EVALUATION OF BUCCINATOR FLAP VERSUS BARDACH TWO FLAPS PALATOPLASTY ON FISTULATION RATE IN PRIMARY REPAIR OF CLEFT PALATE (RANDOMIZED CONTROLLED TRIAL)

Momen Kamal Lashin 1, Dr. Galal Beheri 2, Dr. Walaa kadry 3, Dr. Ramy Ragab El-Beialy 4

1 assistant lecturer, oral and maxillofacial surgery department faculty of dentistry British university in Egypt.

2 Professor of oral and maxillofacial surgery department faculty of dentistry – Cairo university-Egypt.

3 lecturer of oral and maxillofacial surgery department faculty of dentistry – Cairo university-Egypt.

4 Associate professor oral and maxillofacial surgery department faculty of dentistry – Cairo university-Egypt.

Corresponding author: Momen Kamal Lashin
Address: fifth settlement waterway compound
Email: moamen.lashin@bue.edu.eg

Abstract:

Aim: The aim of the study was to evaluate the use of buccinator flap in primary repair of cleft palate on fistulation rate. The goal was to decrease fistulation rate.

Methodology: We studied 46 patients in two groups with complete wide cleft palate the study group patients were repaired by buccinator myomucosal flap during primary repair and the control group patients were repaired by bardach two flap palatoplasty during primary repair. All patients evaluated at 1 week,3,6 months interval to detect fistulation.

Results: fistulation rate was 1 case out of the 23 cases of the study group and 4 cases out of 23 cases of control group this difference was statistically significant.

Conclusion: the use of buccinator flap during primary repair of cleft palate decrease fistulation rate.

KEYWORDS: cleft palate, primary repair, buccinator flap, palatal fistula.
REVIEW OF LITERATURE:

A baby born with communication between oral and nasal cavity through gap between palatal shelves with difficulty in suckling and respiratory tract recurrent infection and later on difficulty in mastication and swallowing process and abnormal speech and hearing patterns which affect their communication and merging with the society affecting his/her chances in education and working environment. McQueen KK (2009).

Bardach depend on greater palatine artery as the main blood supply for the two flaps by preserving the artery during dissection, initial technique of bardach was suitable only for repair of narrow clefts only, later on modification of the technique with more releasing incisions and more dissection allowed for closure of wide clefts with high success rate. Bardach J (1987), Bardach J, Nosal P (1987), Bardach J (1995) et al.

The main drawback of bardach technique that it does not add length to the palatal tissues so there is increased risk for developing VPI postoperatively with subsequent speech problems. Turvey T, Scully R (2009) et al, Bardach J, Mooney M (1982) et al, Bae YC (2002) et al

Palatal fistula is defined as direct communication between oral and nasal cavity through an opening anywhere from incisive foramen to uvula resulting from breakdown of cleft palate repair. Brophy TW (1901) et al, Shah SA (2011) et al. Symptomatic palatal fistula is usually associated with hypernasality and less ability to pronounce the consonants, this is due to air escapement during pronunciation, other symptom is nasal regurgitation of fluids and food during eating, other fistulas may be totally asymptomatic. Bekerecioglu M (2005) et al, Lewis M (1994) et al.

Palatal fistula has a rate ranging from 3-45% and may be presented in multiple forms ranging from tiny non detected by direct vision pinpoint fistula to small or moderate rounded or oval classic shape fistula to total wound dehiscence. Bresnick S (2003) et al, Schendel SA (1999) et al.

Buccinator Myomucosal Flap:

Being a myomucosal flap formed of two layers mucosal layer and muscle layer make buccinator flap ideal for reconstruction of soft palate due to great similarity

www.turkphysiotherrehabil.org
of type of mucosa because buccal mucosa is non keratinized stratified squamous epithelium like soft palate submucosa of soft palate contain muscle and mucous salivary gland and fat cells which is the same in mucosa one of its main advantages is that it contains rich blood supply and increased thickness. Ferrari S (2012) et al, Joshi A (2005) et al.

