Cost-Consequence Analysis of Oral Nutritional Supplementation in Community-Managed Patients with Inflammatory Bowel Disease in Italy

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BACKGROUND

In Italy, approximately 250,000 people are affected by Inflammatory Bowel Disease (IBD) (1). Evidence from the literature indicates that the prevalence of malnutrition in this population ranges from 13% (32,500 patients)(2) to 26% (65,000 patients) (3). Although malnutrition is associated with worse clinical outcomes and increased healthcare costs, global data on its economic impact in IBD remain limited, and no such data are currently available for Italy. Moreover, nutritional screening and the use of oral clinical nutrition are not systematically included in the patient care pathway in Italy, leading to limited recognition of the value of clinical nutrition as a preventive strategy.

OBJECTIVES

- To assess the clinical and economic burden of malnutrition among hospitalized patients with IBD in Italy.
- To evaluate costs and outcomes associated with Oral Nutritional Supplementation (ONS) in patients with IBD in Italy.

METHODS

Initially, a retrospective analysis was conducted on a national administrative database to evaluate costs and outcomes associated with hospitalized IBD patients, both malnourished and not malnourished. Thereafter, a cost-consequence analysis was performed to evaluate costs and outcomes associated with ONS for IBD patients with moderate-to-severe malnutrition administrated in the community setting.

Retrospective analysis

- The outcomes and costs associated with malnourished and non-malnourished hospitalized patients with IBD were obtained through a retrospective analysis conducted using data from the Italian National Hospital Discharge Database (SDO).
- The analysis included patients with a first hospitalization for Inflammatory Bowel Disease (Crohn's disease or ulcerative colitis) between 2015 and 2019.
- Malnutrition was identified through specific ICD-9-CM codes (262, 263.0, 263.1, 263.8, 26.3.9).
- Patients were followed for 1 year to assess clinical outcomes (in-hospital mortality, length of stay, readmissions) and costs based on national DRG tariffs.
- Comparisons between patients with and without malnutrition were performed using 1:1 matching for age, sex, region and Charlson Comorbidity Index. After matching, 3,682 patients were included.

Table 1 – ICD-9-CM Codes Used to Identify the Study Population

Group	ICD-9-CM	Description
Crohn's disease	555.0	Enteritis of the small intestine
	555.1	Enteritis of the large intestine
	555.2	Enteritis of the small and large intestine
	555.9	Enteritis, site unspecified
Ulcerative colitis	556.0	Ulcerative enterocolitis (chronic)
	556.1	Ulcerative ileocolitis (chronic)
	556.2	Ulcerative proctitis (chronic)
	556.3	Ulcerative proctosigmoiditis (chronic)
	556.5	Ulcerative colitis localized to the colon
	556.6	Ulcerative pancolitis
	556.8	Other ulcerative colitis
	556.9	Ulcerative colitis, unspecified

Cost-consequence analysis

- The eligible population for ONS consisted of prevalent IBD patients with moderate-to-severe malnutrition at the national level (Table 2).
- The analysis compared two scenarios: 1) eligible patients do not receive ONS; 2) 30% of eligible patients are treated with ONS in the community setting.
- The analysis was conducted considering a National Health Service (NHS) perspective and a 1-year time horizon.
- The effect of ONS in IBD patients with moderate-to-severe malnutrition was based on the probability of hospitalization for IBD and the probability among hospitalized patients to have a malnutrition status.
- In the absence of data from the literature, the probabilities for IBD patients with moderate-to-severe malnutrition, treated or not treated with ONS, were derived from a national-level survey conducted with six clinical experts (Table 2).
- Hospitalization costs stratified by malnutrition status obtained through the retrospective analysis conducted on Italian National Hospital Discharge Database were used.
- Costs of ONS were estimated considering a monthly cost per patient equal to € 230 (4) and a duration of treatment equal to six month.

