

TOR

32nd Anniversary

OUTCOMES RESEARCH Consortium

2022 Annual Report

- 32nd Anniversary -

About

The OUTCOMES RESEARCH Group was formed in 1990 at the University of California in San Francisco and subsequently became an institute when the group's administrative center moved to the University of Louisville in March of 2000. In 2005, OUTCOMES RESEARCH became a department at the Cleveland Clinic. After 17 years, the Department of OUTCOMES RESEARCH now includes 65 members at the Clinic, among about 200 academic investigators in twenty countries including the Austria, Canada, Ireland, Israel, Japan, China, and the United States. The Consortium is non-profit; its only goal is thus participation in high-quality research.

The Consortium has published more than 1,800 full papers and more than 95 editorials. The collaboration publishes a full paper every other day.

The Consortium is currently involved in about 150 clinical studies, including many large multi-center outcome trials. Funding for the Consortium's funding is from various peer-reviewed granting agencies, and we also collaborate with companies that make innovative devices and drugs, often conducting major trials that lead to regulatory certification. The Consortium facilitates scientific exchange and collaboration necessary for technically complex outcomes studies involving hundreds or thousands of patients. Additional information is available at www.OR.org.

Aspirations

OUTCOMES RESEARCH seeks to understand the end results of particular health care practices and interventions. End results include effects that people experience and care about, such as change in the ability to function. In particular, for individuals with chronic conditions—where cure is not always possible—end results include quality of life as well as mortality. By linking the care people get to the outcomes they experience, OUTCOMES RESEARCH has become the key to developing better ways to monitor and improve the quality of care.

The general goal of the OUTCOMES RESEARCH Consortium is to evaluate inexpensive, low-risk interventions that are easy to implement yet likely to markedly improve outcome. For example, we have shown that simply maintaining intraoperative normo-

thermia markedly reduces the risk of complications — and does so at trivial cost. A consequence of our work is that active intraoperative warming has become routine, whereas it was previously rare. Current focus areas include cardiovascular complications, postoperative delirium, and management of acute surgical pain.

Mission

Be the world's leading clinical anesthesia research organization.

Behaviors

- 1** Publish more high-impact, peer-reviewed clinical research papers (quantified as number times impact) than any other anesthesia organization.
- 2** Recruit more extra-mural clinical research funding than any other anesthesia organization, with “clinical research” being defined as research conducted with human subjects or their data.
- 3** Train clinical investigators at all levels.

Personnel

**Director**

Daniel I. Sessler MD, Cleveland

**Vice-director**

Alparslan Turan MD, Cleveland

2022 Site Directors

1	Donal Buggy	Dublin	Ireland
2	Peter Szumuk	Dallas	USA
3	Yuguang Huang, Dongxin Wang	Beijing	China
4	Thomas Volk	Homburg	Germany
5	Brian Ilfeld	San Diego	USA
6	PJ Devereaux	Hamilton	Canada
7	Barak Cohen	Tel Aviv	Israel
8	Ngai Liu	Paris	France
9	Ashish Khanna	Wake Forest	USA
10	Colin Royse	Melbourne	Australia
11	Bernd Saugel	Hamburg	Germany

Members

1	Alaa A. Abd-Elsayed, M.D.	Madison	USA
2	Basem B. Abdelmalak, M.D.	Cleveland	USA
3	Janet Adegbeye, M.D.	Baltimore	USA
4	Sanchit Ahuja, M.D.	Cleveland	USA
5	Wael Ali Sakr Esa, M.D.	Cleveland	USA
6	Federico Almonacid, MD	Cleveland	USA
7	Nikola Anusic, MD	Cleveland	USA
8	Jorge Andres Araujo Duran, M.D.	Cleveland	USA
9	Harendra Arora, M.D.	Chapel Hill	USA
10	Valentina Assenzo, M.D.	Suresnes, Paris	France
11	Sabry Ayad, M.D.	Cleveland	USA
12	Rovnat Babazade, M.D.	Galveston	USA
13	Gausan Bajracharya, M.D.	Cleveland	USA
14	Ömer Bakal, M.D.	San Antonio	USA
15	Karsten Bartels, MD, PhD, MBA	Omaha	USA
16	Allen Bashour, M.D.	Cleveland	USA
17	Sergio D. Bergese, M.D.	Stony Brook	USA
18	Frederic T. Billings IV, MD, MSc	Nashville	USA
19	Joshua A. Bloomstone, M.D., M.Sc	Phoenix	USA
20	Hagen Bomberg, M.D.	Zurich	Switzerland
21	Mauro Bravo, M.D.	Cleveland	USA
22	Jack Brooker, MD	Cleveland	USA
23	Donal J. Buggy, M.D., FRCPI, FRCACSI, FRCA	Dublin	Ireland
24	Juan Cata, M.D.	Houston	USA
25	Busra Tok Cekmecelioglu, M.D.	Cleveland	USA
26	Praveen Chahar, M.D., F.C.A.R.C.S.I.	Cleveland	USA
27	Athanasiros F. Chalkias, MD, MSc, PhD, FESC, FAcadTM, FCP, FESAIC	Larisa	Greece
28	Surendrasingh S. Chhabada, M.D.	Cleveland	USA
29	Anne Cipriani	Cleveland	USA
30	Sean E.S.. Coeckelenbergh, MD	Villejuif	France
31	Barak Cohen, M.D.	Tel Aviv	Israel
32	Allen Collins	Cleveland	USA
33	Maria J. Corrales-Martinez, MD	Cleveland	USA
34	Jacek B. Cywinski, M.D.	Cleveland	USA
35	Albert Dahan, MD	Leiden	Netherlands
36	Jagan Devarajan, MD	Cleveland	USA

