Guideline topic: Pharmacological management of asthma
Evidence table 4.15: Mometasone Furoate dry powder inhalation evidence

Author	Year	Study type	Quality rating	Population	Outcomes measured	Effect size	Confidence intervals / p values	Comments
Holgate ST, Arshad H, et al. J Allergy Clin Immunol 105 : 906 - 11[1]	2000	RCT double blind placebo control single centre Cross over trial 3 phases with 4-week washout period. MF 50mcg BD v 100 mcg BD 2 weeks each treatment	+	13 pts. Adults 21- 49 years. Non smokers, asthma more than 6months, Baseline FEV > 60% (mean = 90%). Demonstrates sensitivity to inhaled AMP. Beta agonist prn as only asthma medication. ISC within 1 month of study excluded.	a)AMP challenge PC20 (numbers of doubling dilutions) b) FEV1 mean change (L) c)PEFR, asthma symptoms and beta agonist	3.11 (100mcg) 2.81 (50mcg). No diff between treatments. Active better than placebo 0.34 (100 mcg) 0.235 (50 mcg) 0.009 (placebo) No diff between treatments. Active better than placebo Small changes. Numerically better than placebo No difference	P < 0.001 P < 0.05 Not analyzed for significance	Small study with short treatment period (2 weeks). Pt have mild asthma Shows that low doses MF twice daily decreases airway responsivenes to AMP challenge. Also some improvement in lung function.

					use e) adverse events			
Nayak AS, Banov C et al Ann Allergy Asthma Immunol 84 :417 - 424[2]	2000	RCT double blind placebo control multicentre (21 centres in USA). 12 week trial. MF 200mcg OD v 400mcg OD	++	236 pts. 12 to 72 years (mean 33y). Asthma at least 6months. Fev1>55<85% (mean 73%). Beta agonist use at least 3 times/week. No other asthma medication permitted. Excluded if ICS within 3months trial	a)Fev1 change from baseline (L) b) PEFR am change from baseline(L/min) c)worsening asthma (criteria predefined) numbers of patient d) asthma symptoms scores	0.35 (400mcg) 0.35 (200mcg) 0.06 (placebo) No diff between treatments. Active better than placebo. 40 (400mcg) 15 (200mcg) 8 (placebo) 400 mcg better than placebo 200 mcg NOT statistically diff from placebo 9 (400 mcg) 13 (200 mcg) 26 (placebo) active better than placebo small changes. No diff between treatments Active better than placebo 66% (400mcg) 64%(200mcg) 50% (placebo) Active better	P < 0.05 P <0.01 P <0.01 P = 0.88 P < 0.05	Shows that in mild to moderate asthma, ONCE DAILY MF 200 and 400mcg better than placebo. Also 400mcg better than 200mcg in PEFR.

					e)physician evaluation (% pts who improved) f) adverse events	than placebo No difference	P <0.01	
Kemp JP, Berkowitz RB et al J Allergy Clin Immunol 106 :485 -492[3]	2000	RCT, double blind placebo control study. Multicentre (22 centres in USA) 12 weeks treatment MF 200mcg OD v 400mcg OD v 200mcg BD	++	306pts. 12 to 70 years (mean = 31y), Asthma diagnosis >6months. FEV1 55-85% (mean 72%). Beta agonist use at least 3times/week (mean = 4/day EXCLUDED if ICS use in last 3 months. All other asthma medication NOT permitted	a) FEV1 change from baseline (L) b) am PEFR change from baseline (L/min) c)symptom scores	0.40 (200mcg BD) 0.41(400mcg OD) 0.27(200mcg OD) 0.14(placebo) 400mcg and 200mcg BD better than placebo. 200mcg OD NOT diff to placebo 64 (20mcg BD) 52 (400mcgOD) 26 (200mcg OD) 23 (placebo) 400mcg OD and 200mcg BD better than placebo. 200mcg OD not different to placebo. Low at baseline thus small changes.	P < 0.01 P < 0.01	In mild to moderate asthma MF 400mcg OD equally effective as 200mcg BD. Study also showed that 400mcg/day gave better results than 200mcg/day

					d) albuterol use e)physician evaluation (% pts who improved) f)adverse events	400mcg OD and 200mcg BD significantly better than placebo All active better than placebo. 79.7 (200mcg BD) 72.7 (400mcg OD) 62.3 (200mcg OD) 44.6 (placebo) All actives better than placebo No difference	P < 0.05 P <0.01	
Noonan M, Karpel MD et al. An Allergy Asthma Immunol ; 86 :36 - 43[4]	2001	RCT, double blind, double dummy, placebo control. Multicentre (16 centres in USA).MF 200mcg BD v 200mcg OD am v 200mcg OD pm v 400 OD am . 2 week open phase of MF 200mcg BD followed by 12 weeks treatment.	++	307 patients. Aged >12 years (mean 39years). Asthma at least 6months. FEV1 60-90% (mean79%). All using ICS regular (BDP 336/d, Flunisol 1179/d, FP 377/d, Triamcinolone 791/d). EXCLUDED if using long acting beta agonist or oral steroids >14 days in last 6months. All pts given MF 200mcg BD for	a)FEV1 change from baseline (L)	-0.03 (200mcg BD) -0.01 (400cmg OD) 0.03 (200 OD pm) -0.22 (200 OD am) -0.32 (placebo) 200 BD, 400 OD and 200 OD pm better than placebo. 200 OD am NOT better than placebo. 200 OD pm better than 200 OD am	P < 0.01 P <0.01	Pts recruited were using wide range of doses of ICS before start of trial. Also all baseline scores were low. Shows that MF OD 400mcg as effective as 200mcg BD in lung function and asthma control. Also in 200 mcg OD, pm dose better than am dose

