

Evaluation of health-related quality of life and performance in intestinal transplant and rehabilitation patients: a cross-sectional study

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Purpose: We aimed to evaluate health-related quality of life (HRQoL) in intestinal failure (IF) patients after different modes of intestinal rehabilitation.

Methods: HRQoL was assessed using the generic 36-item Short Form Survey (SF-36, ver. 2) and visual analogue scale (VAS) in 6 different areas: diet, sleep, gastrointestinal (GI) symptoms, diarrhea, musculoskeletal pain, and other symptoms.

Results: Twenty-two patients completed the questionnaires, of which 7 had received intestinal transplant (ITx), 9 were continuing home total parenteral nutrition (HPN), and 6 had tapered off total parenteral nutrition (TPN). SF-36 physical component summary scores were highest in the ITx group (median, 65.6; interquartile range [IQR], 31.6–80.3) compared to the HPN (median, 48.4; IQR, 44.7–66.3) or tapered group (median, 54.2; IQR, 45.2–61.6). Mental component summary scores were lowest in the ITx group (median, 48.8; IQR, 37.1–63.6), compared to the TPN (median, 60.2; IQR, 41.6–78.5) or tapered group (median, 51.0; IQR, 48.8–56.0). Differences were not significant in all items of the SF-36. VAS scores showed that patients in the ITx group showed the best results in diet (0.9), gastrointestinal (GI) symptoms (1.4), and musculoskeletal pain (2.4). There was a significant difference in sleep ($P = 0.036$), with the ITx (1.43) and HPN groups (1.33) showing better outcomes compared with the tapered group (4.67). Patients in the tapered group showed the least favorable results in all performance areas, except GI symptoms.

Conclusion: SF-36 did not show a significant difference between the ITx, HPN, and tapered groups, but VAS showed a significant difference in sleep between groups. Further studies, including serial data, will allow a better understanding of the effects of different modes of intestinal rehabilitation.

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INTRODUCTION

Intestinal failure (IF) refers to actual or impending loss of nutritional autonomy caused by bowel dysfunction [1]. IF can be caused by short bowel syndrome (SBS), motility disorders, or extensive mucosal disease, and total parenteral nutrition (TPN) is usually required for nutritional support [2]. While some patients require only temporary parenteral nutrition during which the remaining intestine can adapt, other patients may not succeed in complete adaptation and require lifelong TPN. The success of this process is unpredictable, and long-term TPN may be necessary if oral nutrition results in unacceptable diarrhea or stoma output [3,4]. Patients who ultimately fail to achieve intestinal autonomy will require intestinal transplantation (ITx), depending on the progress of their adaptation to TPN, nutritional status, or development of life-threatening complications [1].

As the management of IF has improved over time, the long-term survival of these IF patients has shown a general improvement. Due to improvements in TPN and catheter management, patients can stay on TPN longer without developing serious complications, and improvements in transplantation (Tx) protocols have led to better long-term survival after ITx. In the past, the indication for ITx has been due to a lack of suitable venous access after recurrent complications of TPN, such as catheter-related infection, liver failure due to TPN, or dehydration despite intravenous fluid supplementation. However, as patients' autonomy has become more important over time, candidacy for ITx is being evaluated on a case-by-case basis for adult patients, and as a result, the evaluation of quality of life (QoL) has become an important aspect in considering ITx [5].

QoL is defined by the World Health Organization as a subjective mindset related to physical, mental, and social well-being and not merely the absence of disease [6]. IF itself is a debilitating condition, and the resultant central TPN or ITx can also severely limit patients' daily activities. Various studies have aimed to evaluate the health-related QoL (HRQoL) of these patients. Since the early 2000s, studies using generic QoL evaluation tools to compare the outcomes between IF patients undergoing home parenteral nutrition (HPN) and ITx have been conducted [7-10]. Some studies have used a newly developed condition-specific tool to assess the QoL related to specific symptoms of SBS and added specific questions related to central TPN to make a better assessment of HRQoL in IF patients [7,11]. The dataset regarding HRQoL of IF patients is still quite small due to the limited number of patients, but it has expanded in recent years.

