Social Obstetrics,KGH 8. Prof.Rema Chandramohan,Prof. of Paediatrics,ICH,Chennai 9. Prof. Susila, Director, Inst. of Pharmacology,MMC,Ch-3 10.Prof.K.Ramadevi,MD., Director, Inst. of Bio-Chemistry,MMC,Ch-3 11.Prof.Bharathi Vidya Jayanthi,Director, Inst. of Pathology,MMC,Ch 12.Thiru S.Govindasamy, BA.,BL,High Court,Chennai	-3: Member
13.Tmt.Arnold Saulina, MA., MSW., :So	: Lawyer ocial Scientist Lay Person
	ay i cison

We approve the proposal to be conducted in its presented form.

The Institutional Ethics Committee expects to be informed about the progress of the study and SAE occurring in the course of the study, any changes in the protocol and patients information/informed consent and asks to be provided a copy of the final report.

Member Secretary - Ethics Committee

MADRAS MEDICAL COLLEGE
CHENNAI-600 003

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YES	NO	NO MRI
YES	YES	YES CT
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