"Superficial Parotidectomy: Are drains essential?"

A dissertation submitted to the M.G.R. Medical University, Tamil Nadu: in partial fulfillment of the requirement for the M.S. Branch I (General Surgery) examination held in April 2016.

Certificate

This is to certify that the dissertation entitled "***Are drains essential in surgeries of the superficial lobe of the parotid gland?"*** is a bonafide work done by

Dr. Aditi Mishra, post graduate resident in Masters of General Surgery 2013-2016 at the Christian Medical College, Vellore, towards partial fulfillment for the MS General Surgery Branch I final examination held in April 2016.

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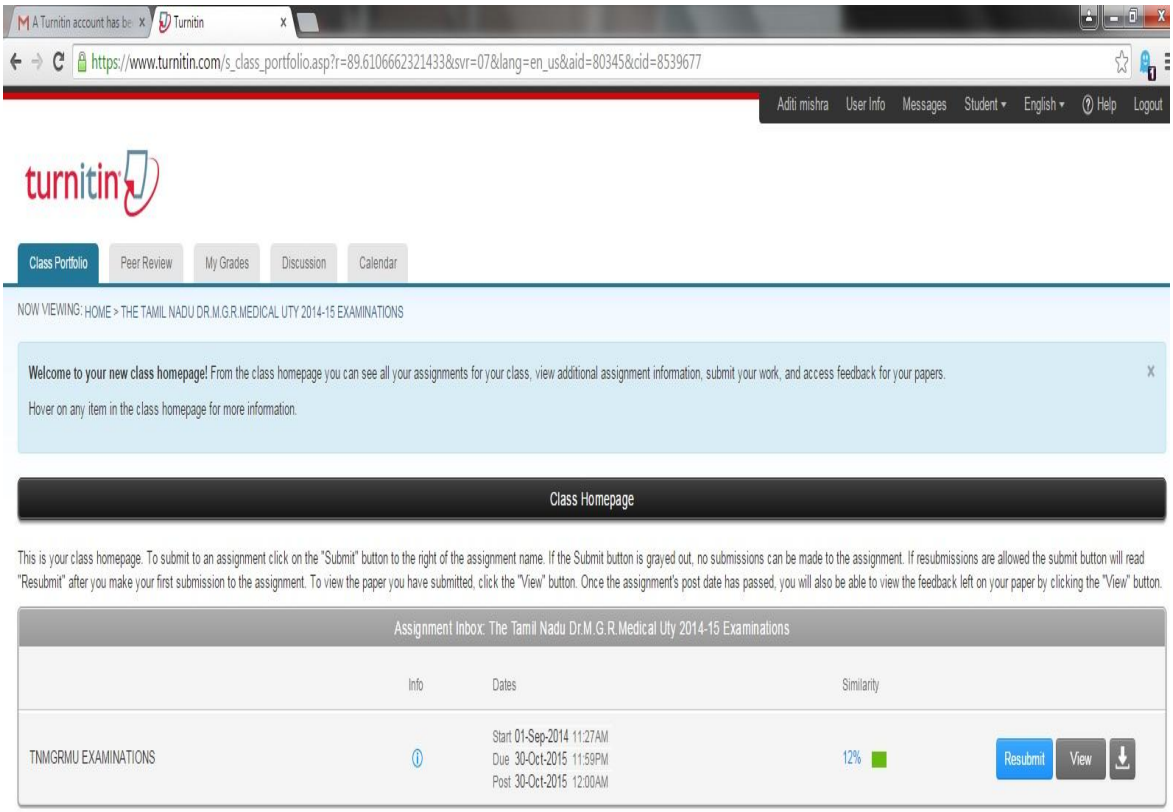
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Contents

ACKNOWLEDGMENTS

This dissertation would be incomplete without expressing my gratitude to those who were involved in its conception and completion.

I thank my guide Dr. Rajinikanth J., AssociateProfessor, Dept. of Surgery, CMC Vellore for his continuous support and guidance.

My thanks to the head of the department and the head of the unit, Dr. John C Muthusamy, Professor, Dept. of Surgery, CMC Vellore for his help and advice.

I would also like to express my thanks to my co-guides, Dr. Pranay Gaikwad and Dr. Amit J. Tirkey , for their continuing support and help towards my thesis.

I thank Dr. Benjamin Perakath, former head of the department of surgery for his support and guidance .

I am grateful to Dr. Jayaseelan, Dept. of Biostatistics, CMC Vellore for helping me with study design and statistical analysis of data and results.

I would like to express my thanks to Ms. Kavitha R., Dept. of Biostatistics for helping me with the statistical analysis of the data.

I express my sincere gratitude to all my teachers and colleagues in the Department of General Surgery for their support and encouragement.

I thank my family for their support and encouragement.

Above all I thank God for his grace and guidance.

INTRODUCTION

Superficial parotidectomy is the procedure of choice for patients with any inflammation, benign or low grade malignant tumor of the superficial lobe of the parotid gland.

Anatomically, the parotid gland is divided into two lobes, superficial and deep based on the course of facial nerve running through the gland. In superficial parotidectomy, the superficial lobe is with preservation of the deep lobe and the facial nerve. Negative pressure drains are then applied to the surgical bed so as to remove any accumulated serous fluid or blood, at a site separate from the incision. These drains are then removed later when the drain output is less than 30-50 ml or at surgeons' discretion (usually on 2nd postoperative day). (1)Purpose of the drain is to detect any bleed, prevention of seroma formation, and detection of any salivary leak.

RATIONALE

Seroma formation rates are highly variable (2% - 44%) (2)(3)(4), depending on surgical experience and center where the procedure is being undertaken. While there are studies indicating seroma formation of 44% even with drain applied(3), studies with early removal of drain even up to 8 hours after the surgery have shown seroma formation to be as low as 2%(4). Such wide variation suggests that meticulous surgical dissection and hemostasis may be more important factors in preventing seroma formation than drain insertion.

Hematoma formation is rare in patients undergoing superficial parotidectomy especially with meticulous hemostasis achieved, incidence varying from 0 to 6% (5). Owing to the clean site of the operation being undertaken and strict asepsis, infection of the incision site is not a routine finding (2-11%) (6).

Temporary facial nerve paralysis is a common complication reported following superficial parotidectomy owing to the retraction of the nerve during the procedure and there have been no reports of seroma or a vacuum drain accentuating the paralysis.

Studies questioning the use of drains in thyroid surgeries have shown no benefit (7) with some even showing a disadvantage of having a drain (8).

Similar studies relating to postoperative drains in laparoscopic cholecystectomy, breast surgeries have found to have similar results (9).

Implications of inserting drain are also to be considered. There is an additional cost incurred and in some patients hospital stay may even be prolonged. Also the drain acts as a cause for patient discomfort as patient may be unable to lie on the side of drain insertion and may have restricted mobility (1). Since the insertion site for drain is different from the incision site, there is an added scar as it heals by secondary intention (1).The effect of having a suction drain placed over the facial nerve, which comes to be superficial after surgery, remains to be evaluated. Although drains are inserted so as to remove fluid accumulation and prevent infection, drains may also increase the risk of infection by retrograde transmigration of bacteria . Drain sites

can lead to pain in the post-operative period. In the event of drain occlusion, the drains may prove harmful by causing a hematoma/ seroma and leading to nidus of infection.

Looking at the significant gaps in knowledge regarding the utility and efficacy of drains that exist today , and the lack of a standard protocol for routine drainage, we would like to scientifically evaluate the use of drains in superficial parotidectomy.

OBJECTIVES

To compare the primary and secondary outcomes of patients undergoing surgery of the superficial lobe of the parotid gland on applying a drain on the post-operative bed as opposed to not applying a drain in the post-operative bed.

PRIMARY OUTCOME:

To compare the rate of clinically significant seroma formation in patients with a drain applied vs. no drain applied.

SECONDARY OUTCOME:

To compare the rate of hematoma formation and surgical site infections in patients with a drain applied vs. no drain applied.

To compare both arms on the basis of hospital stay, need for resuturing, drain insertion or any further interventions.

LITERATURE REVIEW

HISTORY

Historically, there has been much controversy regarding the anatomy and hence possible surgery of the parotid gland. At the end of the 19th century it was widely believed that the facial nerve travelled entwined with the parotid gland and hence it was impossible to operate on the parotid gland without damaging the facial nerve.

The two lobes were first discovered by Gregoire in 1912 on conducting various animal studies and he hypothesized that the two lobes were joined by an isthmus that lay above the entry of the facial nerve.(10) In 1917, Mcwhortor confirmed the existence of two lobes of the parotid gland and hypothesized that the two lobes were connected by tissue that lay between the main trunks of the facial nerve.

The bilobed structure of the parotid gland was discovered and accepted much earlier by the French and German surgeons while the English speaking world only accepted the surgical anatomy as late as 1942.(11)

In 1947, Hamilton bailey described the surgical anatomy of the parotid gland as it is understood today and attempted superficial parotidectomy while preserving

the facial nerve. (11) Of the 77 parotidectomy he performed, 55 were superficial parotidectomies and the remaining were extra capsular dissections.

ANATOMY

The human salivary glands are divided into two groups. Major salivary glands are paired and include parotid glands, submandibular glands and lingual glands while minor salivary glands range in hundreds which line the upper aero digestive tract. The parotid glands are the largest of the salivary glands. The salivary glands serve to provide lubrication , to ease in mastication and to start the process of digestion with the help of salivary amylase enzymes.(12)

EMBRYOLOGY

The salivary glands start to develop in the fetus at 6 weeks of gestation. Solid buds of ectoderm line the primitive mouth and begin to invaginate into the surrounding mesenchyme. Thus the ducts formed are lined by ciliated epithelium while the external aspect consists of myoepithelial cells and stroma. The blind ends of the solid buds go on to form the future parotid glands while the remainder forms the Stenson's duct.

The development of the salivary glands occurs in three stages. The first stage is of Analage formation or the laying of the foundation wherein a solid bud of tissue with surrounding primitive ducts are formed. During the second stage,

there is progressive hollowing of the acini and the solid buds. The third stage marks the period of progressive maturation and development of the acini and reduction in surrounding connective tissue. The facial nerve forms a close relation with the developing gland in early embryonic stages and hence is found in close relation with the gland.

GROSS ANATOMY

The parotid gland is a pyramidal, bilobed paired gland located normally posterior to the mandible and the base of cranium, hence a normal gland is not clinically appreciable.(13) The parotid gland is encased by a tough fascia which is a condensation of the investing layer of the deep cervical fascia.(14)

The parotid gland is related to the masseter muscle on the medial aspect and laterally to the posterior belly of the digastric muscle and the stylohyoid muscle. The parotid bed i.e. structures found deep to the deep lobe of the parotid gland include the internal jugular veins, the internal and external carotid arteries, the last four cranial nerves and the styloid process with the associated muscles. (13)

There is no natural plane found between the gland and the skin and in order to access the gland surgeons raise either a subcutaneous or a subplatysmal flap. The gland is also found to be tethered by fibrous attachments to the external auditory canal, the fibrous layer of the sternocleidomastoid and the mastoid process.

Several important structures traverse the parotid gland, which include:

1. the retro mandibular vein
2. the terminal branch of the external carotid artery that divides into the maxillary artery and the superficial temporal artery;
3. Intraparotid lymph nodes.
4. branches of the facial nerve(15)

THE FACIAL NERVE

The facial nerve is closely associated with the parotid gland and arbitrarily divides the gland, along with the retro mandibular nerve, into the superficial and deep lobe. The differentiation between the lobes is purely anatomical and there is no difference seen microscopically between the two lobes of the parotid gland. There is no anatomical plane that exists between the two lobes.

The nerve exits the skull at the stylomastoid foramen and enters the gland 1 cm from the point of exiting the skull. The Pes Anserinus marks the division of the nerve into two major trunks of the facial nerve i.e. the temporal and the cervicofacial trunks. These subsequently divide to give rise to the branches which are temporal, upper and lower buccal branches, zygomatic, cervical and the marginal mandibular nerves.

The facial nerve is responsible for the motor innervation of the face and any damage to the same may lead to temporary or permanent damage to the function of the one side of the face.

Landmarks commonly used to aid identification of the trunk of the facial nerve are:

1. Conley's pointer -1 cm inferior and deep to the tip of the inferior portion of the cartilaginous canal which indicates the position of the facial nerve,
2. The superior border of the posterior belly of the digastric muscle.

Parotid Duct

It exits the parotid gland from its anterior border to travel parallel to the zygomatic bone, about 1cm below it, anterior to the masseter. It takes a sharp turn at the buccinator muscle to pierce it, and enter the oral cavity opposite to the second upper molar tooth.(16)

SMAS

The Superficial Muscular Apo neurotic System is a network of fibers that connects the facial muscles with the dermis. It attaches superiorly to the zygomatic arch and is continuous with the platysma. The facial nerve courses deep to the platysma and the SMAS in the lower face. Within two layers of

parotid fascia, which extend from the zygoma above, the parotid glands are contained.

HISTOLOGY

Histologically, the salivary glands are divided into predominantly serous, mucous or mixed glands according to the type of secretions produced. The functional unit of salivary glands consists of acini, ducts and associated myoepithelial cells.

Serous glands have pyramidal cells with basally placed nuclei which surround the lumen. These cells have a clear cytoplasm and are mainly involved in secretion of salivary amylase. The serous cell has multiple basophilic granules which are diastase resistant and PAS positive.

Mucinous glands have similar cells with basal nuclei. However the acinar cells contain multiples vacuoles containing mucin.The lumen is continuous with intercalated ducts into which the secretions are poured. The intercalated ducts drain the acini into the striated ducts. The intercalated ducts are lined by cuboidal cells while the striated ducts are lined by columnar cells.

The striated ducts then lead into the interlobular secretory ducts which are lined by pseudo stratified epithelium and occasional mucus cells.

Myo-epithileal cells are stellate cells which are noted to surround the acini and the intercalated ducts. These are composed of actin- myosin ultrastructure which helps in propulsion of the secretions. These cells are located between the basement membrane and the basal surface of the acinar cells and contain long dendrites that wrap around the cells. These cells are difficult to identify on haemotoxylin- eosin staining however are noted on electron microscopy. These cells also contain pinocytic vesicles, lipofuschin and glycogen granules.(17)

The parotid gland consists of the functional unit as well as intralobular and extra lobular adipose tissue which increase with age. The functional unit is mostly serous acini. There are multiple septa which divide the parenchyma. There are multiple lymph aggregates and nodes within the parenchyma which are randomly distributed in the gland. There may be Neisse Nicholson rests within the nodes which are salivary acini or duct rests .

The submandibular gland is a mixed gland with a predominance of serous glands. The sublingual gland is a mixed gland with predominance of mucus glands.

The minor glands of the buccal mucosa and the lateral aspect of the tongue are seromucous whereas those in the ventral tongue, retro molarpad, glossopharyngeal area and palate are predominantly mucous.

PHYSIOLOGY OF SECRETION OF SALIVA

The principal function of the salivary glands is to secrete saliva, which has digestive, lubricative and protective functions in the body.

Secretion

Within the gland, potassium [K+] concentration is high and sodium [Na+]concentration is low. With increasing flow rate, [K+] concentration decreases slightly to level off at a constant value, whereas [Na+] concentration increases.

Chloride concentration predominantly follows [Na+] concentration. Except at low levels of secretion, bicarbonate [HCO3-] secretion in saliva is hypertonic compared to plasma.

Within the duct, [Na+] and [Cl-] are reabsorbed, whereas [K+] and [HCO3-] are secreted. At higher flow rates, less time is available for this exchange and hence the concentration is isotonic to plasma. At lower flow rates, [K+] is higher in

Saliva, [Na+] and [Cl-] are lower, and [HCO3-] remains hypertonic to plasma.

Mostly, however, saliva is hypotonic to plasma since [Na+] and[Cl-] reabsorption is greater than secretion of [K+] and [HCO3-].

Saliva also contains the compounds alpha amylase, lingual lipase,

Lysozymes, glycoprotein, IgA secretory piece and lactoferrin which are detailed below. Also secreted are organic blood group antigens A, B, AB and O. The protein

Kallikrein is also secreted by saliva, which converts plasma protein into bradykinin.

Salivary secretion is regulated by both parasympathetic and sympathetic branches, but more by the parasympathetic arm, through the facial and glossopharyngeal nerves. It leads to acinar activation and ductal transport, leading to glandular vasodilatation and myoepithelial cell contraction. Subsequent to Acetyl choline stimulation of muscarinic receptors, inositol trisphosphate is formed which causes increased Calcium [Ca++] concentration intracellularly. The source of this [Ca++] is either from intracellular stores or from plasma. Thus, [Ca++] acts as a second messenger which controls the volume of salivary secretion. Further secretion is maintained by acetylcholinesterases, which inhibit the breakdown of Acetylcholine (ACh). Atropine, the muscarinic antagonist, decreases salivation by competing with (ACh) for the salivary receptors. Sympathetic stimulation is via the superior cervical ganglion. It leads to myoepithelial contraction, similar to parasympathetic stimulation. Changes in blood flow occur which is biphasic. Initial vasoconstriction occurs due to sympathetic stimulation of alpha-adrenergic

receptor activation which is followed by vasodilatation due to a buildup of vasodilator metabolites. Nor epinephrine binds to alpha adrenergic receptors to form cAMP (3'5'Cyclic Adenosine Monophosphate). This leads to protein phosphorylation and enzyme activation, with increased mucus content in saliva. Antidiuretic hormone (ADH) and Aldosterone affect salivary secretion byincreasing [K+] concentration and decreasing [Na+] concentration. However, it does not affect the rate of secretion.(12)(18)

In the unstimulated state, the quantity of saliva secreted amounts to 1 Liter per day. Sixty nine percent is contributed by the submandibular glands, 26% by parotid, and 5% by the sublingual glands. In the stimulated state, however, 2/3rd of the secretion is from the parotid gland. The minor salivary glands produce 7-8% of salivary flow regardless of stimulation.

