



Prolonged catheter survival in patients with acute kidney injury on continuous renal replacement therapy using a less thrombogenic micropatterned polymer modification

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**2nd Congress of the International Society of Hemodialysis
Hong Kong – August 28-30 2009**

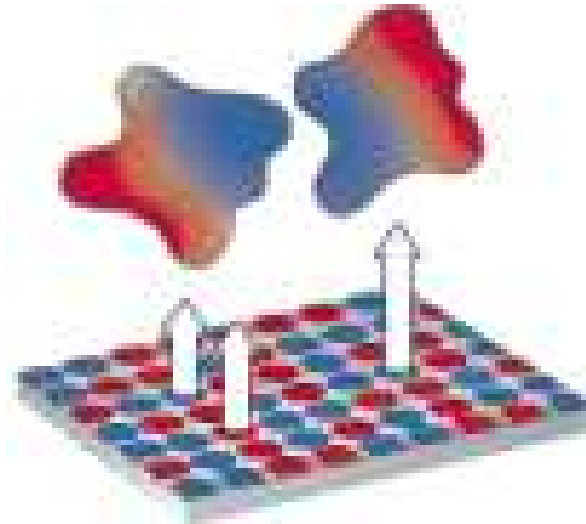


**41st Annual Meeting of the Swiss Society of Nephrology
Interlaken – December 2-4 2009**

Background

- Continuous renal replacement therapy (CRRT) has been increasingly used in critically ill patients with acute kidney injury (AKI).
 - One of the major properties that likely influence the catheter lifespan includes its inner surface specificity.
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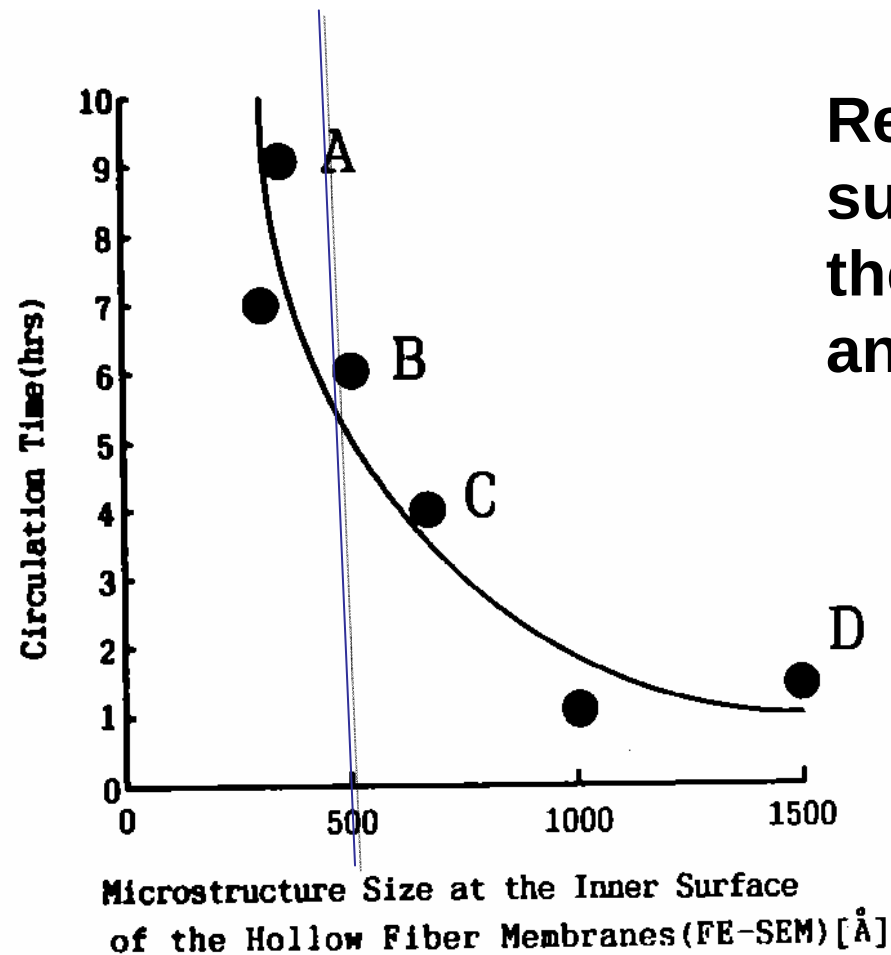
Hypothesis



Schematic view of the theoretical efficacy of the microdomain structure:

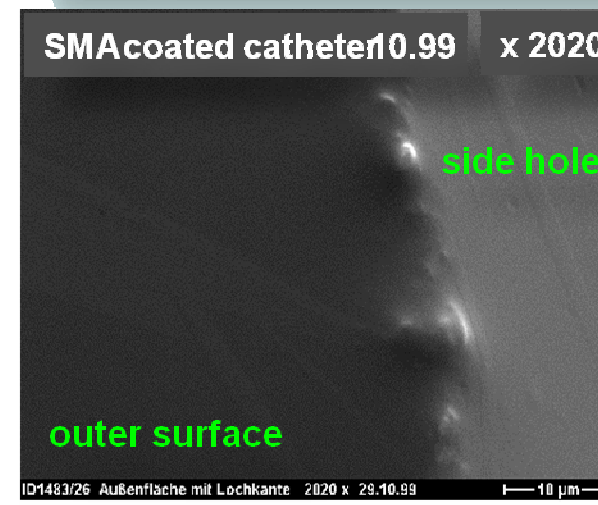
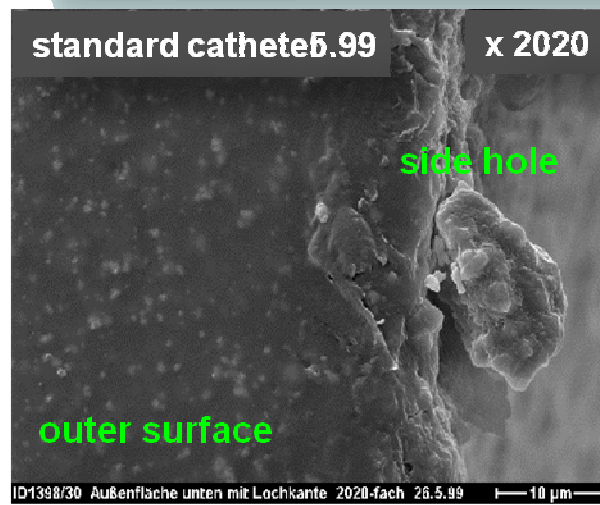
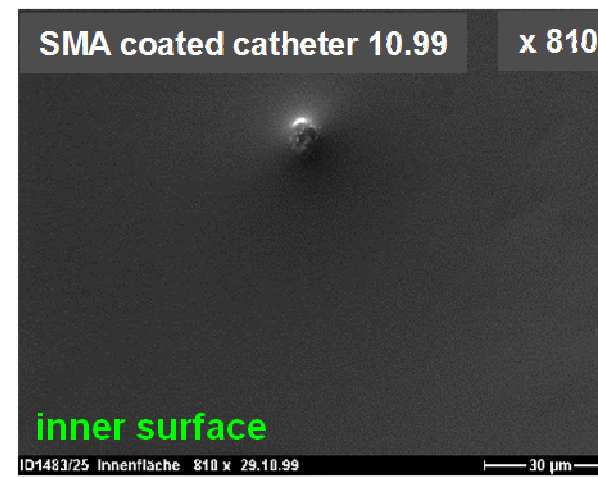
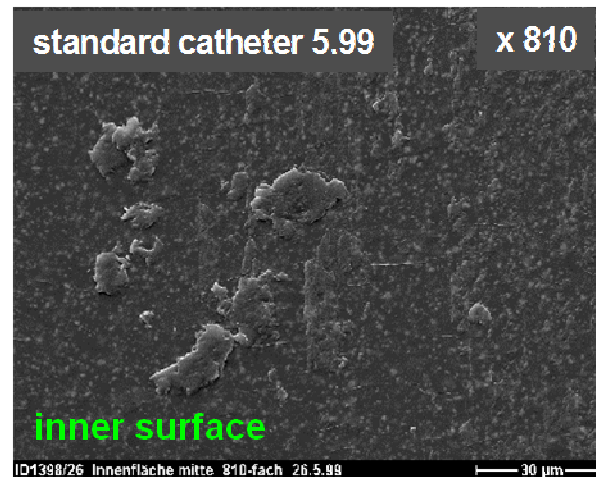
Alternating hydrophobic/-hydrophilic segments creating the biocompatible catheter surface (smDLC).

