



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 ⁶	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 coccooides</i> – <i>Eubacterium</i> rectale in patients with active pouchitis ²⁰	D
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

Gastrointestinal conditions cont.

Condition	Research findings	Class of evidence
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
Cholecystec-tomy	↑ 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

Postoperative and perioperative applications cont.

Condition	Research findings	Class of evidence
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 ¹⁶	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

References

1. Amadi, B. (2005). Improved nutritional recovery on an elemental diet in Zambian children with persistent diarrhoea and malnutrition. *Journal of Tropical Pediatrics*, 51(1), 5–10.
2. Belli, D. C., Seidman, E., Bouthillier, L., Weber, A. M., Roy, C. C., Pletinckx, M., ... Morin, C. L. (1988). Chronic intermittent elemental diet improves growth failure in children with Crohn's disease. *Gastroenterology*, 94(3), 603–610.
3. Duerksen, D.R., Bector, S., Parry, D., Yaffe, C., Vajcner, A., & Lipschitz, J. (2002). A comparison of the effect of elemental and immune-enhancing polymeric jejunal feeding on exocrine pancreatic function. *Journal of Parenteral and Enteral Nutrition*, 26(3), 205–8.
4. Fukuda, Y., Kosaka, T., Okui, M., Hirakawa, H., & Shimoyama, T. (1995). Efficacy of nutritional therapy for active Crohn's disease. *Journal of Gastroenterology*, 30 Suppl(8), 83–7.
5. Gjaffer, M. H., North, G., & Holdsworth, C. D. (1990). Controlled trial of polymeric versus elemental diet in treatment of active Crohn's disease. *The Lancet*, 335(8693), 816–819.
6. Gorard, D. A., Hunt, J. B., Payne-James, J. J., Palmer, K. R., Rees, R. G., Clark, M. L., ... Silk, D. B. (1993). Initial response and subsequent course of Crohn's disease treated with elemental diet or prednisolone. *Gut*, 34(9), 1198–1202.
7. Grogan, J. L., Casson, D. H., Terry, A., Burdge, G. C., El-Matary, W., & Dalzell, M. A. (2012). Enteral feeding therapy for newly diagnosed pediatric Crohn's disease: A double-blind randomized controlled trial with two years follow-up. *Inflammatory Bowel Diseases*, 18(2), 246–253.
8. Hanai, H., Iida, T., Takeuchi, K., Arai, H., Arai, O., Abe, J., ... Watanabe, F. (2012). Nutritional therapy versus 6-mercaptopurine as maintenance therapy in patients with Crohn's disease. *Digestive and Liver Disease*, 44(8), 649–654.
9. Harada, K., Minami, H., Ferdous, T., Kato, Y., Umeda, H., Horinaga, D., ... Mishima, K. (2018). The Elental® elemental diet for chemoradiotherapy-induced oral mucositis: A prospective study in patients with oral squamous cell carcinoma. *Molecular and Clinical Oncology*, 10(1), 159–167.
10. Hirakawa, H., Fukuda, Y., Tanida, N., Hosomi, M., & Shimoyama, T. (1993). Home elemental enterai hyperalimentation (HEEH) for the maintenance of remission in patients with Crohn's disease. *Gastroenterologia Japonica*, 28(3), 379–384.
11. Høj, L., Osterballe, O., Bundgaard, A., Weeke, B., & Weiss, M. (1981). A double-blind controlled trial of elemental diet in severe, perennial asthma. *Allergy*, 36(4), 257–62.
12. Horiuchi, A., Nakayama, Y., Sakai, R., Suzuki, M., Kajiyama, M., & Tanaka, N. (2013). Elemental diets may reduce the risk of aspiration pneumonia in bedridden gastrostomy-fed patients. *The American Journal of Gastroenterology*, 108(5), 804–10.
13. Imamura, H., Nishikawa, K., Kishi, K., Inoue, K., Matsuyama, J., Akamaru, Y., ... Shimokawa, T. (2016). Effects of an oral elemental nutritional supplement on post-gastrectomy body weight loss in gastric cancer patients: A randomized controlled clinical trial. *Annals of Surgical Oncology*, 23(9), 2928–2935.
14. Ishikawa, T., Yasuda, T., Doi, T., Okayama, T., Sakamoto, N., Gen, Y., ... Itoh, Y. (2016). The amino acid-rich elemental diet Elental® preserves lean body mass during chemo- or chemoradiotherapy for esophageal cancer. *Oncology Reports*, 36(2), 1093–100.
15. Kavanaghi, R., Workman, E., Nash, P., Smith, M., Hazleman, B.L., & Hunter, J.O. (1995). The effects of elemental diet and subsequent food reintroduction on rheumatoid arthritis. *British Journal of Rheumatology*, 34(3), 270–3.

