Cleveland Clinic

Department of OUTCOMES RESEARCH

The PROTECT Trial

Aggressive Intraoperative Warming Versus Routine Thermal Management During Noncardiac Surgery

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Department of **O**UTCOMES **R**ESEARCH
(Cleveland Clinic) and 13 Chinese sites

Perioperative Hypothermia

Occurs in nearly all unwarmed surgical patients

Reported major complications (small trials, mostly old)

- Morbid cardiovascular outcomes
- Surgical site infections
- Bleeding & increased transfusion requirement

Other complications

- Decreased drug metabolism and prolonged recovery
- Thermal discomfort and shivering

Hypotheses, all tested at 30 days

Primary: aggressive warming to a core temperature near 37° C prevents a composite of myocardial injury, cardiac arrest, and death

Secondary: aggressive warming to 37° C

- Reduces deep or organ-space surgical site infections
- Decreases red cell transfusions
- Shortens hospitalization
- Decreases hospital re-admissions

Subject Selection

Inclusion

- Major elective noncardiac inpatient surgery
- General anesthesia expected to last >2 hours
- Age over 45 years
- At least one cardiac risk factor

Exclusion

- Body mass index exceeding 30 kg/m^2

Sample size: n=5,056 patients with 3 interim analyses

- 90% power for a 30% reduction in primary composite

Randomized Thermal Management

Routine thermal management: target 35.5° C

- No prewarming or fluid warming
- Forced-air cover, activated if core temp <35.5° C

Aggressive warming: target 37° C

- 30 minutes pre-warming with forced-air
- Warmed intravenous fluids
- Two intraoperative forced-air warming covers

Measurements

Intraoperative core temperature

- Esophagus or nasopharynx)

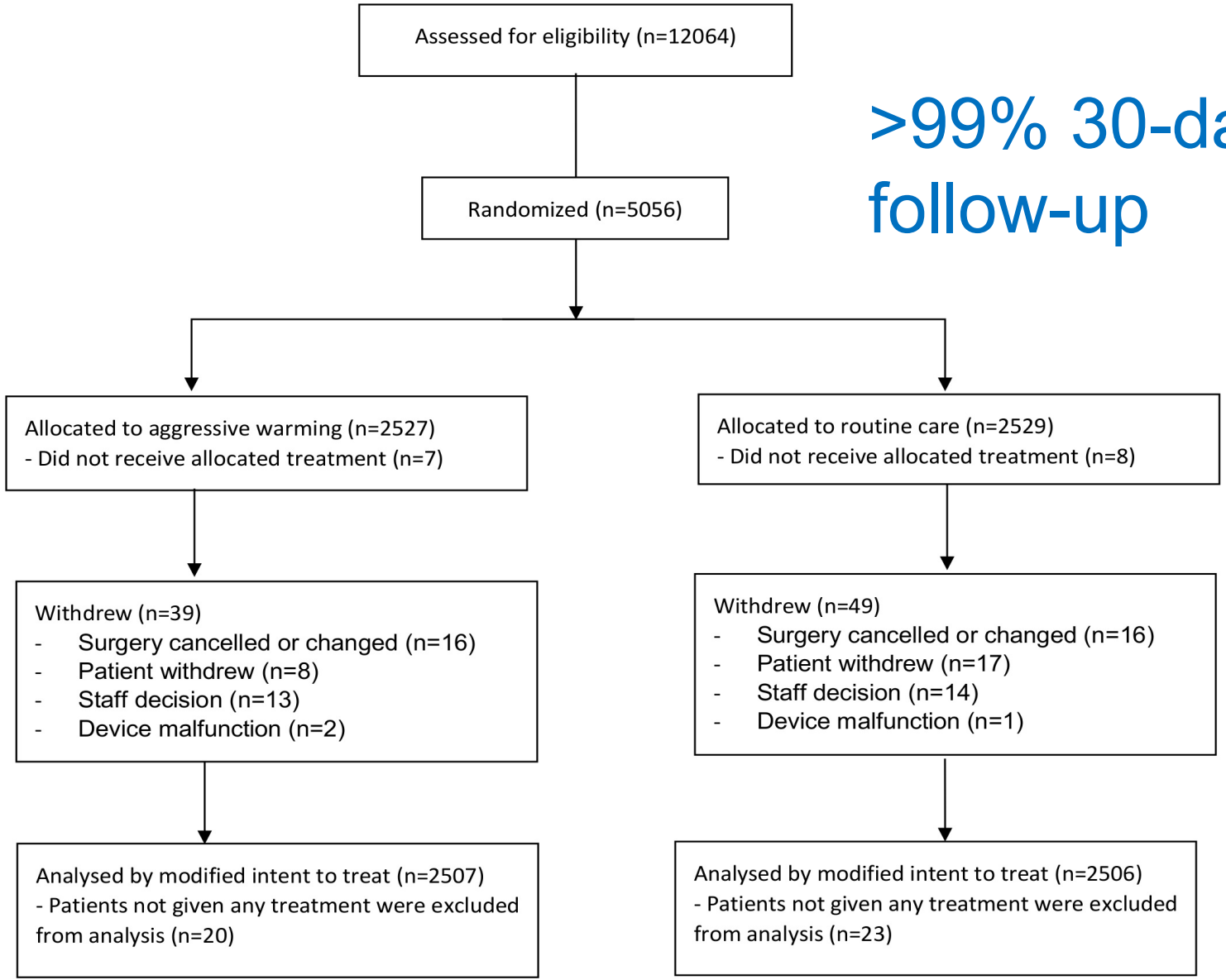
Troponin pre-operative and 1st & 2nd postop mornings

