

Presenter Disclosure Information

Maaret Castrén

FINANCIAL DISCLOSURE:

Study sponsored by BeneChill, Inc

UNLABELED/UNAPPROVED USES DISCLOSURE:

The RhinoChill™ is not available in the US.

The PRINCE Trial

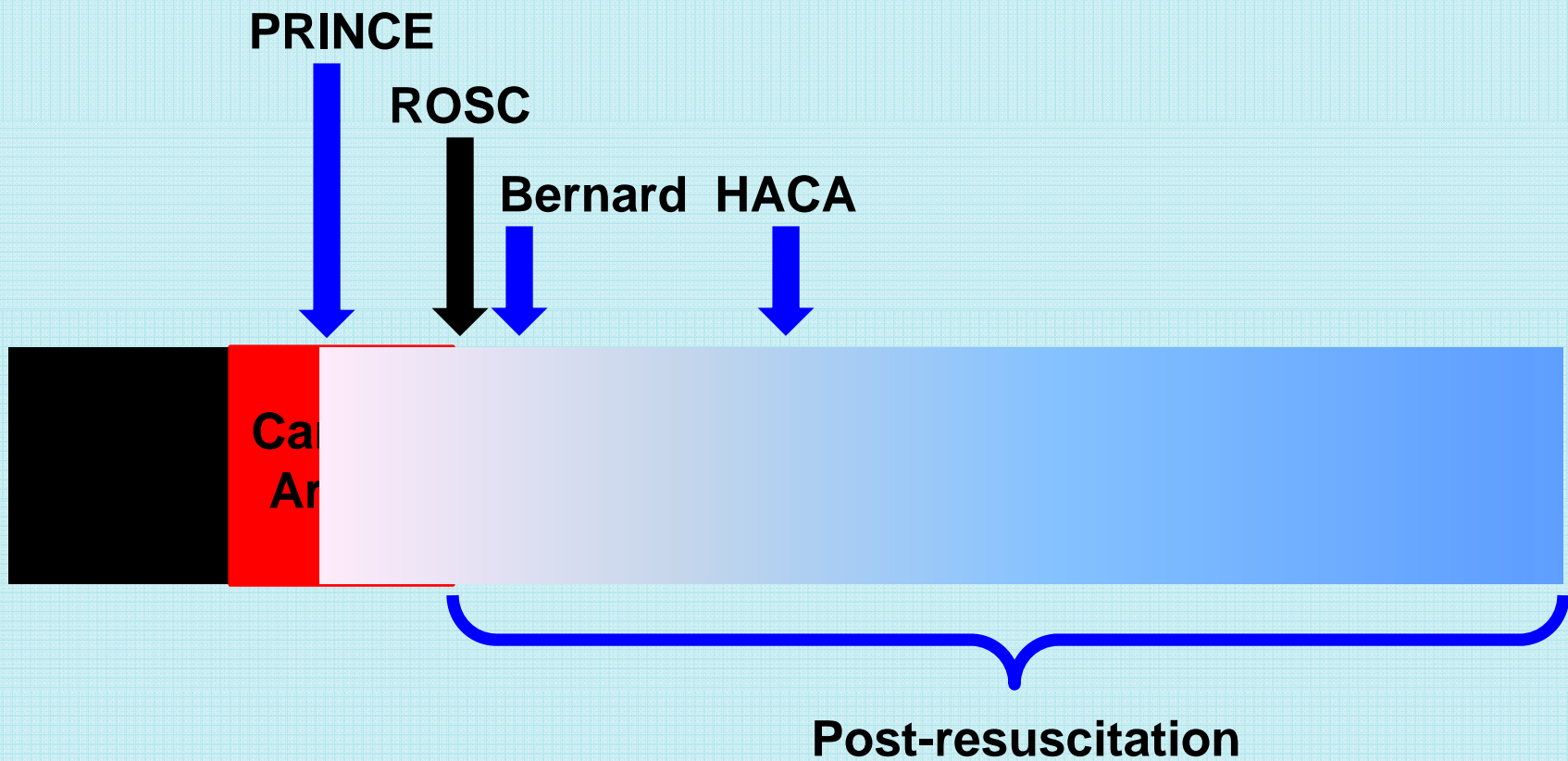
Pre-ROSC Intra-Nasal Cooling Effectiveness

