

PRAGUE-6 Trial

Off-Pump Versus On-Pump
Coronary Artery Bypass Graft
Surgery in Patients With
EuroSCORE ≥ 6

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Off-pump versus on-pump coronary surgery: final results from a prospective randomized study Prague-4

Zbynek Straka, Petr Widimsky, Karel Jirasek, Petr Stros, Jan Votava, Tomas Vanek,
Petr Brucek, Miroslav Kolesar and Rudolf Spacek
Ann Thorac Surg 2004;77:789-793

The online version of this article, along with updated information and services, is
located on the World Wide Web at:

<http://ats.ctsnetjournals.org/cgi/content/full/77/3/789>

ORIGINAL ARTICLE

Off-Pump or On-Pump Coronary-Artery Bypass Grafting at 30 Days

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On-Pump versus Off-Pump Coronary-Artery Bypass Surgery

A. Laurie Shroyer, Ph.D., Frederick L. Grover, M.D., Brack Hattler, M.D., Joseph F. Collins, Sc.D.,
Gerald O. McLaughlin, M.D., Elizabeth Kozora, Ph.D., John C. Lucke, M.D., Janet H. Baltz, R.N.,
et al. for the On/Off Bypass (ROOBY) Study Group

Design of the PRAGUE-6 study

- ▶ Prospective
- ▶ Randomised (on-pump vs. off-pump)
- ▶ Single center
- ▶ Non-selected patients
- ▶ EuroSCORE ≥ 6
- ▶ Including acute coronary syndromes
- ▶ 5 certified heart-surgeons (> 100 off-pump)
- ▶ Intention-to-treat assessment

Primary combined end-point

Combination of:

- ▶ Death
- ▶ MI
- ▶ Stroke
- ▶ New renal failure requiring HD

All in the first 30 days postop.

Baseline characteristics

- ▶ 206 pts randomised/200 operated
- ▶ 108 on-pump (A) vs 98 off-pump (B)
- ▶ 99,5% follow-up

Variable	Group A on pump	Group B off-pump	P-value
Mean age	73.6±7.4	74.7±6.5	0.280
Female gender - no. (%)	46 (42.6)	40 (40.8)	0.888
Mean additive EuroSCORE	7.66	7.69	
Mean logistic EuroSCORE	9.8	10.7	0.849
EF < 30% - no. (%)	12 (11.1)	11 (11.2)	0.885
Recent MI – no. (%)	73 (67.6)	58 (59.2)	0.247
CCS IV – no. (%)	20 (18.5)	20 (20.4)	