Despite ongoing studies, ITx has globally decreased in number over the past decade, from 270 during the peak year of 2008 to 89 in 2022 [12]. ITx and related clinical activity

are largely centered in North America and Europe [13], and consequently, most studies on IF patients have been based on data from these countries. To date, there are no studies regarding the QoL of IF patients in Korea, particularly including ITx patients. The purpose of our study was to capture the status of HRQoL in ITx patients in Korea and compare the results with IF patients undergoing different modes of intestinal rehabilitation.

METHODS

Comparative analysis was done using prospectively collected HRQoL data from patients undergoing regular follow-up at The Catholic University of Korea, Seoul St. Mary's Hospital due to IF. HRQoL data was collected between June 2023 and August 2023, using a self-rated questionnaire. Each patient completed a survey using paper questionnaires, which were completed in person during each patient's recent regular outpatient visit. The results of the questionnaires were manually input into the electronic database. The baseline clinical characteristics of the patients were retrospectively collected from our electronic medical records.

This study was approved by the Institutional Review Board of The Catholic University of Korea, Seoul St. Mary's Hospital (No. KC22QISI0942), which waived the requirement for informed consent.

The patients were categorized into 3 groups according to their current intestinal rehabilitation method: patients who have received ITx were classified as the 'ITx group,' patients continuing on home TPN were termed the 'HPN group,' and those who had received intermittent TPN in the past but had tapered off completely were categorized as the 'tapered group.' Inclusion criteria were (1) age over 18 years, and (2) patients whose last outpatient follow-up visit was within one year. Exclusion criteria were (1) patients under 18 years, (2) patients who have not been followed up within the last year, and (3) refusal to participate or not completing the questionnaire for any reason.

Health-related quality of life assessment

Our questionnaire was composed of 2 parts, the generic 36-item Short Form Survey (SF-36, ver. 2) and 6 additional condition-specific questions using the visual analogue scale (VAS). The details of the questionnaires that were used in our study are shown in Supplementary Materials 1 and 2. Each patient filled in the questionnaire in a quiet setting during a routine follow-up visit after informed consent was obtained.

The SF-36 is a validated survey that is widely used for disease-related QoL studies [14]. This survey is composed of 36 questions evaluating 8 areas of HRQoL: physical function (PF), physical role limitations (RP), bodily pain (BP), general medical

health (GH), vitality (VT), social functioning (SF), emotional role limitation (RE), and mental health (MH). The first 4 items are summarized into a physical component summary score, and the latter 4 are calculated to grade the mental component summary score. Scores for each item range from 0, being the worst condition, to 100, being the best possible condition.

The VAS is a commonly used 10-point scale to rate pain or discomfort, in which 0 indicates the best possible condition with no discomfort at all, and 10 refers to the worst state of QoL to a degree that can be associated with death. Facial expressions that match each score are also presented to help patients understand the degree of discomfort that correlates with each score. The VAS was used to evaluate QoL in 6 important aspects of daily HRQoL in an IF patient: diet, sleep, gastrointestinal (GI) symptoms, diarrhea, musculoskeletal pain, and other symptoms causing discomfort.

Statistical analysis

Analysis was carried out using IBM SPSS ver. 25.0 software (IBM Corp.). Statistical hypotheses used two-tailed, unpaired Student t-test or one-way analysis of variance (ANOVA) with Bonferroni correction for multiple comparisons. Unless otherwise specified, all data are displayed as mean \pm standard deviation.

RESULTS

Twenty-two patients met the inclusion criteria and completed the questionnaires. Seven patients were classified as the ITx group, 9 were in the HPN group, and 6 patients were included in the tapered group. The demographic details of the study cohort are summarized in Table 1. The mean age of the patients was 50.6 ± 15.1 years with a mean follow-up period of 126 ± 68.2

