

Comparison of efficacy of potassium titanyl phosphate laser & diode laser in the management of inferior turbinate hypertrophy: A randomized controlled trial

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Background & objectives: Inferior turbinate hypertrophy (ITH) is a common condition causing nasal obstruction. This study was undertaken to compare the efficacy of potassium titanyl phosphate (KTP) laser and diode laser in the reduction of the turbinate size.

Methods: This randomized controlled trial included 209 patients with ITH. Pre-operative symptoms were assessed based on the Nasal Obstruction Symptom Evaluation (NOSE) score. Diagnostic nasal endoscopy was done to rule out other nasal sinuses. Nasal mucociliary clearance was measured by saccharin transit time (STT). Postoperatively, the NOSE score, STT and complications were assessed at days one and two, at one week, one month and three months.

Results: Of the 209 patients analyzed at day one, the median NOSE score was 50 in the diode group and 40 in the KTP group, and at three months, 15 in the diode group and five in the KTP group. KTP laser showed a 93 per cent improvement in the NOSE score as compared to 77 per cent improvement shown by diode laser group. Among the intra-operative complications, of the 104 patients in the diode group, 6.73 per cent had burning sensation and 91.43 per cent had bleeding, and of 105 patients in the KTP group, 54.29 per cent had burning sensation and 36.54 per cent had bleeding. Among the post-operative complications in the KTP group, 32 and 34 per cent had bloody nasal discharge on days one and two, compared to 12 and 14 per cent in diode group. Crusting was present in 61 and 49 per cent on days one and two in KTP group as compared to 9 and 15 per cent in diode group, respectively. In the KTP group 30 per cent had synechiae as compared to 10 per cent in diode group.

Interpretation & conclusions: KTP laser was more efficacious than diode laser in improving the NOSE scores but with slightly increased rate of complications in early post-operative period. Both the lasers impaired the mucociliary clearance mechanism of the nose till three months of post-operative follow up.

Key words Diode laser - inferior turbinate hypertrophy - KTP laser - laser turbinoplasty - NOSE score

Inferior turbinate hypertrophy (ITH) is one of the common conditions causing nasal obstruction. Turbinate enlargement may occur due to mucosal or bony hypertrophy or both¹. The term turbinate hypertrophy was first coined in the late 1800s to describe the enlargement of the inferior turbinate². Hyperplasia and hypertrophy of the mucosal or osseous layers of the inferior turbinate also provide potential explanations for the mechanism of inferior turbinate enlargement. The hypertrophy is due to the dilatation of the submucosal venous sinusoids. The venous sinusoids are under adrenergic control and usually collapse on sympathetic stimulation³.

ITH may be seen in perennial allergic rhinitis, vasomotor rhinitis, or as a compensatory response to a septal deformity. Chronic inflammatory conditions cause changes in the structure of tissues such as deposition of collagen in submucosal tissue and remodelling of turbinate bone. This renders them incapable of decongestion. ITH can result in nasal obstruction, which is initially managed medically with drugs, and surgery is done in refractory cases. Surgery includes turbinectomy, turbinoplasty, radiofrequency volumetric tissue reduction and laser-assisted turbinoplasty.

Lasers reduce allergic remodelling by creating fibrous granulation tissue eventually forming scar, reducing number and activity parasympathetic nerve fibres, causing regenerating changes in the mucosa which inhibits the release of chemical mediators and pro-inflammatory cytokines⁴. In case of allergic rhinitis, mucosal hypertrophy is the main cause for ITH rather than bony hypertrophy as in compensatory hypertrophy secondary to deviated nasal septum⁵. Though potassium titanyl phosphate (KTP) laser has less penetration into the tissue and causes lesser thermal damage, its high-cost and lesser portability limit its use. Diode laser has more tissue penetration, whereas it is less costly and portable compared to KTP6. Therefore, the objective of this study was to compare KTP laser-assisted and diode laser-assisted turbinoplasty to find the efficacy and complications of these two procedures for turbinate reduction.

Material & Methods

This randomized controlled trial was conducted in the department of Otorhinolaryngology, Jawaharlal Institute of Postgraduate Medical Education & Research (JIPMER), Puducherry, India, from November 2015 to March 2017. The Institutional Ethics Committee approval was obtained and it was registered in the Clinical Trial Registry of India (CTRI/2017/09/009840). Patients with rhinitis (allergic and non-allergic) having bilateral inferior hypertrophy who were above 18 yr of age and refractory to medical treatment (antihistaminics, nasal decongestants and steroid sprays for 12 wk) were included in the study, and patients with bleeding diathesis, acute respiratory tract infections, previous history of nasal surgeries or trauma, gross deviation of the nasal septum and associated sinonasal diseases were excluded.