Peroperative results

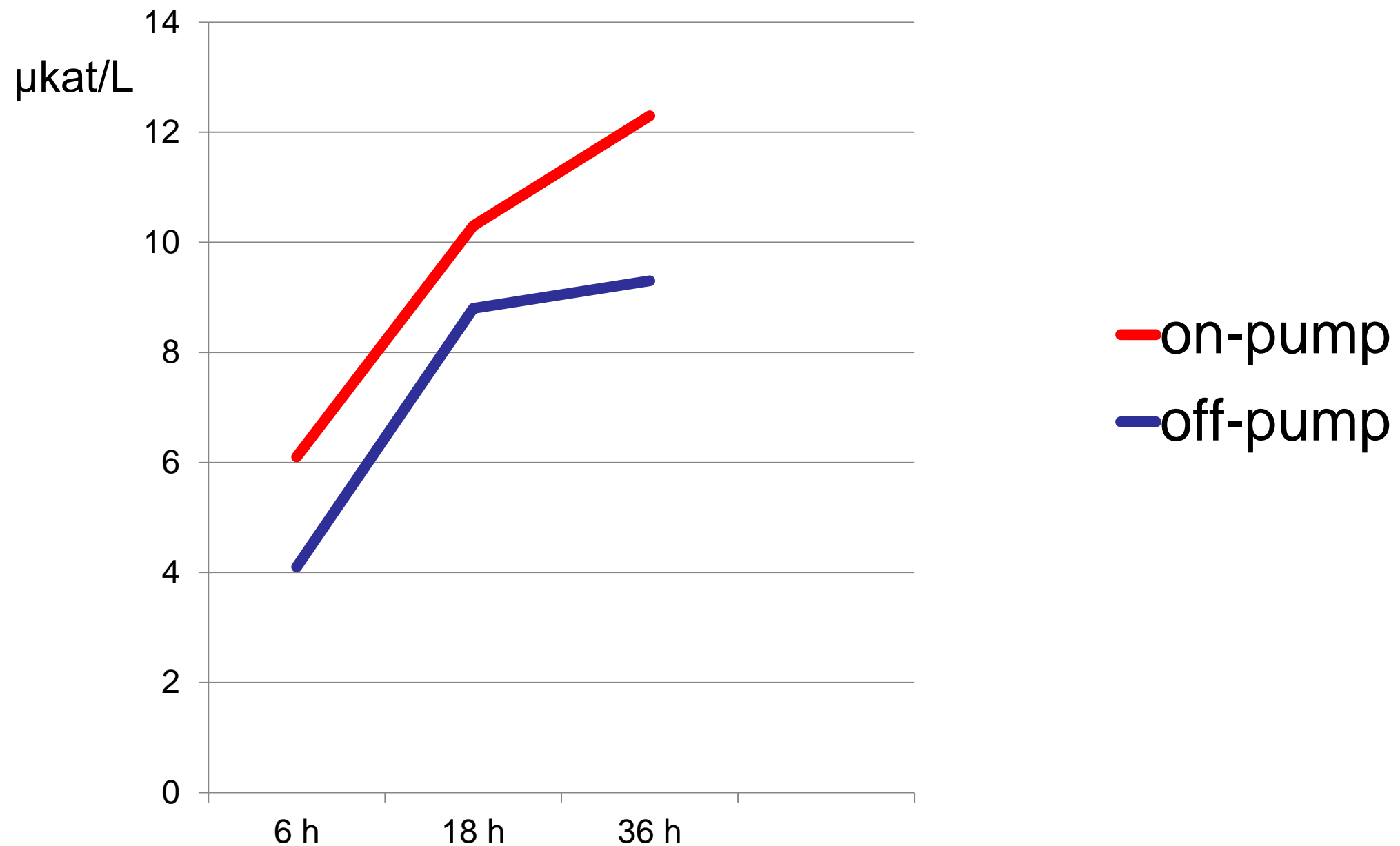
Variable	Group A on pump	Group B off-pump	P-value
No. of dist. anastomosis	282	192	
No. of dist. anastomosis/pt.	2.66	2.04	< 0.001
Converted – no. (%)	0	8 (8.5)	0.002
Site of dist. Anastomosis –no. (%)			< 0.001
LAD	121 (42.9)	112 (58.3)	
RCx	87 (30.9)	43 (22.4)	
RCA	74 (26.2)	37 (19.3)	
CPB time (min)– mean±SD	52.5±19.7		
Cross-clamp (min)– mean±SD	30.3±11.6		

Postoperative results

Variable	Group A on pump	Group B off-pump	p-value	RR (95%CI)
Total blood loss (mL) - median (IQR)	485 (400)	535 (350)	0.577	
Need of RBC transfusion (%)	85 (80.2)	61 (64.9)	0.017	0.81 (0.68-0.97)
Reexploration for bleeding or tamponade (%)	9 (8.5)	3 (3.2)	0.143	0.38 (0.10-1.35)
LCO – No. (%)	29 (27.4)	20 (21.3)	0.329	0.78 (0.47-1.28)
Wound infection (%)	5 (4.7)	2 (2.1)	0.451	0.45 (0.09-2.27)
Hospital stay (d) - mean±SD	8.0 ± 7.6	6.9 ± 6.4	0.255	
Total hospital cost (EUR) - median (IQR)	8205 (2353)	8051 (2856)	0.149	

