

Serious adverse drug reactions rare from certain treatment for vascular tumor in infants

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Sorilla Prey, M.D., of the Université de Bordeaux, France and colleagues examined the safety of propranolol therapy in treating infantile hemangioma, a vascular tumor characterized by rapid growth during the first weeks of life. Severe forms require systemic therapy. Propranolol, a beta blocker, induces regression, but safety data have been lacking for children. The study appears in the January 26 issue of *JAMA*.

Children throughout France with proliferative infantile hemangioma requiring [systemic therapy](#) for life-threatening (i.e., potential airway obstruction) or functional risks or severe ulceration were referred to specialist centers for compassionate use of pediatric oral propranolol. Analyses involved data collected between April 2010 and April 2013. Adverse drug reactions (ADRs) were collected by questioning parents and reviewing the child health record at each monthly visit for up to 2 years.

Of 922 [patients](#) referred, 906 were treated with propranolol and had a median age of about four months. Of the 922 patients, 81 (8.8 percent) had 133 ADRs, including 24 (2.6 percent) with 36 serious ADRs. The most commonly reported ADRs were respiratory disorders (mostly infections), which were reported in 31 patients (serious ADRs related to propranolol in 6 patients). The most serious ADRs were cardiac and metabolic disorders.

"Prescribers must counsel parents at each follow-up visit to discontinue propranolol during fasting and intercurrent illness, especially in the setting of restricted oral intake and respiratory symptoms," the authors write.

More information: *JAMA*, [DOI: 10.1001/jama.2015.13969](https://doi.org/10.1001/jama.2015.13969)

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