Maaret Castrén

On behalf of the PRINCE Investigators

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Background



Prospective, randomized, field study

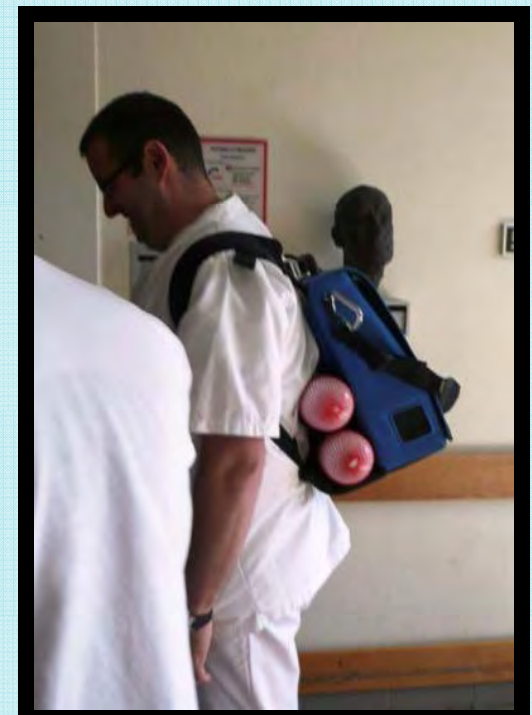


Primary end-points

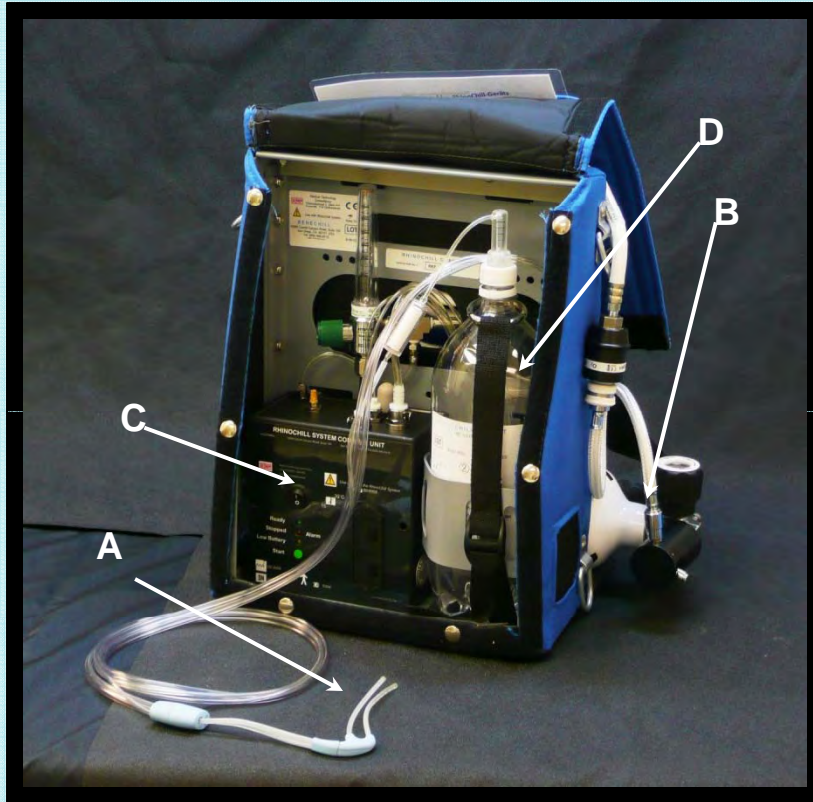
- Safety, feasibility and cooling efficacy of **intra-arrest** cooling using RhinoChill™
- 200 patients

Secondary end-points

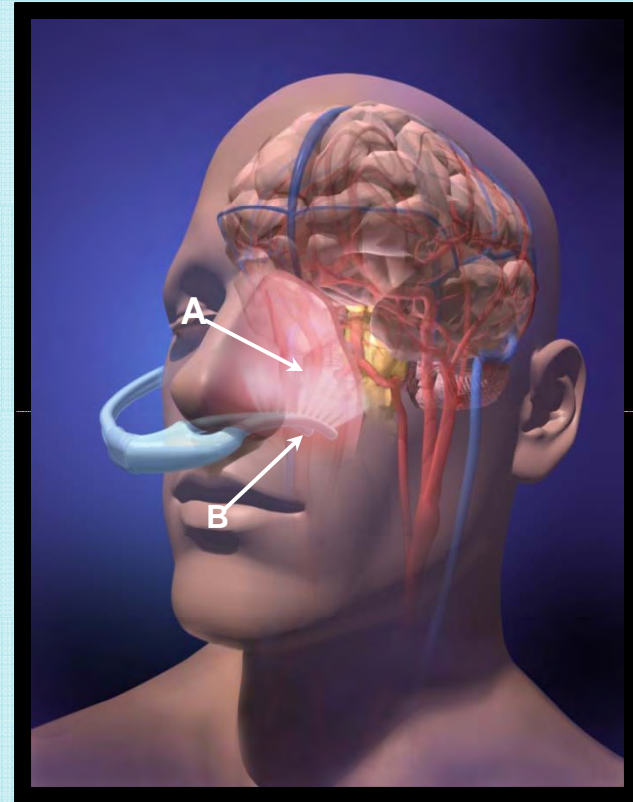
- Minutes to target temperature
- ROSC rate
- Survival to discharge
- Neurologically intact survival



