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RESEARCH

Biomarker-guided strategy for Denver peritoneovenous shunts in refractory ascites: a retrospective single-center study

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Abstract

Purpose This study aimed to evaluate the utility of peritoneovenous shunt (PVS) placement for refractory ascites (RA) based on preoperative biomarkers.

Methods This retrospective cohort study included patients with malignant and cirrhotic RA undergoing PVS placement treated at Sumoto Itsuki Hospital between January 2001 and March 2024. The efficacy of PVSs was defined according to the National Cancer Institute Common Terminology Criteria for Adverse Events (CTCAE). The usefulness of the prognostic nutritional index, neutrophil-to-lymphocyte ratio (NLR), platelet-to-lymphocyte ratio, lymphocyte-to-monocyte ratio, and C-reactive protein-to-albumin ratio as prognostic indicators for the efficiency of PVS was evaluated.

Results In total, 149 consecutive patients (malignant RA, $n=100$; cirrhotic RA, $n=49$) were included in this study. PVS placement satisfied the efficacy criteria for ascites in 102 (68%) patients in the entire cohort. The estimated glomerular filtration rate (eGFR)$\leq$30 mL/min/1.73 m^2 was an independent predictor for the inefficacy of PVSs (odds ratio: 2.82, 95% CI: 1.04–7.73, $P=0.042$). Based on receiver operating characteristic curve and multivariate analysis of the entire cohort, NLR$\geq$5.8 was an independent risk factor for death within 1 week after PVS placement (odds ratio: 18.2, 95% CI: 2.07–29.7, $P=0.016$).

Conclusion PVS placement for RA may be a treatment option when preoperative eGFR is >30 mL/min/1.73 m^2 and NLR is <5.8.

Keywords Refractory Ascites · Peritoneovenous shunts · Estimated glomerular filtration rate · Biomarker · Neutrophil-to-lymphocyte ratio

Introduction

Refractory ascites often occurs in patients with cirrhosis or advanced cancer. RA causes serious abdominal bloating and respiratory distress and reduces the quality of life (QOL) of patients [1, 2]. One means of palliating the various symptoms of RA is PVS placement [3, 4]. PVSs have been reported as a suitable alternative treatment modality when ascites are resistant to medical treatment [5]; however, the optimal strategy for selecting patients suitable for PVSs is unclear and controversial. The Japanese Society of Palliative Medicine summarized the results of past studies on PVSs for malignant ascites in 2017 [6], but only a few cross-sectional reports have analyzed RA data with indications for PVSs, including malignant and cirrhotic ascites [7].

The balance between the advantages (no peritoneal punctures and improved QOL) and disadvantages (adverse events) of shunting must be evaluated to recommend PVSs. In patients with refractory ascites from heterogeneous backgrounds, we hypothesized that nutritional and inflammatory markers could be useful in predicting postoperative prognosis. Factors associated with the efficacy and safety of

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PVSs have been studied; however, no study has explored the usefulness of preoperative markers in predicting the prognosis of patients with RA. Recently, investigators have demonstrated that the presence of a systemic inflammatory response is associated with poor outcomes in patients with various types of cancer or cirrhosis [8–11]. Furthermore, inflammation-based prognostic scores have been reported as predictive factors for prognosis and treatment effectiveness in patients with malignant or benign diseases [8, 9].

This study aimed to evaluate the clinical benefits of PVS placement on patient outcomes, with a focus on preoperative biomarkers, to clarify surgical indications. The findings of this study may provide further insights into the selection of PVS as a treatment modality in patients with RA.

Materials and methods

Study population and preoperative evaluation

This retrospective cohort study recruited consecutive patients with malignant ($n=110$) or cirrhotic ($n=59$) RA in whom PVSs were placed at Sumoto Itsuki Hospital between January 2001 and March 2024. Of these, 20 patients were excluded from the analysis (Fig. 1). A total of 149 patients were included in the current study, including 100 with malignant RA and 49 with cirrhotic RA. Patients were diagnosed with RA if (1) they did not respond to diuretic therapy or (2) they developed side effects (e.g., electrolyte abnormalities and blood pressure drop) that contraindicated the use of diuretics.