Hypothesis



Relationship between the surface microstructure of the membranes and their antithrombogenicity

Structure of surface-modified polyurethane catheters



Study hypothesis

- We hypothesized that the improvement of blood-surface interaction by a reactive polymer film coating might reduce thrombogenic events in the vascular access device and subsequently lead to prolonged catheter survival in the clinical setting.
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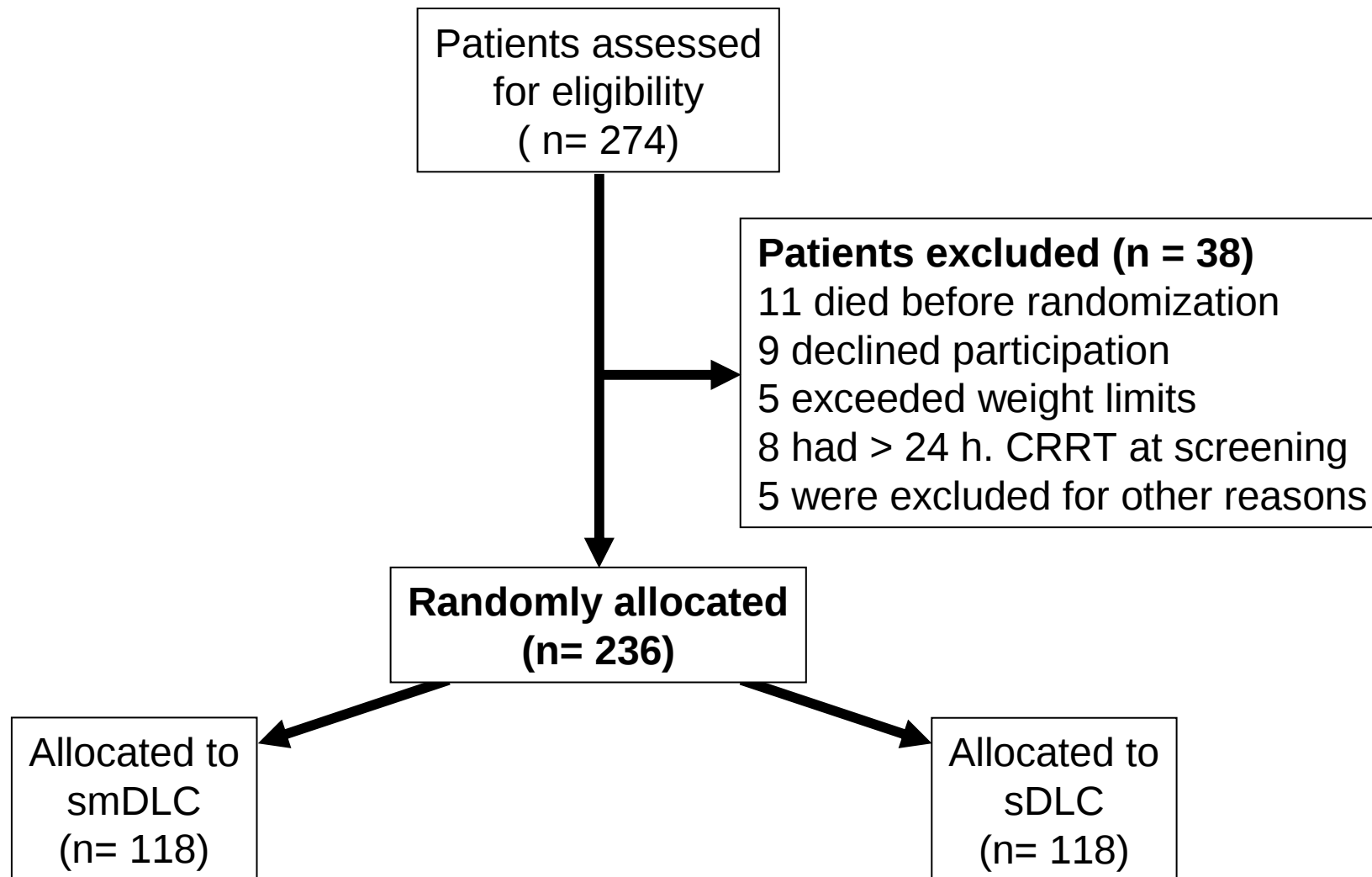
Aim

- We compared, in a randomized single-blinded study, the clinical application of two temporary catheters (TCs):
 - one surface modified catheter (smDLC)
 - GamCath Dolphin[®] Protect (Gambro, Lund/Sweden)
 - one standard double lumen catheter (sDLC)
 - GamCath[®] (Gambro, Lund/Sweden)
 - ICU patients with AKI requiring CRRT (CVVHDF)
 - Both TCs had identical geometry and flow design (i.e. straight, 13F-20cm length).
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Endpoints

- Primary endpoints
 - Efficacy endpoints were defined as the ability to complete at least 72-h CRRT without interruption due to TCs dysfunction and ability to achieve blood flow rates of ≥ 150 mL/min.
 - Secondary endpoints
 - Safety endpoints were defined as the occurrence of catheter-related (CR) bacteremia or local bleeding.
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Trial profile



