APPLICATION REPORT

In-office Radiofrequency Reduction of inferior turbinates of nasal blockage not responding to medical treatment

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Introduction: Nasal blockage is a very common symptom encountered in clinical practice. Common conditions causing long-term nasal congestion include allergic and non-allergic rhinitis, chronic rhinosinusitis with or without nasal polyps and deviated nasal septum. Difficulties breathing through the nose will often result in fragmented sleep, causing daytime tiredness and reduced quality of life through loss of energy and results in decreased daytime productivity causing high cost to society. It is estimated that 20-30% of the population suffer from rhinitis (allergic and non-allergic). First line of treatment has for decades been intranasal corticosteroids (INCS) and or antihistamines. However not all patients respond to medical treatment, and INCS treatment is not affordable by all patients and can at times lead to epistaxis. Patients not responding to medical treatment are often referred to an ENT specialist. A clinical evaluation assesses the size of the turbinates, the position of the nasal septum and presence of nasal polyps or evidence of infection. Traditionally, patients with nasal blockage not responding to medication have been referred to septoplasty and reduction of inferior turbinates under general anaesthesia.



Fig. 1: RaVoR™ bipolar electrode for the inferior turbinates, single-use (REF 70 44 62)

Why Radiofrequency ablation of inferior turbinates? Radiofrequency ablation (RFA) is a method to deliver energy to the submucosal tissue generating a heat induced ablation without damaging underlying bone or the mucosal cover, creating a volumetric reduction of the size of the inferior turbinate. It can be performed in an outpatient setting under local anaesthetic. Previous reports from the literature have shown efficacy. A placebo-controlled trial (sham operation), a rarity in evaluation of surgical methods, showed a significant effect on nasal obstruction at 6-8 weeks post intervention.1 Furthermore, 2 studies have confirmed lasting effect on nasal patency with one study following up for 3 years and the other 5 years.^{2,3}

RFA provides a number of advantages over surgical excision of the turbinates:

• Direct hospital cost is significantly reduced compared to bringing the patient to theatre. RFA provides value for money.

- Time needed to perform the procedure is greatly reduced.
- Waitlist can be reduced.
- Provide patients with better access to
- care as less resources are needed.
- Theatre time is freed up for other surgical procedures.
- The procedure requires minimal skill set of doctors and is easy to learn.

• Patients with co-morbidities, at risk under general anaesthesia, can now be offered treatment.

• There is no down-time for patients as they

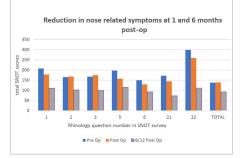


Fig. 2: Reduction of symptoms in the rhinology domain of SNOT-22: 1. Need to blow nose, 2. Sneezing, 3. Runny nose, 5. Post nasal discharge, 6. Thick nasal discharge, 21. Sense of taste/smell, 22. Blockage congestion of nose

are back at normal activities/work the next day. This has turned out to be an important feature of the method and leads to a significant reduction in societal costs.

Other use of the Radiofrequency technique:

It has become a popular method among our registrars to manage epistaxis with the CURIS[®] 4 MHz radiofrequency generator by Sutter. The probe used for turbinate reduction, with two prongs about 2 mm apart is well suited to place over a bleeding vessel for bipolar coagulation. The low thermal heat leaves less smoke, charring and tissue damage compared to traditional diathermy. We are now also using the method to manage epistaxis in HHT patients.

Patient selection: Nasal blockage not responding to medical treatment, where nasal assessment has excluded nasal polyps or marked septal deviation. Mild to moderate septal deviation seems not to affect outcome and can often be ignored, especially if the patient has a history of side changing nasal blockage or is undetermined of which side being the most bothersome.

Contraindications includes allergy to local anaesthetics. Relative contraindications include significant septal deviation and other disease obstructing the nasal cavity such as grade 2-3 nasal polyps or adenoid hypertrophy.

Patient information: We quote an 80 % chance of significant improvement and always leave the

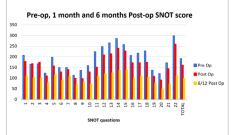


Fig. 3: Reduction in symptom score in the Sino Nasal Outcome Test at 1 and 6 months post-op



Fig. 5: CURIS[®] 4 MHz radiofrequency generator

door open to perform revision RFA or escalate to a surgical reduction of the inferior turbinates should it be deemed necessary. The patients are informed about possible complications which includes infection, crusting and epistaxis. The need for any other pain relievers than paracetamol is unusual.