37	Philip J. Devereaux, M.D., Ph.D.	Hamilton	Canada
38	Aimee Drury	Cleveland	USA
39	Lei Du, M.D.	Chengdu	China
40	Emmanuelle Duceppe, MD., Ph.D.	Montreal	Canada
41	Andra E. Duncan, M.D.	Cleveland	USA
42	Ruthy Edry, M.D.	Haifa	Israel
43	Proshad N. Efune, M.D.	Dallas	USA
44	Michael Eichinger, MD	Graz	Austria
45	Michael Eichlseder, MD	Graz	Austria
46	Elyad Ekrami, MD	Cleveland	USA
47	Hesham Elsharkawy, M.D.	Cleveland	USA
48	Okan Ermis, M.D.	Cleveland	USA
49	Hani Essber, M.D.	Graz	Austria
50	Stephanie Ezeoke, BS	Cleveland	USA
51	Ehab S.A. Farag, M.D., F.R.C.A.	Cleveland	USA
52	Tobias Fink, M.D.	Homburg	Germany
53	John J. Finneran IV, M.D.	San Diego	USA
54	Edith Fleischmann, M.D.	Vienna	Austria
55	Daniel Freidorfer, MD	Graz	Austria
56	Béla Fülesdi, M.D., Ph.D.	Debrecen	Hungary
57	Marcelo Gama de Abreu, M.D., M.Sc., Ph.D., D.E.S.A	Cleveland	USA
58	Richard Gatt, BS	Cleveland	USA
59	Martin V. Grady, M.D.	Mayfield Heights	USA
60	Alper Gulluoglu, MD	Cleveland	USA
61	Hassan Hamadnalla, M.D.	Detroit	USA
62	Yanyan Han, MS	Cleveland	USA
63	Manal Hassan, M.D.	Mayfield Heights	USA
64	Johan Heiberg, MD, PhD, DMedSc, DESAIC	Copenhagen E	Denmark
65	Richard Hofstra, B.S.	Cleveland	USA
66	Yuguang Huang, M.D.	Beijing	China
67	Lisa Humbert, RN	Cleveland	USA
68	Tobias Hüppé, M.D., Ph.D., D.E.S.A., E.D.I.C.	Homburg (Saar)	Germany
69	Takehiko Ikeda, M.D.		Japan
70	Brian M. Ilfeld, M.D., M.S.	San Diego	USA
71	Ilker Ince, MD	Erzurum	Turkey
72	Steven R. Insler, D.O.	Cleveland	USA
73	Daniela C. Ionescu, Ph.D., D.E.A.A.	Cluj-Napoca	Romania
74	Jens-Ulrik S. Jensen, M.D., Ph.D.	Copenhagen	Denmark
75	Yuan Jia, MD	Beijing	China

76	Qiliang Jiang, M.D., Ph.D.	Shanghai	China
77	Roberta Johnson	Cleveland	USA
78	Barbara Kabon, M.D.	Vienna	Austria
79	Deeven Karki, MD	Cleveland	USA
80	Tyler Karras, DO	Cleveland	USA
81	Roop Kaw, M.D.	Cleveland	USA
82	Marta Kevala, MD	Cleveland	USA
83	Ashish K. Khanna, M.D., F.C.C.P., F.C.C.M.	Wake Forest	USA
84	Sandeep Khanna, M.D.	Cleveland	USA
85	Daniel Kim, M.D.	Houston	USA
86	Oliver Kimberger, M.D.	Vienna	Austria
87	Ryu Komatsu, M.D.	Cleveland	USA
88	Orkun Kopac, MD	Cleveland	USA
89	Sascha Kreuer, M.D.	Homburg	Germany
90	Christine Kubulus, MD	Homburg/Saar	Germany
91	Priya A. Kumar, M.D.	Chapel Hill	USA
92	Andrea M. Kurz, M.D.	Cleveland	USA
93	Esra Kutlu Yalcin, M.D.	Cleveland	USA
94	Giovanni Landoni, M.D.	Milan	Italy
95	Valentina Lara-Erazo, MD	Cleveland	USA
96	Kai Li, M.D., Ph.D.	Changchun	China
97	Shuyi Li, M.S.	Cleveland	USA
98	Xu Li, M.D.	Beijing	China
99	Qian Li, M.D.	Chengdu	China
100	Jing Lin, M.D.	Chengdu	China
101	Ke-Xuan Liu, MD, PhD	Guangzhou	China
102	Liu Liu, M.A.	Cleveland	USA
103	Ngai Liu, M.D., Ph.D.	Suresnes	France
104	Xiaodan Liu, MS	Cleveland	USA
105	Vladimir V. Lomivorotov, M.D., Ph.D.	Novosibirsk	Russia
106	Anthony T. Machi, M.D.	Dallas	USA
107	Kamal Maheshwari, M.D., M.P.H.	Cleveland	USA
108	Guangmei Mao, M.S.	Cleveland	USA
109	Maura Marcucci, MD, MSc	Hamilton	Canada
110	Metty Markwei, B.S.	Palo Alto	USA
111	Leonardo Marquez Roa, MD	Cleveland	USA
112	Edward J. Mascha, Ph.D.	Cleveland	USA
113	Takashi Matsukawa, M.D.	Chuo	Japan
114	Felix Maurer, B.S.	Homburg	Germany

