## EVIDENCE-BASED PRACTICE SUMMARY FORM

**Date:** September 23, 2011 **Reviewer:** Brandon D Rachal

Clinical Question: In children with persistent asthma (P) what is the effect of a combination inhaled long acting beta agonist and inhaled corticosteroid (I) in comparison to inhaled corticosteroids alone (c) on asthma control measured by morning peak expiratory flow [PEF] volumes (O) over a 12 week period (T)?

CITATION	POPULATION	STUDY DESIGN		RES	ULTS		VALIDITY THREATS	IMPLICATIONS	QOE
Tal, et al., 2002	<b>286 Total</b> children with asthma, minimum 6	12 week (longitudinal), prospective, double blind,	_ /	AX	PX	Mean Difference	Does not specify a value for asthma symptom score	Statistically significant: Y	High
	months	double dummy randomized, parallel-group study	Exp	257	280	23.1	as an inclusion criterion	Direction of findings: <b>Expected</b>	
	Exp: 148 Boys: 90	IV: inhaled combination	Control	274	285	11.1	Patients with very low or zero asthma symptom	Magnitude of difference:	
	Girls: 58	budesonide/formoterol				AA	score were eligible; mean	Medium	
	Control: 138	Level 1: inhaled combination budesonide/formoterol	p=<0.001  Difference between two groups			<i>,</i> $\mathbf{v}$	baseline asthma symptom score was 0.58 (0-4.8) in	Based on this 1 study I recommend the inhaled	
	Boys: 87	Level 2: inhaled budesonide				groups	control group and 0.67 (0-		
	Girls: 51	DV: morning PEF	12 L/min			Ď.	5.8) in experimental group indicating study population		
	Age Range: 4-17	DV. morning i Er				7	had low to mild asthma inhaled corticosteroids		
	Mean Age: 11 years	Methods: Patients were randomized 1:1					Small number of patients	alone (C).	
	On inhaled corticosteroids (ICS) at	to receive 12 weeks inhaled treatment with either	3 /			A.	in the age range 4-8		
	constant dose for at	budesonide/ formoterol two				$A \mid I \mid$	Overall adherence to		
	least 6 weeks prior to study	inhalations twice daily or an equivalent dose of budesonide, two inhalations	$\mathcal{M}$		П	14	treatment good; does not represent general asthma population		
	FEV <sub>1</sub> 40-90% of predicted value	twice daily			•				
	Ability to demonstrate	Measurements: PEF in L/min using a Mini-							
	correct use of inhaler	Wright peak flow meter recorded by patients via diary							
	Exclusions: Known hypersensitivity	cards	1	<b>A</b> 4	A				
	to study medication	Statistical Analysis: ITT	/ Y			11			
		ANOVA				V			

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CITATION	POPULATION	STUDY DESIGN		RESU	ULTS		VALIDITY THREATS	IMPLICATIONS	QOE
Pohunek, Kuna, &	630 Total children with asthma	12 week (longitudinal), prospective, double blind,	_ /	AX	PX	Mean Difference	Significant proportion of the population (12%) were	Statistically significant: Y	High
Boeck, 2006		double dummy, randomized	Evn	212	241	30		Direction of findings:	
	Exp <sub>1</sub> : 216	parallel-group, active-	Exp <sub>1</sub>	212	241	30		Expected	
	Males: 140	controlled study	Control	216	235	19	Although symptomatic		
	Females: 76	Bratt. JE 1.00					asthma symptom score	Magnitude of difference:	
		IV: inhaled combination	required for inclusion,					Medium	
	Control: 213	budesonide/formoterol	p = < 0.001				mean baseline was only		
	Males: 147	Level 1: inhaled	_				0.63 (0-6) indicating low to mild asthma	Based on this 1 study I	
	Females: 66	budesonide/formoterol	Difference		en two	groups		recommend the inhaled	
		Level 2: inhaled budesonide	10.9 L/m	in		<b>A</b>		combination beta agonist	
	Age Range: 4-11						_	and corticosteroids (I) over	
	Mean Age: 8 years	DV: morning PEF						inhaled corticosteroids	
								alone (C).	
	On ICS at constant	Methods:		40			_ // //		
	dose for at least 3	Patients were randomized to					<i></i>		
	months prior to study	one of three treatment					<i>-</i>		
		groups. Combination							
	PEF ≥50% predicted	budesonide/ formoterol,							
	value	budesonide and formoterol	. // //	/	11				
		separately, budesonide alone							
	Ability to demonstrate		-						
	correct use of inhaler	Measurements:							
	and peak flow meter	PEF in L/min using a Mini-							
		Wright peak flow meter							
	Total asthma symptom	recorded by patients or							
	score of at least 1 (0-6)	family via diary cards							
	on a minimum of 4 of 7				4	47			
	days prior to study	Statistical Analysis:	//8	$\Delta A$					
		ITT	/ W						
	Exclusions:	ANOVA							
	Known hypersensitivity								
	to study medication								

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CITATION	POPULATION	STUDY DESIGN	N RESULTS				VALIDITY THREATS	IMPLICATIONS	QOE
Morice, Peterson,	<b>622 Total</b> children with asthma at least 6	12 week (longitudinal), prospective, phase III, double		AX	PX	Mean Difference	Significant proportion of the population (12%) were	Statistically significant: Y	High
Beckman, & Zuzana, 2008	months	blind, double dummy, randomized parallel-group	Exp <sub>1</sub>	221	251	30.2	aged 4-5	Direction of findings: <b>Expected</b>	
	Exp <sub>1</sub> : 212 Males: 141	study	Control	224	244	19.9	Although symptomatic asthma symptom score	Magnitude of difference:	
	Females: 71	IV: inhaled combination budesonide/formoterol	p = < 0.001		Ţ.	N	mean baseline was only 1.6 indicating to mild to moderate asthma	Medium	
	Control: 207 Males: 137	Level 1: inhaled budesonide/formoterol	Differenc	e hetwe	en twi	o grouns		Based on this 1 study I recommend the inhaled	
	Females: 70	Level 2: inhaled budesonide	10.3	c ocime		groups		combination beta agonist and corticosteroids (I) over	
	Age Range: 6-11 Mean Age: 9 years	DV: morning PEF						inhaled corticosteroids alone (C).	
	On ICS at constant	Methods: Patients were randomized to					~ //		
	dose for at least 30days prior to study	one of three treatment groups. Combination	7/	$\sim$	A	AH	n / /		
	PEF ≥50% predicted	budesonide/ formoterol (DPI), combination	$\mathbf{I}I$						
	value	budesonide/ formoterol (pMDI), budesonide alone	V			u			
	Ability to demonstrate								
	correct use of inhaler and peak flow meter	Measurements: PEF in L/min using a Mini- Wright peak flow meter							
	Total asthma symptom								
	score of at least 1 (0-6) on a minimum of 4 of 7	Statistical Analysis: ITT	$\Lambda$		A	n			
	days prior to study	ANOVA	/ 1						
	Exclusions: Known hypersensitivity to study medication	•			l	y			