16. Kobayashi, K., Katsumata, T., Yokoyama, K., Takahashi, H., Igarashi, M., & Saigenji, K. (1998). A randomized controlled study of total parenteral nutrition and enteral nutrition by elemental and polymeric diet as primary therapy in active phase of Crohn's disease. *Nihon Shokakibyo Gakkai Zasshi*, 95(11), 1212–21.
17. Markowitz, J. E., Spergel, J. M., Ruchelli, E., & Liacouras, C. A. (2003). Elemental diet is an effective treatment for eosinophilic esophagitis in children and adolescents. *The American Journal of Gastroenterology*, 98(4), 777–782.
18. Matsuoka, S., Tamura, A., Nakagawara, H., & Moriyama, M. (2014). Improvement in the nutritional status and clinical conditions of patients with liver failure using a liver diet combined with a branched chain amino acids-enriched elemental diet. *Hepatogastroenterology*, 61(133), 1308–12.
19. McArdle, A.H., Reid, E.C., Laplante, M.P., & Freeman, C.R. (1986). Prophylaxis against radiation injury. The use of elemental diet prior to and during radiotherapy for invasive bladder cancer and in early postoperative feeding following radical cystectomy and ileal conduit. *Archives of Surgery*, 121(8), 879–85.
20. McLaughlin, S. D., Culin, A., Cole, J., Clark, S. K., Tekkis, P. P., Ciclitira, P. J., ... Whelan, K. (2013). Exclusive elemental diet impacts on the gastrointestinal microbiota and improves symptoms in patients with chronic pouchitis. *Journal of Crohn's and Colitis*, 7(6), 460–466.
21. Moore, E.E., & Jones, T.N. (1986). Benefits of immediate jejunostomy feeding after major abdominal trauma: A prospective, randomized study. *The Journal of Trauma: Injury, Infection, and Critical Care*, 26(10), 874–881.
22. Mori, R., Matsuyama, R., Taniguchi, K., Goto, K., Miyake, K., Hiratani, S., ... Endo, I. (2019). Efficacy of prolonged elemental diet therapy after pancreaticoduodenectomy for pancreatic ductal adenocarcinoma: A pilot prospective randomized trial. *Clinical Nutrition ESPEN*, 34, 116–124.
23. Morishita, T., Tsushita, N., Imai, K., Sakai, T., Miyao, K., Sakemura, R., ... Sawa, M. (2016). The efficacy of an oral elemental diet in patients undergoing hematopoietic stem cell transplantation. *Internal Medicine*, 55(24), 3561–3569.
24. Moss, G., & Naylor, E. D. (1994). Postoperative enteral hyperalimentation results in earlier elevation of serum branched-chain amino acid levels. *The American Journal of Surgery*, 168(1), 33–35.
25. Nakano, M., Tominaga, K., Hoshino, A., Sugaya, T., Kanke, K., & Hiraishi, H. (2017). Therapeutic efficacy of an elemental diet for patients with crohn's disease and its association with amino acid metabolism. *Saudi Journal of Gastroenterology*, 23(1), 20.
26. Navarro, J., Vargas, J., Cezard, J. P., Charritat, J. L., & Polonovski, C. (1982). Prolonged constant rate elemental enteral nutrition in Crohn's disease. *Journal of Pediatric Gastroenterology and Nutrition*, 1(4), 541–546.
27. Ogata, Y., Takeuchi, M., Ishibashi, N., Kibe, S., Takahashi, K., Uchida, S., ... Shirouzu, K. (2012). Efficacy of Elental on prevention for chemotherapy-induced oral mucositis in colorectal cancer patients. *Gan To Kagaku Ryoho*, 39(4), 583–7.
28. Ohkura, Y., Haruta, S., Tanaka, T., Ueno, M., & Udagawa, H. (2016). Effectiveness of postoperative elemental diet (Elental®) in elderly patients after gastrectomy. *World Journal of Surgical Oncology*, 14(1).
29. Okada, M., Yao, T., Yamamoto, T., Takenaka, K., Imamura, K., Maeda, K., & Fujita, K. (1990). Controlled trial comparing an elemental diet with prednisolone in the treatment of active Crohn's disease. *Hepato-gastroenterology*, 37(1), 72–80.
30. O'Keefe, S. J. D., Ogden, J., Rund, J., & Potter, P. (1989). Steroids and bowel rest versus elemental diet in the treatment of patients with Crohn's disease: The effects on protein metabolism and immune function. *Journal of Parenteral and Enteral Nutrition*, 13(5), 455–460.