Baseline characteristics

Characteristics	smDLC	sDLC	P value
Patients (n)	118	118	
Age (yr; mean±SD)	55.4±19.2	58.4±16.6	0.85
Weight (kg; mean±SD)	79.5±12.5	80.4±10.3	0.92
Male, n (%)	67 (57)	70 (59)	0.79
Cause of acute kidney injury, n (%)			0.33
septic shock	53 (45)	51 (43)	
cardiogenic	42 (36)	42 (36)	
post surgical	11 (9)	12 (10)	
hypovolemia	7 (6)	8 (7)	
others	5 (4)	5 (4)	
Mechanically ventilated, n (%)	90 (76)	89 (75)	0.98
Required vasopressors, n (%)	72 (61)	70 (59)	0.85
Oliguric, n (%)	84 (71)	83 (70)	0.98
Severity of illness score (APACHE II; mean±SD)	29±8	28±5	0.86
Atrial fibrillation or other sustained arrhythmia, n (%)	28 (24)	30 (25)	0.85

Baseline characteristics

Characteristics	smDLC	sDLC	P value
Diabetes mellitus status, n (%)	28 (24)	27 (23)	0.98
Current Swan-Ganz catheters, n (%)	72 (61)	68 (58)	0.68
Hemoglobin at TCs insertion (g/L; mean $\pm$ SD)	104 $\pm$ 34	102 $\pm$ 31	0.82
Heparin use (prophylactic) (IU; mean $\pm$ SD)	10'500 $\pm$ 2'500	11'000 $\pm$ 2'500	0.91
Heparin use (therapeutic) (IU/kg/h; mean $\pm$ SD)	13 $\pm$ 4	14 $\pm$ 6	0.55
Aspirin use (100 mg/d); n (%)	25 (21)	27 (23)	0.85

CRRT characteristics and outcomes

Characteristics/outcomes	smDLC	sDLC	P value
CRRT Characteristics			
Duration of CRRT (hemodiafiltration) (hours; mean±SD)	141.6±49.7	149.4±51.3	0.89
Total effluent rate (ml/h; mean±SD)	2'783±438	2'814±360	0.92
Total ultrafiltration rate (ml/h; mean±SD)	133±104	130±115	0.94
Dialysate rate (ml/h; mean±SD)	1'759±173	1'831±217	0.86
Actual delivered dosage (ml/kg per h)	33	27	0.02
Patients achieving ≥80% prescribed dosage, n (%)	93 (79)	78 (66)	0.02
Outcomes			
Total ICU days	18±13	20±17	0.58
ICU survival, n (%)	76 (64)	79 (67)	0.79
ICU renal recovery, n (%)			0.75
	all patients	53 (45)	58 (49)
	survivors	85 (72)	84 (71)

Anticoagulation and biological results

Characteristics	smDLC	sDLC	P value
Citrate anticoagulation, n (%)	14 (12)	12 (10)	0.85
Heparin bolus (IU; mean $\pm$ SD)	2'550 $\pm$ 250	2'650 $\pm$ 350	0.74
Continuous heparin dose (IU/h; mean $\pm$ SD) ^a	250 $\pm$ 150	550 $\pm$ 250	0.01
Coagulation factors ^a			
AT III (%)	94.8 $\pm$ 9.8	83.5 $\pm$ 8.7	0.03
Fibrinogen (mg/dL)	439 $\pm$ 105	378 $\pm$ 99	0.04
Thrombocyte count (1'000/ μ L)	232 $\pm$ 57	197 $\pm$ 63	0.02
aPTT (sec; mean $\pm$ SD)	54.8 $\pm$ 12.3	69.5 $\pm$ 18.4	0.02

^aafter 72 h CRRT treatment

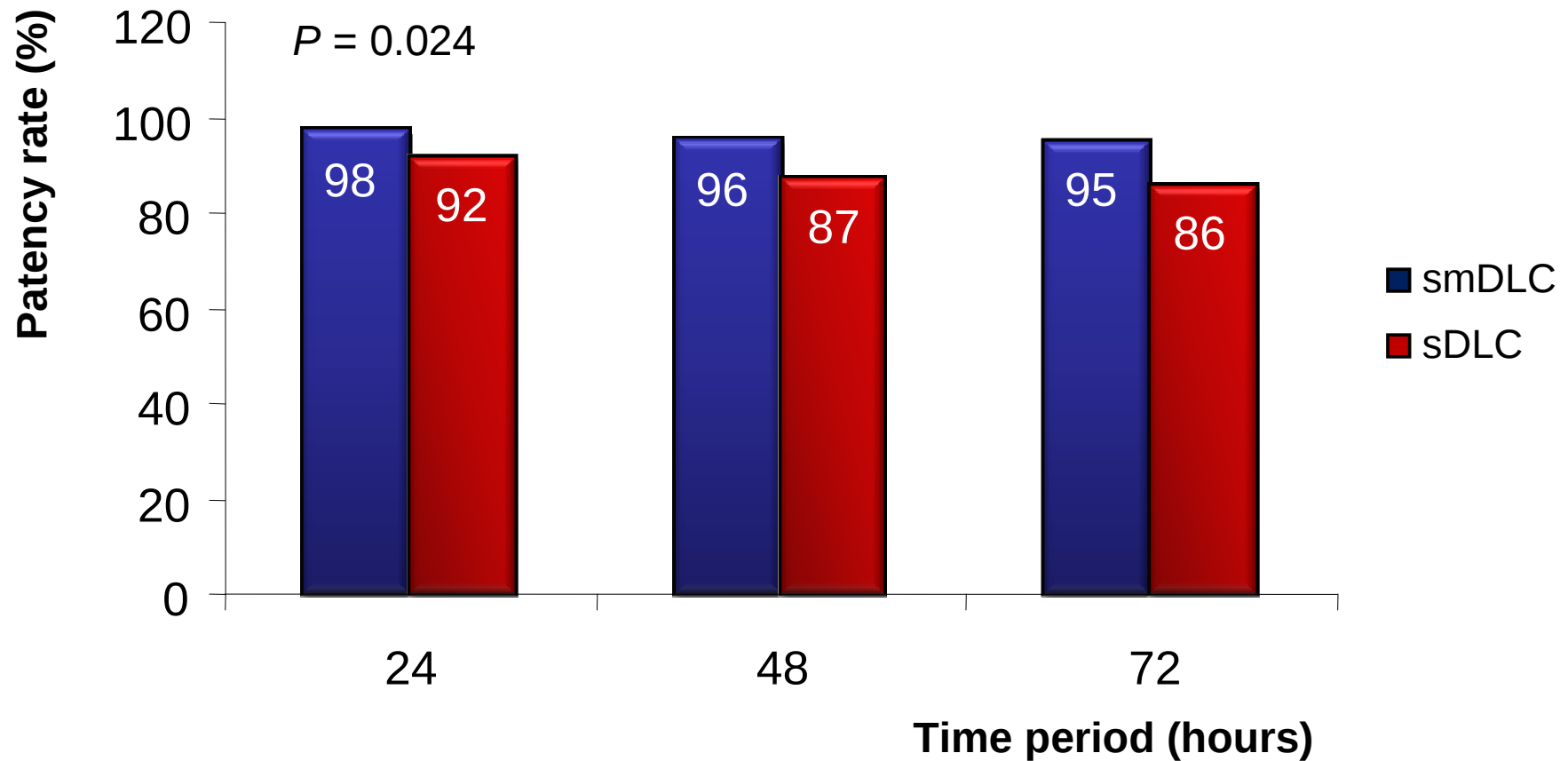
AT III: antithrombin III; aPTT: activated partial thromboplastin time