				2 weeks before randomised.	b) FVC and FEF similar results to FEV1 c) am and pm PEFR d) asthma scores and beta agonist use low at baseline e)physician response-to-therapy scores f) adverse events including serum cortisol challenge tests	 All active treatments better than placebo All active treatments better than placebo All active treatments better than placebo. 200 mcg BD better than 200mcg OD am no difference	P <0.01 P < 0.01 P <0.01 P = 0.05	
BernsteinDI , Berkowitz RB et al Respir Med 93 , 603 - 612[5]	1999	RCT double blind, double dummy, placebo controlled, multicentre (20 centres in USA) MF 100, 200 or 400 mcg, or BDP 168 mcg , all BD. 12	++	365 pts, 12-74 years (mean 37y) Asthma at least 6months. FEV1 60-90% (mean 76%) Been on stable dose ICS for at least 30days. (BDP 345, flunisol 1063, FP 440, TAA 750). EXCLUDED if oral steroids >14 days in	a)FEV1 mean change from baseline (%) b)FVC mean change from	+4.8 (MF 100) +7.1 (MF200) +6.2 (MF400) +3.0 (BDP 168) -6.6% (placebo) Active better than placebo. BDP 168 similar to MF 100 +4.7 (MF100)	P < 0.01	Showed MF200 BD better than MF100 BD and no apparent additional benefit of MF 400 BD. Also MF100 BD similar to BDP168 BD

			week treatment		last 6months.	baseline (%)	+3.3 (MF200)	
							+3.5 (MF400)	
							+2.0 (BDP100)	
							-4.7% (placebo)	P < 0.01
							Active better than placebo	P =0.05
						c)FEF 25 – 75% mean change from baseline	Increase for MF200 greater than MF 100.	P = 0.68
							NO difference between MF200 and MF400	
						d)PEFR am and pm	Increases in active treatment (3.8-9.9%) better than placebo (-3.9% to –7.0%).	P < 0.01
							MF200 better than MF100	P < 0.02
							Small changes. Active better than placebo	P < 0.01
							+22 (MF 100)	
							-21.4 (MF 200)	
						e)asthma symptoms scores low at baseline	-2.3 (MF 400)	
							-21.4 (BDP 168)	
						f)rescue medication use per day change (%)	+25.3 (placebo)	
							MF200, 400 and BDP168 better than placebo	P < 0.01
							56 (MF100)	
							67 (MF200)	
							66 (MF400)	

					g)physician evaluation of improvement (% pts) h)safety (adverse events and cortisol stimulation tests)	51 (BDP 168) 20 (placebo) no difference between active and placebo		
Nathan RA, Nayak AJ et al Ann Allergy Asthma Immunol 86 : 203 - 210[6]	2001	RCT, double blind, double dummy, placebo controlled, 15 centre in USA. MF 100 bd v MF 200 bd v BDP 168 bd 12 week trial	++	227pts, 13-75 years (mean 41 years). Asthma at least 6months. FEV1 60-90% (mean 76%). On ICS stable for 30 days prior to study (BDP 310, Flunisol 1100, FP 360, TAA 720). Theophyline permitted but all other asthma meds NOT permitted	a)FEV1 change from baseline (L) b)FVC and FEF25-75 c)mean am PEFR change from baseline (L/min) d)symptom scores low at baseline e) albuterol use (inhalation/day) change from baseline f) physician evaluation of	0.12 (MF 100) 0.25 (MF 200) 0.11 (BDP 168) -0.21 (placebo) similar changes to FEV1 26.7 (MF100) 37.4 (MF200) 19.3 (BDP 168) -21.4 (placebo) small changes -1.18 (MF100) -0.94 (MF200) -1.05 (BDP 168) +1.31 (placebo) no significant differences	Active better than placebo P < 0.01 Active better than placebo p < 0.01 Active better than placebo p < 0.01 Active better than placebo Active better than placebo p <0.01 Active better than placebo p <0.01	Active treatments in 2 different devices (MDI v DPI). MF 100 and 200 BD effective and well tolerated in asthma control. MF 100 BD similar results to BDP 168 BD. MF 200 BD appeared to be most effective but not achieved clinical significance in this study.

