"A ONE YEAR PROSPECTIVE STUDY TO EVALUATE THE PATENCY OF THE LACRIMAL SAC AFTER USING PAWAR'S INTRACYSTIC IMPLANT FOR PATIENTS OF CHRONIC DACRYOCYSTITIS UNDERGOING DACRYOCYSTORHINOSTOMY AT KLES DR. PRABHAKAR KORE HOSPITAL AND MRC,BELAGAVI "

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LIST OF ABBREVATIONS

OPD	:	Outpatient Department
DCR	:	Dacryocystorhinostomy
MPL	:	Medial Palpebral Ligament
NLD	:	Nasolacrimal Duct
ROPLAS	:	Regurgitation On Pressure over Lacrimal Sac area
TBUT	:	Tear film Break up Time
FDDT	:	Fluorescein Dye Disappearance Test
DCG	:	Dacryocystography
FNLDO	:	Functional Nasolacrimal Duct Obstruction
CT	:	Computed Tomography
MRI	:	Magnetic Resonance Imaging

ABSTARCT

Purpose:

The purpose of this study was to assess the patency of lacrimal duct after inserting Pawar's Intracystic Implant in Dacryocystorhinostomy (DCR) surgery and to evaluate the post-operative complications at post-operative day 1, 7 and 30.

Methods:

This was a one year prospective, longitudinal, interventional, hospital based study carried out over a period of one year. 32 eyes of 32 patients of chronic dacryocystitis who have been recommended to undergo Dacryocystorhinostomy surgery were included after sac syringing and thorough pre-operative examination.

Results:

32 patients underwent Dacryocystorhinostomy using Pawar's intracystic implant. Post-operative lacrimal patency was checked on day 1, 7 and 30. 28 cases (87.5%) showed patency on day 1 which improved to 29 cases (90.62%) on day 7 and 30 cases (93.75%) on day 30. On post-operative day 1, 12 cases (31.25%) had lid edema, 8 cases (25%) had incisional edema, 3 cases (9.38%) had obstruction of passage and 1 case (3.13%) had sac infection. With appropriate medical treatment the postoperative complications came down to 2 cases (6.25%) of incisional edema, 1 case (3.13%) with obstruction of passage and 1(3.13%) with sac infection. On day 30, 1 case (3.13%) had incisional edema (3.13%), 1 had obstruction of passage and 1(3.13%) had sac infection.

Conclusion:

This study showed that Dacryocystorhinostomy using Pawar's intracystic implant gave a good overall result with a 93.75% success rate at day 30 after management of post-operative complications and is a good alternative to conventional external dacryocystorhinostomy.

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INTRODUCTION

Epiphora or watering eye is one of the most common complaints in patients visiting the Ophthalmology OPD as it causes discomfort and is a hinderance in the daily activities of living. The etiology for this can be divided into two categories – reflex hypersecretion and blockage in lacrimal system drainage. One of the early studies on this subject has shown that 48.7% of the cases of epiphora were secondary to lacrimal system block followed by 40% cases due to dry eye reflex hypersecretion.[1,2] Acute or chronic inflammation of the lacrimal drainage system is seen to be the most common cause for blocked nasolacrimal duct leading to epiphora.[3] For over two millennia doctors have worked on creation of an alternate route of drainage to bypass this obstruction.[4]

Historically, Celsus and Galen were the earliest to propose passing a red hot cautery iron through the lacrimal sac into the nose to advancing all the way up to Toti and Caldwell who are credited with the development of the modern dacryocystorhinostomy procedure. Over the years, a detailed understanding of the anatomy and functioning of the lacrimal system has led to development of advanced and sophisticated techniques.[4]

An external dacryocystorhinostomy is performed under direct visualization with careful dissection and hence gives a highly predictable success rate of over 90-95%. A successful dacryocystorhinostomy requires creating a permanent mucosa lined ostium between the lacrimal sac and nose with ostium associated complications like migration of mucosa over the ostium, cicatricial contraction and abnormal healing around the ostium being the commonest causes for failure. To counteract these

complications, the possibility of intubation of the ostium with an inert material was considered.[3]

Implant dacryocystorhinostomy has undergone several modifications over the years since 1985. Dr.M D Pawar developed the Pawar's Intracystic Implant for the purpose of maintaining long term patency of the ostium and promotion of healing without development of any intrasac fibrosis. In addition to this, Pawar's implant overcomes the drawbacks of external dacryocystorhinostomy as it does not require nasal packing or cutting of the medial canthal ligament, requires a smaller incision and smaller sized ostium, lesser postoperative stay and overall has significantly lesser postoperative complications.[5] Signs of failure if recognised and rectified appropriately at the earliest were seen to give a 100% success rate.[6]

All these above mentioned advantages made dacryocystorhinostomy with Pawar's intracystic implant the favourable procedure with a higher success rate as determined by various studies.

In this prospective study we determine the efficacy, safety and rate of postoperative complications in cases of chronic dacryocystitis treated with this procedure.

AIMS AND OBJECTIVES

Primary Objective

To assess the patency of lacrimal duct after inserting Pawar's Intracystic Implant in Dacryocystorhinostomy (DCR) surgery.

Secondary Objective

To evaluate the post-operative complications after insertion of Pawar's Intracystic Implant in Dacryocystorhinostomy (DCR) surgery.

REVIEW OF LITERATURE

HISTORY

The father of medicine 'Sushrutha' described 76 varieties of ocular disease in the Uttara Sthana in chapters 1-19 during the Vedic ages in Hindu ophthalmology where a brief account of treatment of dacryocystitis can be found.

From the earliest times, dacryocystitis was thought to originate from the brain or from rotting of the nasolacrimal bones due to its clinical features involving swellings, abscesses and fistulae at the medial canthus. Vesalius and Fallopius documented diseases of the lacrimal system in the middle of the first century (A. D). It was only in 1702, the clinical features of dacryocystitis were described to be dependent on inflammation of the nasolacrimal duct by George E Stahl. He also described their development into one of three forms -acute, chronic and hydropsia or ulceration(fistula).[7]

ANATOMY OF LACRIMAL DRAINAGE SYSTEM

The origin of the lacrimal apparatus is from the puncta lacrimale which is an orifice located at the apex of the papilla lacrimalis, a prominence located between the ciliated and non-ciliated parts of the medial aspect of the upper and lower eyelid. The upper and lower puncta are situated at a distance of 6 and 6.5mm respectively from the medial canthus and as a result do not overlap. The upper puncta is directed inferoposteriorly and the lower puncta superoposteriorly and hence are visible only on eversion. The dense fibrous tissue arising from the adjoining tarsal plate and fibers of the orbicularis oculi maintains the patency of the puncta.

The two canaliculi arising from the lacrimal puncta are first oriented vertically for 2mm then make a right angled turn medially to run horizontally for 8mm while converging towards each other. A dilatation is present at the right angled turn called the ampulla. The upper and lower canaliculus can enter the lacrimal sac in 3 ways. The most common way is type A, where the two canaliculi perforate the periorbital fascia surrounding the lacrimal sac separately, join together to form the common canaliculus (2-5mm length) after which it enters the lacrimal sinus of Maier which is a small dilatation of the upper part of the sac. The less commonly found variations are type B, where the two canaliculi form a common ostium which connects to the sac wall without formation of the common canaliculus ;and type C, where the upper and lower canaliculus have a separate ostium joining the sac separately. The canaliculi are lined by stratified squamous epithelium with support from elastic tissue and surrounding orbicularis fibres.

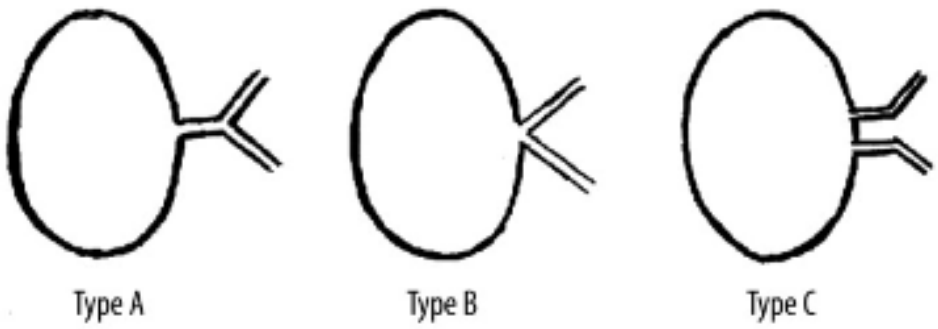


Figure 1: Anatomical variations in entrance of upper and lower canaliculus into the lacrimal sac

A sharp flexure of the common canaliculus at its junction with the sac wall forms an upper and lower mucous membrane fold known as the valve of Rösenmuller and valve of Huschke respectively preventing reflux of fluid. The lacrimal sac is situated in the lacrimal fossa in the anterior part of the inferomedial orbital rim

formed by the lacrimal bone and the frontal process of the maxilla and bounded by the anterior and posterior lacrimal crest. The lacrimal fascia is formed by the periorbita, which splits at the posterior lacrimal crest and reunites at the anterior lacrimal crest thus surrounding the sac. The central aspect of the sac is covered anteriorly and posteriorly by two parts of the medial palpebral ligament which attach to the anterior and posterior lacrimal crest respectively. The part of the sac seen above these ligaments is referred to as the fornix. The structures related to the sac anteriorly are the medial palpebral ligament (MPL) and the angular vein. The latter is situated 8mm from the medial canthus and crosses the MPL at a subcutaneous level. Hence the incision taken for lacrimal sac surgery must not be made more than 3mm away from the medial canthus as sometimes even a branch of the vein may cross the MPL at a distance closer to the medial canthus. The strengthening of the walls of the sac and drainage of tears is assisted by the lacrimal part of the orbicularis oculi muscle knows as the pars lacrimalis or the Horner's muscle.

The orbicularis muscle has two parts- the orbital and palpebral part. The orbital part forms the peripheral fibres arising from the MPL, medial part of superior and inferior orbital margin, maxillary process of frontal bone and frontal process of maxilla. These fibres sweep superiorly and inferiorly and terminate at the lateral palpebral raphe. The palpebral part is divided into the preseptal and pretarsal parts with both parts arising from the lacrimal fascia and posterior lacrimal crest (deep head) and anterior part of medial palpebral ligament (superficial head). The preseptal part passes in front of the orbital septum and pretarsal part in front of the tarsal plate to join at the lateral canthal tendon. The deep fibres of the pretarsal part attach to the upper half of the lacrimal sac in a fan shaped manner through the posterior branch of medial canthal tenson known as the pars lacrimalis or Horner's muscle which aids in

drainage of tears. The lacrimal sac continues as the nasolacrimal duct which ranges between 13-28 mm in length and 3mm in diameter. The intraosseous part of the NLD (12.5 mm) descends posterolaterally in a canal formed by the maxilla anterolaterally and by the lacrimal bone and lacrimal process of inferior concha posteromedially. The intrameatal part (5.5mm) of the NLD continues in the lateral wall of the nose within the mucous membrane till it opens in the inferior meatus.

The lacrimal drainage system comprises of a number of valves which are mucous membrane folds which do not possess the function of a valve. They are the valve of Bochdalek at the origin, valves of Foltz in the canaliculi, valve of Huschke in the common canaliculus, valve of Rosenmüller at the junction with the lacrimal sac, valve of Beraud or Krause and valve of Talliefer in the NLD with the most constant valve being the valve of Hasner at the inferior end.[7–9]

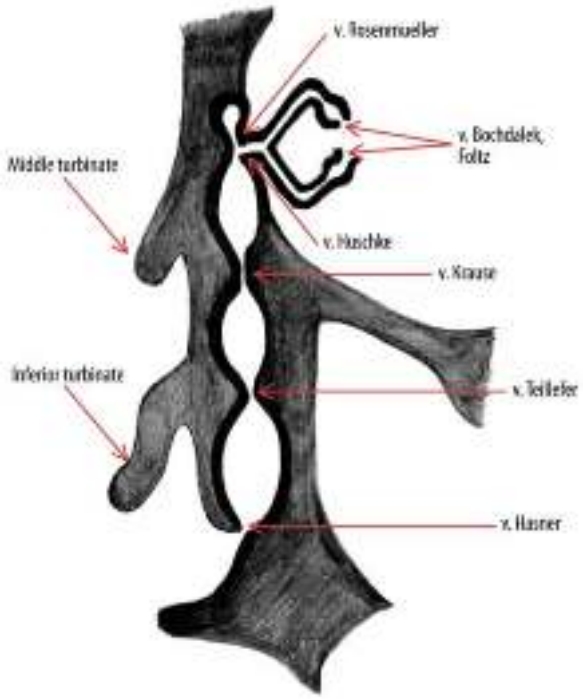


Figure 2: Anatomy of valves of the lacrimal drainage system

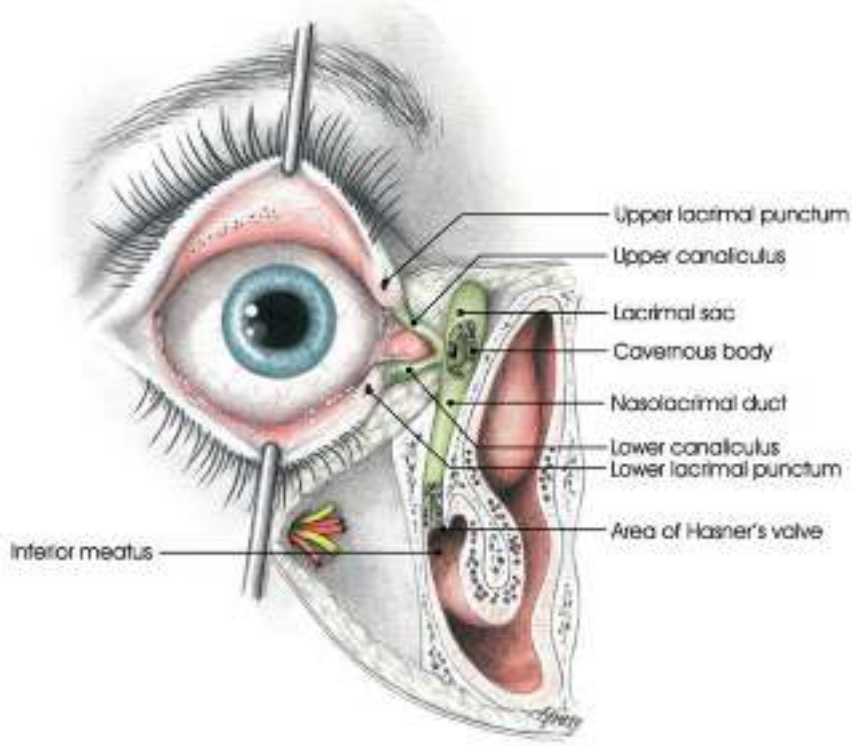


Figure 3: Overview of anatomy of lacrimal drainage system

PHYSIOLOGY OF LACRIMAL DRAINAGE SYSTEM

Normal secretion and drainage of tears is of utmost importance for proper functioning and comfort of the eye. The preocular tear film comprises of 3 components-

- Lipid component (0.1 μm) secreted by Meibomian glands forms the superficial component
- Aqueous component (7 μm) is secreted mainly by the lacrimal gland(95%) and accessory lacrimal glands (glands of Krause, glands of Wolfring) of the lids and consists of electrolytes, water, and a large variety of proteins, peptides, and glycopeptides
- Mucus component (0.2 μm) is produced by the conjunctival goblet cells, corneal epithelial cells, acinar and excretory duct cells of the lacrimal gland and helps the lipid and aqueous layer spread across the cornea

The mucosa of the efferent lacrimal system has defence mechanisms like production of lysozyme, lactoferrin and secretory phospholipase A2 and defensins to protect against dacryocystitis.

Tears produced by the main and accessory lacrimal glands flow along the upper and lower marginal strips which pools medial to the lower puncta in the lacus lacrimalis. These pooled tears enter the puncta due to the following mechanisms:

- Development of negative pressure
- Capillary action of small canaliculi
- Krehbiel's effect -Due to the tone of the orbicularis muscle supplied by the facial nerve, there are alterations in pressure within the sac when the eyes are open. This is because of the impact of the orbicularis tone on both the canaliculi and the sac.

The passage of tears after entering the puncta is based on a number of lacrimal pump theories of which the most recent one is the 'Tricompartmental model of the lacrimal pump' given by Becker in 1992 which stated the following :

During eyelid closure, contraction of the orbicularis muscle assisted by helically aligned connective tissue around the sac expands the common canaliculi and the superior part of the sac while the inferior part of the sac and nasolacrimal duct are compressed. The origin of the Horner's muscle is from the lacrimal fascia and the posterior lacrimal crest and covers majority of the lateral length of the canaliculus causing its compression and medial movement with contraction of the Horner's muscle allowing fluid to pass into the common canaliculus and sac.

