

Management of Home Parenteral Nutrition: A Prospective Multicenter Observational Study

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Key Words

Home parenteral nutrition · Patient characteristics · Underlying disease · Quality of life · Complications

Abstract

Background: There are no specific Swiss home parenteral nutrition (HPN) data showing patient characteristics, quality of life (QoL) and complications. The goal of this study was to collect representative nationwide data on current adult HPN patients in Switzerland for international comparability and benchmarking. **Methods:** This was a multicenter, nationwide, observational study. We conducted interviews for demographics, PN characteristics, QoL and complications. The data were assessed at baseline and after a follow-up of 3 months using a questionnaire. **Results:** Thirty-three adult patients were included. The most common underlying diseases were cancer, radiation enteritis and state after bariatric surgery, and the most prevalent indication was short bowel syndrome. During the 3-month observation period, significant increase or stabilization of body weight occurred in the patients, physical activity scores improved from 34.0 to 39.4 and mental scores improved from 41.9 to 46.4. HPN dependency and traveling restrictions were of the greatest concern. Diarrhea, xerostomia and/or thirst were frequent com-

plaints. **Conclusion:** Anthropometric parameters and QoL improved during the observational period in this HPN cohort. These Swiss HPN data are prerequisite for evaluation and comparison of HPN recommendations and best clinical practice, status of professional care instructions related to HPN effectiveness, quality of treatment and patient safety.

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Introduction

Parenteral nutrition (PN) is life saving and indicated when the gut is not functioning and due to oral or enteral intake not being sufficient to reach appropriate requirement target. Advances in home parenteral nutrition (HPN) enable many patients to survive, to live at home and to have good or reasonably good quality of life (QoL) in their normal environment instead of prolonged hospital stays. Today it represents an established and commonly used procedure [1]. Even in elderly patients with cancer, HPN has been shown to benefit nutritional status and QoL [2]. Patients can be treated in an outpatient setting, resulting in reduced healthcare costs [3].

Since the introduction of HPN in the 1970s, HPN prevalence and incidence have been steadily increasing in

Europe, with a large multicentric survey showing an annual incidence of 4–6 per 10⁶ inhabitants and a prevalence of 2–40 per 10⁶ inhabitants [4–6]. The most common indications for long-term HPN in Europe are Crohn's disease, mesenteric vascular disease, cancer and radiation enteritis [7]. Other more recent studies confirm that malignancy is the single most common indication for HPN [8, 9].

PN causes important restrictions in personal life, particularly, in social life, mainly due to the cyclic nocturnal HPN administration. These patients show reduced QoL, with physical problems, HPN dependency, social restrictions, sleeping problems and financial problems [10].

Shaw et al. [8] performed a first retrospective epidemiological analysis of patients with home artificial nutrition in Switzerland, based on data provided by the leading national insurance provider. Over the 5-year analysis period, from 2005 to 2009, 433 HPN patients were recorded, showing increasing frequency of HPN.

Data on HPN patients' characteristics and living conditions are scarce, and little is known about the challenges and problems these patients face. The goal of this prospective study was to collect representative nationwide data on the current Swiss adult HPN patient group for international comparability and benchmarking.

Material and Methods

Study Design and Patient Selection

This multicenter, nationwide, observational study started in April 2013 and ended in March 2014. General practitioners and hospital physicians taking care of HPN patients were contacted. Their names were accessible through the Swiss Association for Common Tasks of Health Insurers (SVK). The physicians addressed were requested to obtain written consent from their patients to participate in the study. Inclusion criteria were the following: age >18 years, receiving HPN, life expectancy >30 days and signed written consent. Patients fulfilling the inclusion criteria were either visited at home for an interview or interviewed in their hospital's outpatient clinic.

