

Clinical outcome data for off-label medications: The more the better

Karen Psooy, MD, FRCSC

Winnipeg Children's Hospital, University of Manitoba, Winnipeg, MB

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While prescribing medication as approved by Health Canada or the US Food and Drug Administration may be the ideal, the reality is that those of us who treat overactive bladder (OAB) in children do not have that luxury. For us, the off-label use of antimuscarinics is common practice. However, clinicians need to feel confident when making such recommendations. Additionally, parents need to be informed when the medications prescribed for their children are being used off-label; they need to understand why we feel their use is justified and they need to decide if they are comfortable with the recommendation. Given the small market, the pursuit of formal assessment and approval for use of these medications in the pediatric population is unlikely to be undertaken by the pharmaceutical companies. Therefore, clinicians treating pediatric OAB rely on the clinical trials and experience of our avant-garde colleagues to determine the safety, tolerability and clinical efficacy of such medications in our patients.

In their article in this issue of CUAJ, Nadeau and colleagues provide further evidence that the use of solifenacin as a second-line agent for refractory OAB in children is justifiable.¹ This was previously shown in their 2010 publication² using a smaller study group (72 vs. 244 patients) and

a shorter follow-up period (mean of 15.6 vs. 21 months). Following the initial publication, it is likely that many clinicians confidently added solifenacin to their treatment protocol for the management of refractory pediatric OAB. Therefore, for those of us who deal with this condition on a regular basis, this updated publication is not likely to change our management protocols. However, it is important that we do not take a lackadaisical attitude toward prescribing off-label medications. Parents remain anxious about the use of medications for which the product monograph states "Safety and effectiveness in children have not yet been established." The stronger the available evidence is for us to reassure them with, the better for all of us. Studies that show safety, tolerability and efficacy using larger study groups and longer periods of follow-up will always be more valuable than smaller, shorter term studies showing similar findings.

Competing interests: Dr. Psooy declares no competing financial or personal interests.

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Correspondence: Dr. Karen Psooy, Winnipeg Children's Hospital, AE301 - 840 Sherbrook St., Winnipeg, MB R3A 1S1; kpsooy@hsc.mb.ca