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Evaluation of the performance, operability, and safety of Plasauto μ, a new type of machine for cell-free and concentrated ascites reinfusion therapy, in a postmarketing clinical study

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Abstract

Cell-free and concentrated ascites reinfusion therapy (CART) is performed by collecting the ascites from the patient, followed by filtration and concentration. Thereafter, concentrated cell-free ascites is reinfused into the patient intravenously. The new type of machine, Plasauto μ, for managing the process of CART was launched onto the market. We have evaluated the machine through postmarketing clinical study in 17 patients with malignant ascites. The amounts of original and concentrated ascites were 3673 ± 1920 g and 439 ± 228 g, respectively. Recovery rates were acceptable regarding values of total protein, albumin, and IgG that were 55.6% ± 17.3%, 60.2% ± 20.8%, and 58.2% ± 20.5%, respectively. Recovery rates were positively associated with amounts of original ascites and negatively associated with total protein concentration. No adverse events related to the machine were observed. The new type of machine showed preferable performance in processing malignant ascites.

KEYWORDS

a new type of machine, ascites, cell-free and concentrated ascites reinfusion therapy, postmarketing clinical study, recovery rate

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1 | INTRODUCTION

In recent years, cell-free and concentrated ascites reinfusion therapy (CART) has been widely used for malignant ascites in Japan [1–4]. This process is carried out by collecting the ascites from the patient followed by its filtration and concentration. The Filtration filter is used to remove cellular components and the concentration filter is utilized to concentrate the ascites. Thereafter, concentrated cell-free ascites is reinfused to the patient intravenously. Compared to the traditional therapy for malignant ascites by abdominal paracentesis drainage, CART is expected to improve the patients' nutritional status [3]. However, CART is time- and labor-consuming compared to conventional drainage techniques. Especially, in cases of malignant ascites containing many cellular components, such as cancer cells and red blood cells, the CART process sometimes could not be continued due to clogging of ascites filtration and concentration filters. The new type of machine for CART, Plasauto μ, was developed to reduce the laborious nature of this process. It is equipped with the following functions: an automatic membrane washing of clogged filtration filters, self-regulation regarding filtration and concentration processes, auto adjustment for concentrated ascites amounts by measuring their weight, and an illustrated guidance on a screen to easily figure out the process. To evaluate filtration and concentration performance, operability, and safety of the machine, we performed a postmarketing clinical study for Plasauto μ.

2 | PATIENTS AND METHODS

2.1 | Study design

The participants were patients with refractory ascites of cancerous origins for whom attending doctors decided that CART was the appropriate treatment. The inclusion criteria were patients: (i) who underwent CART for refractory ascites of cancerous origins using Plasauto μ (Asahi Kasei Medical Tokyo), (ii) who were 20 years of age or older, and (iii) who provided written informed consent. Since the study aimed to evaluate the machine functions such as automatic membrane washing of clogged filtration filters, ascites with high concentration of cellular products was preferable. Therefore, the patients with liver cancer, gallbladder cancer, bile duct cancer, or pancreatic cancer were excluded from the study. Ascites from these patients tended to be transparent with low concentration of cellular products and expected to have lower frequency of filter clogging when utilizing CART. The primary endpoint was total protein recovery rate. The secondary endpoints were: (i) filtration and concentration performance: amount of processed ascites, concentration ratio of amounts of ascites, total protein concentration ratio, albumin recovery ratio, albumin concentration ratio, IgG recovery ratio, and IgG concentration ratio. (ii) operability: frequency of membrane washing of filtration filter, frequency of alarm, type of alarm, processing time (the total filtration and concentration time), and operating time (processing time and priming time). The calculation formula for each item was as follows: Recovery rate (%) = [Amount of total protein, or albumin, or IgG in concentrated ascites]/[Amount of total protein, albumin, or IgG in original ascites] × 100; Concentration ratio of amount of ascites = [Amount of original ascites/Amount of concentrated ascites]; Concentration ratio of solute = [Concentration of total protein, albumin, or IgG in concentrated ascites/Concentration of total protein, albumin, or IgG in original ascites]; and Achievement rate for concentration of ascites (%) = [Amount of concentrated ascites/Target amount of concentrated ascites] × 100.

