

## Postprint: Meta-Analysis of the Efficacy and Safety of Home Enteral Nutrition in Esophageal Cancer Patients

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### Abstract

**Background:** Esophageal cancer patients frequently experience malnutrition. Domestic and international studies have shown that malnutrition significantly impacts patient recovery. Currently, an increasing number of patients are receiving home enteral nutrition (HEN) during the home care period, but the effectiveness and safety of HEN for esophageal cancer patients remain unclear.

**Objective:** To evaluate the effectiveness and safety of HEN in esophageal cancer patients through Meta-analysis.

**Methods:** Computerized searches were performed on PubMed, Cochrane Library, Embase, Web of Science, CINAHL, Scopus, Wanfang Data Knowledge Service Platform, CNKI, VIP, and China Biology Medicine disc to identify randomized controlled trials on esophageal cancer patients receiving HEN, with the search period from database inception to December 2021. Patients in the experimental group received HEN support (both enteral tube feeding [ETF] and oral nutritional supplements [ONS] were acceptable), while the control group received only conventional oral diet. Two researchers independently screened literature, extracted data, and used the RoB 2.0 tool recommended by the Cochrane Collaboration to assess literature quality. Meta-analysis was performed using RevMan 5.4.1 software.

**Results:** A total of 14 articles were included, comprising 1,040 esophageal cancer patients. Meta-analysis results showed that the experimental group had higher increases in body weight (BW), body mass index (BMI), hemoglobin (HLB), serum total protein (TP), serum prealbumin (PAB), and serum transferrin (TRF) compared with the control group (SMD=0.63, 95%CI (0.40, 0.85),  $P<0.000\ 01$ ; SMD=0.60, 95%CI (0.44, 0.76),  $P<0.000\ 01$ ; SMD=1.58, 95%CI (1.37, 1.79),  $P<0.000\ 01$ ; SMD=1.19, 95%CI (0.79, 1.58),  $P<0.000\ 01$ ; SMD=0.97,

95%CI (0.79, 1.14),  $P < 0.000\ 01$ ; SMD=1.12, 95%CI (0.45, 1.79),  $P = 0.001$  . In both the ETF and ONS subgroups, the experimental group showed higher increases in serum albumin (ALB) than the control group (SMD=1.25, 95%CI (0.82, 1.68),  $P < 0.000\ 01$ ; SMD=0.61, 95%CI (0.26, 0.97),  $P < 0.000\ 01$  . The incidence of malnutrition in the experimental group was lower than that in the control group (OR=0.47, 95%CI (0.33, 0.67) ,  $P < 0.000\ 1$  ) . There was no statistically significant difference in the incidence of gastrointestinal complications between the two groups (RR=1.33, 95%CI (1.00, 1.77) ,  $P = 0.05$  ) . No statistically significant difference was found in quality of life scores between the experimental and control groups (MD=4.97, 95%CI (0.06, 9.87) ,  $P = 0.05$  ) ; the experimental group had higher physical function scores (MD=6.67, 95%CI (2.86, 10.48),  $P = 0.000\ 6$ ) and lower fatigue symptom scores (MD=-7.31, 95%CI (-11.85, -2.77),  $P = 0.002$ ) than the control group. Sensitivity analysis indicated that the pooled results were stable and reliable.

Conclusion: HEN can improve the nutritional status and physical function of postoperative esophageal cancer patients discharged from hospital, and alleviate their fatigue symptoms, without increasing the incidence of gastrointestinal complications, but no improvement in overall quality of life was found.

## Full Text

### The Efficacy and Safety of Home Enteral Nutrition in Patients with Esophageal Cancer: A Meta-Analysis

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## Abstract

**Background:** Malnutrition is a common complication in patients with esophageal cancer, which seriously impacts patient recovery according to domestic and international studies. While an increasing number of patients are receiving home enteral nutrition (HEN) during the home care period, the effectiveness and safety of HEN for esophageal cancer patients remain unclear.

