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Peritoneal Dialysis Catheters for the Treatment of Refractory Ascites

Introduction

Liver cirrhosis remains an incurable disease that can lead to various complications including ascites, hepatic encephalopathy, and esophageal varices.[1] Ascites develops as a part of the natural history of cirrhosis in most patients and is associated with a higher mortality rate, poor quality of life, risk of infections, and renal failure.[1–3] Patients can suffer from anorexia, early satiety, nausea and vomiting, shortness of breath, and limited mobility due to the ascites.[4] For most patients, the condition can be managed with a sodium restriction and diuretic therapy typically including furosemide and spironolactone up to maximum doses of 160 mg and 400 mg respectively.[1,5,6] However, a small subgroup may become refractory to this management. The significance of this stems from the fact that studies have shown among patients with liver disease, ascites contributes to a large extent to lower quality of life scores on standardized surveys.[7]

Refractory ascites is recurrent fluid accumulation in the peritoneal cavity, as an end result of multiple mechanisms, including liver cirrhosis, peritoneal infiltration by a tumor, portal hypertension, lymphangitic carcinomatosis, congestive heart failure, or lymphatic obstruction.[4] It is associated with increased mortality and morbidity, including complications of abdominal wall hernias, spontaneous bacterial peritonitis, kidney dysfunction, and pleural effusions.[3,6,7] In patients with refractory ascites, the mainstay of treatment becomes serial large volume paracentesis (LVP), trans-jugular intrahepatic portosystemic shunts (TIPS), liver transplant or surgical placement of a peritonovenous shunt.[5,6,8] However, transplantation may not be an option due to the limited number of available organs or patient comorbidities, while the other treatment options are associated with higher risk of severe complications, such as bleeding, encephalopathy, and poor health related quality of life.[5,6] Often in many patients LVP becomes the treatment of choice which is not without its limitations including circulatory dysfunction post paracentesis and consequent hyponatremia, kidney dysfunction, viscus puncture, and peritonitis.[1,5,6] In addition, the treatment is resource intense and costly, uncomfortable due to its intermittent nature allowing fluid re-accumulation, and needs to be completed in a clinical setting.

An alternative management for refractory ascites is the placement of a peritoneal dialysis (PD) catheter to drain the fluid. PD catheter placement for ascites drainage has many potential advantages including the ability to drain fluid at home as it accumulates, increased frequency of drainage, and fewer complications such as hernias and leaks.[5,9–12] While PD catheters have been used in malignant ascites showing high technical success rate, complete remission of symptoms, and improved quality of life, the efficacy of this approach as well as the effect on quality of life has not been formally tested for management of ascites with decompensated cirrhosis.[5,9–14] The primary goal of the present study was to evaluate health related quality of life in patients with refractory ascites and demonstrate feasibility of a larger, more definitive randomized control trial using PD catheters compared to recurrent LVP.

Methods

Design

We designed a single center, multi-site, open label, randomized controlled trial comparing bedside PD catheter placement versus usual standard of serial LVP for treatment of refractory ascites. This study was approved by University of Manitoba research ethics board approval with

relevant site approvals at St. Boniface Hospital and Health Sciences Centre. An external data safety monitoring board was established to review the patient data for outcomes and safety at pre-defined time points. Our primary outcomes were improvement of 10 points in the physical component score (PCS) of the Short Form-36 (SF-36) at two months. Secondary outcomes were incidence of mechanical and infectious complications, emergency department utilization, hospitalization and mortality, all other domains of the SF-36, Euroquol-5D (EQ-5D), the Newcastle Patient Reported Ascites Measure and overall health care costs.

