

COMMENTS AND OPINIONS

Direct Medical Cost for Surgical and Medical Treatment of Condylomata Acuminata



We read with interest the article by Alam and Stiller,¹ in particular the conclusions that they reach as to the cost advantages of the treatment modalities considered for external genital warts (EGWs). We have concerns about the article and the conclusions that were reached. The methodology adopted by the authors is inappropriate with regard to the assessment of cost-effectiveness in treating a disease such as EGWs, in which recurrence is a critical issue. Regarding the article by Langley et al,² we were concerned that the impact of high recurrence rates in EGW treatment was only poorly understood and that physicians were accepting claims for cost-effectiveness based on models of treatment that do not represent the decisions faced in a real world environment. Unfortunately, Alam and Stiller explicitly exclude any consideration of recurrence and the long-run efficacy of treatment, therapy switching, and/or the use of combination therapy.³ As a result, their analysis is flawed, and we doubt that their results can be considered a guide to the cost advantages of competing modalities.

We also have concerns with the consensus estimates of "reported effectiveness in clearing condylomata" that were reported in Table 5.⁴ These certainly do not represent what we understand to be the evidence for initial or sustained clearance in a US treating population. We believe that the estimate for podofilox is far too high, and it certainly does not represent the sustained clearance reported for podofilox in the key pivotal studies used for approval by the Food and Drug Administration. Langley et al² compared imiquimod and podofilox as first-line therapy for EGWs and reported the results of those studies that implemented the most acceptable and rigorous study designs (double-blind, randomized, placebo controlled). No specific guidelines for study results were presented by Alam and Stiller.¹ Langley et al² did not eliminate or determine articles based on placebo responses. Indeed, from our reading of the pivotal clinical trial results, in sustained clearance terms and for the indicated treatment regimen, imiquimod has more than twice the sustained clearance of podofilox. As for the therapy options, we think that it would have been useful to your readership for Alam and Stiller to have pointed out that imiquimod is in a new class of products. Imiquimod is an immune response modifier that induces the production of alpha interferon and other cytokines in the skin, which in turn stimulate several other aspects of

the innate immune response. Imiquimod also stimulates acquired immunity, in particular the cellular arm, which is important for control of viral infections and tumors. Imiquimod is also being used extensively, with considerable success, in other dermatological applications.⁵⁻⁸ In this respect, we are concerned that Alam and Stiller failed to recognize the practical impact of imiquimod in a treatment setting. It is incorrect to assume that imiquimod always needs 16 weeks for wart clearance (which is how they estimate the cost of imiquimod use in their model). In the study of Langley et al,² the actual duration of imiquimod therapy was considerably shorter and was modeled accordingly, with a substantial number of patients achieving sustained clearance after the use of only 2 prescriptions covering an 8-week period.

We hope that these comments will be useful to your readership in providing a better understanding of the need for the appropriate cost-effectiveness modeling of competing products in disease states such as EGWs.

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In reply

We are pleased that Drs Kawahara and colleagues took the time to scrutinize our article. We would like to address each of their specific concerns.

First, we disagree with the argument that our cost-effectiveness model was inadequate because it omitted sufficient analysis of disease recurrence. The goal of our study was to compare different treatment modalities, for most of which long-term follow-up data are scanty, questionable,

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