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Endoscopic Septoplasty versus Traditional Septoplasty for Treating Deviated Nasal Septum: A Prospective, Randomized Controlled Trial

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ABSTRACT

Importance: This is the first randomized study to compare the quality of life of patients undergoing endoscopic septoplastycomparedtotraditionaltrans-nasaltrans-speculum(TNTS)septoplasty.Objective:Toassessthe clinicaloutcomesandquality of life results of endoscopic versus TNTS septoplasty in patients with septal deviation and nasal obstruction. Design: Aprospective,randomizedcontrolledtrialcomparing2approachesofseptoplasty:endoscopicandTNTSseptoplastyperformedina single institution during the years 2019 to2020. The follow-up time was 3 months. Setting: A single institution study in atertiaryhealth-carereferralcenter.Participants: Patientswhounderwentprimarysurgery for repairingdeviated nasalseptum due to nasal obstruction, were older than 18 years old, and were eligible for study inclusion. Sixty-five patients wereenrolledinthisstudy,34intheendoscopicarmand 31intheTNTSseptoplastyarm.Theoverallfollow-upratewas94%atthefirstvisit(2weeks)and92%atthelastvisit(12weeks).Thus,thefinalcohortconsistedof60patients,30ineachstudyarm.Thepatients ranged in age from 18 to 71 years (mean 27 years) old. Main Outcomes and Measures: The primary outcome wasthe Sino-Nasal Outcome Test-22 (SNOT-22) score. Secondary outcomes were the Short Form 36 (SF36) QOL score andcomplication rates. Both questionnaires were administered at 2 weeks and 3 months following surgery. Results: Sixty patientscompleted this study, 30 in each study arm. Sino-Nasal Outcome Test-22 scores were improved after 3 months, with no difference between the study arms. There were no cases of septal perforation or profound bleeding requiring repeated surgery.ConclusionsandRelevance:Endoscopicseptoplastyand TNTSshowsimilarresultsfortreatmentofnasalseptumdeviation.

Keywords:
Endoscopic,septoplasty,SMR,qualityoflife

I. INTRODUCTION

Nasal obstruction is one of the most common complaints thatotorhinolaryngologists face in their daily practice. Deviatednasal septum (DNS) is a frequently encountered cause of suchobstruction. In addition to causing breathing difficulties, DNSresults in improper aeration of paranasal sinuses, predisposingtosinusitis,andresultsindryingofmucosa ,leadingtocrustingand epistaxis.[1,2] Deviated nasal septum is sometimes accompanied by hypertrophic nasal turbinates, thus causing sleepdisturbancesandsnoring.[3]

Nasalseptoplastyisacommonsurgicalintervention,directed to improve nasal breathing[4] and sleep disturbances.[3]The traditional trans-nasal trans-speculum (TNTS) septoplastyinvolves submucosal resection of the nasal septum; the com-plication rate is 3%-30%.There is no consensus on the long-termreliefofsymptomsafterthisprocedure.[5,6]

Endoscopic septoplasty is a minimally invasive techniquethat was developed as an alternative to the traditional submucosal resection for correction of DNS. In the last 2 decades,endoscopic sinonasal surgery has been widely used for indica-tions of inflammatory and neoplastic diseases. The excellentvisualization of this approach is presumed to decrease morbidity and postoperative swelling, by limiting the excision to thearea of deviation in the involved area.[2] Furthermore, diagnos-ing and treating abnormalities of the nose during the sameprocedure,includingconchabullosaandpolyps,areoftenonlypossible in the endoscopic approach. Nevertheless, no randomized studies have evaluated the utility of the endoscopic andTNTS techniques for DNS. In this randomized study, we evaluated the results, complications and quality of life (QOL) inpatients undergoing traditional TNTS septoplasty compared toendoscopicseptoplasty.

II. PATIENTS AND METHODS

This prospective, randomized controlled

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trial was conductedafter its protocol was approved by the review board of ourinstitution . The study took place at The department of ENT Great eastern medical school(GEMS), Ragolu Srikakulam, Andhra Pradesh ,India .Patients who underwent primary surgery for repairing DNSdue to nasal obstruction, were older than 18 years old, andwere eligible for study inclusion. Exclusion criteria includedbilateral acute or chronic rhinosinusitis, nasal polyposis, con-cha bullosa, inflammatory disease (eg, Wegener granulomatosis, sarcoidosis), neoplastic nasal pathology, diagnosis ofsystemicconditionsaffectingthenose(eg,cysticfibrosis,Kartagener syndrome), and an intention to undergo revisionsurgery.Between July 2019 and July 2020, patients sched-uled for primary surgery for DNS were enrolled in the studyafter providing informed consent to participate. The randomallocation sequence (1:1) was generated using a computer-generatedlist.The2armsconsistedof:acontrolarmofpatientsundergoingTNTSseptoplastyforDNS;andanexperimental arm, which included patients undergoing endoscopic septoplasty. All surgeries were performed by the samesurgeon