The proportion of nasal obstruction in general population was considered as 20-30 per cent⁶. The sample size was estimated using OpenEpi software version 3.01 (*www.OpenEpi.com*) for comparing two independent proportions using Fleiss method⁷. The proportion of improvement in nasal obstruction in the diode laser group was 73.2 per cent⁸. The proportion of improvement in nasal obstruction in the KTP laser group was 90 per cent⁹. A 15 per cent absolute difference was expected in the proportion with improvement on nasal obstruction symptoms in the KTP laser group. The sample size was calculated as 109 in each group at five per cent alpha error and 80 per cent power.

Overall, 220 cases were assessed for eligibility along with a five per cent margin of lost to follow up. Only 215 were included in the study as two of them declined consent and the remaining three were not fit for the surgery. At the end of the study, six patients were lost to follow up and no extra participants were included in the study. Finally, 209 cases were analyzed with 105 in the KTP group and 104 in the diode group. Block randomization with varying block size was generated using random allocation software to allocate participants to either the KTP laser or diode laser groups. The allocation sequence was concealed using sequentially numbered sealed opaque envelopes. The envelopes were opened just before the surgery.

Pre-operative evaluation: All the patients underwent a complete history and ENT (ear, nose and throat) examination. A diagnostic nasal endoscopy using Karl Storz 0° endoscope (Karl Storz SE & Co. KG, Germany) and computed tomography were done to rule out other sinus pathologies. All the patients were started with topical nasal decongestant, steroid spray and antihistaminic for 12 wk. Patients who had

Table I. Pre-operative con	mparison of baseline p	parameter
between the diode and po	tassium titanyl phospl	hate (KTP)
groups		
Parameters	Diode group	KTP group
	(n-104)	(n-105)

	(n=104)	(n=105)
Age (yr)	34.8±11.1	34.6±10.8
Gender (male/female)	55/49	56/49
NOSE score at baseline, median (IQR)	65 (60-70)	70 (65-75)
STT at baseline (min)	48.2±9.2	48.3±9.3
Duration of surgery (min)	35.1±8.1	34.7±8.1
Values given as mean±SD. A within sampling fluctuation		

within sampling fluctuations. NOSE, Nasal Obstruction Symptom Evaluation; IQR, interquartile range; STT, saccharin transit time

persistent symptoms after 12 wk were considered as non-responsive to medical treatment and considered for surgery. The Nasal Obstruction Symptom Evaluation (NOSE) score¹⁰ and saccharin transit time (STT)¹¹ were noted at the baseline in all the cases (Table I).

Nasal Obstruction Symptom Evaluation (NOSE) score: The symptoms were assessed using the NOSE score¹⁰. This is a subjective, validated instrument which rates the severity of nasal symptoms. It ranges from 0 to 100 comprising five components which are nasal blockade or obstruction (0-4), nasal congestion or stuffiness (0-4), trouble breathing through the nose (0-4), trouble sleeping (0-4), unable to get enough air during exertion (0-4) and each multiplied by 5 to get a maximum score of 100. Scores were noted as 0 - not a problem, 1 - very mild problem, 2 - moderate problem, 3 - fairly bad problem and 4 - very severe problem.

Saccharin transit time (STT): Nasal mucociliary clearance was measured by SST and was determined by placing a saccharin particle on the anterior surface of the inferior turbinate on the one side of the nasal cavity in sitting position with neck slightly flexed¹¹. The patients were asked to intimate when they feel the sweet taste in the mouth, and the time taken for it to do so was noted for each patient preoperatively, at one week, at one month and at three months and interpreted as: 20 min - normal, 21-30 min - prolonged, 31-60 min - severely prolonged and more than 60 min - grossly prolonged.

Surgical procedure: Patients underwent laser treatment for ITH under local anaesthesia. Both nasal cavities

were packed with cotton pledgets soaked with four per cent Xylocaine and 1:200,000 (adding 0.1 ml of 1:1000 adrenaline to 20 ml of local anaesthetic solution) adrenaline, 10 min before the surgery. Both the procedures were done under endoscopic guidance using 0° endoscopes (Karl Storz SE & Co. KG, Germany) connected to cold light source.

