Comparative Safety of Posterior Nasal Nerve Cryotherapy and Radiofrequency Ablation: A MAUDE Database Study

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STUDY OBJECTIVE

- To compare reported adverse events associated with posterior nasal nerve (PNN) ablation devices: cryotherapy (ClariFix) and radiofrequency (RhinAer)
- To characterize differences in the safety profiles of the two modalities.

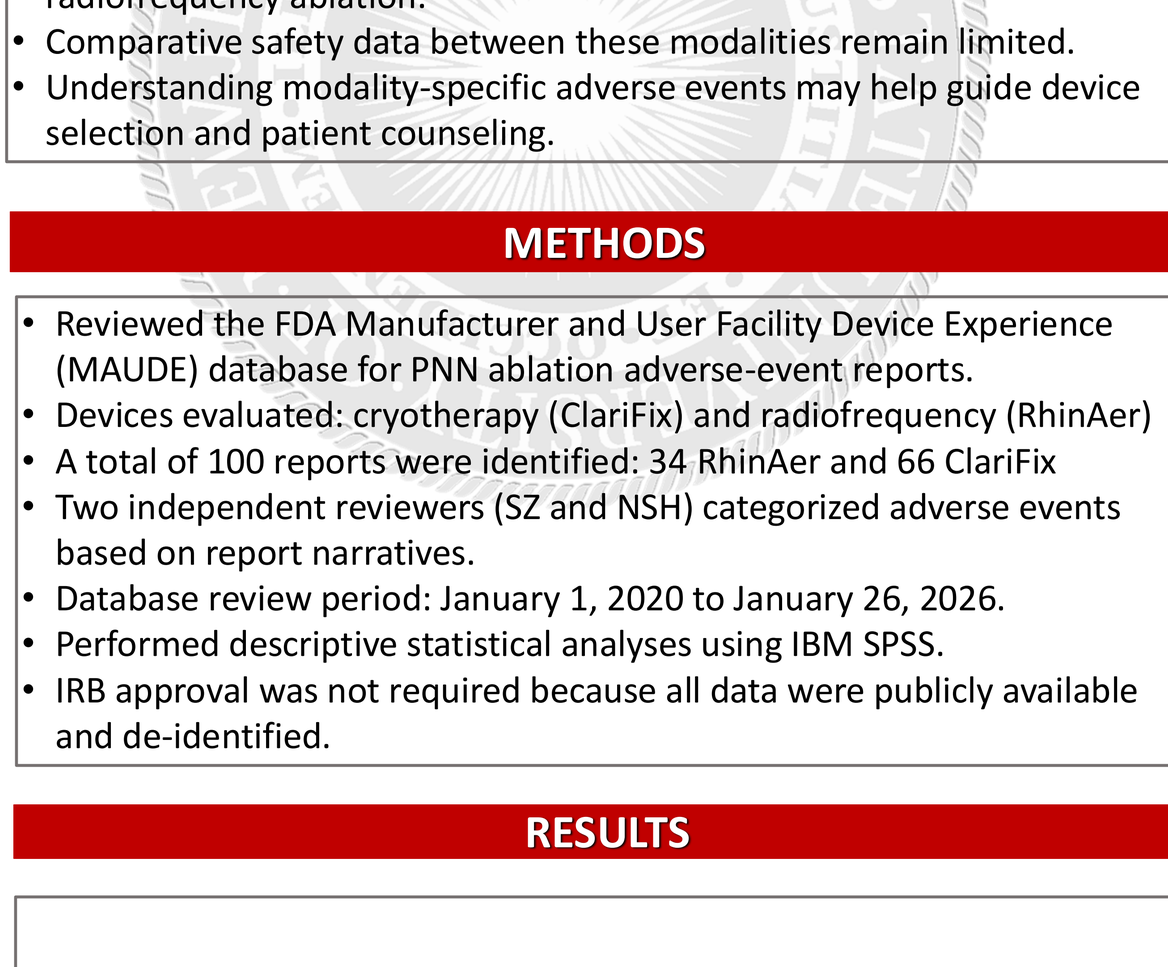
INTRODUCTION

- PNN ablation is an established treatment for chronic rhinitis with refractory rhinorrhea and postnasal drip.
- Common PNN ablation modalities include cryotherapy and radiofrequency ablation.
- Comparative safety data between these modalities remain limited.
- Understanding modality-specific adverse events may help guide device selection and patient counseling.