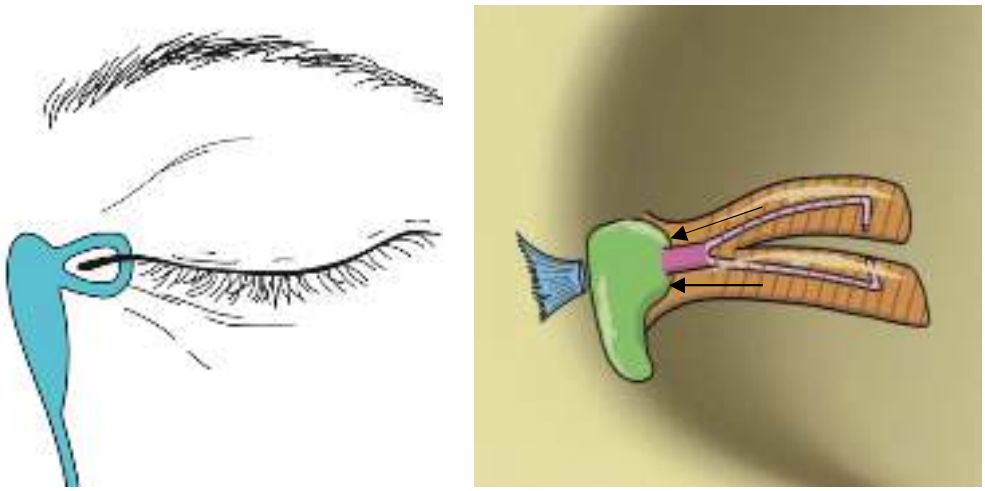


Figure 4: Passage of tears during eyelid closure

When the eyelids open, the orbicularis muscle relaxes and the common canaliculus and superior sac is compressed while both the canaliculi, inferior sac and nasolacrimal duct expand.

Following this, the tears move from the lacus lacrimalis into the canaliculi and the positive pressure created in the superior sac leads to closure of the valve of Rosenmüller and forward passage of tears from the superior into the inferior sac and nasolacrimal duct.

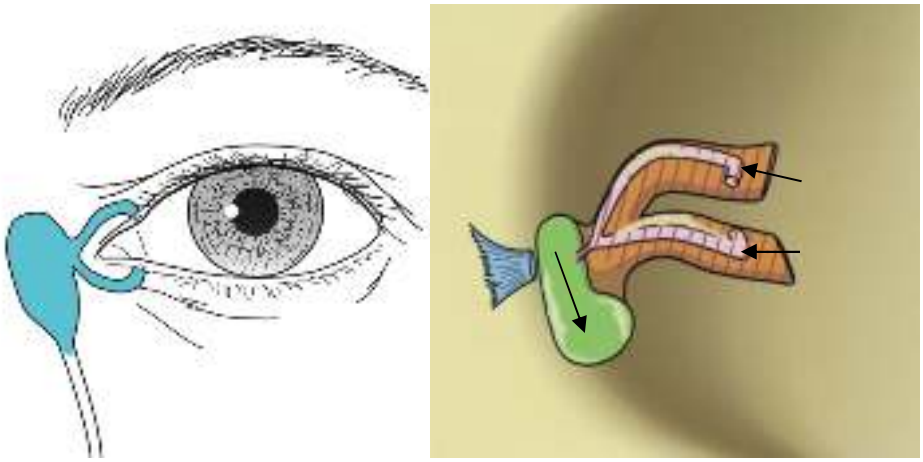


Figure 5: Passage of tears during eyelid opening

The further passage of tears from the nasolacrimal duct into the nose is because of the filling force in the sac, gravitational and siphoning effect.[10–12] On an average, the tear flow rate is 30microL/min and 230 microL of tear volume is completely circulated in 7 minutes.[6]

CLINICAL FEATURES

Patients with excessive watering either due to hyperlacrimation or improper drainage of tears (epiphora) may present with complaints of - discomfort, visual disturbance, foreign body sensation, chronic irritative lacrimal conjunctivitis or excoriation and eczema of the skin of the lids due to constant wiping.

- Causes of hyperlacrimation
    1. Primary hyperlacrimation – Direct stimulation of the lacrimal gland due to lacrimal gland inflammation, neoplasms or parasympathomimetic, cholinesterase inhibitor drugs.
    2. Reflex hyperlacrimation - External ocular surface irritation (conjunctivitis, keratitis) or intraocular disease (iridocylitis, glaucoma) stimulates the sensory division of the trigeminal nerve.
    3. Neurological-
        - Supranuclear- Emotional states, psychological disorders, voluntary lacrimation
        - Infranuclear - Aberrant regeneration of facial nerve (crocodile tears),irritation of the nervus intermedius in cerebellopontine angle tumors

- Causes of epiphora

a) Physiological – Lacrimal pump failure due to laxity of the lower lid or orbicularis muscle in facial palsy, limited mobility of eyelid in burn injuries, scleroderma.

b) Mechanical obstruction – This may be due to a blockage at any level of the lacrimal drainage system-

i. Punctum

- Occlusion may be congenital, post irradiation, secondary to cicatrizing infections, prolonged use of drugs like pilocarpine and idoxuridine
- Abnormal position in ectropion, age related lid laxity

ii. Canaliculi – Obstruction or disruption of anatomy may occur post trauma, post irradiation, cicatrizing conjunctivitis (eg: Herpes zoster), Stevens-Johnson syndrome, canaliculitis (most commonly due to actinomyces), tumors or repeated probing.

iii. Lacrimal sac – Obstruction may be congenital or due to traumatic strictures, tumors, dacryocystitis, scarring following infections like tuberculosis, syphilis.

iv. Nasolacrimal duct- Obstruction may be due to congenital non-canalization or partial canalization or due to acquired causes like trauma (midfacial fractures), infiltrative diseases like sarcoidosis, tumors.

v. Intranasal pathology like atrophic rhinitis, hypertrophied turbinates, deviated nasal septum.[13]

Studies conducted on the etiology of epiphora by Mainville and Jordan showed that 48.7% of the cases were due to lacrimal passage obstruction followed by dry eye related hyperlacrimation.[2] Another study also demonstrated similar results

that majority of the cases - 48.4% were due to lacrimal pathway disorders out of which chronic dacryocystitis accounted for 22.1% of the cases.[1]

DACRYOCYSTITS

Dacryocystitis is infection and inflammation of the lacrimal sac usually secondary to an obstruction in the nasolacrimal duct.

The course of events leading to dacryocystitis starts with swelling of the mucous membrane of the sac or NLD or both followed by stasis of contents, ultimately leading to obstruction of the canal causing distention of the sac whose contents may undergo secondary infection.

Clinically, it may be differentiated into acute and chronic dacryocystitis which will be described in detail.[10,14]

AETIOPATHOGENESIS

1. Anatomical factors

   Structural constrictions of the lacrimal passages play a significant role in the incidence of the disease. In cases of congenital dacryocystitis, lack of complete canalization of the lacrimal system has been implicated to be the cause.

   In the absence of excessive lacrimation, four main causes of epiphora have been noted as follows-

   1. Abnormal anatomy or position of the puncta
   2. Atresia, inflammation, foreign body, tumor obstructing any part of the drainage system
   3. Nasal pathology
   4. Lacrimal pump failure

These chain of events lead to formation of folds in the mucous membrane or a small poorly functioning inferior opening producing a state of chronic stasis ultimately leading to chronic dacryocystitis.[7]

2. Diseases of surrounding adnexa

   Spread of infections from the surrounding bones and tissues is with absolute certainty a cause for onset of inflammation. Conditions causing mechanical compression of the inferior turbinate against the lateral nasal wall, enlargement of the inferior turbinate, nasal septal deviation and chronic inflammation or atrophy of the mucous membrane are frequent causes of constriction of the inferior portions of the lacrimal canals.[7,15] Deviated nasal septum was seen to be the most common cause (55%), followed by hypertrophied turbinates (35%) and allergic rhinitis(10%).[16]

   Spread of inflammation from the surrounding sinuses has also been implicated in dacryocystitis. While some authors deny any association between the two, others have described spread of infection from the sinuses by venous and lymphatic passages or by direct passage from the ethmoids to the sac via the lacunae of the lacrimal bone or by absorption of the thin lacrimal bone by age or pressure.

   Although rare, infiltrating conjunctival infections like trachoma have also been implicated in direct spread and involvement of the lacrimal system.[7]

3. General infections and inflammations

   General diseases may occasionally be root for onset of dacryocystitis.

   In children (0-15 years), the skin and mucous membranes all over the body are involved in small pox and chicken pox which includes the conjunctiva, the nasopharynx and the lacrimal passage. When the vesicles heal, there is secondary infection and subsequent scarring of the mucous membrane of the lacrimal

passages thus predisposing the individual to chronic dacryocystitis following the obstruction.[17]

In a similar way, acute inflammation of the nasal mucosa seen in severe forms of diphtheria, measles, influenza subsequently involves the lacrimal passages leading to partial or complete obstruction.[15]

4. Trauma and surgery

   Nasoethmoid fractures seem to be most common among traumatic causes of NLD obstruction. Amongst operative trauma, endonasal and endoscopic sinus procedures have the highest association.[18] The lacrimal canal and its nasal opening may be injured in other operative procedures as well which involve removal of anterior end of inferior turbinate near its attachment -Denker, Calwell-Luc, Sturmann-Canfield surgeries or the Lautenschlager-Halle operation done for atrophic rhinitis.[15]

5. Systemic Diseases

   Dacryocystitis is also seen to be associated with chronic obstruction seen in cases of Wegener's granulomatosis, sarcoidosis, systemic lupus erythematosus and tuberculosis.[18]

6. Neoplasms

   The most common malignant neoplasm in the patients with Primary Acquired NLD Obstruction was seen to be lacrimal sac lymphoma.

   Among epithelial neoplasms, the most commonly associated neoplasms are Schneiderian papilloma (inverted and exophytic types) and squamous cell carcinoma.[19]

   Other causes include cysts, polyps of the sac or direct extension of a malignant process from the nose or sinuses leading to secondary involvement of the sac.[15]

7. Medications

   Acquired dacryocystitis is also associated with common topical medications like timolol, pilocarpine, dorzolamide, idoxuridine, trifluridine and systemic medications like fluorouracil and docetaxel.[18]

8. Foreign Body

   Nasolacrimal duct obstruction due to a foreign body being lodged is relatively uncommon. It presents as partial or intermittent lacrimal sac obstruction and repeated attacks of dacryocystitis due to decreased drainage and stasis of normal secretions and management depends on the site of blockage.[20,21]

FACTORS INFLUENCING DACRYOCYSTITIS

1. Age

   Cases of dacryocystitis have bimodal distribution occurring just after birth in cases of congenital dacryocystitis or in adults older than 40 years of age.[18]

   Yousuf et.al studied 226 patients of chronic dacryocystitis and found highest incidence in the 50-59 years age group(45.15%).[22]

   On the other hand, Badhu et.al studied 662 patients of chronic dacryocystitis of which majority cases-262 (58.4%) were in the age group of 21–40 years.[16]

2. Sex

   Dacryocystitis in adults was seen to affect 65-75% females and 25-35% males[23][16][24] giving a female: male ratio of 2.3:1.[23] This can be attributed to a narrower bony lumen containing the NLD and hormonal factors in females. Heinonen associated the former with a high nasal index(Width X100/Height) in 1920.[7]Axial maxillofacial CT scans have showed that the adult inferior nasolacrimal duct fossa size increases in both sexes whereas the middle part of the

bony fossa shows an increase in size only in males.[25]Hormonal factors cause general de-epithelization in the body predisposing them to obstructions by these debris. By the same mechanism in the sac and NLD, there is an increased predisposition for obstruction in an already narrow lumen.[26]

3. Racial and geographical factors

   Individuals with brachycephalic heads are at a higher risk to developing dacryocystitis than dolicocephalic or mesocephalic skulls. The reason for this is brachycephalic skulls have a narrower diameter of inlet into the nasolacrimal duct, longer nasolacrimal duct and narrower lacrimal fossa.

   Also, patients with a flat nose and narrow face are more predisposed to developing dacryocystitis which is presumed to be due to the narrow osseous canal.[27]

   Dacryocystitis was also seen to be a rarer entity in the Negro race as they have short, broad, straight canals with large lower orifices with lesser predisposition for obstruction.[15]

4. Hereditary and familial tendency

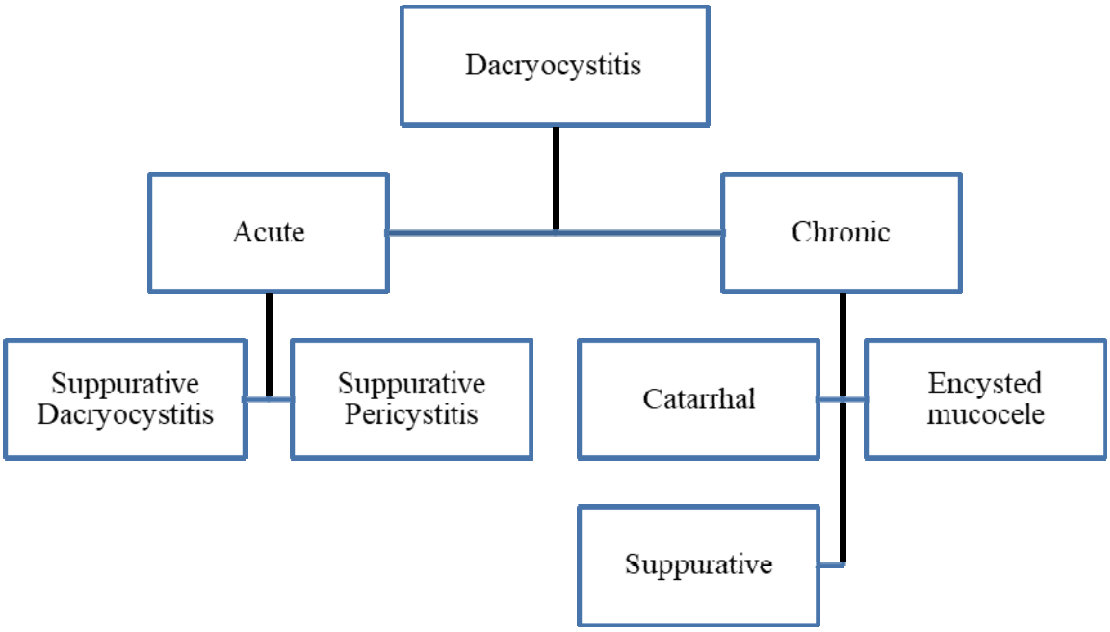
   It is transmitted as a dominant trait by males and females to their children and is seen to be related to the facial structural configuration. However, variations in the mode of transmission exists.

   Nieden described a 9% incidence of hereditary lacrimal system inflammation in 1883.[7]

5. Social factors

   Patients belonging to the lower socioeconomic strata who lack cleanliness and scrupulousness in keeping their eyes clean are more prone to developing dacryocystitis. It was seen to be less common amongst people of urban areas who keep their eyes clean by taking maximum hygienic measures.[28]

CLINICAL FEATURES OF DACRYOCYSTITIS



Flowchart 1: Clinical classification of dacryocystitis

1. Acute Dacryocystitis

   a) Acute Suppurative Dacryocystitis

   - Watering due to obstruction of lacrimal drainage system
   - Redness, oedema of skin of lacrimal sac area which may consequently spread to skin of lower lid, side of nose, down the cheek
   - Local pain radiating to frontal region and teeth
   - Fever, general malaise
   - Application of local pressure may cause regurgitation of pus into conjunctival sac
   - Internal (ethmoido-lacrimal) fistula- if sac bursts into ethmoidal cells leaving behind a contracted, cicatricial sac.

   b) Acute Suppurative Pericystitis - Spread of inflammation into the surrounding tissues

   - Increase in local swelling, pain and tenderness

- Conjunctival chemosis
- Swollen submandibular and pre-auricular lymph nodes
- External lacrimal fistula connecting the sac and external skin

2. Chronic Dacryocystitis

a) Chronic Catarrhal Dacryocystitis-Latent form

- Persistent epiphora
- Conjunctival hyperemia, angular conjunctivitis
- Reflux of fibrinous or mucoid material on sac syringing

b) Lacrimal Mucocele

- When the inflammatory swelling accumulates and the walls of the sac becomes atonic, a fluctuant swelling may form medial to the medial canthus, below the medial palpebral ligament.
- Freely mobile overlying skin with minimal/no tenderness
- On applying pressure, the contents (usually sterile) may empty either into the nose or through the canaliculi
- If the condition remains so for a significant period of time, both the upper and lower exits may get sealed to form an encysted mucocele.
- Although this may cause the swelling to increase in size, the patient experiences relief from the symptoms of epiphora and conjunctival irritation.

c) Chronic Suppurative Dacryocystitis

- Epiphora
- Conjunctivitis
- Reflux of purulent material on applying pressure or sac syringing
- A chronically thickened and inflamed sac may sometimes get filled with pus to form pyocele which may displace globe and affect vision

In all the above mentioned forms of chronic dacryocystitis, the disease is constant and spontaneous resolution is highly unlikely. At the same time, acute attacks may also develop at any point of time.[7]

COMPLICATIONS

Acute Dacryocystitis

1) Severe conjunctivitis, conjunctival hyperemia, chemosis
2) Corneal involvement ranging from superficial marginal punctiform ulcers to corneal necrosis : Lacrimal system obstruction causes delayed clearance of microbes, disrupts the tear film dynamics and alters the normal microbial flora making the conjunctiva and cornea susceptible to infections.[29]
3) Facial erysipelas in streptococcal infections
4) Internal or external fistula
5) Pre septal cellulitis : seen more commonly than orbital cellulitis as spread of inflammation posteriorly is limited by insertion of orbital septum, posterior limb of medial canthal ligament, deep heads of preseptal and pretarsal parts of orbicularis occuli muscle at the posterior lacrimal crest.[30]
6) Orbital cellulitis, orbital thrombophlebitis, panophthalmitis : Once the contents of the sac surpass the posterior barriers, they may gain access to the extra and intraconal space, periocular blood vessels-central retinal and ophthalmic artery and form an orbital abscess.