RhinoChill™ intra-nasal cooling system

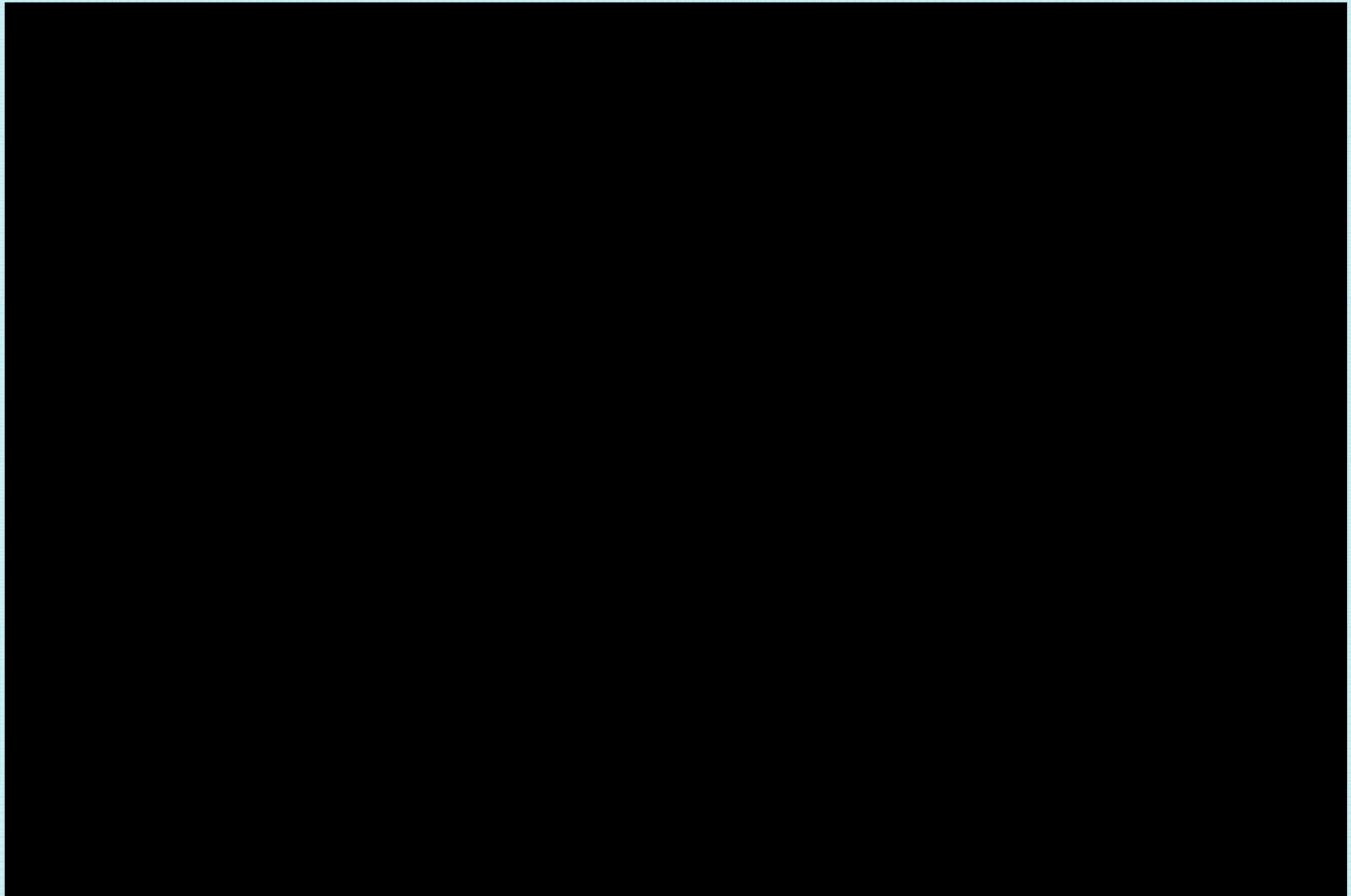


- A: Nasal Catheter
- B: Oxygen Tank
- C: Control Unit
- D: Coolant Bottle



- A: Coolant Spray
- B: Nasal Catheter

