

# EFFICACY AND SAFETY OF VITAMIN E-BONDED POLYSULFONE DIALYZER

## ON NON-ANTICOAGULANT HEMODIALYSIS

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### Background and Aim

- Hemodialysis requires effective anticoagulation to prevent clotting. Systemic anticoagulation reduces clotting risk but also increases bleeding risk.
- Heparin is used to prevent clotting during hemodialysis, but anticoagulant-free hemodialysis is sometimes needed to decrease the risk of bleeding.
- Purpose of this study was to compare vitamin E-bonded polysulfone dialyzer (VPS) with polysulfone dialyzer (PS) during hemodialysis sessions without anticoagulant.

### Methods

- This open-label monocentric randomized study recruited chronic hemodialysis patients with a contra-indication to systemic heparinization.
- Thirty patients undergoing stable hemodialysis were randomly divided into VPS group (n=15) and PS group (n=15) after obtaining written informed consents.
- Exclusion criteria:
  - inflammatory disorder with C-reactive protein level > 50 mg/L
  - anemia with blood transfusion requirement
  - AV fistula dysfunction
- To avoid total circuit clotting, 100-mL saline flushed every hour and visual inspections of dialysis circuit and dialyzer membrane was done.
- In cases of non-obstructive circuit clotting, membrane fiber clotting, or elevated arterial and/or venous pressure, continuous infusion of nafamostat mesilate was added to the hemodialysis circuit.
- At the end of the session, clotting status of dialysis circuit and dialyzer membrane was graded from 0 to 3 by visual inspection. As markers of coagulation status, fibrinogen, thrombin-antithrombin complex and D-dimer were measured at pre- and post- dialysis session.
- All data are expressed as mean ± SD. Differences between two groups were examined using Student's *t*-test. *P* value < 0.05 was considered significant.

### Baseline characteristics of the patients

	PS group (N=15)	VPS group (N=15)	<i>P</i>
Age (years, mean±SD)	67.0 ± 12.0	67.8 ± 9.4	0.42
Sex (M:F, n)	13 : 2	9 : 6	0.05
Duration of HD (years, mean±SD)	6.3 ± 6.3	6.1 ± 6.1	0.67
Causes of renal failure (DM, %)	40.0	53.3	0.24
Anti-coagulation agents (%)	60.0	47.0	0.24