Data Collection

Data were collected using an entry questionnaire and a follow-up questionnaire 3 months later. Patients included in the study either filled out the questionnaire together with their interviewer or on their own. The mean interview duration was about 45 min. The following data were collected: personal and demographic data, social aspects, detailed nutrition regimes and QoL according to the validated Short Form 36 Health Survey version 2 (SF-36v2)TM questionnaire, anthropometric data over time, indications for PN, medical history and prevalence of complications. The documents were available in three languages: German, French and Italian.

Body mass index (BMI) was calculated as weight in kilograms divided by height in meters squared (kg/m²). To assess the effects of HPN on personal life, behavior and emotions, patients were interviewed about the effects of HPN and asked to check all applicable responses. HPN-related complaints could be evaluated by the patients in the questionnaire by choosing from 3 options: 'a little', 'medium' or 'strong'. To assess physical performance and mental health status at different time points (before disease, just before starting HPN and during HPN), the patients could choose between 4 different options ('very good', 'good', 'bad' and 'very bad'). The QoL of the patients on HPN was assessed using the SF-36v2TM questionnaire at the time of entry in the study and at the time point when the patients had to answer the follow-up questionnaires.

The SF-36v2TM is a multipurpose health survey with 36 questions. It yields an 8-scale profile of functional health and well-being scores as well as psychometrically based physical and mental health summary measures and a preference-based health utility index [11]. These 8 scales are reduced to a physical component summary (PCS = physical functioning + physical role + bodily pain + general health) and to a mental component summary (MCS = vitality + social functioning + emotional role + mental health) [12].

Statistical Analysis

The statistical assessment was performed with IBM SPSS statistics for Windows, version 19.0 (IBM Corp., Released 2010, Armonk, N.Y., USA). The Wilcoxon test was used for continuous, non-parametric data. Results are reported as means with SD or as numbers and percentages. A p value of <0.05 was considered statistically significant.

Ethical Approval

This study was conducted in accordance with the ethical guidelines of the 1957 Declaration of Helsinki, and written informed consent was obtained from all participants. Ethical approval for the study was obtained from the Bernese Cantonal Ethics committee (KEK Bern, study no. 068/13), Bern, Switzerland.

Results

Forty-one patients were recorded during the 1-year investigation (fig. 1). Eight of the patients who were comparable to the study population did not consent to participate, while 33 participated (n = 100%) and filled in the entry questionnaire. The follow-up questionnaire was filled in by 24 patients. In 3 patients, the loss of follow-up was because they died during the study period due to the underlying disease (cancer), 4 patients ceased HPN and 2 patients had no more interest in the further participation of the study. This corresponds to about 4 patients per 1 million inhabitants in Switzerland and is comparable with other European countries. All tertiary university hospitals and all important referral centers of different regions of Switzerland, as well as namely physicians, who

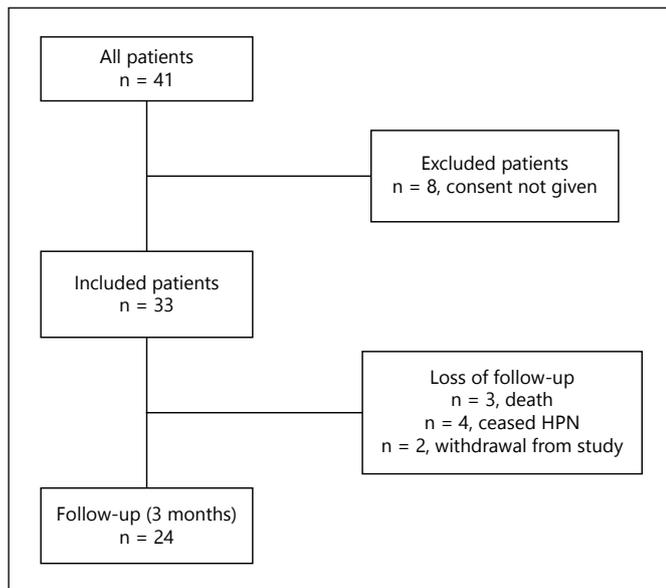


Fig. 1. Study flow diagram.