Participant Selection and Recruitment

We planned to randomize 50 patients based on a power calculation to achieve a clinically meaningful 10-point improvement in the PCS-SF-36 (SE = 5). A computer-generated randomization algorithm was used by a blinded statistician. This is the observed improvement in quality of life from previous studies treating ascites with TIPS. Patients would have been equally divided (25 per arm) and randomized to receive treatment with either PD catheter or current standard of care (LVP). Patient inclusion and exclusion criteria are outlined in *Table 1*. Patients were actively recruited from the University of Manitoba Hepatology Program clinics, and passively by informing doctors at the Health Sciences Centre Emergency Department, Seven Oaks General Hospital Emergency room, General Internal medicine clinics and wards, and from the Bairdmore hepatology clinic at Victoria General Hospital. The target enrollment was ~1 patient per month. Patients in the PD catheter arm received treatment and follow-up at Seven Oaks General Hospital PD program. Recruited patients were defined as refractory according to criteria of having received at least 160 mg Lasix and 400 mg Spironolactone per day, or inability to tolerate dose increases due to circulatory dysfunction, clinical deterioration, or biochemical abnormalities, and the need for recurrent LVP to manage ascites.

Study Procedures

Catheter insertion was to be completed at the bedside in a dedicated procedure room used for routine PD catheter insertions. A specially trained interventional nephrologist used an Argyle PD catheter kit, which are double cuffed curled catheters at 57cm or 62cm lengths, for catheter insertion (*Figure 1*). Several steps were taken to minimize the risk of infection including a dose of pre and post insertion antibiotics (cefazolin or vancomycin), iodine impregnated caps on transfer sets, the catheter was tunneled, and a closed loop system was utilized for drainage. At the time of insertion patients were drained of ascites fluid of 5-10L to decrease chance of catheter leakage. Draining greater than 5L would warrant use of Human Serum Albumin 25%, 100cc for 5-10L and 200cc for 10-15L. Patients returned for follow up at 48 hrs and 96 hrs for initial drain and training with a specialized PD nurse. Patients were told to drain a maximum of 2L per day after the initial drain. Patients in the LVP arm continued with treatment according to regular standard of care including scheduled LVP or presentation to emergency departments for this procedure.

Patients in the PD catheter arm were seen by study personnel in the PD research clinic every 2 weeks, while LVP patients followed up at their regular clinics. LVP patients received treatment as scheduled with their provider, while PD catheter patients drained themselves at home as needed. Patients in the PD catheter arm were asked to log the dates of drainage, amount drained, clinic or ER visits, symptoms, and these would be reviewed by clinic nurse/study coordinator biweekly. In the LVP arm, patients had culture and cell count on fluid removed to evaluate for spontaneous bacterial peritonitis at every LVP session. Patients in the PD catheter arm had culture and cell counts at 0, 2, and 6 months regardless of signs and symptoms of peritonitis. Both groups had standard monthly bloodwork and were to continue diuretic therapy.

Outcomes

The primary outcome was a change in the physical component score of the SF 36 questionnaire at 2 months. Secondary outcomes included technical success rate of tunneled PD catheters, defined as successful positioning of the catheter in the intraperitoneal space with initial drainage of ascites, catheter survival, health related quality of life measures at 0, 2, 4, and 6 months (SF-36, EQ-5D, Newcastle Patient Reported Ascites Measure), complication rate with frequency of catheter related complications, among others listed in detail in the protocol. An independent data and safety monitoring board was to evaluate all outcomes at 3, 6, 12, and 18 months.

Statistical Analysis

Analysis was planned to be done using descriptive statistics. Continuous data would be presented as means ± standard deviation, and categorical data as proportions. Continuous variables would be compared with two tailed t-tests or ANOVA if more than 3 groups. Discrete data would use Mann-Whitney U tests for 2 groups or Kruskal-Wallis Test for 3 or more groups. A p-value of < 0.05 would be significant. For the primary outcome intention to treat analysis would be used with a two tailed test of significance in SF-36 PCS. Additional analyses would include an "as treated" analysis and a sensitivity analysis adjusted for age and MELD score. Continuous secondary outcomes would utilize an intention to treat approach with two tailed tests and Wilcoxon Rank Sum test when appropriate. Categorical outcomes would be compared using chi-squared tests.

