GUIDELINE TOPIC: PHARMACOLOGICAL MANAGEMENT OF ASTHMA
QUESTION: EVIDENCE TABLE 4.24A: OTHER PREVENTOR THERAPIES - CHROMONES IN CHILDREN AGED 5-12

BIBLIOGRAPHIC CITATION	STUDY TYPE	EVIDENCE LEVEL	NUMBER OF PATIENTS	PATIENT CHARACTERISTICS	INTERVENTION	COMPARISON	LENGTH OF FOLLOW-UP	OUTCOME MEASURE	EFFECT SIZE	SOURCE OF FUNDING	ADDITIONAL COMMENTS
Berman, B. A., Fenton, M. M., Girsch, L. S., Haddad, Z. H., Sellars, W. A., Strem, E. L., Thompson, H. C. and Wall, L. E.. Cromolyn sodium in the treatment of children with severe, perennial asthma. Pediatrics. 1975:55;621-9.	RCT	+	276 recruited. 83 removed for variable ICS. 4 dropped out unstated reasons. 189 patients included (141 no ICS, 48 steroid stable).	125 male, 64 female. Age range 5-9 yrs (36.6%), 10-17 yrs (56%), >17 yrs (7.4%). Moderate/Severe asthma. Community (private practice) based. Other co-morbidity mentioned.	2 week usual meds (run in), 4 week 20mg qid DSCG or placebo (spinhaler), 2 week no test drug, 4 week cross over.	Treatment and placebo	12 weeks.	Symptom scores, patient preference, bronchodilator use, side effects.	Wilcoxon comparison p<0.0005 for difference in symptom scores: Wheeze 0.86 vs 1.30, Breathlessness 0.56 vs 0.82, Tightness 0.54 vs 0.82, Cough 0.62 vs 0.92.	Not stated.	There does seem to be some effect of treatment in this study though the outcome measures are non standard and there were multiple sites for the study. It is not clear how successful blinding and placebo were.
Geller-Bernstein, C. and Levin, S.. Sodium cromoglycate pressurised aerosol in childhood asthma. Current Therapeutic Research, Clinical & Experimental 1983:34;345-349.	RCT	+	48 entered trial. 2 withdrawn during run in for non compliance. 26 placebo/DSCG, 20 DSCG/placebo.	Age 4-13 years. Mod Severe/Severe asthma at least 12 months. Extrinsic allergic. Oral bronchodilators (some inhaled). No oral, inhaled steroids or DSCG for at least 6 months before the trial.	2 week baseline. 6 weeks DSCG 2mg Inh/placebo, then swap over for 6 weeks.	Comparison between treatment and placebo.	14 weeks	Symptom score, PEFR, Physician's and parent opinions also noted.	DSCG, placebo, p Mean asthma score baseline 2.7 3 weeks 1.2, 1.8, <0.01. 6 weeks 1.0, 1.4, <0.05. PEFR baseline 206 3 weeks 253, 225, <0.05. 6 weeks 247, 237, ns	Not stated	Although the study has important differences between placebo and DSCG, problems with concealment and low dose (5th current dose) make an interpretation difficult and probably not good to make recommendation from this study.

									26 pts preferred DSCG vs 10 placebo (<0.05)		
Ng, S. H., Dash, C. H. and Savage, S. J.. Betamethasone valerate compared with sodium cromoglycate in asthmatic children. Postgraduate Medical Journal. 1977:53;315-20.	RCT	+	20	Mean age 9.7 yrs (range 6.7- 13.7). Severe asthma with regular time off school. Hospital based study.	Placebo vs DSCV vs Inhaled beclomethasone	Between treatments and placebo	10 weeks	Symptom scores, PEFR (am/pm), bronchodilator use, adverse effects.	(All placebo, DSCG, p) Bronchodilator use 0.85, 0.65, ns. Night symptom score 0.78, 0.54, <0.025. Day symptom score 2.6, 1.7, <0.005. Total symptom score 3.3, 2.3, <0.005. Morning PEFR 150, 172, <0.01. Evening PEFR 159, 187, <0.01.	Glaxo supported placebos (?bias towards beclomethasone)	Yes - there does appear to be some benefit from DSCG in this study. The effect is small especially compared with ICS.
Selcow, J. E., Mendelson, L. M. and Rosen, J. P.. Clinical benefits of cromolyn sodium aerosol (MDI) in the treatment of asthma in children. Annals of Allergy. 1989:62;195-9.	RCT	+	32. 16 each arm.	23 Males, 9 females. Active gp mean age 12.5 (9-16), placebo 14.1 (8-20). Mean FEV1 and reversibility comparable. Other treatments not well listed. Hospital based.	Use of MDI DSCG 2mg qid vs MDI placebo qid for 10 weeks.	Treatment and placebo at different time points. Control period 2 weeks usual DSCG. 4 week period of single blind placebo. If worse (predefined) on placebo, randomized for main study. 10 weeks of random double blind DSCG or placebo MDI.	10 weeks	Diary: Overall asthma severity, symptom severity (separate note of cough, wheeze, breathlessness), sleep difficulty, restriction normal activity (0-3 scale ?validated). Use of concomitant medication, morning and evening PEFR. 2 weekly FEV, FVC, PEFR, physician overall score (0-3 ?validated).	No numerical results given. Esitmated from graphs @ week 10 scoring, all favour DSCG (scale 0-3 Placebo/DSCG, p=x) : overall asthma severity (1.1 vs 0.55, p=0.05), breathlessness (0.65 vs 0.25, p=0.05), Restriction activity (0.15 vs 0.95, p=0.03). Beta 2 agonist use (puffs/day 3.1 vs 0.5, p=0.07), Theophylline use (65mg vs 10mg. NS), FEV1 (%change from baseline 0 vs 20%, p=0.04)	Fison's Corporation.	Conclude that DSCG by MDI in children controls symptoms, improves lung function and decreases need for concomitant bronchodilators. Although reservations exist about the small numbers of patients, lack of numerical results, lack of negative results. The study demonstrates that DSCG by MDI compared with placebo, is able to improve some symptoms scores and lung function following 10 weeks of

											treatment. Dose used not consistent with current dose.