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# ORIGINAL RESEARCH: EMPIRICAL RESEARCH - QUANTITATIVE



# Assessment of compliance with oral nutritional supplementation and exploration of barriers and facilitators for patients after gastrectomy: A mixed-methods study

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#### **Abstract**

Aims: To evaluate the compliance of patients after gastrectomy in taking oral nutritional supplementation and to explore the promoting and hindering factors.

Design: A mixed-methods design with an explanatory sequential approach was employed.

Methods: We conducted a 12-week longitudinal study to evaluate the oral nutritional supplementation compliance of 122 patients after gastric cancer surgery and the factors that affected their compliance. After the quantitative phase, we selected the interview subjects and developed the interview outline based on the analysis of the quantitative results. In-depth interviews (n = 15) were conducted to explain and supplement the quantitative phase results. Data were collected from October 2019 to May 2020.

Results: The average overall compliance rate of oral nutritional supplementation in patients with gastric cancer over 12 weeks was 30.59%. Adverse reactions to oral nutritional supplementation, the identity of the main caregivers and the patient's financial ability were independent factors that affected patient compliance. In subsequent interviews, we extracted four themes: social support plays an important role in patients taking oral nutritional supplementation, adverse reactions discourage patients from continuing to take oral nutritional supplementation, patients' attitudes affect their motivation to take oral nutritional supplementation, and the different needs of patients for oral nutritional supplementation affect patient compliance.

Conclusion: Patients' compliance with oral nutritional supplementation after gastric cancer surgery is very low. Health education should pay more attention to the management of adverse reactions and the role of patients' peers and family members. Oral nutritional supplementation products should be diversified to provide patients with more choices.

Impact: This study clarifies the factors that hinder and promote oral nutritional supplementation compliance and provides an important reference for the establishment and revision of health education strategies for patients after gastric cancer surgery.

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### KEYWORDS

compliance, gastric cancer, mixed method, nursing, ONS, oral nutritional supplements, stomach cancer

# 1 | INTRODUCTION

Postoperative patients with gastric cancer often suffer from malnutrition due to changes in their physiological structure, chemotherapy and postoperative complications. The European Society of Clinical Nutrition and Metabolism (ESPEN) guidelines recommend oral nutritional supplements (ONS) as a first-line nutritional therapy for malnutrition following oncologic surgery (Arends et al., 2017). However, patients' compliance with ONS is generally low, so ONS cannot exert the maximum benefit. Therefore, it is urgent to investigate the level of ONS compliance of patients with gastric cancer and explore the reasons for this phenomenon.

To provide a distinctive reference for the development of ONS management strategies in the future, we used a mixed-methods design with an explanatory sequential approach to explore the factors that promote and hinder the compliance of patients with gastric cancer.

#### 2 | BACKGROUND

Gastric cancer is the fifth most common malignancy and the third most common cause of cancer-related deaths in the world, and it was the cause of death for approximately 841,000 people in 2013 (Bray et al., 2018; Fitzmaurice et al., 2015), Currently, radical gastrectomy is the mainstay of treatment for patients with gastric cancer (Association, 2017), but it also weakens the reservoir function of gastric cancer and changes the structure of the digestive tract (Bae et al., 1998). For these reasons, patients often experience dysphagia, premature satiety, reflux, anorexia and postprandial dumping syndrome, which lead to dramatic weight loss within the first three months after gastrectomy (Fujiya et al., 2018). Studies have shown that 60-85% of patients with upper gastrointestinal malignancies suffer from malnutrition (Baldwin et al., 2006; Deans et al., 2009; Riccardi & Allen, 1999). Malnutrition is associated with lower postoperative quality of life (Guo et al., 2020), longer hospital stays (Guner et al., 2018), and higher complications and morbidity (Choi & Kim, 2016; Yu et al., 2002). Furthermore, malnutrition at 3 months after surgery is significantly associated with the overall survival (OS) and cause-specific survival (CSS) of gastric cancer patients (Fujiya et al., 2018). Therefore, it is urgent to solve the problem of malnutrition after gastric cancer surgery.

The ESPEN guidelines recommend that ONS should be used as a first-line nutritional therapy for malnutrition following oncologic surgery (Arends et al., 2017). Previous studies have shown that ONS can improve the nutritional status of patients with gastrointestinal cancer after surgery (Bae et al., 1998; Smedley et al., 2004). A randomized controlled study showed that taking ONS for

12 weeks after surgery could prevent patients with gastric cancer from losing 1.1 kg (2% of body weight; Hatao et al., 2017). The benefits of ONS are obvious, but the effects of ONS seem to be dose-dependent (de van der Schueren et al., 2018; Dias Rodrigues et al., 2017; Kobayashi et al., 2017); therefore, the main factor in the effect of ONS is patient compliance. However, compliance with ONS is not satisfactory; for example, Grass et al. reported that patient compliance with ONS was as low as 42% (Grass et al., 2015).

To date, studies on the ONS compliance of postoperative gastric patients are limited. In previous studies, compliance was often described as a secondary outcome indicator. Although a recent quantitative study explored factors that hinder the compliance with ONS after gastrointestinal surgery, that study only extracted the influencing factors based on a review of previous studies and then allowed patients to make a choice (Lidoriki et al., 2020). Patients were not interviewed in depth and their own beliefs were not understood, which may have introduced limitations and the exclusion of potential factors that lead to low patient compliance with ONS.