Results

Study enrollment was initiated February 2017. Recruitment took place primarily at Health Sciences Center, the city's major regional tertiary care center, through chart review and advertisement in various locations around the hospital including, ER, clinics, public spaces etc. Due to suboptimal recruitment, amendments were proposed to alter the inclusion and exclusion criteria. Patient charts in hepatology were screened 1-2 weeks prior to clinic visits, if a patient was identified as potentially eligible the research coordinator passed along their names to their attending physician for approval so that they could approach the patient to explain the study. Of the 2302 charts screened 155 were patients who had ascites. Among them, the majority (n=89; 57.4%) hadn't had any LVP's (*Figure 2*). The rest of the patients were not eligible because 17 (10.9%) patient's ascites resolved after the LVP, and 29 (18.7%) had exclusion criteria. The 29 that had exclusion criteria consisted of 10 (34.5%) patients who were being worked up for transplant or other transplant related reasons, 7 (24.1%) had current or prior history of encephalopathy, 5 (17.2%) had current or previous episodes of spontaneous bacterial peritonitis (SBP), 2 (6.9%) had a life expectancy of less than 6 months, 2 (6.9%) were on immunotherapy, 1 (3.4%) was a non-English speaker, 1 underwent TIPS procedure immediately after screening (3.4%), and 1 (3.4%) lived out of town (this is not an exclusion criteria, however, would make participation in the study very difficult with the frequent appointments and follow up). Of the 20 (12.9%) patients that were eligible, 10 were not approved by the attending physician for enrollment and 10 were approached by the coordinator. The 10 patients who were not approved for enrollment by the attending physician included 2 (10%) who declined to be randomized, 1 (5%) who underwent PD catheter assessment but was ineligible due to alcohol use, 1 (5%) who did not show up for the appointment and was thus not asked, and 6 (30%) were not approved for enrollment by the attending physician.

Among the 10 that were approached by the coordinator 2 (10%) preferred to be managed with transplant (they were not on the transplant list), 2 (10%) were not willing to be randomized, 1

(5%) had no support person for PD catheter and a short life expectancy, 1 (5%) would not require recurrent LVP's, and 1 (5%) declined for unknown reasons. 3 (15%) patients consented, 1 (5%) of which withdrew consent immediately after being randomized into the PD catheter arm as it would be difficult for their support person to help with PD catheter drainage. Enrollment was terminated February 2018 for futility in continuing the trial. The two enrolled patients completed the study period and their baseline characteristics can be found in *Table 2*.

Discussion

With an enrollment rate of 0.08% of patients screened over a one-year period there were some unforeseeable barriers to the enrollment and randomization processes. Over the time period, only 155 patients were screened to have ascites which was a rather small population representing 6.7% of the charts screened. Among the 155 patients with ascites only 20 patients (12.9%) were eligible for this trial. Of these, the most significant reason for non-enrollment was lack of physician willingness to enroll patients (30%), followed by patients not wanting to be randomized (20%), and patients wanting to pursue liver transplantation as definitive management (10%). This implies that while lack of eligible patients contributed to the barriers of the study, even those that were eligible displayed hesitancy in randomization, as well as physician reluctance in enrolling their patients. These trends could potentially be explained by the relatively permanent nature of the invasive intervention compared to intermittent nature of LVP's, patient and physician knowledge and attitudes towards PD catheters and their effects and risks in ascites.

The primary limitations of this study were underestimating the number of patients that would not consent to enrollment and the number excluded by physicians. There seemed to have been a lack of equipoise in both groups for different reasons. Physician hesitancy seemed to be due to concerns regarding the risk of infection and subsequent transplant eligibility. To pre-emptively prevent such concerns the study was designed in collaboration with hepatologists and infectious disease specialists to help ensure patient benefit with minimal risk to patients. However, there seemed to be disagreement among hepatology colleagues which limited our enrollment in certain situations. This hesitancy was likely based upon previous research which showed higher risks of infection with PD catheters and poor patient outcomes, and concluded that patients with longer predicted survival (non-malignant ascites) would not overall benefit from the symptom relief, or had inconclusive results.[15–17] For example, Kathpalia et al. reported a 10% rate of spontaneous bacterial peritonitis and an increase in mortality in non-malignant (cirrhotic) ascites patients with an indwelling catheter for ascites drainage.[17] While these were valid concerns it was important to note that our methods outlined a different catheter insertion technique with a keen focus on infection prevention. Previously, our principal investigators showed in their observational study of PD catheters in non-malignant ascites that 1 case of peritonitis developed over 217 catheter months (0.06 episodes per year) compared to the 2016 ISPD guideline of no more than 0.5 episodes per year at risk (1 case over 24 catheter months). Our centre's infection rate proved well below recommend thresholds for catheter related peritonitis.[18,19] The methods employed for catheter insertion can be found in the study procedures but involved the use of a tunneled double cuffed coiled catheter which had shown reduce infection rates in PD[20], the use of prophylactic antibiotics, iodine containing caps for transfer sets, and closed loop systems for draining.