115	Mark Mettler	Cleveland	USA
116	Scott A. Miller, M.D.	Winston Salem	USA
117	Steven C. Minear, MD	Weston	USA
118	Mateo Montalvo, M.D.	Stratford	USA
119	Eassen Mu, M.D.	Beijing	China
120	Rupashi Mukhia, MD	Cleveland	USA
121	Carolin Müller, M.D.	Homburg	Germany
122	Lukas M. Müller-Wirtz, M.D.	Homburg	Germany
123	Yasufumi Nakajima, M.D., Ph.D.	Sayama-City	Japan
124	Rod Nault, M.S.	Cleveland	USA
125	Ben O'Brien, M.D., Ph.D., M.H.B.A., F.R.C.A.	Berlin	Germany
126	Beth O'Brien, B.S.	Cleveland	USA
127	Detlef E.R. Obal, M.D., Ph.D., D.E.S.A.	Palo Alto	USA
128	Sandra N. Ofori, MBBS, FWACP, MSc	Hamilton	Canada
129	Ibrahim Onal, M.D.	Konya	Turkey
130	Makoto Ozaki, M.D., Ph.D.	Tokyo	Japan
131	Matt A. Pappas, M.D., M.P.H.	Cleveland	USA
132	Marie-Odile Parat, Pharm.D., Ph.D.	Woolloongabba	Australia
133	Lijian Pei, M.D.	Beijing	China
134	Yuming Peng, PhD, MD	Beijing	China
135	Silvia E. Perez-Protto, M.D., M.S.	Cleveland	USA
136	Alexander Pichler, MD	Graz	Austria
137	Olga M. Plattner, M.D.	Vienna	Austria
138	Attila Podolyak, M.D.	Cleveland	USA
139	Xuan Pu, M.S.	Cleveland	USA
140	Yuwei Qiu, M.D.	Shanghai	China
141	Shobana Rajan, M.D.	Houston	USA
142	Christian Reiterer, MD	Vienna	Austria
143	David A. Rincón-Valenzuela, M.D., M.Sc.	Bogotá	Colombia
144	Joseph B. Rinehart, MD	Orange	USA
145	Eva Rivas Ferreira, M.D.	Barcelona	Spain
146	Efrain Riveros-Perez, M.D.	Augusta	USA
147	Fabio A. Rodriguez-Patarroyo, M.D.	Cleveland	USA
148	Carolina S. Romero Garcia, MD, PhD, MStat	Valencia	Spain
149	Pavel Roshanov, MD, MSc	London	Canada
150	Julian V. Rössler, M.D.	Cleveland	USA
151	Colin Royse, M.D.	Melbourne	Australia
152	Kurt Ruetzler, M.D., Ph.D., F.A.H.A.	Cleveland	USA
153	Remie Saab, M.D.	Cleveland	USA

154	Leif Saager, M.D.	Goettinghen	Germany
155	Wael Saasouh, M.D.	Detroit	USA
156	Ethan L. Sanford, M.D.	Dallas	USA
157	Bernd Saugel, M.D.	Hamburg	Germany
158	Rita Saynalath, M.D.	Dallas	USA
159	Yehoshua-Nadav Schacham, M.D.	Ramat-Gan	Israel
160	Eitan Scher Nemirovsky, MD	Flint	USA
161	Marc Schmidt, M.D.	Zurich	Switzerland
162	Gokhan Sertcakacilar, MD	Istanbul	Turkey
163	Daniel I. Sessler, M.D.	Cleveland	USA
164	Karan Shaw, M.S.	Cleveland	USA
165	Tetsuya Shimada, M.D.	Tokyo	Japan
166	Maeve Silfe	Cleveland	USA
167	Sumi Singh, MD	Cleveland	USA
168	Alexis Skolaris	Cleveland	USA
169	Nathaniel Smilowitz, MD, MS, FACC, FSCAI	NYC	USA
170	Jeff W. Steiner, D.O.	Dallas	USA
171	Wojciech Szczeklik, M.D., Ph.D.	Krakow	Poland
172	Peter Szmuk, M.D.	Dallas	USA
173	Yasin Tire, MD		Turkey
174	David Torres, M.D.	Santiago	Chile
175	Alparslan Turan, M.D.	Cleveland	USA
176	Tamás Végh, M.D., Ph.D.	Debrecen	Hungary
177	Andrew Volio, D.O.	Cleveland	USA
178	Thomas Volk, M.D.	Homburg	Germany
179	Anupama Wadhwa, M.D.	Houston	USA
180	Ross Waite	Cleveland	USA
181	Michael Walters	Cleveland	USA
182	Catherine I. Wang, M.D.	Beijing	China
183	Dong Wang, M.S.	Cleveland	USA
184	Dong-Xin Wang, M.D., Ph.D.	Beijing	China
185	Jiayi Wang, MD	Shanghai	China
186	Peiyan Wang, MS	Cleveland	USA
187	Yu Wang	Cleveland	USA
188	David West, MD	Graz	Austria
189	Marita Windpassinger, MD	Vienna	Austria
190	Kiran Winemiller, BS	Cleveland	USA
191	Jason Wu, M.D.	Shanghai	China
192	Ece Yamak Altinpulluk, M.D.	Istanbul	Turkey