SurgicalTechnique

TheTNTSseptoplastywasperformedusinga headlight,loups,and a speculum. After injection, a Killian incision was madeusingaNo.15blade.Theincisionwasperformedonthesideofthedeviation.Thenthesubmucosalflapswereelevatedandthedeviatedsegmentwasremovedwithanadequatestrutleftintact to prevent columellar collapse. Cartilage was replacedand nasal packing (Medtronic's Xomed, Jacksonville, Florida)was used. If indicated, inferior turbinate reduction was alsoperformed.Theendoscopicseptoplastywasperformedusinga similar technique, but under visualization with a 4-mm, 0˚rigid endoscope (Stor, Tuttlingen, Germany). The endoscopewasusedtoidentifythedeviatedsegmentoftheseptumandforvisualization during dissection under theflap. If indicated,inferiorturbinatereductionwasalsoperformed.

Outcome Measures

All patients were followed with fiber optic endoscopes duringthe first 3 months after surgery. The primary outcome was thechangeintheSino-NasalOutcomeTest-22(SNOT-22)scores.[7]Sino-NasalOutcomeTest-22waspreviouslyshowntoevaluatesymptomatic relief following septoplasty.[8] The score on theShort Form 36 (SF36) QOL questionnaire[9,10] was a secondaryoutcome. Short Form 36 is a short questionnaire consisting of36 questions regarding patients' global health, and physical,social,andpsychologicaldomains.Postoperative complications (eg, epistaxis, perforation oftheseptum,andformationofsynechiae)wereevaluatedinthe follow-up visits. All outcome measures were evaluated atbaseline (maximum 3 months before surgery), at 2 weeks, andat 3 months after the surgery. Figure 1 shows the flowchart ofthestudydesign.

III. STATISTICAL ANALYSIS

An a priori sample size calculation was performed. UsingSNOT-22 scores as the primary outcome, as per the above,withanaof.05andbof.8,22patientsperarm arerequired to demonstrate a 20-point difference between thearms, which would be deemed clinically significant. Thisdetermineda study population of at least 44 patients intotal. Descriptive statistics were presented as means withstandard deviations. Analysis of variance and w^2 testingwereusedasappropriatefordataanalysis,and alltestswere2-tailed, with a.05 set as the level of significance. Allanalyses weredone using JMP10 softwarefor windows.

IV. RESULTS

Sixty-five patients were enrolled in this study, 34 in the endoscopic arm and 31 in the TNTS septoplasty arm. The overallfollow-up rate was 94% at the first visit (2 weeks) and 92% atthe last visit (12 weeks). Four in the endoscopic arm droppedout,and1intheTNTSarm.Thus,thefinalcohorttconsistedof60patients,30ineachstudyarm.The patients ranged in age from 18 to 71 years (mean 27years) old. Table 1 shows that the mean total operative timewas 24.9±7.9 minutes in the traditional septoplastyarmcompared to 33.8 ±12 minutes in the endoscopic septoplastyarm(P=.001).Therewerenocomplications intheendoscopic