   Rapid visual loss may be seen due to mass effect of abscess causing retinal ischemia, vessel occlusion, thrombophlebitis or optic neuritis.[31]
7) Cavernous sinus thrombosis, osteomyelitis, meningitis, death: Following orbital abscess formation and rapid spread of the disease, any delay in prompt treatment

may lead to intracranial extension and development of the above mentioned complications.

Chronic Dacryocystitis

1) Stenosis of NLD with constant epiphora
2) Sinusitis following inferior spread into the paranasal sinuses
3) Repeated attacks of conjunctivitis
4) Minor corneal lesions due to re-infection by organisms like pneumococci and streptococci.

DIAGNOSTICS

The goal of history, clinical examination and evaluation is to determine the pathology responsible for epiphora, distinguish whether it is due to an anatomical or a functional cause and determine the surgical approach, if it is indicated.[32]

1. Clinical History

   Epiphora must be assessed in terms of time of onset, duration, laterality and nature of discharge. It is also important to note the intermittency and severity of the tearing.

   Unilateral epiphora is suggestive of an anatomical obstruction, infectious, inflammatory or traumatic pathology in the drainage system. Bilateral tearing on the other hand may point to excess secretion in cases of allergic conjunctivitis or iritis.

   History of epiphora in a child since birth points to an imperforate membrane in the Valve of Hasner.

   Association of watery discharge can be made with viral or allergic conjunctivitis, reflex tearing, glaucoma or chronic NLD obstruction whereas purulent discharge

can be associated with bacterial conjunctivitis or acute dacryocystitis. It is important to note previous history of trauma, medical therapy, orbital radiation, recurrent sinus disease, nasal allergies, orbital and intranasal surgery to help identify the probable etiology.[6,33]

2. External examination

   Detailed history followed by external examination, palpation and slit lamp examination is crucial for diagnosis.

   This involves examination of the face, ocular surface, eyelid structure and eye blink in a systematic manner. Periorbital and facial asymmetry, bulge in and around medial canthal area, lid inversion or eversion, discharge are a few points that must be noted.

   Inflammation of the eyelid margin in blepharitis or papilla and eyelids along the canaliculi in canaliculitis leads to excessive lacrimation. Pressure on the swollen canaliculi expressing yellow cheesy material is diagnostic of canaliculitis most commonly due to actinomyces infection.

   Slit lamp examination is crucial to determine relative positions of upper and lower puncta on blinking to note any lag, laxity, entropion or ectropion. In some cases, the puncta may be absent either congenitally or secondary to inflammation.

   Lid laxity with ectropion leads to reflex secretion secondary to corneal exposure and is evaluated using ‘snap test’ in which the speed with which the lid snaps back after it is pulled down and away from the globe and released is noted.

   ‘Pinch’ test is used to estimate horizontal lid laxity where the distance between the eyelid and the globe is measured after pulling the lid away. If it is >8mm, it suggests laxity. This comes under the category of non-obstructive epiphora as it is

the result of delayed drainage and secondary complications. Other causes like lid retraction, proptosis and shallow orbits also come under this category.

Entropion with secondary trichiasis may also cause reflex hypersecretion due to mechanical stimulation of cornea.

Assessment of meibomian glands and tear film must be done to evaluate for dry eye. Excessive tearing can also be due to conjunctivitis, corneal abnormalities, foreign body, contact lens use or any intraocular inflammation.

Medial canthal area must be examined for any swelling especially in the lacrimal sac area which may be suggestive of a mucocele. If associated with redness, swelling and pain it suggests acute dacryocystitis whereas the chronic form may only manifest as a swelling. One must also look for any scars indicative of previous surgery or healed fistulae following trauma or infection which may also have surrounding scarring and fibrosis.[6,33]

3. ROPLAS(Regurgitation On Pressure over the Lacrimal Sac area)

   This is an easy test to perform and must be done before and after sac syringing to confirm the diagnosis. Anterior lacrimal crest is identified and the index finger is directed behind it to apply pressure over the lacrimal sac area.[34] One must then look for any regurgitation from the puncta based on which the result is noted as positive or negative.

   In a positive ROPLAS test, regurgitation may be clear and watery if the sac is atonic, mucoid or mucopurulent in NLD obstruction and blood stained in the case of a malignancy or dacryolith.[6]

Figure 6: ROPLAS Test

4. Schirmer's Test

   This simple test helps assess aqueous tear production and has two parts. Schirmer's test I is performed to evaluate gross tear production and Schirmer's test II for reflex tear secretion. Schirmer's I makes use of a special (no.41 Whatman) filter paper, 5 mm wide and 35 mm long which is folded at the end and placed at the junction of the middle and lateral third of the lower eyelid. After 5 minutes, the strip is removed and wetting is noted in millimetres. Normal range is 10-30 mm wetting at 5 minutes. Schirmer's II test involves performing the same test after instilling a drop of topical anaesthetic. In this test, less than 6mm wetting is considered abnormal.[6,10,35]

5. Tear film Break up Time (TBUT)

   1% sodium fluorescein is instilled into the eye and the patient's cornea is observed on the slit lamp using a cobalt blue filter. The patient is asked to blink and the time taken for the first dry spot to appear is noted as 'tear film break up time'(TBUT).Normal TBUT is 15-30 seconds and a value of less than 10 seconds

is suggestive of dry eye with mucin deficiency causing epiphora due to reflex hypersecretion.[6,36]

6. Fluorescein Dye Disappearance Test (FDDT)

This is an easy, non-invasive physiological test to get an approximate assessment of tear flow rate from the conjunctival sac into the lacrimal drainage system. One drop (5 μL) of 2% fluorescein is instilled into the inferior fornix of an unanaesthetised eye and the residual dye in the tear meniscus is noted at the end of 5 minutes using a cobalt blue filter which is graded as follows-

Table 1: Zappia and Milder Grading of Fluorescein Dye Disappearance Test[37]

Grade	Dye remaining in conjunctival sac	Interpretation
0	No dye	Negative (No obstruction)
+1	Thin fluorescing marginal tear strip present	
+2	+1< Fluorescein present <+3	Positive (Obstruction present)
+3	Wide, brightly fluorescing tear strip	

When correlated with the findings of lacrimal syringing it is of great diagnostic significance. However, when performed alone it cannot differentiate between anatomical or physiological obstruction and the site of pathology.[6,33]

7. Sac syringing

Topical anaesthesia is instilled into the inferior fornix and puncta are dilated using a sharp tipped Nettleship's punctum dilator. The patient is made to look up, traction is applied laterally on the lower lid and inferior punctum is everted. After this, a 15° smoothly curved 24G cannula is fitted on a 2cc syringe filled with sterile water and inserted into the inferior punctum. The tip of the cannula is first placed vertically, then inserted horizontally and advanced for 3-7mm till a hard or soft stop is felt. If a hard stop is encountered, it indicates the cannula is against the bony wall of the lacrimal fossa inside the sac and a soft stop is suggestive of a canalicular obstruction. The sterile water is pushed into the system and either free passage or regurgitation of fluid is noted. In case of regurgitation, site, quantity and nature of fluid must be documented.

Interpretation is as follows -

- Free passage of water into the throat suggests an anatomically patent apparatus
- Regurgitation of fluid back through the same inferior punctum suggests a canalicular block and to confirm the results, syringing is repeated through the upper canaliculus
- Immediate regurgitation of fluid through the opposite(upper) punctum indicates a common canalicular block whereas a delayed regurgitation accompanied by distention of the lacrimal sac suggests NLD block.[6,33]

Correlation of results of FDDT and Sac syringing can be made as follows.[38]

Table 2: Correlation of results of FDDT and Sac syringing

FDDT	Sac Syringing	Interpretation
0,1	Patent	Patent
0,1	Partial Regurgitation	Partially patent
2,3	Complete Regurgitation	Anatomical Block
2,3	Patent	Probable functional block

8. Diagnostic probing

When an obstruction is identified on sac syringing, probing is done to identify the exact location and extent of the blockage. Bowman's probe is used as they are available in different sizes and easy to handle. Both sac syringing and probing are contraindicated in cases of acute dacryocystitis.

The probe is passed into the canaliculus where the blockage was noted on sac syringing or into either canaliculi if the blockage was identified distal to the common canaliculus.

If a hard stop is felt on advancing the probe it indicates the probe has entered the sac lumen and is pressing against the medial wall of the lacrimal bone. If this is accompanied by fluid regurgitation through the opposite punctum, it confirms the blockage is in the distal channels in the sac or NLD. In this case with the probe in the lacrimal sac, the medial canthus should not shift on advancing the probe.

If a soft stop is felt, it suggests a canalicular block and the length of the advanced probe from the punctum must be noted. This is essential to plan the most suitable surgery. A blockage felt at <3mm distance from the punctum suggests a proximal canalicular block, at 3-8mm suggests a mid-canalicular block and beyond 8mm suggests a distal canalicular block. If on advancing the probe there is a medial shift of the inner canthus, it suggests the probe is tugging on the common canaliculus and pushing it towards the lacrimal bone medially.

Differentiating between a hard and soft stop is important to assess further management options according to the location of the block.[6,33]

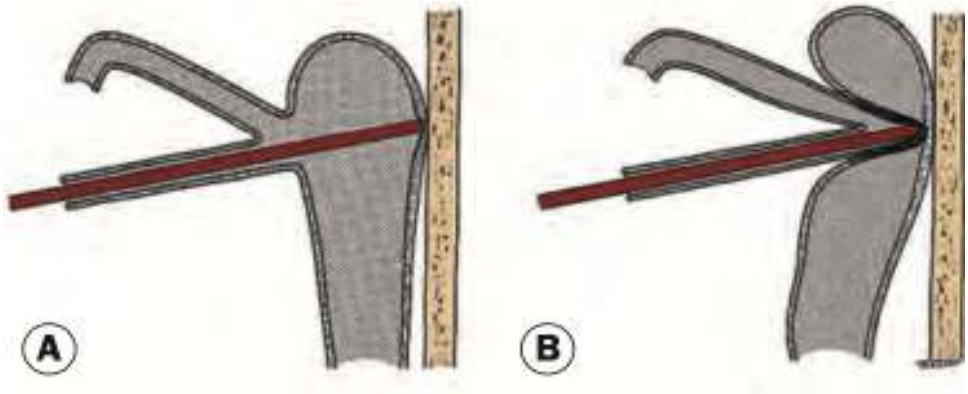


Figure 7: Results of diagnostic probing: A-Hard stop; B-Soft stop

9. Nasal Endoscopy

Nasal conditions, as described earlier are commonly the cause for obstruction at the inferior end of the lacrimal drainage pathways leading to epiphora. As a result, they may hamper the success of a good dacryocystorhinostomy. Examination of the lacrimal area using rigid or flexible endoscopes can help rule out conditions like septal deviation, hypertrophic or atrophic turbinates, polyps or any other anatomical variations even in children. Rigid endoscopes with a 4mm or 2.7mm diameter are used having a 0° or 30° viewing angle. The latter 2.7mm diameter endoscope is useful in children as well as adults having narrow nasal spaces. This

procedure may also be utilized postoperatively to confirm DCR opening, implant location or removal of tissue obstructing the opening.[6,33]

10. Dacryocystography (DCG)

This imaging modality enables us to investigate the lacrimal system for an anatomical location and cause for epiphora.

Procedure : Topical anaesthesia is instilled into both eyes of a patient in supine position. Puncta are dilated and 1 to 2 ml of iodized oil based contrast medium is injected simultaneously into both lacrimal systems under pressure. Mucoid or purulent contents of the lacrimal sac should be washed out prior to the procedure. Following this, films are taken and visualized by digital subtraction technique at 1, 5 and 10 minute intervals with a final film at 30 minutes. Prior to the final film the patient is made to sit erect for 5 minutes to look for failure of gravitational drainage of the dye.

If the passages are normal with no obstruction the dye may take 1.5 to 8 minutes to pass through the entire system. Presence of residual dye in the lacrimal sac or the NLD in the delayed films suggests delayed emptying in functional nasolacrimal duct obstruction (FNLDO).

In the case of a complete obstruction of nasolacrimal duct the films show distention of the sac, no contrast medium in the nose, point of obstruction outlined by the dye with minimal change at the final 30 minute film.

This investigation is also used to grade reflux from the upper punctum, find out the dimensions (mm) of the lacrimal sac and NLD, note any filling defects, stenosis, diverticuli as well as whether the obstruction is partial or complete. DCG provides the advantage of dynamic assessment of the lacrimal drainage system

and excellent anatomical detail in addition to aiding in the diagnosis of a physiological cause for obstruction.[6,39–41]

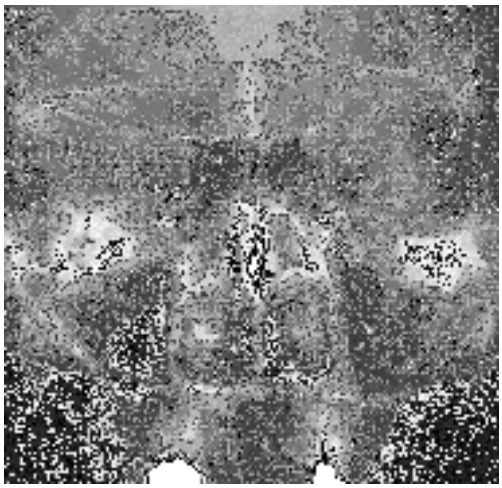


Figure 8: Radiographic dacryocystogram shows normal drainage of contrast media on both sides

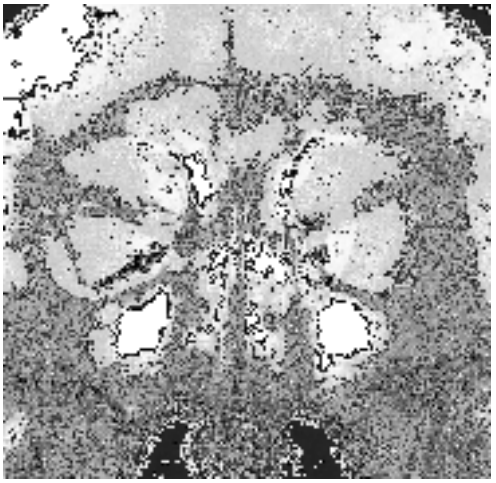


Figure 9: Digital subtraction dacryocystogram shows right duct obstruction with sac dilatation

11. Dacryoscintigraphy

This is a non-invasive physiological test which uses a radioactive tracer detected with a gamma camera. One drop of technetium-99m pertechnetate is instilled into the inferior fornix of both eyes of the patient. No topical anaesthesia is required and patient is asked to sit still and blink normally. At first a dynamic study is conducted where images are taken every 10 seconds for the first 160 seconds following which static images of tracer distribution are taken at 5,10,15 and 20 minutes. Based on these images, 3 categories are made as follows-

- Presac Delay- Delay is at the medial canthus or if at the end of the dynamic study the tracer does not reach the sac.
- Preductal Delay- Early filling of the sac but no emptying seen at the first 5 minute static image.

- Intraduct Delay- Tracer seen in the upper NLD on the 5 minute static image but over the next 15 minutes, no further drainage seen.

A quantitative study of percentage of drainage in different parts of the lacrimal system with can also be obtained. In comparison with DCG it cannot provide the same detailed anatomy but it is a valuable indicator of physiological function of the system.[6,40]

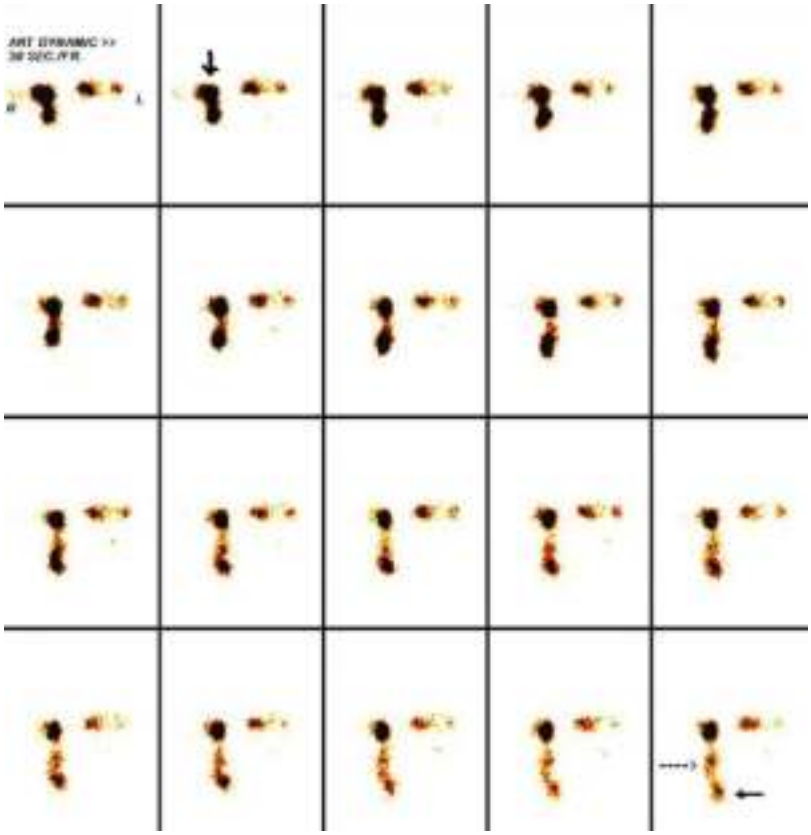


Figure 9: Dacryoscintigraphy reveals normal drainage of tracer till the inferior meatus of nose from the right eye. No drainage of tracer seen into the nasal cavity from the left eye.