193	Dongsheng Yang, M.S.	Cleveland	USA
194	Jean-Pierre Yared, M.D.	Cleveland	USA
195	Oguz Yilmaz, M.D.	Izmir	Turkey
196	Hai Yu, M.D.	Chengdu	China
197	Alexander Zarbock, MD	Muenster	Germany
198	Kan Zhang, M.D.	Cleveland	USA
199	Xiaobao Zhang, M.D.	Lianyungang	China
200	Bing-Cheng Zhao, MD	Guangzhou	China
201	Maedeh Zokaei Nikoo, MD	Cleveland	USA



Consortium dinner in New Orleans

Research Fellows



Name	Origin	Dates	Subsequent Position
1 Omar Bakal, M.D.	Turkey	2019-22	University of Texas, San Antonio
2 Fabio Rodriguez Patarroyo, M.D.	Colombia	2019-	
3 Esra Kutlu Yalcin, M.D.	Turkey	2019-22	Anesthesia residency, Cleveland Clinic
4 Tyler Karras, M.D.	USA	2021-22	Anesthesia residency, Alleghany Health
5 Mateo Montalvo, M.D.	Ecuador	2020-22	Resident, Int Med, Yale Bridgeport Hospital
6 Jorge Araujo Duran, M.D.	Colombia	2020-	
7 Elyad Ekrami, M.D.	Iran	2020-	
8 Federico A. Cardenas, M.D.	Colombia	2020-	
9 Eitan Scher, M.D.	Venezuela	2021-22	Anesthesia residency, McLaren Flint
10 Jack Booker, M.D.	Scotland	2021-	
11 Orkun Kopac, M.D.	Turkey	2021-	
12 Gokhan Sertcakacilar, M.D.	Turkey	2021--22	
13 Yasin Tire, M.D.	Turkey	2021-22	
14 Julian V. Rössler, M.D.	Switzerland	2022-	
15 Busra Tok Cekmecelioglu, M.D.	Turkey	2022-	
16 Nikola Anusic, M.D.	Montenegro	2022-	
17 Rupashi Mukhia, M.D.	Nepal	2022-	
18 Valentina Lara-Erazo, M.D.	Colombia	2022-	

Name	Origin	Dates	Subsequent Position
19 Deeven Karki, M.D.	Nepal	2022-	
20 Sumi Singh, M.D.	Nepal	2022-	
21 Maedeh Zokaei Nikoo, M.D.	Iran	2022-	
22 Lu Wang, M.D.	China	2022-	
23 Maria J. Corrales-Martinez, M.D.	Colombia	2022-	
24 Alper Gulluoglu, M.D	Turkey	2022-	
25 Leonardo Marquez Roa, M.D.	Venezuela	2022-	



Fellows at the ASA

Graduate and Medical Students (full year)

Name	Origin	Dates	Subsequent Position
1 Stephanie Ezeoke, B.S	USA	2021-22	Coordinator, CCF Digestive Disease Institute
2 Kiran Winemiller, B.S.	USA	2021-22	Case Western Dental School
3 Anne Cipraini, B.S.	USA	2021-22	Case Western Medical School
4 Nicole Brown, B.S.	USA	2021-22	
5 Maeve Slife, B.S.	USA	2022-23	University of Cincinnati Medical School
6 Richard Gatt, B.S.	USA	2022-	

Name	Origin	Dates	Subsequent Position
7 Richard Hofstra, B.S.	USA	2022-	
8 Michael Mosqueda, B.S.	USA	2022-	
9 Emily Abramczyk, B.S.	USA	2022-	
10 Michael Ryan, B.S.	USA	2022-	

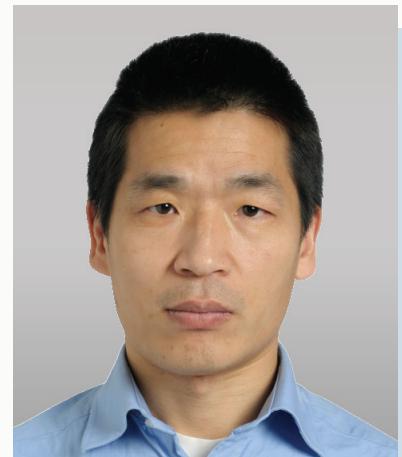
Statistical Team



Director of Biostatistics
Edward Mascha, PhD 2005-



Team Leader/Manager
Lu Wang, MS 2023-



Lead Programmer
Dongsheng Yang, MS 2008-

Name	Dates	Role
1 Edward J. Mascha, PhD	2005-	Staff Biostatistician, Director of Biostatistics
2 Dongsheng Yang, MS	2008-	Statistical Programmer V, Lead Programmer
3 Allen Collins, AA	2012-	Systems Analyst III, Database Developer
4 Liu Liu, MS	2016-	Statistical Programmer III
5 Xuan Pu, MS	2019-	Senior Biostatistician
6 Karan Shah, MS	2020-	Biostatistician
7 Yanyan Han, MS	2020-	Statistical Programmer II
8 Dong Wang, PhD, MS	2021-	Biostatistician
9 Junhui Mi, MS	2021-	Biostatistician
10 Yufei Li, MS	2022-	Biostatistician
11 Shuyi Li, MS	2022-	Statistical Programmer I
12 Xiaodan Liu, MS	2022-	Statistical Programmer I
13 Lu Wang, MS	2023-	Senior Biostatistician, Team Leader/Manager