Diode laser-assisted turbinoplasty: The diode laser (portable 980 nm wavelength Fox Diode Laser from A.R.C, Germany) was used submucosally with a fibre diameter of 600 μ m and power of 5 W in continuous wave mode. The laser was applied submucosally 2-3 passes that were made at the anterior, middle and posterior parts of each turbinate, and the duration of each pass was around 15 sec (Figs 1 and 2).



Fig. 1. Diode laser pointing towards inferior turbinate.



Fig. 2. Diode laser turbinoplasty (intra-operative picture).

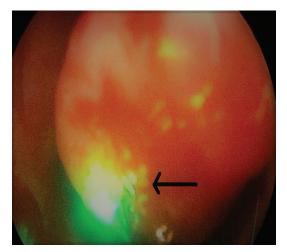


Fig. 3. Potassium titanyl phosphate (KTP) laser pointing towards inferior turbinate.

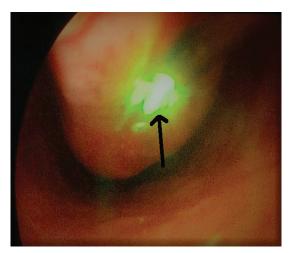


Fig. 4. Potassium titanyl phosphate (KTP) laser turbinoplasty (intra-operative picture).

<u>KTP laser-assisted turbinoplasty</u>: After standard laser precautions, KTP laser parameters were set to 5 W at continuous mode, spot size of 0.6 mm and energy delivered through 400 μ m optical fibre. The laser was applied submucosally in the same way as that for diode laser (Figs 3 and 4).

Post-operative management: Postoperatively, analgesic, antihistaminic and topical nasal decongestant drops were prescribed for five days. No antibiotics or steroids were prescribed as these would mask the surgical outcomes. Follow up visit was done at post-operative day one and two, one week, one month and three months post-surgery. At each follow up visit, the NOSE score and complications of the surgery were noted. STT and nasal endoscopic findings were reassessed at one week, one month and at three months after surgery.

Statistical analysis: The comparison of NOSE score between the two study groups was carried out by using Wilcoxon rank-sum test. The outcome variables such as intra- and post-operative complications and mucociliary clearance between the groups were compared using Fisher's exact test.

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Results

Predominant symptoms of the patients were nasal blockade and nasal congestion. The baseline NOSE score was comparable between the two groups as the median score for the diode group was 65 and for the KTP group was 70. Of the 209 patients, 40 (19.1%) had a history of smoking and 33 (82.5%) had inflamed mucosa. Pre-operative mucociliary clearance was 48.2 ± 9.2 min for the diode laser group and 48.3 ± 9.3 min for the KTP laser group. This suggests that the groups are matched preoperatively and are comparable (Table I). The mean duration of surgery for the diode group was 35.0 ± 8.1 and for the KTP group was 34.7 ± 8.1 min.

Improvement in NOSE score: The median NOSE score in patients receiving diode laser was 50 and those who received KTP laser was 40 on post-operative day one, the difference was significant (P<0.001). This improvement persisted throughout the follow up period of post-operative day two, at the end of one week, one month and three months. The NOSE score improvement was significantly better in the KTP group as compared to the diode group (Table II). It was found that KTP was efficacious than diode by 16 per cent at the end of the three months follow up (Table II). Although the patients had high NOSE scores on post-operative days one and two, these were attributed to crusting and oedema in the early postoperative period.

Intra-operative complications: Of the 209 patients, 6.7 per cent (n=7) in the diode group (n=104) had experienced burning sensation as compared to 54.2 per cent (n=57) in the KTP group (n=105) and the difference was significant (P<0.001). Further, 91.3 per cent (n=95) in the diode group and 36.2 per cent (n=38) in the KTP group had bleeding and the difference was significant (P<0.001). None of the patients required a hospital admission for pain or bleeding.

Complications in post-operative period: Bloody nasal discharge was encountered during post-operative days

Time point	NOSE score		Improvement (%) in NOSE score [†]	
	Diode group	KTP group	Diode group	KTP group
At baseline	65	70	-	-
At one day	50	40	23***	43
At two days	45	40	31***	43
At one week	40	15	38***	79
At one month	30	10	54***	86
At three months	15	5	77***	93

one, two and one week in both the groups. The KTP laser group showed bloody discharge in 32 and 34 per cent during days one and two and diode laser group in 12 and 14 per cent. All the patients were given topical decongestant drops.

