

Clinical Trial of Celecoxib for Recurrent Respiratory Papillomatosis

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Abstract

Recurrent respiratory papillomatosis (RRP), caused by HPV 6/11, is managed by surgery but papilloma frequently recur. COX-2 and its product PGE2 are over-expressed in RRP. Celecoxib, a COX-2 inhibitor, reduces papilloma cell proliferation, increases apoptosis and reduces HPV E6 and E7 expression. A pilot study of celecoxib therapy showed 2 of 3 patients with complete disease remission. We have now conducted a double-blind placebo-controlled phase II clinical trial of the efficacy of celecoxib for RRP. Patients with moderate-to-severe disease were randomized to celecoxib or placebo for 1 year, then switched to the alternate treatment for 1 year. Surgery was performed every 3 months to remove all papilloma and assess rate of regrowth, with biopsies and blood collected at each surgery. Clinical response was defined as reduction in rate of regrowth of $\geq 50\%$ for at least 6 months. Persistence of HPV was measured by qPCR. Fifty-one patients were enrolled, 33 completed the study. 64% had HPV6 and 36% had HPV11. 36% of patients improved on celecoxib, but there was no statistical difference between treatment and placebo groups. The rate of spontaneous improvement was much greater than expected. There was no correlation between HPV type, duration of disease, gender, other demographic characteristics or celecoxib plasma levels and response. Patients with complete response still had latent HPV DNA in their airway epithelium. Immunology studies are in progress. In conclusion, we suspect celecoxib at this dose alone is not an effective treatment of RRP. However, combined with properly performed frequent surgery may positively impact immune response and the course of the disease.

Biography:

Mark Shikowitz is a Professor of Otorhinolaryngology, Head & Neck Surgery at Albert Einstein College of Medicine in New York. He completed his Residency in North Shore-Long Island Jewish

Health System. He certified as American Board of Otolaryngology. He awarded as New York Metro Area Castle Connolly in 2002-2014. He is an active member of American College of Surgeons. Dr. Shikowitz specializes in sinus surgery, endoscopic skull based surgery, facial cosmetic surgery and reconstruction, and head and neck surgery.