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Efficacy of Pigtails for the Management of Refractory Malignant Ascites or Effusion: A Systematic Retrospective Chart Review of an Institution

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ABSTRACT

Introduction: Malignant ascites and effusions have been observed in various diseases and persistent ascites or effusion from any of causes prompts the need for urgent first-line therapies. Refractory forms of ascites and effusion can cause noteworthy symptoms and can severely affect the quality of life (QoL). We therefore assessed the viability, efficacy, and patient-reported results of pigtails in the administration of refractory ascites or effusion due to malignancy.

Aims & Objectives: We aimed to assess the viability, efficacy and patient-reported results of pigtails in the administration of refractory ascites or effusion by malignancy.

Place and duration of study: It was conducted in Vascular Interventional Radiology Department, Dow Institute of Radiology, Dow University of Health Sciences, Ojha Campus for a period of 18 months between January 2021 and June 2022.

Material & Methods: A retrospective chart review from a single center was done. All available data of the Interventional Radiology Department was utilized to identify patients(n=65) with refractory malignant ascites or effusion who underwent pigtail placement. Data analysis was performed using SPSS version 21, $p \leq 0.05$ was taken as significant.

Results: Procedural success rate was 100% for placement and similarly no mortality was observed. Duodenal, liver and ovarian cancer was the primary source of malignancy. The catheters, 8Fr (n=45, 69.20%) and10Fr (n=20, 30.80%) were implanted. Leakage was the highest experienced complication followed by dislodgement. Overall catheter mean survival time was [23.37days, 95%:21.63- 25.10]. The estimated mean [(24.46, 95%21.98-26.94 Vs 22.53, 95%20.08-24.97)] duration of catheter dwelling time for pleural effusion was greater than that of ascites ($p>0.05$). Overall, estimated mean time for 8Fr catheter was greater than that of 10 Fr ($p=0.048$). Infection and leakage had an estimated mean catheter survival time lower than that of dislodgment and occlusion [log rank-chi square 13.64,$p=0.003$].

Conclusion: Procedural success rate achieved was 100% and acceptable outcomes in terms of complications and catheter time. These minimally invasive treatment options should be utilized to soothe symptoms and improve the QoL.Furthermore, experimental studies with bigger sample size assessing the adverse outcome and ascertaining the possible cost savings should be performed.

Keywords: Ascites; Malignant; Pigtail catheter; Pigtail; Pleural effusion; Complications; quality of life; symptoms; palliation.

INTRODUCTION

Malignant ascites and effusions are characterized by a minimum of 500 milliliter (mL) which has been observed in various diseases both benign and malignant[1]. Benign diseases encompass a wide variety of conditions ranging from hepatorenal to cardiac etiologies[2]. Common neoplastic etiologies incorporate endometrial, ovarian, breast, and gastrointestinal cancers. Persistent ascites or effusion from any of neoplastic or non-neoplastic causes prompts the need for urgent first-line therapies[3].

Refractory forms of ascites and effusions can cause noteworthy symptoms, such as orthopnea and dyspnea especially in cases of massive effusion. Abdominal distension, anorexia, heaviness, and trouble ambulating are more marked in patients with massive ascites[4]. These at the end can extremely affect the quality of life (QoL). With terminal malignancies involvement and with the passage of time symptoms are markedly exacerbated affecting the morbidity and psychological status of patients.

Choices chosen more frequently reflect clinician inclinations and procedural accessibility, like dietary restrictions, repeated paracentesis, diuretics, implantable drains, transjugular intrahepatic portosystemic shunts (TIPS) and permanent indwelling devices[5]. Diuretic treatment is imperative first-line mediations at whatever point conceivable, but have a restricted part, particularly in refractory situations.

Patients with low albumin index, such as that with bowel or lymphoma, usually do not improve with salt confinement or diuretics. On the other hand, patients with high albumin index are responsive to these measures, like those of liver and kidney. In few cases, such as those with hepatic metastases, portal hypertension developed may be diuretic responsive[6].