Table 1. Background characteristics of study patients

Characteristic	Group			P-value
	Transplant	Home TPN	Tapered off	
No. of patients	7	9	6	
Sex				0.500
Male	4 (57.1)	5 (55.6)	5 (83.3)	
Female	3 (42.9)	4 (44.4)	1 (16.7)	
Age (yr)	57.4 \pm 16.0	46.6 \pm 11.6	48.8 \pm 18.3	0.356
Age at SBS diagnosis (yr)	46.1 \pm 14.7	38.0 \pm 11.6	38.2 \pm 17.2	0.477
Follow-up (mo)	142.0 \pm 71.1	107.2 \pm 51.4	136.7 \pm 90.1	0.568
Cause of SBS				0.201
Vessel occlusion	4 (57.1)	2 (22.2)	2 (33.3)	
Adhesive ileus	1 (14.3)	1 (11.1)	4 (66.7)	
Trauma	1 (14.3)	1 (11.1)	0 (0)	
Strangulation	0 (0)	3 (33.3)	0 (0)	
Bowel perforation	0 (0)	1 (11.1)	0 (0)	
Desmoid tumor	1 (14.3)	1 (11.1)	0 (0)	
Remnant SB length (cm)	20.7 \pm 21.5	21.0 \pm 17.2	45.8 \pm 11.1	0.028
Remnant colon (%)	41.7 \pm 32.9	64.3 \pm 23.1	80.3 \pm 21.1	0.047
Initial stoma type				0.112
None	0 (0)	4 (44.4)	4 (66.7)	
Jejunostomy	6 (85.7)	4 (44.4)	1 (16.7)	
Colostomy	0 (0)	0 (0)	1 (16.7)	
Duodenostomy	1 (14.3)	1 (11.1)	0 (0)	
Remnant ileocecal valve				0.275
No	7 (100)	7 (77.8)	4 (66.7)	
Yes	0 (0)	2 (22.2)	2 (33.3)	
Previous STEP operation				0.180
No	5 (71.4)	9 (100)	4 (66.7)	
Yes	2 (28.6)	0 (0)	2 (33.3)	
Body mass index (kg/m ²)				
Initial	19.7 \pm 2.9	19.0 \pm 3.0	19.5 \pm 3.6	0.898
Current	19.4 \pm 2.5	21.7 \pm 2.1	19.6 \pm 2.7	0.134
TPN duration (mo)	33.1 \pm 28.2	91.6 \pm 46.5	16.3 \pm 10.5	0.001

Values are presented as number only, number (%), or mean \pm standard deviation.

TPN, total parenteral nutrition; SBS, short bowel syndrome; SB, small bowel; STEP, serial transverse enteroplasty procedure.

months. None of the patients had remaining stomas at the time of the last follow-up. The mean duration of TPN was 91.6 ± 46.5 months in the home TPN group, 33.1 ± 28.2 months in the ITx group, and 16.3 ± 10.5 months in the tapered group ($P = 0.001$). Otherwise, there were no significant differences in baseline characteristics between the 3 patient groups.

36-Item Short Form Survey

Fig. 1 shows the results of each component of the SF-36 in the 3 study groups. Results are presented as median and interquartile range (IQR), and a higher score indicates a better status on each of the items (minimum 0, maximum 100).

The SF-36 physical component summary scores were higher in the ITx group (median, 65.6; IQR, 31.6–80.3) compared to the HPN group (median, 48.4; IQR, 44.7–66.3) and the tapered group (median, 54.2; IQR, 45.2–61.6). However, the differences were not statistically significant ($P = 0.999$). Median scores for bodily pain and general medical health were numerically highest in the ITx group compared to the HPN and tapered groups but without statistical significance.

In contrast, the mental component summary scores were lowest in the ITx group (median, 48.8; IQR, 37.1–63.6), compared to the TPN group (median, 60.2; IQR, 41.6–78.5) and the tapered group (median, 51.0; IQR, 48.8–56.0). However,