**Objective:** To systematically evaluate the efficacy and safety of HEN in esophageal cancer patients through meta-analysis.

**Methods:** We searched PubMed, Cochrane Library, Embase, Web of Science, CINAHL, Scopus, Wanfang Data Knowledge Service Platform, CNKI, VIP, and Chinese Biomedical Literature Database for randomized controlled trials (RCTs) on HEN in esophageal cancer patients from inception to December 2021. Patients in the experimental group received HEN support (both enteral tube feeding [ETF] and oral nutritional supplements [ONS] were acceptable), while the control group received only conventional oral diet. Two researchers independently screened literature, extracted data, and assessed study quality using the Cochrane Collaboration's RoB 2.0 tool. Meta-analysis was performed using RevMan 5.4.1 software.

**Results:** Fourteen articles involving 1,040 esophageal cancer patients were included. Meta-analysis showed that the experimental group had significantly greater increases in body weight (BW), body mass index (BMI), hemoglobin (HLB), serum total protein (TP), serum prealbumin (PAB), and serum transferrin (TRF) compared with the control group [SMD=0.63, 95%CI (0.40, 0.85),  $P<0.00001$ ; SMD=0.60, 95%CI (0.44, 0.76),  $P<0.00001$ ; SMD=1.58, 95%CI (1.37, 1.79),  $P<0.00001$ ; SMD=1.19, 95%CI (0.79, 1.58),  $P<0.00001$ ; SMD=0.97, 95%CI (0.79, 1.14),  $P<0.00001$ ; SMD=1.12, 95%CI (0.45, 1.79),  $P=0.001$ ]. In both ETF and ONS subgroups, the experimental group showed greater increases in serum albumin (ALB) than the control group [SMD=1.25, 95%CI (0.82, 1.68),  $P<0.00001$ ; SMD=0.61, 95%CI (0.26, 0.97),  $P<0.00001$ ]. The incidence of malnutrition was lower in the experimental group [OR=0.47, 95%CI (0.33, 0.67),  $P<0.0001$ ]. No statistically significant difference was found in gastrointestinal complication rates between the two groups [RR=1.33, 95%CI (1.00, 1.77),  $P=0.05$ ]. While overall quality of life scores did not differ significantly between groups [MD=4.97, 95%CI (0.06, 9.87),  $P=0.05$ ], the experimental group had higher physical function scores [MD=6.67, 95%CI (2.86, 10.48),  $P=0.0006$ ] and lower fatigue symptom scores [MD=-7.31, 95%CI (-11.85, -2.77),  $P=0.002$ ]. Sensitivity analysis confirmed the stability and reliability of these findings.

**Conclusion:** HEN can improve nutritional status and physical function while reducing fatigue symptoms in discharged patients after esophageal cancer surgery, without increasing the incidence of gastrointestinal complications. However, no significant improvement in overall quality of life was observed.

**Keywords:** Enteral nutrition; Esophageal neoplasms; Home enteral nutrition; Enteral tube feeding; Oral nutritional supplements; Nutritional status; Quality of life; Randomized controlled trial; Meta-analysis

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## Introduction

Esophageal cancer ranks as the 6th most common malignant tumor and the 4th leading cause of cancer-related mortality in China, representing a major threat to public health [?]. The incidence of malnutrition among esophageal cancer

patients is the highest among all malignancies, reaching 60-85% [?]. For surgical patients in particular, postoperative digestive tract reconstruction leads to malabsorption, further deteriorating nutritional status [?] and increasing complication rates, which can delay or interrupt chemoradiotherapy and severely affect prognosis [?].

While esophageal cancer patients receive adequate nutritional management during hospitalization, they often struggle to maintain proper nutrient intake after discharge due to altered dietary patterns following digestive tract reconstruction, leading to protein-energy malnutrition [?] and gastrointestinal complications [?]. Malnutrition and complications significantly impact treatment response, survival time, and quality of life. Therefore, nutritional support after discharge is crucial, as good nutritional status is essential for rapid functional recovery and improved quality of life.