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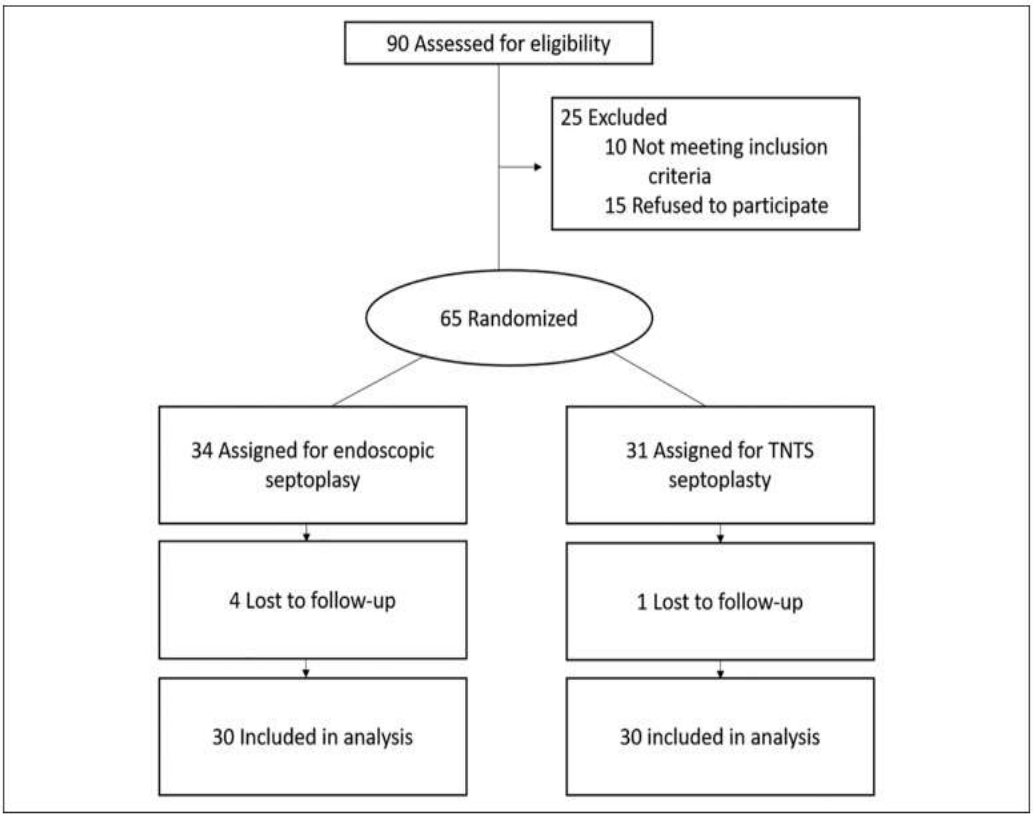

Figure 1. CONSORT flow chart of the study. TNTS indicates trans-nasal trans-speculum.

Table 1. Demographic and Surgical Characteristics of the Cohort.

Variable		Traditional Septoplasty (n ¼ 30)	Endoscopic Septoplasty (n ¼ 30)	Value
Median age, years		24.1	31.5	.02
Gender	Male	25 (83.3%)	26 (86.6%)	.8
	Female	5 (16.6%)	4 (13.3%)	
Overall operating time	Minutes	24.9 + 7.9	33.8 + 12	.001
Intraoperative complications		None	None	
Postoperative complications	Bleeding	1	None	.1
	Septal perforation	None	None	
	Other	1	None	

septoplastyarm,whereasintheTNTSarm,complicationsincluded epistaxis requiring cauterization and a surgical sitegranuloma that was removed in the clinic (P=.1). There werenocasesofseptalperforationineitherofthearms.

We compared the SNOT-22 scores between the 2 studyarms at 3 time points. Prior to surgery, patients in both armshadsimilarscores(mean43.8intheTNTSarmand 46.2intheendoscopic arm, P =.64). Figure 2 shows that the SNOT-22scoresimprovedinbotharmsat2weekspostoperatively(mean30.8intheTNTSarmand41.4intheendoscopicarm).Improvement in nasal symptoms was unremarkable in botharms (Figure 3A). However, in the TNTS arm, the scores werebetterthanintheendoscopicarmregardingthefollowingquestions: less waking up at night (28.1% compared to 8.5%), productivity (20.0% compared to 9.5%), and less embarrassment(22.9% compared to 3.8%). Overall, the scores in the TNTSweresignificantlybetterthanintheendoscopicarmat2weeks(P =.03).The SNOT-22 scores continued to improve following thesurgery,andtherewasnodifferencebetweenthearmsat 3monthspostoperatively(mean21.8intheTNTSarmand

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28.6intheendoscopicarm,P =.1).Atthis pointintime,scores weresimilar forallparameters inbotharms(Figure3B).Lookingspecificallyintothedomainofnasalsymptoms,SNOT-22analysisresultsshowthatthemostsignificantimprovementwasinnasalobstruction,runnynose,andsneezing(25.8%,26.6%,and18.3%intheTNTSarm,and34.4%,20.0%,and25.6%intheendoscopicarm,respectively).Weevaluated changesinQOL,using theSF36 questionnaire.Overall,thetotalscore(from1-100)improvedsignificantlyinthe3monthsaftersurgery(frommean65.8-81.4,P<.001)fortheentirecohort(Figure4).Priortothesurgery,thescoresweresimilarintheTNTSandtheendoscopicarms:mean 66.8 and64.8,respectively, P =.69. Two weeks follow-ingthesurgery,thetotalmeanscoreimprovedintheTNTSseptoplastyarm,from66.8-69.6(P = .4);whileintheendoscopicseptoplastyarm,worsening ,withborderlinestatisticalsignificance, wasobserved,from64.9to 58.3(P = .07). However,3monthspostoperative,botharmsshowedsignificantimprovementinthe SF36comparedtothepreoperative scores:mean83.4intheTNTSarmand81.4intheendoscopicarm(P =.26).SupplementaryFigure1showsforeachstudyarm ,thechangesineachdomainoftheSF36questionnaireduringthefollow-up.