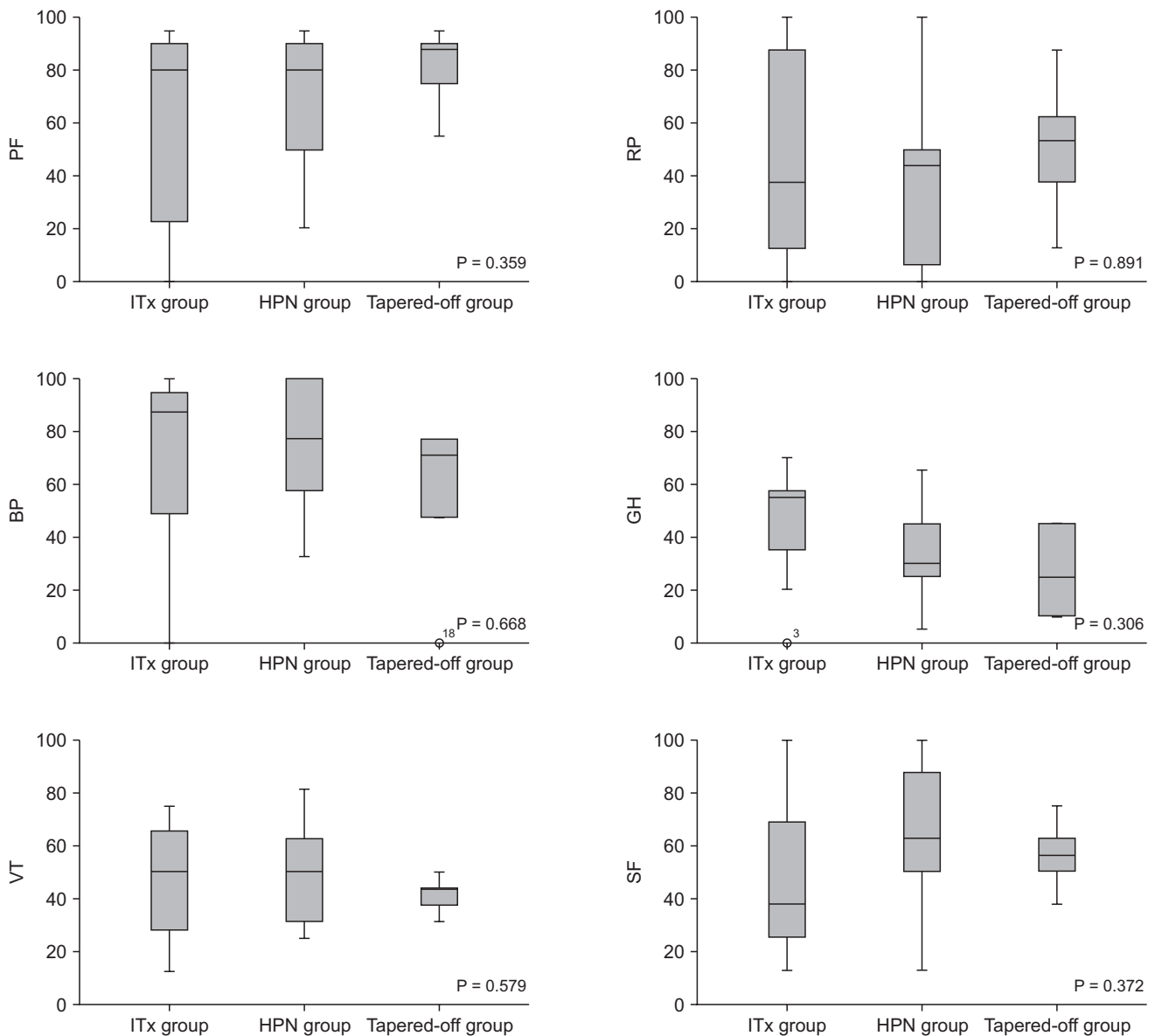


Fig. 1. Health-related quality of life measured by 36-item Short Form Survey (SF-36, ver. 2) in intestinal transplant (ITx), home total parenteral nutrition (HPN), and tapered-off groups. PF, physical function; RP, physical role limitations; BP, bodily pain; GH, general medical health; VT, vitality; SF, social functioning; RE, emotional role limitation; MH, mental health; PCS, physical component summary; MCS, mental component summary.

