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Budesonide vs. Mesalamine in Microscopic Colitis: A Systematic **Review and Meta-analysis of Efficacy and Adverse Events**

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Background

Microscopic colitis (MC) presents with chronic watery diarrhea, abdominal pain, cramping, bloating, nocturnal defecation, and occasional weight loss. The diagnosis is based on colonic tissue biopsy to reveal specific histological features. Several drugs, including mesalamine, budesonide, and other immunomodulators, are used for treating the disease process.

Aim

We aim to compare treatment efficacy and adverse events (AEs) of budesonide and mesalamine therapy in MC in this meta-analysis.

MATERIAL & METHODS

We searched the Cochrane Library, Scopus, Web of Science, and PubMed, comparing mesalamine or budesonide with a control group in the treatment of MC. Outcomes included clinical remission (three or fewer stools/day), stool characteristics (daily stool weight, daily stool frequency, daily stool consistency), and the number of patients with clinical response <50% in the disease activity. Safety endpoints included: Any AE-related discontinuation, including abdominal discomfort, constipation, flatulence, nausea, dizziness, headache, bronchitis, nasopharyngitis, and depression. The metaanalysis was conducted using the generic inverse variance method and performed a subgroup analysis based on the intervention.

Ctucks or Cubarous	lealDate Datial	er.	Moight	Rate Ratio		Rate R
Study or Subgroup	log[Rate Ratio]	3E	weight	IV, Random, 95% Cl		IV, Randon
1.4.1 Budesonide						
Bonderup 2008		0.069643	11.7%			
/liehlke 2002		0.096939	10.6%	1.78 [1.47, 2.15]		
liehlke 2008		0.044133				-
liehlke 2009		0.078571	11.3%	1.29 [1.11, 1.51]		
iehlke 2014		0.091071				
liehlke 2018	0.474	0.114541	9.9%	1.61 [1.28, 2.01]		
ünch 2014	0.464	0.047704				
ubtotal (95% CI)			79.1%	1.44 [1.25, 1.66]		
eterogeneity: Tau² :	= 0.03; Chi ^z = 45.3;	3, df = 6 (P <	< 0.00001); I² = 87%		
est for overall effect	: Z = 5.05 (P < 0.00	001)				
.4.2 Mesalamine						
liehlke 2014	0.68	0.093367	10.7%	1.97 [1.64, 2.37]		
liehlke 2018	0.684	0.106633	10.2%			
btotal (95% CI)			20.9%	1.98 [1.72, 2.27]		
eterogeneity: Tau ^z :	= 0.00; Chi ² = 0.00,	df = 1 (P =	0.98); l² =	:0%		
	: Z = 9.71 (P < 0.00	001)				
est for overall effect						
est for overall effect				4 5 4 5 4 2 4 3 701		
			100.0%	1.54 [1.34, 1.78]		
⁻ est for overall effect - otal (95% CI) -leterogeneity: Tau ² :	= 0.04; Chi ^z = 69.5-	4, df = 8 (P <			0.5	0.7 1