Although the benefits of enteral nutrition support during hospitalization are well-established, the effects of post-discharge enteral nutrition remain understudied. Home enteral nutrition (HEN) refers to the continuation of enteral nutrition support at home under medical guidance for clinically stable patients requiring such intervention [?]. With increasing numbers of patients receiving HEN during the home care period, its specific impact on esophageal cancer patients remains unclear [?]. Current studies show inconsistent conclusions regarding HEN's ability to improve nutritional status and quality of life, and safety concerns persist [?]. Since clinical guidelines consider both enteral tube feeding (ETF) and oral nutritional supplements (ONS) as forms of enteral nutrition described as "nutritional therapy via enteral routes" [?], this study systematically evaluated the effects of HEN on nutritional status, complications, and quality of life in esophageal cancer patients to provide more reliable evidence for clinical application.

## Methods

### 1.1 Inclusion Criteria

- (1) Study type: Randomized controlled trials (RCTs) in Chinese or English;
- (2) Participants: Patients aged  $\geq 18$  years with confirmed esophageal cancer diagnosis who had undergone radical esophagectomy and were discharged;
- (3) Intervention: Experimental group received HEN support (both ETF and ONS acceptable), control group received conventional oral diet only;
- (4) Outcome measures: Primary outcomes included body weight (BW), body mass index (BMI), hemoglobin (HGB), serum total protein (TP), serum albumin (ALB), serum prealbumin (PAB), serum transferrin (TRF), malnutrition incidence, and related complications; secondary outcome was quality of life.

### 1.2 Exclusion Criteria

- (1) Patients with other severe comorbidities such as severe renal impairment or other malignancies;
- (2) Studies combining HEN with other interventions;
- (3) Duplicate publications;
- (4) Articles with unavailable full text, missing data, or incorrect statistical methods;
- (5) Conference abstracts, letters, or grey literature.

**1.3 Search Strategy** We searched PubMed, Cochrane Library, Embase, Web of Science, CINAHL, Scopus, Wanfang Data Knowledge Service Platform, CNKI, VIP, and Chinese Biomedical Literature Database for RCTs on HEN in esophageal cancer patients from inception to December 2021. The search combined MeSH terms and free-text words, adjusted according to each database's characteristics. Reference lists of included studies were also screened for additional sources. Chinese search terms included: esophageal cancer, esophageal malignancy, esophagectomy, home enteral nutrition, jejunostomy, nasogastric feeding, oral nutritional supplements, post-discharge, home care, etc. English search terms included: esophageal neoplasms, esophageal cancer, esophageal carcinoma, esophagectomy, postesophagectomy, enteral nutrition, tube feeding, oral nutritional supplements, aftercare, discharge, home, etc. The specific search strategy for PubMed is shown in Table 1 .

**1.4 Literature Screening and Data Extraction** Two researchers independently screened literature, extracted data, and cross-checked results. Disagreements were resolved through discussion or consultation with a third party. Extracted data included: first author, publication year, sample size, patient age, pathological stage, intervention measures, intervention duration, and outcome indicators.

**1.5 Quality Assessment** Two researchers independently assessed the risk of bias in included studies using the Cochrane Collaboration's RoB 2.0 tool [?], with results cross-checked.

**1.6 Statistical Analysis** Meta-analysis was performed using RevMan 5.4.1 software. For continuous data, standardized mean difference (SMD) or mean difference (MD) was used as the effect measure; for categorical data, odds ratio (OR) or risk ratio (RR) was used, all presented with 95% confidence intervals (95%CI). Heterogeneity was assessed using the Q test ( $\alpha=0.1$ ) combined with  $I^2$  values. If  $P>0.1$  and  $I^2<50\%$ , studies were considered homogeneous and a fixed-effects model was used; if  $P<0.1$  and  $I^2\geq 50\%$ , sensitivity analysis was performed to identify heterogeneity sources. If heterogeneity persisted, a random-effects model was applied [?]. Subgroup or sensitivity analysis was conducted for studies with significant clinical heterogeneity, or descriptive analysis was performed. Statistical significance was set at  $P<0.05$ .