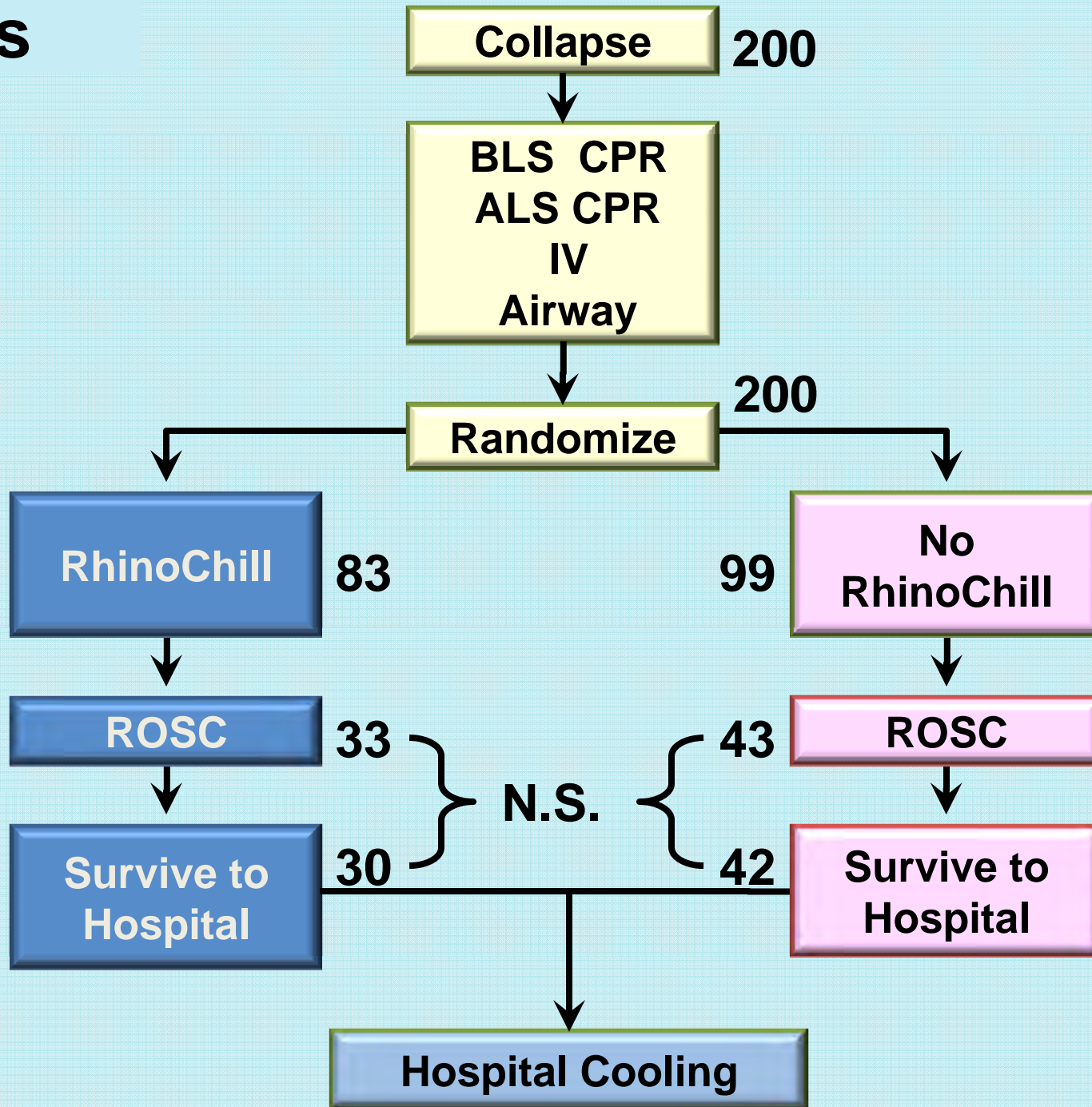
RhinoChill™ Intra-Nasal Cooling System



Inclusions

- All cardiac arrests, irrespective of rhythm
- Collapse witnessed
- EMS CPR \leq 20 min from collapse