Stimulants of salivary secretion include the presence of food in the mouth, chewing and nausea. Inhibitors include sleep, dehydration, fear and fatigue.

Role in digestion

Saliva contains Ptyalin, an alpha-amylase which cleaves the internal alpha-1,4-glycosidic bonds of starch to form maltose, maltotriose and alpha-limit dextrins. Its optimal pH is 7, and rapidly degrades at more acidic pH and readily denatures at ph.<4. Even so, it remains active to break down up to 75% of the carbohydrate content of a meal within the stomach as effective mixing of the food with saliva

takes place in the confines of the stomach. In the absence of Ptyalin, pancreatic amylase breaks down carbohydrates within the small intestine.

Additionally, the lingual salivary glands secrete lingual lipase, which breaks down

triglycerides.

Role in Lubrication

The mucus constituent of saliva facilitates lubrication of food during chewing by mixing with saliva. It eases the process of swallowing. It is also important to facilitate speech.

Role in Protection

Saliva has several antibacterial properties. The secretory piece i.e. a binding agent (glycoprotein) for IgA forms a complex with IGA which is active against bacteria and viruses. Lysozyme in saliva is antibacterial by causing bacterial agglutination and by activating autolysin which degrades cell walls. Lactoferrin in saliva is an iron chelator which inhibits the growth of bacteria which require iron for survival.

Other roles

Saliva serves as a protective buffer by diluting harmful substances and lowering temperature of hot food items. It also helps to clear foul tasting substances. In the stomach, it helps to neutralize acid to some extent. Lack of

salivation, Xerostomia, leads to apthous ulcers, buccal infections and dental

caries.

EPIDEMIOLOGY

The global annual incidence of salivary gland pathologies varied from 0.4-13.5 cases per 100,000 population.(17)

The malignant salivary tumors comprise of 0.4- 2.6 cases per 100,000 population. There is a geographical variation in the incidence and the type of tumors noted. A seven fold increase in Warthin's tumor is noted in Denmark while the incidence of muco-epidermoid carcinoma in U.K(2.1 %) is much lesser as compared to the world incidence of the same (5-15 %).

In the United states, salivary gland tumors form 6% of all head and neck tumor.

There is also an ethnicity related variation in the incidence of tumors. The Malay population of Malaysia has been reported to have a higher incidence of salivary

gland tumors as compared to the Indian or the Chinese resident population. A racial predominance is also seen in the white population.(19) Lymphoepithelial carcinomas which are noted in 1% of salivary gland carcinomas, have a higher incidence in Inuit and Asian populations.(20)

The parotid gland is the most commonly affected amongst the major salivary glands. Of the salivary tumors, the parotid gland tumor contribute about 80-85 % of the pathology.(21)

7-11 % of the salivary gland tumors arise from the submandibular glands while less than 1 % arise from the sublingual glands. The minor salivary glands contribute 9- 23 % of the pathology.(17)

The benign tumors of the salivary glands predominate with an incidence of 54-79% while the malignant tumors range between 21-46%.

There is peculiar variation in the incidence of malignant tumors with respect to the glands affected. The parotid gland is affected by malignancy in 15-32% of the patients. 41-45% of submandibular tumours are malignant while 70-90% of sublingual tumours are malignant. 50% of minor gland tumours are malignant . The floor of the mouth and other minor salivary glands can have malignant tumors 90 % of the time.(17)

The female gender is more commonly affected however a variation may be noted with the type of the tumor.(17)(22)

Benign tumors are most commonly seen at the age of 40-50 years while malignant tumors are seen more commonly at the age of 50-60 years. (17)

Of all the salivary gland tumors, Pleomorphic adenoma is most common with an incidence of 45-50 %. The second most common pathology is Warthin's tumor. The most common malignancy is muco-epidermoid carcinoma in the major glands while the minor glands are most often affected by canalicular adenomas and polymorphous low-grade adenocarcinoma.

ETIOLOGY

Radiation exposure has been noted to have a causative relation with tumor of the salivary glands. Following the Hiroshima and Nagasaki atomic bombings, a rise in the number of parotid gland tumors was noted. A life span study of survivors of the bombing showed an increase in the incidence of mucoepidermoid carcinoma and of warthin's tumors in patients with increasing radiation dosage.(23)

An increased relative risk of 3.5 for benign and 11 for malignant salivary neoplasm was noted in the said populations.(17)

Exposure to therapeutic radiation for head and neck carcinomas is also noted to have a significantly elevated risk for salivary gland tumors. A series also noted a

higher incidence of salivary gland tumors in patients with repeated exposure to dental x-rays.(17)

An increased risk of salivary gland tumor has been noted with patients receiving iodine 131 treatment as there is an increased concentration of the same in the gland.(17)

Therapeutic medical radiation treatment to the head or neck and ultraviolet light treatment to the head or neck were associated with increased risk with an odds ratio of 2.6 and 1.9 respectively .(24)

Multiple viruses have been noted to have an association with salivary gland tumors. These include EBV, HIV and SV40. EBV has been noted to have a correlation with patients affected with lympho-epithelial carcinoma of the salivary glands. A relation has also been noted between SV40 viruses and pleomorphic adenoma.(17)

Patients infected with HIV have also been noted to have a higher risk for developing salivary gland carcinomas. In a study conducted in southern Europe, the age standardized incidence was 33.6 for HIV positive men to develop salivary gland tumors. (25)

There is no positive correlation proven with HPV virus infections.(17)

Certain histological types have a predominance noted in patients with HIV namely lymphoepithileal and less commonly, squamous cell carcinoma.(20)

A definite influence of environmental factors has been noted in the development of both benign and malignant tumors.

Intake of certain foods rich in Vitamin C has been noted to have a preventive role in salivary gland malignancies. Foods rich in cholesterol may pre-dispose to salivary gland tumors.(26)

An increase in incidence of Warthin's tumors has been noted in patients with chronic smoking.(19)

Occupational exposure to asbestos, nickel, and rubber factories has been noted to have a higher risk for development of salivary gland carcinomas.(17)

Hormonal influence over parotid swellings has been widely studied. An associated overexpression of progesterone receptors has been noted in patients with recurrent parotid pleomorphic adenoma.

NON NEOPLASTIC PATHOLOGY OF THE PAROTID GLAND

The salivary glands are affected by benign inflammatory conditions as well as tumors.

Non neoplastic conditions include acute and chronic sialadenitis.

Sialolithiasis is more commonly encountered in submandibular glands, however parotid gland is involved in 6-20 % of the patients affected with the same.

Sialolithiasis is more commonly seen in patients with dehydration, gout, trauma and smoking. Certain drugs such as diuretic and anticholinergics predispose to the formation of these stones(27).

Acute sialadenitis may be associated with sialolithiasis with complaints of pus formation, severe pain and erythema. The same usually subsides with conservative management with antibiotics and analgesia, however with recurrent disease these patients may require surgical intervention.

Rarely the patients may have persistent pus discharge with sepsis and complete blockage of the parotid duct secondary to the stones which may be indicative of a parotid abscess formation. Further evaluation with CT may be required .

Complete chronic obstruction of the salivary duct leads to subsequent drop in the production of the salivary secretion from the affected gland. The gland hence becomes firm in consistency and may resemble a focal mass lesion. Such a lesion may not require any surgical intervention.

The most common cause of parotid gland enlargement is viral parotitis secondary to mumps. The parotid gland appears to be enlarged within 48 hours of the initial prodromal symptom complex.

Multiple other viruses have been implicated in the pathogenesis of the same. These include coxsackie viruses A and B, Epstein-Barr virus parainfluenzavirus, influenza A, and echovirus.

Acute suppurative parotitis is most commonly caused due to staphylococcus aureus. However in post-operative patients the infection is usually polymicrobial. Predisposing factors include elderly patients who have prolonged hospital stay, who are intubated or have been dehydrated.(28)

WHO histological classification of tumours of the salivary glands

Malignant epithelial tumours
Acinic cell carcinoma
Mucoepidermoid carcinoma
Adenoid cystic carcinoma
Polymorphous low-grade adenocarcinoma
Epithelial-myoepithelial carcinoma
Clear cell carcinoma, not otherwise specified
Basal cell adenocarcinoma
Sebaceous carcinoma
Sebaceous lymphadenocarcinoma
Cystadenocarcinoma
Low-grade cribriform cystadenocarcinoma
Mucinous adenocarcinoma
Oncocytic carcinoma
Salivary duct carcinoma
Adenocarcinoma, not otherwise specified
Myoepithelial carcinoma
Carcinoma ex pleomorphic adenoma
Carcinosarcoma
Metastasizing pleomorphic adenoma
Squamous cell carcinoma
Small cell carcinoma
Large cell carcinoma
Lymphoepithelial carcinoma
Sialoblastoma

Benign epithelial tumours
Pleomorphic adenoma
Myoepithelioma
Basal cell adenoma
Warthin tumour
Oncocytoma
Canalicular adenoma
Sebaceous adenoma
Lymphadenoma
Sebaceous
Non-sebaceous
Ductal papillomas
Inverted ductal papilloma
Intraductal papilloma
Sialadenoma papilliferum
Cystadenoma
Soft tissue tumours
Haemangioma
Haematolymphoid tumours
Hodgkin lymphoma
Diffuse large B-cell lymphoma
Extranodal marginal zone B-cell lymphoma

NEOPLASTIC CONDITIONS OF THE PAROTID GLAND

Neoplastic lesions of the parotid gland include benign as well as malignant lesions of the parotid gland.

The parotid gland is most commonly affected by benign lesions as mentioned above.

Pleomorphic adenoma is the most common tumor to affect the salivary glands. Of all pleomorphic adenomas, 80 % arise from the parotid gland, while 10 % arise from the submandibular and the sublingual glands. The lower pole of the parotid gland is the most commonly affected. These tumors are usually well circumscribed and encapsulated, however the capsule may have a variable thickness. These are mixed tumors histologically as the cells are usually epithelial or myoepithelial in origin while the stroma is usually myxoid or chondromyxoid in appearance. These tumors are usually slowly progressive, painless and may very rarely have any neural involvement. (17)

Recurrence rate after surgery for pleomorphic adenoma varies from 1.6 – 3.4 %.(29) (6)

Warthin's tumor is a benign disease almost exclusive to the parotid gland. It is commonly referred to by multiple synonyms such as papillary cyst adenoma lymphomatosum ,cystadenolymphoma and adenolymphoma.(30) The lesion

presents as a painless cystic, fluctuant swelling in the parotid gland. A strong causal association has been noted with cigarette smoking.(19)

Histologically, Warthin's tumors are well demarcated, thinly encapsulated lesions with both solid and cystic components. These lesions tend to be bilateral in 5-18 % of the patients.(30)(17)

Basal cell adenoma is a rare pathological diagnosis in patients with parotid swelling. These are usually basaloid neoplasms of the parotid gland having 2 populations of epithelial cells. These may have various histological types according to the density of cell distribution. These are usually well treated with surgery of the lesion or the affected lobe.(31)(32)

Malignant salivary gland tumours are divided into two distinct

Sub-groups:

1 Low-grade malignant tumor, e.g. acinic cell carcinoma, may mimic benign conditions clinically.

2 High-grade malignant tumours usually present as painless rapidly growing swellings in the parotid region. The tumors may present as discrete masses in the gland with infiltration of the skin. They may also present as diffuse induration in the region of the parotid gland with no obvious mass.

Table Classification of salivary gland tumours (simplified)		
Type	**Sub-group**	**Common examples**
I Adenoma	Pleomorphic Monomorphic	Pleomorphic adenoma Adenolymphoma (Warthin's tumors)
II Carcinoma	Low grade High grade	Acinic cell carcinoma Adenoid cystic carcinoma Low-grade muco-epidermoid carcinoma Adenocarcinoma Squamous cell carcinoma High-grade muco-epidermoid carcinoma
III Non-epithelial tumours		Haemangioma, lymphangioma
IV Lymphomas	Primary lymphomas Secondary lymphomas	Non-Hodgkin's lymphomas in Sjögren's syndrome
V Secondary tumours	Local Distant	Tumours of the head and neck especially Skin and bronchus
VI Unclassified tumours		
VII Tumor-like lesions	Solid lesions Cystic lesions	Benign lymphoepithelial lesion Adenomatoid hyperplasia Salivary gland

TREATMENT

Superficial parotidectomy is the standard treatment of benign as well and low grade malignancies of the parotid gland. The procedure involves removal of the parotid gland lying anterior to the facial nerve while delineating its anatomy and preserving it.

The surgery is undertaken under endotracheal intubation. Local infiltration is advised to allow ease of dissection and to help define planes. The surgery is carried out in stages.

INCISION AND RAISING THE FLAP

A “Lazy S” incision as described by Blair is marked at three different points to facilitate cosmetic closure. The incision runs in a slight S-curve from the preauricular incision halfway down the neck.(15) A modified facelift incision with a SMAS flap is also described by some authors.(2)

Scalpel or scissors are used to develop the skin flap in an anterior direction. The plane of dissection is well below the hair follicles, just above the parotid fascia. The skin flap is raised beyond the anterior border of the gland. The incision is undermined posteriorly in the cervical region allows access to the anterior aspect of the sternomastoid muscle.

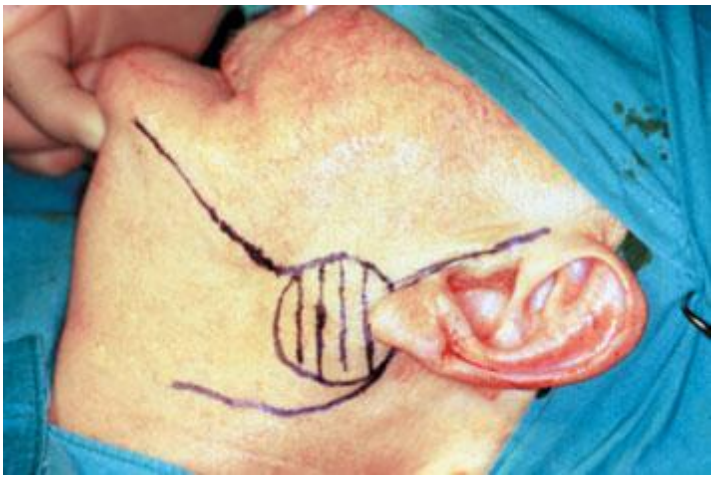


Fig1: Marking of the modified Blair incision

MOBILISATION OF THE GLAND

The objective of this stage is to free the posterior aspect of the gland so as to identify and preserve the facial nerve.

Two avascular planes are developed – along the anterior aspect of the sternocleidomastoid muscle and along the anterior border of the bony and cartilaginous external auditory meatus anterior to the tragus. The two planes are then joined by a combination of scissor and blunt dissection.

The external jugular vein is often encountered at the lower end of the dissection, and is ligated. The gland is gradually mobilized after identifying the posterior

belly of the digastric muscle by sharp dissection up to the anterior aspect of the mastoid process.

LOCALISATION OF THE FACIAL NERVE

The facial nerve is identified by markers as described above. Hemostasis must be attained prior to and during identification of the facial nerve. During dissection, only a bipolar cautery should be used and even that should be avoided in close proximity to the nerve to avoid any thermal or electric injury to the nerve.

Immediately lateral to the nerve, lies the stylomastoid artery, damage to which can lead to bleeding and obscure the vision of the operating surgeon.

Adrenaline soaked gauze can aid in controlling ooze during this phase of surgery.

After localization of the facial nerve, sharp dissection is carried out just anterior to perineural space and the gland is mobilized from a superior to inferior fashion.

Any branch of the nerve adherent to the tumor may require to be sacrificed. Hence a reconstruction can be carried out using the greater auricular nerve.

CLOSURE

The incision is closed in layers after ensuring hemostasis. The classical description of the surgery requires a vacuum suction drain to be placed in the post-operative bed which is removed 24-48 hours after the surgery. (15)

Adequate parotidectomy is defined as a surgery of the superficial lobe of the parotid gland wherein only the affected portion of the lobe is excised. This surgery can be undertaken in patients with a proven benign lesion with almost no risk of malignant transformation.

COMPLICATIONS OF SURGERY

Complications of parotid gland surgery include:

- Infection.
- Hematoma formation
- Transection of the facial nerve and permanent facial weakness
- Temporary facial nerve weakness
- Seroma
- Facial numbness

- Permanent numbness of the ear lobe due to great auricular nerve injury
- Frey's syndrome / gustatory sweating due to aberrant innervation post operatively

DRAINS AND THEIR USAGE IN GENERAL

Suction drains are applied routinely in the surgical practice and done so for a variety of reasons such as:

- To prevent the accumulation of fluid (pus, blood and serous fluids).
- To minimize dead space.
- For early detection of any anastomotic leak

Types of drains:

Open or closed

Open drains (Including plastic sheets or corrugated rubber) drain fluid on into a stoma bag or a gauze pad. They are likely to increase the risk of infection.

Closed drains are formed by plastic tubes draining into a reservoir.AS the system is closed, the risk of infection is reduced.

Active or passive

Active drains are drains acting by negative pressure (which may be low or high pressure) with an intention to actively remove any fluid static in the post-operative bed.

Passive drains have no suction and work according to capillary action and the differential pressure between body cavities and the exterior. Intra- abdominal drains are usually passive drains so as to avoid any vital structures being pulled into the drain due to the vacuum applied.

According to composition

Silastic drains are relatively inert and induce minimal tissue reaction.

Red rubber drains can induce an intense tissue reaction, sometimes allowing a tract to form (this may be considered useful - for example, with biliary T-tubes).

Suction drains are used regularly for surgeries of the head and neck. These can further be sub-divided into high negative pressure and low negative pressure drains. High negative pressure drains typically drain into a bottled reservoir while low negative usually drain into a bulb reservoir or a four way vacuum drain.

These drains are usually inserted at a site separate from the incision.

