Adult cancer patients on home parenteral nutrition in Slovenia, data analysis by the Clinical Nutrition Unit of the Institute of Oncology in Ljubljana, in the period 2008–2012.

Parenteralna prehrana na domu pri odraslih bolnikih z rakom v Sloveniji, analiza podatkov Enote za klinično prehrano Onkološkega inštituta v Ljubljani, v obdobju 2008–2012.

Nada Rotovnik Kozjek,[1] Barbara Koroušić Seljak[2]

[1] *Enota za klinično prehrano, Onkološki inštitut Ljubljana*

[2] *Odsek za računalniške sisteme, Institut »Jožef Stefan«, Jamova c. 39, Si-1000 Ljubljana*

Korespondenca/ Correspondence:
dr. Nada Rotovnik Kozjek
Onkološki inštitut,
Zaloška 2,
Si-1000 Ljubljana
nkozjek@onko-i.si

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Izvleček

Uvod: Parenteralna prehrana na domu (*angl.* home parenteral nutrition, HPN) je vrsta obravnave odpovedi prebavil. V Sloveniji jo pri odraslih bolnikih sistematsko izvajamo od leta 2008 v Enoti za klinično prehrano Onkološkega inštituta v Ljubljani. Namen članka je analizirati slovenske podatke o HPN pri bolnikih z rakom v štiriletnem obdobju od 2008 do 2012.

Bolniki in metode: V Sloveniji je bilo v sistem parenteralne prehrane na domu v obdobju od 2008 do 2012 vključenih 53 bolnikov, ki so imeli ali so bili na zdravljenju zaradi raka, od tega je bilo 19 moških in 34 žensk.

Rezultati: Povprečna starost bolnikov ob vključitvi v sistem HPN je bila 53 let. Bolniki z rakom so predstavljali 74,6 % bolnikov na HPN, ki jih vodimo v Enoti za klinično prehrano. 44 bolnikov je imelo napredovano obliko raka, pri 9 bolnikih ponovitve rakaste bolezni v času opazovanja ni bilo. Med bolniki z napredovano rakavo boleznijo so bili najpogosteje zastopani tumorji prebavil (15 bolnikov z rakom želodca in požiralnika, 11 bolnikov z rakom debelega črevesa in danke) in tumorji rodil (10 bolnic). Pri teh bolnikih je bil najpogostejši vzrok za uvedbo HPN maligna obstrukcija prebavil (77 %). 37 bolnikov z napredovano obliko raka je v opazovanem obdobju umrlo. Mediana preživetja vseh bolnikov z napredovanim rakom je bila 8 mesecev (95 % CI, 3,61 do 12,39 mesecev). Med njimi se je 27 bolnikov med HPN zdravilo s kemoterapijo, radioterapijo ali so bili operirani. Mediana preživetja za te bolnike je bila 11 mesecev (95 % CI, 3,72 do 18,28 mesecev) in za bolnike brez specifične onkološke terapije 2 meseca (95 % CI, 1,26 do 2,74 mesecev). Bolniki, ki so prejemali onkološko terapijo, so imeli značilno daljši čas preživetja ($p < 0,001$). Večina bolnikov (90 %) je imela ves čas HPN vsak dan, to je sedem infuzij na teden. Pri tem je 28 bolnikov (52 %) imelo zaplet z venskim dostopom, najpogostejši vzrok zapleta pa je bila okužba (30 %), ki ni skrajšala preživetja teh bolnikov ($p = 0,44$). Ugotovili smo, da število zapletov ni vplivalo na preživetje opazovanih bolnikov.