Surgical indication and procedure

Patients considered for PVS placement due to ineffective conservative treatment were selected (for inclusion in the current study or for PVS placement surgery). Patients whose general condition was deemed intolerable for PVS placement were excluded. Although informed consent was provided for the original PVS surgery, an opt-out form was employed in the current study for patient data collection. This study complied with the standards of the 1964 Declaration of Helsinki and was approved by the Institutional Ethics Board of the Sumoto Itsuki Hospital in 2024 (approval number # 24–0201).

The procedures were performed under general anesthesia using peritoneovenous shunts (Denver shunts®, Denver Biomaterials, Golden, Colorado, USA). The Denver shunt was devised in 1990 to manually pump ascites utilizing a pump chamber with a check valve [12]. All PVSs were inserted by the same surgeon using fluoroscopic image guidance based on a previously reported technique [7, 13–15]. First, a 3-cm skin incision was made over the lower rib cage, and a pocket for the chamber was created using forceps. Venous access was obtained under ultrasound guidance, followed by the insertion of a guidewire into the subclavian vein. A peritoneal puncture below the costal margin and iliac crest of the right lower abdomen was performed under ultrasound

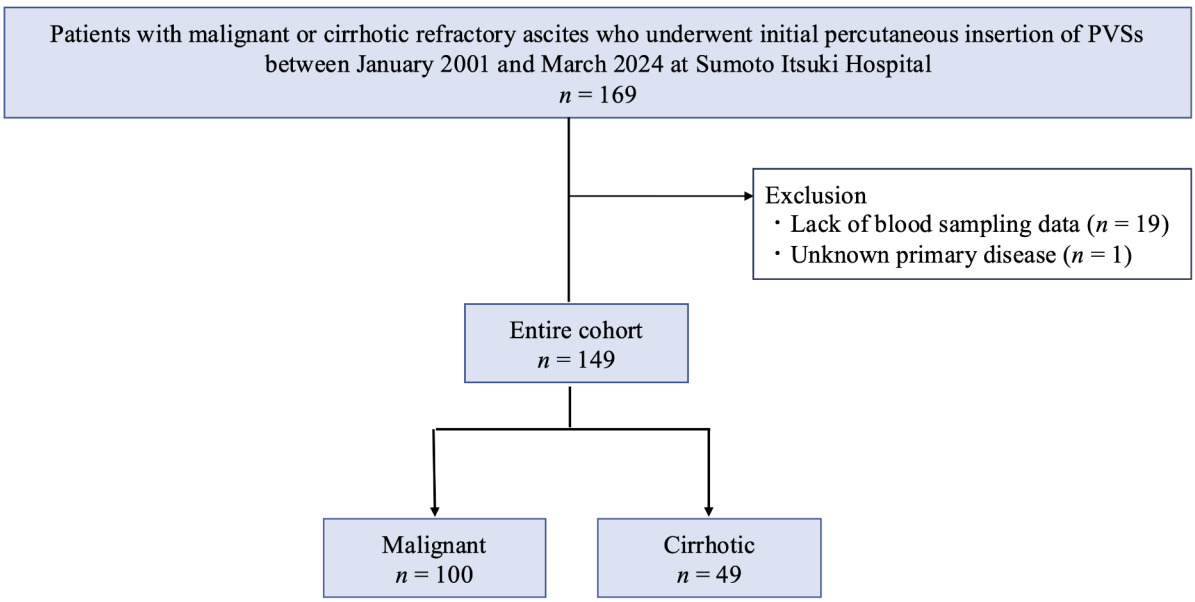

Fig. 1 Flowchart showing patient selection criteria

guidance. Subsequently, a peritoneal catheter was inserted into the abdominal cavity using the Seldinger technique with a 16 F-peel-away introducer under fluoroscopic image guidance. The majority (>85%) of ascites were drained (2500–3500 mL). Through a subcutaneous tunnel, the venous catheter was pulled out via a small incision made at the site of the subclavian guidewire and inserted into the subclavian vein using a 12 F-peel-away introducer. The chamber was placed in the lower rib cage to allow manual compression and prevent occlusion of the system. After the position of the entire system was confirmed by fluoroscopy, the incisions were closed using absorbable sutures.