The foremost common palliative treatment is repeated paracentesis. With frequent re-accumulation of ascites and subsequently, drainage, the patients are prone to multiple trips to the hospital, thus resulting in episodes of infection, peritonitis, hypotension, bowel perforation, and bleeding[7]. In some setups, however, and also in accordance to patientswith the request, repeated paracentesis is preferred over indwelling catheters[8]. The final option relies on the clinician's and patient's decision, restrained information with respect to the administration of refractory ascites or effusions and financial constraints along with their availabilities. Toward, the ends of life, these palliative measures are avoided by many.

The adequacy of pigtail catheters in malignant and non-malignant ascites and effusion still remains ambiguous. Given the lack of data regarding pigtail catheter placement and the lack of a standardised approach for the palliative treatment of patients with refractory ascites or effusions, we evaluated the viability, efficacy, and patient-reported outcomes of pigtails in the administration of refractory ascites or effusion caused by malignancy.

MATERIAL AND METHODS

Design, duration and patients:

A retrospective chart review from a single center was performed in a consecutive manner. All available data from the registries of the Interventional Radiology Department was utilized to identify 65 patients with refractory malignant ascites or effusions who underwent pigtail placement for their management between January 2021 and June 2022. Medical history, procedure details, and clinical follow-up data were evaluated.

Inclusion and exclusion criteria:

We included all adults above 18 years of both genders with refractory symptomatic ascites and effusions who underwent pigtail placement by interventional radiology department.

Patients excluded were those who had pigtail catheter placements at an outside facility. Other non-interventional approaches for removal of ascites or effusion than pigtail placement (like, pharmacology, and chemotherapy) were also excluded.

Patient Selection:

Information available incorporated age, gender, diagnosis, earlier strategy of indication control, French of catheter utilized, means used for pigtail placement, laboratory data, volume drained, infection or occlusion, overall morbidity status, psychological outcome and survival.

Catheter:

Frequency of ascites and effusions, also the clinician's decision was the ultimate requirement for placement of catheter. We decided the catheter on fluid consistency after puncturing at the time of procedure, 8 Fr for transudative, 10 Fr for exudative.

Ethical consideration:

Informed verbal consent taken and study approval was taken from Institutional Review Board approval from Dow University of Health Sciences, Karachi (no. 1090, dated 27th Oct'2022. Punctures made under ultrasound guidance using 16G needle, Seldinger technique employed. 0.035 Wire negotiated through needle and external drainage placed across the wire. Pigtails were sutured. It was the authority of the referring clinician to determine the amount and frequency of fluid aspirated per day.

Follow-up of Patients:

Every patient was followed and assessed by interventional radiologist for catheter's efficacy, fluid drain and its frequency.

Procedural success was defined as appropriate placement with fluid outflow. They were removed after successful treatment, patient death or on patient's and clinician's request. Problems encountered with procedure were reported using Society of Interventional Radiology Criteria[9].

Statistical Analysis:

Data analysis was performed using SPSS version 21. Data normality was assessed using Shapiro-wilk test. Mean and standard deviation or median with interquartile range was calculated based on the distribution of data. Frequency and percentages were calculated for qualitative variables. Association between categorical

variables was determined using Chi square test or Fischer exact test where appropriate. Independent t test or Mann Whitney test were used to calculate mean and median differences respectively. Kaplan–Meier curve was drawn for catheter indwelling time estimation where poor and good outcomes were censored in the analysis. For all statistical tests a $p \leq 0.05$ at 95% confidence interval (Cl) was considered significant.

