Safety of Octreotide in Hospitalized Infants

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Background

- Octreotide is used off-label in infants for treatment of chylothorax, congenital hyperinsulinism, and gastrointestinal bleeding
- The safety profile of octreotide in infants is not well described

Methods

- We identified infants exposed to octreotide from a cohort of 804,172 infants discharged from 333 neonatal intensive care units between 1997 and 2011
- We looked at daily laboratory and clinical information generated from clinical notes
- For infants exposed to octreotide we examined drug indication, infant characteristics, concomitant medications and use over time
- We described pre-specified adverse events (AE) that occurred during exposure to octreotide

Results

1. 384 infants received 441 courses of octreotide
2. Median duration of octreotide course = 10 days (interquartile range: 4, 21)
3. 70/383 (18%) infants exposed to octreotide died before discharge; 11/383 (3%) died during octreotide use
4. Median duration of octreotide course = 10 days (interquartile range: 4, 21)

Table 1: Demographics and baseline characteristics (N = 384)

- Gestational age (weeks): 33 (28, 37)
- White: 171 (47)
- Black: 53 (14)
- Hispanic: 117 (31)
- Other: 16 (4)
- Inborn, n (%): 237 (62)
- Mechanical ventilation*, n (%) 199 (52)
- Weight* (g): 3041 (2297, 3840)
- Inotropes*, n (%): 55 (14)
- Thrombocytosis: > 600,000/mm3
- Liver dysfunction
- Thrombocytosis
- Aspirin
- Mechanical ventilation*: (days) 28 (12,18)
- Weight*: (g) 3041 (2257, 3840)
- Mechanical ventilation*: (n %) 199 (52)
- Inotropes*: (n %) 55 (14)
- Length of stay (days) 62 (32, 115)
- Data presented as median (interquartile range), unless otherwise specified

Table 2: Octreotide indications

- Congenital lymphedema: 1 (0.2)
- Lymphangiectasia: 3 (1)
- Congenital hyperinsulinism: 17 (4.7)
- Hepatic encephalopathy: 21 (5.5)
- Hypoglycemia: 100 (26)
- Hyperglycemia: 2 (0.5)
- Hyperlipidemia: 19 (5)
- Hypothyroidism: 20 (5)
- Hypokalemia: 18 (4.7)
- Hypomagnesemia: 5 (1.3)
- Hypocholesterolemia: 12 (3)
- Hypercholesterolemia: 226 (59)
- Hypocalcemia: 3 (0.8)
- Hypercalcemia: 1 (0.2)
- Thrombocytopenia: < 100,000/mm3
- Thrombocytosis: > 600,000/mm3
- Renal dysfunction
- Urea nitrogen: > 10 mg/dL
- Creatinine: > 2 mg/dL

Table 3: Most common concomitant medications

- Gentamicin: 196 (44)
- Vancomycin: 231 (52)
- Linezolid: 35 (9)
- Leukopenia: < 5000/mm3
- Neutropenia: < 500/mm3
- Leukemia: 100/mm3
- Lymphopenia: 100/mm3
- Anemia: 100/mm3
- Rash: 2

Table 4: Laboratory adverse events

- Arterial hypotension requiring pressors
- Bradycardia
- Hypoglycemia: < 40 mg/dL
- Hyperkalemia: > 6.0 mmol/L
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- Hyperkalemia: > 6.0 mmol/L
- Hypoglycemia: < 40 mg/dL
- Hyperkalemia: > 6.0 mmol/L

Table 5: Clinical adverse events

- Rash: 2
- Nephrotic syndrome
- Pericardial effusion: 11 (3)
- Weight* (g): 3041 (2297, 3840)
- Inotropes*, n (%): 55 (14)
- Thrombocytosis:

Conclusions

- Octreotide is an underutilized drug used off label in critically ill infants
- For this population of sick hospitalized infants, incidence of AE was not higher than expected
- Additional studies are needed to further evaluate the safety, dosing and efficacy of octreotide in infants

References


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