Results



Baseline characteristics and rhythms

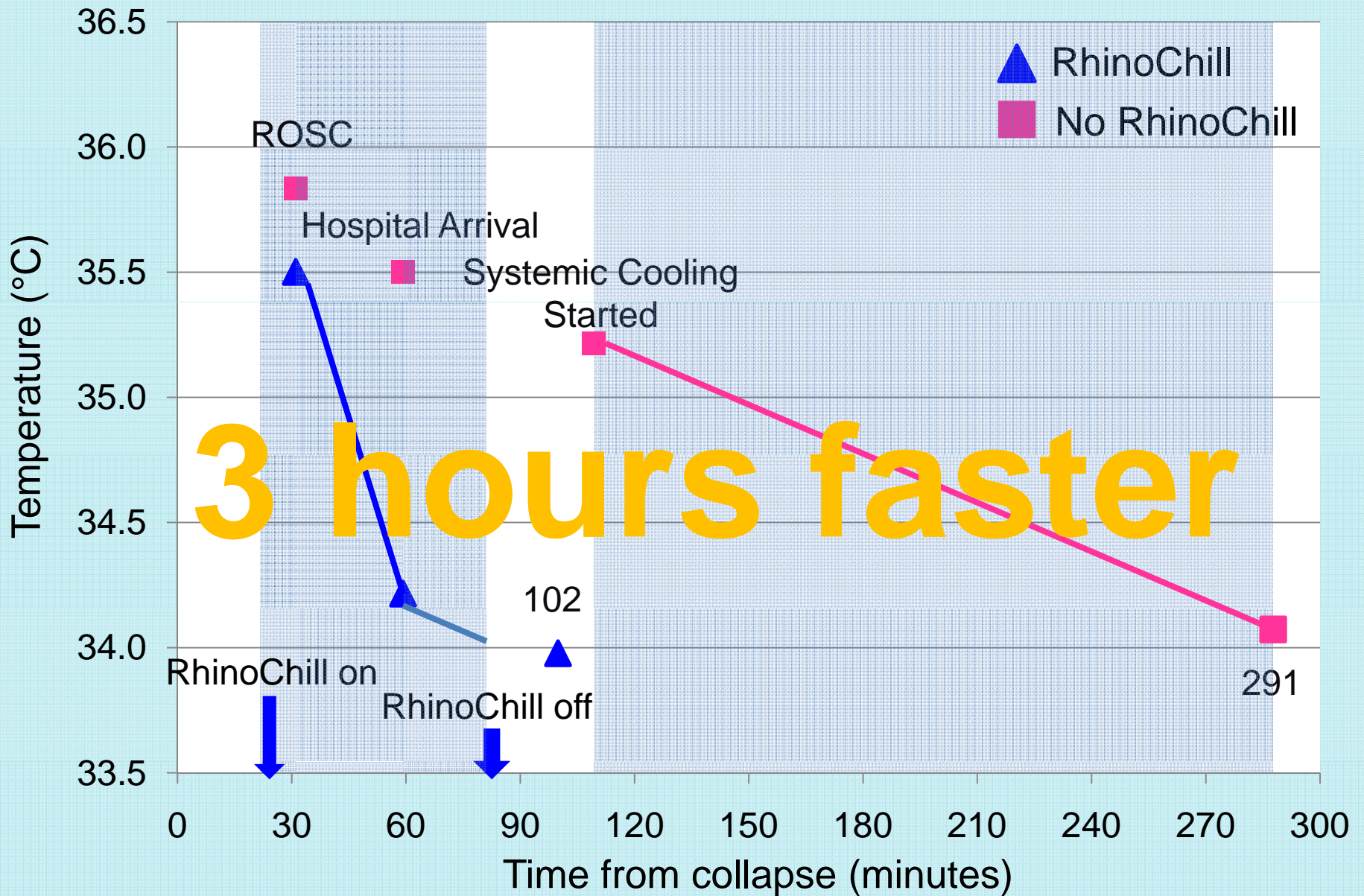
	<i>RhinoChill</i> (n=83)	<i>No RhinoChill</i> (n=99)	<i>p</i>
Bystander CPR (%)	38.6	45.5	0.37
VF (n (%))	24 (29)	32 (32)	0.63
PEA (n (%))	18 (22)	23 (23)	0.86
Asystole (n (%))	41 (49)	44 (44)	0.55

Event timing

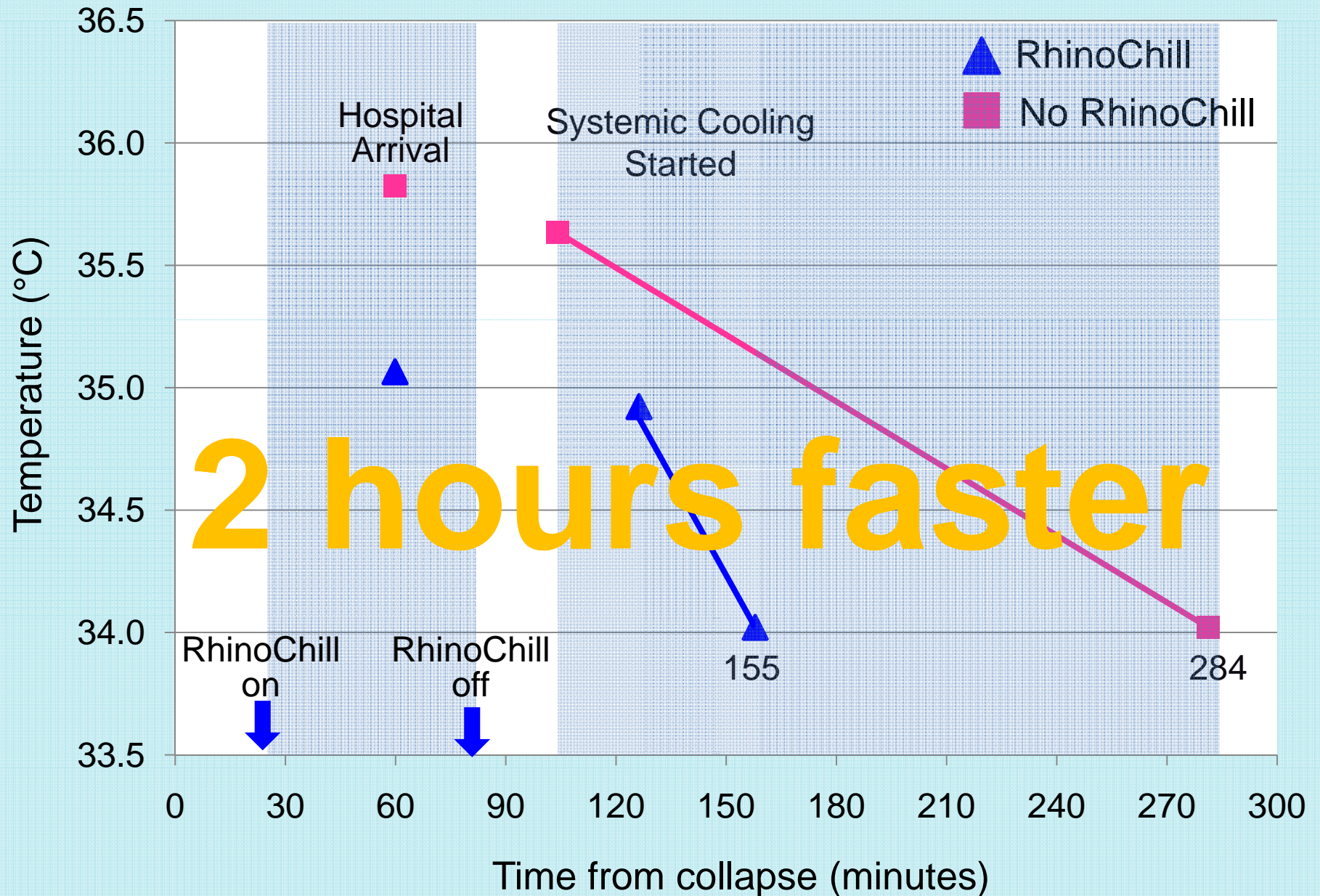
(minutes from collapse, median)