2.2 | Procedure of CART

The ascites of the patient was collected from a drainage line to an ascites collection bag (FCB-01T, Asahi Kasei Medical) by gravity. The amount of original ascites was measured. The original ascites was filtrated and concentrated by the machine as described below. The concentrated ascites was then infused intravenously to the patient at a rate of 100–150 mL/h, which could have been adapted by the doctor according to the patient's condition.

2.3 | Filtration and concentration of ascites

Schematic drawing of processing ascites is shown in Figure 1. At first, the disposables of an ascites filtration filter (AHF-MO), an ascites concentration filter (AHF-UP), a paneled tubing set (AF-MYU), and a concentrated ascites collection bag (FCB-03T) (all disposables are from Asahi Kasei Medical), were placed on the machine. Besides, saline solution (1.8 L) bag and a bucket for waste fluid were placed and then connected according to the guidance displayed on the machine's screen. The whole circuit comprising filtration filter, concentration filter, and tubing set was then primed with saline solution,

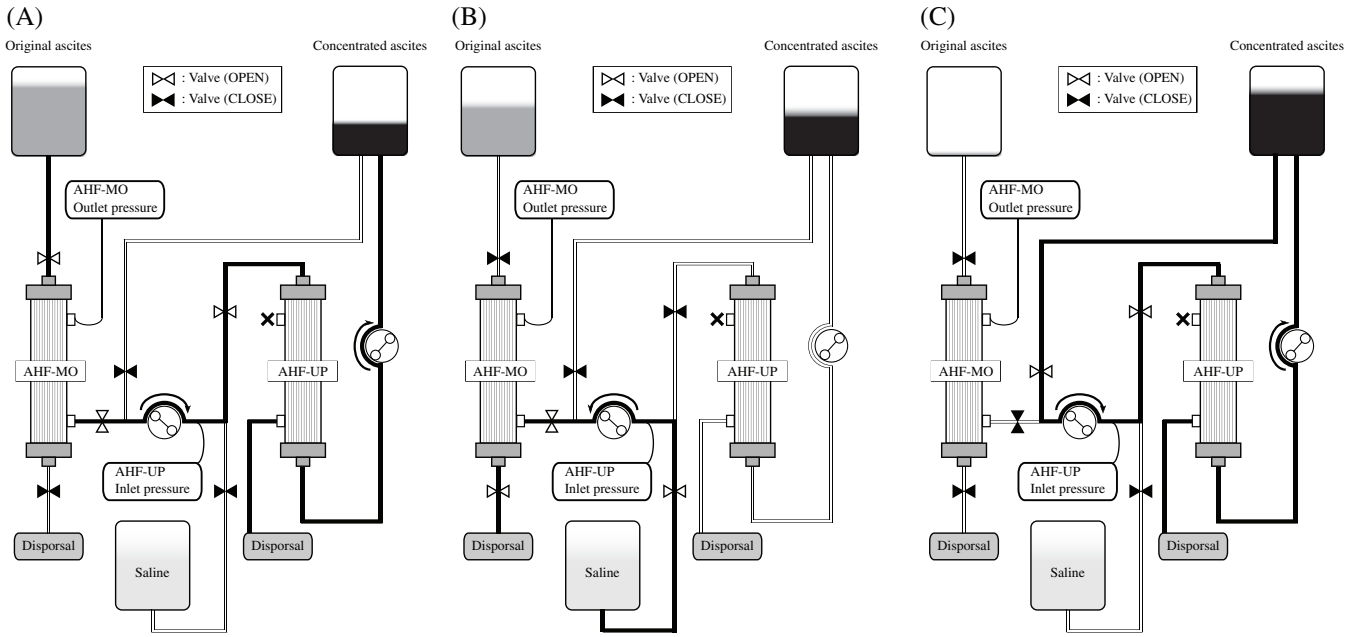
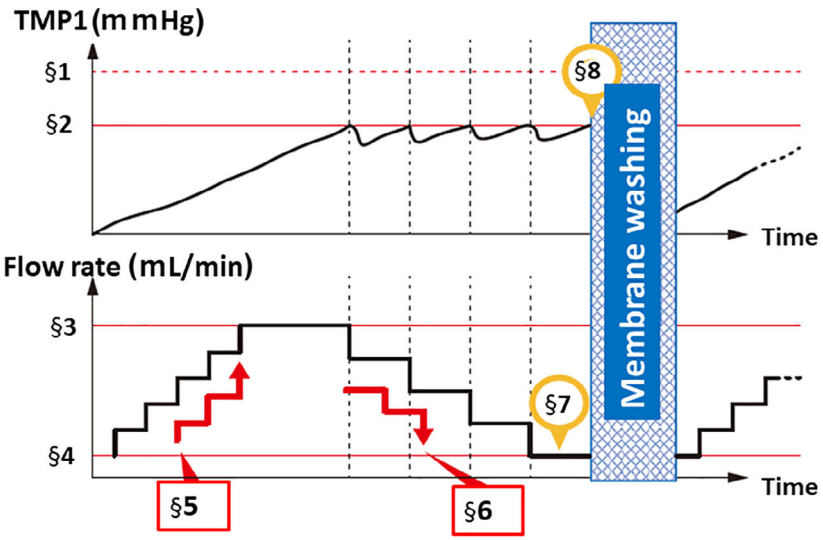


