

Safety and Effectiveness of Indwelling Percutaneous Drainage in Hospitalized Terminally Ill Cancer Patients with Recurrent Ascites

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Objectives: Terminally ill cancer patients in hospice palliative care unit are reluctant to undergo repetitive invasive procedures due to coagulopathies and poor performance or condition, while catheter management such as regular irrigation during hospitalization is easy. The purpose of this study was to investigate the safety and efficacy of indwelling intraperitoneal (IP) catheter in hospitalized terminally ill cancer patients with recurrent ascites.

Methods: A retrospective review was conducted in patients who underwent IP catheter at the hospice palliative care unit of Pusan National University Yangsan Hospital between August 2016 and June 2018. All catheters were inserted by interventional radiologists with radiological guidance. The primary end-points were functional IP catheter maintenance rate, which is catheter maintained with patency for drainage until the intended time.

Results: A total of 25 terminally ill cancer patients underwent IP catheters placements during the study period. All catheters were successfully inserted without major complications, but one patient had trivial bleeding and one other patient had temporary pain. The median time from admission to catheter insertion was 5 days (range, 1 to 49 days). Twenty-one catheters were maintained with function until the intended time, three cases were maintained without function, and the last one was removed early due to obstruction and pain. Finally, the functional IP maintenance rate was 84% (21/25) and the median functional catheter life span was 15 days (95% confidence interval, 10.8 to 17.2).

Conclusion: Our study showed relatively favorable results for IP catheter maintenance and safety in hospitalized terminally ill cancer patients with malignant ascites. (Ewha Med J 2020;43(2):29-34)

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Introduction

Recurrent ascites is a known representative complication for advanced cancer patients, its frequency is known to increase with progressing terminal status in approximately 6% to 10% of patients admitted to hospice palliative care (HPC) units [1].

Symptoms of ascites include pain from tense abdominal extension, nausea and vomiting, reflux esophagitis, respiratory difficulty from diaphragmatic splinting, lower extremity edema, decreased mobility and consequent reduction in quality of life (QoL) [2-4]. Medical treatments using sodium restriction and diuretics are primarily applied for controlling the ascites-related

symptoms [5], but the ascites are not amenable to medical treatment in some patients, eventually repeated paracentesis is widely used for palliation of symptomatic malignant ascites [2,3,6]. However, intermittent paracentesis has a limitation that there is short-term ascites related symptom relief due to rapid re-accumulation, thus leads to frequent repetitive procedures [2,5]. Additionally, repeated paracentesis has a small, but well-defined risk of catastrophic complications including bowel perforation, internal bleeding, or hypotension, as well as trivial complications such as pain or minor bleeding every time a needle is inserted. Clinicians often wait until fluid accumulation is substantial to avoid these risks, and to ensure the ascites is amenable to drainage, resulting in a deterioration in patient QoL [7].

The indwelling intraperitoneal (IP) catheter is an untunneled catheter that can be easily inserted, and can provide durable and effective symptom relief using daily consecutive drainage, avoiding the hazards and disadvantages related to repeated procedures [8–10]. Although there are limitations such as cumbersome catheter management, inconvenience in activities, and relatively short duration of functioning [11], indwelling IP catheters can be a logical choice for controlling ascites-related symptoms in hospitalized terminally ill cancer patients with a limited lifetime of 1 to 2 months and limited activity [12].

Although the practice of indwelling IP catheters is not a new technique [8–11,13], there are scanty data documenting the safety and efficacy of such a technique, especially in hospitalized terminally ill cancer patients [8]. Thus, we investigated the safety and efficacy of indwelling IP catheters in hospitalized terminally ill cancer patients with refractory ascites.

Methods

1. Patients and study design

Terminally ill cancer patients who underwent indwelling IP catheter placement for palliation of refractory malignant ascites in the HPC unit at Pusan National University Yangsan Hospital between August 2016 and June 2018 were enrolled in this study. A terminally ill cancer patient receives no additional anticancer treatment, and has an estimated survival time of less than 1 to 2 months. Of these patients, enrolled patients were as follows: 1) needed paracentesis more than twice a week, 2) without severe coagulopathies with platelet count less than

50,000/mm³ or international normalized ratio higher than 2, and 3) without severe behavioral problems which would make IP catheter insertion difficult. This study was approved by our institutional review board of Pusan National University Yangsan Hospital (05–2019–054), which waived the requirement for informed consent due to the retrospective design of this study.