RESULTS

Medical records of Department of Interventional Radiology were thoroughly scrutinized for data on patients with refractory malignant ascites or effusion who underwent pigtail placement under Ultrasound guidance for their management over a period of one year [June 2022 and January 2021]. Throughout the procedure aseptic measures were ensured as well as proper local anesthesia. A total of 65 patients' data were retrospectively analyzed. The final analysis included data of (n=27) catheters for ascites and (n=37) catheters for pleural effusions; one patient's patho-physiology for the procedure was not retrieved and considered missing. The procedural success rate was 100% for placement without any complications, and similarly, no mortality was observed. Patient mean (SD) age was 58.12±13.46 years (range 25 to 85 years), and more than half (n=33, 50.80%) of the patients were male. Duodenal (n=14, 21.54%), liver (n=13, 20.00%) and ovarian (n=10, 15.38%) cancer was the primary source of malignancy. About half of the patients had abdominal complaints/symptoms such as abdominal distension and pain due to malignancy. Similarly, majority (n=58, 89.20%) had a history of paracentesis, while those who had paracentesis procedure, more than 50% had undergone multiple times (≥6 times). Patients who received initial treatment were (n=38, 58.20%). Radiotherapy and chemotherapy were the commonest treatment modality among them. The Shapiro-Wilk test was considered for normality assessment keeping in view the small sample size. Based on the results, laboratory parameters were summarised using median and interquartile range (IQR). Of the total (n=54, 83.10%) reported complications. Leakage was the highest experienced complication followed by dislodgement. Both peritoneal and pleural procedures had comparable characteristics except volume drain per day (p<0.001) and whose primary causes of malignancy is breast (p=0.028) and lung cancer (p=0.004). Similarly complaints/symptoms due to malignancy also differed between the two procedures (p<0.001) as shown in Table-1.

Characteristic	Total	Ascites (N=27)	Pleural Effusion (N=37)	p-value
Age (years), mean±SD	58.12± 13.5	56.93± 13.23	59.43± 13.62	0.465
Gender [n(%)]				
Male	33(50.80%)	13(48.10%)	20(54.10%)	0.801
Female	32(49.20%)	14(51.90%)	17(45.90%)	
Primary malignancy [n(%)]				
Liver	13(20.00%)	3(11.11%)	10(27.03%)	0.207
Pancreas	7(10.77%)	1(3.70%)	6(16.22%)	0.223
GB	2(3.08%)	1(3.70%)	1(2.70%)	1.000
Breast	5(7.69%)	4(14.81%)	0(0.00%)	0.028
Kidney	7(10.77%)	4(14.81%)	3(8.11%)	0.443
Colon	3(4.62%)	0	3(8.11%)	0.257
Lung	6(9.23%)	6(22.22%)	0	0.004
Small bowel	2(3.08%)	1(3.70%)	1(2.70%)	1.000
Ovary	10(15.38%)	4(14.81%)	6(16.22%)	1.000
Duodenum	14(21.54%)	5(18.52%)	9(24.32%)	0.761
Prostate	2(3.08%)	2(7.41%)	0	0.174
Gastric	2(3.08%)	0	2(5.41%)	0.504
Endometrum	3(4.62%)	0	3(8.11%)	0.257
Unknown origin	1(1.54%)	0	1(2.70%)	1.000
Symptoms/complaints [n(%)]				
Chest complaints	30(46.15%)	23(82.14%)	5(13.51%)	0.000
Abdominal complaints	34(52.31%)	4(17.86%)	29(78.38%)	
Others *	03(4.62%)	0(0)	3(8.11%)	
History of previous paracentesis [n(%)]				
Yes	58(89.20%)	26(96.43%)	31(83.78%)	0.130
No	07(10.80%)	1(3.57%)	6(16.22%)	
Frequency of previous paracentesis [n(%)]				
1-2 times	12(20.70%)	6(22.22%)	6(19.35%)	0.960
3-5 times	15(25.90%)	7(25.93%)	8(25.81%)	
≥6 times	31(53.40%)	14(51.85%)	17(54.84%)	
Previous treatment [n (%)]				
Yes	38(58.50%)	18(64.29%)	20(54.05%)	0.454
No	27(41.50%)	10(35.71%)	17(45.95%)	
Treatment				
Chemothrpy	23(34.40%)	12(42.86%)	11(29.73%)	0.305
Radiotherapy	28(43.10%)	13(46.43%)	15(40.54%)	0.801
Surgery	5(7.60%)	3(10.71%)	2(5.41%)	0.644
Laboratory parameters , median(IQR)				
Hemoglobin	9.50(1.28)	9.50(1.25)	9.50(1.30)	0.633
Platelets	136(123.8)	133(140)	138.00(119)	0.371
INR	1.30(0.28)	1.30(0.30)	1.30(0.20)	0.984
Catheter diameter				
8fr	45(69.20%)	22(78.57%)	23(62.16%)	0.184
10fr	20(30.80%)	6(21.43%)	14(37.84%)	
Complication reported			7(18.92%)	0.745
Yes	54(83.10%)	4(14.29%)	30(81.08%)	

