口服去氨加压素片(DDAVP)治疗儿童原发性夜间遗尿症(PNE)的有效性研究(随机、双盲、安慰剂对照研究)

目的:DDAVP 鼻喷剂已被证实能有效治疗 PNE，而 DDAVP 片剂对于患者和家长可能将是一种更便捷的治疗方法。我们评估了其对减少 PNE 遗尿次数的有效性。**材料和方法**:我们在 14 地区对 141 例 5-17 岁 PNE 儿童进行了项 DDAVP 片剂双盲、安慰剂对照、平行组试验。试验对象要求 2 周内遗尿次数最少要达 3 次。患者被随机安排睡前服用 0.2mg、0.4mg 或 0.6mg 的 DDAVP 或安慰剂。睡前 2 小时开始限制饮水。在最后 2 周治疗期间记录平均遗尿次数减少率,同时记录第 2、4、6 周的应答率和遗尿减少率。**结果**:安慰剂组和 0.2mg、0.4mg.0.6mgDDAVP 组的减少率分别为 9%、20%、30%和 36%。0.6mgDDAVP 组与安慰剂组的遗尿减少率明显不同($p < 0.05$).4 组的完全应答率(0-2 次遗尿)分别为 3%、18%、33%和 24%。其中 0.4mg 和 0.6mg 组与安慰剂组明显不同($p < 0.05$)。4 组中遗尿减少率低于 50%的比例分别为 83%、79%、64%和 61%。片剂治疗 PNE 表现出量效关系,遗尿减少率与剂量在统计学上明显成线性关系($p < 0.05$)。**结论**:每日口服 0.6mgDDAVP 治疗 6 周后可明显减少遗尿次数,增加剂量可提高应答率。

Oral desmopressin: a randomized double-blind placebo controlled study of effectiveness in children with primary nocturnal enuresis

Skoog SJ, Stokes A, Turner KL.

PURPOSE: Desmopressin nasal spray has proved to be efficacious treatment of primary nocturnal enuresis. Oral desmopressin tablets would be a more easily used, convenient vehicle for our patients and their parents. We evaluated the effectiveness of oral

desmopressin in decreasing the number of wet nights in patients with primary nocturnal enuresis. MATERIALS AND METHODS: We performed a double-blind, placebo controlled, parallel group trial of oral desmopressin in 141 children 5 to 17 years old with documented primary nocturnal enuresis at 14 sites. Patients were screened for number of wet nights for 2 weeks before study entry. A minimum of 3 wet nights weekly for 2 consecutive weeks was required for study entry. Patients were randomized to receive 200, 400 or 600 mcg. desmopressin or placebo before bedtime. Fluids were restricted 2 hours before bedtime based on body weight. The primary efficacy variable was mean decrease in the number of wet nights recorded during the last 2-week treatment period. The percentage of responding patients and mean decrease from baseline in number of wet nights at 2, 4 and 6 weeks were also assessed. RESULTS: The decrease in wet nights was 9, 20, 30 and 36% for placebo, and 200, 400, and 600 mcg. desmopressin orally per day, respectively. The 600 mcg. dose of oral desmopressin daily was statistically significantly different ($p < 0.05$) from placebo in decreasing wet nights. A complete or near complete response (0 to 2 wet nights) was noted in 3, 18, 33 and 24% of the patients who received placebo, and 200, 400 and 600 mcg. oral desmopressin daily, respectively. The 400 and 600 mcg. treatment groups were statistically significantly different ($p < 0.05$) from placebo. A less than 50% decrease in wet nights was noted in 83, 79, 64 and 61% of the patients who received placebo, and 200, 400 and 600 mcg. oral desmopressin daily, respectively. Oral desmopressin exhibited a dose response in the treatment of primary nocturnal enuresis. The linear trend for the decrease in wet nights was statistically significant ($p < 0.05$). CONCLUSIONS: A dose of 600 mcg. oral desmopressin daily significantly decreased the mean number of wet nights when administered for 6 weeks. A higher dose may be necessary for an improved response.

*Skoog SJ, Stokes A, Turner KL. the Journal Urology. 1997,158(3 Pt 2):1035-40.