Zaključek: Rezultati naše retrospektivne raziskave so prva analiza slovenskih podatkov o bolnikih z rakom, ki prejemajo HPN zaradi odpovedi prebavil. Mediano preživetje bolnikov je primerljivo z evropskimi podatki, kar neposredno pokaže, da so vključitvena merila za bolnike z rakom v sistem parenteralne prehrane na domu v Sloveniji primerna in da je izvajanje parenteralne prehrane na domu kakovostno. Prav tako uvedba HPN omogoča nadaljevanje specifičnega zdravljenja in značilno podaljša preživetje te skupine bolnikov z neozdravljivim rakom. Rezulti retrospektivne analiza so hkrati tudi izhodišče za nadaljnji razvoj dejavnosti HPN pri bolnikih z rakom v Sloveniji in tudi za razvoj dejavnosti nadomestnega zdravljenja odpovedi prebavil pri vseh bolnikih, ki to potrebujejo.

Abstract

Introduction: Home parenteral nutrition (HPN) represents a kind of therapy for intestinal failure. The system of HPN for adult patients was established in Slovenia by the Clinical Nutrition Unit of the Institute of Oncology, Ljubljana in 2008. The aim of the article is to analyse Slovenian data

on HPN in cancer patients in the four-year period from 2008 to 2012.

Patients and Methods: In the time period from 2008 to 2012, 53 cancer patients were included in the HPN system in Slovenia–19 males and 34 females.

Results: The average age of the patients at enrollment into the HPN system was 53 years. This represents 74.6 % of all patients on HPN who were registered in our unit in this period. 44 patients had advanced cancer and 9 patients had no recurrence of cancer during the observation period. In patients with advanced cancer, tumors of the gastrointestinal tract (15 patients stomach and esophagus, 11 patients colon and rectum) and gynecological cancers (10 patients) were represented most frequently.. Gastrointestinal obstruction (74 %) was the major indication for long-term parenteral nutrition in cancer patients. Thirty-seven patients died during the observation period. Median survival time of patients with advanced cancer was 8 months (95 % CI, 3.61 to 12.39 months). Twenty-seven patients received HPN during anti-cancer therapy (chemotherapy, radiotherapy, surgery). Medians for survival time of patients receiving an anticancer therapy and patients without any therapy were 11 months (95 % CI, 3.72 to 18.28 months) and 2 months (95 % CI, 1.26 to 2.74 months), respectively. The survival of patients with anticancer therapy was significantly longer ($p < 0.001$). The majority of patients (90 %) had HPN each day, 7 times per week. Twenty-eight patients (52 %) had venous access complications . The most common cause of complication was infection in 16 patients (30 %), which did not shorten the survival time of patients with advanced cancer. The number of VAP complications was time-independent and did not affect the survival of the observed patients. The significance value was 0.44 (95 % CI, 0.153–2.275).

Conclusion: The results of the retrospective study represent the first Slovenian data on the survival time of cancer patients on HPN treatment for intestinal failure. The results are comparable to the results from European surveys, which are a direct indicator that inclusion criteria for HPN in cancer patients used in Slovenia are good. Introduction of HPN as a therapeutic option also offers a possibility to continue with anticancer therapy and improve the survival rate of patients with advanced cancer. They are also an indirect sign that the quality of HPN service is good and serves as a platform for further development of HPN in cancer patients in Slovenia, and at the same time for other patients who would need a replacement therapy in the form of HPN owing to intestinal failure.

Introduction

Home parenteral nutrition

Intestinal failure is characterized by an inability to maintain a protein-energy, fluid electrolyte balance, or micronutrient balance when eating a normal diet.[1] The condition may be transient if gut function can be restored. Patients with intestinal failure require parenteral administration of nutrients. Intravenous nutrient administration has been, since its introduction in 1967, the mainstay for standard medical treatment of complete or partial gastrointestinal failure. [2] Long-term parenteral nutrition (PN) is indicated for patients with prolonged gastrointestinal tract failure that prevents the absorption of adequate nutrients to sustain life. The most common underlying diseases according to a European multicentre study in 1997, which included 13 countries and 75 centres, are cancer (42 %), Crohn's disease (15 %), vascular diseases (13 %), radiation enteritis (8 %) and others (18 %), complications following surgery, chronic small bowel disease with severe malabsorption and dysmotility syndromes. [1,3]. Short bowel syndrome (31 %) and intestinal obstruction (22 %) were two major indications for long-term parenteral nutrition. As it is a life-saving therapy for patients with irreversible intestinal failure, it does not require evaluation of efficacy by randomized controlled trial. Its ability to maintain quality of life and promote rehabilitation supports the use of home treatment called home parenteral nutrition (HPN) . [4]