Table 2 – Eligible population for ONS and efficacy data

Epidemiology data	Estimate (%)	Estimate (n)	Source
Prevalent IBD patients	-	250,000	(1)
Prevalent IBD patients with moderate-to-severe malnutrition	21	52,500	(5)
Efficacy data	**No ONS**	**ONS**	**Source**
Hospitalized patients (%)	60	40	Clinical experts
Hospitalized patients with malnutrition status (%)	100	37	Clinical experts

RESULTS

Between 2015 and 2018, 64,307 patients were hospitalized with an IBD diagnosis, of whom 3.1% (1,951) had a diagnosis of malnutrition. Among hospitalized patients with IBD, malnutrition appears to be associated with an increase in in-hospital mortality, length of stay, and annual readmissions. Furthermore, the estimated costs for hospitalized malnourished patients with IBD are higher than those for non-malnourished patients.
Outcomes and costs stratified by malnutrition status are reported in table 3.

Table 3 –Outcomes and Costs Stratified by Malnutrition Status

Outcome	Malnourished patients	Not malnourished patients	Delta	
In-hospital mortality rate	6.3%	4.5%	+ 1.8%	
Hospital stays (days)	30	16	+ 14	
Annual readmissions	1.26	0.71	+ 0.55	
Type of Hospitalization	**Malnourished patients**	**Not malnourished patients**	**Delta**	
			value	**% increase**
First hospitalization cost per patient with IBD	€ 5,097	€ 3,847	€ 1,250	+32.5%
Cost of readmissions for patients with IBD (Inpatient)	€ 5,567	€ 2,519	€ 3,048	+121.0%
Cost of readmissions for patients with IBD (Day Hospital)	€ 193	€ 151	€ 42	+27.8%
Total cost per patient with IBD	**€ 10,857**	**€ 6,517**	**€ 4,340**	**+66.6%**

The cost-consequence analysis conducted using costs estimated from the retrospective analysis showed that the treating 30% of IBD patients with moderate-to-severe malnutrition with ONS in the community setting (15,750 patients) could generate a reduction of about 10% of hospitalized patients with IBD (28,350 vs 31,500 patients) and a reduction of about 12.6% of patients with malnutrition status among those hospitalized (27,531 vs 31,500 respectively) (Table 4).
As a result, treatment with ONS could be associated with a saving for the NHS perspective of about € 29.7 million (Table 4).

Table 4 – Cost-consequence analysis results

Outcomes	No ONS	ONS	Delta	
			Value	% decrease
Hospitalized patients	31,500	28,350	-3,150	(-10.0%)
Hospitalized patients with malnourished status		27,531	-3,969	(-12.6%)
Costs	**No ONS**	**ONS**	**Delta**	
			Value	**% decrease**
ONS cost	0 €	€ 21,735,000	€ 21,735,000	
First hospitalization cost	€ 160,555,500	€ 139,538,700	-€ 21,016,800	(-13.1%)
Cost of readmissions for patients with IBD	€ 175,360,500	€ 145,726,938	-€ 29,633,562	(-16.9%)
Cost of readmissions for patients with IBD (Day Hospital)	€ 6,079,500	€ 5,304,852	-€ 774,648	(-12.7%)
Total cost for IBD patients hospitalized	**€ 341,995,500**	**€ 312,305,490**	**-€ 29,690,010**	**(-8.7%)**

CONCLUSIONS

- This study provides the **first Italian evidence on the economic impact of malnutrition in patients with IBD**, showing its additional **burden** on the NHS.
- The study highlights critical **issues related to the diagnosis of malnutrition**: the prevalence of IBD-related malnutrition reported in hospital discharge records is markedly lower than what is documented in the literature (**3.1% of patients vs. 13%–26%**), suggesting **underdiagnosis or undercoding**. This is likely due to the absence of a more complex DRG and higher reimbursement associated with malnutrition. Consequently, **the actual incidence of malnutrition is likely underestimated.**
- **Cost-consequence analysis** show that implementing **targeted clinical nutrition interventions** within the care pathway of patients with IBD **could optimize healthcare use in Italy and could generate a reduction in costs incurred by NHS.**
- Based on these figures, a **new potential investment in medical nutrition** among IBD patients could lead to improved clinical outcomes and reductions in hospitalization costs.

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