High negative pressure drains consist of a plastic reservoir with indicator wings which help in monitoring vacuum pressure and an opening to allow drainage. As these are closed-circuit, sealed systems, they are safer and easier to monitor and allow for safe disposal of drained fluids.

These drains are typically emptied every 24-48 hours and are typically removed after their function is served. According to quantity and quality of fluid draining, the drains are removed.

COMPLICATIONS OF DRAINS •

1. Breakage—Drains are made of strong polyvinyl chloride plastic or silicone and are therefore not expected to break. However, breakage can occur during removal of the drain. Surgical exploration may be required if breakage does happen.

2. Difficulty in removal— it may become difficult to remove a drain if it remains inserted for a long time. Sometimes the drain may be sutured onto the underlying tissues. The wound may have to open to facilitate removal of the drain. Hence the scar would have to heal with secondary intention with a poor scar.

•

3. Inadvertent removal—Drains may get caught in other tubing or wires and may get pulled out. This may lead to pain and bleeding.
4. Infection—though drains are inserted to prevent accumulation of fluids and hence any infection, they may lead to a retrograde spread of infection. Typically, drains are removed as soon as they are draining a small volume (e.g., < 25 mL per day; < 1 mL per hour) to reduce this risk.
5. Occlusion—Drain tubes can become blocked by blood clot, omentum, or tissue. This can lead to the formation of a seroma or a hematoma and can actually serve as a nidus of infection.
6. Pain—Drain sites can be tender and may prevent the patient from lying on the side of insertion. Some patients may have restricted mobility due to apprehension regarding the drains and hence may be more prone to have deep venous thrombosis.
7. Unsightly scar—a drain site may form a pigmented scar as it heals by secondary intention. To avoid this, the drain should be brought out in a skin crease.
8. Visceral perforation— drains, if left for a long duration, can erode into viscera.

Fig 2: Closed suction drains

IN DEPTH ANALYSIS OF KEY STUDIES

There has always been controversy regarding the role of post-operative drainage. Multiple studies have evaluated the need for post-operative drainage following various surgical procedures.

The rationale for placing drains varies according to the location and nature of the surgery being carried out.

While in thyroid surgeries, the concern is regarding possible hematoma formation and subsequent airway compromise, the use of drains in patients undergoing breast or hernia repair is to prevent possible seroma and wound site infection.

Traditional wisdom was for placement of drains, however with a view of the possible complications arising from drains, there has been quite a controversy over the past few decades regarding the actual advantage offered by drains post operatively.

Even intra- abdominal surgeries such as laparoscopic cholecystectomy which traditionally required drainage have been found to have no advantage with placement of drains. A Cochrane meta-analysis was undertaken by Gurusamy et al reviewed 12 studies with 1831 participants of which 915 were randomized to drain versus 916 participants randomized to 'no drain'. There was no significant

difference noted between the two after analysis on the basis of complications and ease of detection of the same.(33)

In South Korea, a randomized controlled trial looked at the use of insertion of a Jackson Pratt drain in the pediatric population with perforated appendicitis. There was surprisingly a higher chance of complications especially formation of intra- peritoneal abscess formation in patients with drains placed post operatively (22.2% vs. 6.8%, P = 0.00 2). The hospital stay was also noted to be prolonged in the drain arm.(34)

In colorectal surgery, drains are expected to prevent abscess, fluid collection or hematoma formation or to act as an indicator of postoperative complication, or to reduce the severity of complications. However drains have been found not to have any use in any of the above mentioned proposed functions. A Meta-analysis by Tsujinaka et al showed reduced complications in the non-drain group.(35)

POST OPERATIVE DRAINAGE OF THYROID:

Studies as long back as 1988 , as done by Wihlborg et al showed no advantage of drains being placed after routine thyroid surgery.(36)

A prospective randomized controlled trial by Suslu et al, comparing outcomes for patients with regards to drainage in patients undergoing uncomplicated thyroid surgery found no advantage of placing a drain in the post-operative bed. (37)

A similar study was undertaken by Khanna et al which showed that placement of drains after routine thyroid surgery may actually increase fluid collection rather than reduce it. The formation of seroma or hematoma was not related to the size of nodule or type of surgery. The drain was found notto influence complications, and instead lead to an extra scar. Patients who could not be discharged with drains actually were noted to stay longer in the hospital. Hemostasis and finesse of dissection were considered more important factors in determination of seroma formation.(8)

A study conducted by Deveci et al in Turkey conducted a randomized controlled trial with patients following thyroidectomy and compared the length of hospital stay, postoperative pain, complications, and volume of fluid collected in the operative bed. There was no significant difference in the outcomes noted in the patients with drains as compared to those with no drains. A significant difference was noted with regards to hospital stay which was prolonged for patients with drain placed.(7)

A Cochrane meta- analysis conducted by Samraj and Gurusamy compared 13 randomized controlled studies with 1646 participants. 11 studies compared no drainage with drainage and found no difference in re-operation rates; wound infections and incidence of respiratory distress. Post-operative seromas/ hematomas needing drainage or aspiration were significantly decreased by drains (RR 0.51, 95% CI 0.27 to 0.97), but no significant difference was noted after further analysis of the 4 high quality studies (RR 1.82, 95% CI 0.51 to 6.46).(38)

Further a significant increase in the duration of hospital stay was noted in patients with drains in situ.

While the above studies commented on routine thyroidectomy and excluded any additional procedures of the neck simultaneously, a randomized controlled trial by Lee et al found no advantage of drainage in patients undergoing thyroidectomy with central neck dissection. A significant decrease in hospital stay was noted in patients with no drainage was noted with a p value of < 0.05.(39)

HEAD AND NECK & PAROTID SURGERY

Parotid surgeries have traditionally had a drain placed post operatively to prevent any complications. However, theneed for drainage and its optimal duration has not been defined.It is accepted in general to remove the drain if the 24 hour output is between 15- 50ml, varying upon the institution's protocol.

A case control study by Chen et al described post-operative drainage in patients undergoing partial superficial parotidectomy. A significant drop in post-operative drainage was noted within 24 hours of insertion of drains. Hence chen at al suggested that the removal of drains should happen within 24 hours of insertion.(40)

Mofle and Uquahart conducted a study in Wisconsin with 69 patients undergoing superficial parotidectomy. They advocated early removal of drain within 8 hours of the surgery and reported an incidence rate of seroma of around 2 %.(4) A prolonged hospital stay was noted in patients with late removal of drains and the drainage was noted to be considerably higher in patients with malignant pathology compared to benign pathology.

A Randomized controlled trial conducted by Jiang et al compared patients undergoing superficial parotidectomy and assigned patients into a pressure group and a suction group. Patients in pressure group had a pressure bandage

placedafter removal of drains while suction group had a drain placed throughout the procedure. The drain was removed once the output dropped to less than 20 ml in 24 hours. There was no significant difference in the incidence of salivary fistulae or seroma for patients in either group.(41)

A prospective study was undertaken by Harris et al to look at post-operative drainage in patients undergoing major head and neck surgery. 47 patients were included in the study and the drain was removed after 24 hours once the volume dropped below 50 ml. The rate of seroma formation was found to be 9 % .A comparison was made retrospectively with 22 patients having undergone surgeries at another center. The drains in these patients were not removed till a drop to25 ml over 24 hours was noted. Early removal of drain was found to have a significant drop in hospital stay.(42)

Plaza et al conducted a case control study in Spain observing the outcomesof partialsuperficial parotidectomy. Partial superficial parotidectomy(PSP) was defined as removal of a cuff of surrounding parotid gland, but not of normal parotid tissue away from the tumor. While the incidence of the serious complications such as nerve injury etc.was lesser in the PSP arm, the incidence of seroma was significantly higher.They found the incidence of seroma formation to be 28 % in PSParm as compared to 16 % in superficial

parotidectomy in the post-operative period with drains placed in situ in both arms.(43)

Witt et al conducted an observational study regarding the formation of sialocoeles after partial superficial parotidectomy as compared to near total parotidectomy. 100 consecutive partial superficial parotid surgeries and 20 consecutive near-total parotidectomy procedures for formation of a postoperative sialocoele were studied. Evaluation for sialocoele formation was done at 1 week and 1 month postop. The initial 18 sialocoeles were treated with aspirations while the last 21 sialocoeles were treated with observation. Pressure dressings were not used for either group and the drains were removed on the first post-operative day. It was found that there was no difference in the outcome in the patients for whom aspirations were done as compared to those for whom conservative measures were followed. The sialocoeles resolved within 1 month of the surgery. The authors also added that repeated aspirations led to fluid collecting the dead space within 24 hours of aspiration and hence advised only conservative management of seromas.(44)

A retrospective study by Nourei et al looked at the incidence of complications after surgery for benign lesions of the parotid gland. They postulated that a higher incidence of salivary fistula and sialocoeles was noted in patients presenting with sialadenitis as compared to benign lesions.(6)

Tuckett et al studied post-operative complications and found that the extent of resection of the parotid gland was a significant factor determining outcomes. An overall incidence rate of 16.7 % was noted for formation of sialocoeles.Sialocoele was defined as a postoperative fluid-filled neck swelling, confirmed by aspiration of fluid. A salivary fistula was defined as leakage of fluid through the neck wound during the postoperative period when eating.Complications were treated by compression dressings and serial aspiration of fluid collection, until resolution.The authors found that the risk of facial nerve injury increased with increasing extent while the risk of sialocoeles and salivary fistulae were inversely proportional to the extent of resection.(45)

A search for studies using PubMed, google scholar and EuropePubMed did not yield any randomized controlled studies comparing the use of drains in comparison to no drains in parotid surgery.

Though classically drains are used for parotid surgeries, their drainage is seen to be less than the defined significant volume within 8- 24 hours. Furthermore the incidence of seroma varies from 2- 44 % in spite of a drain being placed in the operative bed. On the basis of available literature, it is evident that drains may not be necessary after 24 hours. Also, the rates of sialocele seem to be influenced based on the pathology, extent or surgery.

When seroma/sialocoele does occur, serial aspirations do not seem to alter the outcome and conservative management without aspiration was found be equally effective.

Various studies have found multiple other confounding factors which may be responsible for seroma such as type of surgery, use of surgicel, operating time etc. The time of removal of drain has been defined as within 24 hours of surgery.

Furthermore multiple studies done in other parts of the body have shown that drains contribute significantly to patient discomfort, prolonged hospital stay and hence cost of treatment.

It was hence our intention to evaluate the need for post-operative drainage in patients undergoing surgeries of the superficial lobe and any arising wound complications.

RESEARCH QUESTION

We proposed a research question to see: “Is there any difference in surgical outcomes and post-operative complications in patients undergoing surgery of the superficial lobe of the parotid gland on application of drains as compared to omission of the same. We hence proceeded with a prospective, randomized controlled, non-inferiority trial to assess the outcomes in patients undergoing superficial parotidectomy especially the incidence of clinically significant seroma.

NULL HYPOTHESIS

There is significant difference in outcomes in patients, with an advantage noted in patients having a drain being placed post operatively after surgery of the superficial lobe of the parotid gland.

METHODS

Institutional Review Board (IRB) and Ethics Committee approval was obtained. (Appendix 1)

All patients diagnosed with superficial parotid tumours were referred to our department. An informed consent was obtained (See Appendix) in the patient's own language.

INCLUSION CRITERIA

Patients diagnosed to have benign parotid pathology and undergoing surgery of the superficial lobe of the parotid gland were included in the study.

EXCLUSION CRITERIA

A. Patients aged <18 years of age
B. Pregnant women
C. Patients on anticoagulant therapy
D. Patients undergoing additional head and neck procedures at the time of parotidectomy
E. Any on-table conversion to total conservative parotidectomy or radical parotidectomy due to gross findings suggestive of malignancy.
F. Not consenting
G. Clinical and histopathological evidence of malignancy prior to surgery

METHODOLOGY

- **Method of randomization:** Subjects were randomly allocated into either of the arm by block randomization. 50%, 25% and 25% blocks of 6, 4 and 2 will be done respectively. This was done using SAS software.
- **Method of allocation concealment:** Sealed Opaque envelops generated by computer software as described above by the biostatistician.
- **Blinding and masking:** The trial was a non-blinded, non-masked study in view of the nature of intervention and outcomes under comparison.

Primary Outcome: Incidence of clinically significant seroma in the post - operative period{ time frame : up to 1st OPD visit}

Defined as post-operative swelling which is confirmed by the aspiration of clear fluid from the same.

Seroma was graded as per Common Terminology Criteria for Adverse Eventsversion 3.0 (CTCAE):

grade 1: Asymptomatic.

grade 2: Symptomatic; medical intervention or simple aspiration indicated.

Grade 3: Symptomatic, interventionalradiology or operative intervention indicated.

Proportion of seromas formed in patients having drained in situ was compared with those not having drain in situ.

Secondary Outcome:

1. Hematoma formation

2.Wound site infection as per CDC CRITERIA

SUPERFICIAL INCISIONAL SURGICAL SITE INFECTION

- ❑ Infection occurs within 30 days
- ❑ involves only skin and subcutaneous tissue of the incision
- ❑ at least one of the following:

1. Purulent drainage from the superficial incision

2. Organisms isolated from an aseptically obtained culture of fluid or tissue from the superficial incision

3. At least one of the following signs or symptoms of infection: pain or tenderness, localized swelling, redness, or heat and superficial incision is deliberately opened by surgeon, unless incision is culture-negative

4. Diagnosis of superficial incisional SSI made by a surgeon or attending physician

3. **Prolonged hospital stay**
4. **Gaping of the wound**
5. **Need for resuturing**
6. **Repeated opd visits**
7. **Need for antibiotics**

Target sample size and rationale:

Non-inferiority - Two Groups - Parallel – **Two proportions - Equal Allocation**			
Proportion in the standard treatment	0.2	0.2	0.2
Proportion in the new treatment	0.2	0.2	0.2
Observed/Expected difference in proportions	0	0	0
Non-inferiority margin	-0.15	-0.18	-0.19
Power (1- beta) %	80	80	80
Alpha Error %	5	5	5
Required sample size in each group	88	61	55

Hence a median sample size of 50 was taken in each arm with a total sample size of 100.

We consider that a difference in the rate of complications of less than 5% is of no clinical importance and the non-inferiority margin was chosen to be 5%. The sample size was established at 50 patients in each group to provide appropriate statistical power analyses

Statistical Analyses:

Data was screened for extreme values and outliers using Box-Cox plot and histograms. Data was entered using EPIDATA software and analyses using Excel. Per Protocol and Intention to treat analyses were done. The difference in seroma rates was presented with 95% CI. The conclusion was based on whether the lower limit covers the non-inferiority margin or not.

PROTOCOL

The patients were randomized at the end of the surgery, prior to skin closure, to prevent any bias. A 200 mlVario drain was applied in the post-operative bed. The patients were then shifted to the ward and monitored. They were monitored for any obvious swelling, seroma formation, facial nerve function, hematoma formation or surgical site infections.

The patients were then discharged as per the protocol described below and asked to review in the next OPD – 5-7 days from the surgery. Suture removal was routinely done at this time. In case of any complications, they were advised to report to the ward or inform the investigator by telephone.

1. Drain arm: The drains were emptied every 24 hours and were kept till the output was less than 30 ml over 24 hours. If the drain was removed for any other reason, the reason for the same was documented.The patients were discharged either on the day of drain removal or with the drain if the

volume was higher than 30- 50 ml. If the patients were discharged with the drain, they were taught regarding management of the drain and were asked to review in the outpatient department.

2. Non drain arm: the patients were shifted to the ward and were discharged on the next day if there were no complications. In case of any complications, the same was documented.

OUTPATIENT DEPARTMENT:

The patients were instructed to report on 5^{th}- 7^{th} day post-operative to OPD. They were evaluated for any evidence of seroma, hematoma, surgical site infection and facial nerve function. Any abnormality was reported to the senior surgeons in the unit and findings were confirmed prior to any

Intervention. Sutures were removed by the 7^{th}post-operative day.

The patient was also asked to report to the OPD for the biopsy and was assessed at the same time.