The other important consideration for the physicians when it came to referring their patients was a potential threat to transplant eligibility due to the catheter itself. For this reason, it was included in the exclusion criteria. As transplant patients at our center would be sent a regional hub to have the surgery (Toronto General Hospital), the investigators consulted the surgeons on

the impact of PD catheters on liver transplant eligibility. The surgeons informed our team that PD catheters were not a concern for transplant eligibility or for performing transplant surgery. However, practitioners still elected to exercise caution and excluded patients being worked up for transplant. 10 of the 29 patients with exclusion criteria were related to transplant, which also represented a barrier to enrollment.

Also, the notion that the pathophysiology of cirrhotic ascites was more adequately addressed with sodium restriction rather than insertion of a PD catheter was encountered as well. Physicians emphasized that as ascites results from lower plasma oncotic pressure, an optimally restrictive diet with a sodium intake less than 2g, would decrease the incidence and severity of the ascites. It was counter-intuitive in their view to supply a permanent intervention for symptom management when a pathophysiological and pharmaceutical alternative existed. However, this reasoning could be applied to many conditions in which clinicians provide symptom management irrespective of whether the contributive factor was addressed (ex. smoking in COPD) and does not necessarily reflect patient-centered practice.

On the other hand, patient reluctance was also a significant post eligibility factor for non-recruitment. In this case patient attitudes reflected unwillingness in the randomization process when presented with the two arms of the trial which reflected 20% of the eligible population. When it came to a choice between recurrent trips to the hospital for LVP's and draining fluid more consistently at home, some patients did not want to be put in the LVP group and chose to decline consent. This also played a part in low enrollment. Conversely, some patients also preferred LVP over catheter due to minimal exertion on their part. Some general reasons for hesitance may have included the time and effort by the patient for PD catheter insertion and maintenance, to drain correctly, maintain hygiene, troubleshoot problems, and tolerate the physical presence of the catheter. These do not seem to be a major issue with peritoneal dialysis patients, however PD is a life sustaining therapy whereas this procedure is simply undertaken to relieve symptoms.

Another conceivable limitation included the exclusion of malignancy related ascites which could have potentially added more patients for consideration. Other studies have shown successful recruitment of many patients by including malignant and non-malignant ascites.[9,10,13–16,21] There were two major factors as to why it was not added into the criteria. The first was that the literature describes the benefit in malignant ascites as outweighing the risks and providing patients with symptom relief. There would be very little advantage to reaffirming a well-established practice. As eluded to above, the investigators previously published an observational study which showed significant improvement in quality of life with low rates of peritonitis (.06 episodes per year) for patients who received PD catheter for management of non-malignant ascites.[18] The rationale for this study was to explore those results in an RCT documenting the effect on symptom control and quality of life, and based on those results conducting a multicentered trial examining mortality differences. However, the RCT pilot study proved such a study non-feasible. In addition, when enrollment was not meeting the set target, the investigators consulted with oncology and palliative care about their patients participating in the study and being randomized, but were met with resounding resistance to randomization as the physicians and patients preferred the catheter to LVP's. Our center had provided consultation-based PD catheter insertion for non-renal causes since ~2010, with the uniquely quick procedure and safety measures employed there had been a steep increase in the utilization of such services up to a point where equipoise no longer existed in that group of patients.