12. Computed Tomography (CT) and Magnetic Resonance Imaging (MRI)

CT is a useful investigation for assessing the structures surrounding the lacrimal drainage system like orbital and facial bones as well pathologies associated with the nose and paranasal sinuses.[33]

A study conducted by Papathanassiou et al. comparing Computed Tomography versus Dacryocystography for lacrimal system evaluation, showed that the level of blockage identified was identical for both modalities in 71.4% of the cases whereas DCG was noted to be the superior investigation in 28.5% of the cases. However in 65.3% cases, pathologies of the surrounding structures contributing to lacrimal system blockage was identified only on CT scan and not DCG.[39]

MRI is not used as a standard investigation in lacrimal system imaging and is only suited in cases where soft tissue resolution is required.[6]

MEDICAL MANAGEMENT OF DACRYOCYSTITIS

The different treatment modalities considered in treatment of a case of acute purulent dacryocystitis are as follows-

- Heat application with massage
- Systemic antibiotics (oral or intravenous administration)
- Percutaneous abscess drainage
- Drainage by puncture and aspiration of the lacrimal sac – which may be cultured to provide diagnostic information for appropriate antibiotic to be started.

In a case of acute dacryocystitis, due to the risk of clinical deterioration and further spread of the infection surgical route of management is generally not considered.

Cases of chronic dacryocystitis may initially be treated conservatively till symptoms improve with modalities like lacrimal sac massage and irrigation but majority are considered for surgical management under the cover of pre and post-operative antibiotic prophylaxis.[42]

HISTORY OF DACRYOCYSTITIS SURGERY

Surgical treatment of chronic dacryocystitis by creating an artificial passage into the nose is an ancient method which dates back nearly 2000 years. In the first century, Celsus (25BC-50AD) describes treatment of *aegchiloph* (an abscess of the lacrimal sac) and *aeigiloph* (lacrimal sac abscess with fistulization) by plunging a red hot cautery through the lacrimal bone into the nose to treat this condition based on the theory that the lacrimal bone was the origin of the disease.[43] This was the earliest description of a procedure that combined both dacryocystectomy and dacryocystorhinostomy.

Galen performed a similar procedure in the second century where instead of using cautery he would 'bore a hole with a trephine into the nose' in some cases.[44]

Archigenes, also in the second century suggested incision of the diseased sac followed by application of caustic and boring multiple holes close together through the lacrimal bone into the nose.

In 1713, Anel revolutionized treatment by being the first to introduce a probe through the upper punctum into the lacrimal sac and duct to break down adhesions for which he developed the earliest probes and cannulae. In 1734, Petit incised the infected sac from where he introduced probes to keep the duct open.

In 1650-1730, Woodhouse performed the first surgery resembling modern external DCR[45] by performing complete excision of the sac, boring a hole into the lacrimal bone followed by inserting a cannula made of gold into the nose.[46] Frequent irrigation was done through the cannula and was either changed from time to time or left for several months in the opening.[43]

In the following years similar methods were employed. In 1872, Dupuytren utilized a gold cannula, Callahan utilized a silver tube in 1925 and in 1927 Heermann suggested using a glass tube passing from the lower canaliculus to the nose and permanently leaving it there.[46]

External Dacryocystorhinostomy (DCR)

The technique to external dacryocystorhinostomy (DCR) was described first by Addeo Toti in 1904. After making an external incision and exposing the lacrimal sac, its medial wall was excised using a canalicular probe. The corresponding adjacent lacrimal and maxillary bone and nasal mucosa was resected with a hammer and chisel and the external wound was then closed. External pressure was given from the dressing to push the lateral wall of the opened sac towards the nasal opening such that the canaliculi opening directly into the lateral wall of the nasal cavity.[47] Despite this significant modification, the surgery was not always successful due to frequent granulation tissue formation. The need to suture the lacrimal and nasal mucosal flaps instead of excision was first suggested by Struycken in 1910 following which it was described independently in 1914 by Kuhnt, in 1920 by Ohm and in 1921 by Dupuy-Dutemps and Bourguet.[46] Even though various minor modifications were made throughout the 20th century, DCR today is still performed in a similar way with an improvement in success rate over the years. This can be attributed to improved preoperative assessment by performing radiological investigations for detailed assessment of the anatomy and site of blockage of the lacrimal drainage system, making use of absorbable suture material that is less irritant and development of better instruments. The limitations of the procedure were discovered over the years which included an external scar, damage to the medial canthal anatomical structures,

functional interference with the physiological function of the lacrimal pump, failure related to size and position of the ostium created or scarring within the ostium. Other complications include entry into the ethmoidal sinus and cerebrospinal fluid rhinorrhoea which highlights the importance of understanding the anatomy of surrounding structures.[48]

In 1967, Gibbs introduced intubation with silicone tubes which has been widely used in combination with DCR in cases with canalicular stenosis. The usage of silicone tubes since then proved to be an inert and flexible material helping in preventing adherence of the mucosal lining of the duct and maintaining patency after removal.

After multiple studies, double silicone intubation has been noted to show the maximum success rate in such cases.[49]

Steps of Conventional Dacryocystorhinostomy(DCR)

1. Local anaesthesia for adults and general anaesthesia for children
2. Nasal Packing done to reduce bleeding
3. Local infiltration anaesthesia and surface anaesthesia of conjunctival sac is given by instilling 4% xylocaine with adrenaline 1: 10,000 solution by Stallard technique
4. A curvilinear incision is made, conforming to the anterior lacrimal crest starting 3-4mm away from the medial canthus starting at the upper limit of medial palpebral ligament extending 10-12mm in length.

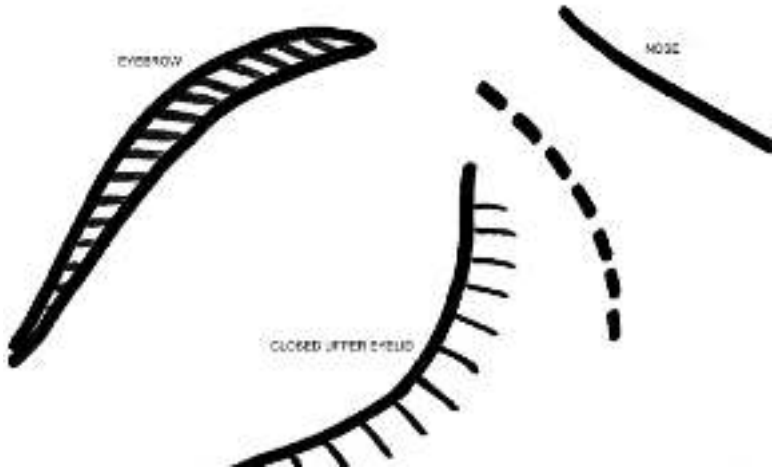


Figure 11: Curvilinear incision made for conventional external DCR

5. Blunt dissection is done, medial palpebral ligament is exposed and orbicularis fibres are separated to expose the periosteum.

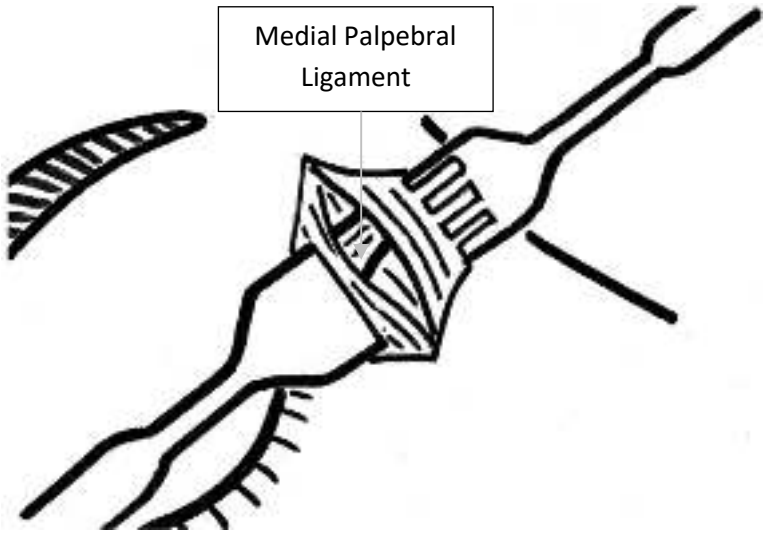


Figure 12: Exposure of medial palpebral ligament (MPL)

6. MPL is cut to further expose the periosteum of the anterior lacrimal crest
7. A mucoperiosteal elevator is used to strip the periosteum off the inferior orbital rim and just anterior to the lacrimal fossa to allow visualization of the lacrimal sac fossa.

8. Keeping the lacrimal sac retracted, further elevation of the periosteum is done over the nasal aspect of the lacrimal bone and posteriorly till the lamina papyracea.
9. At the junction of the lamina papyracea and the lacrimal bone, a small osteotomy is made about 5mm in diameter, sufficient enough to insert the bone punch.

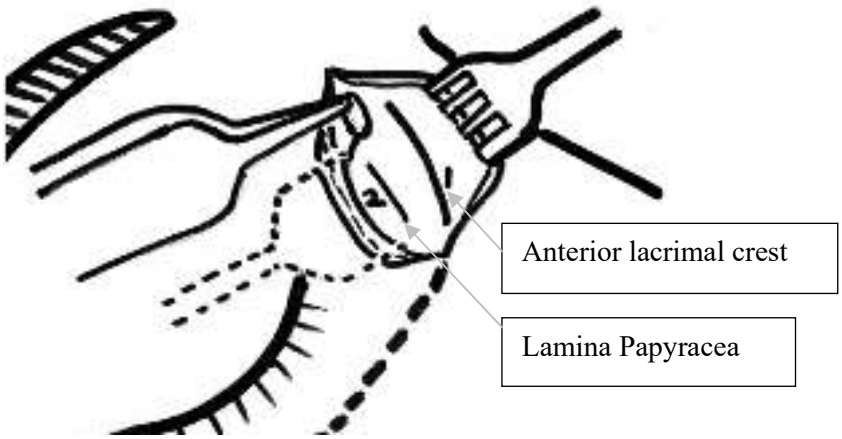


Figure 13: Periosteal elevation to expose lacrimal bone and lamina papyracea

10. Holding the bone punch perpendicular to the punching surface and taking care not to injure the underlying nasal mucosa, ostium is enlarged extending as follows-
    - Superiorly- at or slightly above the level of Medial Palpebral Ligament(MPL)
    - Inferiorly-Till the inferior orbital rim
    - Posteriorly-Till the lamina papyracea
    - Anteriorly-As much as possible

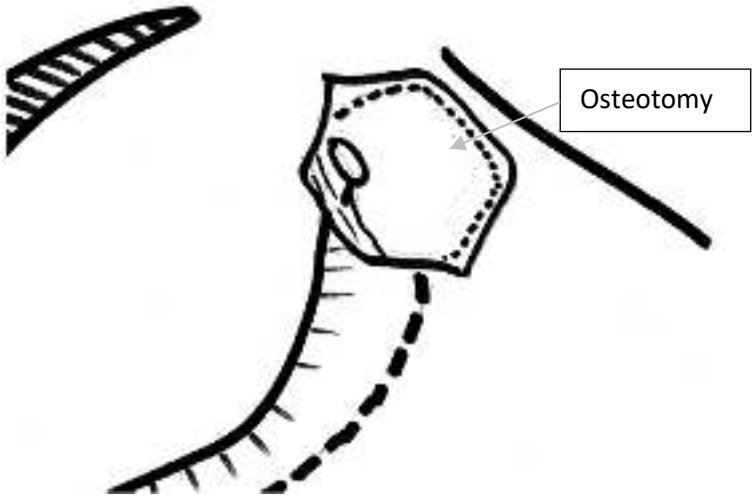


Figure 14: Creation of osteotomy

Figure 15: Endoscopic view of ostium in External DCR

11. For better visualization, the sac may be dilated using viscoelastic injected through the upper punctum after which using a number 11 blade, a long top to bottom vertical incision is taken along the medial wall of the sac so as to create a large anterior and small posterior lacrimal flaps.

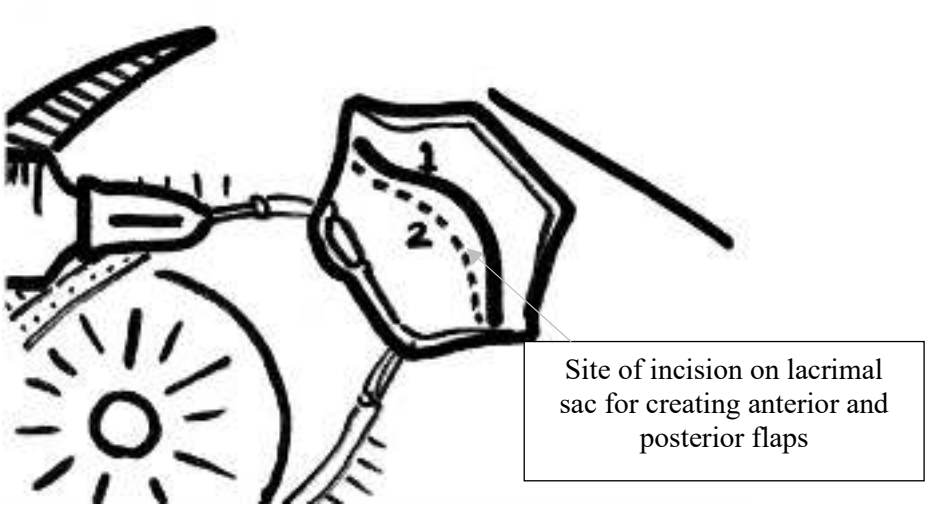


Figure 16: Dilation of lacrimal sac to make the incision for creation of flaps

12. Similarly a long incision is made vertically on the nasal mucosa using a number 11 blade to create a large anterior and small posterior flap.

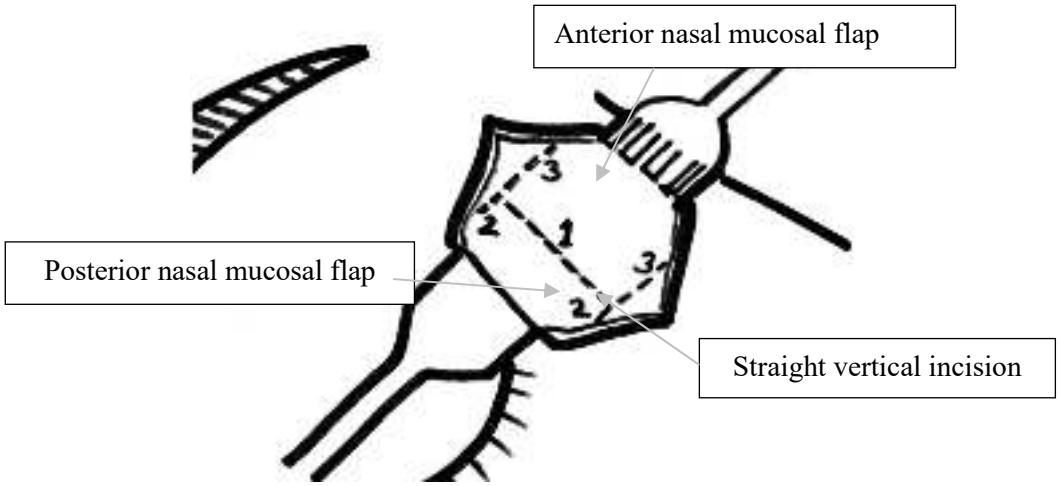


Figure 17: Creation of anterior and posterior lacrimal flaps

13. Posterior nasal and lacrimal flaps are sutured to each other followed by suturing of anterior flaps using 6-0 vicryl.