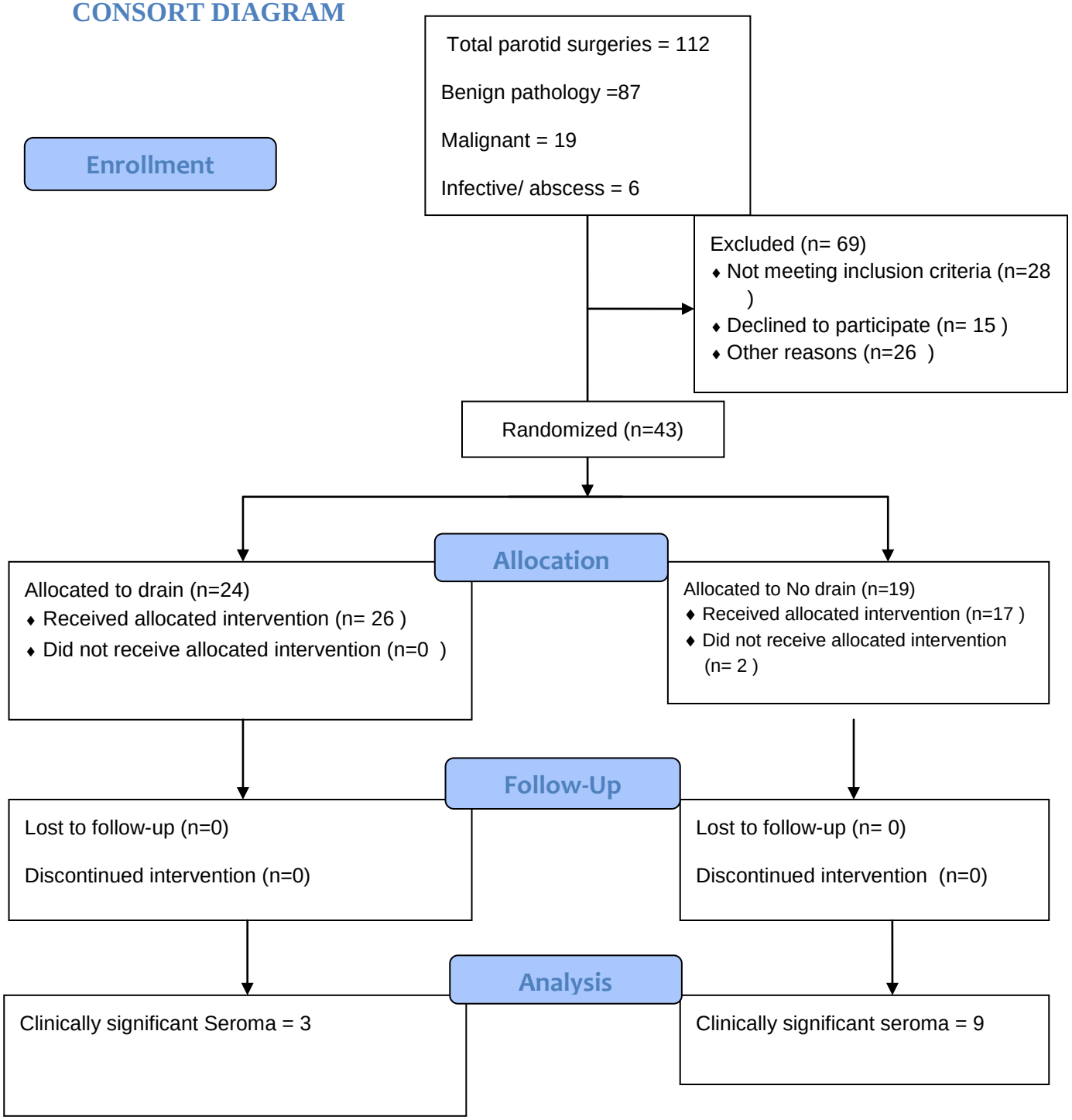
If a patient was found to be fit by this time, he/ she were declared to be fit for discharge from Vellore.

In case of a clinically significant seroma, under aseptic precautions, the same was aspirated and the volume was documented. The patient was

subsequently asked to report to the ward on a daily basis or in case of worsening of symptoms. In case of persistent drainage requiring multiple aspirations, a pressure dressing was applied and if there was no relief, a drain was inserted under aseptic precautions. In case of seroma, the removal of sutures was delayed as wound healing was expected to be prolonged. The wound was serially inspected for gaping, in which case the surgical site was resutured.

Repeated OPD visits, prolonged stay in Vellore were recorded.

CONSORT DIAGRAM



RESULTS

A total of 45 patients were recruited during the study period. 2 patients were excluded from the analysis due to conversion to total conservative or radical parotidectomy. 24 were randomized to drain arm while 19 were randomized to No drainarm. Of the 19 patients randomized to the no drain arm, 2 patients had a drain placed due to intra- operative findings at the end of the surgery at the discretion of the surgeon. Both Intention to treat (ITT) analysis and per protocol (PP) analysis was done to derive the results.

The patients were analyzed as per epidemiological parameters as well as for outcomes such as incidence of seroma, hematoma, and surgical site infections.

DEMOGRAPHICS

1. Gender

Of the 43 patients recruited, 31 were males (72.09%) while the remaining were females (27.91%).

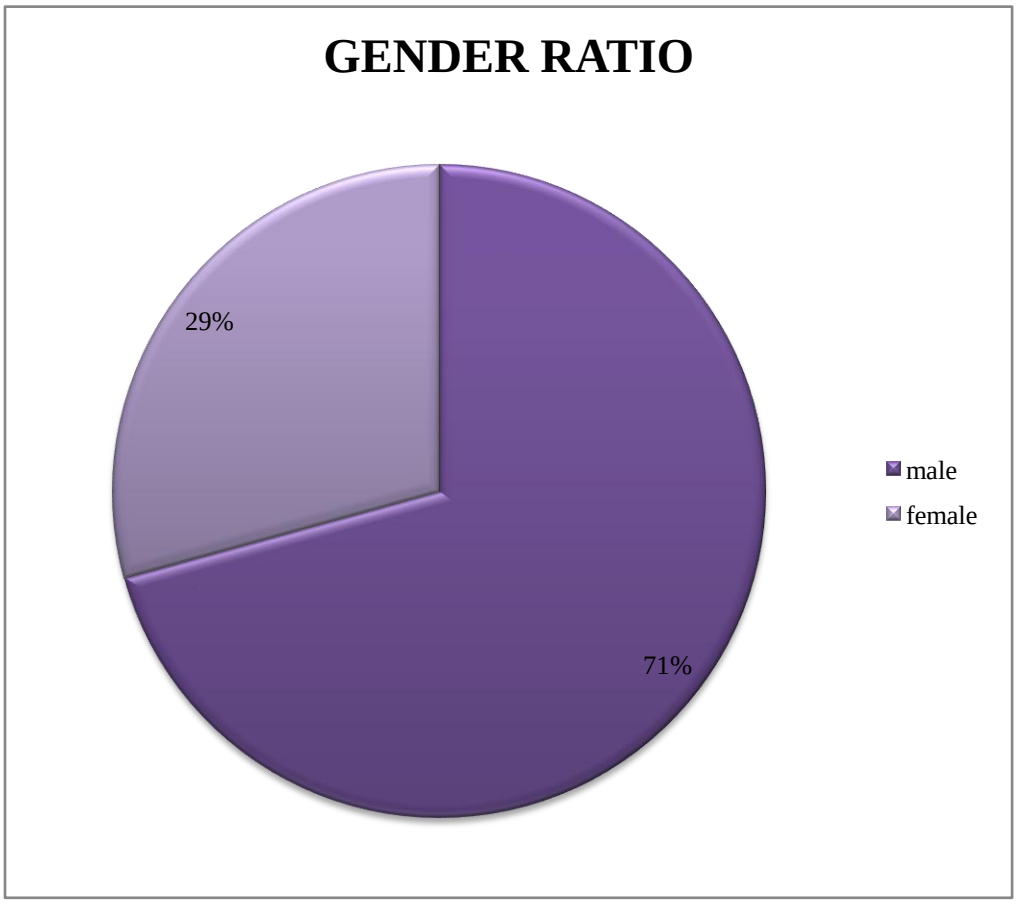


Fig.3 The ratio of males and females in the sample population

2. Duration of complaints

   20 of the patients had complaints for the past 1- 5 years, while 12 had complaints for less than 1 year. 6 patients had complaints of parotid lesions for the past 5- 10 years while 5 had complaints for more than 5 years.

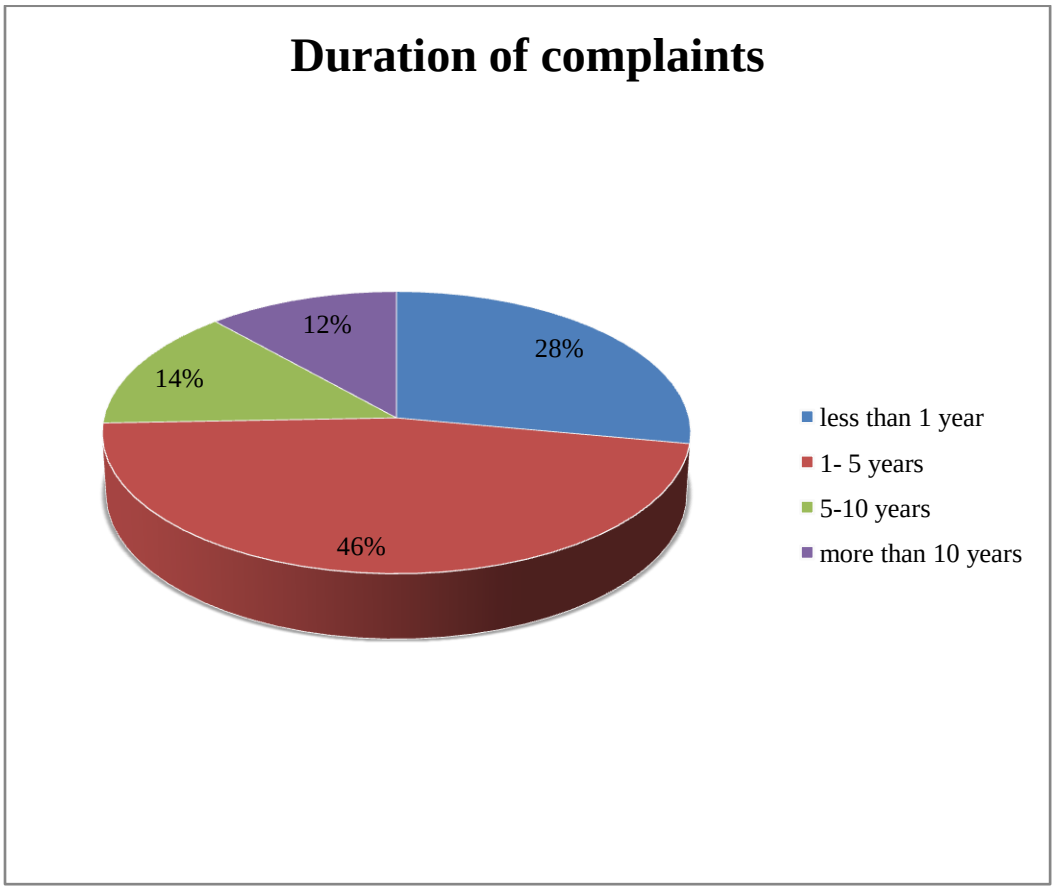


Fig4: Pie chartdepicting duration of complaints

3. Side of lesion

There was an equal distribution with regards to the side affected. Right sided lesions were 21, 20 of the lesions were left sided while 2 patients had bilateral lesions.

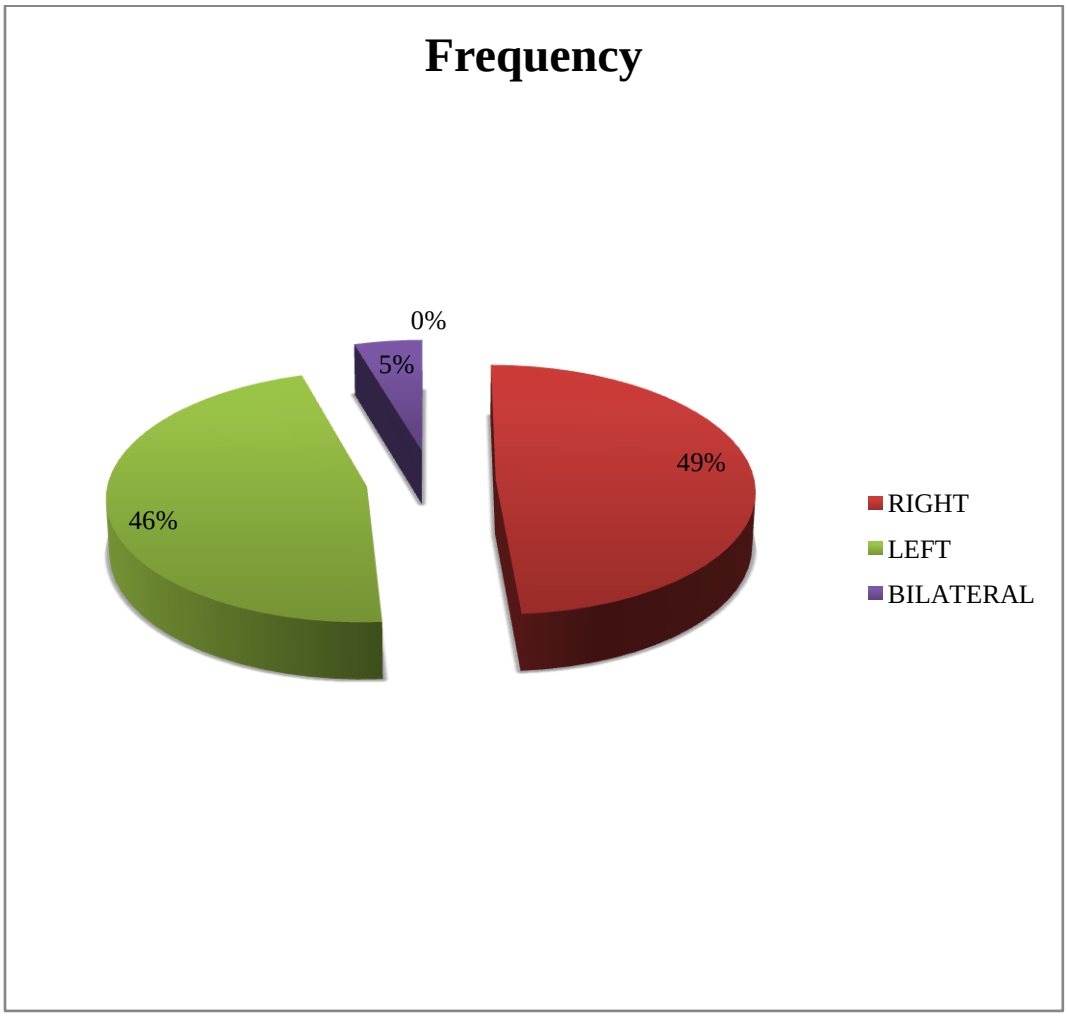


Fig.5: Laterality of lesion

4. Address

A majority of the patients were from West Bengal (18 patients, 41.86%), Tamil Nadu (10 patients, 23.26%) and Jharkhand (7 patients, 16.28%). 2 of the patients were from Bangladesh (4.65 %).

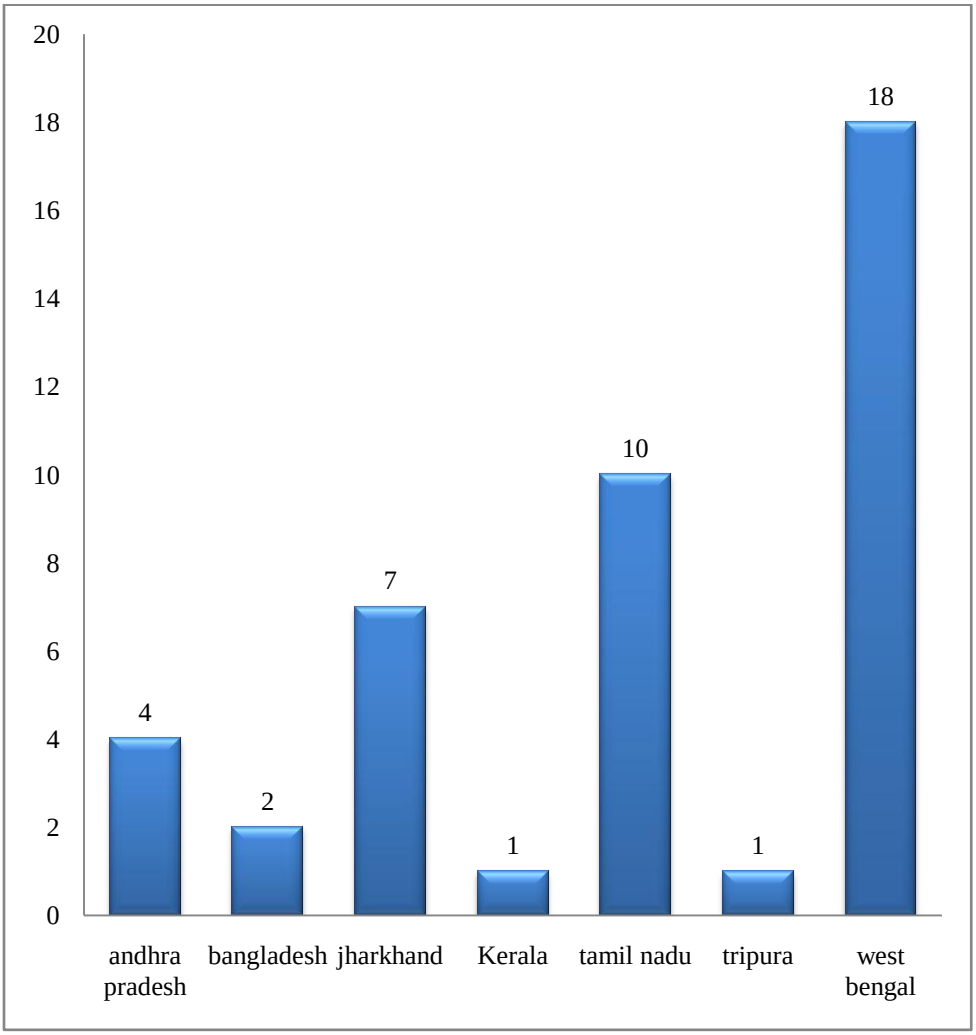


Fig 6: The demographic profile of patients undergoing superficial parotidectomy at our center.

5. Comorbid illnesses

   Of the 43 patients originally recruited, only 14 had prior comorbid illnesses.16.28% of the patients were known diabetics while 9.3 % patients were affected with hypertension.

   Totally 68.89 % of the patients had no prior comorbid illnesses while 31.11 % had prior comorbid illnesses.