No	11(16.90%)	24(85.71%)		
Complications				
Dislodged	15(27.77%)	4(16.67%)	11(36.67%)	
Infection	8(14.82%)	4(16.67%)	4(13.33%)	0.388
Leakage	19(35.19%)	9(37.5%)	10(33.33%)	
Occlusion	12(22.22%)	7(29.17%)	5(16.67%)	
Volume drain per day, median(IQR)	600(400)	500(200)	800(500)	0.000

Table-1: Background and procedural related characteristics of the study patients.

*** Bleeding, lethargy; Individual treatment frequency is greater than previous treatment because of the possible treatment combinations.**

As depicted in Fig-1 more than 50% of the patients experienced post-placement complications. Those who had liver and duodenal cancer had higher complication. However the median differences were statistically insignificant. Liver malignancy and those who had chest symptoms was related with a statistically significantly increased rate of infection ($p<0.05$). Similarly, patients who received chemotherapy as an initial treatment was associated with significantly higher rate of catheter malfunction (occlusion).

Based on the Kaplan-Meier analysis overall catheter survival time was [mean 23.37, 95%:21.63- 25.10; median 28.00, 95%23.34-32.63]. The estimated mean [(24.46, 95%21.98-26.94 vs 22.53, 95%20.08-24.97)] and median [(28.00, 95%22.33-33.67 vs 28.00, 95%20.78-35.22)] time catheter dwelling time for pleural effusion was greater than that of ascites ($p>0.05$). Overall, estimated mean time for 8Fr catheter was greater than that of 10 Fr (24.39 vs.21.14) and the difference was statistically significant ($p=0.048$). Similarly complication such as infection and leakage had an estimated mean catheter survival time lower than that of dislodgment and occlusion and the difference was statistically significant [log rank-chi square 13.64,$p=0.003$] as shown in the Fig-1 (a,b,c,d)

Mortality was noted in two patients with the smallest time being 14 days and the longest being 21 days. In order to reduce bias the outcomes were grouped into two: good outcome includes improved and catheter removed after procedure while poor or worse outcomes comprised of worsened condition or death. Almost (n=40, 61.54%) patients had good outcome. Background and procedural characteristics were compared between the two groups. Patient with poor outcome had significantly higher mean age compared to good outcome.

Similarly gender was significantly different between the two groups. Pancreatic malignancy was associated with a statistically significantly poor outcome ($p<0.05$). Furthermore, those who were implanted with 8Fr catheter had comparatively better outcome. Median volume drain per day was higher in patient with poor outcome compared to good outcome. The details are given in Table-2.