- Site-specific myocardial injury thresholds by generation and type

Deep or organ-space surgical site infections

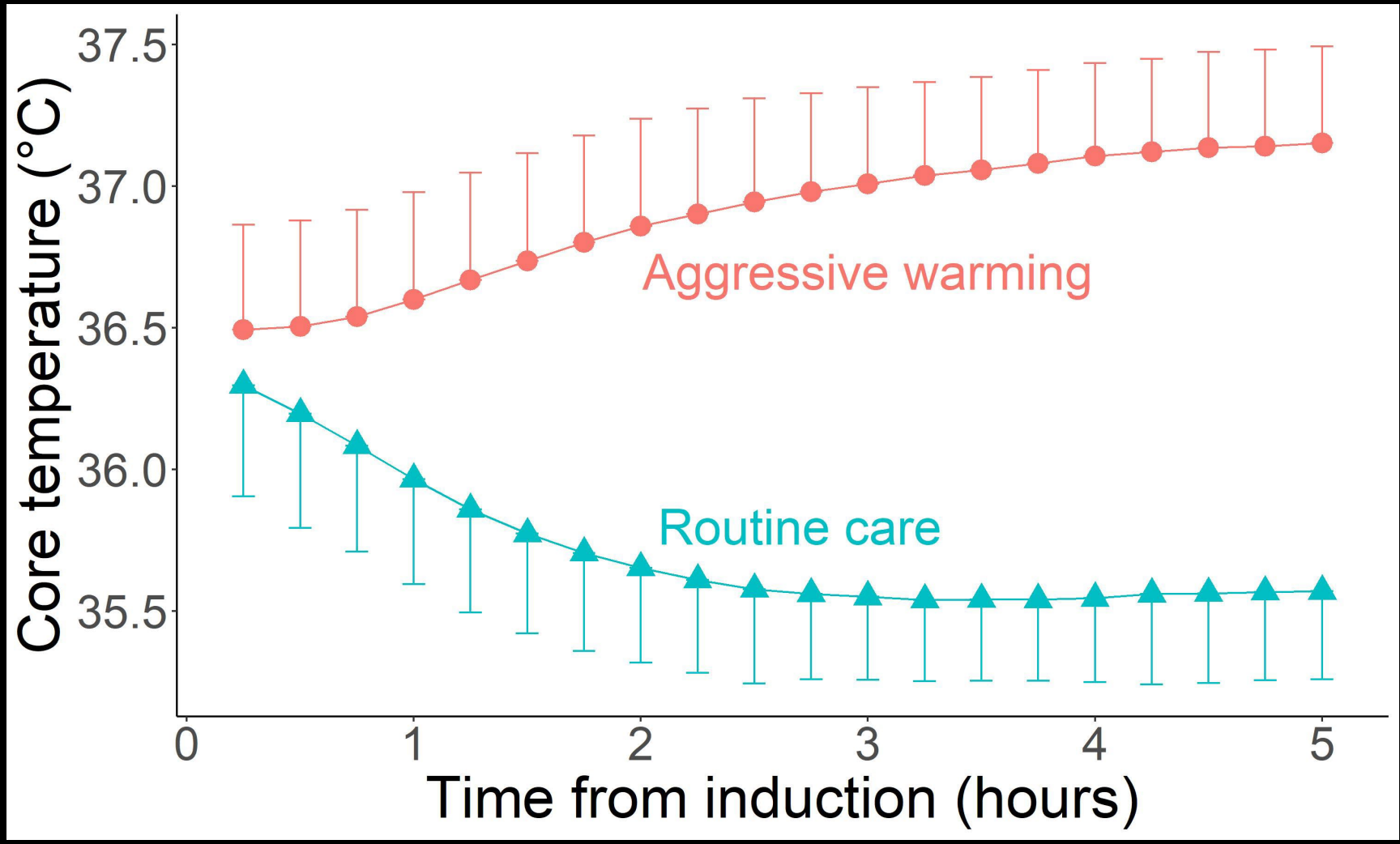
- CDC definitions

Transfused red cell volume

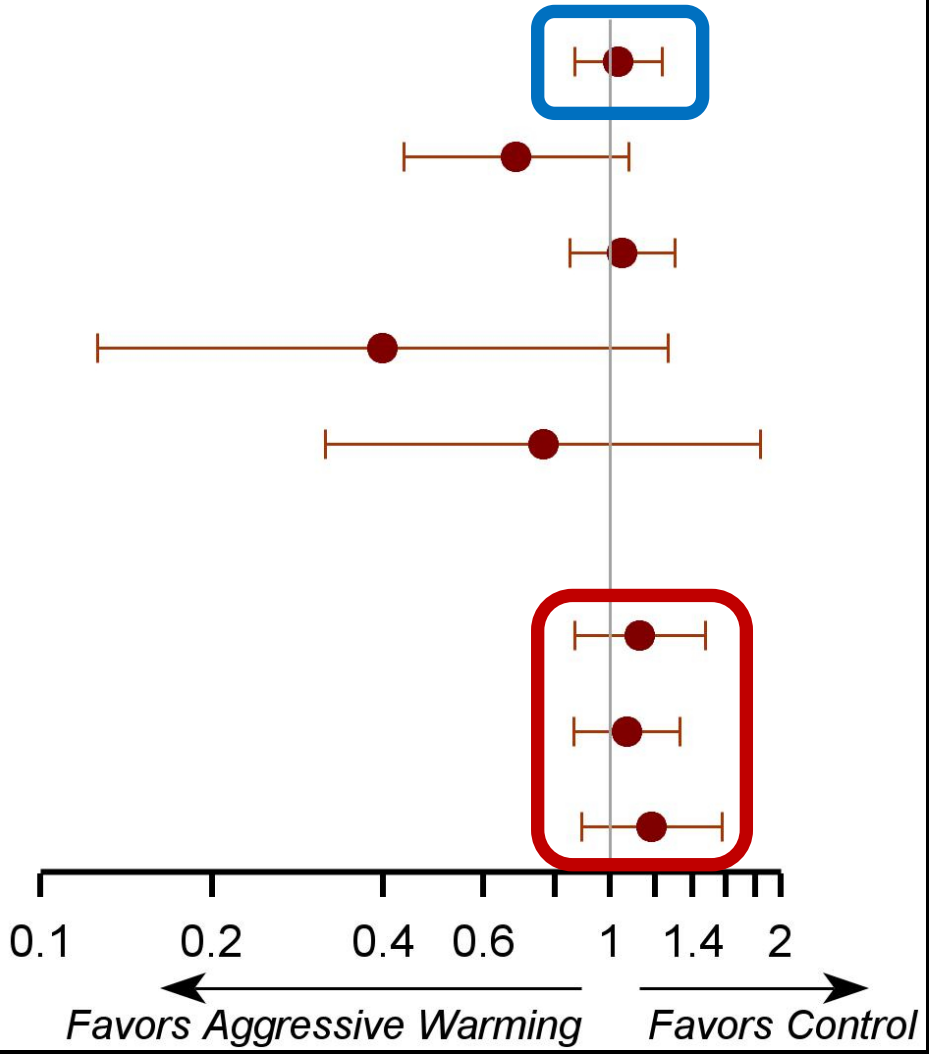


>99% 30-day follow-up

Excellent Thermal Management

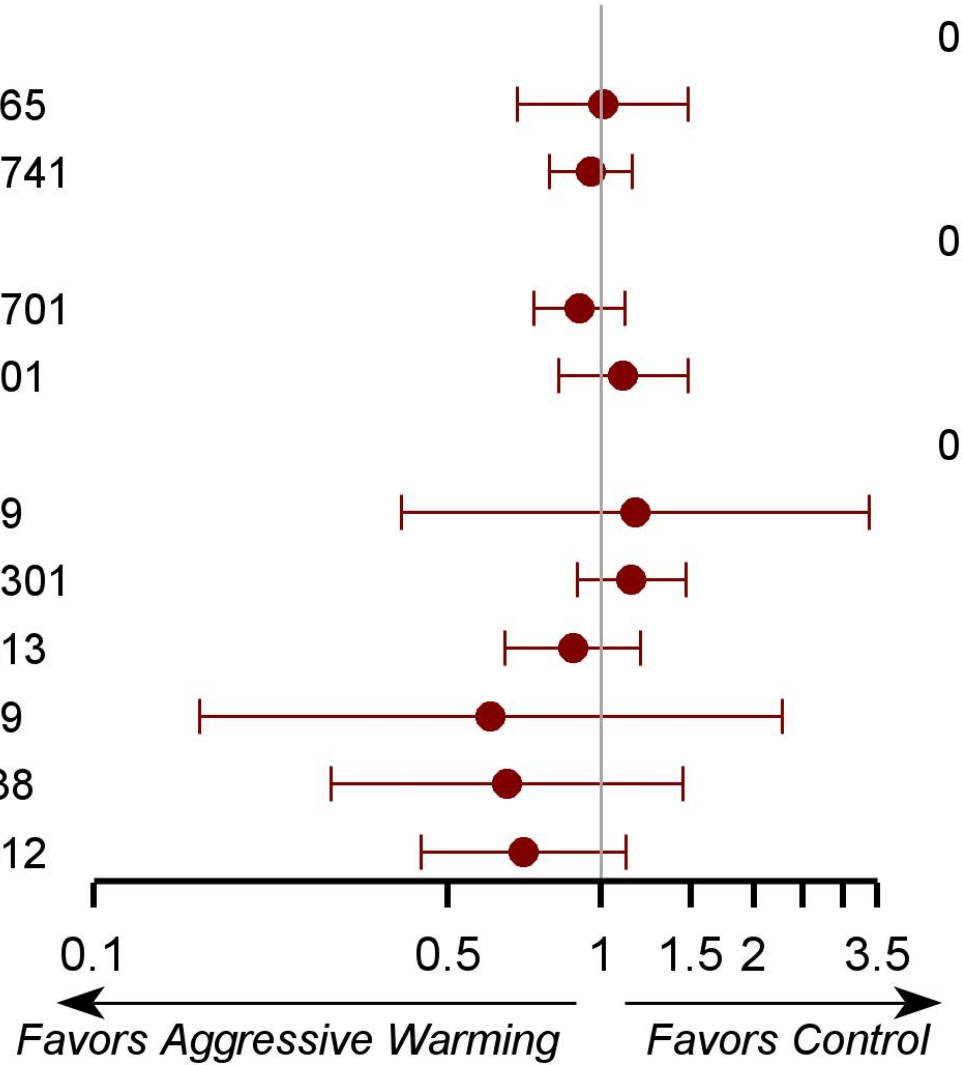


	Aggressive Warming (n/N)	Routine Care (n/N)
Primary outcomes		
