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Complications of Novel Radiofrequency Device Use in Rhinology: A MAUDE Analysis

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Abstract

With the widespread adoption of intranasal radiofrequency (RF) devices, our objective was to report national adverse events (AEs) associated with their use. The Food and Drug Administration's Manufacturer and User Facility Device Experience was queried. A total of 24 device-related AEs were reported, 11 (45.8%) for Celon® (Olympus), 3 (12.5%) for Vivaer® (Aerin), 2 (8.3%) for Neuromark® (Neurent), and 8 (33.3%) for Rhinaer® (Aerin). Seven (63.6%) of the Celon®-related complications were related to tissue necrosis (largely user error-related), but 1 (9.1%) episode of pediatric ocular palsy was also reported. Vivaer® complications included synechiae formation, a mucosal perforation, and a case of empty nose syndrome. Of the posterior nasal nerve ablating devices, 9 of 10 AEs were epistaxes, of which 7 (77.8%) required operative intervention. Surgeons should exercise vigilance and tissue-appropriate device settings when utilizing RF devices. Epistaxis and tissue necrosis may occur, as well as more rare, but devastating, complications.

Keywords

chronic rhinitis, complications, epistaxis, radiofrequency devices, rhinorrhea

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Radiofrequency (RF) devices have quickly emerged as novel treatment options for many otolaryngologic conditions, especially within rhinology.[1] The earliest example (US Food and Drug Administration [FDA]-approved in 2016) is the Celon® Elite/Probreath system (Olympus), which utilizes RF for turbinate reduction.[2] VivAer® (Aerin Medical), FDA-approved in 2017, utilizes RF to directly remodel the internal nasal valve.[3] RhinAer® (Aerin Medical), approved in 2020,[4] and NeuroMark® (Neurent Medical), approved in 2021,[5] both utilize RF to treat chronic rhinitis (CR) by ablating the posterior nasal nerve. Many published studies on device utility suffer from small sample sizes, limiting thorough safety analysis.[2-5] With the widespread development and adoption of intranasal RF devices, new evidence suggests that RF may not be as benign to native tissues as believed.[6] The objective herein was to use the FDA's Manufacturer and User Facility Device Experience (MAUDE) database to detail adverse events (AEs) that have been reported with increased utilization.

Methods

The MAUDE database was queried for AEs reported after Celon® Elite/ProBreath, Neuromark®, VivAer®, and RhinAer® use since database inception to February 2nd, 2023. AEs are voluntarily reported by physicians and patients, but manufacturers are mandated reporters. The events were reviewed and categorized by 3 reviewers (S.J.T., B.F.B., E.H.A.), with any discrepancies discussed and resolved. Duplicate events were removed. As data is public, this study was exempt from review by the UC Irvine Institutional Review Board.

Results

Twenty-four RF device-related AEs were reported, 11 (45.8%) for Celon®, 2 (8.3%) for Neuromark®, 3 (12.5%) for VivAer®, and 8 (33.3%) for RhinAer® (**Table 1**). Seven (63.6%) of the Celon®-related complications were related to tissue necrosis, including a palatal perforation that appeared to be related to user error (settings erroneously placed too high). Notably, 1 (9.1%) pediatric ocular palsy episode was also reported. VivAer® complications included synechiae formation requiring excision, mucosal perforation secondary to tissue necrosis, and a case of patient-reported empty nose syndrome.

Seven (87.5%) of the 8 RhinAer® complications were epistaxes (**Table 2**). Epistaxis frequently occurred within 2 weeks of surgery (71.4%), but as late as Day 33. Three

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Table 1. Details of Radiofrequency Device-Associated Complications