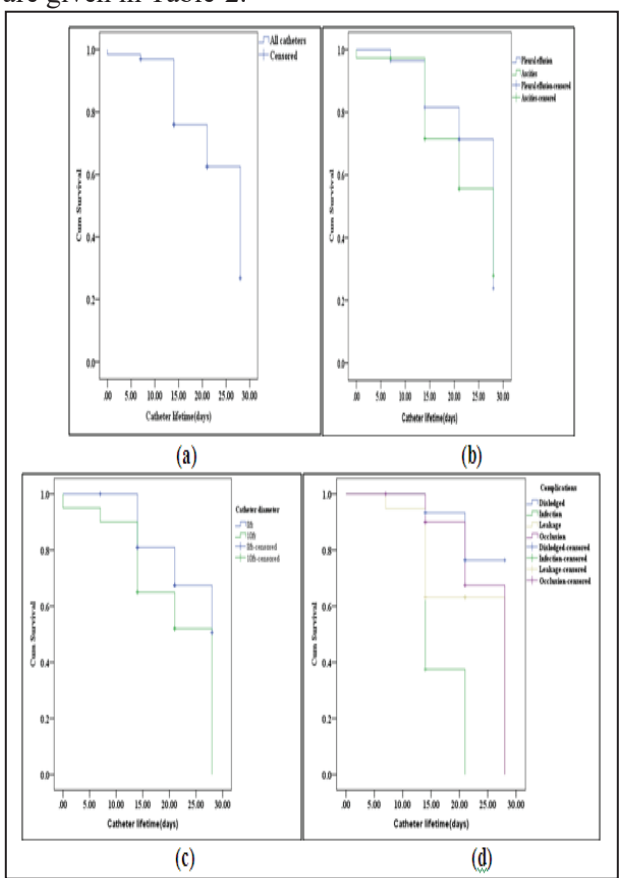

Fig-1: Curves based on Kaplan–Meier method. Both peritoneal and pleural procedures are combined in (A). Comparison of catheter dwelling times between ascites and pleural effusion (B) and between catheter diameters (C), and complications (D)

Characteristics	Poor outcome (N=27)	Good outcome (N=40)	p-value
Age (years), mean ±SD	63.80±13.37	54.33±12.28	0.005
Gender [n (%)]			
Male	18(69.23%)	15(38.46%)	0.023
Female	8(30.77%)	24(61.54%)	
Primary malignancy [n (%)]			
Liver	5(19.23%)	8(20.51%)	1.000
Pancreas	7(26.92%)	0	0.001
GB	1(3.85%)	1(2.56%)	1.000
Breast	1(3.85%)	4(10.26%)	0.028
Kidney	1(3.85%)	6(15.38%)	0.640
Colon	1(3.85%)	2(5.13%)	1.000
Lung	4(15.38%)	2(5.13%)	0.207
Small bowel	1(3.85%)	1(2.56%)	1.000
Ovary	2(7.69%)	8(20.51%)	0.393
Duodenum	4(15.38%)	10(25.64%)	0.373

Prostate	0	2(5.13%)	0.513
Gastric	2(7.69%)	0	0.156
Endometrium	1(3.85%)	2(5.13%)	1.000
Unknown origin	1(3.85%)	0	0.400
Symptoms/complaints [n (%)]			
Chest complaints	11(40.74%)	19(47.50%)	
Abdominal complaints	14(51.85%)	20(50%)	0.594
Others *	2(7.41%)	1(2.50%)	
History of previous paracentesis [n (%)]			
No	4(16%)	3(7.50%)	0.415
Yes	21(84%)	37(92.5%)	
Frequency of previous paracentesis [n (%)]			
1-2 times	3(14.29)	9(24.32)	0.314
3-5 times	4(19.05)	11(29.73)	
≥6 times	14(66.67)	17(45.95)	
Previous treatment [n (%)]			
No	14(56%)	13(32.50%)	0.075
Yes	11(44%)	27(67.50%)	
Treatment			
Chemotherapy	6(24.00%)	17(42.50%)	0.184
Radiotherapy	7(28.00%)	21(52.50%)	0.073
Surgery	1(3.85%)	4(10.00%)	0.641
Laboratory parameters , median(IQR)			
Hemoglobin	9.20(1.20)	9.55(1.45)	0.170
Platelets	130(138.50)	136.00(121.8)	0.604
INR	1.30(0.25)	1.30(0.30)	0.603
Complication reported			
No	3(12%)	8(20%)	0.509
Yes	22(88%)	32(80%)	
Volume drain per day, median(IQR)	600(450)	500(400)	0.032
Catheter dwelling time (Days) median(IQR)	14(7.00)	21(7.00)	0.368

Table-2: Cross tabulation of background and procedural characteristics between outcome.

DISCUSSION

Pleural effusions and refractory ascites are two frequent and distressing side effects of metastatic disease. By draining massive volumes of fluid, they are efficiently handled. Even though complications are rare, regular clinical appointments might be annoying. Pigtail external drainage catheters have been frequently utilised to drain persistent ascites or pleural effusions since the early 1990s. Its household use was also recorded. Nonetheless, they were linked to significant rates of leakage, blockage, and infection. The risk of complication is most likely multifactorial and subordinate on catheter type, sterilization methods, and operator oriented. The literature overview suggests that chances of peritonitis were diminished significantly, with no evidence of peritonitis in our study.

