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Título: Efficacy And Safety Of Sglt2I In Pediatric With Type 2 Diabetes Patients: A Meta-Analysis Of Randomized Controlled Trials

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Resumo: Type 2 diabetes mellitus (T2DM) in children is an increasingly prevalent metabolic disorder. Treatment options for pediatric T2DM have been limited, with few medications approved specifically for this population. Sodium-glucose co-transporter 2 inhibitors (SGLT2i), a class of glucosuric agents, have shown significant efficacy in adults with T2DM, demonstrating benefits in glycemic control, cardiovascular outcomes, and renal protection. These medications, which work by promoting urinary glucose excretion, were approved for use in adults with T2DM in 2013, marking a notable advancement in diabetes management. However, the use of SGLT2i in children with T2DM remains a subject of debate due to limited clinical evidence in this age group. Given the need for expanded treatment options in pediatric T2DM, we conducted a systematic review and meta-analysis to evaluate the current evidence on the efficacy and safety of SGLT2i specifically in children with T2DM. Following PRISMA guidelines, we conducted a comprehensive literature search across PubMed, Embase and Cochrane Library, using 'T2DM', 'SGLT2 inhibitors', and 'randomized clinical trials' as key terms. Efficacy outcomes included change in HbA1c and fasting plasma glucose (FPG) from baseline. Safety outcomes comprised incidence of any adverse events (AEs), hypoglycemia, headache, and gastrointestinal disorders. Data were summarized using mean differences for continuous outcomes and odds ratios for dichotomous outcomes, with 95% confidence intervals. I^2 was used to assess heterogeneity. Statistical analyses were performed using Review Manager 5.4 software. Out of 1287 initially identified studies, 3 were included in the final analysis, comprising a total of 475 patients (172 in the SGLT2 inhibitor group and 162 in the placebo group). The follow-up ranged from 24 to 52 weeks. The mean age of patients ranged from 14.5 to 16.1 years. The gender distribution was approximately 40% male and 60% female across the studies. The pooled mean difference in HbA1c from baseline was -0.64% (95% CI: -1.04, -0.24, $I^2=0\%$, $p=0.002$). Mean difference in FPG from baseline was -23.05 mg/dL (95% CI: -36.08, -10.03, $I^2=0\%$, $p=0.0005$). The odds ratio for any AEs was 1.14 (95% CI: 0.73, 1.78, $I^2=46\%$, $p=0.57$). The odds ratio for hypoglycemia was 0.87 (95% CI: 0.53, 1.44, $I^2=78\%$, $p=0.06$). The most common AEs were headache (OR 1.71, 95% CI: 0.83, 3.53, $I^2=0\%$, $p=0.15$) and gastrointestinal disorders (OR 1.49, 95% CI: 0.61, 3.61, $I^2=0\%$, $p=0.38$). The current data suggest that SGLT2 inhibitors show significant efficacy in reducing HbA1c and FPG in children with T2DM, with a generally favorable safety profile. While these findings indicate that SGLT2i may be a promising treatment option for pediatric T2DM, further research is needed to fully establish their long-term efficacy and safety in this population. Clinicians should carefully consider these results when making treatment decisions for children with T2DM.