Given the severe nutritional status of postoperative gastric patients and the need for long-term ONS after surgery, little is known about the varying trends in compliance and the reasons for differences in ONS compliance in gastric cancer patients. In-depth information obtained from patients may offer a distinctive reference for the development of ONS management strategies in the future.

## 3 | THE STUDY

### 3.1 | Aim

The aim of this study was to evaluate the compliance of patients after gastrectomy in taking ONS and to explore the promoting and hindering factors.

### 3.2 | Design

This study used a mixed-methods explanatory sequential approach to explore the barriers and facilitators of ONS compliance in patients after gastric cancer surgery (Figure 1). First, a longitudinal study was conducted to evaluate the ONS compliance of patients 12 weeks (w) after surgery (each week was a follow-up point). After the quantitative phase, we selected the interview subjects and developed the interview outline based on the analysis of the quantitative phase results. In-depth interviews (n = 15) were conducted to explain and supplement the quantitative phase results.

## FIGURE 1 Study diagram

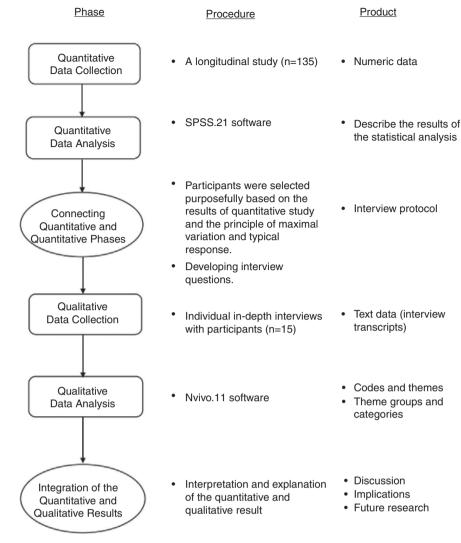


TABLE 1 Inclusion and exclusion criteria

Inclusion	Exclusion
Patients with stage I, II or III gastric cancer were diagnosed by pathology before surgery	Diagnosis of double cancer
Patients who had distal or total gastrectomy PG-SGA Grades B or C	Allergy to milk, soy bean, wheat or salmon
Age 18 years or order	Patients with mental illness, impaired consciousness and inability to communicate normally
No gastrectomy, radiation, chemotherapy before surgery	
Patients have the ability to ingest food orally.	
Patients or his/her family members had a smartphone on which they could use WeChat	
Patients written informed consent	

Abbreviations: PG-SGA: patient-generated subjective global assessments (Grade B: moderately malnourished or at risk of malnutrition, Grade C: severely malnourished); WeChat: as one of the popular social media apps in China.

## 3.3 | Participants

In the quantitative study phase, we used the purposive sampling method to select patients who began to take ONS within seven days after gastrectomy in the gastrointestinal surgery department of a tertiary-class hospital in Jilin Province. The inclusion and exclusion criteria are listed in Table 1. The sample size was 135 subjects, allowing 10% dropped samples and 10% mortality. The calculation formula is as follows:  $n = (Z\alpha/2\sigma/\delta)^2$ , considering  $\alpha = 0.05$ ;  $Z\alpha/2 = 1.96$  based on the Bunout et al. study (Bunout et al., 2004). Written informed consent

was obtained from all participants. In the qualitative study phase, we used the purposive sampling method to select participants who had the willingness and ability to express their own experiences, considering the maximum variability in terms of factors such as ONS compliance, education, age and socioeconomic status based on the results of the quantitative study phase (Palinkas et al., 2015).

## 3.4 | Data collection

## 3.4.1 | Quantitative phase

The patients' baseline data characteristics were collected using a sociodemographic questionnaire and the medical record system. Patients' age, gender, marital status and other data were collected through a sociodemographic questionnaire. Weight, BMI and PG-SGA were evaluated by a clinical dietician before surgery. Information on the surgical procedure, pathological stage and whether patients underwent chemotherapy was collected through the medical record system.

Each patient in this study enrolled in a group chat on WeChat, which is a popular social media app in China (Yu et al., 2019). In our study, the patient's attending physician prescribed ONS to them at the first anus exhaustion time of patient, usually within 7 days after surgery. At this time, patients were required to keep a "weekly ONS diary" (including the start time of ONS, the amount of daily ONS consumed and adverse reactions). The adverse reactions of ONS include bloating, diarrhoea, nausea and vomiting (Lidoriki et al., 2020). The researcher asked the patients for weekly ONS diary photos through WeChat at each follow-up point.

At the end of the 12-w follow-up, weight, BMI and postoperative infection-related complications, including infective diarrhoea, respiratory tract infection, wound infection (n; Beattie et al., 2000; Sultan et al., 2012) and 30-day readmission (n), were collected from the patients through follow-up on WeChat. To identify the relationship between the prognosis of postoperative patients with gastric cancer and ONS, patients' daily oral food intake was collected through daily food diaries provided by the patients (Hubbard et al., 2012). However, elderly patients (≥65 years) constituted a large portion of the participants in our study, and it was difficult for them to keep track of their diet in detail (Seguy et al., 2020). Therefore, the calories in the patients' daily diet were calculated and collected based on the local dietary assessment form (1–5 points) in China (Cong & Shi, 2018).

