COOL RCN

A Prospective, Randomized Trial Examining the Safety and Efficacy of Systemic Hypothermia for the Prevention of RadioContrast Nephropathy

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COOL RCN
Randomized Trial

Pts at risk for RCN (CrCl 20-50 mL/min)
Undergoing diagnostic and/or interventional cath with >50 cc dye
N = 400 pts at up to 35 sites

R

Hypothermia (33-34°C)
Pre contrast and 3 hrs post
+
Hydration (NaCl & $NaHCO_3$)

Control
Hydration (NaCl & $NaHCO_3$)

SCr measured at 24, 48 and 72-96 hrs* (core lab)

1º efficacy endpoint = RCN (SCr ↑>25% from baseline)

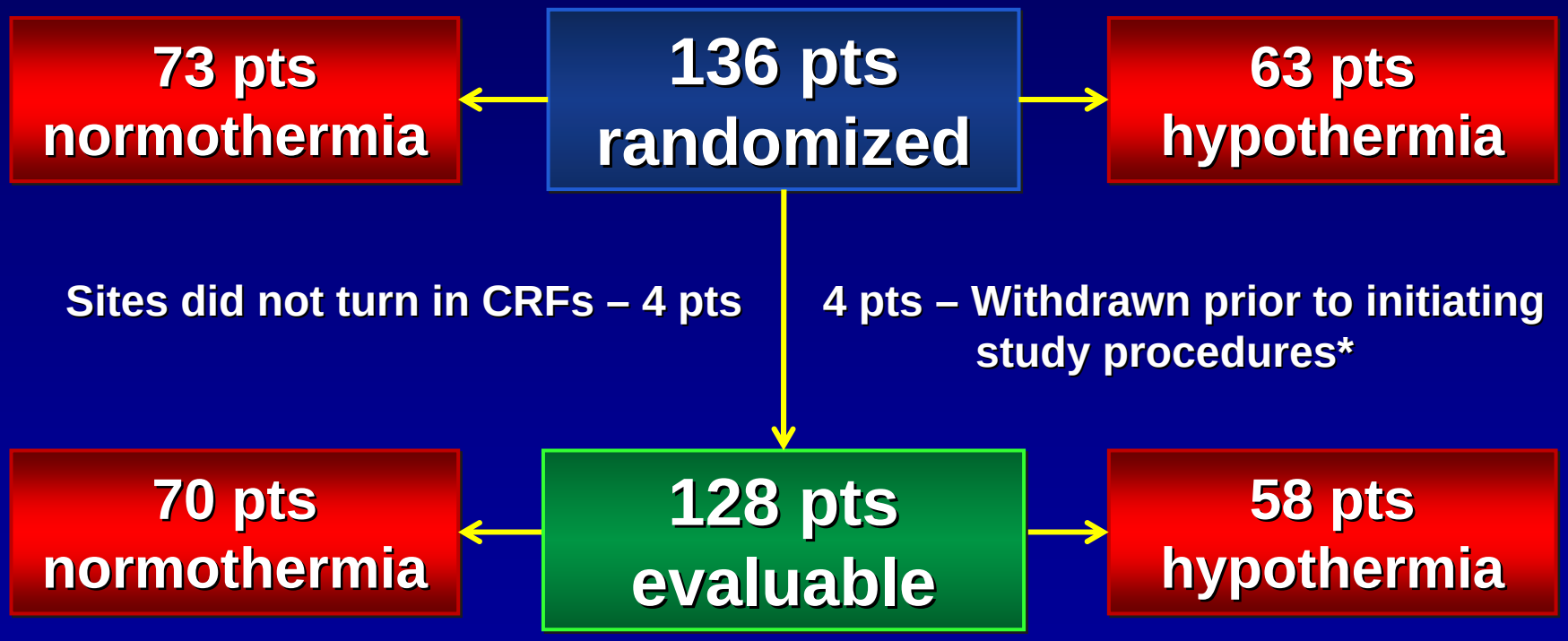
1º safety endpoint = 30d AE (death, MI, dialysis, VF, venous compl requiring surgery, bleed requiring ≥2U transf., rehosp.)