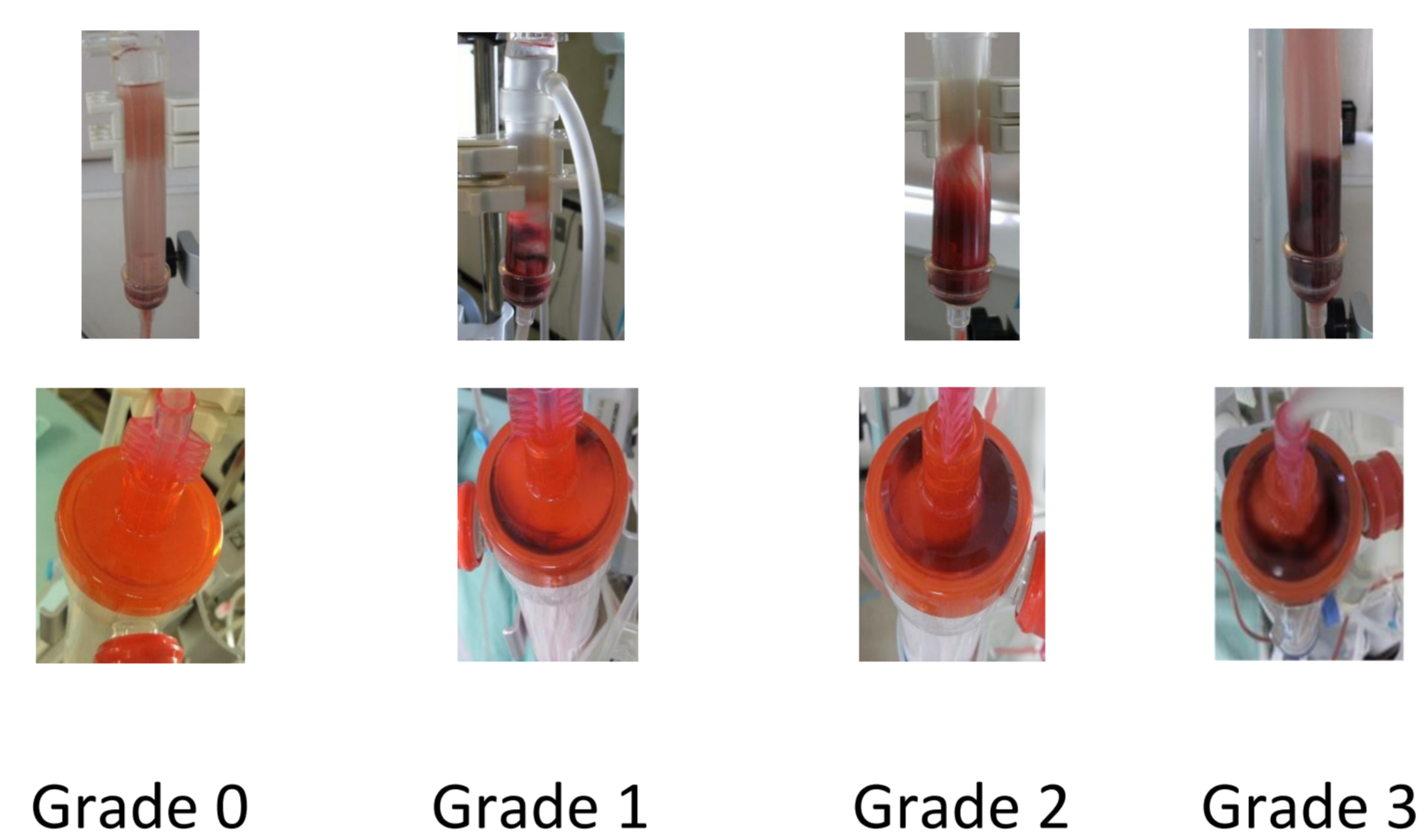
### Baseline laboratory data

	PS group	VPS group	<i>P</i>
Hemoglobin (g/dl)	10.1 ± 2.0	10.6 ± 1.3	0.26
Platelet (10 <sup>4</sup> /μl)	20.9 ± 8.7	17.2 ± 5.6	0.10
Fibrinogen (mg/dl)	316.3 ± 87.1	293.3 ± 71.6	0.22
FDP (μg/dl)	6.4 ± 7.3	5.1 ± 3.5	0.27
D-dimer (ng/ml)	2.7 ± 3.4	2.4 ± 1.9	0.38
Creatinine (mg/dl)	10.0 ± 2.6	8.0 ± 1.8	<0.05

### Results

		PS group	VPS group	<i>P</i>
Clotting score	NM addition	6 (40%)	3 (20%)	0.23
	A-Chamber	1.0 ± 1.1	0.87 ± 0.8	0.35
	V-Chamber dialyzer	0.93 ± 1.0	1.0 ± 1.0	0.43
	score >6 (%)	20.0	6.7	0.08