2. IP catheter insertion procedure and management

All IP catheters were inserted by an interventional radiologist in the angiography room using ultrasound guidance or fluoroscopic imaging. All operators wore aseptic gowns, masks, and gloves, and all the patients received a dressing with aseptic drapes. Seldinger's technique and trocar access were routinely used. The catheter lines were 8.5 French lumens and were made of second-/third-generation polyurethane. The insertion site was the left lower quadrant of the abdomen lateral to the course of the inferior epigastric vessels. The catheters were sutured and they were held in place with a catheter fixation device. The tubes were clamped during transfer from the radiology suite to the ward, as a large volume can be unknowingly removed if the patient is left unattended and there is a delay in transport. The technical success of IP catheter insertion was defined as when ascites was draining through the correctly placed catheter without acute catastrophic complication.

No patient was administered prophylactic antibiotics or anticoagulation drugs for infection or thrombosis. All of the patients received a closed dressing dampened with betadine on the catheter insertion site every 3 days. Saline flushing followed by 10 mL of saline was performed every two or three times a day. Drainage was performed 500 to 2,000 mL per day rather than continuous drainage and re-locked when the target volume was drained.

3. Catheter monitoring and data collection

We checked daily ascites drainage amounts and catheter patency using saline irrigation. And we reviewed medical records related with complications, including pain, edema, bleeding, cellulitis and local or systemic catheter-related infections. Delayed complications were catheter-related infection such as cellulitis or peritonitis, catheter dislodgement, and obstruction. Peritonitis was defined as clinical symptoms such as abdominal pain or fever with positive ascites or blood culture. Catheter

obstruction was suspected when the catheter flow was impossible to back flush with drainage, and it was diagnosed by confirming residual ascites using physical examination or ultrasound. In this case, unless other acute complications developed, we waited for drainage recovery drainage using catheter saline irrigation for 48 hours. When drainage was not recovered, catheter repositioning or change was attempted considering ascites symptoms and life expectancy. On the other hand, if catheter function was lost but the procedure was difficult to perform due to deteriorated performance, or if the patient did not complain of discomfort associated with the catheter itself, the catheter without function was retained. Functional catheter status was defined as adequate drainage without complications leading to catheter removal.

4. Statistical analysis

We summarized baseline demographics and IP catheter-related characteristics using descriptive statistics, including medians, means, and ranges. The primary end points were functional IP catheter maintenance rate, which was defined as IP catheter maintained with patency until the intended time (discharge, transfer, or death), and functional IP catheter life span, which was calculated from the insertion date to the last date of drainage and was assessed using Kaplan–Meier estimates. The secondary endpoints were IP catheter insertion success rate, premature removal rate, and complication rate. The complication and premature removal rates were reported as complications per 1,000 IP catheter days and a simple rate. Statistical analyses were performed using SPSS ver. 17.0 (SPSS Inc., Chicago, IL, USA).

Results

1. Patients and characteristics

In total, 25 terminally ill cancer patients were enrolled in this study during the study period and a total of 503 IP catheter days were analyzed. Patient median age was 62 years (range, 36 to 76 years), and 15 patients (60%) were male. Seventeen cases (68%) had a Karnofsky Performance Scale score of 40 or less (Table 1). The median time from admission to hospice-palliative unit to IP catheter insertion was 5 days (range, 1 to 49 days). By the time of the analysis (September 2018), the median survival time from admission to hospice-palliative unit to death

or the last follow-up was 27 days (95% confidence interval [CI], 24.1 to 29.9; range, 7 to 92) to disease burden on image studies, 18 patients showed definitive peritoneal or omental lesions such as nodular or thickening lesions, while the remaining seven patients showed only liver or intraabdominal lymph node metastasis without definitive peritoneal seeding. The analysis of ascites showed its nature was serous (12, 60%) and bloody (8, 40%) out of 20 patients available for ascites analysis, and malignant cells were identified in 6 (38%) out of 16 patients by checked cytology or cell-block (Table 2).