One of the main goals of HPN is by definition the avoidance of prolonged or recurrent hospitalizations due to malnutrition. It is routine therapy in developed countries. An European survey reported a prevalence of 2–40 patients per million and an inciden-

ce of 4–6 patients per year for HPN in patients with benign primary disease.[3] The incidence and prevalence of HPN varies across Europe, reflecting different organizational structures and treatment strategies. Survival of patients on HPN is mainly determined by the primary disease although adverse events related to venous access and metabolic disturbances associated with intravenous delivery of nutrients may compromise the patient's quality of life. A French study in non-malignant short bowel syndrome has shown that five-year survival is 75 % and is determined by the primary disease.[5]

HPN in cancer patients

Epidemiological data regarding HPN in cancer patients with complete or partial gastrointestinal failure differ widely between countries.[3] In a European survey of 500 patients receiving HPN in 1997 it was found that cancer patients represented 60 % of patients on HPN in the Netherlands, 39 % in Spain, 27 % in Belgium, 8 % in Denmark and 5 % in the United Kingdom.[3] While nutritional support (including HPN as necessary) for cancer patients is generally accepted in relation to malnutrition when the patient is receiving oncological therapy or if the patient suffers severe complications following surgery or specific oncological therapy, this data confirms that the decision to administer HPN to a patient with an incurable cancer is still a source of debate and the approach differs among countries. Some clinicians will consider that medical care including nutritional support is justified as there is an increase in the duration of survival and improvement in the quality of life, while other caregivers may argue that patients will still die despite nutritional support even if small increments in life-expectancy can be obtained, and that measures such as HPN are inappropriately invasive.[6-12] Therefore, HPN in patients with incurable malignant diseases has always been a topic of debate for many reasons, foremost for ethical, economical and quality-of-life issues.

Recent studies and also guidelines from nutritional societies (European Society for Clinical Nutrition and Metabolism, ESPEN) offered the current platform for HPN treatment. [6-8] Considering these recommendations for inclusion of patients in an HPN program, incurable patients in the final phases of life should be excluded. However, incurable patients to whom no more (oncological) treatment will be offered can be included in HPN program provided that their problem is under-nutrition or starvation rather than direct progression of the underlying malignant disease and their death is not imminent. Despite a lack of data on survival benefit, it seems that cancer patients with an expected survival of ≥ 2–3 months might maintain their quality of life (QoL) if receiving HPN.[4,12] Prolonging survival with HPN in starving cancer patients is even more likely in the light of information provided by hunger strikers, which showed that the shortest time to death in a previously healthy adult was 21 days and the longest time was 69 days. [13] Patients with cancer and intestinal failureof any cause are more frail and therefore are expected to be affected more severely by the consequences of starvation.

HPN in cancer patients in Slovenia

In Slovenia systematic treatment of intestinal failure for adult patients has been available since October 2008 at the Institute of Oncology in Ljubljana. Considering the current evidence that malnutrition in cancer patients is associated with worse tolerance to treatment, poorer prognosis, and that it adversely affects quality of life, we used HPN treatment for GIT (gastrointestinal tract) failure according to current guidelines and recommendations and adapted them to individual patients' clinical and life situations. [6,12,14] The development of the system of HPN is also based on the organization of the health system in Slovenia.