Catheter insertion

Characteristics	smDLC	sDLC	P value
Catheters inserted, n (TC/pt)	126 (1.07)	138 (1.17)	0.03
Procedure time (min; mean±SD)	22.4±10.9	21.1±10.2	0.75
Insertion site, n (%)			0.89
right subclavian vein	51 (43)	50 (42)	
right internal jugular vein	47 (40)	51 (43)	
left subclavian vein	17 (14)	15 (13)	
left jugular vein	4 (3)	2 (2)	
Complications at insertion, n (%)			0.98
bleeding	4 (3)	4 (3)	
kinking	4 (3)	2 (2)	

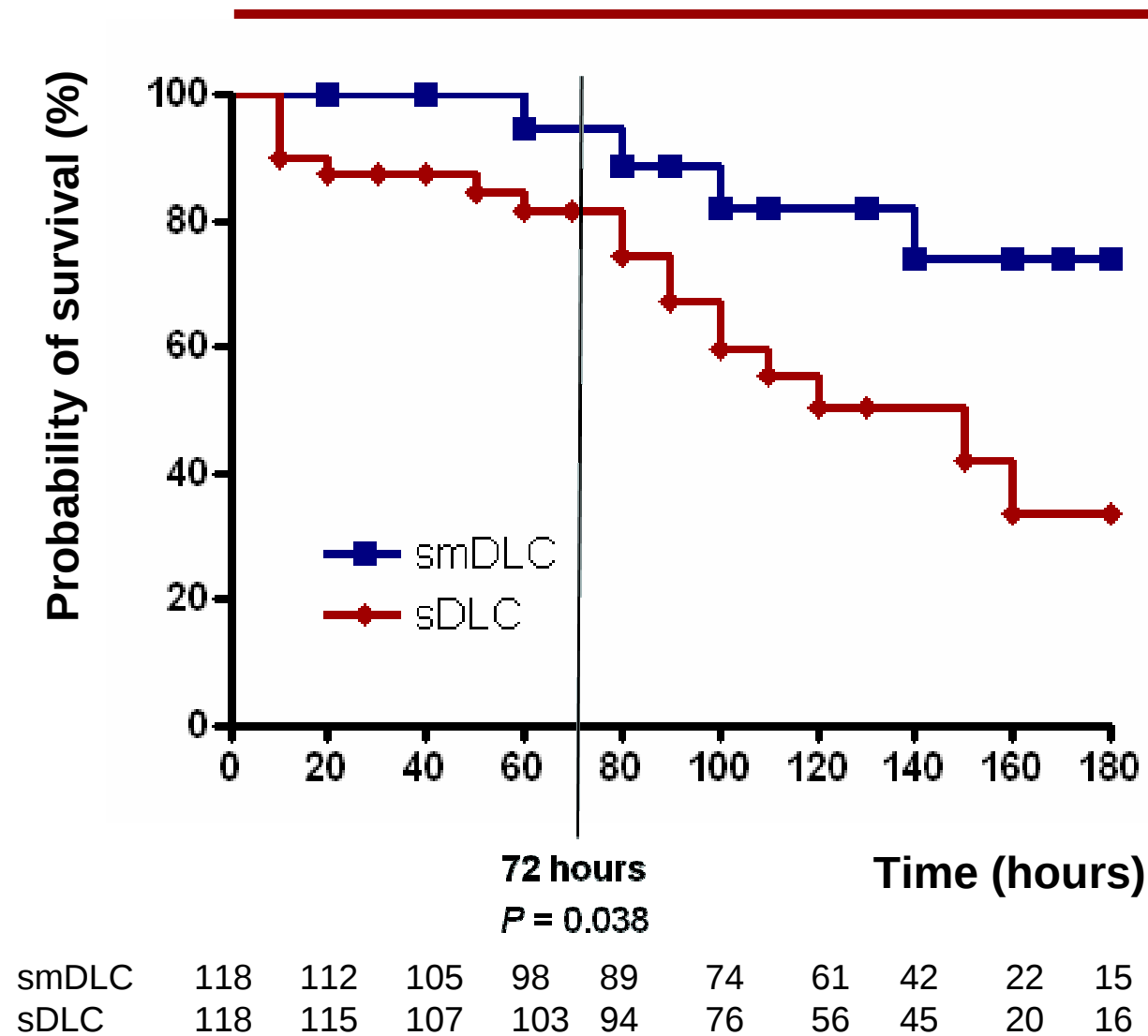