## 3.4.2 | Qualitative phase

Qualitative data were collected using in-depth and semistructured interviews. We developed interview guidelines based on the results of the quantitative study phase and relevant factors affecting ONS compliance reported in studies. The final interview guidelines were refined through pilot interviews with respect to culturally sensitive

and appropriate questions (Additional file 1). All interviews were conducted by the first author by telephone and were transcribed and audio-recorded with the patient's permission. Saturation was achieved when no new topics were identified; at this point, we stopped the interviews (Francis et al., 2010).

### 3.5 | Ethical considerations

The study was conducted in accordance with the Declaration of Helsinki (as revised in 2013). This research was approved by the Ethics Committee of the Nursing School of the University of Ji Lin, China (No. 2019101601). To protect confidentiality during and after the research, all participants were told that their personal information would be maintained and would not be shared or would be shared only in deidentified form.

## 3.6 | Data analysis

# 3.6.1 | Quantitative data analysis

The quantitative data were analysed with SPSS version 25.0. Normally distributed data are presented using the mean (standard deviation); non-normally distributed data are summarized and compared using the median [min, max]. Patients were divided into the high-compliance group (H group) and the low-compliance group (L group) according to the mean compliance of all patients. The Wilcoxon rank sum test was used to assess weight and BMI changes before and 12 weeks after surgery within the two groups. Fisher's exact test, the Mann–Whitney U test and the t-test were used to assess differences in baseline characteristics and other outcome indicators between the two groups. The factors contributing to low compliance at 12 weeks after gastrectomy were identified by logistic regression analysis. Two-tailed p < 0.05 was considered statistically significant. We calculated compliance by the percentage of the actual dose and the doctor's recommended dose of ONS (400 kcal/d).

### 3.6.2 | Qualitative data analysis

Data from the interviews were collected and analysed concurrently. The data were analysed using Colaizzi's seven-step method: (a) record and read all interview materials; (b) extract significant statements (statements that are directly related to the research phenomenon, e.g. words, phrases and sentences); (c) induce and extract meaningful units from significant statements; (d) organize the identified meaningful units into themes, theme groups and categories; (e) developing an exhaustive description (explain the generated themes and select some typical original statements to describe it). (f) identify the fundamental structure of the phenomenon; (g) return the results to the participants for validation of the findings (Holloway & Wheeler, 2002). Specific analysis process and examples, are given

in Additional file 2. NVivo12 (QSR International) was used for data management.

## 3.7 | Validity and reliability

The calculation method for compliance in this study (the percentage of the prescribed dosage consumed) has been applied to many similar studies to calculate the compliance of patients with ONS, and it has been proven to be a reliable method for calculating compliance (Kobayashi et al., 2017; Kong et al., 2017). Scores for the compliance rate ranged between 0% and 100%. If the patient's ONS consumption exceeded the prescribed amount, we intercepted the maximum 100%. Truncated adherence scales are often used in other medication compliance studies (Sattler et al., 2013). This method was considered suitable because for patients who are undernourished or at nutritional risk, consuming more ONS than the prescribed amount is considered beneficial and harmless (Liljeberg et al., 2019).

In the qualitative phase, to preserve the original style of the qualitative data, we used the dialects of the patients whenever possible. After the interviews, two authors independently extracted the themes, theme groups and categories. Based on Polit's method (Polit & Beck, 2016), typical original statements from the transcripts were extracted. To determine whether the results resonated with similar people, all authors reviewed the codebook and content of the transcripts repeatedly. To improve the accuracy of the results, after encoding and analysing the data, a bulleted list of key findings was shared with the participants. When we interviewed the thirteenth and fourteenth participants, no new information was found. To ensure qualitative research data saturation, we added an interview with one participant.

## 4 | FINDINGS

### 4.1 | Sample descriptors

From October 2019 to May 2020, 135 patients from a tertiary-class hospital in Jilin Province were enrolled, and data for 122 patients were available for analysis. The 13 patients deemed ineligible consisted of eight patients who lost contact with the researchers and five patients who died during the study (Figure 2). The baseline characteristics of the patients are given in Table 2.

## 4.2 | Quantitative findings

## 4.2.1 | Patient compliance with ONS

The average overall compliance rate was 30.59%. The ONS compliance of patients showed a decreasing trend with time, from 60.5% at one week after surgery to 16.9% at 12 weeks (Figure 3). To determine the time characteristics of patients taking ONS, we further

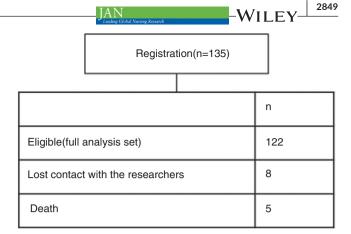


FIGURE 2 CONSORT diagram

observed the changes in the number of people who stopped taking ONS over time. We found that the number of people who stopped taking ONS in the first 5 weeks after surgery increased sharply, but at 5–6 weeks, the number of patients who stopped ONS changed from an upward trend to a downward trend, and the number of people increased more slowly after 6 weeks (Figure 4).

# 4.2.2 | The effect of compliance on nutritional indicators, complications and 30-day readmission rate

To evaluate how ONS influenced outcome indicators and the factors that influenced ONS compliance, patients were categorized into two groups according to their compliance. Fifty-one patients with an average compliance rate of more than 30% over 12 weeks were classified into the high-compliance group (H group). The remaining 71 patients were classified into the low-compliance group (L group).