Table 1. Patient characteristics

Data	Results
Patients, gender, n (%)	
Male	12 (36)
Female	21 (64)
Age at start of HPN, years	
Age, mean \pm SD	53.76 \pm 17.75
Age, median	59
Age, n (%), (f:m)	
<40	8 (24), (5:3)
41–60	11 (33), (9:2)
61–70	10 (30), (5:5)
\geq 71	4 (12), (2:2)
Geographical distribution (Switzerland), n (%)	
East part	1 (3)
North part	2 (6)
South part	3 (9)
Central part	5 (15)
West part	10 (30)
Region of Berne	12 (36)
Marital status	
Married	15 (45)
Single	9 (27)
Divorced	7 (21)
Widowed	2 (6)
Living situation, n (%)	
Partner	15 (45)
With children <18 years or with the parents	3 (9)
Alone	8 (24)
Nursing home	4 (12)
Catheter types, n (%)	
Hickman	18 (55)
Port-a-cath	14 (42)
Dialysis fistula	1 (3)

are familiar with HPN therapies, were contacted but not all of them had patients to contribute. The patients' characteristics are listed in table 1. The mean age on starting HPN was 53.8 ± 17.8 years. At the time of the initial interview, HPN treatment had been initiated on an average of 3.44 years previously, with a wide range from 2 days to 30.75 years. The mean BMI before disease was 28.5 ± 11.4 kg/m² and decreased significantly before starting HPN to a BMI value of 19.6 ± 6.7 kg/m² ($p < 0.001$). At the time point of the first interview, the mean BMI had increased significantly with HPN treatment to 22.0 ± 6.1 kg/m² ($p < 0.001$). The BMI could be kept stable at 21.5 ± 3.2 until the follow-up interview (fig. 2).

Underlying Diseases and Indications for HPN

The underlying diseases and the indications for HPN of the 33 patients are reported in table 2. As underlying disease cancer was predominant ($n = 14$, 42%), followed by post-bariatric surgery and post-radiation enteritis ($n = 4$ each, 12%). In 13 (39%) of the cases, a short bowel syndrome (SBS) was the indication for HPN.

Central Venous Catheter-Related Complications

Most patients ($n = 32$, 97%) used tunneled catheter systems like the Hickman or the Port-a-cath. Only 1 patient was fed through a dialysis arteriovenous fistula. In 45% of the patients ($n = 15$), there was at least one central venous catheter (CVC) replacement during the nutritional treatment, primarily due to infections, CVC occlusions or displacement. Eleven patients (33%) reported at least one infection during the HPN period. Intervention-related CVC complications (e.g. arterial lesions, fixation problems) occurred in 5 patients (15%) and CVC occlusions in 5 patients (15%). During the present observational period (follow-up questionnaire after 3 months from baseline), 6 patients (18%) had to have the CVC replaced due to infectious complications.

Effects of HPN on QoL

Regarding the employment, 85% ($n = 28$) of the HPN patients were no longer employed, either because of physical impairment or because they had already retired ($n = 13$). Nine percent ($n = 3$) had an employment with medium physical activity or were students. Less than half of the patients (39%, $n = 13$) were able to do the housekeeping themselves; 58% ($n = 19$) were dependent on family help. Personal care was performed themselves by 88% ($n = 29$). For attaching and removing the PN, 76% ($n = 25$) relied on external help, such as a homecare service or a nurse.

Fig. 2. The time course of BMI (mean \pm SD).