Both the groups had crusting till one week of follow up period and the KTP group had significantly more (P<0.001) crusting (day 1=61%, day 2=49%) when compared to the diode group (day 1=9%, day 2=15%). The time taken for crusts to disappear was one to three months in both the groups. All these patients were advised alkaline nasal douching three times a day for a period of one week.

Synechia formation was observed in both the groups at the end of one week, one month and three months. Synechia was present in 30 per cent patients in KTP group and 10 per cent patients in diode group. Patients were advised alkaline nasal douching for those who had synechiae at one week.

Saccharin transit time (STT): STT was severely prolonged (31-60 min) in both the groups at one week, one month and three months, and these results were statistically insignificant. This implies that both lasers impaired mucociliary clearance mechanism till three months postoperatively and patients should be followed up for a longer period to document normalization to baseline.

Discussion

Diode laser-assisted turbinate surgery is a wellknown technique for improving nasal airflow. It has tissue cutting-effect which is comparable to that of the carbon dioxide laser and is absorbed by the tissue better than neodymium-doped yttrium aluminium garnet (Nd:YAG) laser. Caffier *et al*¹² assessed

the long-term outcomes of outpatient-based diode laser inferior turbinate reduction in the treatment of refractory rhinitis medicamentosa. They found that 88 per cent of the patients managed to successfully stop decongestant abuse after six months. Volk et al⁸ suggested that diode laser enhanced nasal airflow. They also provided evidence showing the predictive value of rhinomanometry with decongestion for the post-operative improvement of nasal flow. Caffier et al^{13} reported that outpatient endonasal diode laser surgery was an effective, safe and well-tolerated procedure for treating otherwise therapy-resistant perennial and seasonal allergic rhinitis. Parida et al¹⁴ conducted a prospective study with 45 patients and showed that diode laser turbinate reduction caused a significant improvement in the Visual Analogue Scale at the end of one week, one month, three months and six months.

In the present study, the KTP laser was found to improve the NOSE score when compared to diode laser by 16 per cent and the difference was significant. This result was comparable with Orabi *et al*¹⁵ who showed that patients received maximum improvement in nasal obstruction at the end of six weeks when KTP laser was used. Yaniv *et al*¹⁶ showed that 69 per cent of the patients showed improvement after receiving KTP laser at the end of one year. In our study also there was a significant improvement in the NOSE score when compared to baseline and that KTP was better than diode in reducing the symptoms.

Post-operative crusting, bloody nasal discharge and synechiae were more in patients with KTP laser compared to diode laser. Burning sensation/pain in the current study was significantly more with KTP laser than diode laser. Orabi *et al*¹⁵ found that of the 39 patients who underwent KTP laser turbinoplasty, 69 per cent had mild pain, 26 per cent had moderate pain and five per cent had severe pain. In another study the 62 patients who received diode treatment, none of them had pain¹⁷.

The present study showed that the time taken for crusts to disappear was 1-3 months in both the groups. Orabi et al¹⁵ also showed improvement in crusting and obstruction in first six weeks after which a plateau was reached in patients receiving KTP laser. All these patients were advised alkaline nasal douching three times a day. In our study, during the three-month follow up period, the overall synechia rate was significantly more with KTP laser when compared to diode. Parida et al^{14} showed that none of the patients had synechiae at the end of three months after diode laser treatment. STT in our study was prolonged for all the participants during the three-month follow up period. However, this did not correlate with our previous study¹⁸, which showed that in all patients who underwent KTP laser treatment, STT was back to pre-operative levels at three months. Another study by our group¹⁴ showed that STT was back to normal at six months for patients who received diode laser treatment. Our study also showed that both the laser treatments impaired mucociliary clearance mechanism temporarily similar to that shown by Harju *et al*¹⁹.

In conclusion, our findings showed that KTP laser was more efficacious than diode laser with respect to the NOSE score improvement. However, KTP had an increased rate of complications in the postoperative period. Mucociliary clearance mechanism was affected by both the lasers till three months of post-operative follow up. The limitations of our study were that the symptoms were assessed subjectively by the NOSE score which could have been assessed objectively using tools such as acoustic rhinometry and rhinomanometry. Further studies need to be conducted with longer follow up periods to assess the long-term outcomes and to study the mucociliary clearance mechanisms.

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