HPN is considered individually for each patient who fulfils the following criteria:

- inability to eat mainly because of a complete or sub-complete gastrointestinal tract obstruction;
- life expectancy with cancer > 3 months;
- malabsorbtion because of severe treatment side effects;

- short bowel syndrome as a result of surgical treatment;
- no or minimal indolent of vital organs, with no functional deterioration;
- good performance status;
- previous consent of patients and/or their relatives to modify or substantially reduce the nutritional regimen when a functional deterioration of the patient occurs.

A retrospective epidemiological analysis of our database from October 2008 to October 2012 was performed to analyze the use of HPN in cancer patients in Slovenia. The main aim of the analysis was to estimate median survival times of HPN-treated advanced-cancer patients and patients receiving an anti-cancer therapy during the study. We were interested in any impact of VAP complications on the survival and aimed to compare the survival times a) in patients with advanced cancer versus patients in a disease-free state; and b) in patients with cancer during an anticancer treatment versus patients with cancer without any therapy. Our final objective was to estimate hazard risks in patients with VAP complications.

Patients and Methods

In the Clinical Nutrition Unit patients are treated by a multidisciplinary team composed of physicians with special knowledge of clinical nutrition, specialized nurses, dieticians and pharmacists. After a team decision, which also includes an oncologist or an oncological surgeon, that a patient is a candidate for HPN, a central venous catheter (venous access port, VAP), is inserted and the patient and his/her family members are educated on how to administer HPN. The education takes place in the hospital and then patients are discharged to home care. They are followed regularly on an outpatient basis. In general, the initiation of HPN consisted of home nocturnal infusions of an approximate duration of 12 hours. The parenteral nutritional regimen was selected on an individual basis, according to nutritional guidelines for cancer patients and adapted to the patient's metabolic situation. In general, we used nutritional mixtures of glucose, amino acids, lipids and standard amounts of micronutients. In the last 2 years we have been mainly using SMOF lipid (4-oil mix: 15 % fish oil, 30 % soyabean oil, 25 % olive oil and 30 % medium-chain triglycerides) nutrition mixtures in the form of three-chamber bags. Micronutrients (Soluvit, Addamel, Vitalip) are added to nutritional mixtures daily by patients. Laboratory monitoring for substrate utilization, metabolic and infectious complications initially takes place weekly and then gradually shifts to longer intervals, depending on laboratory values and body composition measurements. The effect of nutritional therapy was regularly evaluated by body composition measurements (Quadscan 4000, Bodystat). The HPN service is available on-call seven days per week, twenty-four hours daily.

The records of all adult cancer patients on HPN, treated at the Clinical Nutrition Unit of the Institute of Oncology in Ljubljana from October 2008 to October 2012 were reviewed. The following parameters were analyzed retrospectively: age, gender, type of cancer, number of infusions per week, indication for HPN (malignant bowel obstruction, malabsorption, short bowel syndrome), specific cancer treatment during HPN, metabolic and VAP complications (infections, occlusions, skin necrosis, thrombosis), cause of death and median survival of patients on HPN. All patients who did not fulfill the criteria for standard HPN at home were excluded from the analysis.

Data analysis was performed by using the IBM SPSS Statistics, Version 21 computer program. The proportion of the population of the HPN treated patients who would survive was estimated by the Kaplan-Meier method. The survival analysis was concerned with studying the time between entry to the clinical trial and a subsequent event (such as death or end of the study). We used the following explanatory variables on survival: anticancer therapy (chemotherapy, radiotherapy or surgery) during HPN, cancer recurrence and VAP complications (infection, occlusion, skin necrosis, thrombosis, other). For VAP complications as time-dependent events, data were analyzed using a time-dependent Cox model.

Results

From June 2008 to October 2012, a total of 53 cancer patients were treated with HPN at our Clinical Nutritional Unit–19 males and 34 females (Table 1). This represents 74.6 % of all patients on HPN who were registered by our unit in that time period. The average age at inclusion in the HPN system was 53 years (range, 21–79 years). Forty-four patients had advanced cancer and the majority of patients with bowel failure had cancers of the gastrointestinal tract (Table 1).