Postoperative course and assessments

We retrospectively reviewed patients' charts to assess the complications, mortality, and efficacy of PVSs in providing effective palliation for ascites-related symptoms, particularly focusing on abdominal bloating. Each patient was followed up at our hospital or outpatient clinic and instructed to promptly report any signs of infection, ascites leakage, worsening of abdominal distention, or other adverse effects to our surgical department.

The primary outcome of interest was the clinical efficacy of the PVSs, which was evaluated using subjective symptoms and classified into two groups as previously described by the largest reported study on PVSs [16]: (1) effective, defined as the duration of improvement of ascites symptoms to grade 1 for ≥7 days, according to the National Cancer Institute CTCAE, version 5.0, and (2) ineffective, defined as the duration of improvement of ascites symptoms to grade 2 or failure to achieve improvement in ascites symptoms for <7 days. The cut-off value for renal function as a predictor of PVS efficacy was set at an eGFR of 30 mL/min/1.73 m², corresponding to a CTCAE grade≥3.

Secondary outcomes included patient characteristics, changes in laboratory data, postoperative complications (based on Clavien–Dindo classifications), and the impact of preoperative biomarkers on mortality within one week after PVS placement. The efficacy of the prognostic nutritional index (PNI), NLR, platelet-to-lymphocyte ratio (PLR), lymphocyte-to-monocyte ratio (LMR), and C-reactive protein-to-albumin ratio (CAR) as predictive factors for mortality in patients who underwent PVS placement were evaluated.

Statistical analysis

The Kaplan–Meier method was used to estimate survival curves, with intergroup differences assessed using the log-rank test. A Cox proportional hazards model was used to identify independent predictors of survival, with the significance set at $P<0.05$. Data analysis was performed utilizing the JMP 18 statistical package (SAS Institute, Cary, NC, USA). Quantitative variables were analyzed using the Mann–Whitney *U* test and chi-square test. The cut-off value that best predicted the efficacy of secondary outcome measures was determined using receiver operating characteristic (ROC) curve analysis. Logistic regression analyses were performed for both univariate and multivariate assessments of parameters potentially associated with PVS efficacy and prognosis in the entire cohort.

Results

Baseline characteristics

The characteristics of the 149 consecutive patients (malignant RA, $n=100$; cirrhotic RA, $n=49$) are listed in Table 1. Comparisons between the malignant and cirrhotic RA groups showed that patients in the malignant RA group were older, had a higher proportion of females and NLR and PLR levels, and had lower LMR levels. No significant differences were observed in the PNI and CAR between the groups. The most common symptom of ascites was abdominal distention (98.7%). The preoperative median abdominal girth was 89.5 (range, 71–112) cm for malignant RA and 92.5 (range, 75.5–124.0) cm for cirrhotic RA. Hepatocellular carcinoma was the most common primary tumor in malignant RA, and alcohol consumption was the most common etiology of cirrhotic RA. Primary tumor sites in patients with malignant RA are presented in Online Resource Table 1. A cytological examination was performed in 34.6% of patients with malignant RA in this study.