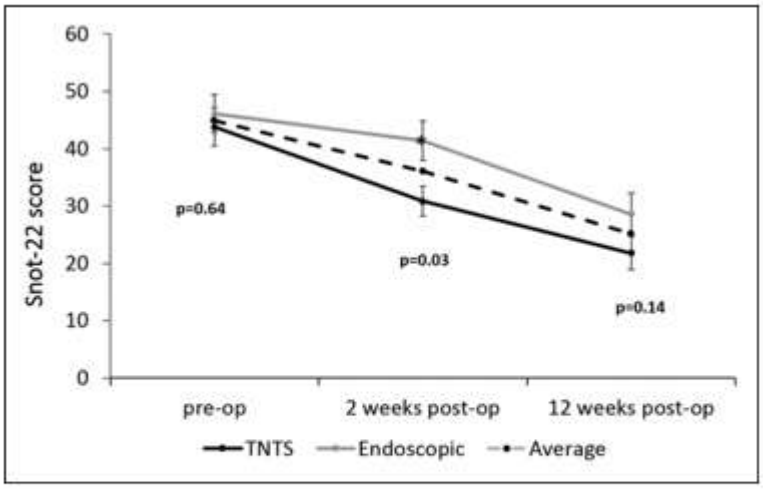

Figure 2. Sino-Nasal Outcome Test-22 score. Analysis of the total SNOT-22 questionnaire scores for both study arms. SNOT-22 indicates Sino-Nasal Outcome Test-22; TNTS, trans-nasal trans-speculum.

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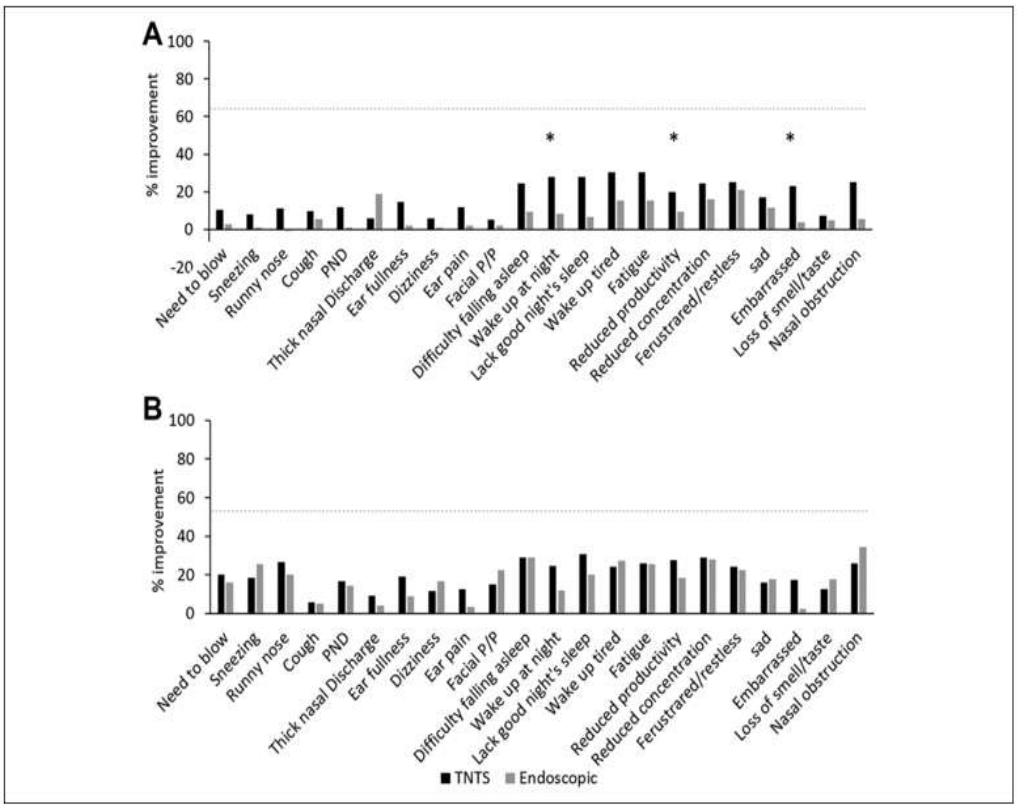

Figure 3. Univariate analysis of postoperative SNOT-22 scores. A, Two weeks postoperative; (B) 3 months postoperative. SNOT-22 indicates Sino-Nasal Outcome Test-22; TNTS, trans-nasal trans-speculum.