Subtoal (95% C) 1.2 Mesalamine Test for overall effect $Z = 21.34 \text{ (P} < 0.0001)$ 1.2 Mesalamine Test for overall effect $Z = 21.34 \text{ (P} < 0.0001)$ 1.2 Mesalamine Test for overall effect $Z = 21.34 \text{ (P} < 0.0001)$ 1.2 Mesalamine Test for overall effect $Z = 21.34 \text{ (P} < 0.0001)$ 1.2 Mesalamine Test for overall effect $Z = 21.34 \text{ (P} < 0.0001)$ 1.2 Mesalamine Test for overall effect $Z = 2.0.50 \text{ (P} = 0.45)$ Test for overall effect $Z = 2.0.50 \text{ (P} = 0.45)$ Test for overall effect $Z = 2.0.50 \text{ (P} = 0.45)$ Test for overall effect $Z = 2.0.50 \text{ (P} = 0.45)$ Test for overall effect $Z = 2.0.50 \text{ (P} = 0.45)$ Test for overall effect $Z = 2.0.50 \text{ (P} = 0.000)$ Test for overall effect $Z = 2.0.50 \text{ (P} = 0.000)$ Test for overall effect $Z = 2.0.50 \text{ (P} = 0.000)$ Test for overall effect $Z = 2.0.50 \text{ (P} = 0.000)$ Test for overall effect $Z = 0.50 \text{ (P} = 0.000)$ Test for overall effect $Z = 0.50 \text{ (P} = 0.000)$ Test for overall effect $Z = 0.50 \text{ (P} = 0.000)$ Test for overall effect $Z = 0.50 \text{ (P} = 0.000)$ Test for overall effect $Z = 0.50 \text{ (P} = 0.000)$ Test for overall effect $Z = 0.50 \text{ (P} = 0.000)$ Test for overall effect $Z = 0.50 \text{ (P} = 0.000)$ Test for overall effect $Z = 0.50 \text{ (P} = 0.000)$ Test for overall effect $Z = 0.50 \text{ (P} = 0.000)$ Test for overall effect $Z = 0.50 \text{ (P} = 0.000)$ Test for overall effect $Z = 0.50 \text{ (P} = 0.000)$ Test for overall effect $Z = 0.50 \text{ (P} = 0.000)$ Test for overall effect $Z = 0.000 \text{ (P} = 5.0 \text{ (M} \text{ (P} = 0.000))$ Test for overall effect $Z = 0.50 \text{ (P} = 0.000)$ Test for overall effect $Z = 0.50 \text{ (P} = 0.0000)$ Test for overall effect $Z = 0.50 \text{ (P} = 0.0000)$ Test for overall effect $Z = 0.0000 \text{ (P} = 0.000)$ Test for overall effect $Z = 0.0000 \text{ (P} = 0.000)$ Test for overall effect $Z = 0.0000 \text{ (P} = 0.000)$ Test for overall effect $Z = 0.0000 \text{ (P} = 0.0000)$ Test for overall effect $Z = 0.0000 \text{ (P} = 0.0000)$ Test for overall e	A Study or Subgroup	log[Rate Ratio]	SE	Weight	Rate Ratio IV, Random, 95% Cl		Rate IV, Rando			A Study or Subgroup	Mean Difference	SE	Weight	Mean Difference IV, Random, 95%
1.22 Mesalamine Calabra de 195 207 0.00 0.01717 17.1% 2.24 [195,257] 1.22 Mesalamine Test or overal effect $Z = 11.2 \ (p < 0.0001)$ Total (95: C) 10.00 0; $Z.22 \ (1,25,257]$ Total (95: C) 10.00 0; $Z.22 \ (1,22,24,251]$ Test or overal effect $Z = 21.5 \ (p < 0.0001)$ Total (95: C) 10.000; $Z.22 \ (1,22.4,2.51]$ Total (95: C) 10.000; $Z.22 \ (1,22.4,2.51]$ Total (95: C) 10.000; $Z.22 \ (1,2.3,2.16]$ Total (95: C) 10.000; $Z.22 \ (2,2.4,2.51]$ Total (95: C) 10.000; $Z.22 \ (2,2.4,2.51]$ Total (95: C) Total (95: C) 10.0000; $Z.22 \ (2,2.4,2.51]$ Total (95: C)	Miehlke 2002 Miehlke 2008 Miehlke 2009 walter 2010 Subtotal (95% CI) Heterogeneity: Tau ² =	0.958 0.839 0.962 0.00; Chi ² = 6.32	0.040816 0.066071 0.053316 df = 3 (P =	27.4% 18.5% 22.7% 82.9%	2.61 [2.41, 2.82] 2.31 [2.03, 2.63] 2.62 [2.36, 2.91] 2.46 [2.27, 2.67]					Bonderup 2003 Bonderup 2008 Münch 2009 Subtotal (95% CI) Heterogeneity: Tau ² =	-588.25 -187.334 : 17208.57; Chi ² = 6	130.4102 96.99133 .09, df = 2 (20.6% 26.3% 80.3 %	-588.25 [-843.85, -332 -187.33 [-377.43, 2 - 351.62 [-534.25, -168 .
I total (95% CI) 100.0% 2.42 [2.24, 2.61] Hetrogeneity: Tau ² = 0.00; Ch ² = 0.00; P = 0	1.1.2 Mesalamine calabrese 2007 Subtotal (95% CI) Heterogeneity: Not ap	0.806	0.071173						÷	1.2.2 Mesalamine Rohatgi 2015 Subtotal (95% CI) Heterogeneity: Not ap	-104.3			