Bhaumik Bhayani et al evaluated the buccinator flap in primary and secondary repairs of cleft palate, in the period from 1999 to 2011, 160 palatoraphe operations used buccinator flap in primary and secondary repairs of cleft palate the results showed that fistulation rate in primary palatoplasty was 4.8% and 8.3% in secondary repairs, speech assessment for babies repaired with buccinator flap in their primary repair showed good speech, babies with secondary repairs with buccinator flap used to repair fistulation or increase length of soft palate in order to overcome VPI showed improvement in speech and decrease in hypernasality. Bhaumik Bhayani (2014) et al.

Bhaumik Bhayani et al (2014) concluded using buccinator flap in primary and secondary repairs offer anatomical and functional repair specially in wide clefts, speech assessment after 6 months following primary repair with buccinator flap was 72% of patients have normal speech pattern while 4% have mildly compromised and 12% for moderately compromised. Bhaumik Bhayani (2014) et al.

In cases of wide clefts, the risk of wound dehiscence and fistulation is higher than narrow clefts this is due to the deficiency in the amount of available soft tissue for repair, transfer of vascularized soft tissue to overcome the inherited deficiency in the amount and quality of soft tissue at cleft site improve the results and decrease potentiality of scaring and long term complications like mid face hypoplasia, shortening of soft palate due to scaring and subsequent development of VPI. Primary repair of cleft palate with buccinator flap is simple and easy and safe procedure to be performed. Jackson IT et al 2004.

THE AIM OF THE STUDY:
The aim of this study was to evaluate the effect of using buccinator flap in primary repair of cleft palate on decreasing fistulation rate.
MATERIALS AND METHODS

Study setting:

Study is to be conducted in the Oral and Maxillofacial Surgery Department – Cairo University. Patients will be selected from the outpatient clinic of the department of Oral and Maxillofacial Surgery - Cairo University.

Eligibility criteria:

Inclusion criteria:
• Patients suffering from wide complete cleft palate. (More than 10 mm)
• Patient age from (9 – 18 months)
• Patients should be free from any systemic disease that may affect normal healing and predictable outcome.
• Patients who will agree to the consent and will commit to follow-up period.

Exclusion criteria:
• Patients with any systemic disease that may affect normal healing.
• Patients who could/would not participate in the follow-up period.
• Patients with Pierre robin syndrome.
• Patients who refused to be included in the trial.
• Patients with secondary repairs.

Intervention:
General operative procedures:

Eligible patients were randomized in equal proportions between study group (primary repair with buccinators flap) and comparator group (primary repair 2 flaps palatoplasty).

For the study group:
Depending on the required amount of tissue, the outline of the flap determined using a surgical marker or methylene blue with superior boundary of the flap
outline determined by the location of the parotid papilla (opening of stemsons duct), and inferior border at lower molars, anterior boundary posterior to oral commissures with 1-2 mm and posterior boundary at pterygomandibular raphe which will act as the pivot for flap rotation. Figure 1

Figure 1: showing marking of buccinator flap.

**Buccinator Myomucosal Harvesting:**

In order to harvest this random buccinator myomucosal flap, the orifice of the Stenson’s duct in the cheek identified and marked with single stitch before start of surgery because blood loss during surgery lead to dehydration of oral tissues which may camouflage the site of the parotid papilla which increase risk of stensons duct injury during buccinator flap harvesting.

The length to breadth ratio of the flap about 1:2 (approximately from 5.5-7.5 mm). After marking of the flap Mepivacaine local anaesthesia with 1:200,000 V.C is injected for haemostasis. Incision of buccal mucosa down to buccinator muscle is made and a split thickness of buccinator muscle is harvested dissection along fat plane posteriorly toward pterygomandibular raphe.

After injection of Mepivacaine local anaesthesia for haemostasis incision and dissection of oral and nasal layers was done and a single suture at uvula figure 18
in order to measure length of palate before adding the buccinator flap to the recipient site.