## Results

**2.1 Literature Search Results** The initial search yielded 1,280 records. After screening, 14 articles [?, ?] were included. The literature screening flowchart is shown in Figure 1 [Figure 1: see original paper].

**2.2 Characteristics and Risk of Bias of Included Studies** Fourteen RCTs published between 2013-2021 were included, conducted in China [?, ?] and the United Kingdom [?]. The studies included 1,040 participants, with the intervention group receiving ETF or ONS in addition to oral diet, while the control group received conventional oral diet only. Intervention duration ranged from 1-2 months. Basic characteristics of included studies are shown in Table 2. All studies showed comparable baselines between groups ( $P>0.05$ ). Nine studies [?, ?, ?, ?] described specific randomization methods, while others only mentioned “random grouping.” One study [?] used an online randomization process for allocation concealment, and one [?] used opaque envelopes. Risk of bias assessment results are shown in Figure 2 [Figure 2: see original paper].

## 2.3 Meta-Analysis Results

**2.3.1 Effects on BW and BMI** Five studies [?, ?, ?, ?, ?] assessed BW changes with a total sample of 317 patients. No significant heterogeneity was found ( $I^2=5\%$ ,  $P=0.38$ ), and fixed-effects model analysis showed greater BW gain in the intervention group [SMD=0.63, 95%CI (0.40, 0.85),  $P<0.00001$ , Figure 3 [Figure 3: see original paper]].

Eight studies [?, ?, ?] assessed BMI changes with a total sample of 634 patients. No significant heterogeneity was found ( $I^2=0\%$ ,  $P=0.57$ ), and fixed-effects model analysis showed greater BMI gain in the intervention group [SMD=0.60, 95%CI (0.44, 0.76),  $P<0.00001$ , Figure 4 [Figure 4: see original paper]].

**2.3.2 Effects on Serum Nutritional Indicators** **2.3.2.1 HLB Changes:** Seven studies [?, ?, ?, ?] assessed HLB changes with a total sample of 448 patients. Significant heterogeneity was observed ( $I^2=89\%$ ,  $P<0.00001$ ), possibly due to intervention type. Five studies [?, ?, ?, ?] used jejunostomy feeding, one [?] used duodenal feeding tube, and one [?] used ONS. Meta-analysis was performed on five studies, with descriptive analysis for the other two.

The five studies showed no significant heterogeneity ( $I^2=26\%$ ,  $P=0.25$ ). Fixed-effects analysis revealed significantly greater HLB increase in the intervention group [SMD=1.58, 95%CI (1.37, 1.79),  $P<0.00001$ , Figure 5 [Figure 5: see original paper]]. Liu [?] conducted an RCT on duodenal feeding tube for 2 months, finding significant HLB improvement post-intervention ( $P<0.05$ ) but no significant between-group difference ( $P>0.05$ ). Chen et al. [?] provided ONS for 2 months post-discharge, also finding significant HLB improvement ( $P<0.05$ ) but no between-group difference ( $P>0.05$ ).

**2.3.2.2 TP Changes:** Eight studies [?, ?] assessed TP changes with a total sample of 690 patients. Significant heterogeneity was found ( $I^2=83\%$ ,  $P<0.00001$ ). Random-effects analysis showed greater TP increase in the intervention group [SMD=1.19, 95%CI (0.79, 1.58),  $P<0.00001$ , Figure 6 [Figure 6: see original paper]].