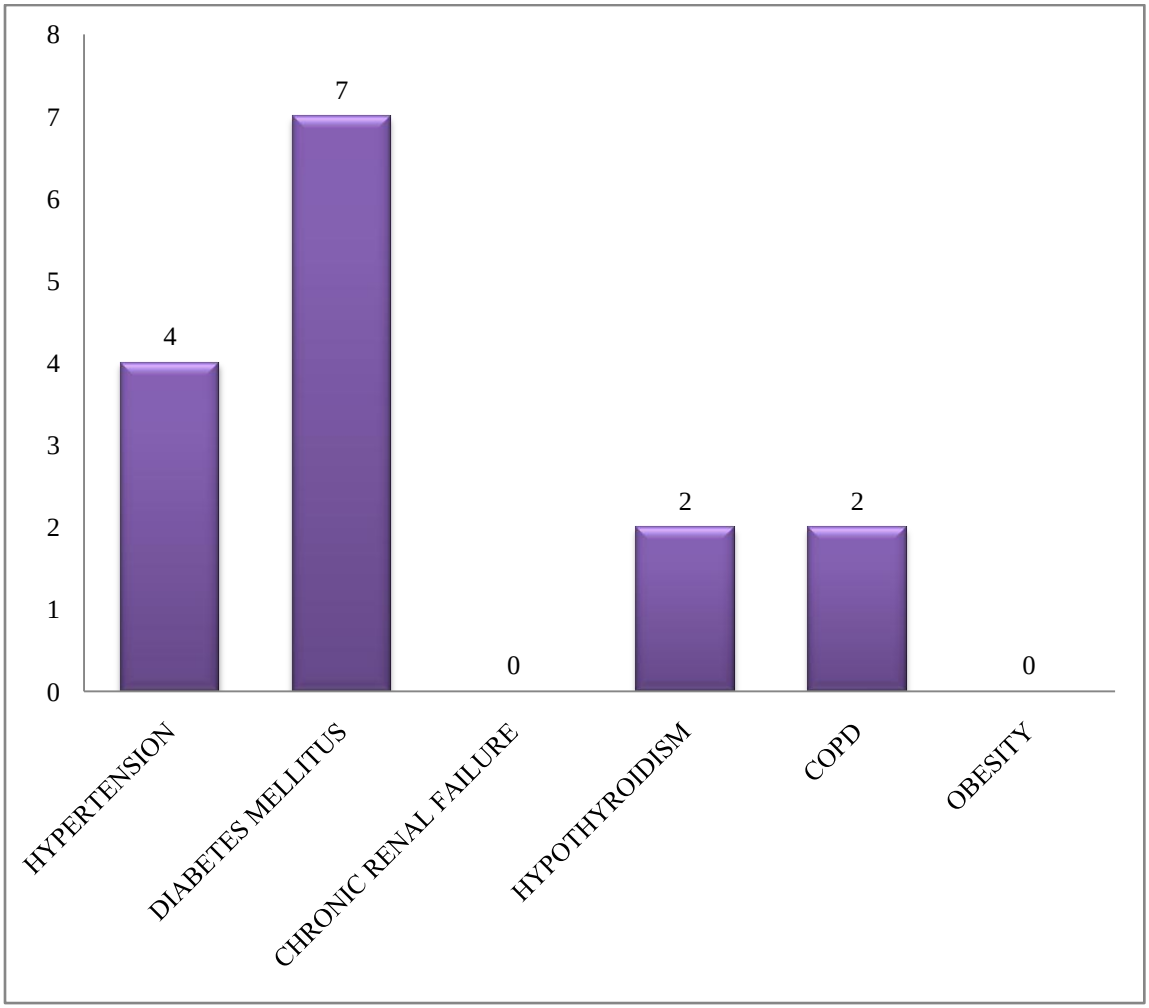


Fig.7: Frequencies of comorbidities in our patients

6. Prior surgeries

3 of the total patients recruited had been operated earlier.

Table 1: Frequency of prior surgery				
prior	**Frequency**	**Percent**	**Cumulative Frequency**	**Cumulative Percent**
No	40	93.33	42	93.33
Yes	3	6.67	45	100.00

Table 2:Time elapsed since previous surgery				
Duration	**Frequency**	**Percent**	**Cumulative Frequency**	**Cumulative Percent**
< 1 year ago	1	33.33	1	33.33
>1 year ago	2	66.67	3	100.00

Two of the patients had ipsilateral lesions operated while one had a contralateral lesion operated upon.

Variable	N	Median	Minimum	Maximum
POD 1 output	25	35.000000	5.0000000	90.0000000
POD2 Output	15	30.000000	0	90.0000000
POD3 output	4	50.000000	40.000000	75.0000000
POD4 output	3	30.000000	30.000000	80.0000000
Date of drain removal	25	3.0000000	2.0000000	6.0000000

Table 4: The drain output according to the post-operative day

The drain arm was monitored every 24 hours and output was recorded. The majority of the patients had the drain removed at 48 hours after surgery. The median volumes draining on the first and second post-operative day were 35 and 30 cc respectively.

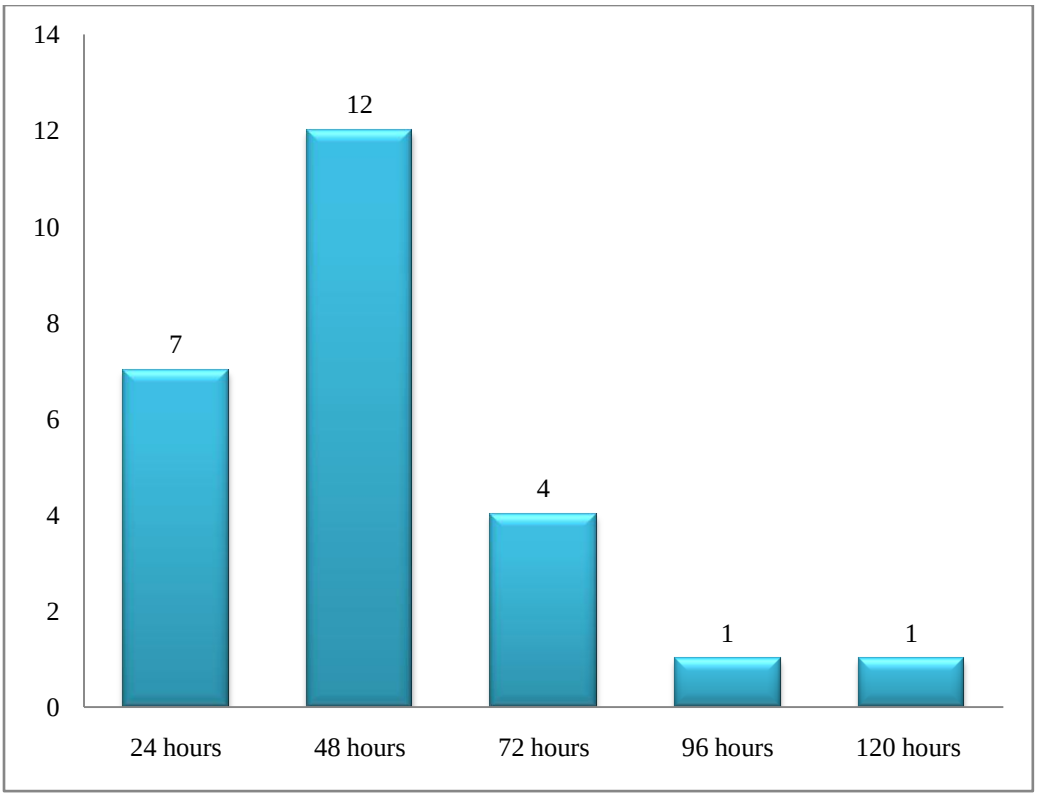


Fig.8: Drain removal since the day of surgery

REASON FOR DRAIN REMOVAL:

The reason for the removal of drain was also documented during the course of the study and was divided into the following categories:

- <30 ml
- surgeon's discretion
- nonfunctional
- slipped out
- others

Only one patient was discharged with drain and was advised follow up on OPD basis.

Table 5: Reason for drain removal				
	Frequency	**Percent**	**Cumulative Frequency**	**Cumulative Percent**
< 30 ml output	23	95.83	23	95.83
Slipped out	1	4.17	24	100.00

It is common practice to remove the drain as soon as it is less than 30 ml over 24 hours.

95.83 % of the patients in the drain arm had drain removed for this reason.

Only 1 patient had the drain slipping out before a drop in output.

Biopsy

Patients with benign pathology, as per clinical and fine needle aspiration, were included in the study. However,any patients found to have malignancy after histopathological assessment were included in the study and followed up as per the protocol described above.

Majority of the patients operated had pleomorphic adenoma (48.84%) while Warthin's tumor was the second most common pathology.

Table 6: Histopathology of the lesions excised				
Biopsy	**Frequency**	**Percent**	**Cumulative Frequency**	**Cumulative Percent**
basal cell adenoma	4	9.30	4	9.30
Kimura's disease	1	2.33	5	11.63
lipoma parotid	1	2.33	6	13.95
low grade mucoepidermoid carcinoma	3	6.98	9	20.93
malignant salivary neoplasm- mammary analogue carcinoma	1	2.33	10	23.26
mild chronic sialadenitis	1	2.33	11	25.58
Myoepithelioma	1	2.33	12	27.91
pleomorphic adenoma	21	48.84	33	76.74
salivary gland fatty infiltration	1	2.33	34	79.07
sinus tract with granulation tissue	1	2.33	35	81.40
warthin's tumor	8	18.60	43	100.00

Of the 43 patients included, 4 patients were diagnosed to have low grade malignancies on histopathological assessment of which 3 were low grade muco-epidermoid carcinoma while 1 patient had mammary carcinoma analogue.

1 patient had chronic sialadenitis. 1 patient underwent parotidectomy for a branchial fistula and the pathology for the same was reported to be a sinus tract with granulation tissue.

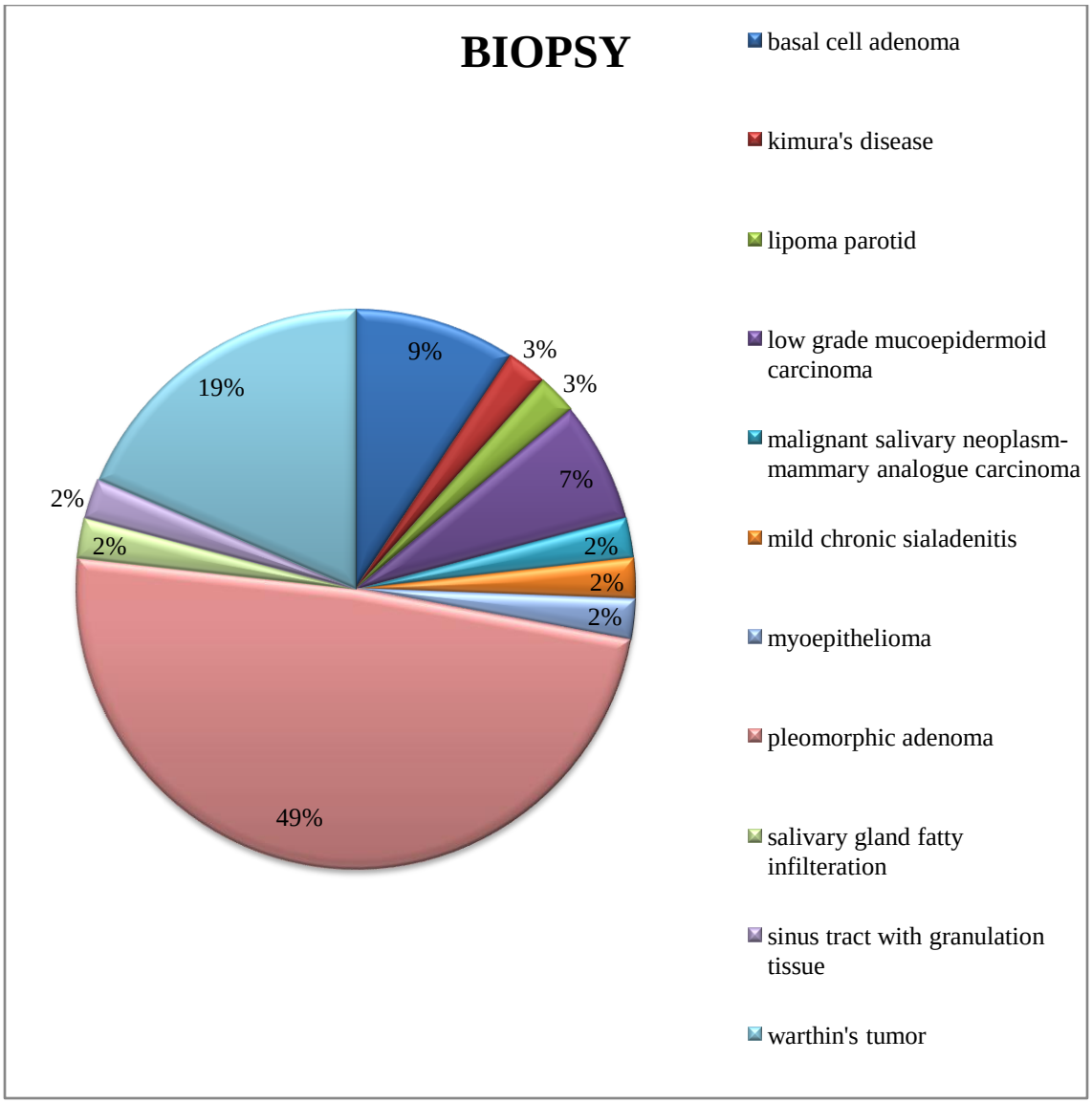


Fig. 10: Histopathology of the lesions operated upon

SEROMA IN COMPARISON TO DRAIN INSERTION

There were 43 patients who were recruited as per our protocol. 24 were randomized to drain group while 19 were randomized to no drain group.

However, 1 patient who wasrandomized to no drain arm eventually had a drain placed, as per the decision of the surgeon (protocol violation). Hence we have analyzed our results as per Intention to treat as well as per protocol analyses.

12 patients were detected to have clinically significant seroma requiring an intervention. Of these, 9 patients were in no drain arm and 3 were in drain arm. The overall incidence rate was 27. 90 %, with 20.9 % arising in the non-drain group.

As per Per Protocol analysis:

Table 7: Seroma formation Vs. drain application

Frequency Percent	**Drain**		
Seroma	**No**	**Yes**	**Total**
No	8 18.60	23 53.49	31 72.09
Yes	9 20.93	3 6.98	12 27.91
Total	17 39.53	26 60.47	43 100.00

P value as per this result was 0.0052 and was deemed significant

ITT ANALYSIS:

Table 8: seroma formation vs. randomization to drain			
Frequency Percent	**Randomization**		
Seroma	**Drain**	**No drain**	**Total**
NO	22 51.16	9 20.93	31 72.09
YES	2 4.65	10 23.26	12 27.91
Total	24 55.81	19 44.19	43 100.00

The P value as per ITT analysis was 0.002 and was also considered significant.

The above results show that the incidence of Clinically significant seroma was significantly higher in the patients with no drain as compared to the drain group.

We also analyzedthe need for aspiration in patients with drain and no drain.

Table 9: Seromas requiring aspiration			
Aspiration	**Drain**		
Frequency **Percent**	**No drain**	**Drain**	**Total**
No	10 23.26	24 55.81	34 79.07
Yes	7 16.28	2 4.65	9 20.93
Total	17 39.53	26 60.47	43 100.00

There was a significant need for aspiration in patients in the no drain group.

In the non-drain arm, of the 9 patients detected to have seroma, 7 required aspirations. In the drain arm, of the 3 patients detected to have seroma, 2 required aspirations. No statistical significance was found.

The mean volume aspirated in no drain arm was 28. 8 cc with a standard deviation of 19.9 whereas the mean volume aspirated in the drain arm was 18.75cc with a standard deviation of 1.76. There was no statistical significance found due to small number of seroma in the drain arm.

Table 10:Average volume aspirated					
drain	N	Mean	Std Dev	Minimum	Maximum
No	7	28.8571429	19.9054312	5.0000000	55.0000000
Yes	2	18.7500000	1.7677670	17.5000000	20.0000000

CORRELATION OF SEROMA WITH HISTOPATHOLOGY:

The relation of seroma formation with the final histopathology was also compared and was not found to be significant.

Though of the 4 malignant cases, 3 did develop seromas, this was not found to be statistically significant.