Postoperative outcomes

The profiles of postoperative complications based on the Clavien–Dindo classification for the entire cohort, except for primary tumor progression in patients with malignant RA, are listed in Table 2. Twenty-six patients (17.4%) with RA demonstrated complications over grade IIIa Clavien–Dindo classification. Abnormalities in coagulation (subclinical dissemination intravascular coagulation [DIC]) occurred in 24 patients (16.1%), although three patients (2.0%) developed clinical DIC. Nineteen patients (12.8%) with RA were suspected of PVS dysfunction and underwent a secondary intervention using a high-flow Denver shunt®. Three patients (2.0%) developed pneumothorax, and two (1.3%) required additional intervention. The median length of hospital stays after PVS placement was 9 (range, 1–264) days in patients with RA. The median abdominal girth after PVS was 82.0 (range, 8.1–111.0) cm. Eleven patients (7.4%) died within one week of surgery due to acute heart failure ($n=6$),

Table 1 Baseline characteristics of patients with refractory Ascites who underwent percutaneous placement of Denver shunt

Patient characteristics	Overall ($N=149$)	Malignant ascites ($n=100$)	Cirrhotic ascites ($n=49$)	P value*
Age (years)[a]	72 (35–95)	75 (42–95)	68 (35–91)	0.015[b]
Sex (male)	95 (63.8)	57 (57.0)	38 (77.6)	0.012
Performance status (ECOG)[a]	2 (1–4)	2 (1–3)	2 (2–4)	0.756
Pleural fluid	78 (52.3)	54 (54.0)	24 (49.0)	0.564
Chief symptoms (CTCAE grade≥3)				0.205
Abdominal distention	147 (98.7)	98 (98.0)	49 (100)	
Anorexia	2 (1.3)	2 (2.0)	0 (0)	
Abdominal girth (cm)	89.7 (71.0–124)	89.5 (71.0–112)	92.5 (75.5–124)	0.078[b]
Serum creatinine (mg/dL)	0.94 (0.38–10.1)	0.90 (0.38–10.1)	0.99 (0.44–8.64)	0.257[b]
eGFR (mL/min/1.73 m^2)	56.3 (4.5–136.2)	55.3 (4.5–121.3)	57.3 (5.3–136.2)	0.450[b]
ALBI score[a]	-1.40 (-2.69 to -0.10)	-1.44 (-2.69 to -0.10)	-1.34 (-2.53 to -0.24)	0.096[b]
MELD score[a]	9.34 (-3.81–36.7)	8.92 (-3.81–36.7)	9.40 (-0.15–30.2)	0.725[b]
Biomarker				
Prognostic nutritional index[a]	31.1 (20.6–55.2)	31.3 (20.6–55.2)	31.1 (23.6–47.5)	0.867[b]
Neutrophil-to-lymphocyte ratio[a]	5.5 (0.6–44.0)	7.27 (0.60–44.0)	3.26 (1.18–32.2)	<0.001[b]
Platelet-to-lymphocyte ratio[a]	167 (12–1298)	217 (12.3–1298)	107 (16.1–734)	<0.001[b]
Lymphocyte-to-monocyte ratio[a]	1.9 (0.4–12.1)	1.6 (0.40–12.1)	2.5 (0.4–7.4)	0.018[b]
C reactive protein-albumin ratio[a]	0.82 (0.03–11.3)	1.03 (0.03–3.92)	0.65 (0.03–11.3)	0.131[b]

Values in parentheses are percentages unless indicated otherwise; [a]values are median (range). *χ^2 test, except [b]Mann–Whitney U test

ECOG, Eastern Cooperative Oncology Group; *CTCAE*, the National Cancer Institute Common Terminology Criteria for Adverse Events; *ALBI*, albumin–bilirubin; *MELD*, model for end-stage liver disease

Table 2 Postoperative complications and outcomes of patients with refractory Ascites who underwent percutaneous placement of Denver shunt