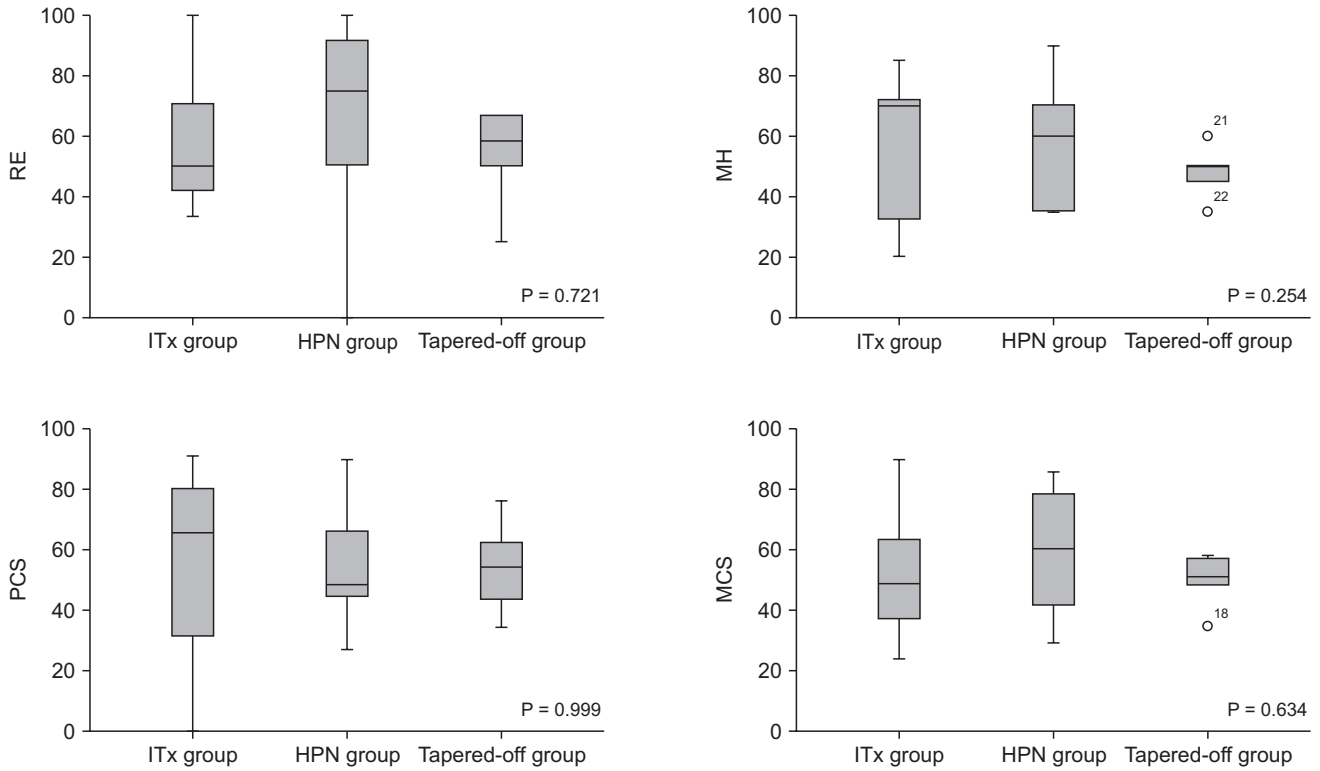


Fig. 1. Continued.

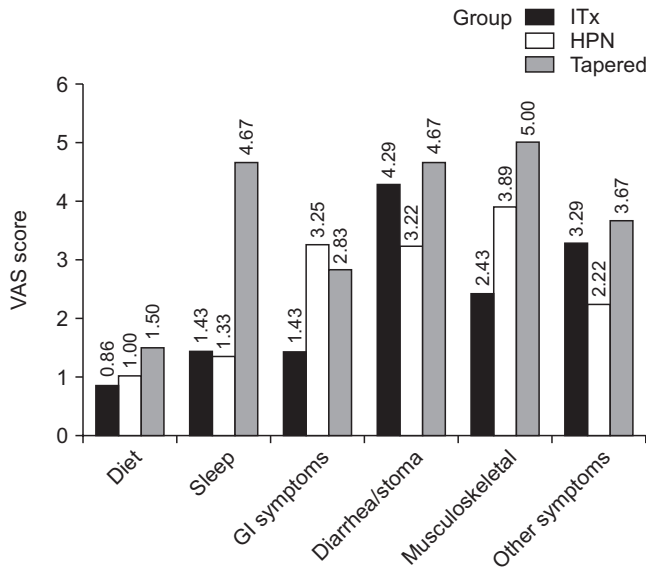


Fig. 2. Health-related quality of life assessment in 6 areas based on visual analogue scale (VAS). GI, gastrointestinal.

this difference also did not show a statistically significant intergroup difference ($P = 0.634$). Scores for social functioning and emotional role limitation were also lowest in the ITx group. While numerically, ITx patients showed higher scores in self-assessed physical health and lower mental health-related scores compared to IF patients currently on HPN or tapered-off TPN,

ANOVA showed no statistically significant difference between the 3 groups in all items of evaluation.