TC: temporary catheter; pt: patient

Patency rate



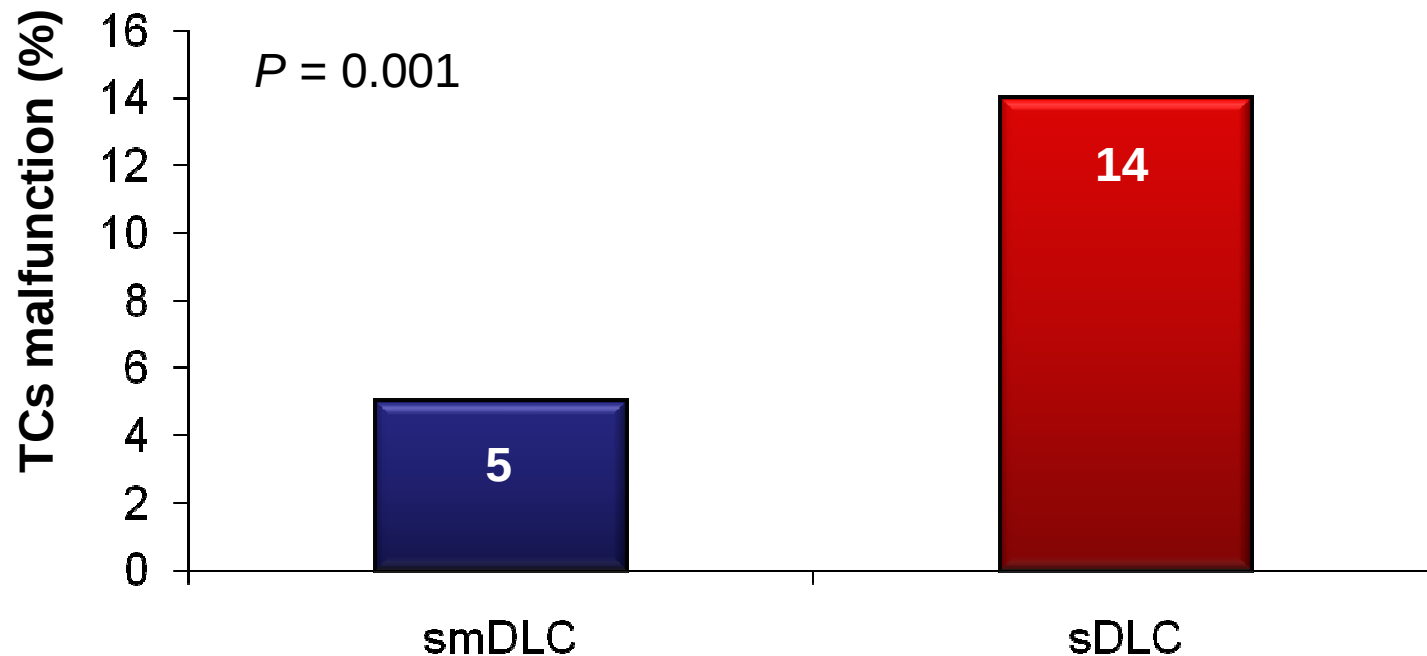
Patency rate at various time points of CRRT

Probability of TCs survival



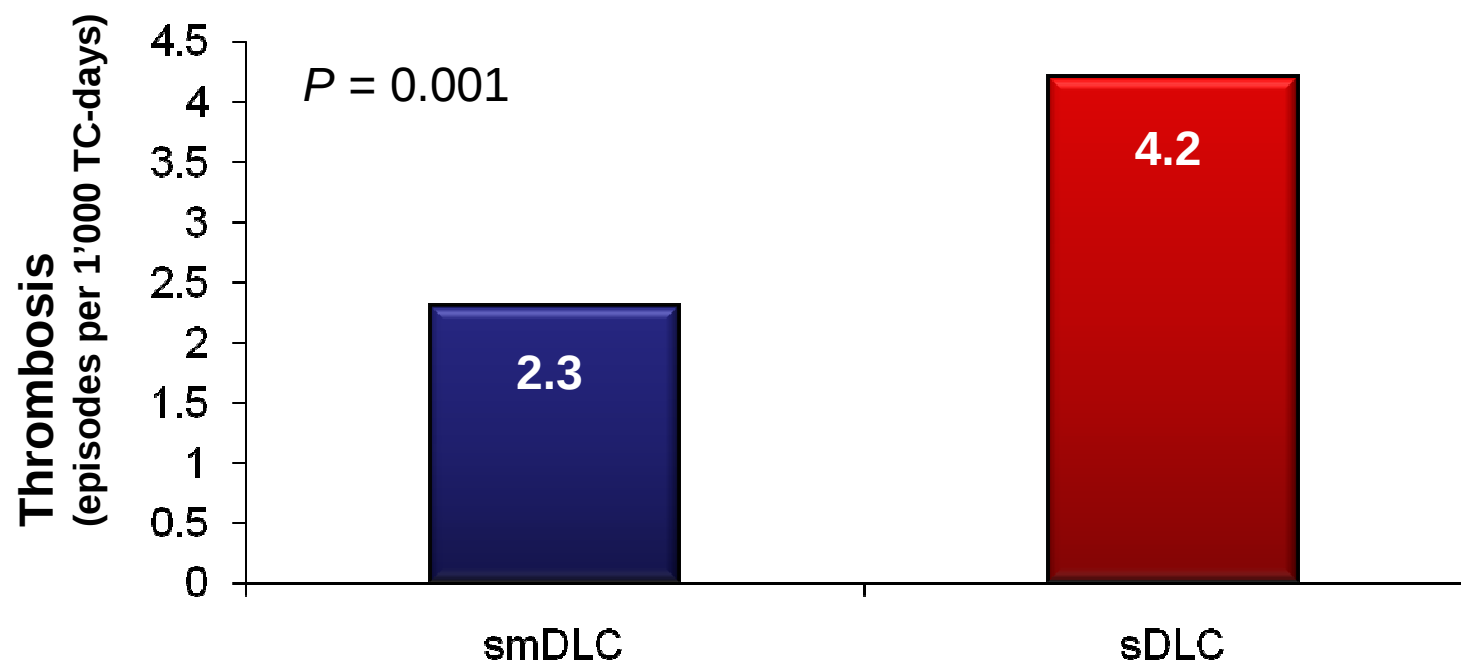
Overall catheter survival (log-rank value = 0.026)

TCs malfunction



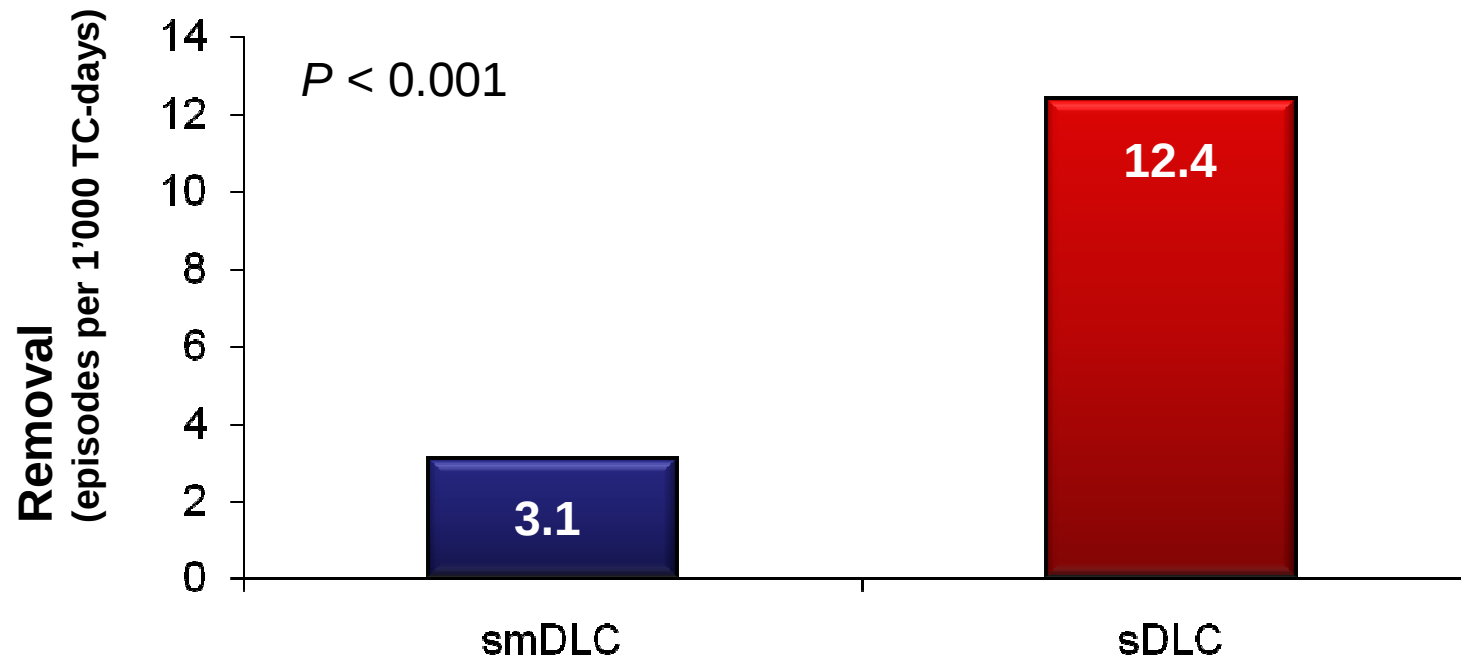
Percentage of TCs malfunction between smDLC and sDLC at 72 h of CRRT. Malfunction defined as $Q_b < 150$ mL/min.

