Abstract

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Itraconazole Serum Levels in the Preterm Neonate

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The increasing use of invasive procedures and antibiotic treatments has caused an increase in candidal infections in preterm neonates. Antifungal drugs currently used are toxic (amphotericin B) or lead to rapid development of resistant *Candida* strains (flucytosine). This has led to a search for new, less toxic, drugs. The bioavailability of itraconazole, an oral antifungal agent with **broad-spectrum** activity and low toxicity, was therefore investigated. Trough and peak serum levels of itraconazole were measured by high performance liquid chromatography in 6 preterm neonates (gestational age, 25.6 ± 0.8 weeks; weight, 760 ± 120 g), 48 h after initiating therapy with itraconazole, 5 mg/kg/day, in hydroxypropyl- β -cyclodextrin solution. The area under the curve could be determined in 4 neonates (gestational age, 25.7 ± 1.0 weeks; weight, 825 ± 55 g) with a dose interval of 24 h. The parameters obtained were: trough, 85 ± 18 ng/ml; peak, 276 ± 41 ng/ml; AUC (0-24 h), $5,138 \pm 1,188$ ng·h/ml. It was concluded that itraconazole, 5 mg/kg/day, is well absorbed and recommended levels are reached in preterm neonates of less than 32 weeks gestational age. No **side-effects** were seen. Itraconazole may be a useful antifungal drug in preterm neonates, but further studies on efficacy and safety are needed.