Biopsy	Frequency	Percent
basal cell adenoma	2	16.67
low grade mucoepidermoid carcinoma	2	16.67
malignant salivary neoplasm- mammary analogue carcinoma	1	8.33
mild chronic sialadenitis	1	8.33
pleomorphic adenoma	4	33.33
sinus tract with granulation tissue	1	8.33
warthin's tumor	1	8.33

TABLE 11: Histopathological correlation with seroma formation

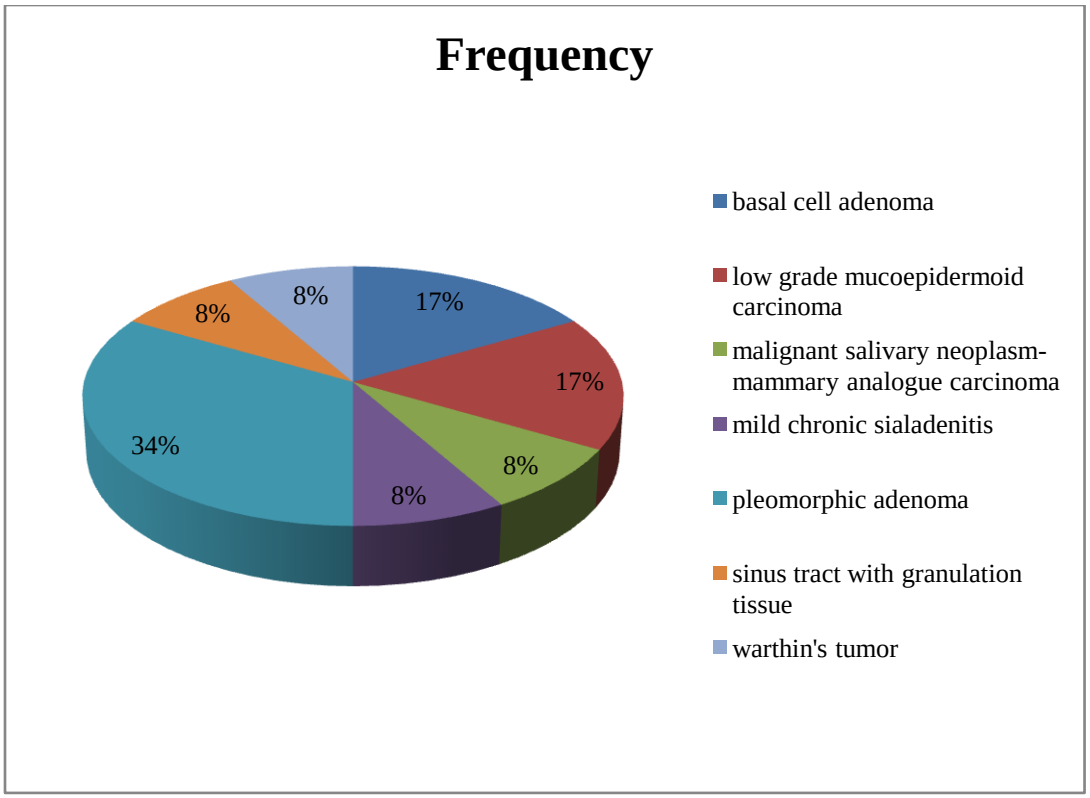


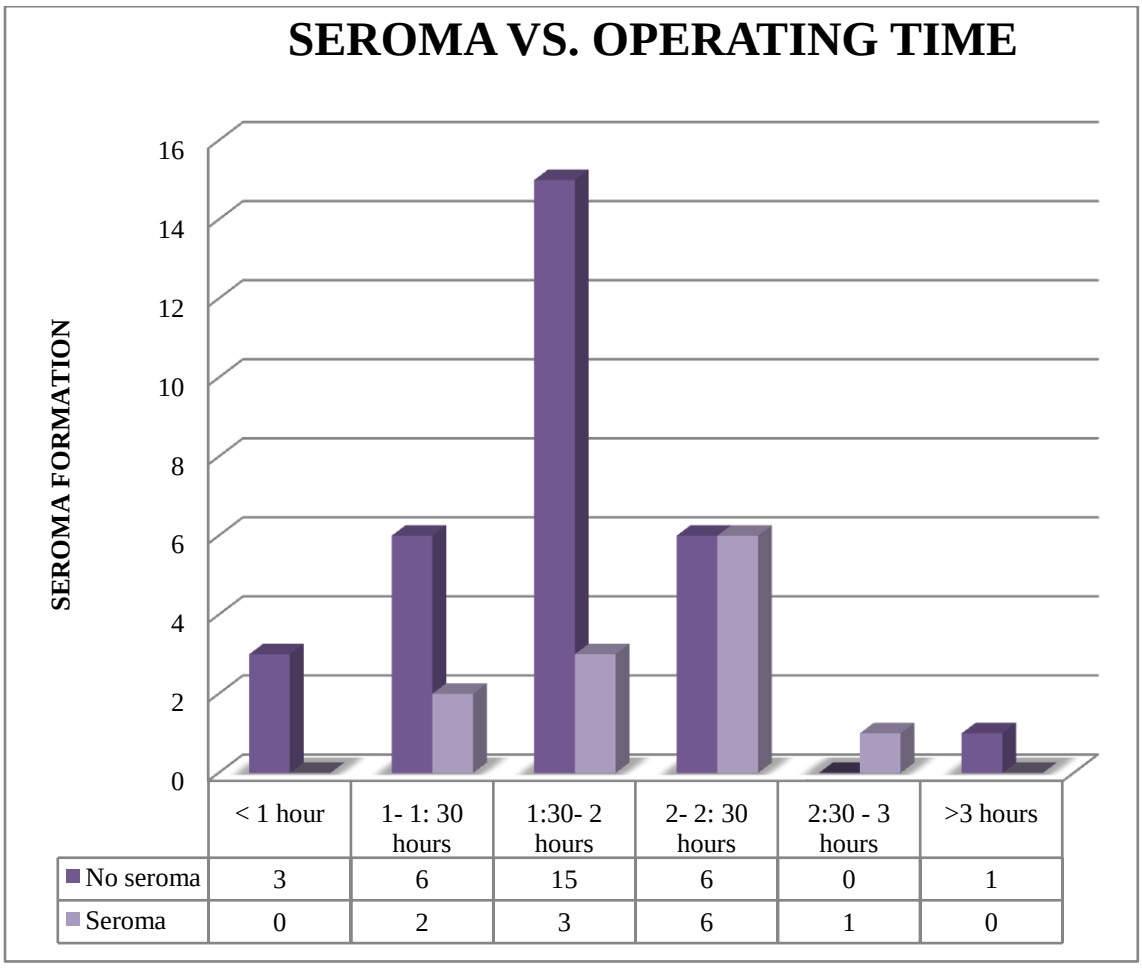
Fig 10: histopathology of patients found to have seroma

CORRELATION BETWEEN SEROMA AND OPERATING TIME

The overall average operating time was 2 hours.

The average operating time in the patients with seroma was around 2 hours and 10 minutes while with patients with no seroma was less than 2 hours.

There was no statistical difference between the two.



CORRELATION BETWEEN SISE OF THE LESION AND SEROMA FORMATION:

The size of the specimen was recorded as per the pathologist and the length, breadth and depth were noted. Of the 43 patients, these details were not available for one patient. We derived the volume of the specimen from the three dimensions in order to see any correlation with size of the lesion and seroma formation.

The mean length, breadth and depth were 5.17 cm, 3.81 cm and 2.34 cm respectively.

The average length of specimen in patients with or without seroma was 5.0 and 5.7 cm respectively.

The average breadth of the specimen was 3.7 and 4.0 in patients with or without seroma.

The average depth was 2.3 and 2.5 cms respectively for seroma and no seroma.

The volume of the specimen was a product of the above three parameters. The minimum volume was 0.75 cc while the maximum volume was 130.2 cc. The Median volume was 45. 7 cc. The Quartiles were calculated for and found to be 22.5 and 88.75 cc respectively.

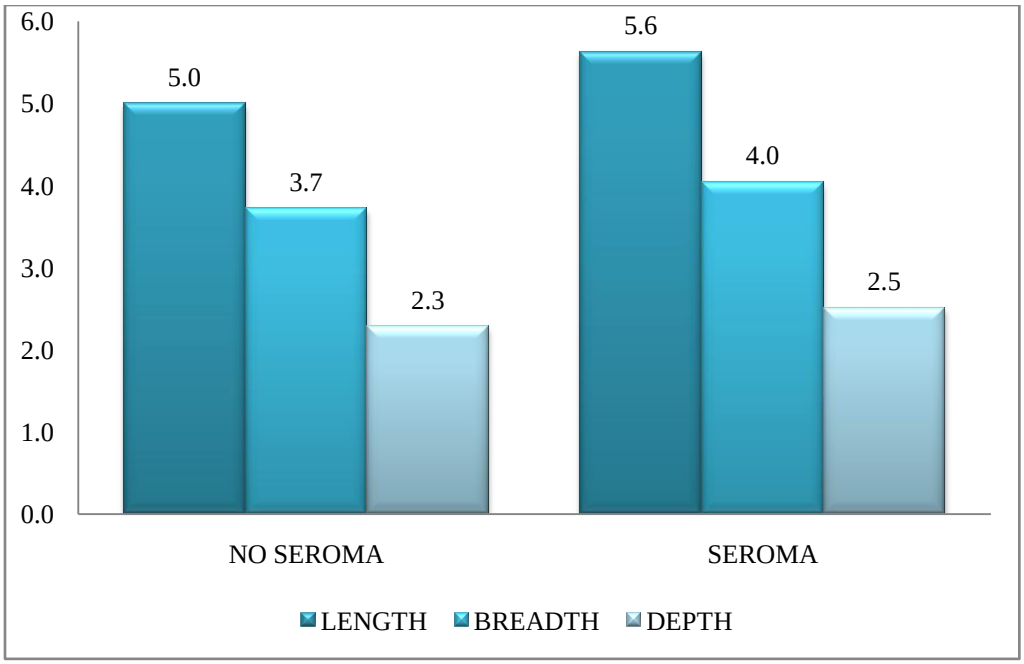


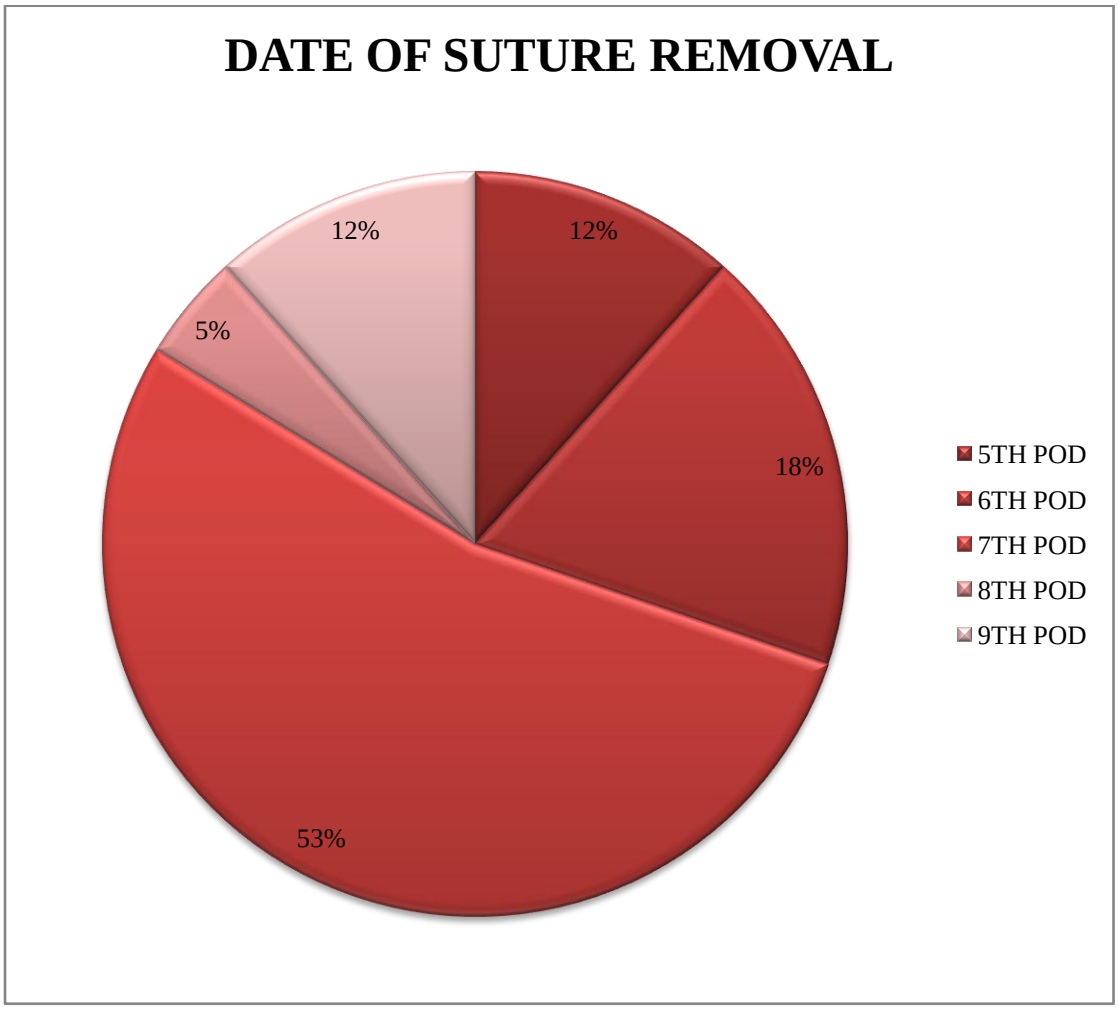
Fig 12: comparison of the average dimensions of the specimen resected in patients with seroma as compared with no seroma.

Table :Seroma formation Vs. volume of specimen				
Frequency Percent	**Volume of specimen**			
Seroma	**0-22.5**	**22.5-88.04**	**>88.04**	**Total**
No seroma	9 21.43	14 33.33	7 16.67	30 71.43
Seroma	2 4.76	7 16.67	3 7.14	12 28.57
Total	11 26.19	21 50.00	10 23.81	42 100.00
Frequency Missing = 1				

There was no significant difference in the incidence of seroma with respect to the specimen dimensions.

AVERAGE TIME OF SUTURE REMOVAL

It is routine practice to remove sutures in the head and neck region by the 5-7thpost-operative day. A majority of the patients had sutures removed on the 7thpost-operative day.



The mean time for suture removal in patients with no seroma was 6.5 days while in patients with seroma was 7.5 days. There was no significant difference noted.

INCIDENCE OF SURGICAL SITE INFECTION/ HAEMATOMA

- There were no patients with surgical site infections or patients requiring antibiotics.
- There were no patients with hematoma post operatively.
- Of all the patients, 2 patients in the non-drain arm had gaping of the wound requiring resuturing.
- Of the patients who presented with seroma, 2 patients in the non-drain arm required a drain to be placed to aid in the drainage of seroma, which was removed with reduction in drainage.
- None of the patients had a prolonged stay in the hospital post operatively; however, 7 of the 43 patients recruited required repeated OPD visits and had a prolonged stay at Vellore.
- Of the 7 patients having a prolonged stay, 6 were due to seroma and its management while 1 was for a histological surprise requiring treatment.
- 3 of the patients reported a seroma after discharge from OPD by telephonic or digital communication. None of the above required any intervention for the same.

DISCUSSION

Various procedures have been described for benign pathology of the parotid gland, especially of the superficial lobe ranging from extra capsular parotidectomy, adequate parotidectomy to superficial parotidectomy. Conventionally, drains are placed after these surgeries to prevent seroma,sialocoele, or hematoma formation. There is no clear consensus regarding time of drain removal in terms of post-operative date or the volume drained. The outcomes under study i.e. Seroma, hematoma and surgical site infection have multiple contributing factors as per modern literature.

Even with the use of drains, the incidence of seroma formation has been found to vary from 2- 44 %. Various factors have been found to be associated such as the type of surgery, use of cautery, use of surgicel etc. Even the management of seromasis variable in different centers, with some opting for drainage, while some opting for conservative management. The implications of having drains placed are many. There is an additional scar which heals by secondary intention. There is an additional factor of patient discomfort, increased cost of treatment and a prolonged hospital stay. As there was no conclusive evidence in modern literature proving the necessity of drains, we proceeded to study the same.

We conducted non-inferiority, randomized controlled trial to evaluate the need to place drains in patients undergoing superficial parotidectomy andto compare the rates of seroma with and without drains.

CLINICALLY SIGNIFICANT SEROMA

A clinically significant seroma was defined as a collection of clear fluid in the post-operative bed which requires intervention in the form of either aspirations or drain placement. This was based on clinical examination suggestive of swelling and fluctuation.

No imaging was used and it was entirely based on clinical examination (presence of fluctuant swelling, serous discharge from the wound.

Similar criteria have been studied with regards to breast surgeries. A retrospective study by Boostrom et al studied the incidence of clinically significant seroma in patients undergoing either breast or axillary surgeries and looked at a total of 561 patients. Clinically significant seroma was defined as a post-operative fluid collection requiring one or more aspirations or drainage. The study compared the incidence of seroma in patients with drain as compared to no drain. Of the 252 patients with drain, 34 developed seroma while 13 of 309 non drain patients developed seroma. It was found that patients in the drain arm had a higher incidence of seroma post operatively.(47)

A study by Michelotti et al analyzed clinically significant seroma following reconstruction in patients undergoing mastectomy with acellular dermis. Clinically significant seroma was defined as seromas arising post operatively

without any precipitating factors which on clinical judgment required drainage either in the operation theatre or the Outpatient department.(48)

Of the 43 patients operated, we had 12 patients with clinically significant seroma requiring an intervention. Of these, 9 patients were in no drain arm and 3 were in drain arm. The overall incidence rate was 27. 90 % with 20.9 % arising in the non-drain group.

We further analyzed the same with respect to various other factors.

PATHOLOGY AND SEROMA FORMATION

Various studies have attempted to understand the relation between post-operative drainage and the final pathology. Mofle and Urquhart found that the final pathology was related significantly to the incidence of seroma. Patients were noted to have a higher chance of seroma if the final biopsy was malignant and also had a prolonged hospital stay.(4)

Noureai et al attempted to analyses the complications arising in patients operated on for benign pathology of the parotid gland. It was noted that there was a significantly higher incidence of salivary fistula and seroma in patients who were found to have sialadenitis.(6)

Malignant pathology was excluded as per our protocol. Of the 4 patients diagnosed to have low grade malignancies post operatively, 3 developed seroma. However, this was too small a size to show any statistical difference.

We found no significant difference in the pathology of the patients in the drain and the non-drain arms.

DRAIN REMOVAL

Multiple studies have been conducted regarding the time of drain removal post operatively.

Mofle et al emptied the surgical drains every 8 hours and a cut off of less than 15 ml over 24 hours was defined and they noted a seroma incidence of 2%.(4) Chen at al defined this cut off as removal once drainage is less than 10 ml over 24 hours.(40)

Jiang J et al removed the drain once the output was less than 20 ml over 24 hours and they found comparable seroma and salivary fistula formation in patients with pressure dressings or with suction drains.(41)

Our unit protocol was to remove the drain once the output was less than 30 ml over 24 hours and we measured drain outputs 24 hourly. The overall incidence of seroma was 27.90 %.

We found no co-relation between drain removal and seroma formation. Majority of the drains were removed within 48 hours of insertion: 7 of the 25 patients had drains removed within 24 hours while 12 of the 25 patients had drains removed at 48 hours.

INTRA- OPERATIVE FACTORS

The type of parotid surgery has been a matter of significant controversy over the past few years with regards to benefits and outcomes.

A few authors have found the incidence of sialocoele formation to be significantly higher in patients undergoing partial superficial parotidectomy as compared to superficial parotidectomy due to remnant normal parenchyma.(43–45). However, Koch et al compared long term complications and patients' perception of the same following surgery and found complications to be significantly reduced following partial superficial parotidectomy. However as ours is a teaching institution, there is a variation in terms of surgeons and techniques. Hence our aim was to analyses surgeries of the superficial lobe of the parotid gland.

