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Comparison of Budesonide Delivery Via Nasal Spray and a Nasal Nebulizer to an In Vitro Adult Model

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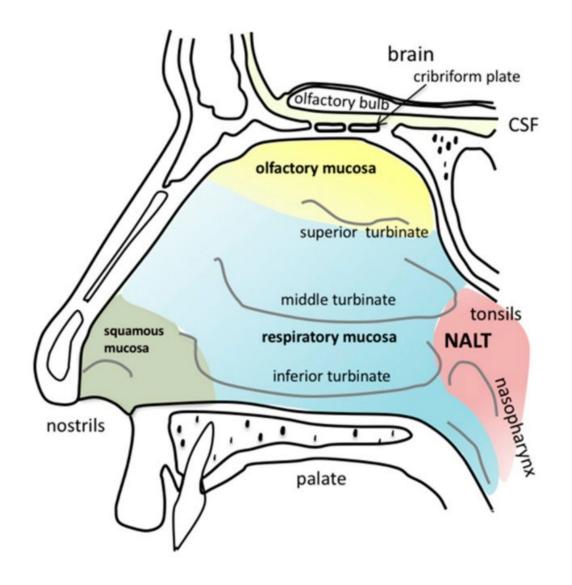






Rationale

Intranasal corticosteroids such as budesonide are widely prescribed in the treatment of perennial allergic rhinitis. However, evidence suggests that most commercially available nasal spray devices deposit the majority of the atomized drug in the anterior portion of the nose, missing most of the nasal mucosa in the inferior and middle turbinate regions.







Methods

We compared the delivery of budesonide via a standard pray pump (2 sprays (64µg), Rhinocort® Aqua) to that of budesonide nebules (Pulmicort Nebuamp, 500µg/2mL) via a novel nasal nebulizer (NasoNeb®).

The model was derived from an MRI scan of a 53-year-old male subject, reported by Guilmette RA and Gagliano TJ1.

The original model geometry has been used multiple times in particle deposition simulations and experiments for the Lovelace Research Institute of Albuquerque, NM.





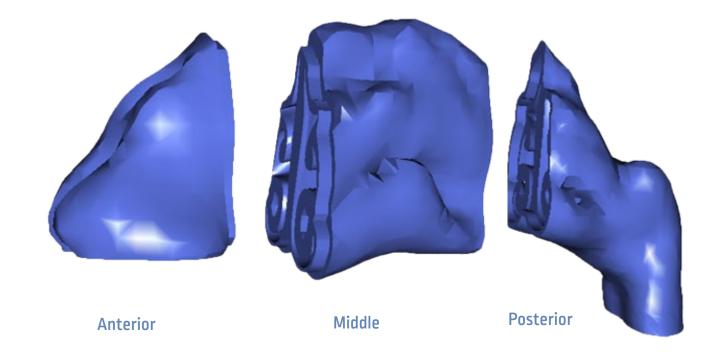




Methods - model

The model was segmented horizontally into anterior, middle and posterior passageways

It was made from sintered nylon (opaque) to be chemically compatible with API recovery solvents







Results

Recovery of budesonide from the model

- More budesonide, in terms of both mass and percent, was delivered from the nasal nebulizer to the middle (Turbinate) region.
- The traditional spray pump delivered most of the medication to the anterior region with limited delivery to the middle and none to the posterior nasopharynx.

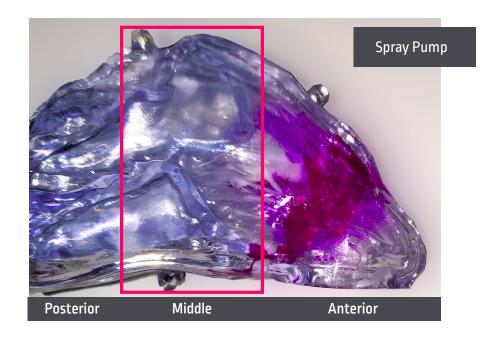
| Mass delivery compared [μg] | | Nasal Segments | | |
|---|-----------|----------------|----------|-----------|
| | | Anterior | Middle | Posterior |
| NasoNeb [®] nebulizer (500μg / 2mL) | Mass (μg) | 81 ± 16 | 173 ± 58 | 39 ± 29 |
| Rhinocort* nasal spray (32µg x 2 sprays) | Mass (μg) | 50 ± 6 | 5 ± 5 | 0 ± 0 |
| NasoNeb® nebulizer Additional mass | Mass (μg) | 31 ± 12 | 168 ± 53 | 39 ± 29 |

| Mass delivery compared [%] | | Nasal Segments | | |
|---|---|----------------|---------|-----------|
| | | Anterior | Middle | Posterior |
| NasoNeb [®] nebulizer (500μg / 2mL) | % | 28 ± 4 | 58 ± 13 | 15 ± 12 |
| Rhinocort* nasal spray (32μg x 2 sprays) | % | 78 ± 9 | 7±7 | 0 ± 0 |
| NasoNeb® nebulizer Additional mass | % | 50 ± 5 | 51 ± 5 | 15 ± 12 |









Conclusion

The use of the nebulizer system may offer an alternative therapy for clinicians to deliver a greater and potentially more effective corticosteroid dose to rhinitis suffers who are unable to achieve relief with other spray devices.

Clinicians should also be aware of the limitations of some commercial nasal spray pumps to deliver medication beyond the anterior portion of the nose.