Common effect	246/2497	239/2490
Average relative effect		
- MINS	233/2470	223/2468
- Non-fatal cardiac arrest	6/2493	15/2486
- Mortality	13/2489	17/2482
Secondary outcomes		
Surgical site infection	178/2487	157/2479
Transfusion requirement	254/2494	236/2486
Hospital readmission	161/2462	135/2447



Primary outcome

Subgroup	Aggressive Warming (n/N)	Routine Care (n/N)	P-value
Age			0.81
<65 years	48/753	51/765	
≥65 years	198/1754	188/1741	
Sex			0.29
Male	169/1668	156/1701	
Female	77/836	83/801	
Surgery type			0.37
Orthopedic	6/56	6/49	
Laparoscopic	110/1313	121/1301	
Open abdominal	75/610	71/613	
Neurosurgical	7/126	3/89	
Urologic	14/138	9/138	
Other	34/261	29/312	



Randomization to 37 v. 35.5° C Core Temp

Does not reduce cardiovascular composite

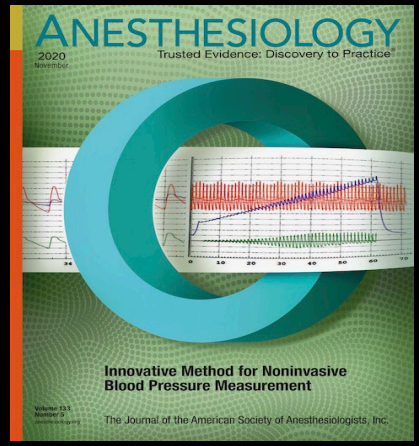
- Individually only powered for myocardial injury