Device	Number of adverse events[a]	Complication type	Number of complications[b]	number requiring postoperative ED visit or admission[c]	Number requiring postoperative intervention[c]	Description and interventions
Celon	11 (45.8%)	Postoperative epistaxis	1 (9.1%)	0 (0.0%)	1 (100.0%)	Postoperative bleed noted with exposed bone (presumably turbinate). Intervention was performed, presumably in-office, though no details were given.
		Tissue necrosis	7 (63.6%)	0 (0.0%)	3 (42.9%)	One involved the palate, 5 involved the turbinate, and another was at an unclear location. Three of the turbinate necroses patients required debridement. One patient was noted to have an infection at the site of necrosis and was started on a course of antibiotics. Six of the descriptions implied settings had been placed too high and were thus user error.
		Ocular palsy	1 (9.1%)	1 (100.0%)	Unknown	The pediatric patient was readmitted the same day for blurry vision and was found to have developed a unilateral sixth nerve palsy. No description of the intervention was given.
		Device failure	2 (18.1%)	0 (0.0%)	0 (0.0%)	In 1 event, the device did not function after the patient was anesthetized, resulting in a canceled procedure. On the other, there was an intraoperative persistent bleed caused by a malfunctioning device (coagulation not functioning), which was resolved with a new device.
VivAer	3 (12.5%)	Synechiae	1 (33.3%)	0 (0.0%)	1 (100.0%)	During a f/u visit, a "mass" was noted on the nasal valve lateral wall unilaterally. This was excised and sent for pathology, which resulted in fibrotic soft tissue.
		Tissue necrosis	1 (33.3%)	0 (0.0%)	0 (0.0%)	7 months after the procedure, the patient developed a mucosal perforation at the area previously treated. Cartilage had remained intact.
		Empty nose syndrome	1 (33.3%)	0 (0.0%)	0 (0.0%)	The patient self-reported symptoms suggestive of empty nose syndrome 4 months after the procedure, including trouble breathing, dry sinuses, pain/discomfort, and cold insensitivity. The patient reported that nose feels "completely empty."
RhinAer	8 (33.3%)	Postoperative epistaxis	7 (87.5%)	7 (100.0%)	7 (100.0%)	Please see **Table 2**.
		Device failure	1 (12.5)%	0 (0.0%)	0 (0.0%)	During the procedure, the handpiece tip fell off while in the nasopharynx. The patient had to be scoped postoperatively, but no foreign body was ever recovered.
NeuroMark	2 (8.3%)	Postoperative epistaxis	2 (100%)	2 (100.0%)[d]	2 (100.0%)	One patient required a sphenopalatine artery ligation, and another required septoplasty and cautery.

Abbreviation: ED, emergency department.
[a]As a percent of all adverse events.
[b]As a percent of device-specific adverse events.
[c]As a percent of device and complication-specific adverse events.
[d]Presentation location is not stated exactly, but given the need for operative intervention, can be assumed patient was admitted or came in through the ED.

Table 2. Details on RhinAer-Related Epistaxis

Patient number	Day of final presentation from the operation	Prior presentation for postoperative epistaxis?	Severe?	Offending vessel/location	Intervention and clinical course
1	Day 33	Yes, presented on Day 31 to ED and was packed	Yes. The patient was hypotensive and tachycardic, requiring a unit of blood, >2 L fluids, and tranexamic acid.	Not specified but states bleeding was posterior	Cautery in the OR. The patient was discharged the same day.
2	Day 21	No	No indication of such	SPA	SPA Ligation
3	Day 5	No	No indication of such	Not specified, but states bleeding was posterior	Packed with a latex balloon and discharged. Seen in-office the next day and doing well.
4	Day 14	No	Yes, received 3 units of blood	Not specified, but states bleeding was in basal lamella area bilaterally	Required bilateral embolization. Admitted for observation with no further incident.
5	Day 14	No	No indication of such	SPA	SPA ligation, followed by postoperative admission for observation. No further issues.
6	Day 14	No	No indication of such	Not specified	Cautery in the OR, followed by overnight observation.
7	Day 14	No	Yes, received a "couple" of units of blood and platelets	Not specified	The patient required suction and cautery. Does not explicitly state that this was done in the OR. The patient was admitted for observation. Of note, the patient was on Clavix.