FIGURE 1 Schematic drawing of processing ascites. (a) The circuit diagram of "filtration and concentration." Original ascites is filtered through AHF-MO and concentrated by passing through AHF-UP. The flow of ascites is shown by the black line. (b) The circuit diagram of "membrane washing." Saline flows into AHF-MO to wash the membrane. The flow of saline is shown by the black line. (c) The circuit diagram of "recirculation." The flow of ascites is shown by the black line. The mode of "filtration and concentration" and "recirculation" is repeatedly switched by automatic control of the gravimeter and adjusted to be the final target concentrated ascites amount.
TMP1 = 30 mm Hg* − (AHF-MO Outlet pressure). TMP2 = (AHF-UP Inlet pressure). *Differential pressure by gravity caused by hanging the original ascites bag on the pole of the machine

FIGURE 2 Schematic drawing of the automatic membrane washing procedure of the ascites filtration filter of Plasauto μ. TMP1 = 30 mm Hg* − (AHF-MO Outlet pressure). *Differential pressure by gravity caused by hanging the original ascites bag on the pole of the machine [Color figure can be viewed at wileyonlinelibrary.com]



§1, Upper limit level of TMP1. §2, Pressure level for automatic control start.
§3, Upper restriction of the flow rates for preferable operation.
§4, Lower restriction of the flow rates for preferable operation.
§5, The flow rate is increased step by step automatically to the upper restriction of the flow rate when the status of the membrane shows no abnormality.
§6, The flow rate is decreased step by step automatically to keep TMP1 under the upper limit.
§7, The membrane washing procedure starts automatically if the level of the flow rate reaches the lower restriction level and §8, TMP1 increases to the pressure level of automatic control start.

followed by leakage tests for both filters. These processes were automatically performed by the machine after pressing the screen key. The ascites collection bag filled with ascites from the patient was set to the machine and connected to the circuit. The operator inputted the total amount of the patient's ascites, the target amount of the concentrated ascites, and the type of ascites whether bloody or nonbloody by visual evaluation. Other parameters including "upper limit level of TMP1 (30 mm Hg − [AHF-MO Outlet pressure])," "pressure level for flow rate control start," and "upper and lower restriction levels of the flow rate" were set to the default values of 350 mm Hg, 300 mm Hg, 50 mL/min, and 45 mL/min for nonbloody ascites and 100 mm Hg, 80 mm Hg, 50 mL/min, and 45 mL/min for bloody ascites, respectively. These values could be modified by the operator if necessary. Concentrating the ascites was then started by pressing the start key. The procedures of "filtration/concentration," "membrane washing," and "recirculation" were regulated automatically by the machine. The membrane washing function procedure was automatically performed by the machine, if necessary. This occurred when the filtration flow rate reached the lower restriction level and TMP1 reached the automatic control start pressure level. The operating principle of membrane washing procedure is schematically shown in Figure 2. The final amount of concentrated ascites was adjusted by controlling the weighing scale of the machine to match the target concentrated fluid amount.