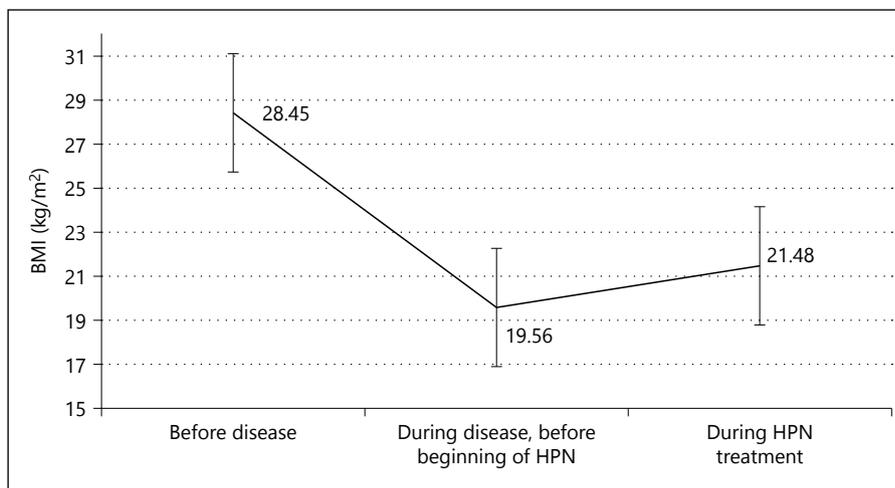
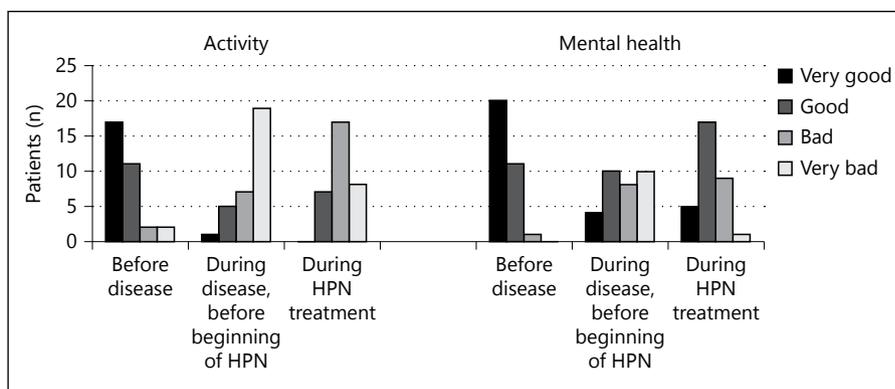


Fig. 3. Activity and mental health follow-up.



Performance level and mental health status are shown in figure 3. Before the disease, 52% (n = 17) of patients were very active. During the disease, but just before beginning HPN, 58% (n = 19) were not active at all. This improved during treatment with HPN, with 52% (n = 17) of patients reporting they were a little active. The mental health status was rated very bad in 30% (n = 10) during the disease, just before starting HPN. During HPN treatment, only 3% (n = 1) described their mental status as very bad. Almost all patients showed improved physical and mental QoL after 3 months (PCS 34.02 vs. 39.37; MCS 41.91 vs. 46.35), as shown in figure 4. Only 2 patients (6%) considered themselves healthy, while 7 (21%) described themselves as fairly healthy. Most patients reported in the QoL questionnaire that their health was not excellent at all (n = 12, 36%).

Aspects of HPN treatment that were reported as most disturbing were the restricted ability to travel and the impossibility to participate in social events (n = 21, 64%) and the dependency on the treatment (n = 19, 58%). Sleep

Table 2. Underlying diseases and indication for HPN

Diagnosis	n (%)
Cancer	14 (42)
Complications of surgery	5 (15)
Post-bariatric	4 (12)
Others	1 (3)
Radiation enteritis	4 (12)
Crohn's disease	3 (9)
Systemic sclerosis	2 (6)
Congenital bowel disease (Hirschsprung disease)	1 (3)
Motility disorders	1 (3)
Caecum perforation	1 (3)
Mesenteric infarction	1 (3)
Glycogenosis type Ia (-> severe inappetence)	1 (3)
Indication for HPN	n (%)
SBS	13 (37)
Malabsorption	10 (29)
Fistula	4 (11)
Obstruction	3 (9)
Severe malnutrition prior to surgery	1 (3)
Other	4 (11)

Fig. 4. QoL follow-up.

