Cost-minimization Analysis of Two Surfactant Treatments for Respiratory Distress Syndrome


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INTRODUCTION:
Surfactant therapy has improved morbidity and mortality of respiratory distress syndrome (RDS) (1-3). Despite showing a favorable economic impact versus non-treatment (4,5), surfactant product expenditures are of concern (mean annual institutional cost, $113,000, and >$300,000 in large NICUs) (6). Thus, a cost-minimization analysis would be helpful in comparing the relative economic impact of available respiratory surfactants.

COMPARATIVE TRIALS:
Study 1 (Speer C, et al.) (7): Seventy-three preterm infants were randomized to 200mg/kg poractant alfa (33) or 100mg/kg beractant (40). Both agents were effective, with similar reductions in oxygenation and ventilatory requirements. Infants treated with poractant alfa had a higher arterial/alveolar oxygen tension ratio and required a lower peak inspiratory pressure and mean airway pressure (p<0.05—0.001). While AE profiles were comparable for both products, mortality was 3.0% in the poractant alfa group and 12.5% in the beractant group (NS). Fewer additional doses were required in poractant alfa vs. beractant infants, 23 vs. 49.

Study 2 (Ramanathan R, et al.) (8): Two hundred and ninety-three infants were randomized in a controlled trial to an initial dose of 100 (96) or 200 (99) mg/kg of poractant alfa or 100 (98) mg/kg of beractant. All groups were comparable for birth weight gestational age, gender, race, and steroid exposure: Mean FiO2 Alveolar for both poractant alfa groups was lower in than in the beractant group (p < 0.005). Post conception mortality at 36 weeks in the ≤32 week gestation infants was lower in the 200mg/kg poractant alfa group vs. the 100mg/kg beractant group: 3% vs. 11%. Fewer additional doses (based on continued ventilation and FiO2 of >0.3 to maintain ≥85% 2ndation) were needed in the 200 mg/kg poractant alfa group compared with the 100mg/kg beractant group. 36 vs. 67 (p = 0.002).

OBJECTIVE:
To compare the economic profiles of two surfactants, beractant and poractant alfa based upon average wholesale (AWP) pricing and FDA approved dosage.

METHODS:
A cost-minimization analysis (CMA) was used due to comparable clinical profiles. Three models were employed:
• Model 1: Single-use per vial, individual infant weight (Speer, Ramanathan)
• Model 2: Single-use per vial, individual infant weight (Ramanathan)
• Model 3: Multiple-use per vial, individual infant weight (Ramanathan)

All models employed the following assumptions:
• Initial and follow up doses are per the approved FDA label for both products.
• Infants required a second, third and even fourth dose based upon the clinical data to achieve a response. Additional 100mg/kg doses were as follows: Poractant alfa: 23 3 49 Ramanathan: 36 67
• AWP (April, 2003) (9):
  Small Vial: $454.80 (4 mL) $504.96 (8 mL)
  Large Vial: $610.80 (1.5 mL)

Models 1 and 2 involved single-dose (per FDA label) per vial with the remaining solution left. Model 1 utilized mean infant weight from the Speer and Ramanathan studies. Two 1.5 mL poractant alfa vials were used in the analysis.

Model 2 employed individual patient weights from the Ramanathan trial to more accurately calculate the number of vials based upon the actual patient dose and appropriate vial size with the least costly vial is selected for each patient based on exact weight dosing.

Model 3 utilized the same individual patient weight calculations from the Ramanathan trial. Rather than using one use per vial, this model considered multiple uses per single vial. The analysis factored the number of mL utilized to calulate cost. The large vial was used as the least costly vial from which to draw doses. Comparative analysis was presented as cost/patient and cost/cost/0 (normalized for 40 infants for Speer and 100 infants for Ramanathan). Results from Models 2 and 3 were statistically evaluated utilizing a t-test of unequal variances and a Mann Whitney U. This was due to the availability of mean and SD infant weight data from the Ramanathan trial.

RESULTS:

Comparative Total Comparative Cost for Single-use Models

<table>
<thead>
<tr>
<th>Model</th>
<th>FDA Approved Doses</th>
<th>Total Cost/100mg/kg Dose x of 100mg/kg Doses</th>
</tr>
</thead>
<tbody>
<tr>
<td>Speer</td>
<td>Cost $232</td>
<td>$135,535</td>
</tr>
<tr>
<td>Beractant</td>
<td>Cost $455</td>
<td>$119,821</td>
</tr>
</tbody>
</table>

Adjust for Equivalent Patient Cohort Size

For Speer or 100 for Ramanathan Infants

DISCUSSION:
All models found poractant alfa to be less costly than beractant. This was based upon dosing schedule per product package inserts, AWP, and comparative trial data.

CONCLUSION:
This analysis suggests that poractant alfa may offer cost savings. The amount (and direction) of savings can vary with multiple factors. Further evaluation of institutional level data will allow us to validate this initial analysis. It would be reasonable for institutions to examine their respiratory surfactant usage patterns and patient mix more closely to assess potential savings.

REFERENCES:

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DISCLOSURES:
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