By comparing the outcome indicators of patients in the two groups, we found that the 12-week weight loss of patients in the H group was significantly lower than that in the L group (0.9 [-1, 2.5] vs. 3 [1, 4], U = 1191.5, p = 0.001). In the H group, there was no significant difference between pre- and postoperative weight or BMI (weight, 58.7 [51.3, 64.9] vs. 58 [51, 65], z = -1.558, p = 0.119; BMI, 20.8 [19.5, 23.1] vs. 20.7 [18.7, 22.3], z = -1.600, p = 0.110), while there were statistically significant differences in the L group (weight, 63.5 [57, 70] vs. 60 [55, 65], z = -6.049, p < 0.001; BMI, 22.6 [20.3, 24.4] vs. 21.8 [19.5, 23.1], z = -6.102, p < 0.001). The rates of 30-day readmission, wound infection, respiratory tract infection and infective diarrhoea did not differ significantly between the two groups (Table 3).

## 4.2.3 | The factors influencing ONS compliance

Univariate analysis showed that household per capita monthly income (U = 1190.0, p = 0.001), caregivers (U = 1166.0, p < 0.001), education level (U = 1408.0, p = 0.029), weight (U = 1373.5, p = 0.023), BMI (U = 1307.0, p = 0.009) and PG-SGA score (patient-generated subjective global assessments;  $10.92 \pm 9.16$  vs.  $8.07 \pm 4.17$ ,

**TABLE 2** Characteristics of patients (N = 122)

Variable	Value
Gender, n (%)	
Male	86 (70.5)
Female	36 (29.5)
Age (years), mean (SD)	61.3 ± 10.8
Weight (kg), mean (SD)	61.9 ± 10.7
Body mass index (kg/m²), mean (SD)	22.1 ± 3.3
PG-SGA, mean (SD)	9.26 ± 6.8
Marital status, n (%)	
Spouse deceased or divorced	15 (12.3)
Married	107 (87.7)
Caregivers, n (%)	
The patient himself	11 (9)
Children or spouse	81 (66.4)
Both children and spouses	30 (24.6)
Household per capita monthly income, $ $	
<1000	24 (19.7)
1001–3000	58 (47.5)
3001–5000	31 (25.4)
>5000	9 (7.4)
Education level, n (%)	
Primary school or below	31 (25.4)
Junior high school	41 (33.6)
High school	35 (28.7)
College or university	15 (12.3)
Residence, n (%)	
Urban	82 (67.2)
Rural	40 (32.8)
Surgical procedure, n (%)	
Distal gastrectomy	93 (76.2)
Total gastrectomy	29 (23.8)
Approach, n (%)	
Open	21 (17.2)
Laparoscopic	101 (82.8)
Pathological stage, n (%)	
1	50 (41.0)
II	35 (28.7)
III	37 (30.3)
Adjuvant chemotherapy, n (%)	
Yes	86 (70.5)
No	36 (29.5)
110	
The texture types of ONS, n (%)	
	16 (13.1)
The texture types of ONS, n (%)	16 (13.1) 106 (86.9)

Abbreviations: ONS, or all nutritional supplement; PG-SGA, patient-generated subjective global assessments.

t=-2.312, 95% CI, -5.292 to -4.11; p=0.022) at baseline and adverse reactions to ONS (p=0.023) were the factors that influenced ONS compliance, with significant differences (Table 4). These factors were identified by binary logistic regression analysis, which revealed that household per capita monthly income of 3001–5000  $\pm$  (OR, 9.364; 95% CI, 1.986 to 44.164; p=0.005), the combination of children and spouses as caregivers (OR, 7.527; 95% CI, 1.094 to 51.806; p=0.040), and adverse reactions to ONS (OR, 0.298; 95% CI, 0.100 to 0.887; p=0.030) were factors that were independently associated with patients' ONS compliance (Table 5).

## 4.3 | Qualitative findings

Through interviews with 15 participants (Table 6), four themes were found to influence the ONS compliance of patients after gastrectomy.

# 4.3.1 | Social support plays an important role in patients taking ONS

Social support can be provided by informal networks of friends, families and ethnic communities (Gagnon et al., 2013; Guruge & Humphreys, 2009). Our research found that support from patients' family members and peers was an important factor that affected patients' compliance with ONS. The participants' families could urge them to take ONS in a timely manner when they were lazy or did not want to maintain the diet and provided the participants with material and emotional support.

My wife made me drink nine or ten spoonsful at a time, and then one time I only drank five, and she got angry. (01)

I always said I did not want to drink it, but my wife said, 'For your health recovery, you should drink it even if I borrow money.' Ha. (08)

Of course, some participants were not so lucky; a lack of caregivers made it difficult to keep up with ONS or even to eat regularly.

My child lives in another city, and my husband is sick in bed, so I have to take care of him. I do not have the energy to cook myself four or five meals a day, although I would like to... let alone nutritional powder. (11).