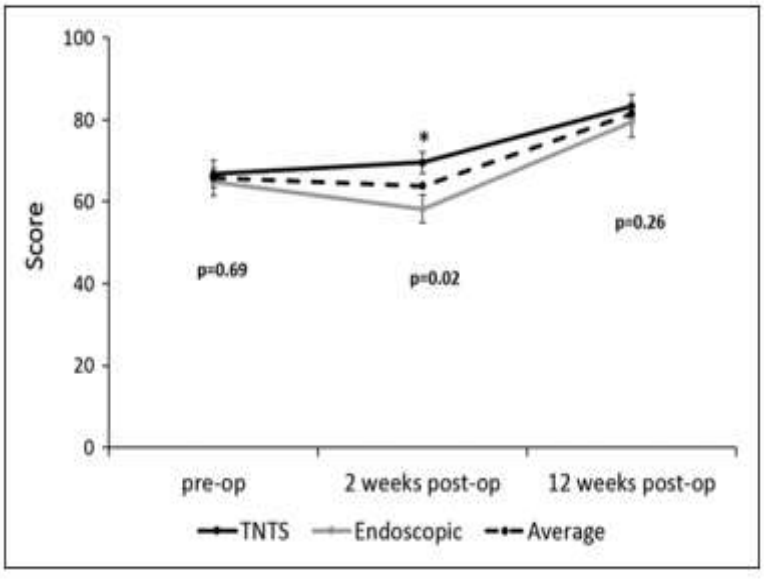

Figure 4. Short Form 36 score. Analysis of the total SF36 scores for both study arms. SF36, indicates Short Form 36; TNTS, trans-nasal trans-speculum.

V. DISCUSSION

Submucosal resection is a common operation performed withthe aim of improving nasal breathing, nasal symptoms, andsometimes snoring in patients with DNS. The traditional sep-toplasty procedure involves submucosal resection of the ante-rior septum. Not all patients experience improvement in theirsymptomsorinQOLafterthisoperation.Withthei ntroductionof the endoscopic sino-nasal approach for septoplasty, thisstudy aimed to compare the outcomes of the 2 approaches onnasalsymptomsandqualityoflife.

Thedemographicandsurgicalparameterswe resimilarbetween the arms except that the mean age was lower in thetraditionalseptoplastyarm.Twoweekspostoperati vely,patients who underwent traditional septoplasty reported betterQOL scores than patients who underwent endoscopic septo-plasty. The QOL of all the patients was improved at 3 monthsfollowing the operation, as evaluated by the SNOT-22 andSF36 questionnaires. After 3 months, the results of surgeryweresimilarinthe2arms.

Trans-nasal trans-speculum septoplasty is considered thetraditional approach for submucosal resection and has beenutilized for decades by the majority of ENT surgeons. How-ever, long-term assessments of this surgery are contradictory,with most publications rating it as unsatisfactory. Studies thatevaluatedsuccessratesaccordingtovariousdefiniti onsofsuc-cess, reported rates of 27% to 84%, 6 months to 11 years aftersurgery.[11-16] Some used functional measures,[11-14] while othersused subjective questionnaires and assessed the QOL of thepatients after the surgery.[15,16] The complication rate of TNTSseptoplasty varies between 3% and 30%, with contradictoryreportsonthelong-termreliefofsymptomsafterthisprocedure.[5,6]Endosc opic septoplasty is a recently developed techniquethat has gained popularity in the last decade. The effectivenessofthisapproachwasevaluatedusingobje ctivefunctionaltests,anatomicalresults,andcomplicat ionrates.[1,2]However,nopublished study prospectively evaluated changes in QOL fol-lowingthisprocedure.Whencomparingbothapproach es,theendoscopicapproachaccounted for a longer operating time with results that weresimilar to TNTS (with the same complications rate and similarQOL scores). Due to the enhanced depth of vision it allows,endoscopic septoplasty may be advantageous for correction ofaposteriorvomerdeviation,conchabullosa,orchoan alobstruction (adenoid enlargement or tail of the inferior turbi-nate). Where there is a localized septal deviation, the endo-scopic approach may help to guide the incision and orient thecorrection to a more limited area of the septum. Any finaldecisionshouldbebasedonsurgeonpreferencean dfamiliaritywitheachapproach.

VI. CONCLUSION:

In conclusion, this study showed that septoplasty, both byTNTS and endoscopy, is effective in improving the symptomsandgeneralQOLofpatientswithDNS.

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