	Overall ($N=149$)
Complications (Clavien–Dindo Grade≥IIIa)	
Any*	26 (17.4)
DIC	3 (2.0)
Acute heart failure/pulmonary edema	6 (4.0)
Gastrointestinal bleeding	2 (1.4)
Drowsy	0 (0)
Renal failure	4 (2.7)
Respiratory failure	1 (0.7)
Pneumothorax	2 (1.3)
Ascites infection	1 (0.7)
Pleural effusion	0 (0)
Fatigue	0 (0)
Anemia	0 (0)
Nausea	0 (0)
Hypertension	0 (0)
Abdominal pain	0 (0)
PVS dysfunction	19 (12.8)
Outcomes	
Postoperative hospital stays (days)[a]	9 (1–264)
Abdominal girth (cm)[a]	82.0 (8.1–111)
Death within 1 week	11 (7.4)

Values in parentheses are percentages unless indicated otherwise; [a]values are median (range)

*Some patients had multiple postoperative complications

DIC, disseminated intravascular coagulation; *PVS*, peritoneovenous shunt

DIC ($n=1$), sepsis ($n=1$), renal failure ($n=1$), or primary disease ($n=2$).

PVS placement and efficacy

PVS placement satisfied the efficacy criteria for ascites symptoms in 102 (68%) patients in the entire cohort, including 66 (66%) patients with malignant RA and 36 (74%) patients with cirrhotic RA (Fig. 2). The efficacy of PVSs was not significantly different between the malignant and cirrhotic RA groups ($P=0.332$). The median overall survival (OS) was 25 days (95% CI: 19–32) for malignant ascites and 124 days (95% CI: 47–219) for cirrhotic ascites (Online Resource Fig. S1).

Predictors for the efficacy of PVSs and cut-off values

The association between preoperative variables and PVS efficacy was investigated. In patients with RA undergoing PVS placement, an eGFR of ≤30 mL/min/1.73 m^2 ($n=22$, odds ratio: 2.82, 95% CI: 1.04–7.73, $P=0.042$; Table 3) was the most significant independent predictor of PVS ineffectiveness. Age, sex, performance status, malignancy, presence of pleural fluid, albumin–bilirubin score, the model for end-stage liver disease score, PNI, NLR, PLR, LMR, and CAR revealed no association with the ineffectiveness of PVSs.