Statistical Team

Honors and Awards

Name	Honor	Organization
1 Bernd Saugel	Editor	British Journal of Anaesthesia
2 Alparslan Turan	Editor-in-chief	Journal of Clinical Anesthesia
3 Alparslan Turan	Caregiver Award	Cleveland Clinic
4 Xuan Pu	Caregiver Award	Cleveland Clinic
5 Dept. Statistical Team	Caregiver Award	Cleveland Clinic
6 Ashish Khanna	Master of Science in Translational & Health Systems	Wake Forest
7 Jack Brooker	1st & 2nd place abstract awards	Ohio Society of Anesthesia
8 Yasufumi Nakajima	Professor & Chair	Kindai University Faculty of Medicine
9 Brian Ilfeld	Labat Award	American Society of Regional Anesthesia & Pain
10 Thanos Chalkias	Fellow	European Society of Anaesthesiology & Intensive Care
11 Donal Buggy	Doctor of Science	Mater Misericordiae University Hospital
12 Basem Abdelmalak	Board of Directors	American Society of Anesthesiologists
13 Basem Abdelmalak	Board of Directors	Society for Airway Management

Consortium Research Awards

The Gladys Sessler Prize is an endowed award that is given yearly. All members of the OUTCOMES RESEARCH Consortium are eligible. This year's award was to **Bernd Saugel**.



The Best Fellow Award is given to the Department of OUTCOMES RESEARCH fellow who is voted by the faculty to have performed at the very highest level. This year's award was given to **Esra Kutlu Yalcin**.

The Consortium Symposium Keynote Talk honors someone from outside the Consortium (and often outside anesthesia and medicine) who presents interesting material to attendees at our session at the Annual Meeting of the American Society of Anesthesiologists. This year's presentation was **Dr. Ruth Bernstein** (Dan Sessler's sister). Dr. Bernstein is an endowed Associate Professor of Nonprofit Management at Pepperdine University teaching nonprofit management classes and the Service Leadership capstone course. Her publication and research interests focus on diversity, equity and inclusion in leadership and governance, with an emphasis on nonprofit organizations. Her publications have appeared in numerous nonprofit and management journals and she has published two recent books. The first, Performance through Diversity and Inclusion: Leveraging Organizational Practices for Equity and Results (Routledge) with Paul Salipante and Judith Weisinger and the second, Diversity and Inclusion in Nonprofit Governance—No More Excuses! (Sagamore-Venture) with Chris Fredette.