**2.3.2.3 ALB Changes:** Ten studies [?, ?, ?, ?] assessed ALB changes with a total sample of 800 patients. Significant heterogeneity was observed ( $I^2=84\%$ ,  $P<0.00001$ ), possibly due to intervention type. Eight studies [?, ?, ?] used ETF and two [?, ?] used ONS, prompting subgroup analysis.

In the ETF subgroup, significant heterogeneity remained ( $I^2=85\%$ ,  $P<0.00001$ ). Random-effects analysis showed greater ALB increase in the intervention group [SMD=1.25, 95%CI (0.82, 1.68),  $P<0.00001$ ]. In the ONS subgroup, no significant heterogeneity was found ( $I^2=40\%$ ,  $P=0.20$ ). Fixed-effects analysis showed greater ALB increase in the intervention group [SMD=0.61, 95%CI (0.26, 0.97),  $P<0.00001$ , Figure 7 [Figure 7: see original paper]].

**2.3.2.4 PAB Changes:** Seven studies [?, ?, ?, ?, ?] assessed PAB changes with a total sample of 560 patients. No significant heterogeneity was found ( $I^2=0\%$ ,  $P=0.85$ ). Fixed-effects analysis showed greater PAB increase in the intervention group [SMD=0.97, 95%CI (0.79, 1.14),  $P<0.00001$ , Figure 8 [Figure 8: see original paper]].

**2.3.2.5 TRF Changes:** Four studies [?, ?] assessed TRF changes with a total sample of 351 patients. Significant heterogeneity was observed ( $I^2=88\%$ ,  $P<0.0001$ ). Sensitivity analysis did not substantially change results. Random-effects analysis showed greater TRF increase in the intervention group [SMD=1.12, 95%CI (0.45, 1.79),  $P=0.001$ , Figure 9 [Figure 9: see original paper]].

**2.3.3 Effects on Malnutrition** Seven studies [?, ?, ?, ?, ?] assessed the proportion of patients at nutritional risk or with malnutrition. Four studies [?, ?, ?, ?] used the Nutritional Risk Screening 2002 (NRS 2002), two [?, ?] used the Patient-Generated Subjective Global Assessment (PG-SGA), and one [?] used the Mini Nutritional Assessment (MNA), with a total sample of 566 patients. No significant heterogeneity was found ( $I^2=36\%$ ,  $P=0.15$ ). Fixed-effects analysis showed lower malnutrition incidence in the intervention group [OR=0.47, 95%CI (0.33, 0.67),  $P<0.0001$ , Figure 10 [Figure 10: see original paper]].

**2.3.4 Effects on Gastrointestinal Complications** Six studies [?, ?, ?, ?] assessed gastrointestinal complication rates with a total sample of 414 patients. No significant heterogeneity was found ( $I^2=39\%$ ,  $P=0.15$ ). Fixed-effects analysis showed no statistically significant difference between groups [RR=1.33, 95%CI (1.00, 1.77),  $P=0.05$ , Figure 11 [Figure 11: see original paper]].

**2.3.5 Effects on Quality of Life** Four studies [?, ?, ?] assessed quality of life with a total sample of 168 patients. Three studies [?, ?, ?] using the EORTC QLQ-C30 questionnaire were included in meta-analysis, while one [?] using EORTC QLQ-C18 was descriptively analyzed.

The three studies showed no significant heterogeneity ( $I^2=5\%$ ,  $P=0.35$ ). Fixed-effects analysis revealed no significant difference in overall quality of life scores between groups [MD=4.97, 95%CI (0.06, 9.87),  $P=0.05$ , Figure 12 [Figure 12: see original paper]]. However, the intervention group had significantly higher physical function scores [MD=6.67, 95%CI (2.86, 10.48),  $P=0.0006$ , Figure 13 [Figure 13: see original paper]] and lower fatigue symptom scores [MD=-7.31, 95%CI (-11.85, -2.77),  $P=0.002$ , Figure 14 [Figure 14: see original paper]].