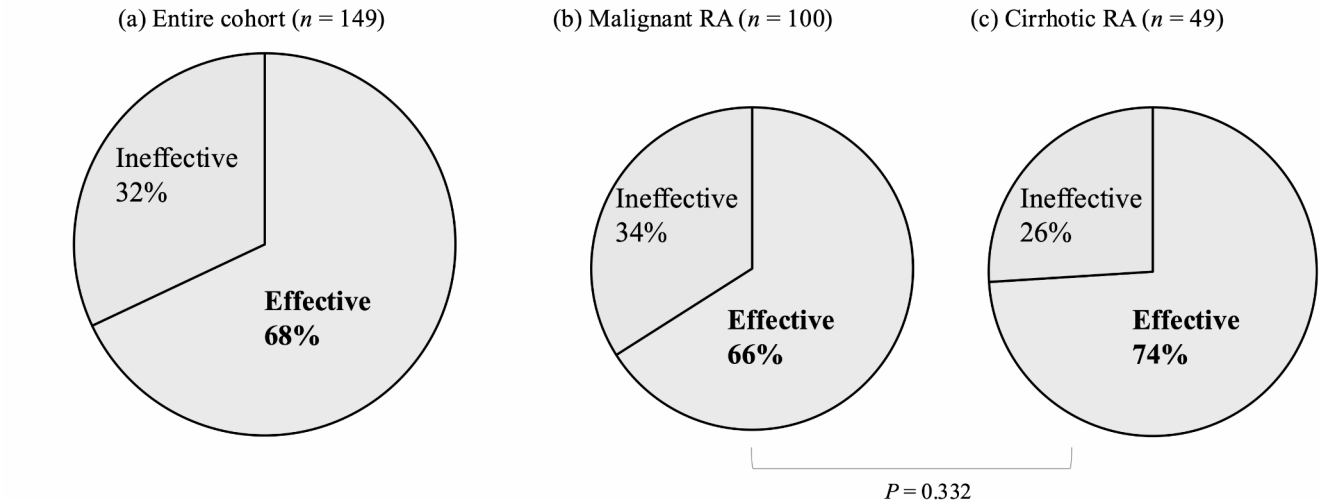

Fig. 2 Efficacy of PVS placement in the (**a**) entire cohort; (**b**) malignant RA subgroup; and (**c**) cirrhotic RA subgroup. No significant difference was found between malignant and cirrhotic RA with respect to the therapeutic efficacy of PVSs ($P=0.332$). *PVS*, peritoneovenous shunt; *RA*, refractory ascites

Table 3 Preoperative factors associated with ineffectiveness of PVSs in entire cohort

Variable	Univariate analysis		Multivariate analysis	
	Odds ratio (95% CI)	*P* value*	Odds ratio (95% CI)	*P* value*
Age (years)[a]	1.02 (0.99–1.05)	0.229[b]		
Sex (male)	0.87 (0.43–1.80)	0.724		
Performance status (ECOG)≥3	1.13 (0.46–2.79)	0.791		
Malignant ascites	1.43 (0.67–3.04)	0.353		
Pleural fluid	1.05 (0.53–2.10)	0.889		
eGFR≤30 (mL/min/1.73 m^2)	3.23 (1.26–8.44)	0.015	2.82 (1.04–7.73)	0.042
ALBI score	1.34 (0.74–2.79)	0.418[b]		
MELD score	1.02 (0.98–1.07)	0.387[b]		
Biomarker				
Prognostic nutritional index[a]	0.94 (0.88–1.00)	0.055[b]		
Neutrophil-to-lymphocyte ratio[a]	1.08 (1.04–1.14)	<0.001[b]	1.03 (0.97–1.10)	0.249[b]
Platelet-to-lymphocyte ratio[a]	1.00 (0.99–1.00)	0.220[b]		
Lymphocyte-to-monocyte ratio[a]	0.74 (0.55–0.97)	0.041[b]	0.96 (0.70–1.26)	0.798[b]
C reactive protein-albumin ratio[a]	1.23 (1.04–1.49)	0.019[b]	1.24 (0.97–1.59)	0.079[b]

Values in parentheses are percentages unless indicated otherwise; [a]values are median (range). *χ^2 test, except [b]Mann–Whitney *U* test

ECOG, Eastern Cooperative Oncology Group; *ALBI*, albumin–bilirubin; *MELD*, model for end-stage liver disease; *PVSs*, peritoneovenous shunts; *CI*, confidence interval; *eGFR*, estimated glomerular filtration rate

Prognostic impact of biomarkers

The association between preoperative serum biomarkers (PNI, NLR, PLR, LMR, and CAR) and death within seven days of PVS placement was investigated. Analysis of ROC curves showed that NLR was most strongly associated with death within one week in five biomarkers, with an AUC of 0.816 (Online Resource Fig. S2). The highest Youden index, 5.8, was identified as the optimal cut-off value for the NLR. An NLR≥5.8 was the strongest independent predictor of death within 7 days after PVS placement (odds ratio: 18.2, 95% CI: 2.07–29.7, $P=0.016$), exceeding the predictive value of sex (Table 4). Moreover, the OS of RA among patients with an NLR<5.8 (median survival time [MST]: 59 days) was significantly greater than that of patients with an NLR≥5.8 (MST: 20 days, $P<0.001$; Online Resource Fig. S3).