Figure 18: Suturing of lacrimal and nasal flaps

14. Closure of the orbicularis is done followed by skin closure using continuous/interrupted sutures.[50,51]

Complications of external DCR(52)

Intraoperative

1. Uncontrolled bleeding
2. Damage to lacrimal flaps and nasal mucosa
3. CSF leak if ostium extends higher up

Postoperative(Early and Late)

1. Wound dehiscence
2. Infection
3. Granuloma formation at ostium site
4. Intranasal synechiae
5. Prominent external scar
6. Sump syndrome- Dependent fluid continues to accumulate in an incompletely opened lacrimal sac where pressure over the medial canthus shows regurgitation but syringing shows patency.
7. Failure of DCR

Endonasal Dacryocystorhinostomy

Caldwell introduced the concept of endonasal dacryocystorhinostomy in 1893. In this procedure he passed a metal probe through the canaliculus to lacrimal sac into the nostril followed by using an electric burr to create a middle meatal osteotomy endonasally.(53) Since there was difficulty in visualization of the nasal anatomy, this procedure did not gain much popularity initially.(48) In 1914, a modification was introduced by West in which by resecting the lacrimal bone and superior maxilla, a window osteotomy was created to gain entry to the nasolacrimal duct.(54) Endonasal dacryocystorhinostomy became popular only after the 1970s with the development of nasal use of 0° and 30° angled rigid endoscopes and functional endoscopic sinus surgery which led to better visualization of the nasal cavity.(55) In 1989, McDonough and Meiring published the first modern-day approach.(56)

Endonasal dacryocystorhinostomy provided the advantage of a less invasive surgery, lesser complications of bleeding, lesser duration of surgery, retention of orbicularis oculi pump function, no disruption of medial canthal tendon and avoiding an external scar.(24,57) However it is associated with a steeper learning curve due to the struggle of correctly locating the osteotomy, inability to create an opening that is large enough, removing excess mucosa and chances of injury to surrounding structures thus giving a varying success rate with different surgeons.(24)

Massaro et al brought in the technique of endonasal laser assisted DCR in 1990. He performed this technique in a cadaveric study in which bone removal was done using argon blue green laser using coagulation at low power and tissue vaporization at high power to form a 4-6mm ostia in the lacrimal fossa. Endocanalicular laser assisted DCR was demonstrated in cadaveric specimens

initially by Levin and Stormogipson in 1992 and later by Silkiss et al and Michalos and Pearlman using Nd:YAG laser or a "thulium-doped or holmium-doped" version. Subsequently in further studies carbon dioxide (CO2) and potassium titanyl phosphate (KTP)/neodynium-yttrium-garnet (YAG) lasers were employed for removal of bone.[54] The advantage of laser endonasal DCR is that it can be performed on patients with significant adnexal inflammation, patients taking anticoagulants, is a minimally invasive with shorter operative time, preserves lacrimal pump function, provides better hemostasis and shows lesser rates of haemorrhage. However it requires expensive equipment and laser precautions need to be taken during the procedure.[33]

Conjunctivodacryocystorhinostomy

This procedure is used to bypass upper lacrimal system obstruction by inserting a Lester Jones Pyrex glass tube and creating a new passage for tears to drain from the conjunctival sac to the nasal cavity.[58] An external DCR approach is employed to create the osteotomy required for placement of the tube such that the proximal end lies at the medial canthus and the distal end in the middle meatus. The main complications encountered after this procedure were seen to be extrusion of the tube, obstruction of passage, granuloma and infection.[33,52]

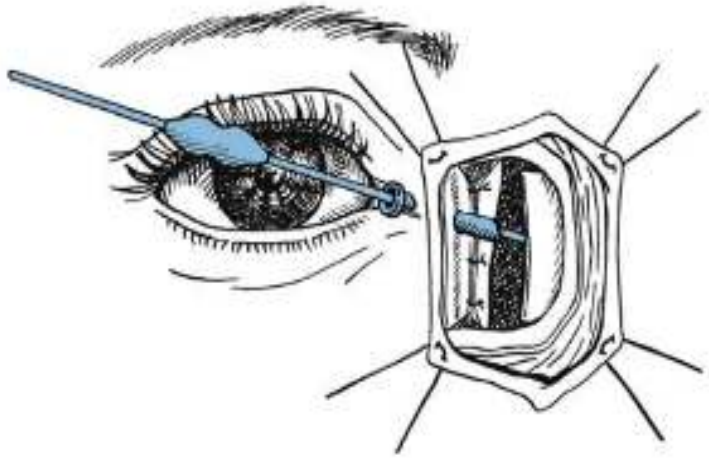


Figure 19: External approach Conjunctivodacryocystorhinostomy with tube insertion

Balloon Dacryoplasty

This procedure was introduced by Munk et.al in 1990 in which a 3 mm lubricated balloon is passed through the superior punctum into the distal NLD after which the balloon is inflated to 8atm for 90 seconds, deflated and again reinflated to 8atm for 60 seconds. Similarly the procedure is repeated in the proximal portion of the NLD. The main drawback of the modality was lack of cost effectiveness.[52]

Implant Dacryocystorhinostomy

The gold standard and most commonly performed procedure today is still conventional external DCR as it provides a highly predictable result with meticulous dissection being done under direct visualization.

However, it has its own set of disadvantages which led to the development of the above mentioned procedures.

The disadvantages of conventional external DCR are as follows-

1. Nasal packing is a necessity in order to prevent intra and post-operative bleeding
2. Large sized ostium of 12-14mm diameter is required
3. More bleeding and tissue handling
4. Contraindicated in
    a. Children- <3 years of age as bones are thin and fragile
    b. Old age- Mucous membrane becomes atrophic
5. More time consuming

In order to overcome these limitations of conventional DCR, Implant DCR was introduced by Dr. M D Pawar in 1985 with the objective of maintaining long term patency of the ostium as well as to enhance healing of the flaps and the ostium.[59]

The Pawar's implant was initially made from the leftover silicone pieces from Denver's Hydrocepalic shunts after hydrocephalous surgery. They were modified in 1987 to have a collar of 5mm, tube of length 12-15mm with an inner and outer diameter of 2 and 2.5 mm respectively. Another change was made in 1995 where the inner and outer diameter of the tube was made 2.5 and 3mm respectively. The collar of the implant was made 2mm thick with a 5mm vertical width and 8mm horizontal width and multiple holes were provided at the proximal and distal end of the tube in order to allow better drainage through the implant. Post operatively, in 10% of the cases expulsion of the implant was seen for which collar was modified and 3mm haptics were introduced.

The modified Pawar's intracystic implant is made of medical grade silicone elastomer which is inert and provides the advantage of excellent tissue compatibility and minimal thrombogenicity thus being the most suitable material for implantation. It has a tubular shape with a collar at one end which sits in the lacrimal sac and is available in three sizes- 13,15 and 17mm with holes at the proximal and distal end for better drainage. The diameter of the collar is 2X5X8mm, inner and outer diameter of the tube is 3 and 3.5mm and diameter of the holes provided is 1mm. A single implant sterilized by ethylene oxide is provided in gamma rays sterilized packet.[5,6,59]

Figure 20 : Pawar's Intracystic implant

Advantages of Implant DCR

1. Nasal packing not necessary

   The size of the ostium in DCR using Pawar's intracystic implant was much smaller in comparison to the 10x12mm ostium made in conventional external DCR which made it necessary to do nasal packing in the latter to prevent intra and post-operative bleeding. Also since the bleeding observed in cases operated

using Pawar's implant was minimal, it further supported that nasal packing was not required.[59]

2. Small incision lacrimal bypass surgery

   In order to make a larger sized ostium in conventional external DCR, a larger external incision has to be made measuring about 12-14 mm in length along the anterior lacrimal crest in comparison to the 5-6 mm sized incision that is made in cases of Pawar's implant since the diameter of the ostium in these cases is only 3mm.[59]

3. Medial Palpebral Ligament (MPL) not cut

   In cases operated using Pawar's implant, the size of the ostium made is only 3mm in diameter and hence there is no need to cut the MPL and no anatomical disturbance. This is in contrast to an external DCR which creates a 10x12 mm ostium and necessitates cutting of the MPL.[59]

4. No need of creating sac flaps, nasal mucosal flaps and anastomosis

   DCR using Pawar's intracystic implant makes use of a perforator passed through the posteromedial wall of the lacrimal sac, lacrimal bone and nasal mucosa to create an ostium of 3mm diameter in which the implant is placed. In this way stricture formation is prevented by prolonged dilatation and promotion of epithelial canalization at the ostium site. This techniques invalidates the need for creation of flaps and anastomosis.[60]

5. Easy and less time consuming

   The operating time showed significant differences as it takes 60 mins to 2 hours on an average in conventional DCR surgery and 30-45 minutes in DCR using Pawar's implant.[60]

6. Minimal intra and post-operative bleeding complication

   Lesser tissue manipulation and smaller sized ostium.[5] is responsible for minimal intra and post-operative bleeding. In a study by Chandravanshi et.al.[59] and Pawar (5), grade 1(5ml) bleeding was noted in surgery with Pawar implant as compared to grade 2-3(>10ml) in a conventional procedure.

7. Success rate is better than conventional DCR surgery

   Study by Chandravanshi et. al showed a 96.66% success rate at 3 months after management of failed cases in DCR with Pawar implant as compared to 85% in conventional DCR.[59] Similar results were noted in study by Mishra et.al where usage of Pawar's implant gave a 97% success rate compared to 94% in conventional DCR.[3]

METHODOLOGY

This present study was conducted at Department of Ophthalmology, KLES Dr. Prabhakar Kore Hospital and Medical Research Centre, Belagavi on patients who are diagnosed with chronic dacryocystitis to assess the safety and efficacy of using Pawar's Intracystic implant in cases undergoing Dacryocystorhinostomy(DCR).

METHOD OF DATA COLLECTION

STUDY POPULATION :

All patients attending the OPD of the Department of Ophthalmology, KLES Dr. Prabhakar Kore Hospital and Medical Research Centre who have been diagnosed with chronic dacryocystitis and have been recommended to undergo Dacryocystorhinostomy meeting the inclusion criteria.

STUDY DESIGN:

A one year Prospective, Longitudinal, Interventional, Hospital based study.

STUDY DURATION:

1 year: 1st January 2020-31st December 2020

SAMPLE SIZE:

32

SAMPLING PROCEDURE

The minimum sample size formula based on prevalence is :

$$n = \frac{z_\alpha{}^2 P(1-P)}{d^2}$$

P : Percentage of prevalence

D : Percentage likely difference in the prevalence.

z_α : Level of significance

With P = 78% and d = 20% of P = 15.6%, the sample size is 27.

To make the study more confirmative, the sample size will be raised to 32.

SELECTION CRITERIA

Inclusion Criteria:

1. Cases having obstruction at NLD

Exclusion criteria:

1. Patients having obstruction of common canaliculus.
2. Patients with fibrosed sac.
3. Patients with bleeding disorders.

CONSENT AND ETHICAL CLEARANCE

Ethical clearance was obtained from the local institutional ethical committee.

Informed/ written consent of parents was taken after explaining in detail about the methods and procedures involved in the study in their own vernacular language.

Data regarding demographic parameters such as age, sex, occupation and address were noted on a predesigned proforma by the investigator at the time of first visit.

Detailed history of the following symptoms was noted

- Watering
- Discharge
- Redness
- Pain
- Diminution of vision
- Past history of similar symptoms
- Systemic conditions-Diabetes Mellitus, Hypertension

Ocular Examination

- Best corrected visual acuity will be noted using Snellen's visual acuity chart.
- Ocular examination proper (Lids, lacrimal sac, conjunctiva, cornea, Anterior chamber, iris, and lens)

- Detailed Slit Lamp examination to rule out other ocular co-morbidities.
- Posterior segment evaluation using direct and indirect ophthalmoscopy
- Lacrimal sac syringing to know the patency of lacrimal passages.
- Basal parameters such as Pulse Rate, Blood Pressure will be assessed.
- Routine laboratory investigations including
    a. Hemogram
    b. Random Blood Sugar levels
    c. Prothrombin Time and INR/Bleeding time and Clotting time
- The study included 32 patients, all of whom who underwent Dacryocystorhinostomy using Pawar's intracystic implant.
- Single surgeon performed all the surgeries using the standard technique
- 31 cases were operated under local anaesthesia and 1 under intravenous sedation following aseptic precautions.
- One day prior to surgery patient will be instructed to
    a. Instil antibiotic eye drops: Moxifloxacin eye drops in both eyes once every hourly for four times
    b. Start a course of oral antibiotics: Tab.Levofloxacin 500mg OD

SURGICAL TECHNIQUE

- Local infiltration anaesthesia of the sac with Stallard technique using 2% lignocaine with adrenaline 1: 10,000 solution and ocular surface anaesthesia using proparacaine eye drops instilled 2-3 times.
- Straight or curved incision 3mm medial to medial canthus and about 5mm in length along the anterior lacrimal crest is taken on the skin and subcutaneous tissue is dissected without cutting the medial canthal ligament.

- Fibres of orbicularis muscle separated with a blunt dissector and lacrimal fascia is cut to expose the lacrimal sac.
- Antero-lateral incision of 3.5mm long is made on the anterior surface of the lacrimal sac.
- Perforator of 3mm diameter oriented posteriorly, medially and inferiorly is passed obliquely through antero-lateral opening of the sac to perforate the postero-medial wall of the lacrimal sac and is then rotated to further perforate the lacrimal bone and nasal mucous membrane.

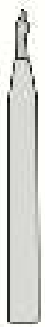


Figure 21: Perforator used in Dacryocystorhinostomy using Pawar's intracystic implant

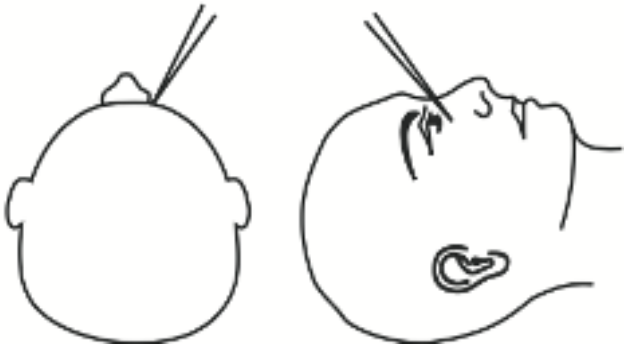


Figure 22: Orientation of perforator posteriorly, medially and inferiorly for insertion into the lacrimal sac

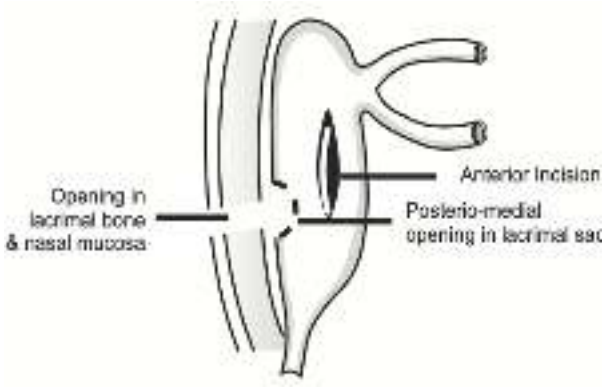


Figure 23: Ostium created in lacrimal sac, bone and nasal mucosa after passage of perforator

- A sterile Pawar's intracystic Implant is mounted on the introducer of 3mm diameter and passed through the antero-lateral opening of the sac in the nasal cavity negotiating the posterior-medial opening wall of the lacrimal sac and newly fashioned ostium.

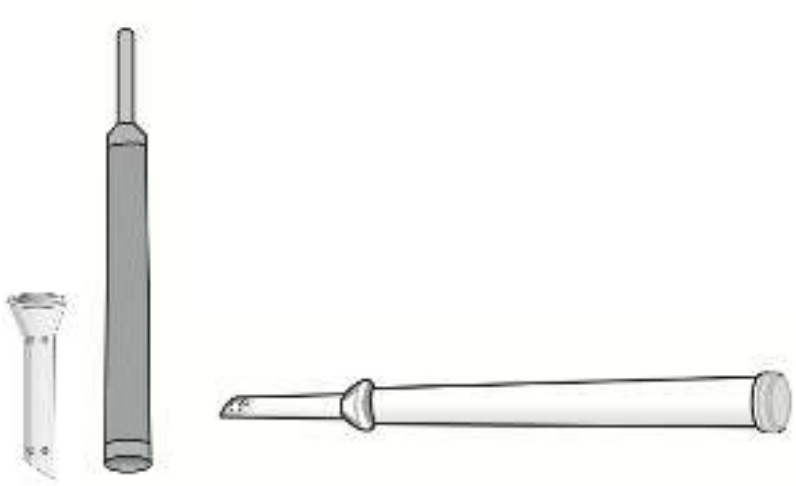


Figure 24: Pawar implant loaded on the introducer

- The sterilized implant is placed in such way that the wider collar portion of the implant lies in the cavity of the lacrimal sac and other distal narrow tube portion of the implant open either in the middle meatus or inferior meatus of the nasal cavity.
- Placement of implant in the sac is confirmed and the sac, muscle and skin is closed in layers using 6-0 vicryl.
- Ciprofloxacin antibiotic eye ointment put over the wound.
- Eye padded and patched.
- Postoperatively, all patients will receive
  - Systemic oral antibiotics : Tab. Levofloxacin 500mg OD for 3 days
  - NSAIDS : Tab. Diclofenac 50mg BD for 3 days
  - Local antibiotic ointment : Ciprofloxacin eye ointment 2 times a day
  - Antibiotic eye drops : Moxifloxacin eye drops 4 times a day
  - Decongestive nasal drops : Oxymetazoline nasal solution 3 drops 3 times a day in the nostril of operated site
  - Saline nasal drops : 10 drops 3 times a day in the nostril of the operated site
- The skin sutures are removed after 7 days.
- Postoperative visits are scheduled at day 1,7 and 30 days to assess anatomical and functional outcome.
- At each visit the following parameters shall be assessed.
  a. Visual Acuity
  b. Examination of incision site in terms of
     a. Pain , tenderness
     b. Approximation of margins
     c. Signs of infection

b. Lacrimal Sac patency

c. Post-operative complications

Since the study is of observational study the plan of analysis will be as follows.

For the continuous quantitative variables mean and standard deviation will be calculated. For the purpose of comparison if the data is divided into two groups with respect to certain qualitative characteristic, the continuous variables will be compared using suitable tools of statistics like unpaired student's t test. The pre and post treatment measures will be compared using student's paired t test.

Discrete variables will be represented by median. Suitable graphs will be used to depict the comparison.

The categorical data will be expressed in terms of rates, ratios, and percentages. The association between the outcome, clinical and demographic characteristics will be tested using Chi-square test, test of proportion or Fisher's exact test.

When we compare two independent groups having quantitative values, generally student's unpaired t test is applied. For discrete variables nonparametric tests will be used.

Apart from the above suitable tools like ANOVA, correlation, regression etc., will be used according to the need.

For all the tests the value of p less than 5% (0.05) will be considered significant.

RESULTS

The present study was conducted at the Department of Ophthalmology, KLES Dr.Prabhakar Kore Hospital and Medical Research Centre, Belagavi during the study period from 1st January 2020 to 31st December 2020.