Publications

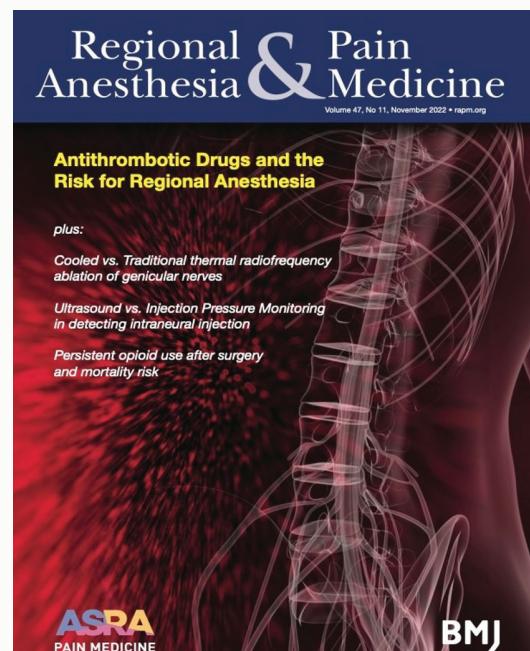
Contribution to the World's Literature

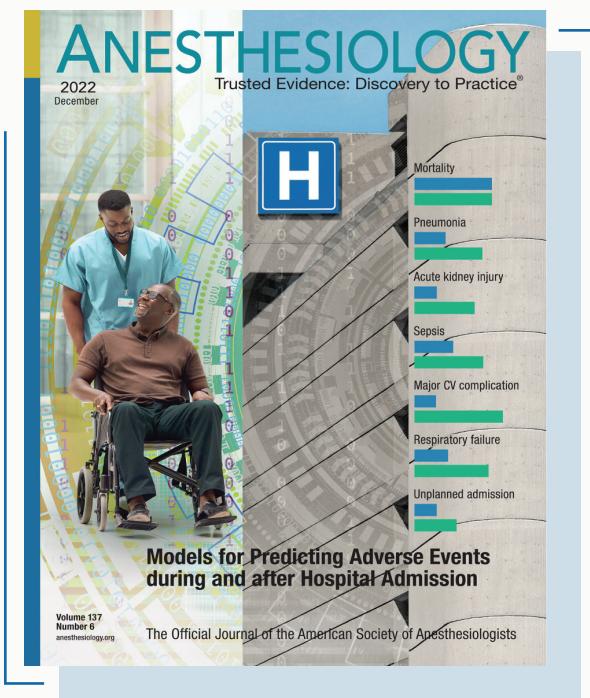
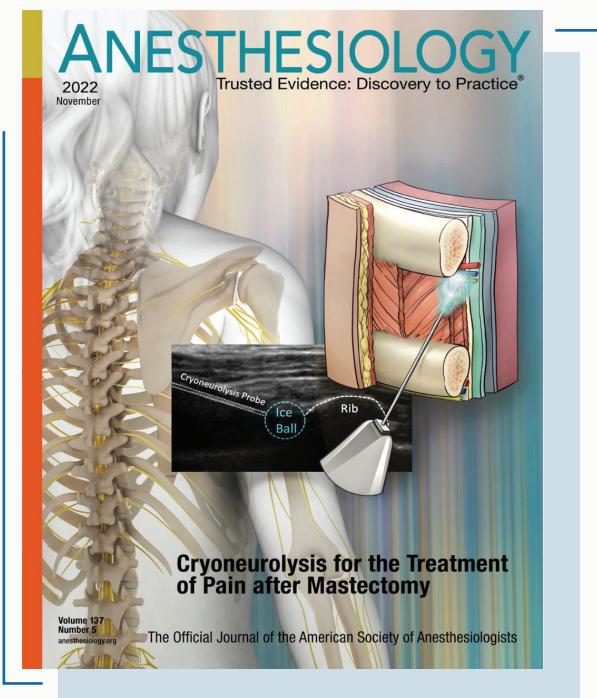
An article by Pagel and Hudetz (BMC Anesthesiology 12:5, 2012) evaluated anesthesia publication trends. In 2010, the last year they report, there were 1277 clinical research articles published in the most influential anesthesia journals, including: ***Anesthesiology, the British Journal of Anaesthesia, Anesthesia & Analgesia, Anaesthesia, European Journal of Anaesthesia, Canadian Journal of Anesthesia, Journal of Cardiothoracic and Vascular Anesthesia, Journal of Clinical Anesthesia, and Acta Anaesthesiologica Scandinavia***. Last year, the Consortium published more than 60 papers in the 14 journals they considered. The OUTCOME RESEARCH Consortium thus publishes more than 5% of the clinical research in high-profile general anesthesia journals. Of note, the Consortium also publishes nearly as many papers in specialty journals ranging from pain to critical care to neuroscience, and in major multi-specialty journals. **Overall, the Consortium publishes a full paper every other day.**

Since inception, the Consortium has published more than **1,800** full papers and more than **95** editorials.

Links to PDF versions of most full papers: <http://www.or.org/bibliography/>

Consortium Articles Featured on Journal Covers This Year





This Year's Featured Paper

Featured Paper #1

Devereaux PJ, Marcucci M, Painter TW, Conen D, Lomivorotov V, Sessler DI, Chan MTV, Borges FK, Martinez-Zapata MJ, Wang CY, Xavier D, Ofori SN, Wang MK, Efremov S, Landoni G, Kleinlugtenbelt YV, Szczeklik W, Schmartz D, Garg AX, Short TG, Wittmann M, Meyhoff CS, Amir M, Torres D, Patel A, Duceppe E, Ruetzler K, Parlow JL, Tandon V, Fleischmann E, Polanczyk CA, Lamy A, Astrakov SV, Rao M, Wu WKK, Bhatt K, de Nadal M, Likhvantsev VV, Paniagua P, Aguado HJ, Whitlock RP, McGillion MH, Prystajecy M, Vincent J, Eikelboom J, Copland I, Balasubramanian K, Turan A, Bangdiwala SI, Stillo D, Gross PL, Cafaro T, Alfonsi P, Roshanov PS, Belley-Cote EP, Spence J, Richards T, VanHelder T, McIntyre W, Guyatt G, Yusuf S, Leslie K, Poise-3 Investigators: Tranexamic Acid in Patients Undergoing Noncardiac Surgery. *N Engl J Med* 2022; 386: 1986-97 [Accompanied by an editorial 386:2052-2053, 2022]

BACKGROUND

Perioperative bleeding is common in patients undergoing noncardiac surgery. Tranexamic acid is an antifibrinolytic drug that may safely decrease such bleeding.