Peer effects played an important role in patients' compliance with ONS. Although some participants had stopped taking ONS themselves, when they found that other wardmates were actively

FIGURE 3 Average compliance rate to oral nutritional supplement

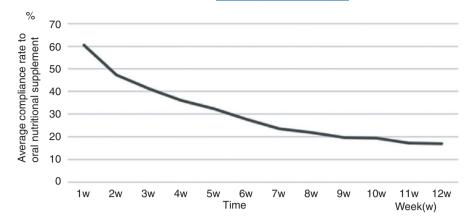


FIGURE 4 Number of people who gave up taking oral nutritional supplement

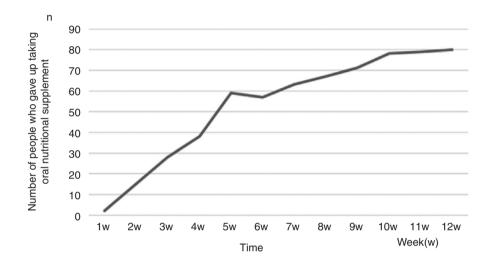


TABLE 3 Influence of compliance on nutritional indicators, complications and 30-day readmission rate

Variable	High-compliance group (n = 51)	Low-compliance group (n = 71)	p value
Weight (kg)			
Baseline	58.7 [51.3, 64.9]	63.5 [57, 70]	0.023 <sup>†,*</sup>
Week 12	58 [51, 65]	60 [55, 65]	$0.273^{\dagger}$
<i>p</i> -value	0.119 <sup>‡</sup>	<0.001 <sup>‡</sup>	
BMI (kg/m²)			
Baseline	20.8 [19.5, 23.1]	22.6 [20.3, 24.4]	0.009 <sup>†,*</sup>
Week 12	20.7 [18.7, 22.3]	21.8 [19.5, 23.1]	$0.176^{\dagger}$
p-value	0.110 <sup>‡</sup>	<0.001 <sup>‡</sup>	
Weight loss (kg)	0.9 [-1, 2.5]	3 [1, 4]	$0.001^{\dagger,*}$
Wound infection (n)	3	8	0.356§
Respiratory tract infection (n)	4	6	<b>1</b> §
Infective diarrhea (n)	3	3	0.694§
30-day readmissions (n)	5	4	0.489 <sup>§</sup>

Statistical significance was set at p < 0.05.

†Mann-Whitney U test.; ‡Wilcoxon rank sum test.; §Fisher's exact test.; \*p < 0.05.

taking ONS, they did so as well. Some participants observed severe weight loss in their wardmates who did not follow their doctors' instructions, which created a backward conditioning for patients and became a reason to keep taking their ONS.

During my chemotherapy, I found that all my ward-mates drank the nutrition powder. With their encouragement, I thought I should drink it, and then I started drinking it again. (02).

TABLE 4 Differences in baseline characteristics and indicators between the two groups

Variable	High-compliance group $(n = 51)$	Low-compliance group ( $n = 71$ )	p value
Age (years), mean (SD)	62.25 ± 11.0	60.6 ± 10.7	$0.414^{\dagger}$
Gender			0.814 <sup>‡</sup>
Male	35	51	
Female	16	20	
Baseline weight (kg), median (range)	58.7 [51.3, 64.9]	63.5 [57, 70]	0.023 <sup>§,</sup>
Baseline BMI (kg/m²), median (range)	20.8 [19.5, 23.1]	22.6 [20.3, 24.4]	0.009§
Baseline PG-SGA, mean (SD)	10.92 ± 9.16	8.07 ± 4.17	$0.022^{\dagger}$
Marital status, n			0.268 <sup>‡</sup>
Spouse deceased or divorced	4	11	
Married	47	60	
Caregivers, n			<0.001 <sup>§</sup> ,
The patient himself	2	9	
Children or spouse	27	54	
Both children and spouses	22	8	
Household per capita monthly income, n			0.001 <sup>§</sup>
<1000	4	20	
1001-3000	22	36	
3001-5000	21	10	
>5000	4	5	
Education level, n			0.029 <sup>§</sup>
Primary school or below	8	23	
Junior high school	18	23	
High school	16	19	
College or university	9	6	
Surgical procedure, n			0.396 <sup>‡</sup>
Distal gastrectomy	10	19	
Total gastrectomy	41	52	
Approach, n			0.630 <sup>‡</sup>
Open	10	11	
Laparoscopic	41	60	
Pathological stage, n			0.557 <sup>§</sup>
1	23	27	
II	13	22	
III	15	22	
Adjuvant chemotherapy, n			0.693 <sup>‡</sup>
Yes	14	22	
No	37	49	
The texture types of ONS, n			0.058 <sup>‡</sup>
Liquid	48	58	
Powder	3	13	
Score of the local dietary assessment form	3.39 ± 0.30	3.43 ± 0.20	0.396 <sup>†</sup>
Adverse reactions to ONS, n			0.023 <sup>‡</sup>
Yes	8	25	
Diarrhoea	2	14	
Bloating	4	6	
9			

TABLE 4 (Continued)

Variable	High-compliance group (n = 51)	Low-compliance group (n = 71)	p value
Nausea	2	2	
Vomiting	0	3	
No	43	46	

Statistical significance was set at p < 0.05.

Abbreviations: ONS, oral nutritional supplement; PG-SGA, patient-generated subjective global assessments.

†Two independent samples t-test.; ‡Fisher's exact test.; \$Mann-Whitney U test.; \*p < 0.05.