32 patients of chronic dacryocystitis who were eligible to undergo dacryocystorhinostomy were enrolled in this study.

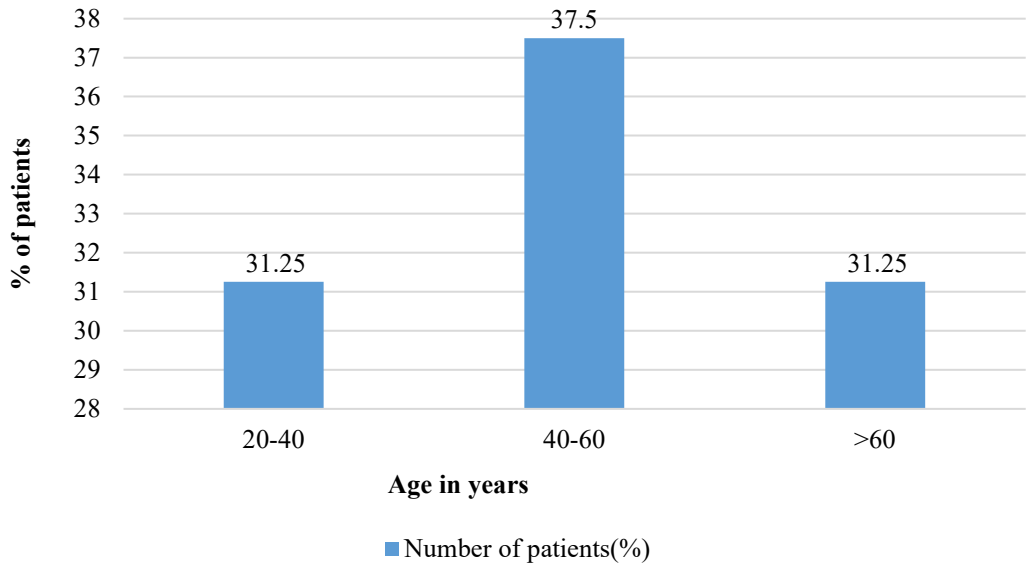
Age and sex distribution, affected side, intraoperative time, intraoperative bleeding , patency on post-operative day 1,7 and 30 and post-operative complications on day 1,7, 30 was used for data analysis.

Data was analysed using R software version 4.1.1 and Excel. Categorical variables are given in the form of frequency table. Continuous variables are given in Mean ± SD/ Median (Min, Max) form. Cochran's Q test is used to compare the patent status and complications over the time points. Pairwise McNemar test is used as post hoc analysis. P-value less than or equal to 0.05 indicates significance.

Table No. 3 : Age Distribution of patients

Age in years	No. of Patients (%)
20-30	4 (12.5%)
30-40	6 (18.75%)
40-50	5 (15.63%)
50-60	7 (21.88%)
60-70	7 (21.88%)
≥70	3 (9.38%)
Mean ± SD	48.88 ± 15.47

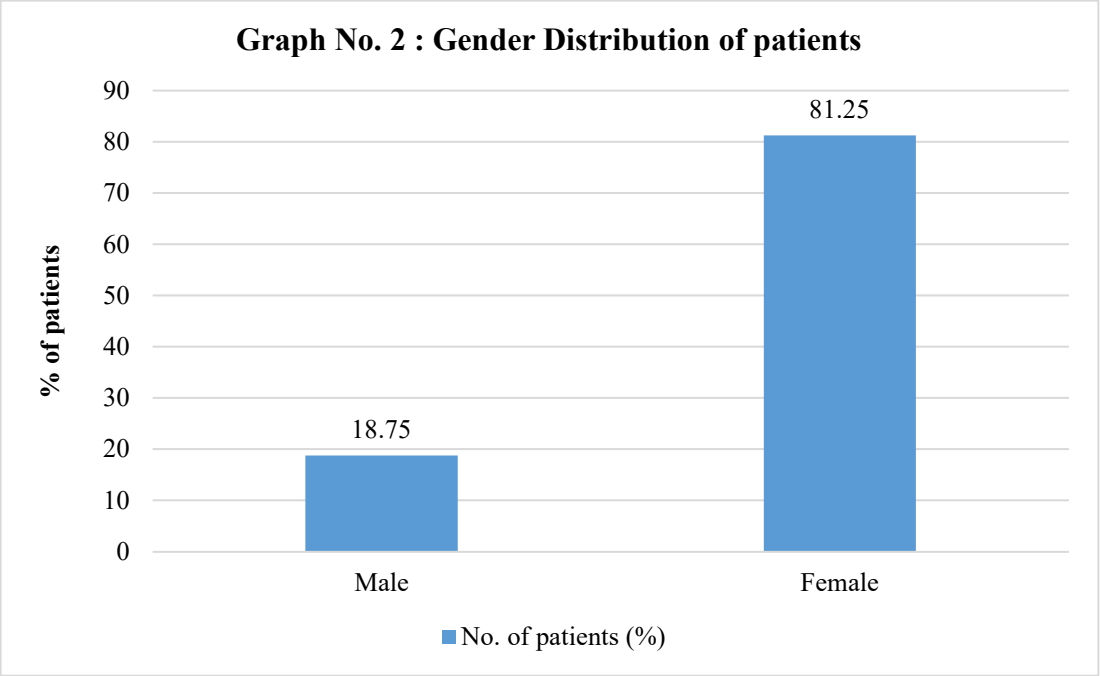
Graph No. 1 : Age Distribution of patients



In the present study, the mean age was 48.88 ± 15.47 years and majority of the patients belonged to the range of 40-60 years age group.

Table No 4 : Gender Distribution of patients

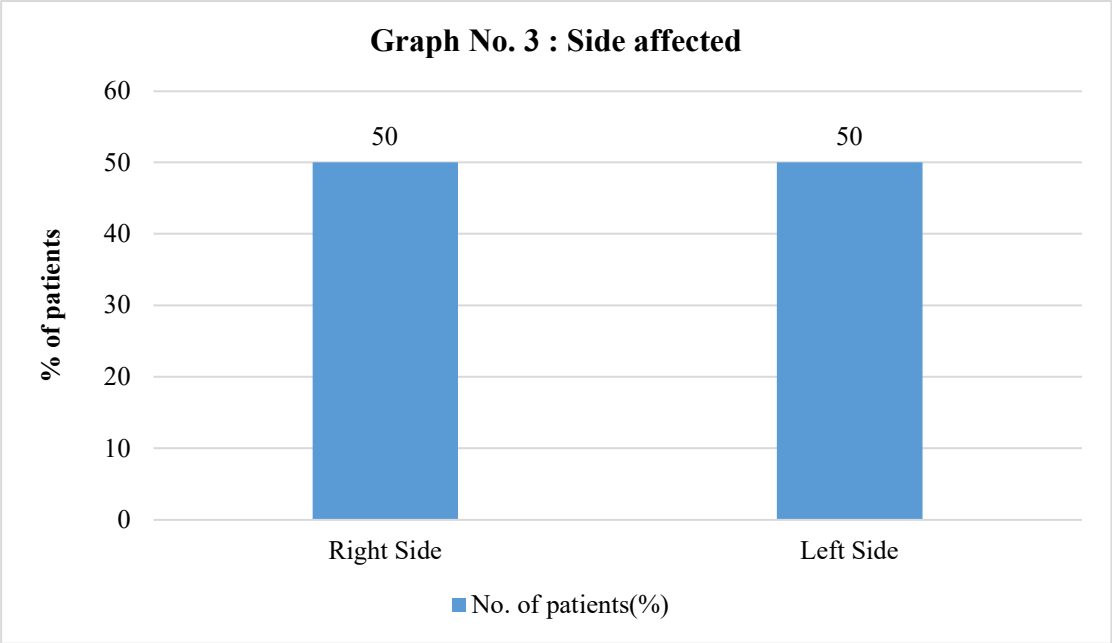
Gender	No. of Patients (%)
Male	6 (18.75%)
Female	26 (81.25%)
Total	32



In the present study 18.75% were male and 81.25% were female with male : female ratio of 1:4.33 showing a female predominance.

Table No. 5 : Side affected

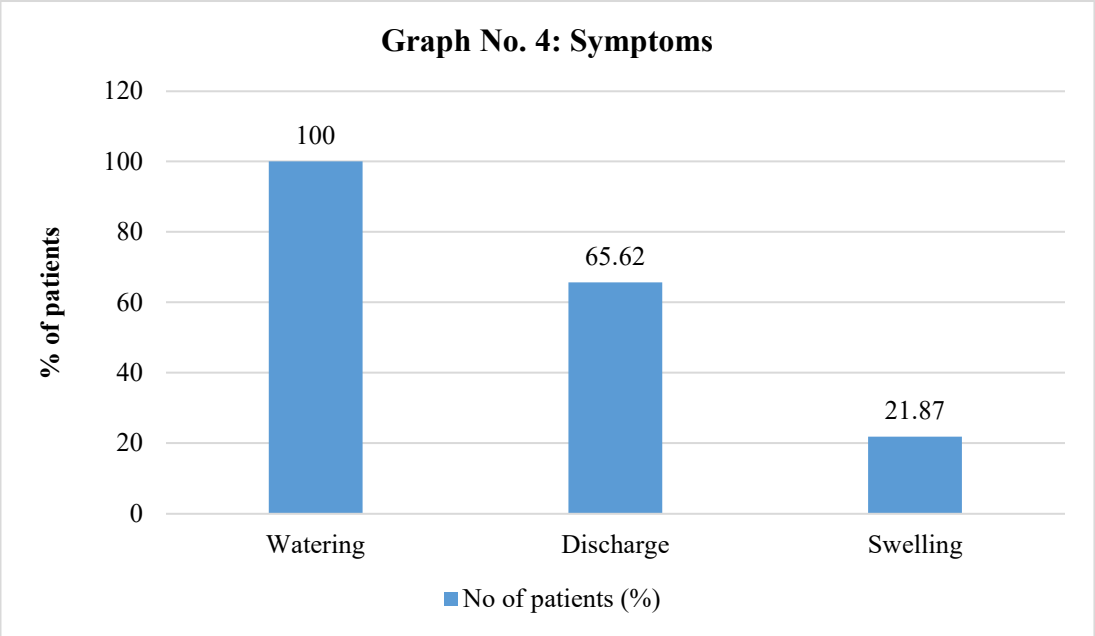
Affected eye	No. of Patients (%)
Right	16 (50%)
Left	16 (50%)
Total	32



In the present study, right and left side were equally affected with 16(50%) cases in both groups.

Table No. 6 : Symptoms

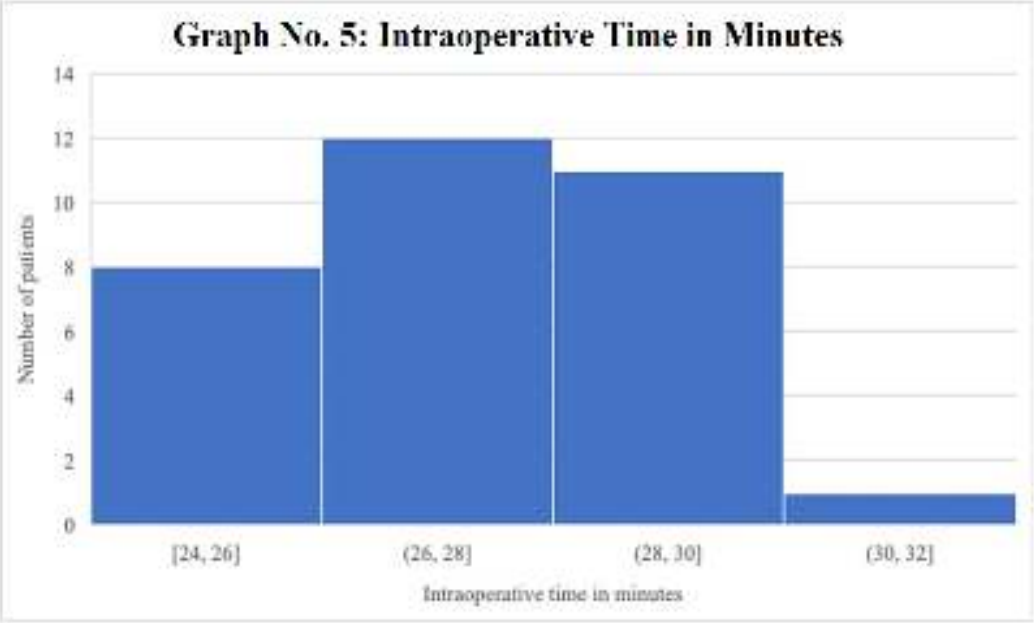
Symptom	No. of Patients (%)
Watering	32(100%)
Discharge	21(65.62%)
Swelling	7(21.87%)



In the present study 32(100%) of the patients experienced watering, 21(65.62%) had discharge and 7 (21.87%) had presence of a swelling medial to the medial canthus. In patients having sac swelling it was noted that making the incision and placement of the implant was easier and the implant sat well in situ. If purulent discharge was noted, inflammation was first brought under control with systemic antibiotics.

Table No. 7: Intraoperative Time

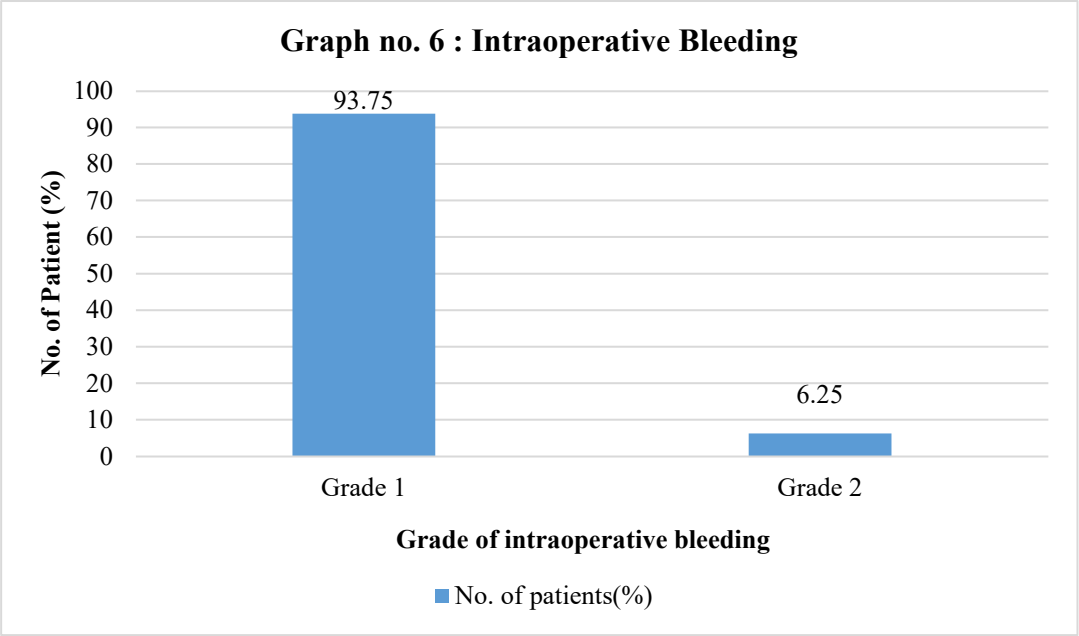
Symptom	No. of Patients (%)
Mean ± SD	27.83 ± 1.88
Median (Min, Max)	28.18 (24.01, 31.46)



In this study mean intraoperative time required was 27.83 ± 1.88 minutes.

Table No. 8: Intraoperative Bleeding

Grade	No. of Patients (%)
Grade 1	30 (93.75%)
Grade 2	2 (6.25%)
Total	32

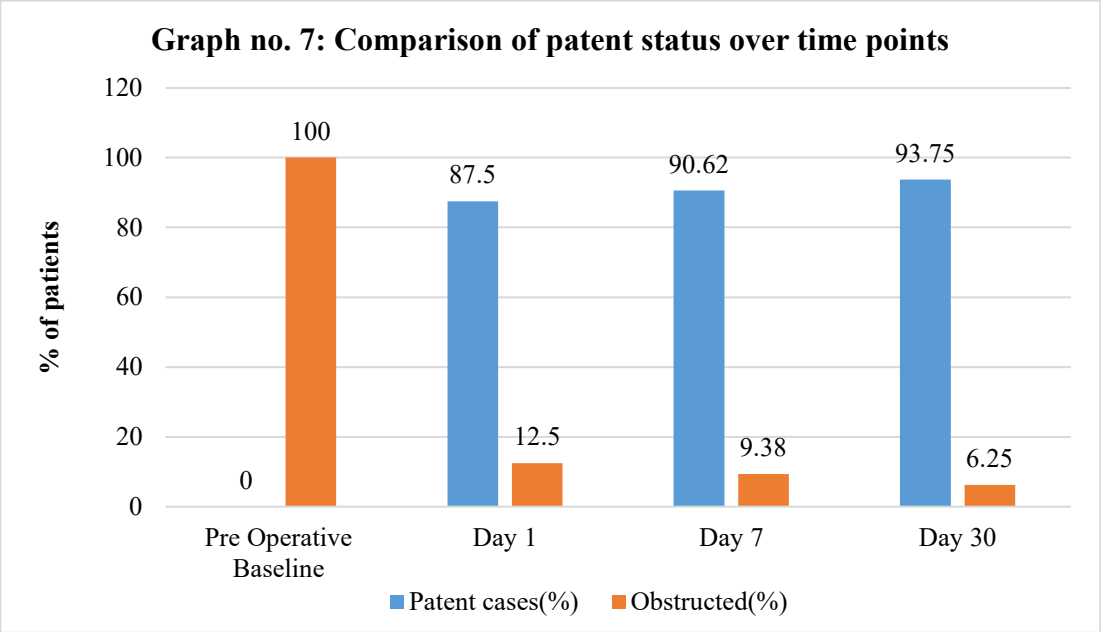


In this study, majority of the patients (93.75%) had Grade 1 (≤ 5 ml) intraoperative bleeding and 6.25% of the patients had Grade 2 (≤ 10 ml) bleeding.