While there were unforeseeable limitations there were also structured strengths to the study design. Which included a robust protocol created in consultation with multiple specialties including oncology, hepatology, nephrology, and palliative care, etc., rigorous procedural and patient outcome safety monitoring, and receptive investigators adapting to enrollment concerns. The study was designed to include a relatively representative patient population without other variables impacting the results, such as comorbidities (severe coagulopathy, HIV/AIDS, SBP). Of the 29 patients excluded, 19 were non-transplant related with the largest percentage having consisted of encephalopathic (current or prior) patients, followed by those who had had SBP's. Combined these represented 63.2% of the non-transplant related exclusions. These factors were associated with poor outcomes, and a higher risk of infection as thus were excluded. Furthermore, the study outcomes considered impact on quality of life, as well as technical success of the catheter insertion; both of which necessitated consideration as a device was being assessed as an intervention.

Based on the obstacles faced in our trial it was evident that while the study question remains valid, it required further research. The study population or design would need to be altered to attempt to circumvent barriers. Firstly, our centre's easily accessible catheter insertion for ascites of various causes hindered our recruitment, but at a center where the procedures are not similar and there remains equipoise it could be feasible, Alternatively, unique study designs that create prioritized opportunity for patients in either arm to receive PD catheters should they choose (i.e. after study completion) may have also helped with enrollment and allowed patients to benefit from the study. Secondly, the knowledge and attitudes about PD catheter insertion techniques, infection prevention, and outcomes needed to be more widely shared with colleagues and specifically those earlier in their training, perhaps at grand rounds or other teaching settings to conceivably have produced a clinical environment conducive to such a study. Our centre offers safe, effective, and successful catheter insertions which have the potential for broadening the clinical applications of the procedure to benefit patients. Lastly, while the first two points were significant barriers for eligible patients, it was worth noting that the overall incidence of refractory non-malignant ascites requiring serial LVP's was low (20 patients over 1 year). While their enrollment could have changed the trajectory of the study, a small population gives rise to less eligible candidates. This could have been mitigated by conducting the study in multiple and larger centres where refractory ascites was more prevalent. Due to the findings of this study we plan to pursue a formal nationwide survey examining equipoise for this procedure among physicians caring for ascites patients. This would help to address attitudes and knowledge of physicians across Canada and would direct the future inquiry of the study question.

Conclusion

While the effects of PD catheters in malignant ascites on quality of life and symptom relief are well established, we proposed a pilot randomized controlled trial to determine if such a correlation existed with non-malignant ascites. The study site had been providing this service on a referral-based system as an alternative for LVP's in recurrent non-malignant ascites for several years at the time of the study with excellent technical success and safety outcomes, particularly infection risk. Recruitment for the study was conducted over 1 year from February 2017 to February 2018 and resulted in enrollment and completion of 2 study subjects. Based on the results of the study, this was non-feasible as an RCT. Physician and patient hesitancy proved significant factors in non-enrollment of eligible patients. Potential reasons included concerns about infection, transplant eligibility, randomization, and time and effort required for PD catheters among others. The total population of eligible patients was only 0.87% of the total screened charts which also highlighted the small sample size of those with refractory non-

malignant ascites. A survey was proposed to determine the attitudes of physicians across Canada and determine whether equipoise exists on this topic.