### Examples of different grades by visual inspection of clotting

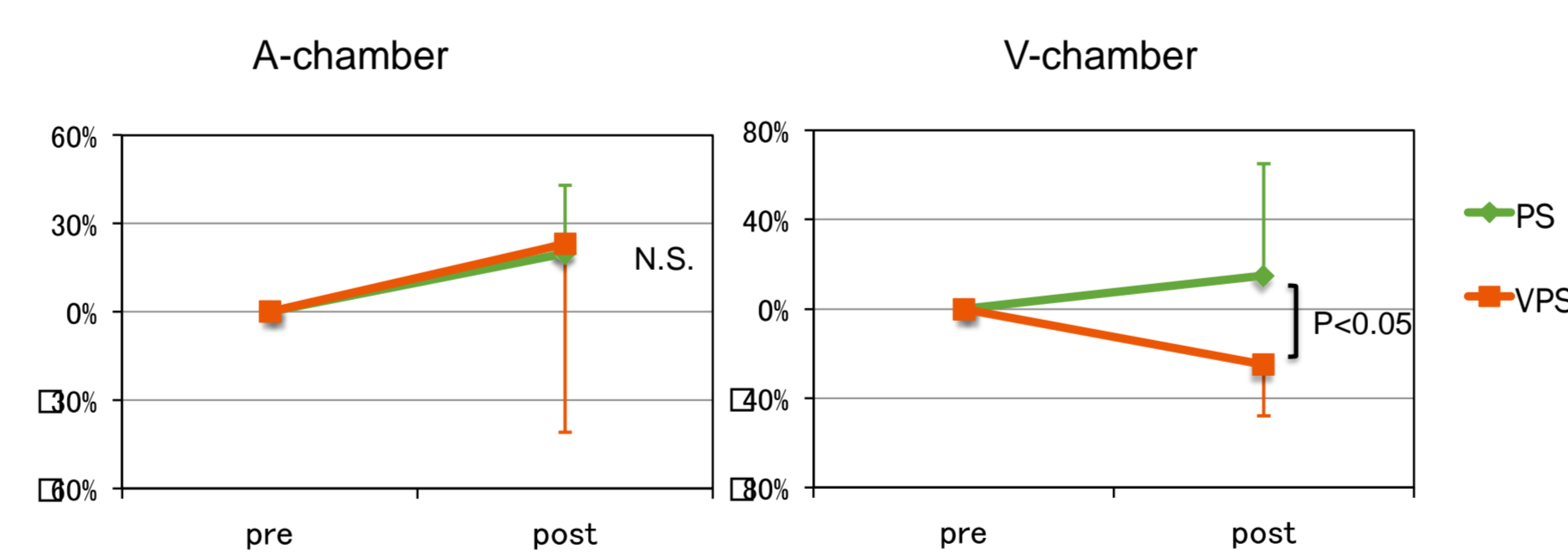


Grade 0 Grade 1 Grade 2 Grade 3

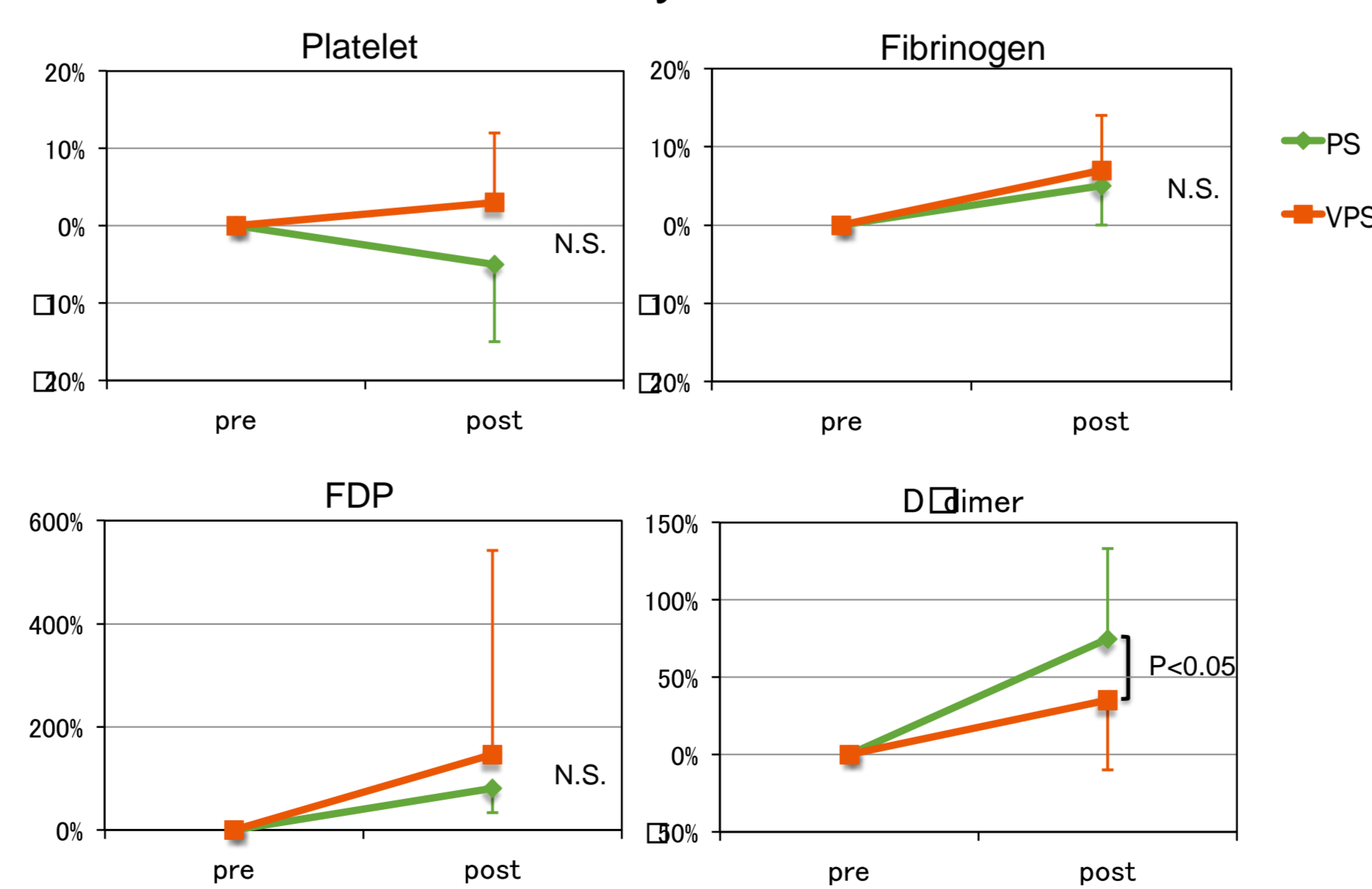
### Arterial and venous pressure after dialysis session

		PS group	VPS group	<i>P</i>
A	pre (mmHg)	209.6 ± 58.4	211.2 ± 44.1	0.47
	post (mmHg)	250.3 ± 79.4	242.6 ± 82.8	0.41
V	pre (mmHg)	88.0 ± 32.3	99.6 ± 36.2	0.18
	post (mmHg)	108.4 ± 56.6	99.0 ± 51.4	0.32

### Percent change of arterial and venous pressure after dialysis session



### Percent change of coagulation status after dialysis session



### Summary

- Every hemodialysis session was not interrupted by major circuit clotting.
- PS membrane dialysis session was needed much more nafamostat mesilate addition compared with VPS.
- Partial circuit clotting evaluated by clotting grade was higher in PS than in VPS. Percent change of venous pressure after hemodialysis session increased in PS (+15.0%), but decreased in VPS (-2.5%, *p*<0.05).
- In coagulation status, percent change of D-dimers significantly increased in PS (+74.5%), compared with in VPS (+35.0%, *p*<0.05).

### Discussion

- The use of vitamin E-bonded dialyzer is associated with less clotting in patients with persistent clotting problems (Huraib S *et al. Am J Nephrol*, 2000, Aoun B *et al. Saudi J Kidney Dis Transpl*, 2010).
- Vitamin E-bonded polysulfone dialyzer is superior to non-anti-coagulant hemodialysis based on venous pressure (Torato T *et al. ASAIO J*, 2013).
- Vitamin E-bonded membrane reduces platelet activation mediated superoxide anion (Tsukao H *et al. J Artif Organs*, 2013).

### Conclusion

- These data suggest that VPS is safe and useful for non-anticoagulant hemodialysis in patients with contra-indication to systemic anticoagulation.
- These results are not generalizable safely to patients with active infection, not assessed in the present study.

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