
Pharmacokinetics Of Lidocaine Delivered From A Transmucosal Patch In Children, Andrea Leopold, D.D.S., M.S.^{1,2} Stephen Wilson, D.M.D., M.A., Ph.D.^{1,2} Joel Weaver, D.D.S., Ph.D.² Amr M. Moursi, D.D.S., Ph.D.^{1,2} Columbus Children's Hospital¹ and The Ohio State University, College of Dentistry², Columbus, Ohio.

Objectives: The DentiPatch™, Lidocaine Transoral Delivery System (Noven Pharmaceuticals) is indicated for mild topical anesthesia of mucosal membranes in the mouth. The DentiPatch™ is a mucoadhesive patch containing 46.1 mg of lidocaine (20% concentration). Current studies in adults report that DentiPatch™ application produces very low plasma concentrations of lidocaine. However, it is not known what plasma levels are obtained when the same dosage is used in children. Therefore, the purpose of this study was to determine whether the plasma lidocaine concentrations generated by the DentiPatch™ are within a safe range for children.

Methods: The sample in this study was 18 children ages 2-7 years old, requiring general anesthesia for comprehensive dental care. A 20% lidocaine DentiPatch™ was placed on the buccal mucosa above the maxillary incisors for five minutes. Blood samples were drawn prior to the placement of the DentiPatch™ and at various time intervals after removal of the patch. Blood samples were analyzed by fluorescence polarization immunoassay to determine the plasma concentration of lidocaine and its major metabolite, MEGX. **Results:** The lidocaine and MEGX absorbed from the DentiPatch™ did not cause toxic plasma levels in children.

However, plasma concentrations were much higher than in adults and were high enough to require inclusion in the calculation of total lidocaine administered to a pediatric patient. **Conclusions:** The accumulated plasma levels of lidocaine and its metabolites should be considered cumulatively when potential toxicity is being determined. When using the DentiPatch™, the results of this study can serve as an aid in calculating the maximum total lidocaine dose which can be safely used in a pediatric dental patient.