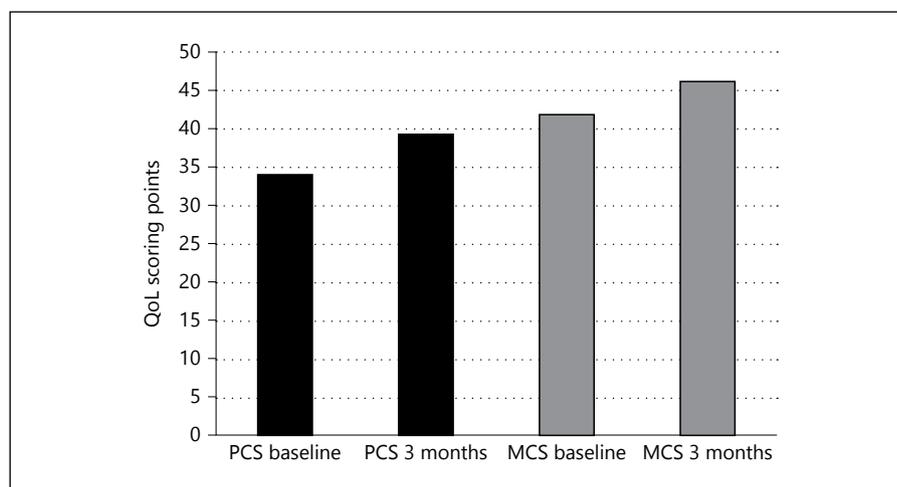
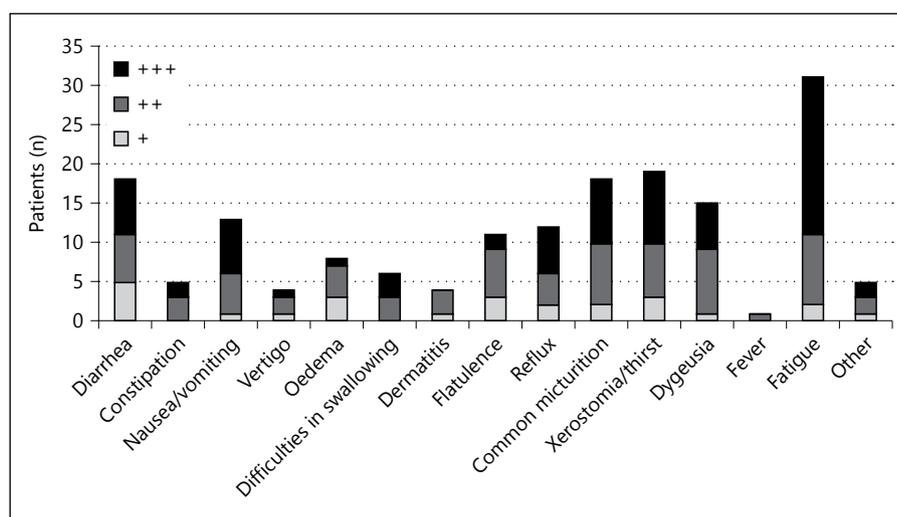


Fig. 5. HPN-related complaints.



disturbances because of noise generated by the mechanical infusion pump were mentioned 8 times ($n = 8$, 24%). Fear of further health complications ($n = 5$, 15%) and problems in partnership/family life ($n = 3$, 9%) were also listed. The HPN-related complaints are shown in the figure 5. The complaint cited most often was by far fatigue ($n = 31$, 94%). Rarely occurring complaints were pains, spasms, difficulty in controlling blood sugar level, night sweats and post-prandial health problems.

Discussion

The present prospective study is the first detailed analysis of HPN patients in Switzerland. We consider this survey as representative for the population of HPN patients

in our country. Of the 41 HPN patients identified, 33 were included. The University Hospital of Berne provided 36% of the recruited patients, far more than any other site, which may be due to the long lasting clinical experience with this population. HPN is prescribed not only by important referral centers, but also by general practitioners taking care of these patients. There are no regular follow-ups, aspects or guidelines for HPN prescriptions and care in Switzerland.