**TABLE 5** Binary logistic regression of factors influencing ONS compliance

			95% CI			
Variable	В	OR	Lower	Upper	р	
Educational level						
Primary school or below		r				
Junior high school	0.613	1.846	0.537	6.345	0.330	
High school	0.323	1.382	0.388	4.923	0.616	
College or university	1.276	3.582	0.733	17.507	0.115	
Household per capita monthly	income					
<1000		r				
1001-3000	1.195	3.310	0.772	14.187	0.107	
3001-5000	2.237	9.364	1.986	44.164	0.005*	
>5000	1.187	3.278	0.417	25.683	0.259	
Caregivers						
The patient himself		r				
Children or spouse	0.642	1.900	0.322	11.227	0.479	
Both children and spouses	2.019	7.527	1.094	51.806	0.040*	
Adverse reactions to ONS						
No		r				
Yes	-1.212	0.298	0.100	0.887	0.030*	
Baseline weight	0.013	1.013	0.933	1.100	0.759	
Baseline BMI	-0.089	0.915	0.691	1.212	0.535	
Baseline PG-SGA	0.078	1.081	0.979	1.195	0.125	

Statistical significance was set at p < 0.05. \*p < 0.05.

Abbreviations: ONS, oral nutritional supplement; PG-SGA, patient-generated subjective global assessments; *r*, reference.

A wardmate who shared a ward with us drank a little at the beginning, and then she didn't drink it; she has dropped 10 kg now. Fortunately, I have been taking it, so I did not undergo weight loss. (01).

# 4.3.2 | Adverse reactions discourage patients from continuing to take ONS

ONS, as an oral enteral nutritional supplement, may cause adverse reactions such as nausea, vomiting, abdominal distension and diarrhoea. Patients usually stop taking ONS because of the adverse reactions.

I have diarrhoea approximately 30 minutes after drinking it. I drank it for a while when I was hospitalized, but when I was discharged home, I did not. (15)

A while ago, I felt sick after drinking it (ONS) and then vomited. I didn't dare to drink it anymore. I thought, I don't eat much at ordinary times and I vomited out like this, which is definitely not good for my body, so I thought I would stop drinking it. (09).

I feel uncomfortable after drinking it, and I feel bloated. Fortunately, I drank less and felt better. (01)

TABLE 6 Participant characteristics for semi-structured interviews

Participant ID	Gender	Age	Average compliance (%)	Group	Education level	Household per capita monthly income (¥)
01	Male	47	31.7	Н	Primary school or below	3001-5000
02	Female	48	71.5	Н	Junior high school	1001-3000
03	Male	68	18.8	L	Junior high school	1001-3000
04	Male	43	8.0	L	Junior high school	1001-3000
05	Male	65	100	Н	College or university	3001-5000
06	Female	41	74.2	Н	College or university	3001-5000
07	Female	47	11.0	L	College or university	3001-5000
08	Male	55	16.5	L	Junior high school	<1000
09	Female	51	93.8	Н	College or university	>5000
10	Female	41	5.3	L	College or university	3001-5000
11	Female	50	3.8	L	Junior high school	<1000
12	Male	64	49.1	Н	Junior high school	3001-5000
13	Male	51	85.4	Н	Primary school or below	1001-3000
14	Male	67	81.3	Н	High school	3001-5000
15	Male	43	24.2	L	Junior high school	>5000

# 4.3.3 | Patient attitudes affect their motivation to take ONS

During the interviews, we found that different attitudes of patients can affect their motivation to take ONS. For example, patients' evaluation of their own health status affects their motivation to take ONS.

After the operation, I felt scared because I could not eat anything, and I lost weight repeatedly.... I do not have a stomach and I cannot absorb nutrients... This disease absorbs nutrients from my body. I am afraid of death, so I have been taking ONS. (02).

I always felt that I was in good health before and after the operation, and I have not considered supplementing nutrition through other channels, so I feel that it is not necessary to drink ONS. (15).

We found that patients' attitudes towards the performance of ONS affected their feelings about it. Although some patients took ONS, no effect was found in the short term, so their belief in its usefulness decreased.

I feel that drinking it cannot solve any problems, and it does not seem to help me... I do not think this thing is very helpful to the disease, and I have not gained weight. (14)

During the interviews, we found that patients' different attitudes towards tonics affected their compliance with ONS. Some patients thought that some tonics were more effective than taking ONS. This may be due to deep-rooted traditional Chinese concepts.

When I feel that I eat less, I want to eat some sea cucumber... I don't feel that the nutrient powder has a high nutritional content and is not as nutritious as sea cucumber. (12).

Different attitudes of patients towards their doctors' orders affected their motivation to take ONS. Patients with a high level of education followed doctors' orders and nurses' health education, while those with a low level of education did the opposite.

Since the doctors and nurses recommended drinking this (ONS), then I would drink this. I feel that my body can't quickly recover with tonics. It should be done gradually. Now, using supplements such as ginseng, I am afraid that the effect will be counterproductive and may not be good for the recovery of the stomach. (09, College or university).

After going home, I drank it (ONS) for about a month. The doctor asked me to drink 18 spoons a day. I did not think it was necessary, and I only drank five spoons a day. After I drank all the cans I brought home from the hospital, I stopped taking it. (03, Junior high school).

Three tablespoons of ONS in 100 ml of water...I did not like the smell. I drank it in a hurry. (15, Junior high school)

# 4.3.4 | The different needs of patient for ONS affect patient compliance

We found that patients' demand for ONS products affected their compliance with ONS. For example, if patients were dissatisfied with the flavour, texture, packaging or price of ONS, their compliance with ONS was reduced.