After closure of nasal layer incisions are made on the marked-out lines and unilateral BMFs raised from the donor site, and immediately transferred to the recipient site to primarily repair cleft palate then the flaps sutured to the recipient site using Monocryl 5-0 thread

Primary Closure of oral layer by Suturing of the two palatine flaps at the area of hard palate, and reconstruction of muscle sling and oral layer of soft palate by suturing of the anteriorly and posteriorly based triangles with buccinator flap in order to increase length of soft palate with three-layer closure (oral-muscle-nasal) figure 2.

![figure 2](image_url): showing rotation of the buccinator flap and closure of oral layer.

**For Control group:**

Patients of control group repaired with bardach 2 flap palatoplasty by dissecting oral layer pedicled on greater palatine artery and nasal layer at area of hard palate and 3 layers (oral-muscle-nasal) layers at area of soft palate with primary closure.

**Timeline:** patients of both groups were evaluated for healing and presence of fistulation at 1 week, 3, 6 months.

**Results:**

**For study group:** 1 case out of 23 cases showed fistulation.
for control group: 4 cases out of 23 cases showed fistulation.

Statistical analysis of the data:

Data were fed to the computer and analysed using IBM SPSS software package version 20.0. (Armonk, NY: IBM Corp). Qualitative data were described using number and percent.

The Kolmogorov-Smirnov test was used to verify the normality of distribution. Quantitative data were described using range (minimum and maximum), mean, standard deviation, median and interquartile range (IQR). Significance of the obtained results was judged at the 5% level.

The used tests were:
1- Chi-square test: For categorical variables, to compare between different groups
2- Fisher’s Exact: Correction for chi-square when more than 20% of the cells have expected count less than 5
3- Student t-test: For normally distributed quantitative variables, to compare between two studied groups.
DISSCUSION:

Cleft anomalies are one of the most common abnormalities that affect newborn and their parents both physically, emotionally and socially because every cleft baby affect society directly by preventing one or both of his parents from playing their role in the community as cleft baby need more time and effort than normal baby to get the adequate required care in order to be well nourished and rehabilitated to join life during early adulthood. It is a long journey starting at birth by feeding problems and growth problems and go through multistage surgeries and revisions with multiple speciality team approach to repair and rehabilitate the baby.

The old concept in cleft management was to anatomically reconstruct and close the gap. With time a lot of long-term post-surgical complications started to appear regarding growth restrictions due to scared and dissected flaps to be advanced to close the gap, other complications related to speech and social communication skills affected the cleft baby on terms of career development and self-development. This long term complications alerted the teams working in cleft care to shift the old concept of static anatomical closure to dynamic functional closure reconstructing and restoring the normal function of tissues not only the normal shape this was done through preoperative preparations which led to the appearance of preoperative orthopaedics and naso alveolar moulding and the use of tissue expanders in order to increase the amount of available tissues for primary tension free closure to minimize scaring tendency which affect flexibility of the tissues and so affect functional rehabilitation programs in the postoperative period to restore the function of the tissues specially muscle action.

Original defect in the cleft tissues is the decrease in the power of regeneration and compromised growth ability which is intrinsic factor in the anomaly which lead to arrest of fusion and merging of the embryonic processes during embryonic life, this fact render the need to transfer and advance tissues over the cleft gap to maximize amount of soft tissue available for cleft closure with tension free anatomical and functional primary repair in order to be able to do this some cases necessitate the use of local flaps to close wide clefts.
Cleft palate repair is considered one of the most challenging types in cleft care this is due to many factors like limited accessibility and convenience of surgery, risk of postoperative trauma to flaps due to intra oral environment and during eating of hard food or making negative suction during drinking using straw or trauma to flaps by tongue of the baby exploring the gap that was there and suddenly it disappeared. Early wound dehiscence and fistulation lead to several complications like hypernasality, nasal regurgitation and long-term affection of speech and the need for a re-do surgery with new dissection and new scaring with direct effect on muscles of soft palate motility which subsequently lead to more resistant cases to speech therapy that may necessitate VPI correction surgery like pharyngoplasties or buccal myomucosal flap.

