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Title

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Role of obesity in a randomized placebo-controlled, double-blind trial of difluoromethylornithine plus sulindac for the prevention of sporadic colorectal adenomas.

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Abstract

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Background: Chemoprevention with difluoromethylornithine (DFMO) plus sulindac markedly reduces risk of recurrence in colorectal adenoma (CRA) patients. Obesity is associated with risk of CRA and colorectal cancer (CRC). This study investigates how obesity influences CRA characteristics at baseline and risk of recurrence after treatment with DFMO plus sulindac vs. placebo.

Methods: Our analysis included subjects enrolled in a phase III CRA prevention clinical trial investigating DFMO plus sulindac vs. placebo. Patients were classified by obesity (BMI > 30 kg/m²) status at baseline. Pearson's χ^2 statistic or Fisher's exact test and Mann-Whitney U test were used to compare baseline characteristics with regard to obesity status. Log-binomial regression analysis was used to determine the relative risk of metachronous adenoma, adenoma with advanced histology, or multiple adenomas, adjusted for covariates.

Results: At baseline, obesity was associated with increased adenoma number (p = 0.017), size (p = 0.003), advanced histology (p = 0.042), high-risk adenomas (p = 0.0002), and distal adenomas (p = 0.038). Obesity did not modify adenoma recurrence after treatment with DFMO plus sulindac or placebo (p = 0.80).

Conclusions: Our results provide supporting evidence for the association of obesity with high-risk adenoma features at baseline; however, obesity does not substantially modify CRA risk reduction after treatment with DFMO plus sulindac vs. placebo.

Clinicopathologic characteristics at baseline

	All (n=375)	BMI < 30 (n=251)	BMI > 30 (n=124)	P
Number of adenomas				0.017
Mean (95% CI)	2.5 (1-7)	2.3 (1-6)	2.8 (1-8)	
Median	2.0	2.0	2.0	
Adenoma size				0.003
<10 mm	250 (66.7%)	180 (71.7%)	70 (56.5%)	
>10 mm	125 (33.3%)	71 (28.3%)	54 (43.5%)	
Multiple adenomas				0.01
< 3	251 (67.5%)	179 (71.9%)	72 (58.5%)	
≥ 3	121 (32.5%)	70 (28.1%)	51 (41.5%)	
Advanced adenoma histology				0.042
Yes	69 (18.4%)	39 (15.5%)	30 (24.2%)	
No	306 (81.6%)	212 (84.5%)	94 (75.8%)	
Location				0.038
Proximal	136 (36.4%)	100 (40.0%)	36 (29.0%)	
Distal	238 (63.6%)	150 (60.0%)	88 (70.0%)	
High-risk adenomas				0.0002
Yes	212 (56.5%)	125 (49.8%)	87 (70.2%)	
No	163 (43.5%)	126 (50.2%)	37 (29.8%)	

Author Disclosure

Employment or Leadership Position	Consultant or Advisory Role	Stock Ownership	Honoraria	Research Funding	Expert Testimony	Other Remuneration
		Cancer Prevention Pharmaceuticals				