METHODS

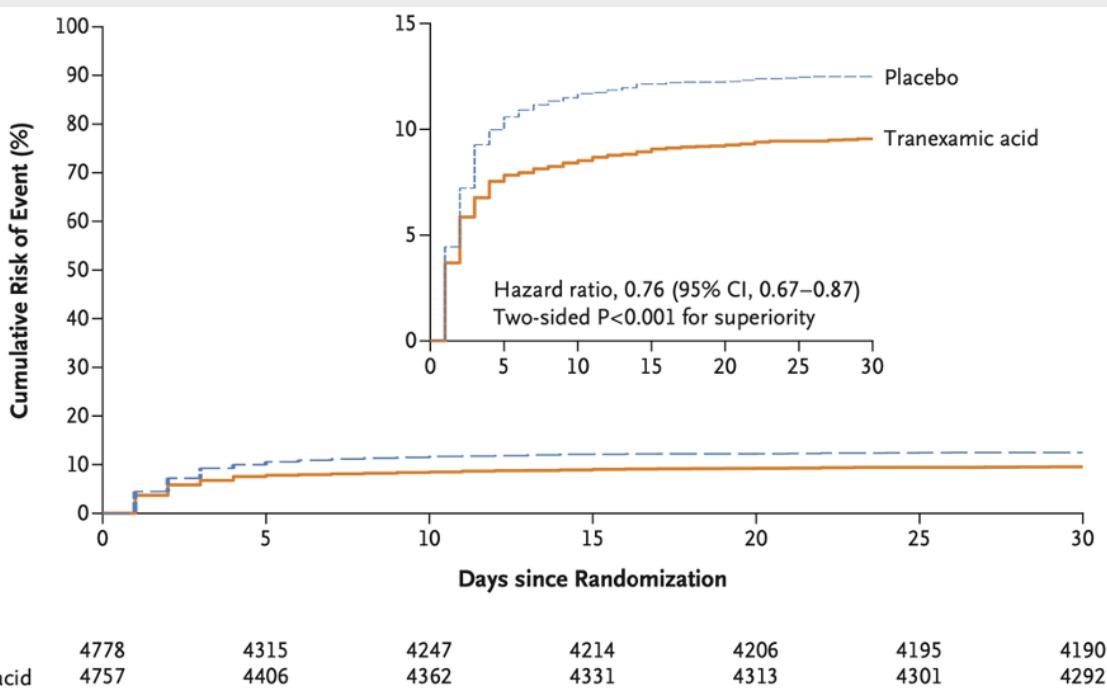
We conducted a trial involving patients undergoing noncardiac surgery. Patients were randomly assigned to receive tranexamic acid (1-g intravenous bolus) or placebo at the start and end of surgery (reported here) and, with the use of a partial factorial design, a hypotension-avoidance or hypertension-avoidance strategy (not reported here). The primary efficacy outcome was life-threatening bleeding, major bleeding, or bleeding into a critical organ (composite bleeding outcome) at 30 days. The primary safety outcome was myocardial injury after noncardiac surgery, nonhemorrhagic stroke, peripheral arterial thrombosis, or symptomatic proximal venous thromboembolism (composite cardiovascular outcome) at 30 days. To establish the noninferiority of tranexamic acid to placebo for the composite cardiovascular outcome, the upper boundary of the one-sided 97.5% confidence interval for the hazard ratio had to be below 1.125, and the one-sided P value had to be less than 0.025.

RESULTS

A total of 9535 patients underwent randomization. A composite bleeding outcome event occurred in 433 of 4757 patients (9.1%) in the tranexamic acid group and in 561 of 4778 patients (11.7%) in the placebo group (hazard ratio, 0.76; 95% confidence interval [CI], 0.67 to 0.87; absolute difference, -2.6 percentage points; 95% CI, -3.8 to -1.4; two-sided $P < 0.001$ for superiority). A composite cardiovascular outcome event occurred in 649 of 4581 patients (14.2%) in the tranexamic acid group and in 639 of 4601 patients (13.9%) in the placebo group (hazard ratio, 1.02; 95% CI, 0.92 to 1.14; upper boundary of the one-sided 97.5% CI, 1.14; absolute difference, 0.3 percentage points; 95% CI, -1.1 to 1.7; one-sided $P = 0.04$ for noninferiority).

CONCLUSIONS

Among patients undergoing noncardiac surgery, the incidence of the composite bleeding outcome was significantly lower with tranexamic acid than with placebo. Although the between-group difference in the composite cardiovascular outcome was small, the noninferiority of tranexamic acid was not established.



A composite of life-threatening bleeding, major bleeding, and bleeding into a critical organ at 30 days. Fibrinolysis and improved coagulation did not increase myocardial events or seizures. Tranexamic acid was thus both safe and effective. The inset shows the same data with an expanded Y scale.

Featured Paper #2

Sessler DI, Pei L, Li K, Cui S, Chan MTV, Huang Y, Wu J, He X, Bajracharya GR, Rivas E, Lam C, and the PROTECT investigators: Aggressive intraoperative warming versus routine thermal management during noncardiac surgery: the PROTECT trial. *Lancet* 399:1799-1808, 2022 [Accompanied by an editorial 399:1757-1759, 2022]

BACKGROUND

Moderate intraoperative hypothermia promotes myocardial injury, surgical site infections, and blood loss. Whether aggressive warming to a truly normothermic temperature near 37°C improves outcomes remains unknown. We aimed to test the hypothesis that aggressive intraoperative warming reduces major perioperative complications.

METHODS

In this multicentre, parallel group, superiority trial, patients at 12 sites in China and at the Cleveland Clinic in the USA were randomly assigned (1:1) to receive either aggressive warming to a target core temperature of 37°C (aggressively warmed group) or routine thermal management to a target of 35.5°C (routine thermal management group) during non-cardiac surgery. Randomisation was stratified by site, with computer-generated, randomly sized blocks. Eligible patients (aged ≥45 years) had at least one cardiovascular risk factor, were scheduled for inpatient non-cardiac surgery expected to last 2–6 h with general anaesthesia, and were expected to have at least half of the anterior skin surface available for warming. Patients requiring dialysis and those with a body-mass index exceeding 30 kg/m² were excluded. The primary outcome was a composite of myocardial injury (troponin elevation, apparently of ischaemic origin), non-fatal cardiac arrest, and all-cause mortality within 30 days of surgery, as assessed in the modified intention-to-treat population. This study is registered with ClinicalTrials.gov, NCT03111875.

