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Thesis Abstract (2002)

VALIDITY OF IN VITRO TESTS FOR NASAL DELIVERY SYSTEMS AS SURROGATES FOR IN VIVO DEPOSITION PATTERN AND BIOLOGIC RESPONSE

Nasal spray pumps are used to treat local and systemic conditions, yet only limited research has focused on formulation and device characteristics necessary to optimize drug delivery and clinical response. To fill this void, gamma scintigraphy was used to identify sites of nasal deposition in humans following use of mechanical spray pumps and a nasal nebulizer to administer radiolabeled formulations. To assess the resulting regional deposition pattern, a novel method using inhaled radioactive xenon gas to delineate the borders of the nasal cavity was developed.

A pilot study determined that deposition pattern in the nasal cavity could be altered by delivery of smaller nebulized droplets (6 μ m) compared to large, droplets produced by a mechanical spray pump (79 μ m). The deposition results from the nasal nebulizer were statistically different from, and covered more surface than those from the spray pump in eight healthy volunteers. A second patient study investigated if alterations in spray pattern and spray angle from two aqueous spray pumps produced different nasal deposition patterns. The deposition patterns were not significantly different and did not correlate with in vitro spray pattern and plume geometry measurements.

To determine if differences in particle size, spray pattern and spray angle, that did not alter deposition pattern, could result in altered drug absorption or drug response, radiolabeled nicotine nasal spray (Nicotrol[®] NS) was administered to eight healthy, smoking volunteers. Neither absorption nor biological response to nicotine was altered although the spray pumps exhibited statistically different in vitro performance. This study indicated that in vitro test results can differentiate between two spray pumps but these differences do not produce differences in deposition pattern. It also appears that differences that are based on in vitro tests between the pumps do not translate into differences in the rate and extent of drug absorption or the biological response. Based on these findings, in vitro tests for nasal sprays are not appropriate surrogates for in vivo deposition pattern and biological response. Additional research is needed to define the range of spray pump characteristics, namely droplet size, that are likely to produce differences in drug response.

Education Summary

- Aug 1996 - May 2002: Ph.D in Pharmaceutical Sciences, Major: Industrial Pharmaceutical Research, University of Maryland
- Aug 1991 - May 1996: B.S. in Pharmacy, Duquesne University, Pittsburgh, PA. Graduated Magna cum laude

Employment Summary

- June 2002- Present: [Next Breath LLC](#), Director, Nasal Drug Delivery.
- Aug 1996 - May 2002: Graduate Student, Department of Pharmaceutical Sciences, University of Maryland, Baltimore, MD. Developed and tested a novel nasal delivery device, developed an imaging method for to define the shape of nasal cavity, particle size measurements (Malvern Mastersizer, Andersen Cascade Impactor, Aerosizer), spray pattern analysis, plume geometry and velocity testing, high speed photography, propellant density determination, phase doppler

analysis, HPLC, image acquisition and analysis by gamma scintigraphy, handling radioactivity, study coordination with human volunteers, addressing bioequivalence issues surrounding nasal products, writing internal S.O.P.s, writing study protocols for Investigational Review Board submission, statistical analysis and data management.

- June 1998 - Present: Intern, Magellan Laboratories, Research Triangle Park, NC. Initial project involved evaluation of physical and chemical stability of IV solutions in a GLP setting. Ongoing research consists of bioanalysis of a nasally administered drug by LC/MS.
- May 1996 - Present: Pharmacist, Rite Aid, Baltimore, MD. Interact with physicians to make decisions about drug therapy and counsel patients on their disease state and medication.
- Aug 1996 - Dec 1996: Teaching Assistant, Duquesne University, Pittsburgh, PA. Responsible for instruction and supervision of an industrial pharmaceutical manufacturing course.

Publications

- **J.D. Suman**, B.L. Laube, T. Lin, G. Brouet, and R. Dalby. Relevance of In Vitro Tests of Nasal Solutions to Predict In Vivo Deposition. *Pharmaceutical Research*, 19 (1) : 1-6 (2002). Highlighted as the editors selection in *AAPS News Magazine*, (5) 1, January 2002.
- **J.D. Suman**, B.L. Laube, and R. Dalby. Comparison of Nasal Deposition and Clearance of Aerosol Generated by a Nebulizer and Aqueous Spray Pump. *Pharm. Res.* 16: 1648-1652 (1999).
- **Julie D. Suman**, Beth L. Laube, and Richard Dalby, *Nasal Nebulizers Versus Aqueous Nasal Spray Pumps: A Comparison of Deposition Patterns in Human Volunteers*. Respiratory Drug Delivery VI, Interpharm Press, Inc., Buffalo Grove, IL, 1998.
- Shailaja Somaraju, **Julie D. Suman**, Richard N. Dalby, and Walter F. Stridick, Semi-Automated Spray Pattern Testing of Nasal Sprays. *Pharmaceutical Technology* 21 (5) May 1997.