The age and gender distribution in our study are comparable to those of other surveys, which also showed a much higher rate of female HPN patients [4, 13–15]. This is influenced by the underlying diseases, for example, post-radiation enteritis occurring in patients with gynecological malignancies. SBS may also be more likely to occur in women due to the shorter length of their small

intestine [16]. A final reason is the increasing number of bariatric patients in Switzerland, of which 75% are women [17].

Compared to other studies, the mean duration of HPN in our cohort is slightly lower (mean 3.44 years), but with a broader range (0.1–31 years) [10, 18]. There was also greater variation in our study due to the inclusion of a patient with Hirschsprung disease requiring HPN since birth and due to the inclusion of a patient with SBS since more than 30 years, corresponding to almost 9 times the mean duration of HPN.

Approximately, half of our patients have had at least one CVC replacement during HPN treatment. The complication mentioned most often was CVC infection. This corresponds with the results of previous studies: 28.6% had at least one catheter sepsis and 50% had at least one catheter change. CVC infection rate ranged between 0.38 and 4.58 episodes per 1,000 catheter days [19, 20]. To prevent infections and other catheter-related complications, good clinical practice and an experienced multidisciplinary team are mandatory [21]. Six patients (18%) needed a catheter replacement because of infectious complications in the 3 months of follow-up. This rate has to be interpreted with caution, because of the short follow-up period and because many patients just had started with the HPN therapy. The procedure in case of suspected CVC-related infection and subsequent removal is managed in a similar way throughout Switzerland. When a catheter infection is suspected, peripheral blood culture samples and culture samples from each catheter lumen are taken. If there is a definitive sign of local infection, for example, purulent secretion at the exit site, or a catheter-induced sepsis, the CVC is removed immediately and an antibiotic therapy is started [22].

In a European multicenter study, Van Gossum et al. [4] showed almost the same distribution of underlying diseases (cancer 42%, Crohn's disease 15%, vascular diseases 13%). Recently, the ESPEN HPN-Chronic Intestinal Failure Special Interest Group (European Society of Clinical Nutrition and Metabolism) created a survey to describe the use of HPN in post-bariatric surgery, including the indications and outcome. An interesting finding in our study is that 4 patients (nearly 15%) of our study population need HPN after bariatric surgery. Patients undergoing malabsorptive procedures are at risk of developing nutritional deficiencies and protein-energy malnutrition (PEM). A small number of patients will develop PEM and will therefore require HPN months to years after bariatric surgery. Bariatric surgery has increased significant-

ly in the last years in Switzerland, with 750 bariatric interventions in 2001 compared with 4,000 in 2013 [17]. Not much is known about this group of patients requiring HPN to compensate for complications or side effects after bariatric surgery [23, 24]. Given the proportion of morbidly obese people in the Swiss population (in 2012: 11% men and 9% women) [25], post-bariatric PEM will be an emerging problem in the future.

On the other hand, other indications have dramatically decreased, noticeably, the 4% proportion of AIDS patients in earlier years, most of who died of wasting syndromes due to the lack of effective therapies [4, 26]. New treatments, better outcome and prevention strategies have increased survival and decreased the need for HPN in such patients [27]. This was also reflected in the fact that there were no AIDS patients in the current study. In the study of Van Gossum et al. [4], cancer was in first place (39%) at almost the same rate like in our survey. The proportion of HPN patients with oncological tumors has increased over the past years in Europe [28]. Previous Swiss data about the indications for home artificial nutrition demonstrated that neoplasms were the most frequent underlying disease (51%), diseases of the digestive system on the second place (10.4%) and diseases of the nervous system in third place (9.6%) [8]. In our study, there were no patients with underlying neurological disorders. This is probably due to the fact that patients with neurological disorders can mostly be treated with enteral nutrition, including PEG [29]. Another important fact is the change in official recommendations for HPN over the last years, repositioning HPN as a palliative treatment in cancer patients because of the relatively small proportion of PN-associated comorbidity risk factors [14, 30]. Regarding the indications for HPN, we found that SBS is the most frequent indication (37%), consistent with other published data [31, 32].