TCs thrombosis



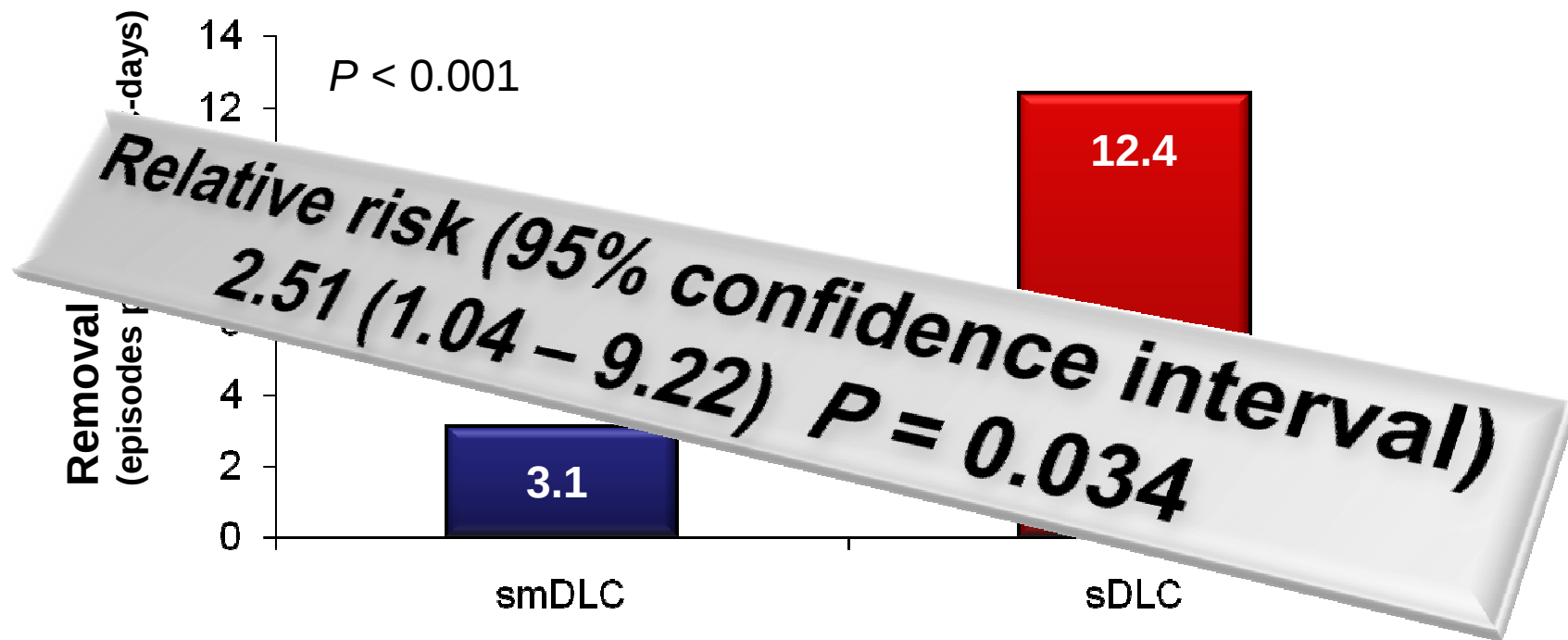
TCs thrombosis episodes per 1'000 days

Premature removal (< 72 hours) for TC flow problems



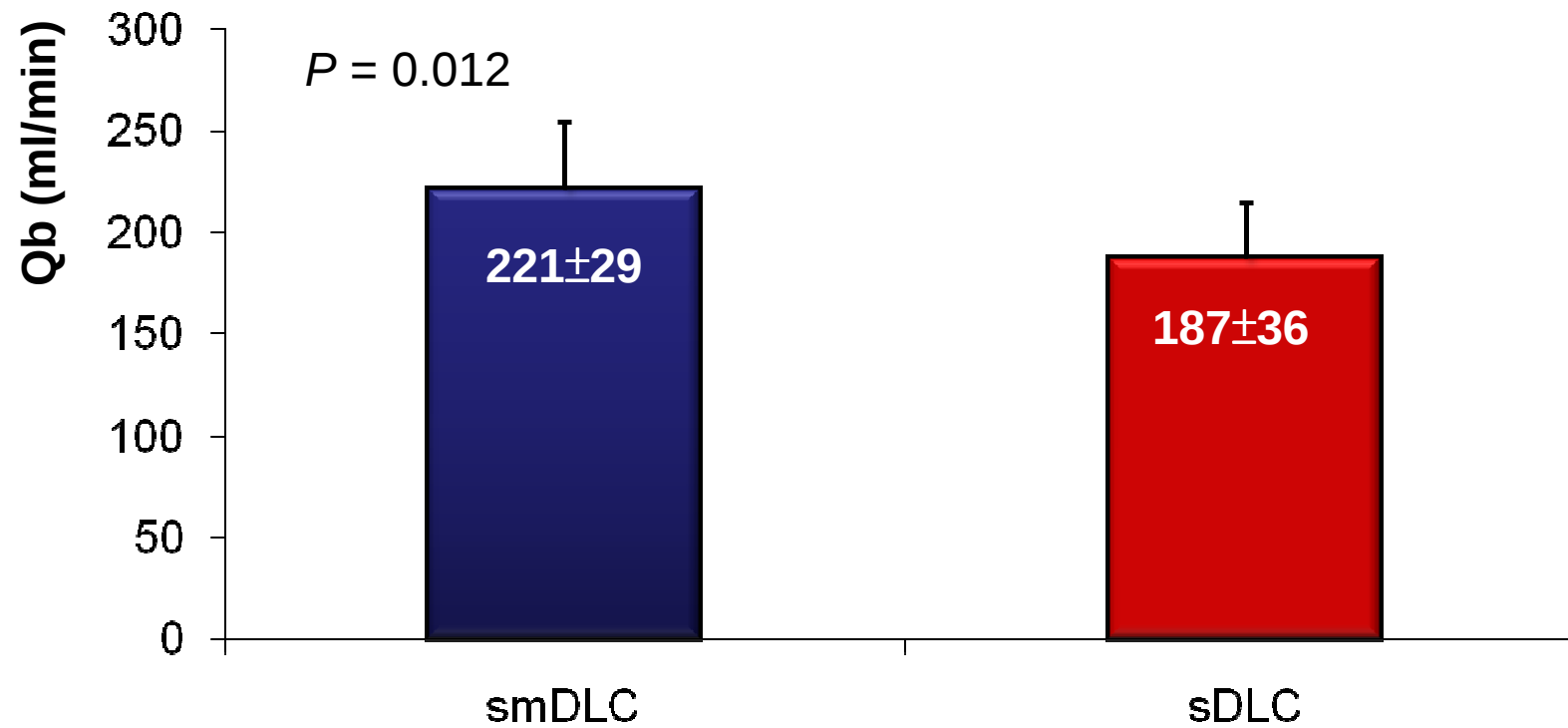
Premature removal (< 72 hours) per 1'000 days