There is no literature to suggest that increased operating time leads to increased drain output or sarcomaformation. In our study, most patients were operated in a time range of 2-3 hours. There was a significant variation in operating time as surgeries performed by trainees were also included in the study.

There is literature which pertains to increased post-operative seroma or sialocoele formation with usage of cautery and surgicel. Herbert et al found a higher incidence of seroma with the use of surgicel (49). Lee et al compared multiple intra- operative factors such as tumor size and the use of sealing devices in patients undergoing partial superficial parotidectomy. Though there were more sialocoeles noted in patients having harmonic usage, this difference was not statistically significant. Furthermore they found that an anterior position of the tumor was the only statistically significant factor influencing sialocoele formation.(50)It was a routine practice for us to use bipolar cautery during the surgery. Surgicel usage was not evaluated.We also compared possible seroma formation with the specimen removed as an indirect indicator of extent of dissection. This was a derived variable wherein the length, breadth and depth of the specimen as per the pathologist were charted and multiplied. There was no significant increase in seroma formation with increase of volume of specimen excised.

MANAGEMENT OF SEROMA

Classical management of seroma has been described as repeated aspiration of collected fluid and pressure dressings.

Witt et al studied seroma formation in patients undergoing partial superficial parotidectomy as compared to near total parotidectomy. They advised management of seroma conservatively with observation as there was no significant relief following aspiration. It was noted that the seroma resolved within 1 month of the surgery irrespective of aspiration.(44)

We managed all seromas detected with needle aspiration, failing which drain was inserted to reduce the collection. A wide variation in the volume of fluid aspirated was noted in the non-drain arm ranging from 5- 55 cc. This may be due to an investigator's bias as there may have been an earlier intervention in the patients with no drain.

Hematoma was defined as a collection of blood in the operative bed. The incidence of hematomas following parotid gland has been found to be 0- 2 % as per current literature. We encountered no hematoma during our study.

Surgical site infection was defined as per CDC guidelines.(51) Theoretically a collection of fluid in the operative field may predispose to a surgical site infection. However this has not been validated as per current literature. As this is essentially a clean surgery with no contamination, there were no infections noted during the course of our study.

Facial nerve paralysis is a common and disabling complication following surgery of the parotid gland. Facial nerve palsy was evaluated using House Brackman scoring system evaluating three distributions of innervation of the face. There was no significant increase in facial nerve palsy noted .(46)

Hospital stay : the incidence of sialocoele was found to have prolonged stay as per Mofle et al.(4) Multiple studies evaluating the use of drains in other parts of the body have found a longer hospital stay in patients with drains. The overall mean duration of stay was found to be 2.5 days. There was no significant difference in the duration of hospital stay in the patients with seroma.

Wound gaping and resuturing was required for two of the patients in the non-drain arm who presented with seroma. There was no available literature regarding these two parameters.

LIMITATIONS

A. The estimated sample size was 100 with 50 in each arm.The study was powered to see a difference in the rate of seroma (non-inferiority trial). We could recruit only 43 patients during the study period and of the 43 analyzed, there is an overwhelming evidence to suggest that the incidence of seroma formation is significantly higher in patients with no drain placed post operatively.
B. Since this was a non-blinded, non-maskedstudy, a possible Hawthorne effect could not be excluded, i.e., a change in practice due to an awareness regarding being observed.
C. At the time of the current study, no analysis was undertaken to compare any difference in seroma formation between various subtypes of parotid surgeries.

CONCLUSION

There is a significant increase in the incidence of post-operative seroma when drains were not placed following superficial parotidectomy and we would advocate placing drains to prevent complications. The ideal cut-off volume to remove the drain is yet to be identified.

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PROFORMA

Performa 1: study id:

Name: Gender: m/f

Address:

Contact no.:1.

Preoperative evaluation:

Side of mass: right/left/bilateral

Duration of complaints: <1 year/1-5 years/5-10 years/>10 years.

Prior surgery for same condition: yes/no

If yes: < 1 year ago /> 1 year ago

Ipsilateral /contralateral

Comorbid conditions: please encircle if present:

Hypertension/diabetes/chronic renal failure/thyroid/copd/obesity

Examination of mass: size of mass: clinically ----------

radiologically: _____

Prior FNAC histopathology: performed at CMC/ slide review

Clinical diagnosis: _____

Proposed surgery: _____

Consent for inclusion: Yes / No

Performa 2: (TO BE FILED AT OR)

Intraoperative factors:

Block no.:

Drain: yes/no

Intraoperative findings: _____

Conversion to other procedure: total/ radical parotidectomy

If yes, state reason:

_____

Performa 3: (to be filed at the ward)

Post op:

DRAIN/ NO DRAIN

Drain functioning: yes/no

Drain output	POD 2	POD 3	POD 4	POD 5	POD 6

Day of removal: 2 / 3/ 4 / 5 / discharged with drain in situ

Reason for removal: <30 ml/ surgeon's discretion/ nonfunctional/ slipped out/others

If others please state why: _____

Seroma: Yes / No Hematoma: Yes / No

If yes, noted on post op day: _____

If yes, aspiration needed: yes/no Volume aspirated: ___

No. of aspirations required: _____

HMB SCORE:

POD 2	POD 3	POD 4	POD5

Discharge: date of discharge:

Patient discharged with drain: Yes/ No

Stay prolonged: Yes / No

If yes: please state cause: _____

_____

Any other complications:

HMB SCORE:

Performa 4:

First opd visit:

DRAIN/ NO DRAIN

Removed: Yes / No

Reason for removal: <30 ml/ surgeon's discretion/ nonfunctional/ slipped out/others

If others please state why: _____

COMPLICATIONS:

Seroma: Yes / No Hematoma: Yes / No

If yes, noted on post op day: _____

If yes, aspiration needed: yes/no Volume aspirated: ___

No. of aspirations required: _____

HMB SCORE:

Wound site infection: Yes / no

Need for antibiotics: Yes / no

Wound gaping: Yes / No

Resuturing: Yes /No

Drainage of seroma done: Yes / No

Suture removal: Day 5/ day 6/ Day 7

Biopsy report (with size of specimen): _____

_____

Wound site dehiscence: Yes / No

Wound site infection: Yes / No

Aspiration needed: yes/no Volume aspirated: ___

Need for repeated OPD visits: yes/no

No. Of aspirations done:

Discharge: date of final discharge from OPD:

Patient discharged with drain: Yes / No

Stay at Vellore prolonged: Yes / No

If yes: please state cause: _____

_____

Any other complications:

CONSENT FORMS

INFORMED CONSENT

A Randomized Controlled Trial comparing the complication rates between having Drain in situ vs no drain in situ in patients undergoing Superficial Parotidectomy

Information sheet

You are being requested to participate in a trial evaluating the benefits and disadvantages of having drain in situ in patients undergoing superficial parotidectomy. Drains have been routinely utilized to evacuate the surgical site of any residual fluid or blood. However the benefits of having a drain placed have been recently questioned. Hence the investigators of this study would like to conduct a study that compares the benefits and disadvantages of having a drain placed in the post-operative period vs having no drain. 100 patients are expected to participate in said trial.

What is a drain and its purpose following a surgery?

A drain is a hollow tube made of silastic material placed under vacuum under the cover of the skin after tissue has been dissected out.

A drain is frequently utilized to remove any excess fluid that may accumulate under the cover of the skin and soft tissue is blood or fluid that maybe normally collected in the region after a surgery is over. Drains are usually inserted at a site separate from the incision site and are removed on the post-operative day with minimal output or at surgeon's discretion.

Having a drain placed may help to prevent any seroma formation which is the collection of clear fluid under the skin or a hematoma which is the collection of blood under the cover of the skin.

What are the reasons for not placing a drain?

Even after placing a drain in the postoperative bed, various hospitals document seroma formation up to 40 %. Also the rates of hematoma and infection rates are minimal with proper dissection irrespective of whether drain is placed or not. Also it is unknown if there is a known advantage of having a drain in preventing any of the said complications.

Drains add to the cost of treatment and also lead to an additional scar at the site of the drain insertion.

If you take part what will you have to do?

If you agree to participate in this study, you will be assigned to different treatment groups in a random manner and neither you nor your treating doctor will be aware of which group you will come to lie in. At the end of the surgery a pre assigned envelope will decide whether drain is to be placed in situ or not. You shall be observed for any complications such as seroma, hematoma, infections or facial nerve abnormality till you are discharged.

You will be expected to come for a review to the hospital 1 week after the surgery and you will be observed for any of the said complications. No additional procedures or blood tests will be conducted routinely for this study.

If at any time you experience any problems, you will be expected to report this to the doctor.

Can you withdraw from this study after it starts?

Your participation in this study is entirely voluntary and you are also free to decide to withdraw permission to participate in this study. If you do so, this will not affect your usual treatment at this hospital in any way.

What will happen if you develop any study related injury?

We do not expect any injury to happen to you but if you do develop any side effects or problems due to the study, these will be treated at no cost to you. We are unable to provide any monetary compensation, however.

Will your personal details be kept confidential?

The results of this study will be published in a medical journal but you will not be identified by name in any publication or presentation of results. However, your medical notes may be reviewed by people associated with the study, without your additional permission, should you decide to participate in this study.

CONSENT TO TAKE PART IN A CLINICAL TRIAL

Study Title:*A Randomized Controlled Trial comparing use of drain vs. no drain in patients undergoing superficial parotidectomy.*

Study Number:

Participant's name:

Date of Birth / Age (in years)

I_____

_____, wife/husband/ son/daughter of _____

(Please tick boxes)

Declare that I have read the information sheet provide to me regarding this study and have clarified any doubts that I had. [ ]

I also understand that my participation in this study is entirely voluntary and that I am free to withdraw permission to continue to participate at any time without affecting my usual treatment or my legal rights [ ]

I also understand that neither I, nor my doctors, will have any choice or knowledge of whether I will be assigned to group having drain in situ or no drain [ ]

I understand that I will receive free treatment for any study related injury or adverse event but I will not receive and other financial compensation [ ]

I understand that the study staff and institutional ethics committee members will not need my permission to look at my health records even if I withdraw from the trial. I agree to this access [ ]

I understand that my identity will not be revealed in any information released to third parties or published [ ]

I voluntarily agree to take part in this study [ ]

Name:

Signature:

Date:

Name of witness:

Relation to participant:

Date:

OFFICE OF RESEARCH
INSTITUTIONAL REVIEW BOARD (IRB)
CHRISTIAN MEDICAL COLLEGE, VELLORE, INDIA.

Ethics Committee Registration No : ECR/326/INST/TN/2013 issued under Rule 122D of the Drugs & Cosmetics Rules 1945, Govt. Of India.

Dr. George Thomas, D Ortho., Ph D.,
Chairperson, Ethics Committee

Dr. B. Antonisamy, M.Sc., Ph D., FSMS, FRSS.,
Secretary, Research Committee

Prof. Keith Gomez, B.Sc., M.A (S.W), M.Phil.,
Deputy Chairperson, Ethics Committee

Dr. Alfred Job Daniel, D Ortho, MS Ortho, DNB Ortho
Chairperson, Research Committee & Principal

Dr. Nihal Thomas,
MD., MNAMS., DNB (Endo), FRACP (Endo), FRCP (Edin), FRCP (Glasg)
Deputy Chairperson
Secretary, Ethics Committee, IRB
Additional Vice Principal (Research)

February 08, 2014

Dr. Aditi Mishra
PG Registrar
Department of Surgery
Christian Medical College,
Vellore 632 004

Sub: **Fluid Research grant project:**
A Randomized controlled trial comparing the use of drains versus no drains in patients undergoing superficial parotidectomy.
Dr. Aditi Mishra, Surgery, Dr. Pranay Gaikwad. S, Dr. Rajinikanth. J., Dr. L. Jeyseelan, Biostatistics, Dr. Amit jiwan tirkey, General Surgery.

Ref: IRB Min. No 8524 [INTERVEN] dated 30.10.2013

Dear Dr. Aditi Mishra,

I enclose the following documents:-

1. Institutional Review Board approval
2. Agreement

Could you please sign the agreement and send it to Dr. Nihal Thomas, Addl. Vice Principal (Research), so that the grant money can be released.

With best wishes,

Dr. Nihal Thomas
Secretary (Ethics Committee)
Institutional Review Board

Dr. NIHAL THOMAS
MD.,MNAMS.,DNB(Endo),FRACP(Endo),FRCP(Edin),FRCP(Glasg)
SECRETARY - (ETHICS COMMITTEE)
Institutional Review Board,
Christian Medical College, Vellore - 632 002.

Cc: Dr. Rajinikanth. J, Surgery Unit – I, CMC

Ethics Committee Silver, Office of Research, 1st Floor, Carman Block, Christian Medical College, Vellore, Tamil Nadu 632 002.
Tel : 0416 - 2284294, 2284202 Fax : 0416 - 2262788, 2284481 E-mail : research@cmcvellore.ac.in

February 08, 2014

Dr. Aditi Mishra
PG Registrar
Department of Surgery
Christian Medical College,
Vellore 632 004

Sub: **Fluid Research grant project:**
A Randomized controlled trial comparing the use of drains versus no drains in patients undergoing superficial parotidectomy.
Dr. Aditi Mishra, Surgery, Dr. Pranay Gaikwad. S, Dr. Rajinikanth. J., Dr. L. Jeyseelan, Biostatistics, Dr. Amit jiwan tirkey, General Surgery.

Ref: IRB Min. No 8524 [INTERVEN] dated 30.10.2013

Dear Dr. Aditi Mishra,

The Institutional Review Board (Blue, Research and Ethics Committee) of the Christian Medical College, Vellore, reviewed and discussed your project titled "A Randomized controlled trial comparing the use of drains versus no drains in patients undergoing superficial parotidectomy." on October 30th 2013.

The Committee reviewed the following documents:

1. IRB application format
2. Curriculum Vitae' Drs. Aditi Mishra, Rajinikanth. J, L. Jeyseelan, Amit Jiwan Tirkey
3. Proforma
4. Consent form (English, Hindi &Tamil)
5. No of documents 1-4

The following Institutional Review Board (Research & Ethics Committee) members were present at the meeting held on October 30th, 2013 at 9.45 am in the CREST/SACN Conference Room, Christian Medical College, Bagayam, Vellore 632002.

Ethics Committee Silver, Office of Research, 1st Floor, Carman Block, Christian Medical College, Vellore, Tamil Nadu 632 002.
Tel : 0416 - 2284294, 2284202 Fax : 0416 - 2262788, 2284481 E-mail : research@cmcvellore.ac.in

Name	Qualification	Designation	Other Affiliations
Dr. George Thomas	MBBS, D Ortho, PhD	Orthopaedic Surgeon, St. Isabella Hospital, Chennai, Chairperson, Ethics Committee, IRB.	External, Clinician
Dr. B. Poonkuzhali	M Sc, PhD	Professor, Haematology, CMCH.	Internal, Basic Medical Scientist
Dr. Asha Mary Abraham	MBBS, MD, PhD	Professor, Virology, CMCH.	Internal, Clinician
Dr. Molly Jacob	MBBS, MD, PhD	Professor, Biochemistry, CMCH.	Internal, Clinician
Dr. B.S. Ramakrishna	MBBS, MD, DM, PhD, FAMS, FA Sc, AGAF, FNA	Retired Professor, Vellore	External, Clinician
Dr. Anuradha Bose	MBBS, DCH, MD,MRCP, FRCPCH	Professor, Child Health, CMCH.	Internal, Clinician
Dr. Biju George	MBBS, MD, DM	Professor, Haematology, CMCH.	Internal, Clinician
Dr. Vinod Joseph Abraham	MBBS, MD, MPH	Professor, Community Medicine, CMCH.	Internal, Clinician
Dr. Sukriya Nayak	MBBS, MS	Professor, General Surgery, CMCH	Internal, Clinician
Dr. Deepak Abraham	MBBS, MS	Professor, Endocrine Surgery, CMCH.	Internal, Clinician
Rev. Dr. T. Arul Dhas	M.Sc, BD, DPC, PhD (Edin)	Chaplaincy Department, CMCH.	Internal, Social Scientist
Dr. Suresh Devasahayam	BE, MS, PhD	Professor of Bio-Engineering, CMCH.	Internal, Basic Medical Scientist

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Dr. Binu Susan Mathew	MBBS, MD	Associate Professor, Clinical Pharmacology CMCH.	Internal, Pharmacologist
Mrs. Mary Johnson	M.Sc	Professor, Child Health Nursing	Internal, Nurse
Dr. B. Antonisamy	M.Sc, PhD, FSMS, FRSS	Professor, Biostatistics, CMCH, Member Secretary, Research Committee, IRB.	Internal, Statistician
Prof. Keith Gomez	BSc, MA (S.W), M. Phil (Psychiatry Social Work)	Student counselor, Loyola College, Chennai, Deputy Chairperson, Ethics Committee, IRB	External, Lay Person & Social Scientist
Mrs. Pattabiraman	B. Sc, DSSA	Social Worker, Vellore	External, Lay person
Mr. C. Sampath	B. Sc, BL	Legal Expert, Vellore	External, Legal Expert
Mrs. Selva Titus Chacko	M.Sc	Professor, Medical Surgical Nursing, CMCH.	Internal, Nurse
Dr. P. Zachariah	MBBS, PhD	Retired Professor, Vellore	External, Scientist
Mr. Samuel Abraham	MA, PGDBA, PGDPM, M. Phil, BL.	Sr. Legal Officer, CMCH.	Internal, Legal Expert
Dr. Jayaprakash Muliyil	B. Sc, MBBS, MD, MPH, Dr PH (Epid), DMHC	Retired Professor, Vellore	External, Scientist & Epidemiologist

Ethics Committee Silver, Office of Research, 1st Floor, Carman Block, Christian Medical College, Vellore, Tamil Nadu 632 002.
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Dr. Nihal Thomas,
MD., MNAMS., DNB (Endo), FRACP (Endo), FRCP (Edin), FRCP (Glasg)
Deputy Chairperson
Secretary, Ethics Committee, IRB
Additional Vice Principal (Research)

Dr. Nihal Thomas	MD MNAMS DNB(Endo) FRACP(Endo) FRCP(Edin) FRCP (Glasg)	Secretary IRB (EC)& Dy. Chairperson (IRB), Prof. of Endocrinology & Addl. Vice Principal(Research), CMC.	Internal, Clinician

We approve the project to be conducted as presented.