Visual analogue scale score

Fig. 2 summarizes the results of the VAS survey for each group. A lower score indicates a lower degree of difficulty or pain in each of the items. Patients in the ITx group showed the lowest scores in diet (0.9), GI symptoms (1.4), and musculoskeletal pain (2.4), demonstrating the lowest scores overall. Patients in the tapered group showed the least favorable results in all performance areas, except for GI symptoms. ANOVA showed a statistically significant intergroup difference in sleep ($P = 0.036$), with the ITx group (1.43) and HPN group (1.33) showing significantly better outcomes compared with the tapered group (4.67). In other items, the difference was not statistically significant.

DISCUSSION

In patients who need lifelong TPN, HPN is the primary treatment for irreversible IF, and ITx is the life-saving treatment for those patients who are at risk of death because of life-threatening complications of HPN or underlying nonmalignant GI diseases [15].

Data from the International Transplant Registry reports 4,709 adult and pediatric ITx patients up to 2023 worldwide [12].

However, the number of ITx and clinical activity is centered in North America and Europe and remains very low in Asian countries [16]. Currently, The Catholic University of Korea is the only tertiary center involved in ITx in Korea. The first ITx in Korea was performed in 2004 for a 56-year-old woman with mesenteric thrombosis who received an intestinal graft from her 27-year-old daughter at The Catholic University of Korea, Seoul St. Mary's Hospital [17,18]. As of 2023, a total of 26 ITx (isolated ITx, 23; multivisceral Tx, 2; modified multivisceral Tx, 1) have been performed in Korea. Of these, 18 (isolated ITx, 17; modified multivisceral Tx, 1) were conducted at Seoul St. Mary's Hospital. There were 13 adult (≥ 18 years) and 5 pediatric (< 18 years) recipients. Indications for Tx in these patients were as follows: SBS resulting from mesenteric vessel thrombosis ($n = 5$), strangulation because of internal hernia/midgut volvulus ($n = 3$), necrotizing enterocolitis ($n = 1$), trauma ($n = 1$), and mesenteric lymphangiectasia ($n = 1$); dysmotility disorder, including chronic intestinal pseudo-obstruction with myopathy ($n = 3$) and Hirschsprung's disease ($n = 2$); and GI stromal tumor ($n = 2$).

Since ITx is not a common option in Korea, the only choice for many SBS patients is to continue on lifelong HPN. Previous studies have reported an improved state of HRQoL in ITx recipients compared with IF patients [19]. Many studies on the QoL in IF patients on long-term or permanent TPN have reported a severe impairment in QoL compared to the general population [20-23]. A study by Jeppesen et al. [24] mentioned that HRQoL in permanent HPN patients was comparable to renal failure patients undergoing hemodialysis. In IF patients with severe malnutrition, HPN has been associated with improved HRQoL, but no comparison of QoL in HPN patients and ITx patients has been reported.

Contrary to results from previous studies, we found that the HPN group did not show a significantly reduced QoL compared to the ITx group. Despite central catheterization, social functioning, emotional role limitation, and mental component summary showed the highest scores in the HPN group. Contrary to our expectations, this reflects that improved TPN protocols, vein access care, and patient education on TPN have led to significant improvements in the QoL in HPN patients. We try to minimize the time of TPN infusion by using cyclic TPN and checking the status of the central vein access to prevent infection or thrombosis. Also, TPN is infused using a portable infusion pump, which minimizes the patients' daily activities and may have contributed to the favorable mental health scores in the HPN group. We believe that these efforts may have contributed to the high HRQoL and mental health scores of the HPN patients.

Although some patients were able to completely taper off TPN due to stable nutritional status after intestinal adaptation, this did not always lead to higher levels of HRQoL. The tapered

group showed the lowest scores in general medical health and vitality. Additionally, the tapered group showed the worst scores in 4 of the 6 areas rated with VAS (sleep, diarrhea, musculoskeletal pain, and others). These findings imply that even when TPN can be tapered off, lifelong routine follow-up and timely management are necessary for the HRQoL of patients.