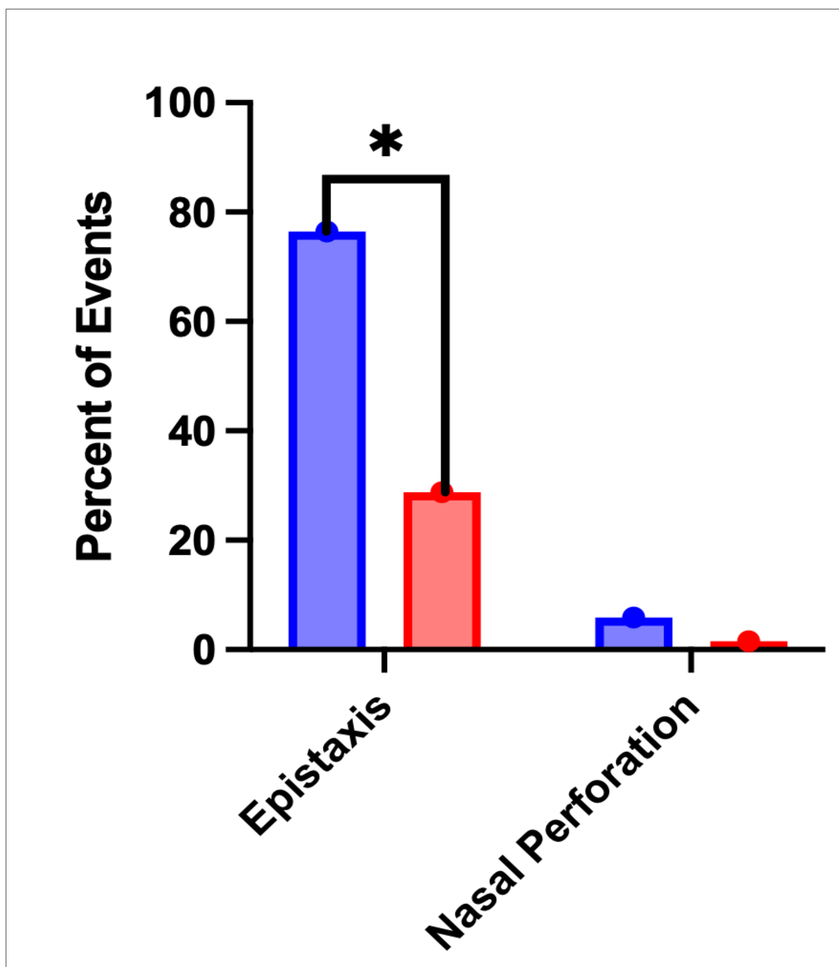
METHODS

- Reviewed the FDA Manufacturer and User Facility Device Experience (MAUDE) database for PNN ablation adverse-event reports.
- Devices evaluated: cryotherapy (ClariFix) and radiofrequency (RhinAer)
- A total of 100 reports were identified: 34 RhinAer and 66 ClariFix
- Two independent reviewers (SZ and NSH) categorized adverse events based on report narratives.
- Database review period: January 1, 2020 to January 26, 2026.
- Performed descriptive statistical analyses using IBM SPSS.
- IRB approval was not required because all data were publicly available and de-identified.

RESULTS



RESULTS



- A significantly greater proportion of RhinAer reports involved patient complications compared with ClariFix reports (88.24% vs 33.33%, $p < 1 \times 10^{-6}$).
- Notably, epistaxis (76.46% vs. 28.79%, $p < 1 \times 10^{-7}$) and events requiring clinical management (91.18% vs. 62.12%, $p < 0.005$) were more frequently reported with RhinAer than ClariFix.
- ClariFix demonstrated a significantly greater proportion of device-related complications compared with RhinAer reports (66.67% vs. 11.76%, $p < 1 \times 10^{-6}$).
- Nasal perforation rates were not significantly different between modalities (5.88% vs. 1.52%, $p = 0.26$).

DISCUSSION

- Both cryoablation and temperature-controlled radiofrequency are effective in-office treatments for medically refractory chronic rhinitis with comparable symptom improvement, suggesting that differences in safety and tolerability may be important considerations when selecting between modalities.[1]
- The higher reported epistaxis and overall complication rate with RhinAer may reflect the direct thermal or mucosal contact and tissue penetration of the electrode, whereas the higher proportion of device-related complications with ClariFix is consistent with the device-integrity issues seen in trials.[2]
- As a passive surveillance system, the MAUDE database is subject to underreporting and incomplete, inaccurate, or delayed reports, limiting the ability to estimate the true incidence or prevalence of adverse events.[3]
- These findings reflect reporting patterns rather than true complication rates, highlighting the need for prospective studies to validate differences in adverse-event incidence.

CONCLUSION

- ClariFix and RhinAer devices demonstrated distinct adverse-event reporting patterns in the MAUDE database.
- RhinAer accounted for a higher proportion of reports involving patient complications, particularly epistaxis and events requiring clinical management.
- ClariFix was more frequently associated with device-related complications, suggesting differing safety profiles between the two modalities.
- Although the MAUDE database is limited by passive reporting, the distinct adverse-event profiles between PNN ablation modalities identified may help inform preprocedural counseling, including the risk of epistaxis and need for clinical management with radiofrequency and potential device-related complications with cryotherapy.

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