Table 1: Patients' characteristics.

Demographic data:	
Patients (number)	53
Gender M/F (numbers)	19/34 (36% / 64%)
Age (years, age range)	53 (21-79)
Oncological data:	
Patients with advanced cancer	44 (83%)
No cancer recurrence	9 (17%)
Type of cancer	
Cancer of of the upper GIT (gastric, esophageal)	15 (28%)
Colon, rectal cancer	16 (30%)
Gynaecological cancer	12 (23%)
Other :	10 (19%)
Neuroendocine tumours of GIT	3
Pancreatic cancer	2
Lyposarcoma	2
MDS	1
Prostatic cancer	1
Lung cancer	1
Cancer treatment	
Chemotherapy	21(23%)
Radiotherapy	2 (4%)
Chemo- and radiotherapy	3 (6%)
Surgery	1 (2%)
Indications for HPN	
malignant obstruction of GIT	34 (64%)
malabsorption	9 (17%)
short bowel syndrome	6 (11.5%)
combined	4 (7.5%)
Number of infusions per week	
7 days	48 (90%)
6 days	1 (2%)
5 days	3 (6%)
3 days	1 (2%)

Legends: GIT - gastrointestinal tract, VAP - venous access port, MDS - myeloproliferative disease syndrome

Thirty-seven patients (84 %) with advanced cancer had died up to October 2012.

The main indication for HPN in patients with advanced cancer was malignant obstruction of the bowel in 34 patients (74 %). The majority of all patients received HPN each day, 7 times per week; 90 % of the total number and 97 % of patients with advanced cancer. Median for survival time of HPN--treated patients with advanced cancer was 8 months (95 % CI, 3.61 to 12.39 months). The indication for HPN in patients who were in a disease-free state until October 2012, was malabsorbtion in 5 patients and short bowel syndrome in 4 patients.

During the HPN treatment, 27 HPN--treated advanced-cancer patients were receiving an anticancer treatment. Medians for survival time of these patients receiving an anticancer therapy and patients without any therapy were 11 months (95 % CI, 3.72 to 18.28 months) and 2 months (95 % CI, 1.26 to 2.74 months), respectively. In Figure 1, Kaplan-Meier survival curves in 27 HPN--treated advanced-cancer patients during an anticancer treatment versus 17 HPN-treated advanced-cancer patients without any therapy are presented. The significance value of the logrank test that weighs all time points the same is less than 0.001.

During the HPN treatment, 24 patients (45 %) had central line (VAP) complications. The main complication was VAP infection in 16 patients (30 %), which did not shorten the survival time of patients with advanced cancer ($p = 0.44$). Other VAP complications were occlusion of the port in 10 patients, skin necrosis at the insertion pinpoint in 3 patients and thrombosis of the VAP in 2 patients. One VAP had distal fragmentation, which was left in situ without any side effects. Eight patients had multiple complications. Most (5) patients with two VAP complications experienced a combination of infection and occlusion, two patients had a combination of infection and skin necrosis. One patient with three complications experienced occlusion, skin necrosis and other complications. No patients had major metabolic complications. Medians for survival time to the next complication of the HPN--treated patients with none, one or two VAP