2.4 | Registered facilities

Registered institutions included Fujita Health University Hospital, National Cancer Center Hospital, Japanese Red Cross Osaka Hospital, Japanese Red Cross Medical Center, Cancer Institute Hospital of JFCR, Tokyo Women's Medical University Hospital, and University of Tokyo Hospital.

2.5 | Ethics

The study protocol conforms to the provisions of the Declaration of Helsinki (as revised in Fortaleza, Brazil, October 2013). This study was approved by the Ethics Committee of the Fujita Health University School of Medicine (HM19-362). All participants provided written informed consent prior to their inclusion in the study.

2.6 | Data management and statistics

Data management and statistical analyses were outsourced to the Mebix Corporation. In safety assessment, the analysis was performed to evaluate the participants whose ascites were processed by Plasauto μ at least once among those enrolled in the study. In all other evaluations, the Full Analysis Set was used for analysis. Continuous data were expressed as means and SDs. Differences in the recovery rate between bloody and nonbloody ascites, heparin in the bag and nonheparin in the bag, with and without membrane washing, alarm occurrence or not were analyzed using Student's t test. Correlations between the two groups were assessed using the Pearson correlation coefficient. A p value less than 0.05 was considered statistically significant.

3 | RESULTS

3.1 | Basis of the enrolled patients

Out of the 19 enrolled patients, CART was discontinued in two patients before the machine was used. Therefore, data of the patients ($n = 17$) were used in the evaluation. The basic information of the enrolled patients is summarized in Table 1. The enrolled patients included 4 males and 13 females, with a mean age of 65.5 ± 14.1 years. Their diseases were gastric cancer in six cases, colon and rectal cancer in four, caecum cancer in two, uterine cancer in two, peritoneal cancer in two, and ovarian cancer in one. The type of ascites was bloody in seven cases and nonbloody in 10. In seven cases, 5000 units of heparin were injected in their original ascites bag.

3.2 | Filtration and concentration performance

The procedure of CART in each patient is summarized in Table 2. The amount of original ascites and processed ascites were 3673 ± 1920 g and 439 ± 228 g, respectively. The concentration ratio of amount of ascites was 8.9 ± 2.8. Total protein, albumin, and IgG levels in the original ascites were 3.0 ± 1.2 g/dL, 1.4 ± 0.6 g/dL, and 621 ± 281 mg/dL, respectively. In contrast, total protein, albumin, and IgG levels in the concentrated ascites were 13.0 ± 4.0 g/dL, 6.4 ± 2.3 g/dL, and 2797 ± 1322 mg/dL, respectively. The recovery rates of total protein, albumin, and IgG were 55.6% ± 17.3%, 60.2% ± 20.8%, and 58.2% ± 20.5%, respectively. The concentration ratios of total protein, albumin, and IgG were 4.7 ± 1.5, 5.1 ± 1.8, and 5.0 ± 1.8, respectively. The achievement rate for concentration of ascites was 99.7% ± 11.1%. However, the ratios were widely distributed; four cases had achievement ratios less than 90% and more than 80%, while three cases had less than 120% and more than 110%.