References

1. Senousy BE, Draganov P V. Evaluation and management of patients with refractory ascites. *World J Gastroenterol*. 2009;15(1):67-80. doi:10.3748/wjg.15.67.
2. Planas R, Montoliu S, Ballesté B, et al. Natural History of Patients Hospitalized for Management of Cirrhotic Ascites. *Clin Gastroenterol Hepatol*. 2006;4(11):1385-1394. doi:10.1016/j.cgh.2006.08.007.
3. Scaglione S, Kliethermes S, Cao G, et al. The epidemiology of cirrhosis in the United States a population-based study. *J Clin Gastroenterol*. 2015;49(8):690-696. doi:10.1097/MCG.0000000000000208.
4. Moore CM, Van Thiel DH. Cirrhotic ascites review: Pathophysiology, diagnosis and management. *World J Hepatol*. 2013;5(5):251-263. doi:10.4254/wjh.v5.i5.251.
5. Wong DKH. Management of Ascites. *Hepatol Diagnosis Clin Manag*. 2012;27(Table 2):80-92. doi:10.1002/9781118314968.ch6.
6. Singhal S, Baikati KK, Jabbour II, Anand S. Management of refractory ascites. *Am J Ther*. 2012;19(2):121-132. doi:10.1097/MJT.0b013e3181ff7a8b.
7. Les I, Doval E, Flavià M, et al. Quality of life in cirrhosis is related to potentially treatable factors. *Eur J Gastroenterol Hepatol*. 2010;22(2):221-227. doi:10.1097/MEG.0b013e3283319975.
8. Runyon BA. Management of adult patients with ascites due to cirrhosis: An update. *Hepatology*. 2009;50(4):1321. doi:10.1002/hep.23261.
9. Lungren MP, Kim CY, Stewart JK, Smith TP, Miller MJ. Tunneled peritoneal drainage catheter placement for refractory ascites: Single-center experience in 188 patients. *J Vasc Interv Radiol*. 2013;24(9):1303-1308. doi:10.1016/j.jvir.2013.05.042.
10. Savin M, Kirsch M, Romano W. Peritoneal ports for treatment of intractable ascites. *J Vasc Interv Radiol*. 2005:363-368.
11. Tapping CR, Ling L, Razack A. PleurX drain use in the management of malignant ascites: Safety, complications, long-term patency and factors predictive of success. *Br J Radiol*. 2012;85(1013):623-628. doi:10.1259/bjr/24538524.
12. Barnett T, Rubins J. Placement of a permanent tunneled peritoneal drainage catheter for palliation of malignant ascites: a simplified percutaneous approach. *J Vasc Interv Radiol*. 2002:379-383.
13. Belfort M, Stevens P, DeHeak K. A new approach to the management of malignant ascites: a permanently implanted abdominal drain. *Eur J Surg Oncol*. 1990:47-53.
14. Monsky WL, Yoneda KY, MacMillan J, et al. Peritoneal and Pleural Ports for Management of Refractory Ascites and Pleural Effusions: Assessment of Impact on Patient Quality of Life and Hospice/Home Nursing Care. *J Palliat Med*. 2009;12(9):811-817. doi:10.1089/jpm.2009.0061.
15. Caldwell J, Edriss H, Nugent K. Chronic peritoneal indwelling catheters for the management of malignant and nonmalignant ascites. 2018;31(July):297-302. doi:10.1080/08998280.2018.1461525.
16. Knight JA, Thompson SM, Fleming CJ, et al. Safety and Effectiveness of Palliative Tunneled Peritoneal Drainage Catheters in the Management of Refractory Malignant and Non-malignant Ascites. *Cardiovasc Intervent Radiol*. 2018;41(5):753-761. doi:10.1007/s00270-017-1872-1.
17. Kathpalia P, Bhatia A, Robertazzi S, et al. Indwelling peritoneal catheters in patients with cirrhosis and refractory ascites. *Intern Med J*. 2015;45(10):1026-1031.

doi:10.1111/imj.12843.
18. Hingwala J, Whitlock R, Dunsmore S, Armstrong S, Tangri N, Komenda P. Peritoneal dialysis catheters to treat refractory non-malignant ascites. *Perit Dial Int*. 2017;37(4):481-482. doi:10.3747/pdi.2016.00282.
19. Li PK, Szeto CC, Piraino B, de Arteaga J, Fan S, Figueiredo AE, Fish DN, Goffin E, Kim YL, Salzer W, Struijk DG, Teitelbaum I JD. ISPD Peritonitis Recommendations: 2016 Update on Prevention and Treatment. *Ispd*. 2016;Sep 10;36((March):481-508. doi:10.3747/pdi.2016.00078.
20. Boujelbane L, Fu N, Chapla K, et al. Percutaneous versus surgical insertion of PD catheters in dialysis patients: A meta-analysis. *J Vasc Access*. 2015;16(6):498-505. doi:10.5301/jva.5000439.
21. Christensen L, Wildgaard L, Wildgaard K. Permanent catheters for recurrent ascites—a critical and systematic review of study methodology. *Support Care Cancer*. 2016;24(6):2767-2779. doi:10.1007/s00520-016-3145-y.