31. Olausson, R., Lovik, A., Tollefsen, S., Andresen, P., Vatn, M., Delange, T., ... Lundin, K. (2005). Effect of elemental diet on mucosal immunopathology and clinical symptoms in type 1 refractory celiac disease. *Clinical Gastroenterology and Hepatology*, 3(9), 875–885.
32. O'Morain, C., Segal, A. W., & Levi, A. J. (1984). Elemental diet as primary treatment of acute Crohn's disease: a controlled trial. *BMJ*, 288(6434), 1859–1862.
33. Orenstein, S. R. (1986). Enteral versus parenteral therapy for intractable diarrhea of infancy: A prospective, randomized trial. *The Journal of Pediatrics*, 109(2), 277–286.
34. Papadopoulou, A., Rawashdeh, M., Brown, G., McNeish, A., & Booth, I. (1995). Remission following an elemental diet or prednisolone in Crohn's disease. *Acta Paediatrica*, 84(1), 79–83.
35. Peterson, K. A., Byrne, K. R., Vinson, L. A., Ying, J., Boynton, K. K., Fang, J. C., ... Clayton, F. (2013). Elemental diet induces histologic response in adult eosinophilic esophagitis. *American Journal of Gastroenterology*, 108(5), 759–766.
36. Pimentel, M., Constantino, T., Kong, Y., Bajwa, M., Rezaei, A., & Park, S. (2004). A 14-day elemental diet is highly effective in normalizing the lactulose breath test. *Digestive Diseases and Sciences*, 49(1), 73–77.
37. Podas, T., Nightingale, J. M., Oldham, R., Roy, S., Sheehan, N. J., & Mayberry, J. F. (2007). Is rheumatoid arthritis a disease that starts in the intestine? A pilot study comparing an elemental diet with oral prednisolone. *Postgraduate Medical Journal*, 83(976), 128–131.
38. Sagar, S., Harland, P., & Shields, R. (1979). Early postoperative feeding with elemental diet. *BMJ*, 1(6159), 293–295.
39. Sanderson, I. R., Udeen, S., Davies, P. S., Savage, M. O., & Walker-Smith, J. A. (1987). Remission induced by an elemental diet in small bowel Crohn's disease. *Archives of Disease in Childhood*, 62(2), 123–127.
40. Shichinohe, T., Sasaki, T., Kitashiro, S., Morita, T., Ono, K., Senmaru, N., ... Hirano, S. (2017). Impact of elemental diet on early recovery after laparoscopic colectomy: Findings of a randomized controlled trial. *Surgery Today*, 47(2), 166–173.
41. Spirtos, N. M., & Ballon, S. C. (1988). Needle catheter jejunostomy: A controlled, prospective, randomized trial in patients with gynecologic malignancy. *American Journal of Obstetrics and Gynecology*, 158(6), 1285–1290.
42. Takagi, S., Utsunomiya, K., Kuriyama, S., Yokoyama, H., Takahashi, S., Iwabuchi, M., ... Shimosegawa, T. (2006). Effectiveness of an "half elemental diet" as maintenance therapy for Crohn's disease: A randomized-controlled trial. *Alimentary Pharmacology and Therapeutics*, 24(9), 1333–1340.
43. Tanaka, Y., Takahashi, T., Yamaguchi, K., Osada, S., Shimokawa, T., & Yoshida, K. (2016). Elemental diet plus glutamine for the prevention of mucositis in esophageal cancer patients receiving chemotherapy: A feasibility study. *Support Care Cancer*, 24(2), 933–941.
44. Tanaka, Y., Ueno, T., Yoshida, N., Akutsu, Y., Takeuchi, H., Baba, H., ... Yoshida, K. (2018). The effect of an elemental diet on oral mucositis of esophageal cancer patients treated with DCF chemotherapy: A multi-center prospective feasibility study (EPOC study). *Esophagus*, 15(4), 239–248.
45. Teahon, K., Bjarnason, I., Pearson, M., & Levi, A. J. (1990). Ten years' experience with an elemental diet in the management of Crohn's disease. *Gut*, 31(10), 1133–1137.
46. Thomas, A. G., Taylor, F., & Miller, V. (1993). Dietary intake and nutritional treatment in childhood Crohn's disease. *Journal of Pediatric Gastroenterology and Nutrition*, 17(1), 75–81.
47. Toyomasu, Y., Mochiki, E., Yanai, M., Suzuki, M., Yanoma, T., Kimura, A., ... Kuwano, H. (2019). A prospective pilot study of an elemental nutritional supplement for prevention of oral mucositis during S-1 adjuvant chemotherapy for gastric cancer. *Surgical Oncology*, 29, 97–101.