Podium Presentations

- **Julie Suman**, A Practical Guide to Performing In Vitro Tests on Nasal Delivery Systems, presented at Emerging Topics in Development of Pulmonary and Nasal Delivery Systems at the American Association of Pharmaceutical Scientists Annual Meeting and Exposition (AAPS), October 2000.
- **Julie Suman**, Beth Laube and Richard Dalby, Are In Vitro Tests of Nasal Solutions Predictive of In Vivo Deposition? Presented at Respiratory Drug Delivery VII and published in the Conference Proceedings, Serentec Press Inc, Raleigh, NC, p137. May 2000.
- **Julie Suman**, Characterization of Aqueous Nasal Spray Pumps to Predict In Vivo Deposition" presented at the United States Pharmacopeia Fellowship Recognition Event, May 2000.
- **Julie D. Suman**. Nasal Nebulizers. Presented at Nasal Delivery-Beyond Aqueous Spray Pumps, American Association of Pharmaceutical Scientists Annual Meeting and Exposition, November, 1998.
- **J.D. Suman**, B.L. Laube, T. Lin, G. Brouet, and R. Dalby. In Vitro Performance Measurements of Aqueous Nasal Spray Pumps May Not Predict In Vivo Deposition Pattern, presented at AAPS, November 1998.

Poster Abstracts

- **Julie D. Suman**, Beth L. Laube, Ta-Chun Lin, Guillaume Brouet and Richard Dalby. In Vitro Performance Measurements of Aqueous Nasal Spray Pumps May Not Predict In Vivo Deposition Pattern. AAPS National Meeting, November, 1999.

- **Julie D. Suman**, Beth L. Laube, and Richard Dalby. Nasal Clearance of Radiolabel in Human Volunteers: Nasal Nebulizers versus Aqueous Nasal Spray Pumps. PharmSci 1(1) S-140 November, 1998.
- Walter F. Stridick, **Julie D. Suman**, Richard Dalby, and Guillaume Brouet. The Effect of Various Actuation Forces on Particle Size of Different Aqueous Nasal Spray Pumps and Formulation, PharmSci 1(1) S-214 November, 1998.
- **Julie D. Suman**, Beth L. Laube, and Richard Dalby. Nasal Nebulizers Versus Aqueous Nasal Spray Pumps: A Comparison of in Vivo Deposition Patterns, presented at Philadelphia Pharmaceutical Forum, March 1998.
- Richard N. Dalby, Dudley Demarest, R. Gary Hollenbeck, James Leslie, Martin P. Redmon, Dayna Jarvis, Bipin Mistry, Shailaja Somaraju and **Julie D. Suman**. In vitro metered dose inhaler performance: an accelerated stability study comparing (R)-albuterol hemisulfate and Ventolin. Pharm. Research 14(11) S-136 November, 1997.
- Shailaja Somaraju, **Julie D. Suman**, Richard Dalby, Russ Fuchs, and Walter Stridick. A Novel Semi-automated Method for Determination of Spray Patterns from Metered Dose Nasal Pumps, presented at Philadelphia Pharmaceutical Forum, March 1997.

Honors and Awards

- United States Pharmacopeia Fellowship (\$15000/year), 1999-2000 & 2000-2001
- American Foundation for Pharmaceutical Education (AFPE) Pre-doctoral Fellowship (\$6000/year), 1998, 1999 & 2000
- Graduate Student Merit Award, University of Maryland Graduate Student (\$2000), 1998
- Best Poster, University of Maryland Graduate Student Research Day, 1998
- Phi Lambda Sigma-GlaxoWellcome-AFPE First Year Graduate Scholarship (\$7500), 1996
- Excellence in Pharmacy Award, Mylan Pharmaceuticals, Inc., 1996
- Rho Chi Honor Society-recognizes pharmacy students in the top 10% of their class, 1994

Organizations

- Pharmaceutical Graduate Student Association (Secretary)
- American Association of Pharmaceutical Scientists
- American Pharmaceutical Association
- Kappa Psi Pharmaceutical Fraternity, Inc.

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