	<i>RhinoChill</i> <i>(n=83)</i>	<i>No RhinoChill</i> <i>(n=99)</i>	<i>p</i>
1st Rescuer CPR	8	8	0.62
ALS Arrival	12	11	0.54
Airway	18	16	0.10
Randomization	21	18	0.01
Nasal cooling	23	--	--
ROSC	32	30	0.18
Hospital Arrival	59	60	0.99

Time to target brain temperature (tympanic)



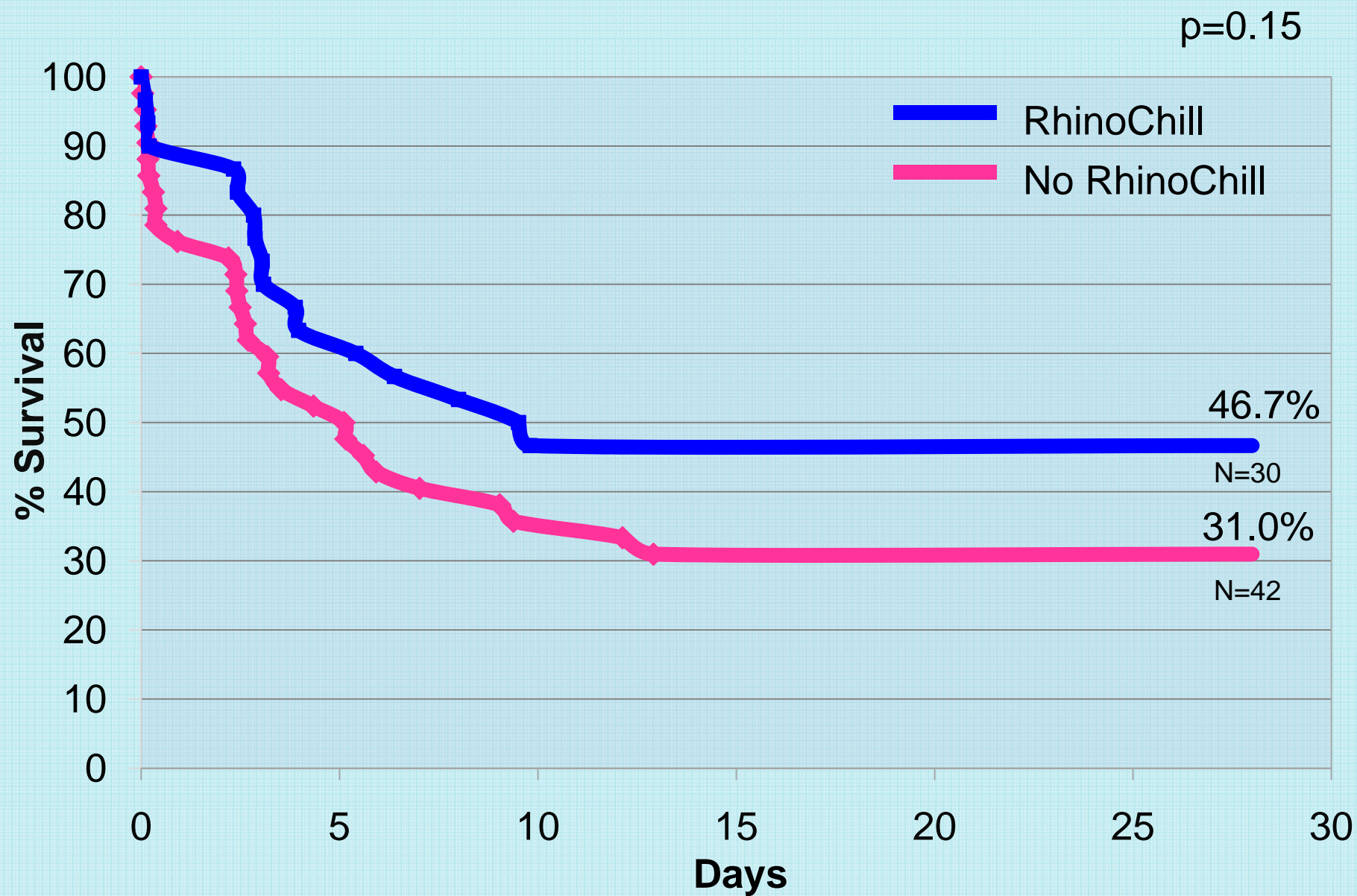
Time to target body temperature (core)