2. IP catheter efficacy

All catheters were successfully inserted in two patients with trivial complications (bleeding and pain). No catastrophic complications such as viscus perforation or excessive bleeding were encountered during tube insertion and adequate drainage. So, the success rate for IP catheter insertion was 100%.

Twenty-one of the 25 cases had functional catheter until the intended time (discharge, transfer, or death); 16 cases maintained their catheter until death, and five cases were transferred to another palliative care hospital. The remaining four patients

Table 1. Baseline patient characteristics (n=25)

Characteristics	Value
Age (yr)	62 (36–76)
Sex	
Male	15 (60)
Female	10 (40)
Primary cancer type	
Gastric cancer	5 (20)
Biliary tract cancer	11 (44)
Pancreas cancer	6 (24)
Breast cancer	2 (8)
Ovary cancer	1 (4)
Disease presentation status	
Initially metastatic status	18 (72)
Recurrent status	7 (28)
Karnofsky Performance Scale	
50–60	8 (32)
30–40	14 (56)
10–20	3 (12)

Values are presented as median (range) or number (%).

Table 2. Nature of ascites (n=25)

Characteristics	Value
Analysis of paracentesis	
Nature of ascites*	
Serous (yellow)	12 (60)
Bloody	8 (40)
Serum ascites albumin gradient*	
>1.1	12 (60)
<1.1	8 (40)
Cytology or cell-block [†]	
Malignant cell	6 (38)
Non-malignant cell	10 (42)
Disease burden on image studies	
None	0 (0)
Peritoneal seeding	18 (72)
Liver, intraabdominal lymph node	7 (28)
Symptom related with ascites [†]	
Abdominal distension	25 (100)
Dyspnea (shortness of breath)	8 (32)
Low extremity edema	11 (44)

Values are presented as number (%).

*Twenty patients who underwent ascites analysis by paracentesis before insertion of indwelling intraperitoneal catheter.

[†]Sixteen patients available for cytology or cell-block analysis.

[‡]Duplicated selection was possible.

were maintained without catheter function (three patients) or the catheter was removed (one patient). Thus, the functional catheter maintenance success rate was 84%, and the median functional catheter life span was 15 days (95% CI, 9.5 to 20.5; range, 2 to 68) (Table 3).

3. IP catheter complications and removal

Eleven complications (21.8/1,000 catheter days) occurred with the 25 episodes of catheterization. The most frequently documented complications were catheter obstruction in five cases (20%, 9.94/1,000 catheter days), followed by pain in three cases (12%, 5.96/1,000 catheter days), and leakage, bleeding and insertion site cellulitis in one case (4%, 2.0/1,000 catheter days) (Table 4). Of the five patients who developed obstruction, the catheter was immediately removed in one patient due to associated infection, four patients underwent tube changes with a large size catheter of 10.2 French. However,

Table 3. Results of indwelling IP catheter (n=25)

Characteristics	Value
Success rate of IP catheter insertion	25 (100)
Complication at the time of insertion	
None	23 (92)
Bleeding (Hematoma)	1 (4)
Pain	1 (4)
Bowel injury	0 (0)
Causes of catheter removal	
Transfer with functional status of catheter	5 (20)
Deaths with functional status of catheter	16 (64)
Deaths without functional status of catheter	3 (12)
Early removal due to catheter related complication	1 (4)
Functional IP catheter maintenance rate	21 (84)
Median functional IP catheter life span (day, 95% CI)	15.0 (9.5–20.5)

Values are presented as number (%) unless otherwise indicated. IP, intraperitoneal; CI, confidence interval.

Table 4. IP catheter-related complication

Characteristics	Number (%)	Rate (per 1,000 catheter days)
No complication	19 (76)	
Complication*	11 (24)	21.87
IP catheter related Infection [†]	1 (4)	1.99
Catheter obstruction	5 (20)	9.94
Leakage	1 (4)	1.99
Pain	3 (12)	5.96
Bleeding	1 (4)	1.99

IP, intraperitoneal.

*Duplicated selection was possible.

[†]IP catheter related infection included symptomatic peritonitis, cellulitis, and abscess.

only one patient's catheter was functional until the end-time. The remaining three patients developed catheter obstruction again. There was no IP catheter complication-related death.