Abbreviations: ED, emergency department; OR, operating room; SPA, sphenopalatine artery.

(37.5%) episodes were severe requiring transfusions. Only 1 (14.3%) was successfully treated with packing, and 6 (85.7%) required operative intervention (2 sphenopalatine artery [SPA] ligations, 1 bilateral embolization, and 3 cauteries). Both Neuromark® complications were related to epistaxis, 1 requiring SPA ligation and the other septoplasty and cautery (**Table 1**).

Discussion

Although the exact utilization of these 4 devices is not publicly available, the fact that only 24 device-related AEs were reported suggests that these devices are largely safe to use in trained hands, at least with recent experience. Between the devices used for nasal obstruction, VivAer® and Celon®, only 14 AEs were reported. While Celon® had the most with 11, it has also been FDA approved for the longest period, a rate of fewer than 2 reported events per year. The most common complication was tissue necrosis, with descriptions suggesting user error with high power settings. No AEs were encountered in the seminal studies on Celon®[2,7] and VivAer® use.[3] Our results, alongside evidence regarding RF's danger to underlying tissue,[6] suggest tissue necrosis may be an emerging long-term complication to remain mindful of in select patients. Nonetheless, there was 1 devastating complication reported in the MAUDE dataset—an abducens palsy in a pediatric patient. Although it is not clear how this injury occurred in isolation, it is possible the device tip penetrated or overheated adjacent structures. This highlights the importance of direct/endoscopic visualization. We were unable to find reports of Celon®-induced tissue necrosis or nerve palsy in the literature.

On the other hand, despite being approved within the last 2 to 3 years, RhinAer® and Neuromark® had 10 AEs reported, 9 of which were epistaxes presenting anywhere from 5 to 33 days postoperatively. Many of these episodes were severe, with 3 requiring blood transfusions and all but 1 requiring operative intervention. Interestingly, between 164 people enrolled in 3 separate studies on these devices,[4,5,8] only 1 episode of mild epistaxis was reported. While likely rare, it is possible that the SPA or a branch is directly provoked or exposed, which can lead to delayed epistaxis. Regardless of the mechanism, this data suggests epistaxis after the use of these devices should be taken seriously and surgeons should counsel patients appropriately.

The foremost limitation is that MAUDE relies on voluntary reporting by physicians and patients and mandated reporting by manufacturers (who may not be made aware of some AEs), and thus almost certainly underreports complications and likely biases to more severe AEs. This may be amplified by certain complications being underdiagnosed due to a lack of appropriate follow-up or following symptoms clinically (ie, without endoscopy), like tissue necrosis. Second, there is limited long-term data, especially for RhinAer® and Neuromark®. The devices reported herein address different tissues, which may have varied long-term responses. Many variables were also inconsistently reported, such as age, precluding subgroup analysis. Finally, it is possible that some of the AEs reported that device usage was unrelated. Nevertheless, this study suggests surgeons should exercise vigilance and tissue-appropriate device settings when utilizing RF devices, as well as inform patients of potential risks. Severe epistaxis and tissue necrosis may occur, as well as more rare, but devastating, complications. More broadly, surgeons who are early adopters of new technologies that have been marketed as "minimally invasive" should monitor and survey patients to ensure safety in their hands.

Author Contributions

Sina J. Torabi, conception and design, acquisition, analysis, interpretation, drafting, final approval, accountable; **Benjamin F. Bitner**, conception and design, acquisition, analysis, interpretation, revisions, final approval, accountable; **Eric H. Abello**, conception and design, analysis, interpretation, revisions, final approval, accountable; **Theodore V. Nguyen**, conception and design, analysis, revisions, final approval, accountable; **Brian J.F. Wong**, conception and design, interpretation, revisions, final approval, accountable; **Edward C. Kuan**, conception and design, interpretation, revisions, final approval, accountable.

Disclosures

Competing interests: Edward C. Kuan is a consultant for Stryker and three-dimensional Matrix; these disclosures are not relevant to this study. The other authors declare no relevant conflict of interest.

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