



The elemental diet

Clinical applications

Rating scales for evidence-based decision support

Not all evidence is equal and practitioners should know exactly what kind of evidence is being referenced with regard to specific ingredients or treatment methods.

The rating scale below was established to clearly prioritize meta-analyses and systematic reviews of human trials, followed by randomized, double-blind placebo-controlled (RDBPC) human trials, which collectively represent the first three tiers. Thereafter, non-RDBPC human trials, animal trials, and theoretical research are ranked in succession, respectively.

Class	Qualifying studies	Minimum requirements
A	Systematic review or meta-analysis of human trials	
B	Human RDBPC	≥ 2 studies and/or 1 study with ≥ 50
C	Human RDBPC or RCT	1 study < 50 subjects
D	Human trials or In-vivo animal trials	
E	In-vitro studies	
F	Theoretical based on biochemistry/ physiology/pharmacokinetics	

RDBPC = Randomized Double-Blind Placebo-Controlled

RCT = Randomized Controlled Trials



Clinical applications of the elemental diet

Research has demonstrated the beneficial effects of the elemental diet in treating various gastrointestinal conditions, as well as improving postoperative clinical outcomes, cancer treatment-related side effects, and other conditions. Incorporating the rating scale outlined on the previous page, the following guide provides a summary of the results of clinical trials examining the effects and possible clinical applications of the elemental diet.

Gastrointestinal conditions

Condition	Research findings	Class of evidence
Crohn's disease	Effective in the long-term management of Crohn's disease when taken in conjunction with a normal diet (e.g., 50% elemental formula, 50% normal diet); ^{10, 42, 48, 50} reverses growth arrest in pediatric Crohn's disease patients prior to puberty ²	A
	↓ disease activity; ↑ nutritional status ^{25, 54}	C
	Effective in inducing remission of active Crohn's disease; ^{4, 10, 45, 54} comparatively lower remission rate in patients with certain complications (e.g., stenotic bowel lesions, abdominal masses, fistulas, anal lesions) ⁴	C
	As effective in inducing disease remission as 6-mercaptopurine ⁸	C
	As effective or more effective in inducing remission as polymeric formulas ^{5, 7, 16, 49}	C
	↓ disease activity comparable to or more than steroid medication (e.g., prednisolone); ^{6, 26, 29, 30, 32, 34, 39, 46, 54} ↓ prednisone requirements; ² suppressed steroid dependence in pediatric patients ²⁶	C
Chronic pouchitis	↓ median stool frequency; ↓ Pouch Disease Activity Index (PDAI) scores; ↑ concentration of <i>Clostridium coccoides</i> – <i>Eubacterium rectale</i> in patients with active pouchitis ²⁰	D

Gastrointestinal conditions cont.

Condition	Research findings	Class of evidence
Eosinophilic oesophagitis	↓ symptoms and eosinophilic inflammation; induction of clinical remission ⁵¹	D
	↓ esophageal tissue eosinophil content, mast cell content, parabasal layer thickness, and endoscopic furrows and exudates after four weeks; no change in symptoms and endoscopic fixed strictures ³⁵	D
	Improvements in vomiting, abdominal pain, and dysphagia; ↓ median number of esophageal eosinophils per high-powered field (HPF) ¹⁷	D
Intractable diarrhea	Faster resolution of malabsorption and diarrhea; ↓ complications; ↓ cost of hospitalization compared to total parenteral nutrition (TPN) in infants; similar correction of malnutrition ³³	C
Persistent diarrhoea-malnutrition syndrome (PDM)	↑ weight gain despite lower calorie intake; ↑ haemoglobin concentration; similar improvements in diarrhea frequency, global recovery score, and mortality rates compared to standard nutritional rehabilitation ¹	C
Small intestinal bacterial overgrowth (SIBO)	Normalization of lactulose breath tests (LBT): 80% by day 15, 85% by day 21; ↓ bowel symptoms in IBS patients with abnormal LBT ³⁶	D
Type 1 refractory celiac disease (RCD)	Histological improvement; ↓ epithelial IL-15, IFN-secreting mucosal T cells, and IFN-messenger RNA levels ³¹	D



Postoperative and perioperative applications

Condition	Research findings	Class of evidence
Celiotomy	↓ septic complications compared to control group ²¹	C
Cesarean section	Earlier return to normal bowel sounds and a regular diet compared to routine postoperative dietary management ⁵²	C
Cholecystectomy	↑ serum BCAAs and glucose levels; may improve postoperative GI function, wound healing, and sepsis resistance ²⁴	D
Crohn's disease resection	↓ clinical and endoscopic recurrence after resection for Crohn's disease ⁵³	C
Gastrectomy	↑ nutritional status; ↓ weight loss and reduction in BMI; ↓ hospital stays; ↓ postoperative and systemic complications in elderly patients (≥80 years) compared to control group ²⁸	C
	↓ weight loss in gastric cancer patients ¹³	C
Gastrointestinal operations	↑ energy intake; ↓ weight loss and hospital stays; less pronounced negative nitrogen balance compared to control group ³⁸	C
Gynecologic cancer-related operations	↑ calorie intake; improvement in serum transferrin levels and postoperative nutrition compared to control group ⁴¹	C
Hematopoietic stem cell transplantation (HSCT)	↓ frequency of oral mucositis; ↓ median hospitalization period ²³	C
Laparoscopic colectomy	↓ hospital stays; earlier resumption of sufficient oral food intake and defecation compared to control group ⁴⁰	C
Pancreatectomy	↑ pancreatic exocrine secretion with elemental formula (EF) and polymeric immune-enhancing formula (PIEF) compared to baseline and control group; no significant difference in pancreatic exocrine secretion between EF and PIEF ³	C
Pancreato-duodenectomy	↑ lymphocyte counts and ↓ neutrophil-to-lymphocyte-ratio (NLR) compared to control group; prevention of complications and readmission ²²	C

Cancer treatment side effects

Side effect	Research findings	Class of evidence
Chemoradiotherapy-induced oral mucositis	↓ incidence of oral mucositis ^{9,14,44,47}	C
	↑ rate of completion of chemoradiation compared to a control group ⁹	C
	↑ preventative effect against oral mucositis when administered with glutamine compared to glutamine alone and a control group ⁴³	C
Chemoradiotherapy-induced sarcopenia	↑ lean body mass compared to azulene oral rinse control group in esophageal cancer patients ¹⁴	C
Chemoradiotherapy-induced stomatitis	↓ severity in colorectal cancer patients ²⁷	D
Radiation injury	Prophylactic effect against acute phase of radiation injury when administered before, during, and after radiotherapy for invasive bladder cancer; earlier return to positive nitrogen balance and bowel sounds; normal morphologic findings and levels of enzyme activity in the brush border (ileal mucosa); absence of severe or bloody diarrhea ¹⁹	D



Other conditions

Condition	Research findings	Class of evidence
Aspiration pneumonia	↑ gastric emptying; ↓ episodes of aspiration compared to standard liquid diets in bedridden percutaneous endoscopic gastrostomy (PEG) patients ¹²	C
Liver failure	↑ nutritional state; ↓ clinical symptoms when consumed with an energy- and protein-restricted liver diet ¹⁸	D
Perennial asthma	Improvement in asthma compared to a control group ¹¹	C
Rheumatoid arthritis	Improvement in certain clinical parameters (e.g., grip strength, Ritchie articular index, early morning stiffness (EMS), etc.); ^{15,37} comparable to prednisolone treatment ³⁷	C

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