Scintigraphic evaluation of the EASYNOSE nasal nebuliser in a nasal cast model.

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Introduction

The Easynose new nasal nebuliser has recently proved its efficacy to target nasal cavities including ethmoid and maxillary sinuses of healthy volunteers and to limit lung penetration(1,2). However, in vivo scintigraphy studies analysing nasal aerosol deposition have some limitations to quantify precisely the aerosol deposition due to the determination of regions of interest (ROIs) within the nasal cavities(3-5). Therefore, these in vivo studies don’t allow reliability of results. The use of in vitro models very close to human nasal cavities should bring more precision in the quantification of the nasal aerosol deposition.

In this study, the efficacy of the Easynose nebuliser to target nasal cavities, and in particular the regions of ethmoid and maxillary sinuses (MS), identified sites of infection, was evaluated by scintigraphic method in two new nasal casts, in order to improve reliability of previously obtained in vivo results.

Material and Methods

Nasal casts (fig. 1)

Two models were made from a sinus CT-scan of an healthy volunteer: one with the original scanner size (women nasal cavities or small model) and the second larger (similar to human nasal cavities or large model). Models were built in 4 independent areas:
- Area 1: nose and nasal valve;
- Area 2 and 3: complicated complex (OMC and sinuses);
- Area 4: nasal and oro-pharynx.

Deposition experiments (fig. 2)

Fig. 2 shows how the nasal cast model was connected to the Easynose and to a respiratory pump. For each experiment the nebuliser was filled with 3 mL of DTPA ÷ 7(140mCi) and the nebulisation time was limited to 10 minutes.

After nebulisation, images were registered (gamma Siemens) during 2 minutes for the lung filter and the nasal cast (lateral view of the nasal cast profile) and anterior view of each area).

The NASAL/LUNG reposition and the distribution of nasal aerosol deposited in each area was determined. Aerosol deposited in MS and in ethmoid was also determined, using specific ROIs.

Determination of MS and ethmoid ROIs (fig. 3)

ROIs of both models were determined by applying radioactive ink solution with a brush on each area of the models. Images of the NASA FOSSA below (including ethmoid), the MAXILLARY SINUSES above and the NASA FOSSA + MAXILLARY SINUSES, were registered.

From these images, ROIs were defined for MS and for ethmoid (in areas 1, 2, 3) and then applied on aerosol images to determine aerosol activity deposited in these anatomical regions.

Aerosol deposition Images (fig. 4)

Profile images of both models obtained after Easynose nebulisation showed a peripheral deposition of aerosol in the nasal cavities.

Deposition Nasal Lungs (Table 1)

For both models, a 90 % of the aerosol was deposited in the nasal cast and < 1 % in the lung (fig. E). Results are in accordance with in vivo results of aerosol deposition obtained in healthy volunteer with the same nebuliser(2). Moreover, results validate experimental conditions for the simulation of the presence of a soft palate.

Aerosol distribution in nasal cast (Table 2)

Fig. 4: Right lateral view Images of aerosol deposited in the small nasal cast model (1) and in the large nasal cast model (2), registered after nebulisation with the Easynose.

Table 1:

<table>
<thead>
<tr>
<th>Area</th>
<th>Nasal cavity</th>
<th>Lung</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nasal area (small)</td>
<td>94.6 ± 0.1%</td>
<td>0.6 ± 0.1%</td>
</tr>
<tr>
<td>Nasal area (large)</td>
<td>99.2 ± 0.4%</td>
<td>0.8 ± 0.4%</td>
</tr>
<tr>
<td>Maxillary sinuses</td>
<td>45.1 ± 7.3%</td>
<td>13.8 ± 3.0%</td>
</tr>
<tr>
<td>Maxillary sinuses</td>
<td>15.0 ± 1.5%</td>
<td>4.1 ± 0.5%</td>
</tr>
</tbody>
</table>

Table 1: in vitro aerosol deposition distribution. A) small nasal cast model; B) large nasal cast model. A1 in vivo nasal cast model.

The aerosol distribution from areas 1 to 4 was similar for both models with a maximal value in the area 1, due to the restriction passage of nasal valve (1,2) and then a slower decrease until the area 4 (oro-pharynx). The difference between both models may be due to a difference in the size of the anatomical structures of models such as nostril or the nasal valve passage.

Results

This study demonstrates that the Easynose nebuliser is effective to target nasal cavities, and is adapted for nasal treatment. It allows a peripheral deposition of aerosol in the nasal cavities, beyond the nasal valve, including maxillary sinuses and ethmoid, and predicts a minimal lung deposition.

Conclusions

The limitation of the scintigraphic method described in in vivo aerosol deposition studies (quantification problem due to anatomical localisation) remains present for in vitro studies using nasal casts very close to human. The possibility to examine independently the different parts of the models has improved the reliability of image processing.