Zeng et al. [?] reported higher overall quality of life scores in the intervention group at 4 and 12 weeks post-surgery ( $P<0.05$ ), with better performance in physical, social, and role functions, lower fatigue scores, and superior outcomes in weakness, reflux, and appetite compared to the control group. No significant difference in overall quality of life was found between groups at 24 weeks post-surgery.

## Discussion

This meta-analysis demonstrates that HEN effectively improves post-discharge BW, BMI, and serum nutritional indicators such as ALB and PAB in esophageal cancer patients, with comprehensive nutritional assessment showing significantly reduced malnutrition incidence. HEN did not increase gastrointestinal complication rates. While HEN did not improve overall quality of life, it significantly enhanced physical function and reduced fatigue symptoms.

Postoperative weight loss is nearly universal in esophageal cancer patients, attributable to altered digestive anatomy, physiological changes in gastrointestinal hormones, decreased appetite, and inadequate nutritional intake. After discharge, the direct effects of surgical trauma diminish while malnutrition from digestive tract reconstruction becomes the primary concern, serving as an independent risk factor for complications and prognosis [?]. Previous studies found that approximately 72% of patients achieved only 50-85% of required calories through conventional oral diet at discharge [?], whereas post-discharge ETF can supplement unmet daily needs, and ONS provides more balanced protein and calories than regular diet [?, ?], thereby improving nutritional status.

Significant heterogeneity in ALB levels was observed across studies, but sensitivity analysis confirmed robust results, with all studies showing ALB improvement albeit to varying degrees. TRF analysis also revealed substantial heterogeneity, with Cao et al. [?] identified as the source. This may be attributed to lack of post-discharge follow-up guidance, leading to unbalanced nutrient intake and minimal TRF improvement, highlighting the importance of follow-up care.

Due to digestive tract reconstruction, patients require 3-6 months to adapt to

new dietary patterns, yet most experience gastrointestinal complications (e.g., reflux, anorexia, diarrhea) within one year post-discharge [?], potentially leading to early HEN termination [?]. Therefore, safety assessment is crucial. This meta-analysis found no significant difference in gastrointestinal complications between groups, likely due to professional HEN support teams providing follow-up on dietary intake, physical condition, and complications [?], with dietitians or clinicians monitoring compliance through dietary records and addressing issues via telephone or outpatient visits to prevent complications [?, ?]. This underscores the necessity of post-discharge follow-up and the need to refine follow-up protocols to ensure patient safety.

Quality of life is a critical measure of surgical success, and poor quality of life is an independent risk factor for mortality [?]. Poor quality of life after esophagectomy is associated with decreased physical function, anorexia, and fatigue [?], which can delay chemoradiotherapy and prevent completion of cancer treatment [?]. Therefore, optimizing postoperative physical condition and alleviating symptoms is essential. This study found that although HEN did not improve overall quality of life, it significantly improved physical function and reduced fatigue symptoms. HEN may enhance physical function and relieve fatigue by providing adequate nutrition, thereby helping patients complete full cancer treatment. Treatment cost is another important consideration; if too expensive, patients may decline HEN. This meta-analysis found no significant difference in the economic impact dimension of EORTC QLQ-C30, suggesting HEN does not increase economic burden. However, these studies did not report detailed cost-effectiveness data, warranting further exploration.

Some included studies had methodological limitations that may introduce bias. Additionally, due to reporting limitations, this study only compared short-term post-discharge HEN outcomes, leaving long-term effects of ETF and ONS unknown. Finally, most evidence was derived from Chinese populations, limiting generalizability to other regions.

In conclusion, HEN effectively improves nutritional status, physical function, and fatigue symptoms in postoperative esophageal cancer patients without increasing gastrointestinal complications. Healthcare providers should guide patients on HEN precautions before discharge and ensure adequate follow-up. More high-quality, large-sample RCTs are needed to provide stronger evidence for HEN implementation in esophageal cancer patients.

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