Table no. 9 : Comparison of patent status over time points.

Patent status	Time points				p-value
	Pre-operative baseline	1 day	7 days	30 days	
Obstructed	32 (100%)	4 (12.5%)	3 (9.38%)	2 (6.25%)	**<0.001[C]***
Patent	0	28 (87.5%)	29 (90.63%)	30 (93.75%)	

*Abbreviation: C – Cochran's Q test, * indicates statistical significance*

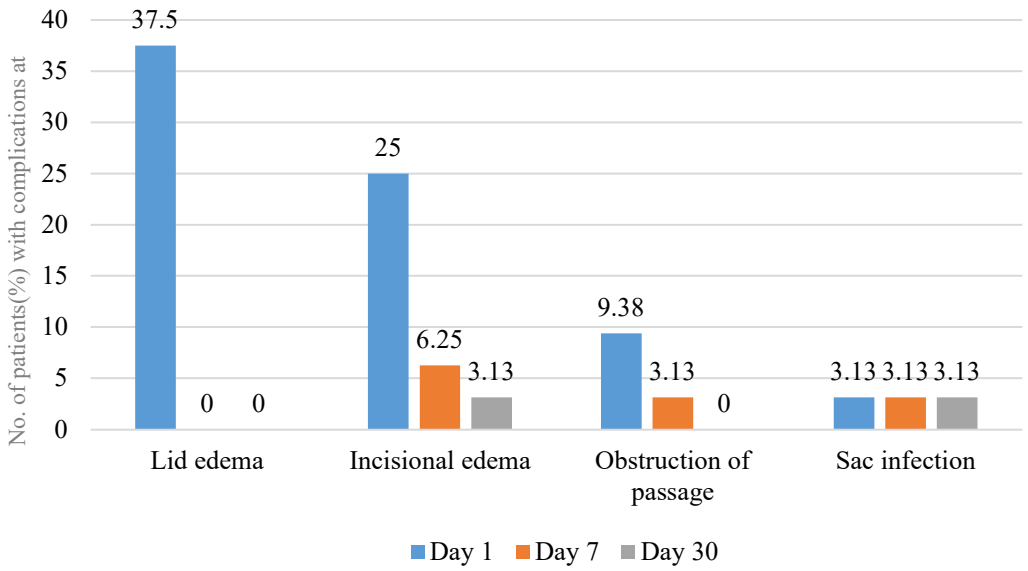


From Cochran's Q test, we observe that, there is significant difference in patent status over time points. From pairwise McNemar test, we observe that, there is significant difference in patent status between baseline to 1 day (p-value < 0.001), 7 days (p-value < 0.001) and 30days (p-value < 0.001).

Table no. 10 : Comparison of complications over time points

Complications	Number of Subjects (%)		
	Day 1	Day 7	Day 30
Lid edema	12 (37.50%)	-	-
Incisional edema	8 (25%)	2 (6.25%)	1 (3.13%)
Obstruction of passage	3 (9.38%)	1 (3.13%)	-
Sac infection	1 (3.13%)	1 (3.13%)	1 (3.13%)

Graph no. 8 : Comparison of complications over time points



In this study out of 32 subjects, 12 (37.50%) had lid edema, 8 (25%) had incisional edema, 3 (9.38%) had obstruction of passage and 1 (3.13%) had sac infection.

On post-operative 7th day, 2 (6.25%) had incisional edema, 1 (3.13%) had obstruction of passage and 1(3.13%) sac infection and at post-operative 30th day, 1 (3.13%) had incisional edema and 1 (3.13%) had sac infection.

Table no. 11 : Overall post-operative outcome at different time points

	Day 1	Day 7	Day 30
Patent	28	29	30
Obstructed	4	3	2
Total	30	30	30

DISCUSSION

Implant DCR was first introduced by Dr. M.D Pawar (Nagpur) in 1985. It was initially made from leftover silicone pieces from Denver's Hydrocepalic shunts after hydrocephalous surgery but has undergone several structural modifications over the years and is now made of medical grade silicone elastomer having maximum tissue compatibility and minimal thrombogenicity.[5,59]

Conventional DCR has been the gold standard for treatment of nasolacrimal duct obstructions since its description by Toti in 1904 but showed major drawbacks like longer intraoperative time, intraoperative hemorrhage, patient discomfort and failure due to ostium related compliations.

Implant dacryocystorhinostomy has tackled all these shortcomings as demonstrated in various studies by Mishra et. al,[3] Chandravanshi et. al,[59] Anup Mondal et. al [25] showing lesser intraoperative bleeding, intraoperative time required and post-operative complications.

1. Age

In this study mean age of the patients was 48.88 ± 15.47 years with majority of the patients belonging to the 40-60 years age group.

Previously conducted studies have shown similar results - study of 226 patients conducted by Yousuf et. al showed maximum incidence in the 50-59 years age group (45.15%),[22] study by Jacobs B.H showed highest incidence in the 40-55 years age group[61] and the age of onset for initiation of an acquired nasolacrimal duct obstruction was shown by Dalgleish to be at 35-40 years of age.[62] Some other studies

have shown variable results as well; Study by Badhu et. Al showed maximum age of incidence in the 21-40 years age group[16] and study by Wadgaonkar et. al showed maximum cases in the 60-70 years age group.[28]

2. Sex

In the present study 81.25% were female and 18.75% were male with male: female ratio of 1:4.33 showing a female predominance.

This is in accordance with female gender predisposition described in literature as females have narrower nasolacrimal duct containing bony lumen and other hormonal factors which contribute to their increased predisposition for an acquired obstruction.[7]

3. Laterality

In this study right side was affected in 16 cases (50%) and the left side was affected in 16 cases (50%). A study by Dalgleish showed no side predilection and that the number of cases of right and left sided obstructions is comparable in all age groups and both sexes.[62] Similarly in this study both groups had equal number of cases.

4. Intraoperative Time

Study by Chaudhari et. al showed time duration for conventional external DCR surgery to be around 60 minutes to 2 hours as compared to a procedure with Pawar implant requiring 30-45 minutes.[60]Similarly Chandravanshi et. al also demonstrated that an external DCR required 110.5 mins and Pawar implant required 27.33 minutes on an average.[59] In this study average time required for Pawar implant

insertion was 27.83 ± 1.88 minutes which was similar to the intraoperative time noted in other studies. As shown in the previous studies dacryocystorhinostomy with Pawar implant significantly reduces intraoperative time in comparison to a conventional DCR due to smaller ostium, no need for creation and suturing of mucosal flaps, minimal tissue handling and significantly reduced intraoperative bleeding

5. Intraoperative bleeding

One of the biggest advantages of Pawar implant over conventional DCR is significantly reduced intraoperative bleeding. Study by Chandravanshi et. al showed conventional DCR had grade II (6-10 ml) to grade III (>10ml) bleeding in comparison to grade I bleeding in majority of the cases operated with Pawar implant due to smaller size of ostium and minimal tissue manipulation. Chaudhari et. al and Gupta et. al also showed moderate to severe(>25 pellets used without use of suction) bleeding in a conventional DCR as compared to minimal(<25 pellets) bleeding in DCR with Pawar implant.[25,60]

Similar results were seen in the present study as well with 93.75% (30 cases) showing grade I bleeding and 6.25% (2 cases) having grade II bleeding.

6. Post-operative nasolacrimal duct patency

32 patients included in this study showed delayed regurgitation of fluid from the opposite punctum on sac syringing preoperatively. Post operatively sac syringing was done on day 1, 7 and 30. It was seen that 28 patients (87.5%) showed patency on day 1, 29 (90.62%) on day 2 and 30 (93.75%) on day 30.

4 patients (12.5%) showed non patency on day 1 due to incisional edema with obstruction of passage in 1 case (3.13%), sac infection in 1 (3.13%) and obstruction of passage in 2 cases (6.25%). Number of patent cases improved to 29 (90.62%) by day 7 and to 30 (93.75%) by day 30 with medical management of obstructed cases.

Results were comparable to Chaudhari et. al study who showed a 90% success rate,[60] Gupta showing 90% success at 3 months,[63] Chandravanshi et. al who showed a 96.66% success rate with Pawar implant versus a 85% success rate in conventional DCR at 2 months improving to 96.66% at 3 months in the former group after management of failed cases[59] and Mishra et. al showing a success rate of 90% at one month improving to 97% with Pawar implant versus a success rate of 91% improving to 94% in external DCR at 6 months.[3]

7. Post-operative complications

In this study out of 32 subjects, 12 (37.50%) had lid edema, 8 (25%) had incisional edema, 3 (9.38%) had obstruction of passage and 1 (3.13%) had sac infection on post-operative day 1.

Lid edema subsided with conservative management and was absent in all cases at the 7^{th} and 30^{th} post-operative day follow up.

Incisional edema seen in 8 cases on post-operative day 1 also subsided with medical management in majority of the cases and was seen in only 2 cases (6.25%) on the 7^{th} post-operative follow up. On the 30^{th} day post-operative follow up, incisional edema persisted for 1 case (3.13%) which ultimately led to extrusion of the implant from the incision site at 5 months post operation. This case was re-operated with a conventional external dacryocystorhinostomy procedure.

Obstruction of passage was seen in 3 cases (9.38%) on day 1.In 2 of these cases crusting was noted at the lower end of the implant and hence diagnostic nasal endoscopy with crust removal was performed. Subsequently on post-operative day 7, obstruction of passage persisted in 1 case (3.13%) and was advised betadine wash with lacrimal massage in addition to the post-operative medication. On the day 30 follow up patency on syringing was achieved in this case as well.

Sac infection was seen in 1 case (3.13%) on 1^{st}, 7^{th} and 30^{th} post-operative day due to which lacrimal sac syringing could not be performed. Treatment was given with local and systemic antibiotics and anti-inflammatory drugs.

1 case showing patency on post-operative day 1, 7 and 30 also underwent extrusion of implant through the nasal cavity 6 months post-operative and was managed with repositioning and resuturing of the implant to the sac.

CONCLUSION

The present study was conducted on 32 eyes of 32 patients who underwent dacryocystorhinostomy with Pawar's intracystic implant at the Department of Ophthalmology, KLES Dr.Prabhakar Kore Hospital and Medical Research Centre, Belagavi during the study period, from 1st January 2020 to 31st December 2020.

The patients diagnosed with chronic dacryocystitis willing for dacryocystorhinostomy with Pawar's intracystic implant meeting the inclusion criteria were included in this study.

The following conclusions were drawn from the study:

- Females were seen to be affected 4 times more as compared to men. (Male : Female – 1 :4.33)
- Majority cases of dacryocystitis (37.5%) were found in the 40-60 years age group.
- Average intraoperative time was 27.83 ± 1.88 minutes which is significantly reduced when compared to the time required for an average conventional DCR procedure.
- Intraoperative bleeding was seen to be minimal, that is grade I (<5ml) in majority (93.75%) cases.
- 30 cases out of 32 showed patency with lacrimal syringing on the day 30 post-operative follow up(p-value < 0.001) giving a 93.75% success rate.
- Post-operative complications seen were managed medically and resolved by the 30th post-operative day in majority of the cases(93.75%).Only 2 cases(6.25%)

showed complications that did not resolve by day 30 and required surgical intervention subsequently. This showed a good overall postoperative outcome.

This study concluded that dacryocystorhinostomy with usage of Pawar's intracystic implant has multiple advantages over dacryocystorhinostomy without an implant.

This procedure did not require nasal packing due to minimal risk of bleeding with smaller size of ostium and minimal tissue handling. Intraoperative time is significantly reduced due to the ease of inserting the implant after creation of the ostium without creation of sac and nasal mucosal flaps. Overall post-operative outcome was also seen to be favourable.

SUMMARY

Epiphora is one of the commonest symptoms and patients present with to an ophthalmology OPD as it causes discomfort, visual disturbance, foreign body sensation and excoriation and eczema of the skin of the lids due to constant wiping. Dacryocystitis is one of the major causes for chronic watering , discharge and swelling in the lacrimal sac area and may be congenital or acquired. Dacryocystorhinostomy is considered as the gold standard for cases of chronic dacryocystitis and ever since its first description by Toti in 1904, it has undergone several modifications over the years. One of the recent modifications developed by Dr. M.D Pawar from Nagpur has been placement of an silicone implant to assist in maintenance of patency between the lacrimal sac and middle or inferior meatus of the nose. The aim of this study was to evaluate the patency and post-operative complication profile in cases of chronic dacryocystitis undergoing dacryocystorhinostomy using Pawar's intracystic implant.

The study included 32 eyes of 32 patients of chronic dacryocystitis who underwent dacryocystorhinostomy using Pawar's intracystic implant at Department of Ophthalmology, Dr. Prabhakar Kore Hospital and Medical Research Centre, Belagavi from January 1st, 2020, to December 31st 2020.

Preoperatively the patients underwent sac syringing to determine the level of the obstruction in the lacrimal system. Patients with a nasolacrimal duct obstruction underwent dacryocystorhinostomy using Pawar's intracystic implant operated by a single surgeon. The intraoperative time and bleeding was noted. Post-operative patency was checked on day 1,7 and 30.

28 cases (87.5%) showed postoperative patency on day 1, 29 cases(90.62%) on day 7 and 30(93.75%) on day 30. Out of 32 subjects, 12 (31.25%) had lid edema, 8 (25%) had incisional edema, 3 (9.38%) had obstruction of passage, 1 (3.13%) has sac infection on post-operative day 1.On day 7, lid edema resolved and other complications also came down with 2 cases (6.25%) of incisional edema, 1 case(3.13%) with obstruction of passage and 1(3.13%) with sac infection. On day 30, 1 case(3.13%) had incisional edema(3.13%), 1 had obstruction of passage and 1(3.13%) had sac infection.

This study showed that dacryocystorhinostomy using Pawar's intracystic implant has a good efficacy and safety profile with a 93.75% success rate.

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ANNEXURE-I

CONSENT FOR PARTICIPATION IN RESEARCH STUDY

Title of Research Study: A ONE YEAR PROSPECTIVE STUDY TO EVALUATE THE PATENCY OF LACRIMAL SAC AFTER USING PAWAR'S INTRACYSTIC IMPLANT FOR PATIENTS OF CHRONIC DACRYOCYSTITIS UNDERGOING DACRYOCYSTORHINOSTOMY AT KLES DR. PRABHAKAR KORE HOSPITAL AND MRC, BELAGAVI

Principal Investigator:

_____

Post Graduate student,
Department of Ophthalmology,
Jawaharlal Nehru medical college,
K.L.E University, Belagavi-590010

Guide:

_____

Professor,
Department of Ophthalmology,
Jawaharlal Nehru medical college,
K.L.E University, Belagavi-590010

Introduction and Purpose

The purpose of this study is to evaluate the outcome of using Pawar's Intracystic implant in patients of chronic dacryocystitis undergoing dacryocystorhinostomy at a Tertiary Care hospital located in Southern India in terms of patency of the lacrimal sac and complications post operatively.

Procedure

If you agree to be a part of this research study, then you will be asked the relevant history and will be subjected to relevant clinical examination and investigations.

Risks and Benefits

The risks associated with dacryocystorhinostomy surgery are applicable here. You will have a good post-operative prognosis with higher success rate of lacrimal sac patency, lesser intra and post-operative bleeding along with other complications as compared to conventional external dacryocystorhinostomy surgery.

Alternatives

Taking part in this study is voluntary. You may choose not to take part in this study. If you decide to take part, you can later change your mind and withdraw from the study. Your decision will not change the present or future healthcare or other services that you receive. The study doctor may stop your participation in this study at any time. If you choose not to take part in this study, you will receive the standard treatment for patients with your condition.

Privacy and Confidentiality

All information collected about you during the course of the study will be kept confidential to the extent permitted by the law. The code numbers will identify you in this research record. Information from this study may be published but my identity will be confidential in any publication.

Financial incentives for participation

You will not be paid/offered and gifts/incentives for participating in this study.

Authorization to publish the results

The results of the study would be forwarded to KLE University, Belgaum as part of requirement towards the compensation of my M.S degree, review and publishing.

In case of any queries during the study or in the future you may contact following person.

1. **Dr. ROOPA BELLAD** M.B.B.S, M.D., DCH Professor of Paediatrics, Chairman of JNMC Institutional Ethics Committee on Human Subjects Research, J N Medical College, Belagavi. Phone no : 9448113403

CONSENT TO PARTICIPATE IN RESEARCH TRIAL

I voluntarily agree to take part in this study. By signing this consent form I am not giving up any of my legal rights. I may withdraw from the study at any time. My signature below indicates that I have read the consent form or it has been read to me in my own vernacular language, including the risks and benefits and I have had all my questions answered.

