ABSTRACT

Characterizing deposition of nasal delivery technologies is challenging because in vitro spray tests do not correlate to deposition, and in vivo gamma scintigraphic studies are only valid if the radiolabel deposition matches the drug. We used a regionally divided nasal cast to show radiolabel remained associated with drug when formulated as a solution or suspension, and delivered from a standard nasal spray device (D1) or modified nasal delivery device (D2). The in vivo deposition was then characterized by measuring the radiolabel deposition in humans. It is believed this data represented drug deposition because (1) the nasal cast showed drug and radiolabel remained associated, and (2) radiolabel clearance rate was greater in arms that deposited more in the ciliated posterior nasal cavity and lower with the high viscosity suspension.

RESULTS

After 60 minutes

• Radiolabel from D1 cleared more quickly than D2
• Images suggest clearance was from the ciliated posterior nasal cavity
• Suspension cleared slightly slower than solution

DISCUSSION

• D1 nasal spray deposited more in the posterior nasal cavity than is typically expected of nasal sprays
• The clearance of the radiolabel was consistent with the initial deposition of the radiolabel
• D2, which deposited more to the nonciliated anterior nasal cavity, had slower clearance
• Within the posterior ciliated region, the lower viscosity solution delivered by D1 cleared more quickly than the higher viscosity suspension
• This method appeared to accurately characterize initial nasal drug deposition because
  • the cast showed drug and radiolabel deposition matched
  • the rate of clearance was consistent with the ciliation at the initial deposition site and formulation viscosity

REFERENCES