Patients and Methods: A prospective intervention study was conducted at the ENT department of the Royal Brisbane & Women's Hospital. A cohort of 191 adult patients with nasal obstruction refractory to medical management were treated with radiofrequency ablation (RFA) to both inferior turbinates. Sino Nasal Outcome Test (SNOT-22, a questionnaire covering nasal symptoms, as well as sleep quality, facial pain and overall well-being) was used at baseline and then 1 month and 6 months after RFA.

A vasoconstrictive and local anaesthetic nasal spray is used to both nostrils. Followed by an injection of the anterior portion of the inferior turbinate with 1-2 ml of xylocaine/ adrenaline. The RFA probe is inserted submucosally, medial to the turbinate bone, often 2 insertion sites per side with about 10 seconds of energy delivery per insertion, or until the mucosa starts blanching. A short observation

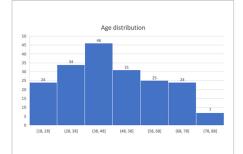


Fig. 4: Age distribution



Please turn over the page for detailed information on the Sutter products. As seen in: ent and audiology news | November/December 2019 | VOL 28 NO 5 | Page 28 period, approximately 30 minutes post-op is recommended. No packing is used. Nasal saline washes are recommended the first postoperative week.

Results: There was a significant reduction in the rhinology symptoms of the SNOT-22 questionnaire at both 1 and 6 months postoperative compared to baseline. No patient had to be admitted due to complications from the procedure. Pain was minimal and all patients returned to normal activities the day after the procedure. Crusting and minor epistaxis, not requiring medical attention, was seen occasionally during the first postoperative week. The Royal Brisbane & Women's Hospital New Technology Funding and Evaluation Program has calculated the cost of RFA of inferior turbinates at the ENT outpatients to AUD 184 per patient compared to the surgical procedure where the cost has been estimated at AUD 4500 to 6000. Of our cohort of 191 patients, only 6 were referred on to surgery of the septum and turbinates under general anaesthesia. Our waitlist for turbinate surgery has been reduced from over 1 year to about 6 weeks.

Conclusion: Radiofrequency ablation of inferior turbinates have provided consistent results reducing nasal blockage, with few patients referred to further surgery. It has also proven to be safe. Return of investment compared to surgical procedure is tremendously high. Not the least, it is a popular method with patients, as the postoperative morbidity is limited and there is no down-time from work or daily activities.



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References: 1. Bipolar radiofrequency volumetric tissue reduction of the inferior turbinates: evaluation of shortterm efficacy in a prospective, randomized, single-blinded, placebo-controlled crossover trial. Bran et el. Eur Arch Otorhinolaryngol. 270(2):595-601 June 2012, 2. Radiofrequency volumetric inferior turbinate reduction: long-term clinical results. E De Corso et al. Acta Otorhinolaryngol Ital 36(3) Jun 2016, 3. Long-term Results of Radiofrequency Turbinoplasty for Allergic Rhinitis Refractory to Medical Therapy. Hsin-Ching Lin et al. Arch Otolaryngol Head Neck Surg 136(9) Sep 2010.

Product Information

	R	aVoR™ (Radiofreque	ncy Volume Reduction)		
	Q	ty REF	Description		
	1	70 44 62	RaVoR™ bipolar electrode for the inferior turbinates single-use, work length 110 mm	with protective insulation,	
	Option	al: reusable RaVoR™	bipolar electrode for the inferior turbinates (REF 70 04	62)	
				Unit settings / Other accessories*	
[REF 87 00 10] CURIS [®] 4 MHz radiofrequency generator				CURIS® 4 MHz radiofrequency generator	
	set with single-use			RaVoR [™] bipolar electrode: Bipolar RaVoR Power adjustment: 10 watts	
Qty.	REF	Description			
1	36 01 00-01		diofrequency generator user manual and test protocol)	Valid for the CURIS* with the orange label.	
1	36 01 10	Foot switch two pe	edals for CURIS $^{\odot}$ (cut & coag), cable length: 4 m		
1	37 01 54L Bipolar cable for CURIS®, length: 3 m		CURIS®, length: 3 m	4 MHz radiofrequency generator	
1	36 07 04	Monopolar handp	iece (pencil) cut & coag, shaft 2.4 mm, cable: 3 m	RaVoR™ bipolar electrode: Bipolar RaVoR	
1	36 03 36	Cable for single u	se natient plates length: 3 m	Power adjustment: 10 watts	

36 02 38 Cable for single-use patient plates, length: 3 m 1 (x50) 12 80H Patient plates, single-use, 5 x 10 pcs. (not shown)



* Please consider that this information is not meant to serve as a detailed treatment guide. Always adjust according to patient and application.

Product availability is subject to regulatory approval in individual markets. Products may therefore not be available in all markets. Lengths for orientation purposes; may vary slightly.



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