Tables and Figures

Legend

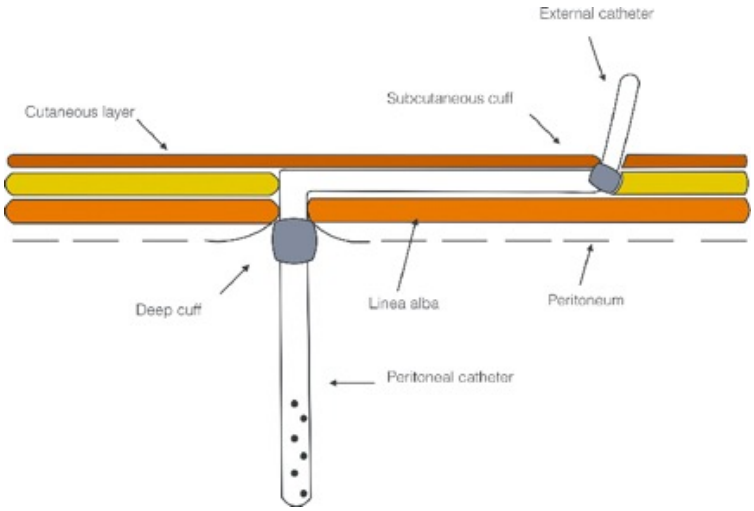
1. Table 1 outlines the inclusion and exclusion criteria utilized for participant selection.
2. Figure 1 displays what a double cuffed peritoneal catheter would look like in the abdomen after insertion.[1] (Obinwa O, McLoughlin J, Kavanagh D, Wall C. Peritoneal Dialysis Catheters. *Some Spec Probl Perit Dial*. 2016;(September). doi:10.5772/64024.)
3. Figure 2 depicts a flow chart of the charts screened, eligible patients, and the reasons for non-enrollment.
4. Table 2 describes the baseline characteristics of the 2 patients who enrolled into the study and completed the study.

1. Table 1: Inclusion and Exclusion Criteria for Patient Selection

Inclusion Criteria
Males and non-pregnant females > 18 years of age
Liver cirrhosis as defined by histological, clinical, or radiological criteria
Refractory non-malignant ascites requiring 2 or more LVP's in 4 mo.s
No contraindications for bedside PD catheter insertion (eg. prior major abdominal surgery, ostomies, large hernias, inability to lie flat, bleeding diatheses)
Patient has support person to help with catheter
Exclusion Criteria
Prior liver transplant
In process for liver transplant or on the waitlist
Current or previous spontaneous bacterial peritonitis - defined as PMN >250 cells/mm^3, or bacteria in ascitic cultures
Malignant ascites
Severe coagulopathy - INR >1.5 or platelets <50 x 10^9/L not reversible at time of catheter insertion
Loculated ascites
Presence of HIV/AIDS
Immunomodulatory treatment use in last 4 months
Expected survival <6 mo. and/or MELD score >30
Hepatic encephalopathy requiring hospitalization in last 6 mo.s
History of non-compliance/ suspected failure to comply
Allergies to vancomycin and cephalosporins