*Pts w/SCr ↑25% or ≥0.5 mg/dL at day 3 had an additional blood draw between day 7 – 10

136 pts randomized

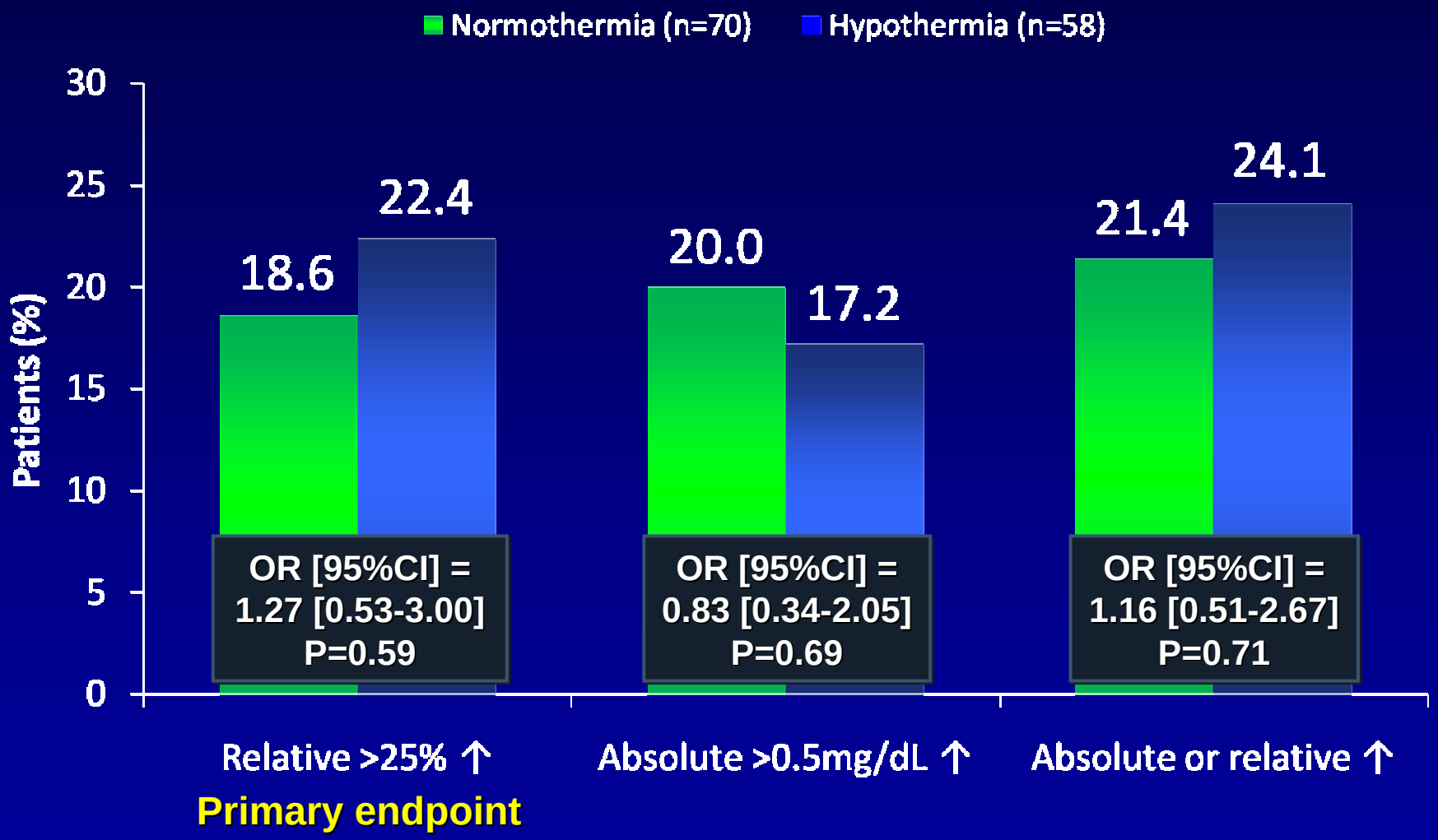
between March 2006 and August 2007

Study terminated early due to financial insolvency of Radiant; Radiant assets were purchased by ZOLL Circulation, who funded completion of the study



*Pul edema (1); IV diuretics (1); polycythemia (1); pt withdrew (1)

Development of RCN



Adverse Events at 30 Days

	Normothermia N=70	Hypothermia N=58	P value
Mortality, all cause	1.4%	5.2%	0.22
AMI	1.4%	3.4%	0.45
Dialysis	2.9%	0%	0.50
Ventricular fibrillation	0%	0%	1.0
Venous compl. surgery	0%	0%	1.0
Bleeding transf. $\geq$2U	12.9%	6.9%	0.26
Rehospitalization	18.6%	22.4%	0.59
Composite adverse events	37.1%	37.9%	0.93

Conclusions

- In pts at high risk for RCN undergoing invasive cardiology procedures hydrated with NS + $NaHCO_3$, systemic hypothermia using the Reprieve® system:
  - May be safely achieved and is well tolerated
  - Does not result in a significant reduction in RCN