TABLE 1 Ascites characteristics and operability

Case number	Cancer type	Age	Sex	Type of ascites[a]	Heparin in the bag	Processing time[b] (min)	Operation time[c] (min)	Number of washing	Types of alarms[d]
1	Gastric cancer	72	F	(−)	(−)	73	99	0	1
2	Gastric cancer	55	F	(−)	(−)	—	—	—	—
3	Gastric cancer	57	F	(+)	5000 U	186	204	1	1, 3, 4
4	Gastric cancer	57	F	(+)	5000 U	240	258	1	1, 3, 4
5	Gastric cancer	77	F	(−)	5000 U	259	277	3	2, 3, 5
6	Gastric cancer	76	M	(+)	5000 U	173	192	1	5, 6
7	Colorectal cancer	86	F	(−)	(−)	62	92	0	0
8	Colorectal cancer	31	F	(−)	5000 U	—	—	—	—
9	Colorectal cancer	68	M	(−)	5000 U	98	117	0	0
10	Colorectal cancer	59	F	(−)	5000 U	90	108	0	0
11	Caecum cancer	84	M	(−)	(−)	89	147	0	1
12	Caecum cancer	84	M	(−)	(−)	94	114	0	0
13	Uterus cancer	74	F	(+)	(−)	97	125	3	0
14	Uterus cancer	60	F	(+)	(−)	57	82	0	0
15	Peritoneum cancer	60	F	(+)	(−)	66	100	1	0
16	Peritoneum cancer	60	F	(+)	(−)	56	81	1	0
17	Ovarian cancer	54	F	(−)	(−)	142	168	0	1

[a]Type of ascites: (+) Bloody, (−) nonbloody.
[b]Processing time: the total filtration and concentration time.
[c]Operation time: processing and priming time.
[d]The types of alarms are as follows: 0, no alarm; 1, weight measurement abnormality; 2, upper limit level of transmembrane pressure of ascites filtration filter; 3, upper limit level of transmembrane pressure of ascites concentration filter; 4, concentration limit; 5, pump cover open; 6, upper limit level of washing pressure.

3.3 | Factors affecting the recovery rates

The factors affecting the recovery rates of total protein, albumin, and IgG are indicated in Table 3. The recovery rates were positively associated with the amount of original ascites and negatively associated with total protein in original ascites. Type of ascites evaluated as either bloody or nonbloody, heparin addition in the bag, existence of membrane washing procedure, or alarms during the procedure were not associated with the recovery rate.

3.4 | Evaluation of operability

In evaluation of operability, two patients' data were missed because the operation log data could not be obtained accidentally. The mean processing time was 120 min, and the mean total operation time was 144 min. Membrane washing of the ascites filtration filter was performed in seven cases: once in three cases, twice in one case, and thrice in three cases (Table 1). Alarms occurred in seven patients (Table 1). Total amount of ascites was processed in each of the 17 cases.

3.5 | Evaluation of safety

One adverse event of stomach pain was observed in patient #5 (Table 1), when ascites was being collected through paracentesis before utilizing the machine. The process was continued and completed the therapy without further complications. No other adverse events such as elevation of body temperature related to the CART procedure were reported during the study.

4 | DISCUSSION

All original ascites had been processed in each of the 17 cases, and automatic membrane washing was performed in seven cases. If the machine did not have an automatic membrane washing procedure, interruption of the therapy or reduced recovery rate might have been observed in these seven cases. The protein recovery rate as a primary endpoint was 55.6% ± 17.3%. This result was lower than that of a previous report by Hanafusa et al. [1] that revealed a value of 72.0% ± 18.1%. However, it was comparable to that reported by Yamada et al. [3]: 59% ± 23%. The protein recovery rate is thought to