Premature removal (< 72 hours) for TC flow problems



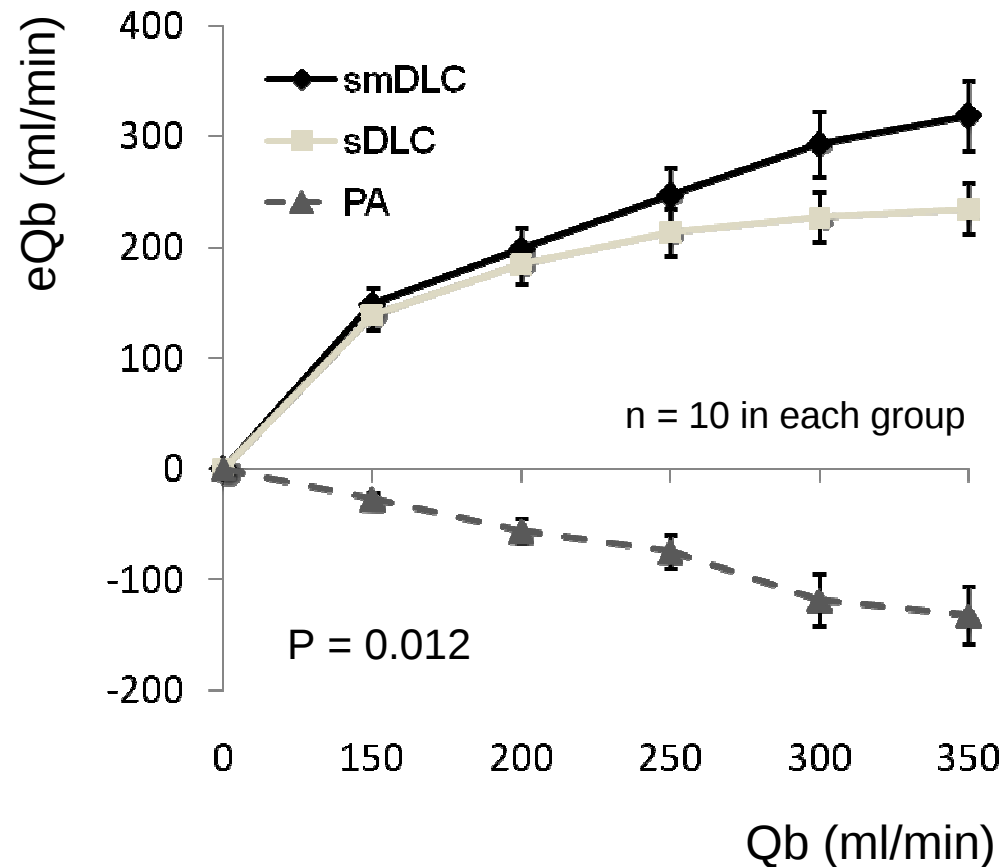
Premature removal (< 72 hours) per 1'000 days

Blood flow rate



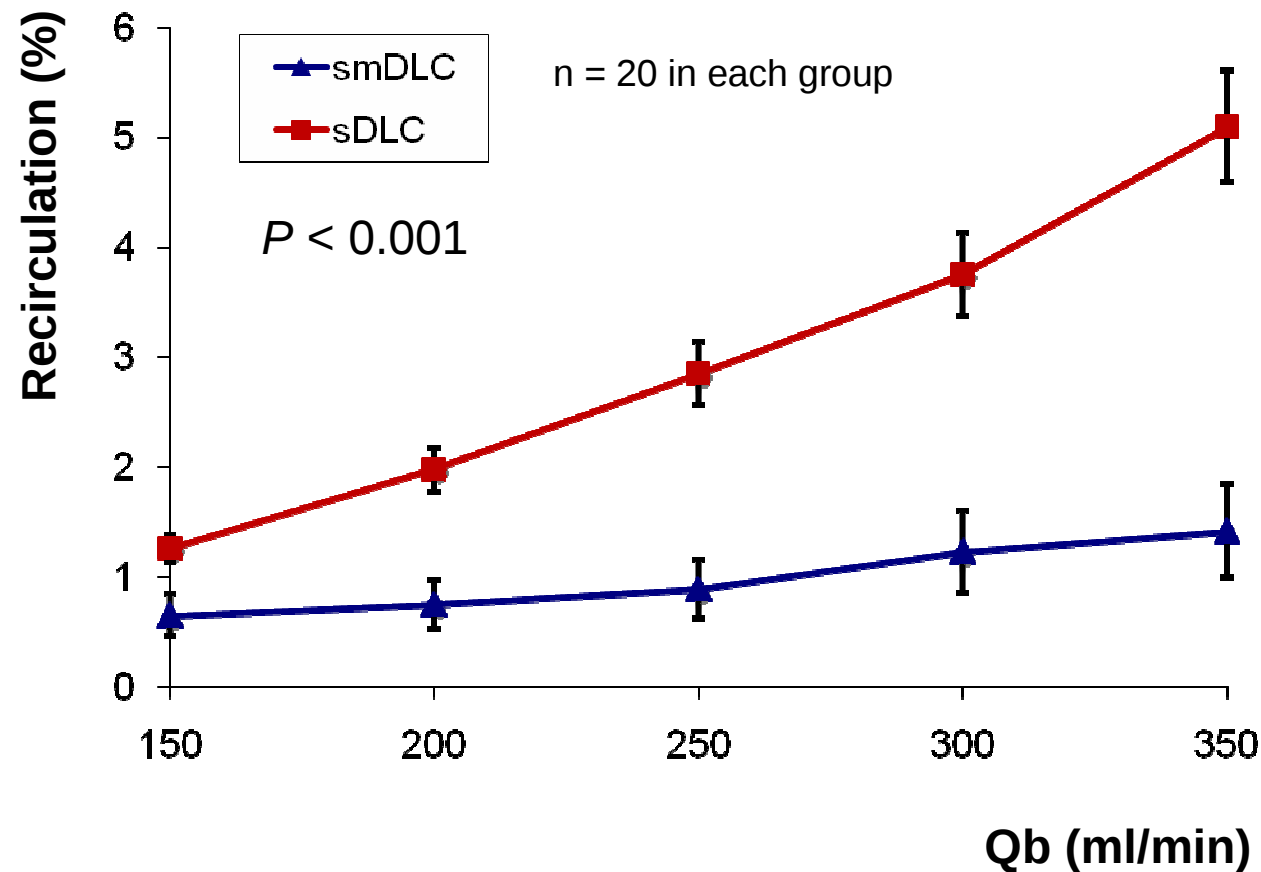
Comparison of Qb (mean±SD) for the two TCs