48. Tsertsvadze, A., Gurung, T., Court, R., Clarke, A., & Sutcliffe, P. (2015). Clinical effectiveness and cost-effectiveness of elemental nutrition for the maintenance of remission in Crohn's disease: a systematic review and meta-analysis. *Health Technology Assessment*, 19(26), 1–138.
49. Verma, S., Brown, S., Kirkwood, B., & Gaffer, M. H. (2000). Polymeric versus elemental diet as primary treatment in active Crohn's disease: a randomized, double-blind trial. *The American Journal of Gastroenterology*, 95(3), 735–739.
50. Verma, S., Kirkwood, B., Brown, S., & Gaffer, M. H. (2000). Oral nutritional supplementation is effective in the maintenance of remission in Crohn's disease. *Digestive and Liver Disease*, 32(9), 769–774.
51. Warners, M. J., Vlieg-Boerstra, B. J., Verheij, J., van Rhijn, B. D., Van Ampting, M. T. J., Harthoorn, L. F., ... Bredenoord, A. J. (2017). Elemental diet decreases inflammation and improves symptoms in adult eosinophilic oesophagitis patients. *Alimentary Pharmacology & Therapeutics*, 45(6), 777–787.
52. Weinstein, L., Dyne, P. L., & Duerbeck, N. B. (1993). The PROEF diet — A new postoperative regimen for oral early feeding. *American Journal of Obstetrics and Gynecology*, 168(1), 128–131.
53. Yamamoto, T., Nakahigashi, M., Umegae, S., Kitagawa, T., & Matsumoto, K. (2006). Impact of long-term enteral nutrition on clinical and endoscopic recurrence after resection for Crohn's disease: A prospective, non-randomized, parallel, controlled study. *Alimentary Pharmacology & Therapeutics*, 25(1), 67–72.
54. Zoli, G., Care, M., Parazza, M., Spano, C., Biagi, P. L., Bernardi, M., & Gasbarrini, G. (1997). A randomized controlled study comparing elemental diet and steroid treatment in Crohn's disease. *Alimentary Pharmacology and Therapeutics*, 11(4), 735–740.





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