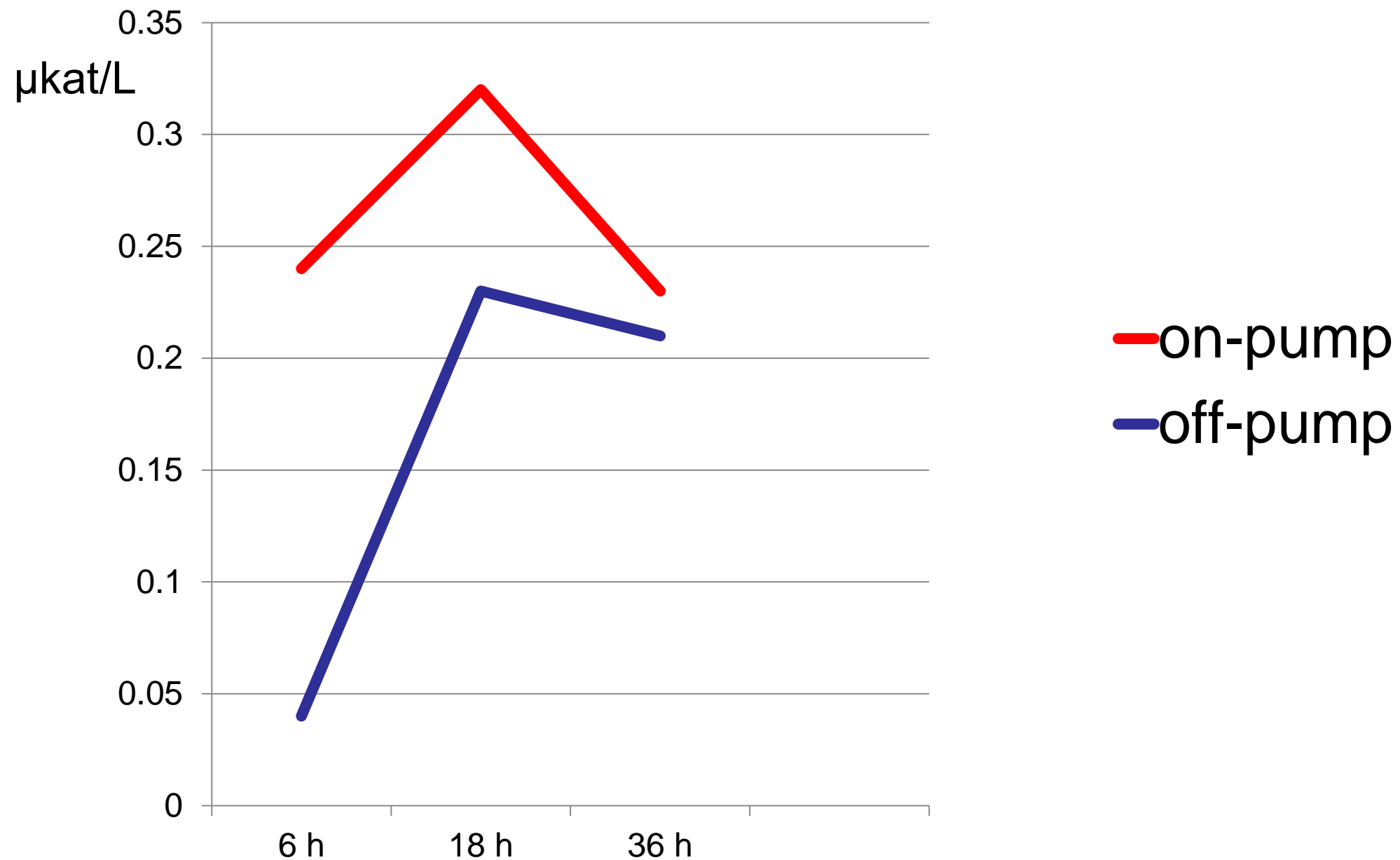
Cardio-specific enzymes release

CK (creatine kinase)