Adverse Events

Procedural device-related events	<i>RhinoChill</i> n=83	<i>No RhinoChill</i> n = 99
Nasal discoloration	13 (15.6%)	0 (0%)
Epistaxis	3 (3.6%)	0 (0%)
Peri-oral bleed	1 (1.2%)	0 (0%)
Periorbital emphysema	1 (1.2%)	0 (0%)
	<i>RhinoChill</i> n=30	<i>No RhinoChill</i> n = 42
Device-unrelated serious adverse events sepsis, AMI, re-arrest...	6 (20%)	14 (33.3%)

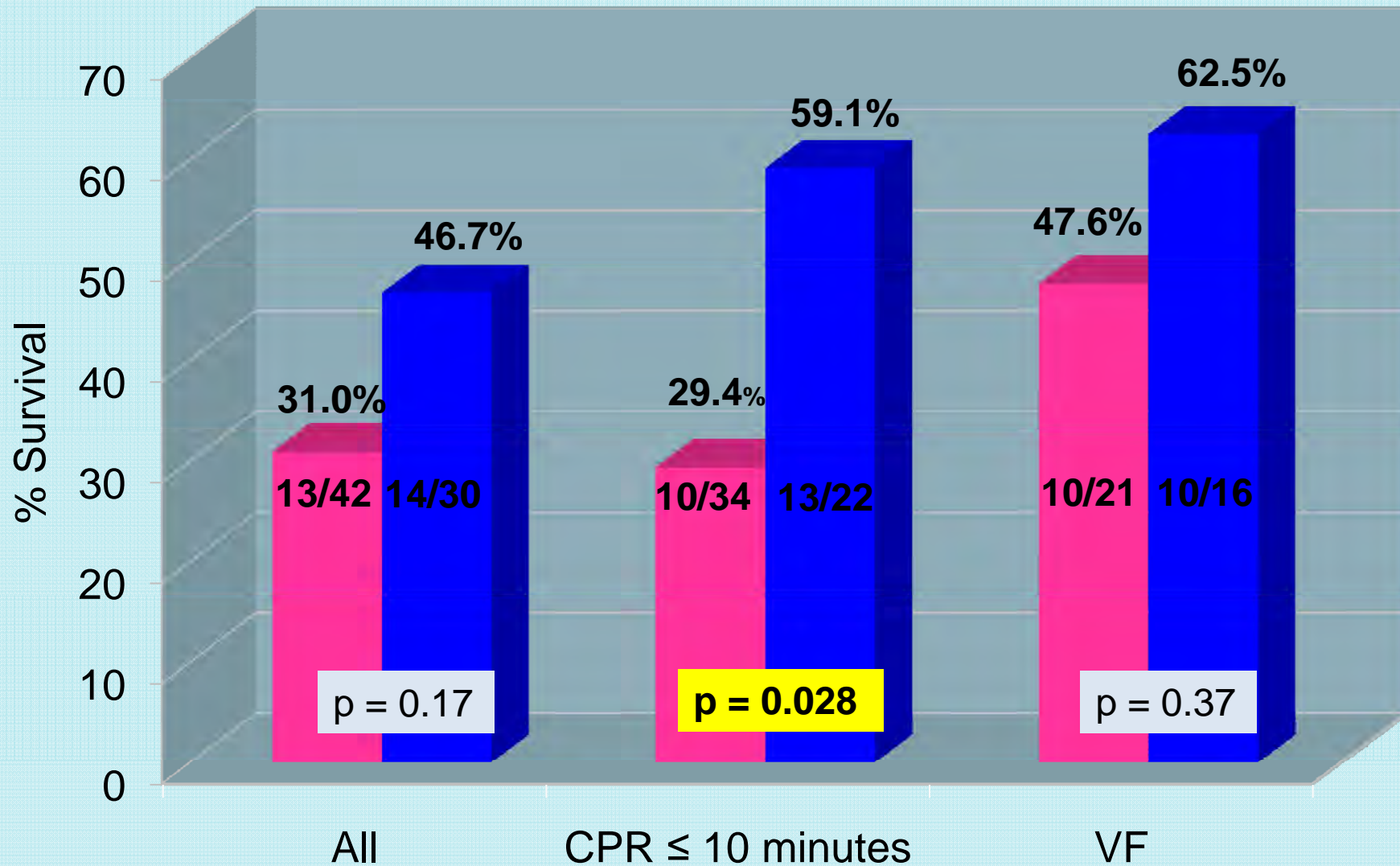
Kaplan-Meier survival for admitted patients