In differentiation, in our clinical involvement, as reflected by the review chart audit, all the patients had untunneled catheters, and as it were 14.82% patients had a reported infection. As compared to recent study[18] 69 were studied and 43.5% showed infections.

Our study showed that the mean life of catheter was 23.37 days, which can be an impressive length of time for a patient with symptomatic progressed terminal cancer. Literature showed a median length of placement of catheter being 36 days[12].

Generally, critical situations were less, and patients appeared able to endure their catheter. We used ultrasound for catheter placement.

The chance of bowel perforation or lung injury is decreased when catheter is placed under sonographic guidance, particularly when bowel or lung are fixed to parietal peritoneum or pleura due to either prior chemotherapy, radiotherapy or multiple paracentesis[10]. In some setups CT is popular as means of its insertion. Though, it is predominant to ultrasound in recognizing neoplastic masses and adjoining organs from the ascite or pleural fluid within the depth[11]. Therefore, cost may be imperative to consider in selecting the imaging guided pigtail catheter arrangement.

Generally, the literature is indecisive in predicting the effectiveness of indwelling catheters for the terminal ascites or effusion. We reviewed the data enveloping over few years and assessed different articles[12,13] In differentiation, in our clinical involvement, as reflected by the review, all the patients had untunneled catheters, and as it were 14.82% patients had a reported infection. As compared to recent study[18] 69 were studied and 43.5% showed infections.

Our study showed that the mean life of catheter was 23.37 days, which can be an impressive length of time for a patient with symptomatic progressed terminal cancer. Literature showed a median length of placement of catheter being 36 days[12].

Different strategies have been utilized including tunnelling and non-tunnelling catheters, multiple paracentesis, and pharmacological measures. Lack of total detailing of clinical results restricted our capacity to draw firm conclusions with respect to the ideal administration of headstrong refractory ascites and effusion. In any case, it showed up that pigtail catheters may well be effectively utilized to overcome the symptoms if adverse situations are monitored.

This study has certain limitations, the worth mentioning is its retrospective design and small, heterogenous sample size. We were not able to get

other valuable data, such as albumin values and quality-of life. No culture surveillance was done for a fluid which is why we might be missing out any subclinical infections. Our concerns were symptomatic improvement in abdominal pain, distension, chest pain and dyspnea for maximum outcome. How far is the procedure successful for refractory ascites or effusion relies on multiple factors, type of fluid (transudative/exudative), catheter French, operator oriented and patient's care. Maximum optimization for catheters is still uncertain, particularly those with cancers. Realizing that patients with malignant ascites are anticipated to outlive some months, treatment objectives are pointed at minimally-invasive approaches to diminish side effects and improve the quality of life.

Dietary restrictions and diuretics are initial management followed by massive paracentesis for symptomatic relieves. The usefulness of diuretics in particular depends on distinctive pathophysiologic mechanism for pleural fluid or ascites accumulation[14].

Our literature review and small sample size claim this to be effective means for palliation with minimal infection in our study. Our experience, therefore, strongly favors this measure for malignant ascites and effusion instead of returning to the setups for repeated paracentesis.

The proposed measure, therefore, has a technical success rate with minimum rates of complications as ascertained in literature[15-17].

CONCLUSION

Patients with refractory malignant ascites or effusion who underwent pigtail placement under Ultrasound guidance for their management achieved 100% procedural success rate and acceptable outcomes in terms of complications and catheter time. On reviewing between the size of catheter when compared to complication rate, 10 Fr would drain better because of its wide bore and it's efficacy in both transudative and exudative fluids but those who were implanted with 8Fr catheter had comparatively better outcome. These minimally invasive treatment options should be utilized to soothe symptoms and improve the QoL. These patients with refractory ascites or effusion can be independently and effectively managed with pigtails rather than referring for repeated paracentesis. Furthermore, experimental studies with bigger sample size assessing the adverse outcome and ascertaining the possible cost savings should be performed.

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