I was thinking about changing the (ONS) flavour to vanilla or chocolate. I feel very happy to eat sweets. (06)

I think the flavour should be changed slightly and its capacity should be reduced because this is so selective. For example, I can buy two small cans of different flavours so that I can intersperse and drink, and maybe I can continue to stick to it. (07).

Although they have the same energy, I feel that what I eat has more energy than what I drink. For example, if you make a small bread and a bag of milk, they have the same energy, and I think bread can relieve hunger even more. (12).

This is definitely a burden to my family. My husband has had a cerebral infarction for 6 years, and there is no source of income at home.... (11)

Chemotherapy, as an important adjuvant treatment after gastric cancer surgery, can affect the patient's normal taste while suppressing tumour cells. The feelings of such patients cannot be ignored:

At that time, when I first drank it, I felt it was okay, but then I felt it like pine oil, and I could not swallow it. (04)

It tastes like rust, do you understand this? (06)

In contrast, patients with good compliance indicated that they could accept the taste, price and texture of ONS.

I think this (ONS) is easy to digest, and the taste is relatively popular. We generally accept it, and I also like the taste. (05)

For me, the economy has no impact, and this thing is not that expensive. (12)

I feel that its most prominent advantage is that it is easy to digest, and it does not need to be chewed; just drink it directly. (05)

## 5 | DISCUSSION

In this study, an explanatory sequential mixed-method study was used to explore the factors that facilitate and hinder the compliance of patients with gastric cancer after surgery. The results of quantitative research showed that the compliance of patients with gastric cancer with ONS decreased over time, and compliance was at a very low level at the end of 12 weeks (16.9%). The average overall compliance rate was 30.59%. The level of compliance significantly affected the weight loss of patients. High ONS compliance seems to be able to maintain stable body weight and BMI, but low adherence can cause weight and BMI to decrease significantly. We found that adverse reactions, the identity of the main caregivers, and financial ability were independent factors that affected patients' compliance with ONS. In subsequent interviews, we extracted four themes: social support plays an important role in patients taking ONS, adverse reactions discourage patients from continuing to take ONS, patients' attitudes affect their motivation to take ONS and the different needs of patient for ONS affect patient compliance.

Weight loss reduces the quality of life, increases chemotherapy compliance and reduces the survival rate of gastric cancer patients (Aoyama et al., 2013; Climent et al., 2017; Yu et al., 2002). Our study found that patients' high compliance with ONS could effectively prevent weight loss. However, in a study by Seong et al., patients' compliance with ONS was at a high level (80% of patients' adherence was >50%), but this did not prevent weight loss in patients (Kong et al., 2017). In this study, high compliance may have been related to the short intervention time (8 weeks), and ONS may not have had a significant effect on body weight in this short time. Studies by Sultan et al. and Kobayashi et al. have confirmed this point (Kobayashi et al.. 2017; Sultan et al., 2012). In their studies, the intervention time was 12 weeks, and the effect of ONS on weight loss was significantly different, which is consistent with the results of our study. If ONS has a significant impact on the weight of patients, patients need to continue to take ONS for a long time.

Poor nutritional status of patients increases the incidence of infections and increases the 30-day readmission rate (Dan et al., 2019; Kato et al., 2016; Zhou et al., 2017). In our study, patients' high ONS compliance was not related to postoperative infection complications or the 30-day readmission rate, which may be related to the use of intact protein-based ONS rather than immunonutrition in our study. The studies of Marano et al. and Banerjee et al. confirm our point (Banerjee et al., 2017; Marano et al., 2013). These studies found that immunonutrition can reduce postoperative infection complications and the 30-day readmission rate. However, immunonutrition does not significantly improve the patient's long-term nutritional status (Wan et al., 2020). At the same time, it has the disadvantages of poor taste and high price, so it is not suitable for long-term use (Wan et al., 2020). The taste of intact protein-based ONS is better than that of immunonutrition, the price is relatively low, and it is more suitable for long-term use to improve the nutritional status of patients (Hatao et al., 2017; Kobayashi et al., 2017). Therefore, whether

immunonutrition and intact protein-based ONS should be used in different time periods after surgery is worthy of consideration.

In our study, the adverse effects of ONS included diarrhoea, bloating, nausea and vomiting. Klang et al. noted that the osmotic load of enteral nutrition can cause diarrhoea (Klang et al., 2013). Our interviews found that the patients who took ONS too guickly had diarrhoea, as patients did not like the taste of ONS products. ONS has a high energy density if it enters the intestinal tract at a rapid rate and can cause osmotic load and diarrhoea. With regard to health education, medical staff should pay attention to the management and prevention of adverse reactions and let patients slowly sip ONS to prevent diarrhoea (Parenteral and Enteral Nutrition Branch of Chinese Medical Association, 2017). As discussed in the study by Marušić et al. (2018) adding the prevention and early detection of adverse drug reactions to health education can improve patients' compliance with drugs. As a common adverse reaction of intact protein-based ONS, bloating was the second most common adverse reaction in this study. The reason may be that intact protein-based ONS contains dietary fibre (Wang, 2017). Dietary fibre cannot be digested and absorbed in the small intestine but can be partially fermented in the large intestine, and patients with weak intestinal function cannot easily expel the gas produced by bacterial decomposition, which can cause abdominal distension (Nakao et al., 2002). A recent study has shown that short peptide enteral nutrition can reduce bloating compared with whole protein preparations, so patients with poor digestion can choose short peptide-based ONS or intact protein-based ONS that do not contain cellulose (Huang et al., 2020).