Table 4 Preoperative factors associated with death within 7 days after PVSs in entire cohort

Variable	Univariate analysis		Multivariate analysis	
	Odds ratio (95% CI)	*P* value*	Odds ratio (95% CI)	*P* value*
Age (years)[a]	0.97 (0.92–1.02)	0.274[b]		
Sex (male)	8.85 (2.86–32.1)	0.002	4.94 (1.43–5.79)	0.025
Performance status (ECOG)≥3	5.61 (1.03–42.2)	0.046	3.70 (0.61–30.3)	0.157
Malignant ascites	4.65 (0.83–87.0)	0.085	1.74 (0.21–37.2)	0.632
Pleural fluid	1.41 (0.39–5.74)	0.600		
eGFR≤30 (mL/min/1.73 m^2)	1.68 (0.23–7.93)	0.541		
Neutrophil-to-lymphocyte ratio≥5.8	4.29 (1.35–13.6)	0.014	18.2 (2.07–29.7)	0.016

Values in parentheses are percentages unless indicated otherwise; [a]values are median (range). *χ^2 test, except [b]Mann–Whitney *U* test

ECOG, Eastern Cooperative Oncology Group; *CI*, confidence interval; *eGFR*, estimated glomerular filtration rate; *PVSs*, peritoneovenous shunts

Discussion

The present study demonstrated that an eGFR > 30 mL/min/1.73 m^2 was a predictor for PVS efficacy. In addition, an NLR < 5.8 was a predictor for favorable survival in patients with RA undergoing PVS placement. These results indicate that in patients with RA who have an eGFR ≤ 30 mL/min/1.73 m^2 and an NLR ≥ 5.8, the use of PVS should be avoided. To the best of our knowledge, this is the first study to focus on preoperative biomarkers in evaluation of the efficacy and mortality associated with PVS placement.

Various treatment methods, including simple drainages, PVSs, and cell-free and concentrated reinfusion therapies, have been used for symptom relief in patients with RA. However, owing to the technical challenges and serious complications associated with such procedures, fewer than 1000 cases of PVSs are performed annually in Japan [6]. At our institute, we believe that expeditious RA control using PVSs may enhance patients' QOL and prognosis. Therefore, over the past two decades, PVS placement was carried out by the same surgeon at our institution. Although many reports on PVSs have been published [7, 13, 17], few studies have examined the association between preoperative clinical values and postoperative outcomes of Denver shunts. Therefore, the optimal indications for performing PVS placement remain unclear. According to a multicenter study of 133 cases of malignant RA reported by Sugawara et al., a CTCAE grade 2 or higher and elevated serum creatinine levels at baseline were significantly associated with the efficacy of PVSs [16]. In contrast, our study demonstrated that preoperative eGFR impacts the effectiveness of PVSs. Since serum creatinine levels depend on muscle mass, they vary widely among individuals, making them a less reliable predictor of patient benefits in RA. Calculation of eGFR is based on age and gender in addition to creatinine levels, making it a more accurate reflection of renal function. The present study validated that preoperative renal function is associated with the efficacy of PVSs. This finding is biologically plausible because patients with insufficient urine volume may struggle to tolerate the rapid increase in plasma volume immediately after PVS insertion [18].

One noteworthy result of this study was the clarification of the prognostic advantage of calculating preoperative NLR in patients with RA who are considered for PVS placement. Recent studies have demonstrated that evaluating preoperative nutritional status and inflammatory markers can be useful in developing strategies to improve the short- and long-term outcomes of patients with malignant or benign diseases [19–21]. Although preoperative NLR plays a pivotal role in various solid cancers or cirrhosis, the exact mechanism that explains poor survival outcomes in patients with cancer, cirrhosis, and a high blood NLR has not been clearly elucidated [22, 23]. In terms of renal function, short-term mortality following PVS placement in patients with high NLR may be associated with a systemic inflammatory response. Some researchers have reported that elevated NLR correlates with increased tumor necrosis factor-alpha levels and systemic inflammation in patients with end-stage kidney disease [24, 25]. Furthermore, previous studies have indicated that NLR serves as a predictive factor for renal reserve and function [26].