PMN = polymorphonuclear leukocytes, MELD = Model for End-Stage Liver Disease

2. Figure 1: Position of Double Cuffed Peritoneal Dialysis Catheter in Abdomen



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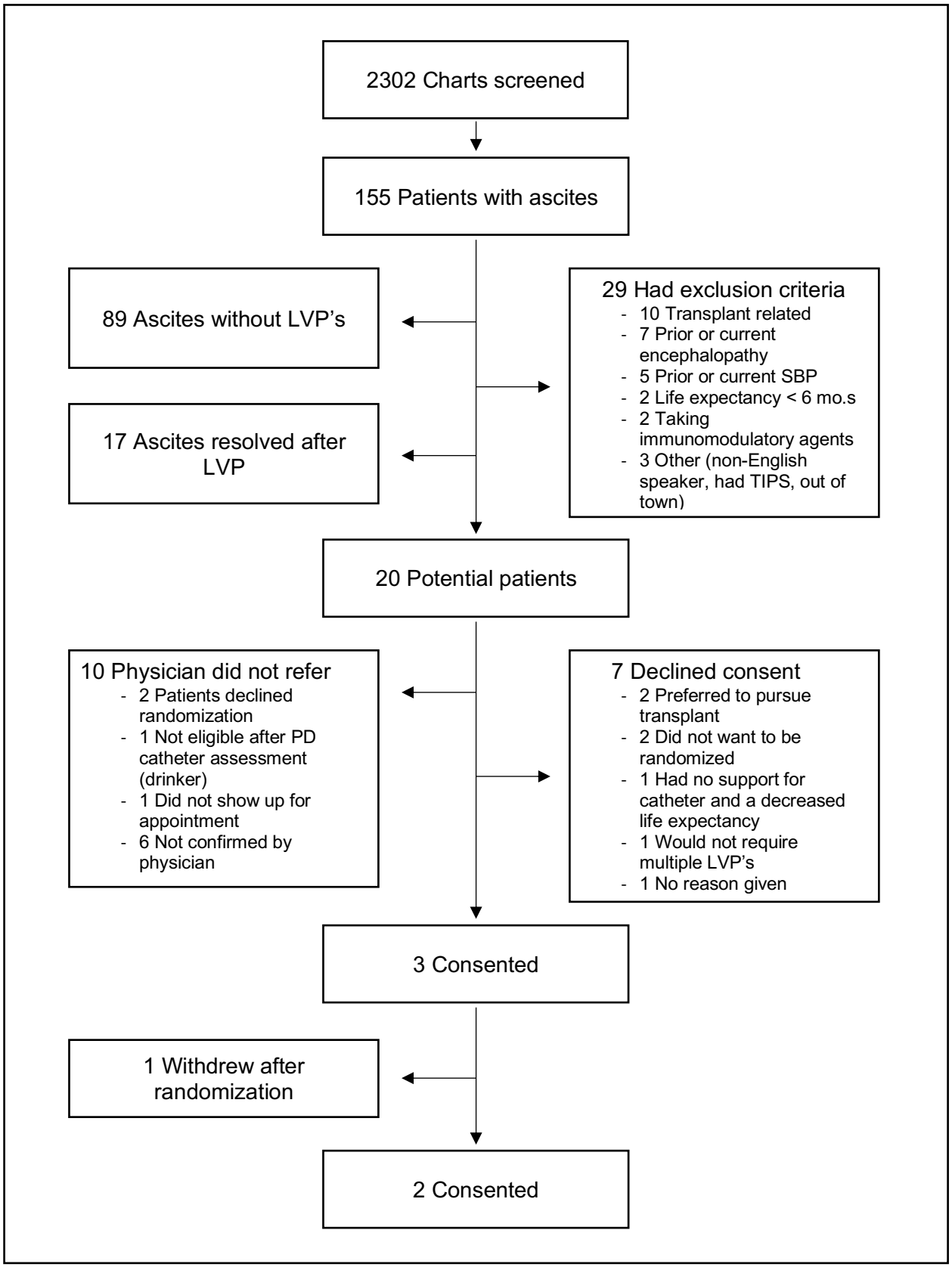
3. Figure 2: Screened Patients and Reasons for Non-participation in the Study



4. Table 2: Baseline Characteristics of Enrolled Patients

	Patient 1	**Patient 2**
Randomized Group	PD catheter	LVP
Age	61	68
Sex	Female	Male
BMI	39.8	32.3
Cause of Cirrhosis	NASH	NASH
Symptoms of ascites	SOB on exertion, fatigue, decreased appetite, heartburn	Abdominal fullness, discomfort, pain
Co-morbidities	HTN, pre-diabetes, TIA, A. fib, OA of the knees, RTKR, esophagitis and duodenal ulcer, mental health	HTN, dyslipidemia, non-specific interstitial pneumonia, pulmonary resection 2^{o} to pulmonary fibrosis, hx. of mild encephalopathy
Smoking Status	Non-smoker	Not collected
Alcohol Intake	None	Not since diagnosis
*Volume of ascitic fluid**	12 L	>5 L

NASH = Non-alcoholic steatohepatitis, SOB = shortness of breath, HTN = hypertension, TIA = transient ischemic attack, A. fib = atrial fibrillation, RTKR = Right total knee replacement, hx = history. * = from current most LVP prior to consent for study