In the interviews in this study, many participants mentioned that the flavour made it difficult for them to accept ONS, and they had different requirements for the flavour of ONS; this finding is consistent with other quantitative studies (Hogan et al., 2019; Lidoriki et al., 2020; Sørensen et al., 2003). Studies have shown that the sense of taste decreases with age, with an increased demand for sweetness (Mojet et al., 2001). In our study, the taste of the ONS products was slightly sweet, and some elderly people may have stopped taking ONS because of its poor taste. The texture of ONS also affects patient compliance. Liquid food does not need to be chewed, but the gastric emptying speed of liquid food is higher than that of solid food (Almiron-Roig et al., 2003). Liquid ONS lacks the experience of chewing before swallowing, which reduces the satisfaction of food intake (He et al., 2017). It may be necessary to produce more textured and flavoured ONS products and let patients choose their favourite flavour and texture. The income of patients is also an independent influencing factor of ONS compliance, so the impact of ONS price on patients' ONS compliance cannot be ignored. The reimbursement ratio of medical insurance could be expanded, or the process could be improved to reduce the production cost and price of ONS preparations. It is worth noting that in our study, the convenience of using ONS was an important factor that affected compliance. It would therefore be a wise choice for manufacturers to produce ONS in small packages.

Our research results provide an important reference for the establishment and revision of health education strategies for patients after gastric cancer surgery. First, the harms of malnutrition should be emphasized in the health education of postoperative gastric patients. In the quantitative phase, we found an interesting point: patients in group L had a higher body weight, BMI, and PG-SGA at baseline than those in group H (Table 4). It can be inferred that better nutritional status before surgery seems to reduce patients' compliance with ONS. The interviews seemed to support this: although every patient in our study suffered from malnutrition, there was a large gap in patients' perception of their own nutritional status. Patients who thought they were well-nourished felt that it was unnecessary to take ONS. This finding suggests the need to emphasize the harms of malnutrition in daily health education to attract patients' attention. Second, it is necessary to strengthen health education for caregivers of patients. Our research found that family members play a large role in whether patients take ONS, which suggests that we should attach importance to the education of patients' family members, improve their awareness of ONS, and encourage them to actively participate in patients' dietary care. As in the study by Santos al., family participation care should be vigorously advocated to improve patients' drug compliance (de Lima Santos & Silva Marcon, 2014). Third, peer-participatory health education seems to be effective. In our interviews, the patients mentioned that the ONS tasted bad during chemotherapy. However, we did not find a significant difference in chemotherapy between the H and L groups. Four to six weeks after surgery is the peak period of chemotherapy (Crookes et al., 1997; Sasako et al., 2011), but in the quantitative phase of our study, many patients chose to restart ONS 5-6 weeks after surgery (Figure 4). Peer support seems to explain these contradictions. As the patient with code 2 mentioned in the interview, her wardmate's encouragement during chemotherapy made her start taking ONS again. Studies by Fusfeld et al. and Jessop et al. showed that obtaining peer support and spiritual care has a decisive effect on adherence to drug treatment (Fusfeld et al., 2013; Jessop et al., 2004). Therefore, patients should be closely followed up in the first five weeks, when the number of patients who stop ONS increases sharply, and patients with good compliance should be encouraged to share their experiences in group chat.

## 6 | LIMITATIONS

The quantitative part of this study was one-armed rather than a randomized controlled trial. In this study, the patients' health education did not specifically emphasize the prevention and identification of ONS adverse reactions, which may affect patient compliance with ONS. This study was conducted in a hospital in north-eastern China, and compliance with ONS may be affected by national conditions. Because COVID-19 patients are isolated at home, we could not ask all patients to return to the hospital to check blood nutrition indicators and evaluate the PG-SGA. Furthermore, this study used only weight and BMI to measure the postoperative nutritional status of patients, which may have certain limitations.

# 7 | CONCLUSIONS

Our research shows that the compliance of patients after gastric cancer surgery with ONS is at a very low level, and the level of compliance affects the weight loss of patients after surgery. Patients' economic income, caregivers and adverse reactions are independent factors that affect ONS compliance. Health education should pay more attention to the management of ONS adverse reactions, encourage patients to communicate their experiences, and encourage patients' families to participate in their daily diet care. In addition, ONS products should be diversified to provide patients with more choices, and it is advisable to produce ONS in smaller packages.

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#### **CONFLICTS OF INTEREST**

The authors declare no conflict of interest

#### **AUTHOR CONTRIBUTIONS**

GYW, XYZ, HYH: Made substantial contributions to conception and design, or acquisition of data, or analysis and interpretation of data; GYW, HY, HX: Involved in drafting the manuscript or revising it critically for important intellectual content; GYW, HY, HX, HQL, XYZ, HYH: Given final approval of the version to be published. Each author should have participated sufficiently in the work to take public responsibility for appropriate portions of the content; XYZ, HY, GYW: Agreed to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

## PEER REVIEW

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### SUPPORTING INFORMATION

Additional supporting information may be found online in the Supporting Information section.

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