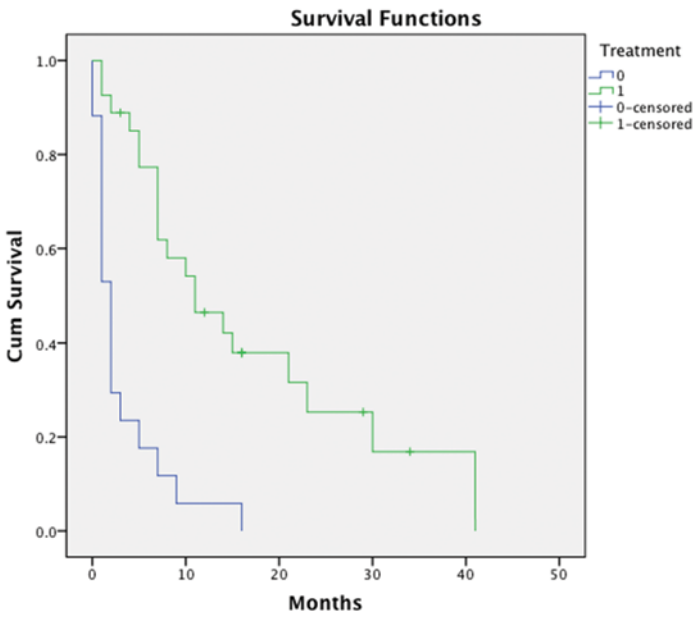

Figure 1: Kaplan-Meier survival curves in HPN-treated advanced-cancer patients receiving an anticancer therapy versus HPN-treated advanced-cancer patients without any therapy. The treatment value 0 means no therapy nad 1 an anticancer therapy.

complications were 8 months (95 % CI, 4.33 to 11.67 months), 5 months (95 % CI, 2.66 to 7.34 months) and 4 months (95 % CI, 0.40 to 7.60 months), respectively. No patient died because of VAP complications.

Considering VAP complications as time-dependent events, data were analysed using a time-dependent Cox model. The analysis showed that the number of VAP complications did not affect the survival of the observed patients. The significance value was 0.44 (95 % CI, 0.153–2.275).

Discussion

The current study represents a data overview of the cohort of adult cancer patients on HPN who were treated at the xInstitute of Oncology in Ljubljana. Bearing in mind that this is the only hospital in Slovenia with an organized HPN service for adult patients, the study represents the first national data of cancer patients treated with HPN for intestinal failure. In the 4-year period from 2008 to 2012 we treated 53 patients, 44 of them had incurable cancer and 9 patients presented with bowel failure after cancer treatment. This group of patients represents 74.6 % of patients treated with HPN during that period at our Unit of Clinical Nutrition. In comparison with data from a 1997 European survey, the percentage is high and reflects the fact that the Institute of Oncology is primarily a hospital for cancer treatment. Regarding global epidemiological data, probably there are still patients in Slovenia who would need HPN treatment for intestinal failure due to benign diseases.[3]

In clinical practice the patient who is a candidate for HPN will typically have little or no oral intake due to partial or complete malignant obstruction of the gastrointestinal tract and relatively good performance status with normal function of other vital organs. All other symptoms which can limit food intake (pain, depression) must be treated and controlled.[12] Patients who are treated with HPN may be those with peritoneal carcinomatosis, and slow-growing tumours, such as ovarian carcinoma, retroperitoneal cancers, and some intra-abdominal recurrences. The analysis of our data has shown a similar clinical situation for our patients (Table1). The average age at the time of inclusion in HPN treatment was 53 years, the youngest patient being 21 and the oldest 79 years of age. From the age range we can see that the performance status of the patient and not the age was the limiting inclusion criterium. The most frequent indication for HPN treatment in cancer patients was malignant bowel obstruction. Twenty-seven patients still had active cancer treatment, which was also possible because of nutritional support with HPN (Table 1).