Although DIC is commonly reported as a severe complication of PVS placement, our study observed a lower incidence of clinical DIC (2.0%) than other studies [16, 27]. This result may be due to our method of removing most of the ascitic fluid prior to PVS insertion. Infusing excessive ascites into the circulation dilutes clotting elements and activates coagulation [27]; hence, discarding the ascitic fluid may help mitigate this risk.

Elevated NLR reflects an enhanced systemic inflammatory response, often associated with increased levels of circulating cytokines and other factors that impair immune surveillance [28], which may explain the correlation between NLR and long-term impacts on OS in malignant diseases or cirrhosis. Therefore, pre-treatment serum NLR could serve as a robust biomarker for predicting patient OS. However, no previous studies have explored OS in patients with RA undergoing PVS placement. In this retrospective

study, we evaluated the surrogate biomarker for short- and long-term survival in patients with RA undergoing PVS placement, and found that a preoperative NLR < 5.8 can serve as a cut-off value for predicting OS.

Sugawara et al. reported that renal dysfunction is a cause of early postprocedural death [16]. Similarly, Bieligk et al. identified preoperative renal function as a prognostic indicator following PVS insertion [18]. However, our study found no significant association between preoperative renal function and prognosis after PVS placement. This discrepancy may be attributed to our institution's policy of initiating transient dialysis for patients with preoperative renal impairment when postoperative urine output cannot be maintained. As a result, intensive management of patients with poor renal function may contribute to improved prognosis following PVS insertion.

Given that patients with RAs are considered a hospice population with relatively short post-operative survival, the decision to introduce PVSs should be carefully assessed based on each patient's overall condition and social background. Future studies comparing treatment efficacy and survival between patients who underwent PVSs and those who received transjugular intrahepatic portosystemic shunt or peritoneal puncture will be necessary.

The present study has some limitations. As parts of the study design that were retrospective, the follow-up management changed over the long study duration. This was a single-facility study, and a regional bias might have existed in the targeted patient population. Third, currently, no established consensus exists regarding the evaluation of the efficacy of PVSs. Although underlying diseases were heterogeneous, duplicate cancers were excluded from this study; therefore, the potential for confounding was effectively eliminated. Finally, this study included patients with cirrhosis and hepatocellular carcinoma (classified as malignant RA) because cirrhosis is a significant risk factor for hepatocellular carcinoma, and the two conditions are often intertwined in clinical practice. Cirrhosis is a high-risk factor for hepatocellular carcinoma, and the two are easily mixed in clinical practice. Despite these limitations, our study has notable strengths. The present study is the largest single-center study to date and has a rigorous study design due to the uniformity of operative procedures being conducted under the supervision of the same surgeon. Hence, our results significantly contribute to the strategy for PVS placement.

Conclusion

The present study demonstrated that an eGFR > 30 mL/min/1.73 m² is a predictive marker of PVS efficacy. Furthermore, a preoperative NLR < 5.8 is strongly associated with favorable short- and long-term prognosis following PVS placement. Thus, selecting patients for PVS insertion based on preoperative biomarkers may be a viable management strategy for patients with RA.

Supplementary Information The online version contains supplementary material available at https://doi.org/10.1007/s00423-025-03710-y.

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Author contributions Study conception and design: Y.S and S.K Acquisition of data: Y.H, M.N, Y.H, M.Y, T.Y, K.F, and I.F Analysis and interpretation of data: Y.S and S.K Drafting of manuscript: Y.S and S.K Critical revision of manuscript: T.F.

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Data availability No datasets were generated or analysed during the current study.

Declarations

Ethical approval This study complied with the standards of the Declaration of Helsinki and was approved by the Institutional Ethics Board of the Sumoto Itsuki Hospital in 2024 (approval number # 24–0201). Reporting of this study adhered to the STROBE guidelines.

Consent to participate Informed consent was obtained from all individual participants included in the study.

Consent to publish Patients signed informed consent regarding publishing their data and photographs.

Competing interests The authors declare no competing interests.

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