B Rate Ratio Rate Ratio Study or Subgroup Iog Part Ratio SE Weight M, Random, 95% CI M, Random, 95% CI 1.1.1 Budesonide SE Weight M, Random, 95% CI M, Random, 95% CI SE Weight M, Random, 95% CI 1.1.1 Budesonide 0.8 0.079269 1.3 (budesonide SE Weight M, Random, 95% CI 1.3 (budesonide Wagner 2014 0.8 0.079269 1.3 (budesonide SE Weight M, Random, 95% CI 1.3 (budesonide Wagner 2010 0.845 0.34439 1.75% 2.23 (1.32, 2.49) 1.45% Wagner 2010 0.990 0.087257 1.46% (2.00, 2.49) 1.45% 5.257 (2.45) Wagner 2010 0.992 0.053316 0.05% (2.5) (2.32, 2.31) 1.45% 1.75 (2.466.017) 1.45% (2.57, 2.45) Weight M, Charleson JB 0.05% (2.57, 2.36, 2.31) 1.31 (budesonide 1.600.017 (2.45% (2.53, 2.31) 1.45% (2.53, 2.32) Weight M, Charleson JB 0.05% (2.57, 2.36, 2.31) 1.31 (budesonide 1.600.017 (2.45% (2.53, 2.33) 1.76 (2.54% (2.54, 2.53, 2.33) 1.76 (2.54, 2.53, 2.35) 1.76 (2.54, 2.53, 2.55) Weight M, Chandon JB 0.05% (2.56, 2.36, 2.36, 2.36, 2.36, 2.	Heterogeneity: Tau ² = Test for overall effect Test for subgroup diffe	Z = 22.54 (P < 0.0	00001)	0.08); I ^z =	- 53% -	0.5	0.7	1.5	◆ 2	Total (95% CI) Heterogeneity: Tau ² = Test for overall effect:	: 18210.69; Chi ² = 8 Z = 3.56 (P = 0.000	4)	P = 0.03);	l²= 65%
toogspard 2019 0.6 0.109694 10.2% 13.2 [1.47, 2.66] Methike 2019 0.8 0.07296 13.8% 2.211.93, 2.57] Methike 2019 0.789 0.093622 11.3% 2.2011.93, 2.57] Minch 2014 0.8 0.07295 13.8% 2.211.93, 2.57] Wagner 2010 0.909 0.060739 12.4% 2.48[2.08, 2.49] Wagner 2010 0.902 0.05311 0.0% 2.50[2.14, 2.93] Subtotal (95% C) 76.7% 2.29[2.14, 2.45] 4.45 5.55[5.3, 37] Feator overail effect Z = 24.11 ($P = 0.000$). ($P = 0.23$). ($P = 20\%$ 2.00 [2.47, 1.53] 5.00 [2.42, 2.93] Methike 2002 -3.50 4.348469 3.7% 4.50 5.55 5.50 5.50 55 55 55 55 55 55 55 56 57.5 57.5 55 55 55 56 57.5 57.5 55 55 56 57.6 7.7 5.2.20 2.47.1.53 53 56 56 67.6 7.9.20 7.3 1.9.3.2.3.245 55 55 55 55 56 56	Study or Subgroup	log[Rate Ratio]	SE	Weight						В				Mean Difference
Test for overall effect Z = 14.64 (P < 0.00001) Test for subaroup differences: Ch ^{ar} = 8.63, df = 1 (P = 0.003), P = 88.4% Test for subaroup differences: Ch ^{ar} = 8.63, df = 1 (P = 0.003), P = 88.4%	krogspard 2019 Miehike 2014 Miehike 2014 Minch 2014 Wagner 2010 Wagner 2010 Wagner 2010 Subtotal (95% CD) Heterogeneity: Tau" = Test for overall effect 2 Test for overall effect 2	0.8 0.789 0.845 0.909 0.917 0.962 0.00; Chi [#] = 6.93, z = 24.11 (P < 0.0 0.44 0.632 0.01; Chi [#] = 1.67,	0.072959 0.093622 0.034439 0.086735 0.079847 0.053316 df=5 (P=0 00001) 0.09949 0.110459 df=1 (P=0 0001)	13.8% 11.7% 17.5% 12.4% 13.1% 0.0% 78.7% 0.23); I ^P = 11.2% 10.2% 21.3% 0.20); I ^P =	2.23 [1:93, 2.57] 2.20 [1:83, 2.64] 2.33 [2:16, 2.49] 2.48 [2:00, 2:94] 2.62 [2:30, 2:94] 2.62 [2:30, 2:91] 2.29 [2:30, 2:91] 2.29 [2:14, 2.45] 2.69 [1:92, 2:34] 1.65 [1:20, 1.69] 1.68 [1:52, 2:34] 1.70 [1.41, 2.05] 40%			+	•	1.3.1 Burdesonide Bajor 2008 Bonderup 2008 Bonderup 2008 Mehike 2009 Miehike 2009 Munch 2009 Subtotal (95% C) Heterogeneilty Tau Test for overail effec 1.3.2 Mesalamine Rohagi 2015 Subtotal (95% C) Heterogeneilty. Not Test for overail effec	-2.6 -3.5 -4.4 -3.1 -3.16 - - = 0.73; Chi ^a = 37.6; t: Z = 8.43 (P < 0.00 -0) -0)	2 0.38979 7 0.48061 5 0.35816 5 0.44846 7 0.24540 2 0.24132 2, df=5 (P - 1001) 6 0.53265	6 14.3% 2 13.4% 3 14.6% 9 13.7% 8 15.5% 7 15.5% 87.1% < 0.00001, 3 12.9% 12.9%	 6 -2.62 [-3.38, -1.86] 6 -3.57 [-4.51, -2.63] 6 -4.45 [5.15, -3.76] 7.50 [-4.38, -2.62] 6 -3.71 [-3.65, -2.66] 7.20 [-2.47, -1.53] 6 -3.59 [-3.33, -2.45] 7.8 [-3.39, -2.45] 7.8 [-3.93, -2.45] 6 -0.60 [-1.64, 0.44] 6 -0.60 [-1.64, 0.44]
	Test for overall effect 2	Z = 14.64 (P < 0.0)	00001)			0.5	0.7 1	1.5	2	Heterogeneity: Tau ^a Test for overall effect	t: Z = 6.96 (P < 0.00	001)	< 0.00001); I ² = 89%
	(Figure B) Clinical Remission							Figur	e C: S	Sto	ol	weight		

(Figure A) Adverse Events