Our investigation also focused on the QoL of HPN patients. Both physical and mental QoL, assessed by the non-disease-specific SF-36v2, improved over time in our patients. Many other studies determined the QoL using the Karnofsky score, the SF-36 or a new specific questionnaire for HPN patients. Overall, patients with HPN have poorer QoL than healthy people or patients with chronic illnesses [13, 19, 32–34]. An earlier study with only 13 participants showed that none of those HPN patients had a regular employment, but 46% did most of the house-keeping [35]. Our data showed that 85% of patients had no employment, and only 39% were able to do the house-keeping on their own.

The additional subjective definition of physical performance and mental health status were also investigated by Winkler et al. [36], who achieved greater insight into the lives of HPN patients and their definition of QoL. In our study, most of the patients reported that they were 'very active' or 'active' before disease, comparable with healthy individuals. In the immediate period before starting HPN, most of the patients felt very tired, adynamic and 'not active'. Fortunately, after initiation of HPN, the performance level increased after weeks in most patients, showing the positive effects of HPN on well-being, body function and performance levels. The results concerning mental health were similar, with 'poor' mental health reported before starting HPN and 'good' mental health after initiation of HPN.

We conclude that our population profits by HPN from a better health status. Other studies confirm our findings showing improved QoL with HPN in both patients with benign and malignant underlying disease [37–39].

Restricted travel options, limited social interaction and activities as well as loss of independence were the most frequent complaints related to HPN. Other studies showed similar results, mostly evaluated in surveys: the lack of freedom, being dependent and limitations in social life [40, 41]. Moreover, Huisman-de Waal et al. [42] showed social and somatic impacts of HPN therapy on daily life, which are comparable with our data (e.g. fatigue, xerostomia, diarrhea; fig. 5).

Strengths and Limitations of the Study

This prospective study provides the first detailed analysis of HPN patients in Switzerland. It is intended to regularly follow-up (in longer time periods) this cohort. The presented data will form the basis for a national HPN registry, which is needed to evaluate the specific situation of this cohort in the national (healthcare) context.

The fact that the follow-up of the study was only 3 months, and 3 patients had just started HPN before inclusion in the study is a limitation. The short duration was chosen to minimize patients lost to follow-up. Second, it was difficult for most patients during the survey to distinguish between HPN-related side effects and side effects due to underlying disease, and it was very challenging to determine whether improved or worsened QoL was caused by the underlying disease or is a direct consequence of the HPN. A disadvantage of our study is that we do not have the information about how many patients were eligible for the present study, but did not give their consent to the physicians in charge.

Conclusion

We conclude that PN is life saving and shows physical and mental benefit for HPN patients, but there are also negative implications for QoL, especially in terms of social and emotional aspects and loss of autonomy. The number of patients after bariatric surgery seems to increase steadily, and PN is effective in this population. This first prospective analysis of Swiss HPN patients, focusing on anthropometric parameters and QoL, shows major improvements over the 3 months study period. These patients should be monitored over the long term to evaluate and compare outcomes and the impact of HPN on the underlying disease and HPN-associated complications. A national registry is a prerequisite for international comparability and benchmarking and can help to improve treatment quality and safety as well as to define best practices of HPN.

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Statement of Authorship

The authors declare that they have written the text themselves, and the work described herein is their own, unless otherwise acknowledged in the text. All sentences or passages quoted in this paper from other people's work have been specifically acknowledged by clear cross-referencing to author, work and page(s). All authors have participated sufficiently, intellectually or practically, in the present work and take public responsibility for the content of the article.

Disclosure Statement

None of the authors has a conflict of interest to declare.

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