



Crohn's Disease Decision Aid Leads to More Patients Choosing Combination Therapy in a Cluster Randomized Controlled Trial

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Disclosure of Conflicts of Interest:

Entity	Grant	Personal Fees	Role
Abbvie	X	X	Grant support, Speaker for CME activities, Consultant
Sebela		X	Consultant
Takeda	X	X	Grant support, Speaker for CME activities, Consultant
Celgene		X	Consultant
Salix		X	Consultant
Amgen		X	Consultant
Lilly		X	Consultant
Pfizer	X	X	Grant support, Consultant
Prometheus		X	Consultant
Theradiag	X	X	Grant support, Consultant
Bristol-Meyers Squibb		X	Consultant
Crohn's & Colitis Found	X		Grant support
Patent pending			System and method of communicating predicted medical outcomes
Patent issued			Methods and compositions for bowel cleansing before a medical procedure

Background and Aim

- Early intensive therapy with the combination of a biologic agent and an immunomodulator (IM) yields the highest chance of achieving steroid free remission in patients with Crohn's disease.
- However, this approach is used infrequently, likely related to patient and provider concerns about adverse events, and the inability to stratify patients with low versus high risk of developing complications of their disease.
- A decision aid including an online program reviewing benefits and risks of treatment options combined with a personalized risk prediction tool (PROSPECT) for Crohn's disease was developed.
- **The aim of this study was to determine the influence of this decision aid on the proportion of patients choosing combination therapy for treatment of their Crohn's disease.**

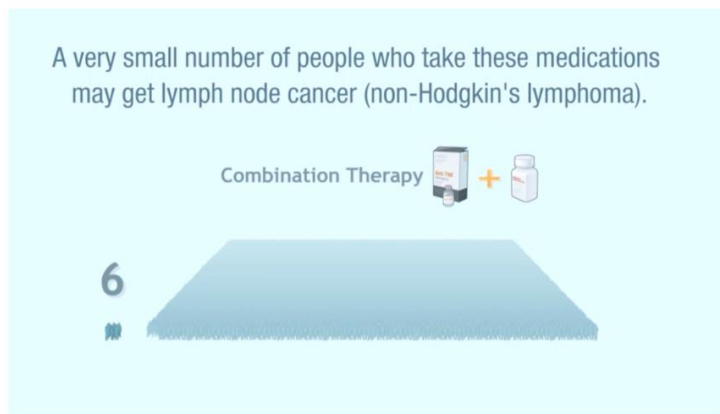


Methods

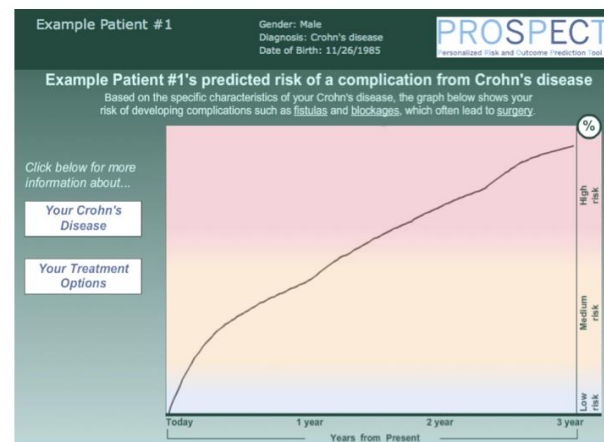
- Patients with Crohn's disease were prospectively recruited from 16 GI practices across the US (8 academic, 8 community based).
- Patients had to be within 15 years of diagnosis, without any current or prior disease complications, not currently on IMs or biologics but considered a candidate for these treatments by their provider.
- Cluster randomized trial with 8 practices in the intervention arm (received Decision Aid) and 8 practices in the control arm (standard of care).