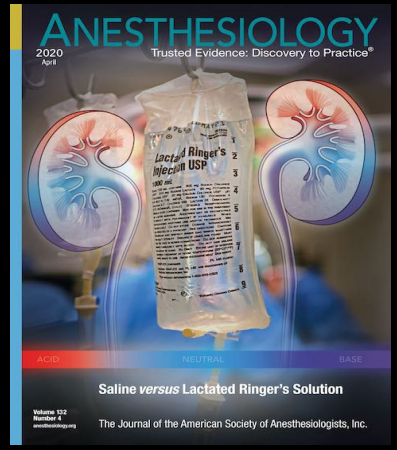
Does not reduce

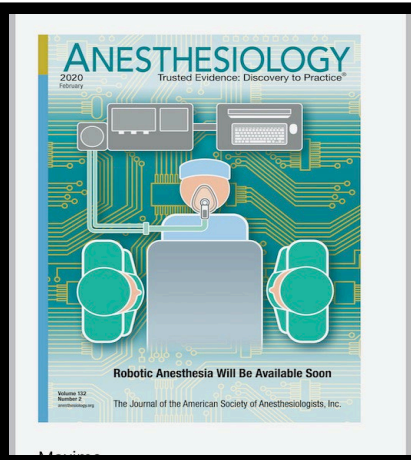
- Surgical site infections
- Transfusion requirement
- Duration of hospitalization or readmissions

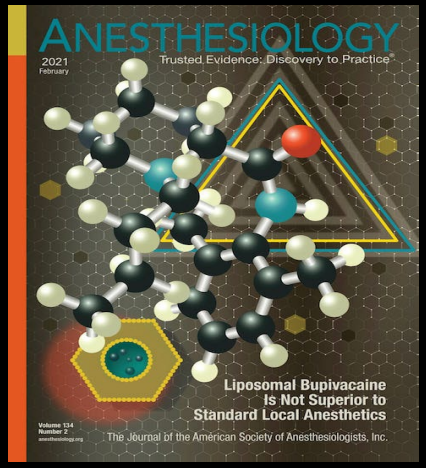
Intraop temps ≥35.5° C appear to be safe

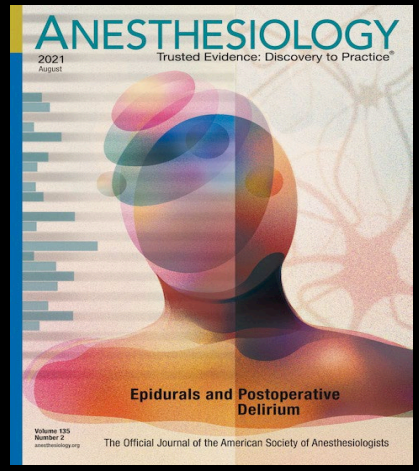
And that's all folks…

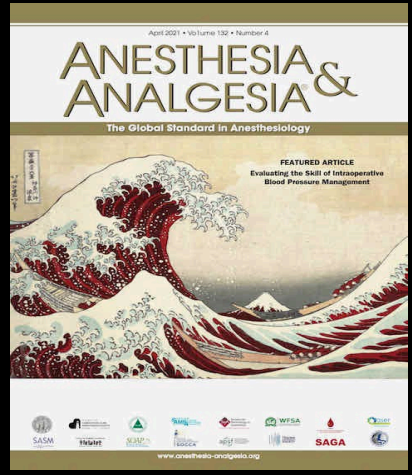


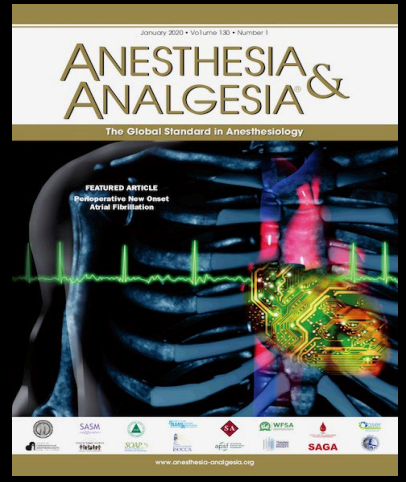


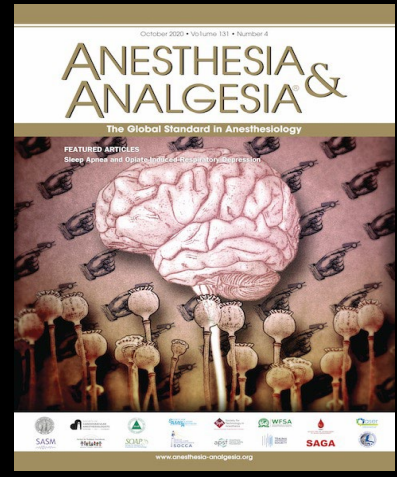












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