TABLE 2 Summary of the CART procedure of each patient

Case number	Original ascites				Concentrated ascites						Concentration ratio of amount of ascites	Recovery rate		
	Amount (g)	TP (g/dL)	ALB (g/dL)	IgG (mg/dL)	Amount (g)	Target amount (g)	Achievement rate (%)	TP (g/dL)	ALB (g/dL)	IgG (mg/dL)		TP (%)	ALB (%)	IgG (%)
1	1990	3.9	1.8	583	335	400	83.8	11.0	5.6	1665	5.9	47.5	52.4	48.1
2	2840	3.2	1.8	454	385	—	—	12.5	7.5	1789	7.4	53.0	56.5	53.4
3	7293	2.4	1.0	779	745	750	99.3	16.8	6.9	5460	9.8	71.5	70.5	71.6
4	7137	2.4	0.9	802	820	800	102.5	15.5	6.0	5096	8.7	74.2	76.6	73.0
5	5165	3.7	1.9	704	653	550	118.7	18.0	10.2	3740	7.9	61.5	67.9	67.2
6	3890	2.0	1.2	392	400	390	102.6	12.6	7.5	2415	9.7	64.8	64.3	63.3
7	2205	2.6	1.2	570	195	230	84.8	9.7	4.9	2199	10.7	34.7	38.0	35.9
8	1500	4.6	2.5	897	75	—	—	19.0	10.5	3739	18.5	22.3	22.7	22.5
9	6207	0.3	0.1	43	672	800	84.0	2.1	1.0	399	8.9	78.6	112.2	104.2
10	3425	1.4	0.6	421	330	320	103.1	9.5	3.9	2940	9.7	69.9	66.9	71.9
11	3290	3.7	1.8	728	405	410	98.8	16.5	8.4	3156	8.1	54.9	57.4	53.4
12	3290	3.9	1.9	787	450	410	109.8	15.5	7.5	3317	7.3	54.4	54.0	57.6
13	3145	3.4	1.2	775	430	440	97.7	10.2	4.3	2325	7.3	41.0	49.0	41.0
14	1665	3.2	1.7	331	225	200	112.5	13.8	7.8	1411	7.4	58.3	62.0	57.6
15	2490	4.0	1.5	945	255	300	85.0	12.0	5.0	3025	9.8	30.7	34.1	32.8
16	1805	4.8	1.7	1121	255	250	102.0	14.4	5.7	3518	6.6	45.1	50.4	47.2
17	5880	1.9	0.9	216	835	750	111.3	11.1	5.6	1348	7.0	83.0	88.4	88.6
Mean ± SD	3673 ± 1920	3.0 ± 1.2	1.4 ± 0.6	621 ± 281	439 ± 228	467 ± 212	99.7 ± 11.1	13.0 ± 4.0	6.4 ± 2.3	2797 ± 1322	8.9 ± 2.8	55.6 ± 17.3	60.2 ± 20.8	58.2 ± 20.5

Abbreviations: ALB, albumin; CART, concentrated ascites reinfusion therapy; TP, total protein.

TABLE 3 Correlation factor analysis for the recovery rates

	Recovery rate of total protein	Recovery rate of albumin	Recovery rate of IgG
Amount of original ascites (g)	$r = 0.788$ $p = 0.0002$	$r = 0.749$ $p = 0.0005$	$r = 0.768$ $p = 0.0003$
Total protein concentration of original ascites (g/dL)	$r = -0.744$ $p = 0.0006$	$r = -0.743$ $p = 0.0006$	$r = -0.669$ $p = 0.0034$
Bloody ($n = 7$)/ nonbloody ($n = 10$)	55.1% ± 16.5%/56.0% ± 18.7% $p = 0.92$	58.1% ± 14.5%/61.6% ± 25.0% $p = 0.74$	55.2% ± 15.4%/60.3% ± 24.0% $p = 0.63$
Heparin in the bag (+, $n = 7$)/(−, $n = 10$)	54.4% ± 18.9%/58.5 %± 14.0% $p = 0.66$	59.6% ± 23.4%/61.7% ± 15.0% $p = 0.85$	57.4% ± 22.6% / 60.2% ± 16.2% $p = 0.80$
Membrane washing (+, $n = 7$)/(−, $n = 8$)	55.6% ± 16.6%/60.1% ± 16.2% $p = 0.60$	59.0% ± 14.9%/66.4% ± 23.4% $p = 0.48$	56.6% ± 16.1%/64.7% ± 22.4% $p = 0.44$
Alarm (+, $n = 7$)/ (−, $n = 8$)	65.3% ± 12.0%/51.6% ± 16.9% $p = 0.097$	68.2% ± 12.0%/58.3% ± 24.4% $p = 0.35$	66.5% ± 13.4%/56.0% ± 23.3% $p = 0.32$