As a rule in cleft care your first shoot is your best shoot because primary repair using fresh tissues with adequate blood supply and flexibility dissected and advanced and closed primarily with minimum surgical trauma and tension free followed by normal healing cascade will always result in best outcome. Using of local flaps during secondary repairs of cleft palate to repair fistulas and wound dehiscence following poor primary repair is common because scaring of tissues from first surgery decreases elasticity and flexibility of the available soft tissues which decrease mobility and advancement of tissues to do the secondary repair.

The increased rate of palatal fistula following primary repair of cleft palate especially wide and complete clefts with low experience of the operating surgeon led to poor prognosis of the baby with long term complications affecting speech and growth of midface which necessitate secondary repairs and revisions in order to enhance the quality of patient life.

Repair of large fistulas may require rotation of local flaps for example tongue flap or buccal myomucosal flap, buccinator flap has advantage over tongue flap in the postoperative care as tongue flap require limitation of mouth opening and limitation of tongue movement to allow healing of the flap before its separation from tongue in second surgery, another advantage of buccinator myomucosal flap is that anatomical and histological resemblance exist between buccinator
myomucosal flap and soft palate because both are formed of non-keratinized mucosa and muscle in the submucosa which make its sensation more comfortable to the patient than the papillary texture of the tongue flap. Buccinator muscle as apart of buccinator myomucosal flap has abundant blood supply from facial artery and vein at its posterior-inferior part, posterior superior vessels supply the muscle from its superior posterior angle, buccal artery supply the muscle from its posterior edge at pterygo-mandibular raphe, pterygoid venous plexus has direct communication with buccal venous plexus. Szeto C (2011), Van Lierop (2008) et al, This maximizes blood supply which is necessary factor in healing process of the flap.

Bhaumik Bhayani et al evaluated the buccinator flap in primary and secondary repairs of cleft palate, in the period from 1999 to 2011 ,160 palatoplasty operations used buccinator flap in primary and secondary repairs of cleft palate the results showed that fistulation rate in primary palatoplasty was 4.8% and 8.3% in secondary repairs, speech assessment for babies repaired with buccinator flap in their primary repair showed good speech, babies with secondary repairs with buccinator flap used to repair fistulation or increase length of soft palate in order to overcome VPI showed improvement in speech and decrease in hypernasality.

In our study we used bardach two flap palatoplasty as a control group because it is suitable for management of wide clefts with decreased fistulation rates, the choice of the comparator was done to evaluate if the use of buccinator flap in primary repair will decrease fistulation rate more than bardach technique.

The use of buccinator flap for secondary repairs of cleft palate is a famous technique with high success rate to manage large fistulas and for lengthening of soft palate in management of velopharyngeal insufficiency to enhance speech in cleft patients with short soft palate and abnormal muscle action of levator and tensor palati muscles.

Using buccinator flap in primary repair of cleft palate add extra tissues which in turn maximize tissues available for tension free functional closure of the cleft palate and decrease scaring potentiality which decrease negative effect of scaring on midface growth and speech by decreasing scaring of soft palate musculature which result from excessive dissection to reconstruct the muscular sling at mid line
which in turn decrease long term affection of speech due to short soft palate and subsequent velopharyngeal insufficiency.

In cases of wide clefts, the risk of wound dehiscence and fistulation is higher than narrow clefts this is due to the deficiency in the amount of available soft tissue for repair, transfer of vascularized soft tissue to overcome the inherited deficiency in the amount and quality of soft tissue at cleft site improve the results and decrease potentiality of scaring and long term complications like mid face hypoplasia, shortening of soft palate due to scaring and subsequent development of VPI. Primary repair of cleft palate with buccinator flap is simple and easy and safe procedure to be performed. Jackson IT et al 2004.