The cumulative median survival time for all patients with advanced cancer was 8 months (95 % CI, 3.61 to 12.39 months). The overall survival time of this group of patients was more than 2–3 months and clearly exceeds the recommendation for expected survival times for cancer patients on HPN according to ESPEN guidelines inclusion criteria.[4] In comparison with other surveys, the median survival time in our group of patients was in the upper range. The median survival time of patients with incurable cancer was 140 days (20–783 days) amongst 68 patients who were treated in Israel (15) and 40 days for 60 patients who were followed up in Belgium.[1] The retrospective study of 75 cancer patients from nine institutions included in the Italian HPN Registry showed a median survival time of 4 months.[17] In a study from China parenteral nutrition pro-

longed the survival time of 115 patients associated with malignant gastrointestinal obstruction by 5 months.[18] In our study, the survival time of patients who were still on active anti-cancer therapy was significantly longer than the survival time of patients without active therapy (11 months versus 2 months, $p < 0.001$). Bearing in mind that HPN is a life-saving therapy, the survival benefit in this group of cancer patients is clear and also contributes to the quality of life in this group of cancer patients.[2-4,16,19] HPN treatment for intestinal failure was, in this clinical situation, a mainstay for further anti-cancer therapy. Also, considering data for the group of patients without any anticancer treatment, there is good survival benefit regarding inclusion criteria for life expectancy in this group of patients too. In practice, the therapy with parenteral nutrition for bowel insufficiency due to malignant disease in these patients was longer because of a long HPN-learnig period. They had to be hospitalized for 2 to 4 weeks because of educational activities. This time was not included in our analysis.

We did not record any major metabolical complications in cancer patients on HPN, which indicates that the choice of nutritional solutions and metabolic monitoring was good. The most frequent complication of HPN was VAP infection in 28 % of patients,in which is in the range of infectious complications reported by other HPN centers.[20] All VAP infections were successfully treated with appropriate antibiotic therapy, and in the majority of cases the central line was replaced by a new one. No patient died because of HPN complications.

Some patients with complete intestinal obstruction required the placement of a percutaneous endoscopic gastrostomy (rarely surgical) used for discharging the gastric stasis of liquids.[15] Surgical gastric stoma was performed in one patient with pancreatic cancer, who belonged to the group of patients with incurable cancer. She was on long-term HPN with good QaL and her survival time was 1206 days on HPN.

Our data confirm our clinical practice that the decision to start HPN in a patient with incurable cancer should always be taken on an individual basis by a multidisciplinary team. Before starting HPN we have to consider crucial issues regarding nutritional support in a patient with incurable cancer in depth. First and foremost, the negative impact of low nutritional intake on life expectancy and the performance status of the cancer patient were taken into consideration. Advantages and potential discomfort should be clearly explained to the patient in advance to balance their expectations with the realistic outcomes to be expected from HPN. As the HPN training period for patients and their relatives usually takes a few weeks this issue must also be discussed because these patients have limited life expectancy and some of them do not want to spend this time period in hospital. In future, we intend to perform the part of educational activities in a home setting. This will improve the median survival time of all groups of patients on HPN and contribute to a better quality of life of cancer patients and lower costs of treatment with HPN. Moreover, the monitoring of the patient must be done regularly and must include all aspects of palliative care. It is also very important to have a clear definition of and agreement from all parties (patient and medical staff) on the criteria for withholding and withdrawing nutritional support if there is no beneficial effect for the patient.[21,22]

Nine patients were considered as patients after cancer treatment with bowel failure and dependent on HPN. Survival over a 1-year period from the date of inclusion in HPN therapy for 7 patients was 100 % and the survival time of 1 cancer patient reached almost 5 years. These data seem to be similar to the survival times in the group of patients with non-malignant bowel insufficiency.[5]

Conclusion

The results of this retrospective study represent the first Slovenian analysis of the survival time of cancer patients on HPN treatment for intestinal failure. The results are comparable to results from global surveys, which is a direct indicator that the inclusion criteria for HPN in cancer patients used in Slovenia are good. They are also a good in-

direct sign that the quality of HPN service is good and serves as a platform for further development of HPN in cancer patients in Slovenia. Thus, we can conclude that cancer patients should not be deprived of HPN if they fulfill inclusion criteria and a multidisciplinary team and system for HPN are available. Our data also indicate that there is still need for the development of the field of HPN for patients with intestinal failure due to benign diseases.

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