The Institutional Ethics Committee expects to be informed about the progress of the project, any **adverse events** occurring in the course of the project, any **amendments in the protocol and the patient information / informed consent**. On completion of the study you are expected to submit a copy of the **final report**. Respective forms can be downloaded from the following link: http://172.16.11.136/Research/IRB_Polices.html in the CMC Intranet and in the CMC website link address: http://www.cmch-vellore.edu/static/research/Index.html.

The trial need to be registered with Clinical Trial Registry India (CTRI) http://ctri.nic.in before commencing.

The study will need to be submitted to a three monthly data-safety monitoring board (DSMB) review with duly filled in form found in the link http://172.16.11.136/Research/IRB_Polices.html

In case of adverse event, it has to be reported to the IRB Compensation Committee with duly filled in SAE format addressed to Dr. Denise Fleming, Clinical Pharmacology, CMC as a hard copy. The soft copy addressed to saeclinpharm@gmail.com and copy to research@cmcvellore.ac.in.

Ethics Committee Silver, Office of Research, 1st Floor, Carman Block, Christian Medical College, Vellore, Tamil Nadu 632 002.
Tel : 0416 - 2284294, 2284202 Fax : 0416 - 2262788, 2284481 E-mail : research@cmcvellore.ac.in

Fluid Grant Allocation:

A sum of 68,640 INR (Rupees Sixty Eight Thousand Sis Hundred and Forty only) will be granted for 2 years.

Yours sincerely

Dr. Nihal Thomas
Secretary (Ethics Committee)
Institutional Review Board

Dr. NIHAL THOMAS
MD, MNAMS.,DNB(Endo),FRACP(Endo),FRCP(Edin),FRCP(Glasg)
SECRETARY - (ETHICS COMMITTEE)
Institutional Review Board,
Christian Medical College, Vellore - 632 002.

Cc: Dr. Rajinikanth. J, Surgery Unit – I, CMC

slno	add	sex	som	dur	prior	prioryes	prioryes2	comrb	htn	dm	crf	thy	copd	obes	diag	random	drain	findlen	findbred
1	andhra pra	1	1	1	0			0							pleomorph	1	1	2	2
2	jharkhand	2	2	2	0			0							basal cell a	2	0	3	4
3	bangladesh	1	1	3	0			0							pleomorph	1	1	3	3
4	west benga	1	1	2	0			1	0	1	0	0	0	0	pleomorph	2	1	3	3
5	west benga	1	2	2	0			1	0	0	0	0	1	0	pleomorph	1	1	3	3
6	west benga	1	1	2	0			0							pleomorph	1	1		
7	tamil nadu		2	2	0			0							pleomorph	2	0	4	5
8	west benga	2	2	1	0			1	1	0	0	0	0	0	left sialoco	1	1		
9	jharkhand		1	3	0			1	0	1	0	0	0	0	cystic tumc	1	1	6	4
10	jharkhand	2	1	2	0			1	0	0	0	1	0	0	pleomorph	1	1	3	3
11	tamil nadu	1	1	1	0			0							pleomorph	2	0	2	1
12	west benga	1	2	3	1	1		0							branchial fi	2	0		
13	tamil nadu	2	2	2	0			0							pleomorph	2	0	3	4
14	jharkhand	1	2	3	0			1	1	0	0	0	0	0	pleomorph	2	0	3	4
15	west benga	1	1	1	0			1	0	1	0	0	0	0	warthin's t	2	0	3	2
	west benga	1	2	4	0			0										4	3
17	west benga	2	2	4	0			1	0	1	0	0	0	0	cystic lymp	1	1	4	3
18	tamil nadu	2	2	1	0			0							pleomorph	1	1	3	3
19	tamil nadu	1	2	2	0			0							pleomorph	2	0	4	3
20	tripura	1	2	1	0			0							warthin's	2	0	2	3
21	jharkhand	1	1	3	0			0							pleomorph	1	1	4	4
22	andhra pra	1	1	2	0			0							warthin's t	2	0	3	4
23	bangladesh	2	2	2	0			0							pleomorph	2	0	4	3
24	jharkhand	1	1	1	0			1	1	1	0	0	0	0	basaloid neoplasm				
25	west benga	2	2	2	0			0							pleomorph	2	0	3	3
26	tamil nadu	1	2	2	0			0							pleomorph	1	1	7	4
27	kerela	2	2	2	0			0							pleomorph	1	1	3	2
28	jharkhand	1	2	4	1	2	1	0							pleomorph	2	0	3	3
29	west benga	1	1	4	0			0							plemorphic	1	1		
30	tamil nadu	1	2	4	0			0							pleomorph	1	1	3	3
31	west benga	2	1	3	0			1	1	0	0	0	0	0	1.6	2	0	2	2
32	tamil nadu	1	1	1	0			0							pleomorph	1	1	4	4
33	west benga	1	1	4	0			0							pleomorph	1	1		
34	west benga	1	3	1	0			0							warthin's t	1	1		
35	west benga	1	3	1	1	1	2	0							warthin's t	2	0	2	2
36	west benga	1	1	2	0			0							pleomorph	1	1	3	2
37	jharkhand	1	1	2	0			0							pleomorph	1	1	4	4
38	andhra pra	1	2	1	0			0							pleomorph	1	1	2	1
39	west benga	1	1	2	0			1	0	1	0	0	1	0	warthin's t	2	0	5	5
40	tamil nadu	1	1	2	0			1	0	1	0	0	0	0	pleomorph	1	1	2	3
41	tamil nadu	2	2	1	0			0							pleomorph	2	0	3	3
42	andhra pra	2	1	2	0			0							pleomorph	1	1	3	3
43	west benga	1	1	1	0			1	0	1	0	0	0	0	warthn's tu	1	1	2	2
44	west benga	1	1	2	0			1	1	0	0	1	0	0	pleomorph	2	1	6	6
45	west benga	1	2	2	0			0							pleomorph	1	1	4	4

or time	convert	convertyes	drain1	draind1	draind2	draind3	draind4	drainrem	drainremre	ser	heam	asp	vol	no	hmb2	hmb5	dds	ds
1:55	0		1	75	50			3	1	0	0	0			121	121	4/28/2014	0
2:00	0		0							1	0	0			222	222	5/3/2014	0
2:00	0		1	10	10			3	1	0	0	0			111	111	5/4/2015	0
2:00	0		1	80	75	40		4	1	0	0	0			111	111	5/10/2014	0
1:15	0		1	25				3	1	0	0	0			111	111	5/10/2015	0
1:55	0		1	75	70	50	30	5	1	0	0	0			666	666	5/15/2014	0
1:00	0		0							0	0	0			112	112	5/24/2014	0
1:29			1	35	30			3	1	1	0	1	20	1	112	112	6/18/2014	0
1:00	0		1	35				3	1	0	0	0			115	115	10/4/2014	0
2:00			1	50	30			3	1	0	0	0			112	112	9/27/2014	0
2:30	0		0							0	0	0	0	0	222	222	9/25/2014	0
2:30	0		0							1	0	1	30	1	112	112	10/12/2014	0
1:45	0		0							0	0	0			223	223	11/7/2014	0
1:00	0		0							0	0	0			223	223	10/29/2014	0
3:30	0		0							0	0	0			234	234	10/12/2014	0
	1	malignant lesion																
1:40	0		1	80	70	50	30	4	1	0	0	0			112	112	6/14/2014	0
1:30	0		1	10				2	1	0	0	0			111	111	9/8/2014	0
1:29	0		0							0	0	0			111	111	8/2/2014	0
2:25	0		0							0	0	0			111	111	11/12/2014	0
2:00	0		1	50	40			3	1	0	0	0			213	113	11/27/2014	0
2:10	0		0							1	0	1	50	1	111	111	12/6/2014	0
2:20	0		0							0	0				113	113	6/27/2014	0
	1	suspicion of malignancy																
2:00	0		0							0	0	0			112		11/6/2014	0
2:00	0		1	50	30			3	1	0	0	0		0	111	111	12/15/2014	0
2:20	0		1	90	90	75	80	4	4	0	0	0			223	223	1/18/2015	0
3:00	0		0							0	0	0			111	111	1/17/2015	0
2:00	0		1	30	0			3	1	0	0	0			113		3/7/2015	0
2:00	0		1	50	30			3	1	0	0				111	111	3/5/2015	0
2:00	0		0							1	0	0			113	113	3/27/2015	0
2:15	0		1	30				3	1	0	0	0			111	111	3/27/2015	0
2:30	0		1	50	30			6		0	0	0			111	111	4/12/2015	1
1:30	0		1	20				2	1	0	0	0			111	111	5/18/2015	0
1:30	0		0							0	0	0			111	111	4/26/2015	0
1:30	0		1	30				2	1	0	0	0			111	111	4/2/2015	0
2:30	0		1	50	10			3	1	0	0	0			112	112	4/17/2015	0
1:40	0		1	5				2	1	0	0				111	111	5/9/2015	0
2:15	0		0							0	0				112	112	6/6/2015	0
2:00	0		1	50	25			3	1	0	0	0			111	111	6/28/2015	0
1:30	0		0							0	0				234	234	5/14/2015	0
2:00	0		1	5				2	1	0	0				111	111	5/28/2015	0
2:00	0		1	10				2	1	0	0	0			111	111	6/13/2015	0
2:30			0							1	0	1	30	2	113	113	6/13/2015	0
2:10	0		1	29				2	1	0	0	0			111	111	6/11/2015	0

hospstay	prolong	drremov	drainrem1	ser1	heam1	asp1	vol1	no1	hmb	ssi	antib	gape	resutur	sutremov	biopsy	specleng	spec bread	specdept	dehies
4	0	0		0	0	0			121	0	0	0	0	7	warthin's tu	5.8	4	2	0
4	0	0		0	0	0			222	0	0	0	0	9	basal cell a	4	3.5	2.5	0
3	0	1	1	0	0	0			111	0	0	0	0	7	salivary gla	5	4.5	2	0
4	0	1		0	0				111	0	0	0	0	7	pleomorph	6.2	5.3	3	0
4	0	1		0	0	0			111	0	0	0	0	7	pleomorph	6	4.8	2.8	0
2	0	1	1	0	0	0			555	0	0	0	0	7	pleomorph	5	4.5	2	0
2	0			0	0	0			662	0	0	0	0	7	pleomorph	6	4.5	1	0
6	0	1		0	0	0			113	0	0	0	0	7	mild chroni	5	3	1.5	0
4	0	1		0	0	0			115	0	0	0	0	5	basal cell a	7	2.5	5	0
4	0	1		0	0	0			111	0	0	0	0	7	pleomorph	4	4	1.7	0
2	0			1	0	1	25	3	222	0	0	0	1	7	malignant s	7.5	4	1.6	0
3	0			1	0	1	25	2	112	0	0	0	0	7	sinus tract	6	4	2	0
3	0			1	0	1	12	5	133	0	0	0	0	7	pleomorph	7	4	3.5	0
2	0			0	0				223	0	0	0	0	6	myoepithe	6.5	6	3	0
3	0			0	0				113	0	0	0	0	7	warthin's tu	4	2	1.5	0
4	0	1		0	0	0			112	0	0	0	0	8	low grade r	4.5	3.5	1.2	0
4	0	0		0	0	0			111	0	0	0	0	6	pleomorph	2.5	1.7	1.5	0
2	0	0		0	0	0			111	0	0	0	0	7	pleomorph	4.5	4	2.5	0
2	0			0	0				111	0	0	0	0	7	warthin's tu	3	3	1.5	0
2	0	1		0	0	0			111	0	0	0	0	7	pleomorph	6.4	4	3.4	0
2	0	0		1	0	0			111	0	0	0	0	9	warthin's tu	6	4	2.8	0
3	0	0		1	0	1	50	2	111	0	0	1	1	7	pleomorph	7	4.5	3.5	1
2	0			0	0	0			112	0	0	0	0	5	pleomorph	4.3	3.7	2.7	0
4	0	1		0	0	0			111	0	0	0	0	6	kimura's di	8	5	3.2	0
3	0	1		0	0	0			223	0	0	0	0	5	pleomorph	6.5	4	2.5	0
2	0			1	0	1	5	3	111	0	0	0	0	9	pleomorph	5	4	1.5	0
4	0	1		0	0	0			113	0	0	0	0	7	pleomorph	7	6	3	0
2	0	1		0	0	0			111	0	0	0	0	7	pleomorph	5	4.5	3	0
3	0	0		1	0	0			114	0	0	0	0	7	low grade r	3	3	2	0
3	0	0		0	0	0			111	0	0	0	0	9	pleomorph	4	3	3	0
3	0	1	1	0	0	0			111	0	0	0	0	7	basal cell a	6	4.3	3	0
2	0	1		0	0	0			111	0	0	0	0	6	warthin's tu	4	2.5	2	0
3	0	0		0	0	0			111	0	0	0	0	5	warthin's tu	2.8	2.2	2	0
2	0	1		0	0	0			111	0	0	0	0	7	basal cell adenoma				0
3	0	1		0	0	0			112	0	0	0	0	5	pleomorph	8	5	1	0
4	0	1		0	0	0			111	0	0	0	0	8	pleomorph	1.5	1	0.5	0
2	0	0		0	0	0			112	0	0	0	0	6	warthin's tu	6	5	4	0
3	0	1		0	0	0			111	0	0	0	0	7	lipoma par	5.5	3.5	3	0
2	0	0		1	0	1	55	3	234	0	0	0	0	9	low grade r	6	4	2	0
2	0	1		0	0	0			111	0	0	0	0	7	pleomorph	3	2.5	0.56	0
2	0	1		0	0	0			111	0	0	0	0	6	warthin's tu	1.3	1	0.6	0
2	0			1	0	1	5	1	113	0	0	0	0	6	pleomorph	5	6.2	4.2	0
2	0	1		0	0	0			111	0	0	0	0	6	pleomorph	6.5	4.5	3.4	0
2.883721																			

asp2	vol2	no2	opdrepeat	finds	prolong1	return	serds	interven
0			0		0	0	0	0
0			0	5/12/2014	0	0	0	0
0			0	5/8/2014	0	0	0	0
0			0	5/15/2014	0	0	0	0
0			0	5/12/2015	0	0	0	0
0			1	5/22/2014	0	0	0	0
0			0	6/26/2014	0	0	0	0
0			0	6/18/2014	0	0	0	0
0			0	10/9/2014	0	0	0	0
0			0	10/2/2014	0	0	0	0
0			1	10/16/2014	1	1	0	0
0			0	10/16/2014	0	0	0	0
0			1	11/24/2014	1	1	0	0
0			0	11/3/2014	0	0	0	0
0			0	10/16/2014	0	0	0	0
0			0	6/26/2014	1	0	0	0
0			0	9/18/2014	0	0	0	0
0			0	8/14/2015	0	0	0	0
0			0	11/20/2014	0	0	0	0
			0	12/4/2014	0	0	0	0
1	30	4	1	1/12/2015	1	0	0	0
1	50	3	1	7/14/2014	1	0	0	0
0			0	11/10/2014	0	0	0	0
0			0	12/22/2014	0	0	0	0
0			0	1/19/2015	0	0	0	0
0			1	1/29/2015	1	0	0	0
0			0	3/12/2015	0	0	0	0
0			0	3/16/2015	0	0	0	0
0			0	4/2/2015	0	0	0	0
0			0	4/9/2015	0	0	0	0
0			0	5/4/2015	0	1	1	0
0			0	4/30/2015	0	0	0	0
0			0	4/30/2015	0	0	0	0
0			0	4/9/2015	0	0	0	0
0			0	4/23/2015	0	0	0	0
0			0	6/22/2015	0	0	0	0
0			0	6/11/2015	0	0	0	0
0			0	7/2/2015	0	0	0	0
0			1	5/21/2015	1	0	1	1
0			0	7/6/2015	0	0	0	0
0			0	6/18/2015	0	0	0	0
0			0	6/18/2015	0	0	0	0
0			0	6/8/2015	0	0	0	0

ABSTRACT

TITLE OF THE ABSTRACT: “Is post-operative drainage necessary for patients undergoing superficial parotidectomy?”

DEPARTMENT: General surgery

NAME OF THE CANDIDATE: Dr. Aditi Mishra

DEGREE AND SUBJECT: M.S., General surgery

NAME OF THE GUIDE: Dr. Rajinikanth J.

OBJECTIVES:

This prospective randomized clinical trial was conducted to evaluate the necessity of drainage after superficial parotidectomy for benign parotid disorders.

METHODS:

From 2013-2015, all patients who underwent total superficial parotidectomy for benign parotid disorders were randomly allocated to be drained or not, post-operatively. Operative and postoperative outcomes including complications (seroma, hematoma), necessity for aspiration of seroma, re-suturing and hospital stay were all assessed. The sample size was ascertained to be 50 in each arm and the allocation was on the basis of computer generated opaque envelopes.

RESULTS:

25 patients were in the drain arm while 17 had no drain placed. The Incidence of seroma was analyzed on the basis of ITT and per protocol analysis. We found a statistically significant increased incidence of seroma formation, needing repeated aspiration in the patients with no drains. We analyzed various other factors such as operating time, the HPE report, and size of specimen and found no statistical correlation with the formation of seroma.

CONCLUSION:

These findings suggest that postoperative complications are increased when postoperative drainage is not done following superficial parotidectomy. In the light of these findings, the routine use of drains is recommended following parotid surgeries.

KEYWORDS: Seroma, Post-operative drainage, superficial parotidectomy, sialocoele.