Jackson IT et al postulated that buccinator flap donor site can be closed primary with low morbidity rate and almost neglected scaring potentiality, buccinator flap used in primary repair of cleft palate may not require the need of subsequent separation of the flap and even if the flap is obscuring the eruption of teeth its separation can be carried out under local anaesthesia in outpatient clinic or under sedation. Jackson IT et al (2004).

In our study low morbidity rate at donor site with primary closure of the donor site with neglected postoperative complications of mild pain and oedema, in follow up period no case needed secondary surgery for separation of the base of the flap from pterygomandibular raphe.

Harvesting of the buccinator myomucosal is a simple and easy to apply technique with low complication rate both intra-operative and post-operative.

A common complication following harvesting unilateral buccinator flap in adults is facial asymmetry in our study we noted that harvesting of unilateral buccinator flap did not cause any facial asymmetry in the 23 patients of the study group. In our study rotation of the buccinator flap in horizontal position with rotation of anteriorly based and posteriorly based triangles eliminated the need for secondary surgery to separate the buccinator flap because horizontal orientation during primary repair allowed the base of the buccinator flap to be positioned posterior to the teeth.
Mamdouh abou el-hassan et al in 2020 evaluated the success rate of speech outcome following buccinator muscle myomucosal flap and levator muscle repositioning used to manage velopharyngeal insufficiency and he found that success rate is 83.3% and rate of minor complications was 10% Mamdouh abou el-hassan et al 2020. which is matching with other studies with success rate from 46-96% and rate of minor complication 8-31% Speech assessment of the patients of study group 6 months post-operative showed 70% normal pattern of speech and 20% abnormal speech patterns due to low social skills and 1 case showed abnormal speech due to postoperative fistula and one case showed abnormal speech due to abnormal function of the muscle sling of soft palate.

In our study we operated 46 patients in 2 groups, study group 23 patients were repaired by buccinator myomucosal flap in the primary repair and control group 23 patients were repaired by bardach 2 flap palatoplasty, evaluation of both groups at 1 week, 3,6 months interval to evaluate rate of fistulation as primary outcome. The fistulation rate in the study group repaired with buccinator flap was 1 case out of the 23 cases while in control group repaired with bardach two flap palatoplasty was 4 cases out of 23 cases.

Statistical analysis of this data showed that effect of using buccinator flap in primary repair of cleft palate decrease fistulation rate in a statistically significant difference compared to control group repaired with bardach 2 flap palatoplasty.

The only case in the study group that showed fistula was managed by rerotation of the flap and primary closure in three layers during dissection of the flap we noted that flap viability and blood supply was optimum and complete healing of the flap with fistula closure was noted at 7 days postoperative.

CONCLUSION :

From our study we concluded that:

1. Buccinator myomucosal flap is a reliable technique in primary and secondary management of cleft palate patients.
2. Buccinator myomucosal flap is a simple and easy to apply technique with low morbidity rate of donor site and low intra and postoperative complications.

3. Training on harvesting buccinator myomucosal flap should be a tool in the hand of the cleft surgeon to help him optimizing the treatment outcome for cleft patients.

4. Buccinator myomucosal flap is flexible and malleable flap that has excellent ability to be rotated and advanced in many directions with many patterns of orientation that help in closing wide palatal defects.

5. Using of buccinator myomucosal flap in primary repair of soft palate decreases fistulation rate by adding extra tissues with abundant blood supply to the cleft tissues that are originally deficient.

References:


Bardach J, kelly KM. Does interference with mucoperiosteum and palatal bone affect craniofacial growth? An experimental study in beagles. Plastic and reconstructive surgery. 1990 Dec 1; 86(6);1093-100.


Bhaumik Bhayani-Well Hospital, Gujarat Housing Board - M/53, Opp. Swaminarayan Temple, Kalawad Road, Rajkot-360 001, GujaratIndia


McQueen KK, Magee w, Crabtree T, Romano c, Burkle 2009