Discussion

The current study was conducted to evaluate the safety and efficacy of indwelling IP catheters in homogenous hospitalized terminally ill cancer patients in HPC. All IP catheters were inserted safely and the functional IP catheter maintenance rate

was 84%, showing acceptable results. Considering characteristics of hospitalized terminally ill cancer patients who have short life expectancy and poor general condition, IP catheters may be used to manage the symptoms caused by refractory ascites with an acceptable safety profile. To our knowledge, this is the first study to investigate indwelling IP catheters in hospitalized HPC patients.

For the management of refractory ascites, three invasive methods using permanent or long-term devices have been applied and studied as follows: tunneled catheters [14–17], peritoneal ports [18–21], and IP catheters [9–11]. The tunneled catheter or peritoneal port have the advantage of being able to be used over a permanent or long-term period, but there is a complication risk including wound dehiscence because a complicated procedure is needed for the insertion process [12,14]. Therefore, it is not appropriate for terminally ill cancer patients, because they have a limited life expectancy of less than 1 to 2 months and the risk of delayed wound healing due to poor general status. On the other hand, indwelling IP catheters as untunneled catheters can be easily inserted [12]. However, there are limitations for patient activity due to the risk of catheter dislodgement, and the need for proper management such as frequent irrigation to prevent complications considering the relatively high risk of infection or obstruction [8,11]. The indwelling IP catheter has mainly been used only in hospitalized patients due to its restriction on activities of daily life and a shorter dwelling durability, so there are scanty data except three prior studies [9–11], unlike other tunneled catheters or ports. However, in the case of terminally ill cancer patients admitted to the HPC unit, proper catheter management is relatively easy due to admission status, limited activity which reduces the risk of catheter dislodgement, the limited survival duration of 1 to 2 months reduces the likelihood of catheter-related complications which increase along with dwelling time, and their well-tolerated insertion procedure. Considering the limited life expectancy of such patients, managements of refractory ascites should be minimally invasive with maintaining effectiveness. The ideal treatment should aim to control symptoms and improve QoL with the least patient discomfort. Thus, indwelling IP catheters are the best option for hospitalized terminally ill cancer patients with refractory ascites, and the results of our study support this notion.

The loss of catheter function, such as obstruction and pre-

mature removal, was 16%, which is less than the 35% reported in a previous study [11]. It is possible that our patients in HPC settings were less likely to receive strict work-ups for clinical problems including fever. Further, the retrospective design of this study resulted in less detection of complications. On the other hand, catheter management in these hospitalized patients was relatively good because of catheter management including frequent irrigation by a healthcare provider rather than self-care by themselves. Additionally, as expected, limited survival duration after catheter insertion (median, 19 days; 95% CI, 8.6 to 29.4) may contribute to a reduced possibility of catheter-related complications. For example, considering that the median time for development of catheter-related infection and obstruction, which were the most common complications in previous studies, were 42 and 25 days, respectively [11], a short survival duration in this study may serve as a basis for explaining the low incidence of complications. This is more evidence that indwelling IP catheters may be more effective for patients in HPC settings.

The current study had several limitations due to its retrospective design. First, relatively definitive complications were likely to be clearly identified, but trivial complications such as pain or leakage might be missing. For example, in the case of complications such as leakage, 4% to 10% of tunneled catheters developed leakage [15,16], but only 4% in this study, which suggests a limitation due to the retrospective design. However, since all patients were in admitted status, the obstructions and infections that were most important for functional catheter maintenance were relatively accurately identified through daily check-ups. Second, patient-reported outcomes such as symptom improvement or QoL would be of critical importance for evaluating IP catheters in standard practice, but they could not be checked in the current study.

Despite these limitations, this study is the first to investigate the indwelling IP catheter in homogeneous hospitalized HPC patients with specific characteristics. However, the successful management of malignant ascites using IP catheters is most likely multifactorial, and dependent on underlying malignancy, catheter thickness, procedure, and operator experience, performance status, and comorbidities. Thus, to clarify the management strategies for malignant ascites using indwelling IP catheters, future prospective clinical trials to investigate adequate catheter thickness according to characteristics of the ascites

(e.g., serum ascites albumin gradient levels), most appropriate time for catheter insertion, and patient-reported outcomes are needed.

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