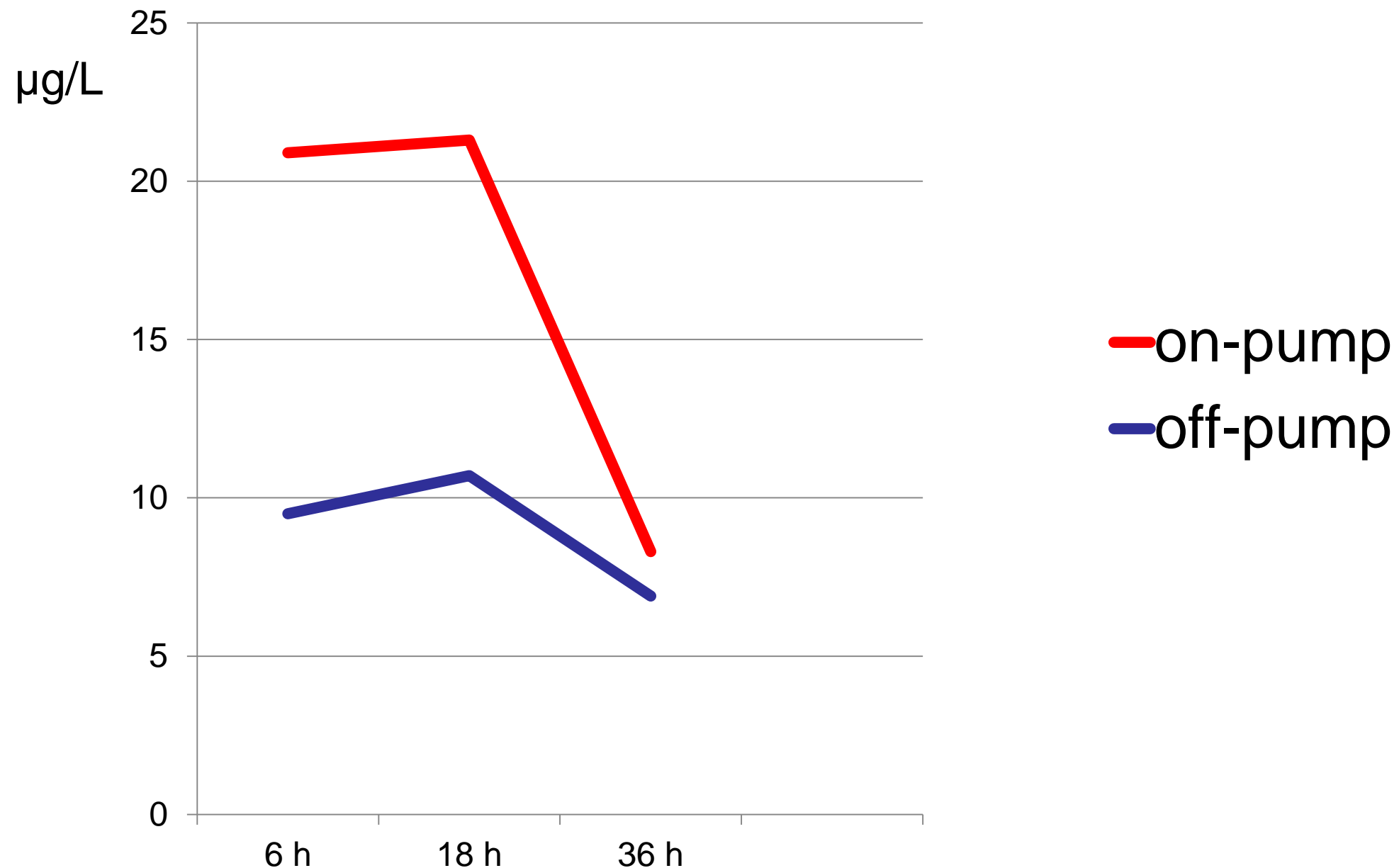
Cardio-specific enzymes release

CK-MB (creatine kinase-MB)



