A NOVEL TECHNIQUE FOR THYROPLASTY TYPE 1, WITH PROLENE MESH IMPLANT.

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Objective: To evaluate a new approach of vocal cord medialization using prolene mesh as an implant material for thyroplasty type 1.

Study Design: Interventional, prospective study.

Place and Duration of study: Ent unit of a tertiary care hospital in Pakistan from May 2020 to January 30 2021.

Materials and Methods: Patients of age 15 years onwards and with vocal cord paralysis/ paresis due to multiple causes were included in the study. Patients with neoplasm, trauma and underlying muscular dystrophy were excluded. All patients were counselled properly and given the choice of intervention by prolene mesh implant. Consenting patients were subjected to routine blood investigations with fiber optic laryngoscopy and imaging with Computerized Tomography scan (where applicable). Procedure was be performed under local anesthesia with mild sedation, so that the patient will remain vocally responsive for the assessment of voice and breathing intraoperatively. Pre and postoperative voices were recorded with a standard microphone at 15cm distance from the mouth in a quiet room. Maximum phonation time (MPT) while vocalizing the vowel sound 'eee' and Maximum words count (MWC) in a single breath (counting numbers) were recorded pre and post operatively. Maximum three attempts were allowed to each patient and the better score of the three was recorded in the data. For subjective assessment of voice quality Visual (1-10) analogue score (VAS) was used both pre and postoperatively.

Hospital ethical committee's approval was taken and clinical trial registration was obtained from *clinicaltrials.org*. The surgery will be performed under local anesthesia (lignocaine with adrenaline 2%) and procedural sedation with propofol 25-100mcg/kg/min (only sedative dose) will be administered, so that the patient remains vocally responsive during the procedure. Incision will be made at the lower border of thyroid cartilage under aseptic measures. Skin flaps will be raised in sub-platysmal plane, strap muscles will be separated in the midline to expose the laryngeal cartilaginous framework. A simple laryngeal window approach will be used to place the Ethicon prolene mesh 6 x 6cm Swiss roll, secured with prolene 2/0 suture trimmed to the required size. Post op voice analysis will be done on 7^{th} day and 14^{th} post-operative day. Monthly follow up will be advised after that.

The results will be analyzed using IBM SPSS Statistics version 20. Variables defined would be compared between the pre-operative and postoperative groups. For normal data paired sample t-test would be used and for abnormally distributed data non parametric t-test would be used. P-value of less than 0.05 will be taken as significant.

Results: In this study, 39 patients satisfied the inclusion criteria. There were 23 females (38.5%) and 15 male (61.50%) patients. 26 patients (66.67%) had unilateral Vocal Cord

dysfunction while 13 (33.33%) had bilateral dysfunction. 46.15% (n=18) of these were post thyroidectomy, 20.51% (n=8) patients had idiopathic vocal cord paralysis and 33.33% (n=13) had miscellaneous causes. The median time passed since development of disease to the time of surgery was 6 months with a range of 2 months to 120 months.

The categorical data analysis was done with paired sample t-test, which indicated an improvement in Visual analogue (1-10) score of voice quality post operatively from 4.77 to 7.64 (p value <0.001). MWC increased from 11.33 to 18.28 (p value <0.001). The median increase in MPT in our study was about 5 seconds (n=39) (p value <0.001). For male patients median MPT increase was 7 seconds (n=15) and for females 4.5 seconds (n=24). These parameters indicated significant benefit to the patient and improvement in the quality of life.

There were no major complications observed in our study except for one instance of skin infection and hematoma. There were no graft displacements, extrusions and airway obstruction in our study. Four of our patients suffered temporary voice change due to upper respiratory tract infection which recovered in a span 5 days.