Committee on Drugs

Naloxone Dosage and Route of Administration for Infants and Children: Addendum to Emergency Drug Doses for Infants and Children

The following addendum from the Committee on Drugs was prepared in response to numerous requests for reference material or rationale to support the dosage of naloxone for infants and children[1] currently recommended by the Committee on Drugs.

The currently recommended dose of naloxone is 0.1 mg/kg for infants and children from birth to 5 years of age or 20 kg of body weight. Children older than 5 years of age or weighing more than 20 kg may be given 2.0 mg. These doses may be repeated as needed to maintain opiate reversal.[1] The higher dose recommendation is based, in part, on a concern that 0.01 mg/kg, currently recommended in approved labeling, may not provide optimal opiate reversal in some infants.[2] In addition, it is intended to simplify naloxone dosing and provide greater probability of optimal opiate reversal in most patients.

Because doses as high as 0.4 mg/kg have been administered to newborns without ill effect,[3] it is felt that the higher dose poses no increased risk. Naloxone doses ranging from 0.005 to 0.4 mg/kg have been reported in the pediatric literature.[2–10] Individual doses up to 0.4 mg/kg[3] and constant intravenous infusion of 0.16 mg/kg/h for 5 days[4] have not been associated with naloxone-related adverse effects. The average half-life of naloxone in premature newborns is 70 minutes.[5]

The Committee's naloxone dosing recommendation has been incorporated recently into the joint American Heart Association (AHA)/American Academy of Pediatrics (AAP) textbook on neonatal resuscitation[11] and the accompanying test materials. However, a discrepancy persists between the routes of administration recommended by the Committee and the routes of administration recommended in the AHA/AAP neonatal resuscitation guidelines. The AHA/AAP neonatal resuscitation guidelines suggest that naloxone be administered intravenously, intramuscularly, subcutaneously, or intratracheally. The Committee has recommended the intravenous and intratracheal routes consistently. Although there are no well-controlled studies in infants and children directly comparing the intravenous and intratracheal vs intramuscular or subcutaneous routes of administration, the Committee's recommendation is based on a concern that absorption of intramuscularly or subcutaneously injected medication may be erratic and/or delayed in the patient who is hypotensive, hypoperfused, and/or peripherally vasoconstricted.

The recommendations in this statement do not indicate an exclusive course of treatment or procedure to be followed. Variations, taking into account individual circumstances, may be appropriate.

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