be associated with the amount and total protein concentration in original ascites. Actually, our results showed that the recovery rates were positively associated with the amount of original ascites and negatively associated with total protein in original ascites. Therefore, higher total protein concentration and lower amount of original ascites in our study than those in the study by Hanafusa et al. [1] may be one of the reasons for a lower total protein recovery rate. The other possibility of lower protein recovery rate is loss of proteins during the membrane washing process of the membrane during the CART process. These factors relating to protein recovery should be evaluated in future studies.

Concentration ratio of the amount of ascites has been previously reported to be 9.2 ± 4.9 [1] or 11.9 ± 10.7 [3]. However, the result of this study was 8.9 ± 2.8. Based on previous experience, recovery rate tends to be at a higher level when concentration ratio is set to a lower level especially in cases of ascites with a higher total protein concentration. Based on this finding, concentration ratio of the amount of ascites might have been set at a lower level in this study compared to previously reported studies.

There were outliers regarding achievement ratios for the concentration of ascites and we speculated the following facts. Those who had higher achievement ratios more than 100% experienced premature termination of concentration procedure probably because the transmembrane pressure of the concentration filter (TMP2) exceeded the upper limit of the safety range. Such patients tended to have a high concentration of ascitic protein. The ascitic fluid that had not been fully concentrated was manually collected and put into the collecting bag in those patients, which increased the volume of the concentrated ascites and resulted in a higher achievement ratio. To overcome the problem of the elevation of TMP2 and to improve the achievement ratio, the program of the machine was planned to version up. The revised program regulates the concentration process by adjusting the TMP2 within the proper range, instead of regulating the target amount of concentrated ascites. On the other hands, when the achievement ratio was lower than 100%, there were possibilities that the measurement of the amount of original ascites was larger than the actual weight, or the target amount of concentrated ascites was changed during the CART process.

In this study, the effects of fibrin clotting and coagulation-fibrinolysis system on the filtration–concentration performance were not investigated. This factor might be important for the filter clogging and the membrane washing process.

The processing time may be extended using the conventional method by slowing down the processing speed to cope with the increased transmembrane pressure of filtration filter. In contrast, after clogging is improved by automatic membrane washing procedure to cope with increases in TMP1, the processing speed can proceed as planned by using the new type of machine. However, the time is extended when additional concentration is performed by recirculation to reach the set amount of ascites.

4.1 | Limitations

This study has several limitations as one-armed observational study with small number of cases.

5 | CONCLUSION

In this study, the new type of machine, Plasauto μ, showed preferable performance in processing malignant ascites.

CONFLICT OF INTEREST

This study was financially supported by Asahi Kasei Medical Co., Ltd. There are no other conflicts of interest for this study.

REFERENCES

1. Hanafusa N, Isoai A, Ishihara T, Inoue T, Ishitani K, Utsugisawa T, et al. Safety and efficacy of cell-free and concentrated ascites reinfusion therapy (CART) in refractory ascites: post-marketing surveillance results. PLoS One. 2017;12(5): e0177303.
2. Ito T, Hanafusa N. CART: cell-free and concentrated ascites reinfusion therapy against malignancy-related ascites. Transfus Apher Sci. 2017;56(5):703–7.
3. Yamada Y, Inui K, Hara Y, Fuji K, Sonoda K, Hashimoto K, et al. Verification of serum albumin elevating effect of cell-free and concentrated ascites reinfusion therapy for ascites patients: a retrospective controlled cohort study. Sci Rep. 2019;9(1): 10195.
4. Yamada Y, Yamaguchi A, Harada M, Kurasawa Y, Hara Y, Yamazaki D, et al. Protein concentration of refractory ascites in cancer patients is reflected by the presence and severity of peritoneal and liver metastasis. Ther Apher Dial. 2017;21(3):263–9.

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