Blood flow rate



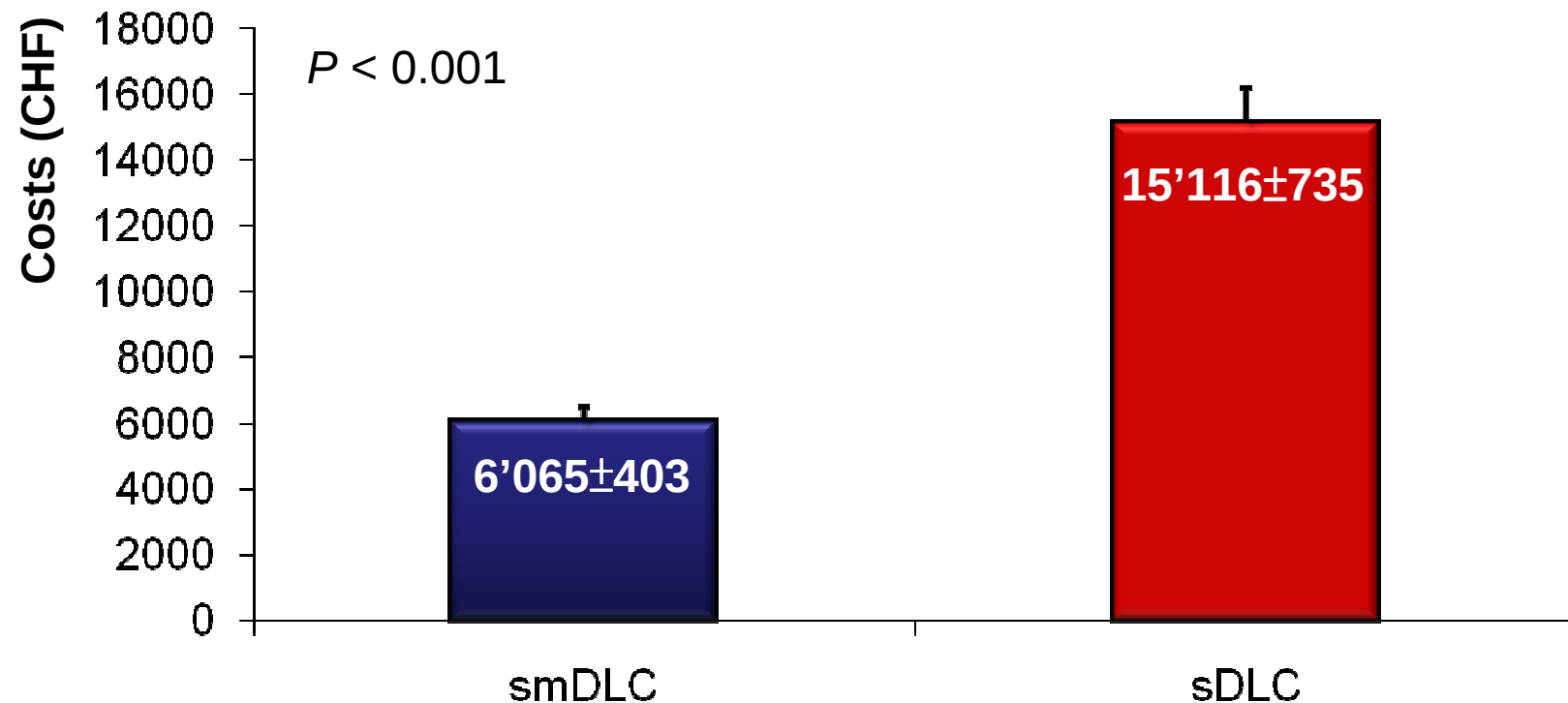
Relationship between roller pump setting of dialysis machine and actual flow rate by Transonic™ device, for smDLC and sDLC at 72 h of CRRT.

Recirculation



Recirculation in forward flow measured by Transonic™ device, for smDLC and sDLC at 72 h of CRRT.

Costs of TCs exchange due to dysfunction or thrombosis



Comparison of costs due to TCs dysfunction (mean±SD): Mean cost/TC exchange 755.80.- CHF without VAT – 6.8% and 16.9% of smDLC and sDLC were exchange, respectively.

CR bloodstream infection or local bleeding

Complications	All ¹ Count	Rate*	smDLC ¹ Count	Rate*	sDLC ¹ Count	Rate*	P value ²
All organisms	12	171	3	43^a	9	129^a	0.012
Coagulase-negative <i>Staphylococcus</i>	5	71	2	29	3	43	0.068
<i>S aureus</i> [†]	4	57	1	14	3	43	0.016
Gram-negative bacteria	2	29	0	0	2	29	0.013
Other gram-positive cocci	1	14	0	0	1	14	0.032
Bleeding	3	43	2	29	1	14	0.69

¹Calculated for 7 days (168 hours) CRRT

²Between smDLC and sDLC complication rates

*Rate: Count x 100 divided by total days (7 d.)

[†]No *S aureus* strains resistant to methicillin

^a**episodes per 1'000 TC-days**

3.4 for smDLC vs. 9.3 for sDLC (P = 0.008)

Conclusions

- Micropatterned surface coating with a polyurethane polymer significantly increased TC survival with lower dysfunction rate and better bacteriological barrier than sDLC in critically ill patients with AKI necessitating CRRT.
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