

Molluscum contagiosum: the rise and fall of imiquimod

Editorial

The trajectory of imiquimod began in 1997 when it first received approval from the US Food and Drug Administration (FDA) for the treatment of genital warts in adults. Soon, dermatologists and physicians adopted imiquimod as a viable option to treat molluscum contagiosum (MC) in children. Important to note that the off-label use of imiquimod was supported by small randomized controlled trials (RCT) and isolated case reports, besides the premise that the treatment would be successful because molluscum also represents a viral infection. However, such studies with small numbers of patients were not sufficient for the FDA. In 2006, the FDA requested 3 studies in order to evaluate the real effectiveness of imiquimod in the treatment of molluscum contagiosum in pediatric patients (2-12 years): 2 double-blind controlled and 1 pharmacokinetic. The results were not encouraging, since the efficacy of the topical application three times a week for up to 16 weeks has not been demonstrated. In one RCT, which enrolled 323 children, complete clearance at 18 weeks occurred in 24% of imiquimod-treated group and 26% of vehicle-treated group; another double-blind study, which enrolled 379 children, complete clearance occurred in 24% and 28%, respectively. The author used exactly these words to describe the results: "The studies failed to demonstrate efficacy."¹

Furthermore, higher rates of lymphadenopathy, otitis media, conjunctivitis and local skin reactions (erythema was the most common) were observed in imiquimod-group. The study also highlights a search on AERS database that revealed nine cases of erythema multiforme in adult patients and a case of Henoch-Schölein purpura in 3 years old boy treated for MC with imiquimod. Abnormal hematological findings were also more common in imiquimod group, leucopenia or neutropenia were associated to systemic effects of imiquimod.¹ Curiously these two important RCTs have never been published. Only the pharmacokinetic study was published in 2008.² Therefore, these RCTs remained in a "literature limbus"; not even mentioned in the Cochrane systematic review of treatment for MC, until 2013.³ In 2015, this scenery changed when Kenneth A. Katz revealed these two unpublished RCTs⁴ and this year two reviews didn't recommend imiquimod as a routine treatment for MC.^{5,6} In Brazil there's no RCTs data regarding imiquimod use, but according to my personal observation the use of imiquimod for MC increased over the past three years in my country and (unfortunately) imiquimod is often mentioned in continuing medical education courses as a viable alternative for the treatment of MC in children. This is the moment

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for a change of attitude when prescribing, since I believe it is not valid to use a medicine that has no proven effectiveness. Purposely, this editorial has been written critically, aiming to guide the use of scientific knowledge in medical decisions.

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Conflict of interest

The author declares no conflict of interest.

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