Cardio-specific enzymes release

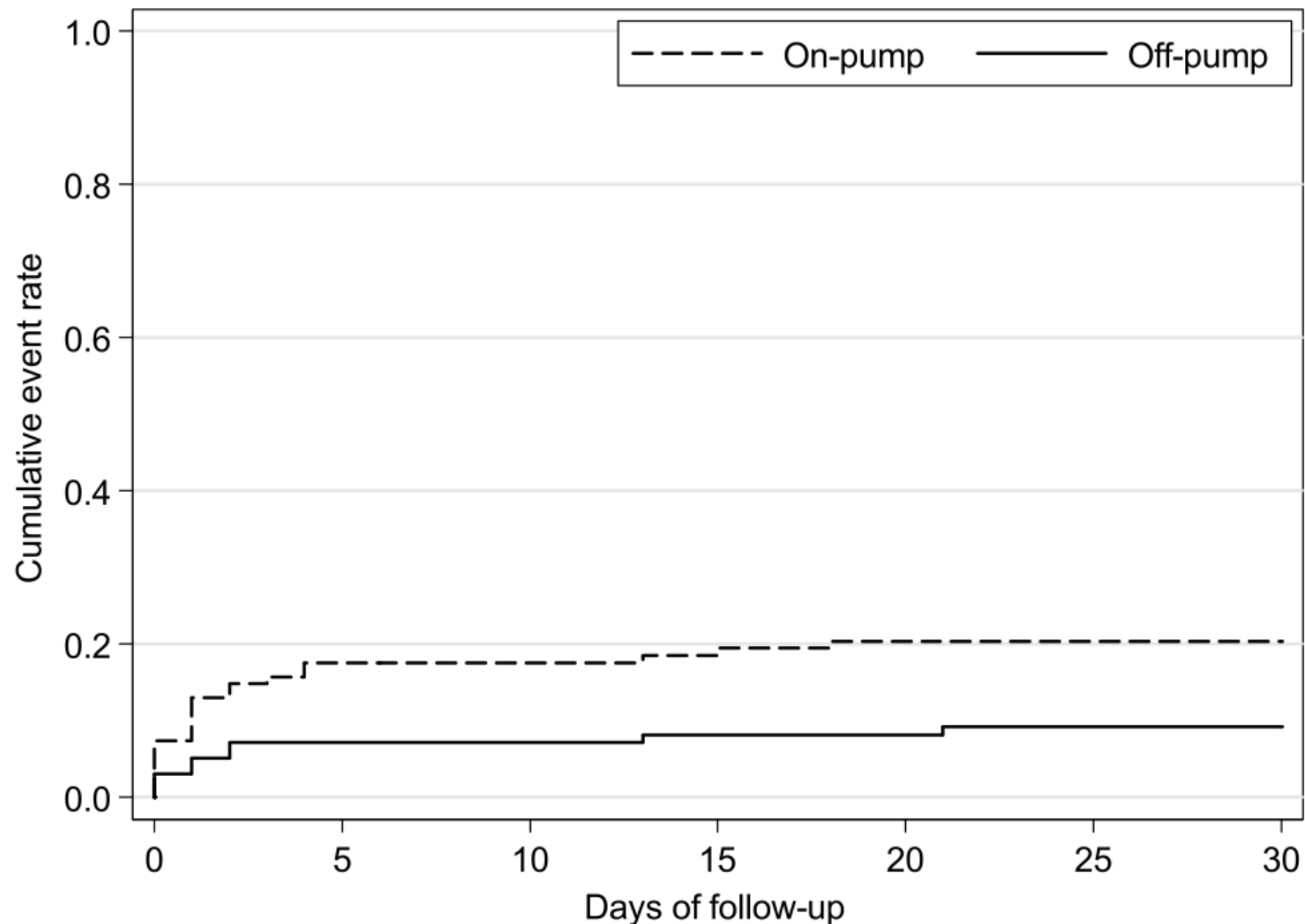
CK-MB mass (creatine kinase-MB mass)



PRAGUE 6 primary combined end-point 30 days follow-up (intention-to-treat)

Variable	Group A (107) on pump	Group B (98) off-pump	p-value	RR (95%CI)
Combined prim. end-point No. (%)	22 (20.6)	9 (9.2)	0.028	0.41 (0.19-0.91)
Death	6 (5.6)	4 (4.1)	0.623	0.73 (0.21-2.58)
AMI	13 (12.1)	4 (4.1)	0.048	0.32 (0.11-0.99)
Stroke	3 (2.8)	2 (2.0)	0.726	0.73 (0.12-4.35)
Hemodialysis required	5 (4.7)	1 (1.0)	0.163	0.22 (0.03-1.85)

The incidence of combined primary end point in the first 30 days postoperatively (Kaplan-Meier failure function)



Limitations

- ▶ Small collection of patients (206)
- ▶ Single center study
- ▶ 5 operating surgeons
- ▶ Short-term results (30 day follow-up)

Conclusions I.

- ▶ Off-pump surgery in high-risk patients is associated with a lower incidence of serious complications
- ▶ Off-pump surgery is a safer way of direct revascularization in these patients

Conclusions II.

- ▶ Off-pump patients tend to have a lower incidence of secondary end-points
 - need of RBC transfusion
 - reexploration for bleeding or tamponade

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Thank you for
attention