					improvement g) adverse events	between treatments no difference		
O'Connor B, Bonnaud G et al Ann Allergy Asthma Immunol 86 :397 - 404[7]	2001	RCT, parallel gp, double blind (for MF dosage), evaluator-blind (for MF v FP) 60 centres in 20 countries. MF100 bd v MF 200 bd v MF 400 bd v FP 250 bd For 12 weeks MF in DPI and FP in diskhaler	++	733 pts. Age 12–79 years (mean 40-42y) Asthma at least 6months. FEV1 60-90% (mean 75%) On dose ICS for at least 30days (BDP 400-1000, Bude 400-800, Flunis 500-1000, FP 200 to 500, TAA 600-800). Excluded if had oral steroids more than 14days in last 6months, more than 12inhalations/d beta agonist. NO other asthma medication allowed apart from theophylline	a)FEV1 mean change from baseline (L) b)am PEFR mean change from baseline (L/min) c)FEF 25 – 75% d) FVC e)asthma	0.07 (MF 100) 0.16 (MF200) 0.19 (MF400) 0.16 (FP 250) NO difference between MF 200, 400 and FP250. MF 400 better than MF100 15 (MF 100) 29 (MF 200) 30 (MF 400) 32 (FP 250) All 4 treatments improved MF 400 and FP250 showed improvement compared to MF 100 NO difference between treatments Baseline scores very low. Small changes. FP and MF400 appeared to be the best in most scores -13.23 (MF100)	P = 0.02 P <0.05 P < 0.05	Large study. Single blind for the FP part of the study due to device. Shows that MF 200 and 400 BD more efficacious than MF 100 BD and comparable to FP 250 BD. Also no statistical difference MF 200 and MF 400, thus appears no added benefit of MF 400 bd to MF 200 bd

					scores f)albuterol use mean change from baseline (mcg /day) g)physician evaluation of improvement g)safety and adverse events	-94.84 (MF 200) -38.10 (MF400) -52.06 (FP 250) MF 200 biggest improvement compared to MF100 MF 200, 400 and FP 250 rated the same. MF 100 rated lower No difference between treatments. MF100 most withdrawals due to treatment failure (7%) cf 4% for the rest	P <0.01	
Bousquet J, D'Urzo A et al Eur Respir J ; 16 : 808 – 816[8]	2000	RCT, double blind for MF dosage, evaluator blind for MF v BUD, parallel group study. 57 centres in 17 countries. MF DPI 100, 200 and 40 BD and BUD turbohaler 400 BD. 12	+ (as single blind for one aspect of study)	730 pts, 12 – 76 years (mean 39-42y) Asthma for at least 6months. FEV1 60-90% (mean 76%) Using ICS for at least 30days and on stable dose (BPD mean 679-736, BUD mean 645–688, Flunisolide mean 422-45	a) mean change FEV1 (L) b) PEF am (L/min) c) Evaluation of asthma symptoms	0.10 (100mcg) 0.16 (200mcg) 0.16 (400mcg) 0.06 (BUD 400) 18.2 (100mcg) 37.8 (200mcg) 37.3 (400mcg) 24.7 (BUD) Low at baseline for all.	P<0.05 of MF 200 and 400BD cf BUD 400mcg BD P<0.05 MF 200 and 400mcgBD cf 100mcgBD	Mometasone 200mcg BD and 400mcg BD are more effective than BUD 400mcg BD

		weeks treatment			(Patient rated) d) Use of salbutamol (mcg/day) e)Physician evaluation (mean scores) f) adverse effects	Improvement in am wheezing was significantly greater for MF 400mcgBD than BUD or MF 100 NS differences between MF 200 and 400 groups MF 200BD required less than BUD group 2.43 (100mcg) 2.33 (200mcg) 2.25 (400mcg) 2.53 (BUD) All treatments were well tolerated	P<0.05 P<0.05 MF 200 and 400 cf BUD	
Fish J, Karpel J et al J. Allergy Clin. Immunol 2000 ; 106: 852-860[9]	2000	RCT double blind, placebo control 21 centres 12 week of MF 400 and 800mcg BD vs placebo then 9 month open-label phase	+	132 patients age 13-83 years (mean 52) on oral corticosteroids daily or alt day for >5months/6 months before enrolment. Stable on minimum effective dose in range of 5-30 mg daily or 10 to 60mg alt days. FEV1 >40-85% of	a) change in daily oral prednisolone dose at 12 weeks b) oral prednisolone use- % change in dose at 12 weeks c)Change in	+11.8mg placebo -6.33mg MF-400 -3.19mg MF 800 -46.0% MF 400mcg BD -23.9% MF 800mcg BD + 164.4% placebo	P<0.05 P<0.01	Inhaled MF 400mcg and 800mcg BD reduce daily OCS requirements compared to placebo Further reductions in OCS requirements were achieved with long-term MF treatment in the open –label phase

				predicted (mean 61%). Some pts also on ICS BDP 430mcg/d, FP 666-953/d, TAA1000/d, Flunisoli1400/d All regular ICS stopped and replaced with study treatments	FEV1 (L) at 12 weeks c)FVC, PEF at 12 weeks d)Symptoms and rescue medication f) adverse events	-0.19 Placebo 0.25 MF 400mcg BD 0.17 MF 800mcg BD significant increase compared to placebo Both significantly improved with both doses of MF compared to placebo No difference	P<0.01 P<0.01	Although high doses of MF used, HPA function and bone density NOT studied

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