Decision Aid and Patient Characteristics

Web-Based Crohn's Decision Aid



Individual Risk Prediction Tool

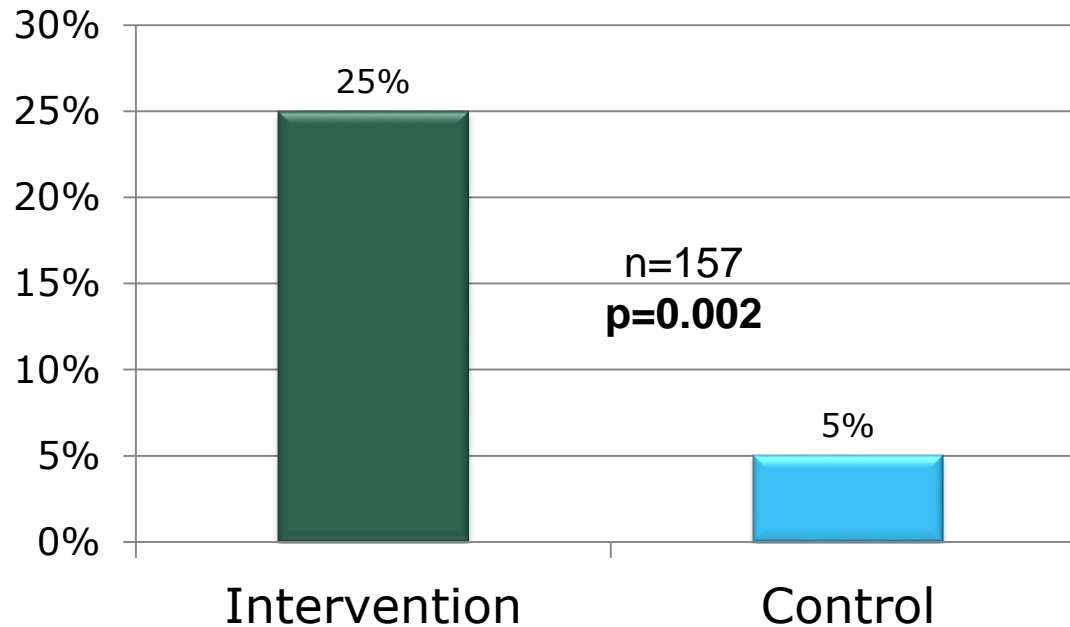


Patient Characteristics

	Intervention (N=133)	Control (N=69)
% Female	51.9%	65.2%
Median age in yrs (range)	32 (18-69)	31(18-69)
Median time since Diagnosis, yrs (range)	1.38 (0.02-15.07)	2.31 (0-14.25)
Disease Location		
Small bowel only	35%	46%
Small bowel + colon	29%	34%
Colonic only	36%	20%

Results

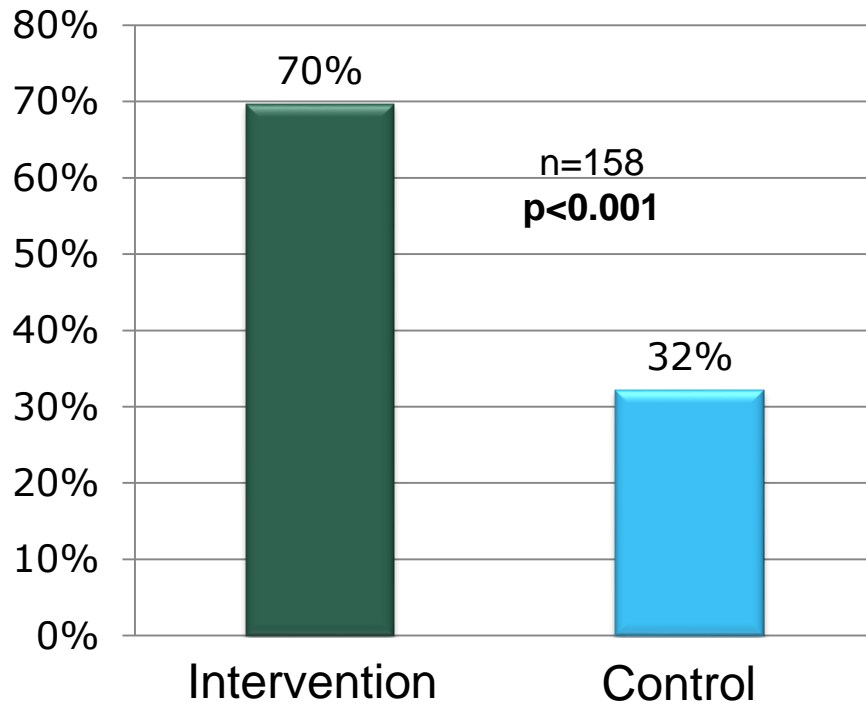
Selecting Combination Therapy (Primary Outcome)



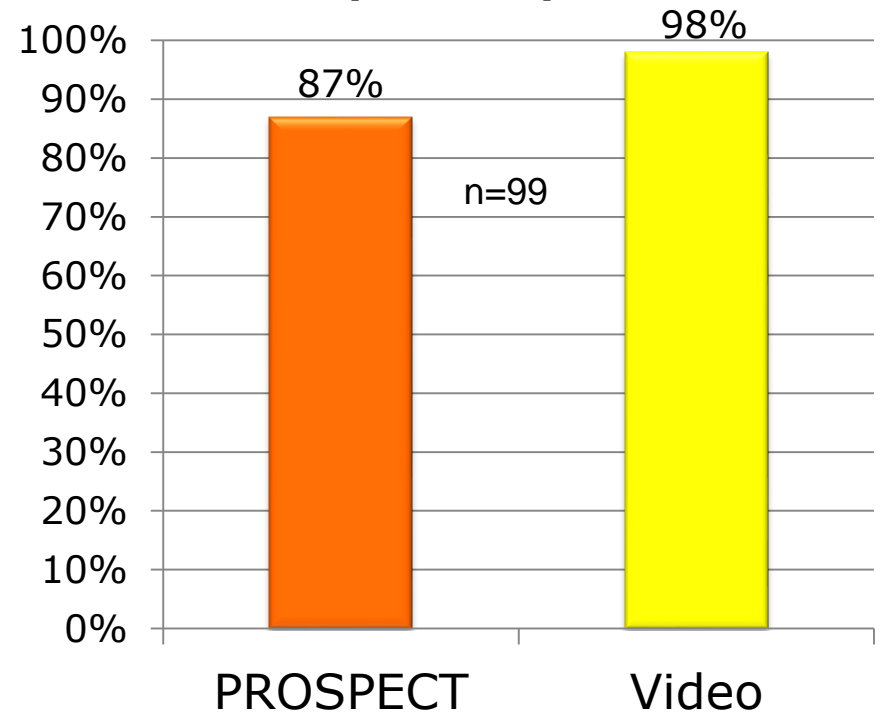
- Choosing **NO** therapy: 1% in intervention vs 17.5% control ($p < 0.001$)
- **Decisional conflict** lower in intervention group vs control group ($p = 0.04$)