QoL has been an important issue in studies involving IF patients. The first study addressing HRQoL in IF patients was published in 1998, which showed an improvement in HRQoL after ITx using a specifically designed QoL instrument to evaluate various physical and mental aspects in HPN patients and ITx patients [19]. Several other studies have implemented the SF-36 to compare the HRQoL in small study groups. A study published in 2006 by Pironi et al. [25] compared HPN and ITx patient groups using the generic SF-36, which showed that physical components had lower values while mental health components had a higher score in ITx groups. Another study evaluated the QoL of IF patients before and after ITx, using the SF-36, VAS, and Karnofsky scale to evaluate the performance status, which did not show a significant interval change during follow-up [26]. Other studies also evaluated ITx patients' HRQoL using other QoL instruments such as EuroQol 5-level EQ-5D (EQ-5D-5L), condition-specific HPN-QoL/ITx-QoL, and a modified version of the HPN-QoL focused on the impact of SBS (SBS-QoL) [11,27,28].

Since the aforementioned generic tools failed to show a significant change in QoL over time in ITx groups, efforts to develop a disease-specific instrument that can effectively analyze the aspects that impact patients' QoL have been made [7,28,29]. Berghöfer et al. [28] first developed and validated the SBS-QoL which evaluated 17 items covering general physical health, mental status, and daily social activities. Lloyd et al. [29] used the SBS-QoL results to determine a subset of items that reflected the actual health status of SBS patients and designed a scoring algorithm that can help estimate the health status of patients.

Although these studies report that the SBS-QoL was better than generic tools in evaluating the HRQoL of SBS patients, from our experience, many of the older patients had difficulty completing the questionnaire because of its length, involving 49 detailed questions. Also, the changes in recall intervals of the group of questions and changes in scale (1 to 4, 1 to 10, -5 to +5) were confusing for some patients. Therefore, we applied the generic SF-36 and added 6 simple disease-specific items that could be evaluated using the VAS. Further studies should be conducted to develop a QoL evaluation tool suited for Korean SBS patients.

While several studies have been done regarding self-evaluated HRQoL, data on IF patients' nutritional outcomes, such as micronutrient levels, BMI, and body composition, have

not been reported. There have been some studies reporting the clinical outcomes comparing the nutritional status of ITx and TPN patients [8-10], but no studies have comprehensively described the nutritional outcomes alongside the results of HRQoL. Further studies, including sequential follow-up data on HRQoL and the nutritional outcomes, may provide a more comprehensive understanding of the general outcomes of chronic IF patients.

The strengths of the study are that this is the first attempt to evaluate the HRQoL of IF patients in Korea after ITx or TPN. The consistency of the treatment protocol, etiology, and ethnicity in our study group helps to obtain a better understanding of the long-term outcome of SBS patients in actual clinical settings. Although the case volumes are small due to the scarcity of the condition, good compliance of our patients has helped in collecting detailed data. Since 2004, Seoul St. Mary's Hospital has pioneered the successful implementation of ITx and care for IF patients in Korea. The majority of IF patients are being referred to our center, and our data is representative of the Korean IF patient population. The survival rates of these patients are increasing over time, which will lead to increased data and a better understanding of Korean SBS patients in the future.

There are some limitations in our study. We only collected the HRQoL data once, and since we do not perform ITx regularly, it was impossible to collect data in the same post-treatment intervals. The indications for ITx have changed over time, and since the small study group has been followed up for a long period, some patients have switched between treatment options, which may have caused some bias. Since this is our initial attempt at evaluating self-evaluated QoL, we hope that this data may provide a baseline for further longitudinal studies. Also, a comparison of pre- and post-treatment may be done for future ITx patients, based on this study's methods.

In conclusion, the SF-36 did not show a significant difference between the ITx, HPN, and tapered groups, but the VAS showed a statistically significant difference in sleep between the 3 patient groups. Also, we found that tapering off TPN did not

show a significant improvement in physical or mental HRQoL, supporting a need for these patients to continue regular follow-up after discontinuing TPN. Further studies, including serial follow-up data, will allow for a better understanding of the effects of different modes of intestinal rehabilitation.

SUPPLEMENTARY MATERIALS

Supplementary Materials 1 and 2 can be found via <https://doi.org/10.4174/ast.2025.108.1.31>.

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Conflict of Interest

Jeong-kye Hwang, serving as the editor board of *Annals of Surgical Treatment and Research*, did not participate in the review process of this article. No other potential conflicts of interest pertinent to this article were reported.

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