Participant's Name:_____

Name of legally authorized representative/guardian:_____

Signature / Left Thumb impression of participant or legally authorized representative _____

Witness name :_____

Signature or

Left Thumb impression:_____

Investigator's name: _____

Date:_____

Place:_____

Signature : _____

Guide: _____

Signature:_____

ANNEXURE II

DATA COLLECTION INSTRUMENT

"A ONE YEAR PROSPECTIVE STUDY TO EVALUATE THE PATENCY OF THE LACRIMAL SAC AFTER USING PAWAR'S INTRACYSTIC IMPLANT FOR PATIENTS OF CHRONIC DACRYOCYSTITIS UNDERGOING DACRYOCYSTORHINOSTOMY AT KLES DR. PRABHAKAR KORE HOSPITAL AND MRC,BELAGAVI "

PROFORMA

PATIENT INFORMATION:

IP NUMER: OP NUMBER:

NAME: _____

AGE: _____ GENDER: F/M

PHONE NUMBER: _____

ADDRESS: _____

_____

DATE OF ADMISSION: _____ DATE OF DISCHARGE: _____

Is patient eligible for study?

Has informed consent been given?

CHIEF COMPLAINTS:

Watering: RE/LE/BOTH EYES

Duration: _____

Discharge: RE/LE/BOTH EYES

Duration: _____

HISTORY OF PRESENTING ILLNESS:

Watering: Present/Absent

Discharge: Present/Absent

Swelling: Present/Absent

Diminution of vision: Present/Absent

Pain: Present/Absent

Redness: Present/Absent

Spectacle use:

Other complaints: _____

PAST HISTORY:

Similar complaints: yes/no

If yes, specify _____

Ocular trauma: Yes/No

Form of trauma_____

Duration _____days/months/years

Ocular surgery: Yes/No

Type of surgery_____

Duration _____days/months/years

Diabetes: Yes/No

Duration _____days/months/years

Hypertension: Yes/No

Duration _____days/months/years

Any other medical disorders

FAMILY HISTORY:

Similar complaints:

Any other significant family history:

PERSONAL HISTORY:

Smoking: Yes/No

Duration _____days/months/years

Alcoholism: Yes/No

Duration _____days/months/years

Other addiction: Yes/No

Duration _____days/months/years

GENERAL PHYSICAL EXAMINATION:

Appearance: well-built/moderately built/poorly built/emaciated

Pallor: Present/Absent

Pulse: _____ beats/minute BP: _____mm Hg

Temperature: _____°F Respiratory rate: _____/minute

SYSTEMIC EXAMINATION:

CVS: Normal/Abnormal

Specify: _____

RS: Normal/Abnormal

Specify: _____

CNS: Normal/Abnormal

Specify: _____

GIT: Normal/Abnormal

Specify: _____

OCULAR EXAMINATION:

Head posture: Erect/Tilted

Visual axis: Parallel/Deviated

Facial symmetry: Symmetrical/Asymmetrical

Extra-ocular movements: Normal/Restricted/Partially restricted

RE. Binocular LE

VISUAL ACUITY:

	RE	LE
DISTANT		
PINHOLE		
NEAR		
WITH GLASSES		

ANTERIOR SEGMENT:

	OD	OS
LIDS		
LACRIMAL SAC Swelling On pressure On eversion of punctum Scars/Fistula Inflammatory signs		
CONJUNCTIVA		
SCLERA		
CORNEA		
ANTERIOR CHAMBER		
IRIS		
PUPIL		
LENS		

FUNDUS EXAMINATION	OD	OS
GLOW		
MEDIA		
DISC		
C:D RATIO		
BLOOD VESSELS		
BACKGROUND		
MACULA		

DIAGNOSIS:

INVESTIGATIONS:

1.Lacrimal Patency

	Patent / Partially Patent / Blocked
RE Regurgitation Immediate/Delayed Clear/Mucoid flakes	
LE Regurgitation Immediate/Delayed Clear/Mucoid flakes	

2.IOP

	BY NCT	BY Schiotz		
		5.5g	7.5g	10.5g
RE				
LE				

3.Blood Sugar: _____mg% (RBS/FBS)

4. BP: _____mm Hg

5.PT: _____sec

INR: _____

6.BT: _____sec

CT: _____sec

TREATMENT GIVEN PREOPERATIVELY:

OPERATIVE PROCEDURE: Dacryocystorhinostomy using Pawar's Intracystic Implant

Date: _____

Eye to be operated: Right/Left/Both

Anaesthesia: Local/General

Operative Complications: Present/Absent

If present, specify_____

Post-operative Complications: Present/Absent

If present, specify_____

OPERATING SURGEON: _____

SURGEON'S SIGNATURE_____

POSTOPERATIVE FOLLOW UP PLAN

1)VISUAL ACUITY:

OD/OS	**DAY 1**	**DAY 7**	**DAY 30**
DISTANT VISION			

2)ANTERIOR SEGMENT:

OD/OS	**DAY 1**	**DAY 7**	**DAY 30**
LIDS			
LACRIMAL SAC Swelling On pressure On eversion of punctum Scars/Fistula Inflammatory signs			

CONJUNCTIVA			
SCLERA			
CORNEA			
ANTERIOR CHAMBER			
IRIS			
PUPIL			
LENS			

4)Lacrimal Patency

	Patent / Partially Patent / Blocked
RE Regurgitation Immediate/Delayed Clear/Mucoid flakes	
LE Regurgitation Immediate/Delayed Clear/Mucoid flakes	

OUTCOME: Improved/Deteriorated

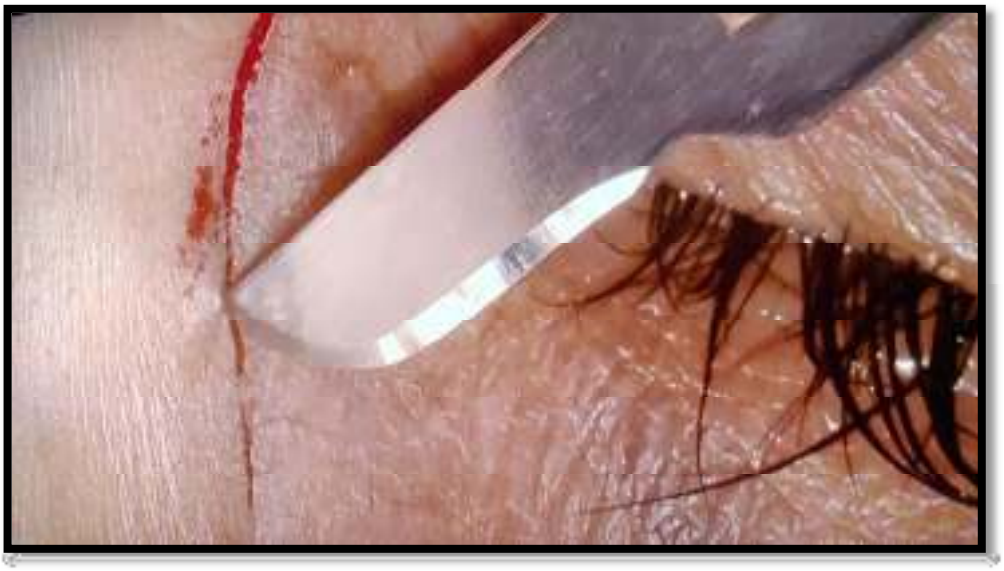
COMPLICATIONS

	OD/OS	**DAY 1**	**DAY 7**	**DAY 30**
1	Lid edema			
2	Incisional edema			
3	Hemorrhage from nasal mucosa			
4	Sac infection			
5	Wound gape			
6	Wound Infection			
7	Obstruction of passage			
8	Hypertrophic scar			
9	Extrusion of implant			

ANNEXURE III-PHOTOGRAPHS

Photograph 1: Evaluation of patency by sac syringing

Photograph 2: OT trolley preparation for DCR using Pawar's implant



Photograph 3: Incision made 3mm medial to medial canthus

Photograph 4: Separation of fibers of orbicularis oculi without cutting Medial Palpebral Ligament (MPL)

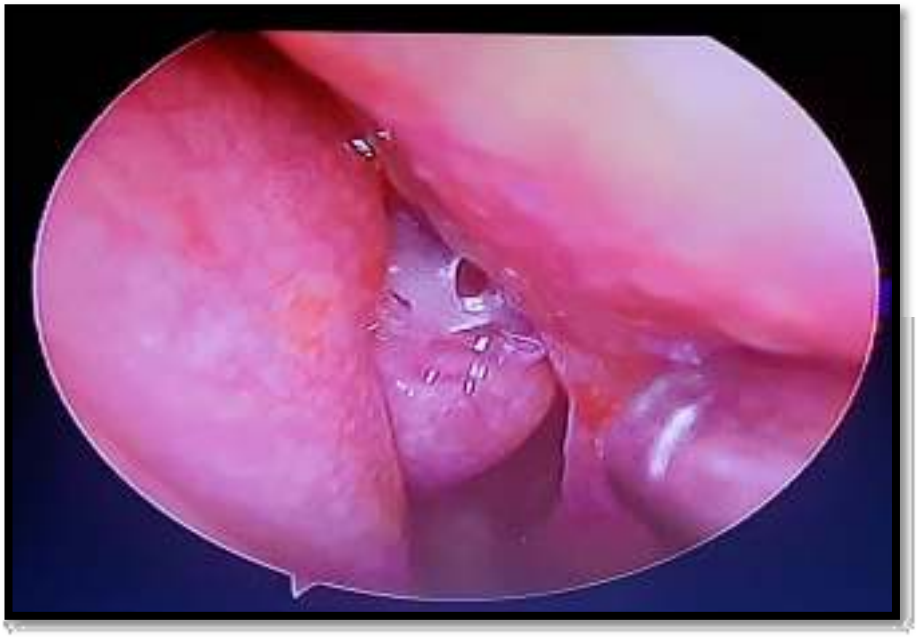
Photograph 5: Incision made in anterior wall of lacrimal sac

Photograph 6: Passage of perforator through the lacrimal sac, bone, and nasal mucosa to create an ostium

Photograph 7: Pawar implant loaded on introducer

Photograph 8: Placement of Pawar implant in ostium

Photograph 9: Lacrimal sac sutured using 6-0 vicryl



Photograph 10: Distal end of Pawar implant seen in the inferior meatus on nasal endoscopy

ANNEXURE IV -MASTER CHART

Patient No	Age (Years)	Sex	Eye	Vision	Chief Complaints	NLD Patency - Regurgitation			Diagnosis	Intraoperative Time (minutes)	Intraoperative bleeding	NLD Patency			Complications		
						Timing	Nature of regurgitation	Side of punctum				POD 1	POD 7	POD 30	POD 1	POD 7	POD 30
1	76	F	L	CF 1m CF 1m	Watering Discharge	Delayed	Mucoid flakes	Opposite	L CDC	25.21 mins	G 1	P	P	P			
2	75	M	L	CF 1m HMCF PL+PR acc	Watering Discharge Swelling	Delayed	Mucoid flakes	Opposite	L CDC	26.02 mins	G 1	P	P	P	Lid edema, Incisional edema		
3	48	F	R	6/6 6/6	Watering	Delayed	Clear fluid	Opposite	R CDC	27.22 mins	G 1	P	P	P			
4	52	F	R	6/9 6/9	Watering Discharge	Delayed	Mucoid flakes	Opposite	R CDC	29.32 mins	G 1	P	P	P	Lid edema, Incisional edema		
5	24	M	L	6/6 6/6	Watering	Delayed	Mucoid flakes	Opposite	L CDC	24.01 mins	G 1	P	P	P	Lid edema, Incisional edema	Incisional edema	
6	30	F	L	6/6 6/6	Watering Discharge	Delayed	Mucoid flakes	Opposite	L lacrimal fistula	26.33 mins	G 1	P	P	P			
7	55	F	L	6/24 6/24	Watering	Delayed	Clear fluid	Opposite	L CDC	30.22 mins	G 1	P	P	P			
8	52	F	R	6/9 6/9	Watering Discharge	Delayed	Mucoid flakes	Opposite	R CDC	29.12 mins	G 1	P	P	P	Lid edema		
9	40	F	L	6/6 6/6	Watering	Delayed	Mucoid flakes	Opposite	L CDC	27.12 mins	G 1	P	P	P			
10	34	F	R	6/6 6/6	Watering	Delayed	Mucoid flakes	Opposite	R CDC	28.34 mins	G 1	P	P	P			
11	32	F	R	6/18 6/6	Watering Discharge	Delayed	Mucoid flakes	Opposite	R mucocele	30.06 mins	G 2	R	R	R	Incisional edema, Obstruction of passage	Incisional edema,Obstruction of passage	Incisional edema
12	62	M	R	6/24 6/24	Watering Swelling	Delayed	Mucoid flakes	Opposite	R CDC	29.32 mins	G 1	P	P	P			
13	29	F	R	6/6 6/6	Watering Discharge Swelling	Delayed	Mucoid flakes	Opposite	R CDC	25.32 mins	G 1	R	P	P	Mild lid edema, Mild incisional edema, Obstruction of passage		

14	60	F	R	6/24 6/18	Watering Swelling	Delayed	Mucoid flakes	Opposite	R CDC	27.42 mins	G 1	P	P	P	Mild upper lid edema		
15	34	M	R	6/6 6/6	Watering Discharge	Delayed	Mucoid flakes	Opposite	R CDC	24.01 mins	G 1	P	P	P			
16	62	F	L	6/36 6/36	Watering Discharge	Delayed	Mucoid flakes	Opposite	L CDC	25.12 mins	G 1	P	P	P			
17	65	F	R	6/9 6/6	Watering Discharge	Delayed	Mucoid flakes	Opposite	R CDC	28.24 mins	G 1	P	P	P	Lid edema		
18	70	F	L	CF 1m 6/12(P)	Watering Discharge	Delayed	Mucoid flakes	Opposite	L CDC	29.21 mins	G 1	P	P	P			
19	43	F	L	6/9 6/12	Watering Discharge	Delayed	Clear fluid	Opposite	L CDC	27.02 mins	G 1	P	P	P			
20	64	F	R	PL+PR acc CF 1m	Watering Discharge	Delayed	Mucoid flakes	Opposite	R CDC	27.32 mins	G 1	P	P	P			
21	62	F	L	6/24 6/60	Watering	Delayed	Clear fluid	Opposite	L CDC	28.24 mins	G 1	P	P	P	Upper lid edema		
22	26	F	L	6/6 6/6	Watering Swelling	Delayed	Clear fluid	Opposite	L CDC	29.12 mins	G 1	P	P	P	Lid edema		
23	22	M	R	6/9 6/6	Watering	Delayed	Mucoid flakes	Opposite	R CDC	27.02 mins	G 1	R	R	P	Lid edema, Incisional edema, Obstruction of passage	Obstruction of passage	
24	47	F	R	6/18 6/6(P)	Watering Discharge	Delayed	Mucoid flakes	Opposite	R CDC	26.33 mins	G 1	P	P	P			
25	50	F	L	HMCF PL+PR acc 6/24	Watering Discharge Swelling	Delayed	Mucoid flakes	Opposite	L CDC	27.33 mins	G 1	P	P	P			
26	69	F	R	CF 2m 6/60	Watering Discharge	Delayed	Mucoid flakes	Opposite	R CDC	28.12 mins	G 1	P	P	P			
27	34	F	L	6/9 6/9	Watering Discharge	Delayed	Mucoid flakes	Opposite	L CDC	29.12 mins	G 1	P	P	P			
28	53	M	R	CF 1m 6/12(P)	Watering Discharge	Delayed	Mucoid flakes	Opposite	R CDC	31.46 mins	G 2	Not performed	Not performed	Not performed	Lid edema,Incisional edema,Sac infection	Sac infection	Sac infection
29	45	F	L	6/18 6/12(P)	Watering	Delayed	Clear fluid	Opposite	L CDC	30. 12 mins	G 1	P	P	P			
30	55	F	L	6/24 6/24	Watering Discharge	Delayed	Mucoid flakes	Opposite	L CDC	29.32 mins	G 1	P	P	P	Incisional edema		
31	57	F	L	6/36 6/36	Watering Discharge	Delayed	Mucoid flakes	Opposite	L CDC	28.34 mins	G 1	P	P	P			
32	37	F	R	6/6 6/6	Watering Discharge	Delayed	Mucoid flakes	Opposite	R CDC	30.12 mins	G 1	P	P	P	Lid edema		

ANNEXURE V - KEY TO MASTER CHART

No. : Patient number

Sex : M = Male

F = Female

Eye : Affected eye

L = Left

R = Right

Diagnosis : L CDC = Left sided Chronic Dacryocystitis

R CDC = Right sided Chronic Dacryocystitis

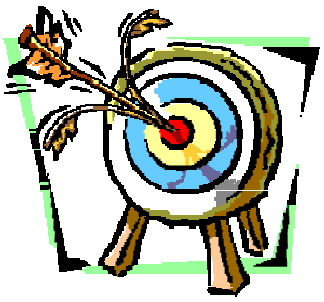
Intraoperative Bleeding : G 1 = Grade 1

G 2 = Grade 2

NLD Patency : P = Patent

R = Regurgitation

Introduction



Aims & Objectives

Review of Literature

Methodology

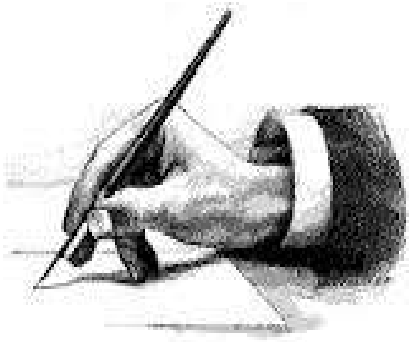
Results

Discussion

Conclusion

Summary

Bibliography



Annexure-I

Annexure-II

Annexure-III

Annexure-IV

Annexure-V