Survival to discharge

Admitted patients, chi-square

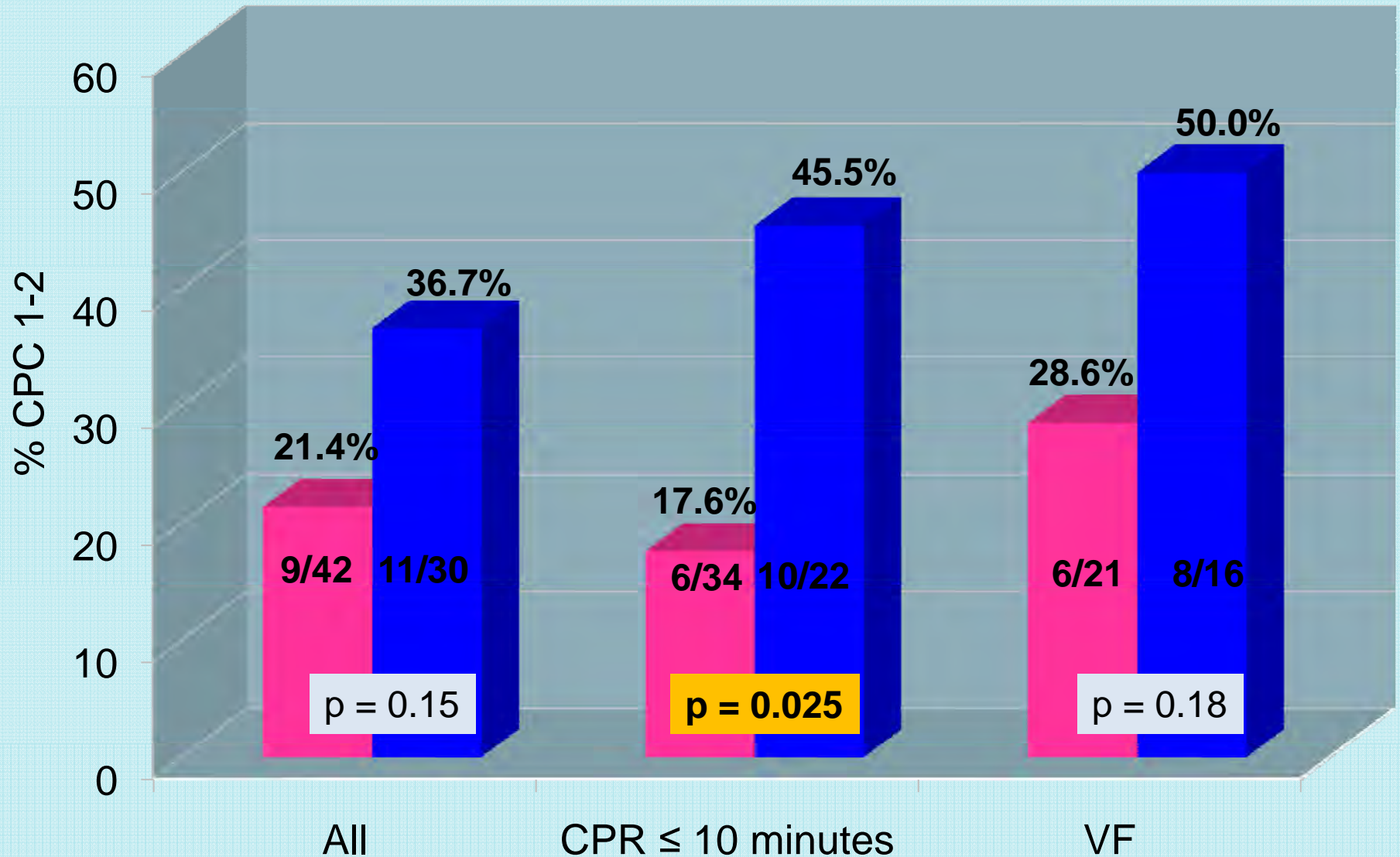
RhinoChill
No RhinoChill



Neurologically intact survival

Admitted patients, chi-square

RhinoChill
No RhinoChill



CONCLUSIONS

- First randomized *intra-arrest* cooling study
- Intranasal cooling with RhinoChill™ feasible and safe during arrest
- Target temp of 34°C reached several hours earlier with intranasal cooling
- Survival and neurologically intact survival to discharge significantly higher when CPR initiated ≤ 10 min.

LIMITATIONS

- No data on CPR quality
- Post-resuscitation protocol uncontrolled

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