Secondary Outcomes

Is the planned treatment what you want? (% "Yes")

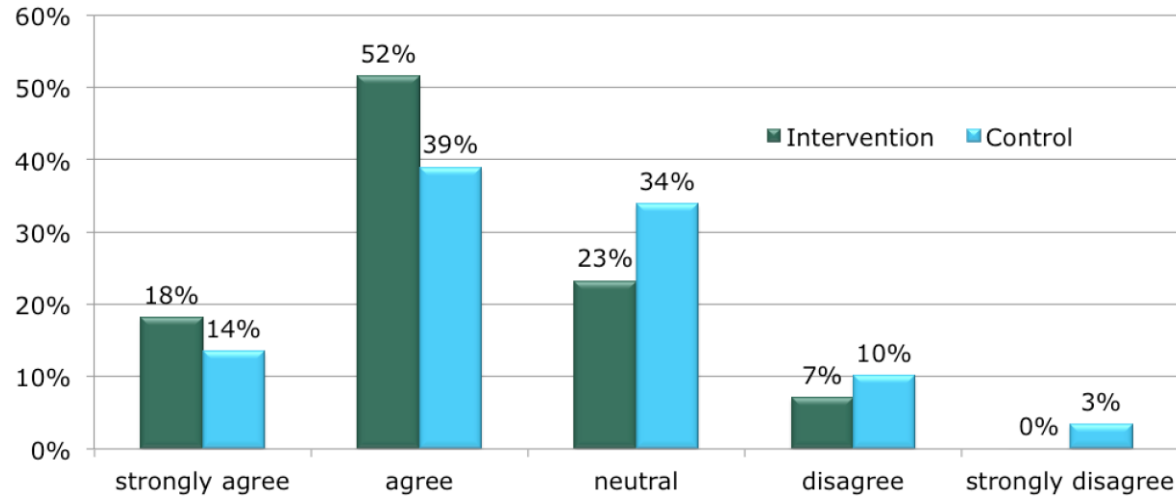


Increase Disease Understanding (% "Yes")



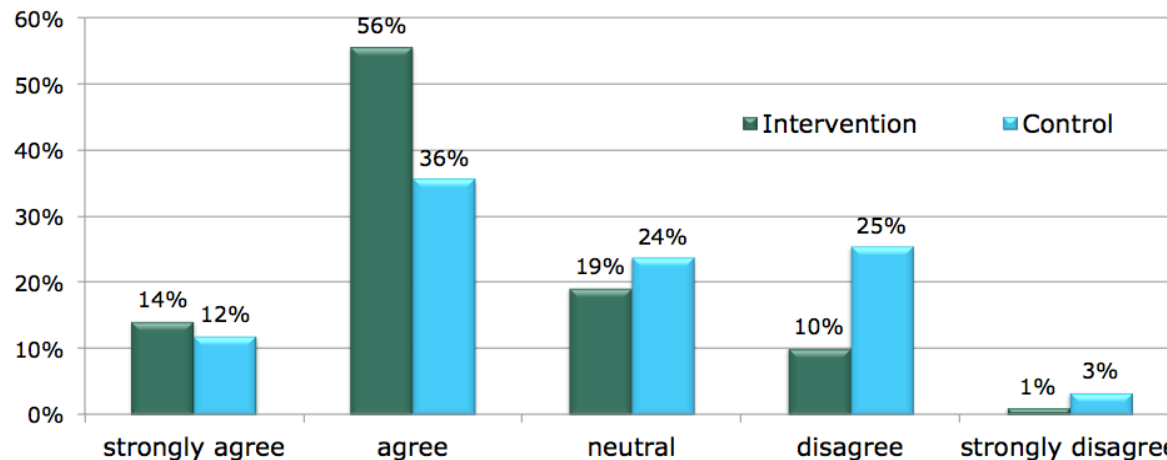
Secondary Outcomes (Trust in Physician)

Your doctor is extremely thorough and careful



n=158
p=0.04*

You completely trust your doctor's decisions about which medical treatments are best for you



n=158
p=0.007*

*for strongly agree + agree

Conclusion

- The Crohn's disease decision aid consisting of the online program and PROSPECT tool led to a significantly higher proportion of patients selecting combination therapy.
- In addition, the decision aid led to:
 - Fewer patients on NO medical therapy
 - Lower decisional conflict amongst participants
 - Increased proportion of those who received the treatment that they wanted
 - Increased understanding of their disease
 - Increased trust in their physicians



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