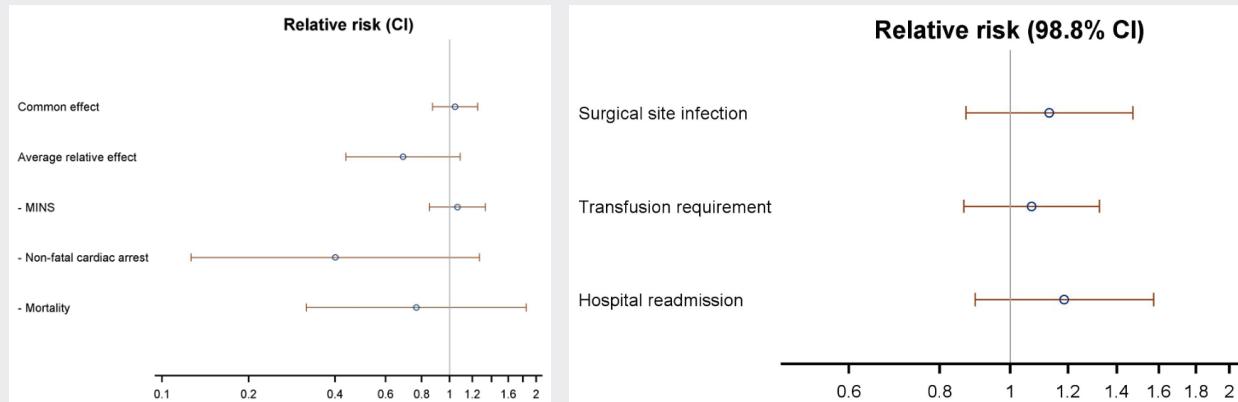
FINDINGS

Between March 27, 2017, and March 16, 2021, 5056 participants were enrolled, of whom 5013 were included in the intention-to-treat population (2507 in the aggressively warmed group and 2506 in the routine thermal management group). Patients assigned to aggressive warming had a mean final intraoperative core temperature of 37.1°C (SD 0.3) whereas the routine thermal management group averaged 35.6°C (SD 0.3). At least one of the primary outcome components (myocardial injury after non-cardiac surgery, cardiac arrest, or mortality) occurred in 246 (9.9%) of 2497 patients in the aggressively warmed group and in 239 (9.6%) of 2490 patients in the routine thermal management group. The common effect relative risk of aggressive versus routine thermal management was an estimated 1.04 (95% CI 0.87–1.24, $p=0.69$). There were 39 adverse events in patients assigned to aggressive warming (17 of which were serious) and 54 in those assigned to routine thermal management (30 of which were serious). One serious adverse event, in an aggressively warmed patient, was deemed to be possibly related to thermal management.

INTERPRETATION

The incidence of a 30-day composite of major cardiovascular outcomes did not differ significantly in patients randomised to 35.5°C and to 37°C. At least over a 1.5°C range

from very mild hypothermia to full normothermia, there was no evidence that any substantive outcome varied. Keeping core temperature at least 35.5°C in surgical patients appears sufficient.



The randomized intervention was aggressive warming to 37°C v. 35.5°C. Forest plot of the primary outcome which was myocardial injury, arrest, and death within 30 days (left). Forest plot of secondary outcomes (right). The circles represent the relative risk comparing aggressive warming to routine care. The error bars present the confidence interval (CI).

Featured Paper #3

Meersch M, Weiss R, Kullmar M, Bergmann L, Thompson A, Griep L, Kusmierz D, Buchholz A, Wolf A, Nowak H, Rahmel T, Adamzik M, Haaker JG, Goettker C, Gruendel M, Hemping-Bovenkerk A, Goebel U, Braumann J, Wisudanto I, Wenk M, Flores-Bergmann D, Bohmer A, Cleophas S, Hohn A, Houben A, Ellermann RK, Larmann J, Sander J, Weigand MA, Eick N, Ziemann S, Bormann E, Gerss J, Sessler DI, Wempe C, Massoth C, Zarbock A: Effect of intraoperative handovers of anesthesia care on mortality, readmission, or postoperative complications among adults: *The HandiCAP randomized clinical trial*. *JAMA* 327:2403-2412, 2022 [Accompanied by an editorial 327:3997-3999, 2022]

IMPORTANCE

Intraoperative handovers of anesthesia care are common. Handovers might improve care by reducing physician fatigue, but there is also an inherent risk of losing critical information. Large observational analyses report associations between handover of anesthesia care and adverse events, including higher mortality.

OBJECTIVE

To determine the effect of handovers of anesthesia care on postoperative morbidity and mortality. Design, Setting, and Participants: This was a parallel-group, randomized clinical trial conducted in 12 German centers with patients enrolled between June 2019 and June 2021 (final follow-up, July 31, 2021). Eligible participants had an American Society of Anesthesiologists physical status 3 or 4 and were scheduled for major inpatient surgery expected to last at least 2 hours.

INTERVENTIONS

A total of 1817 participants were randomized to receive either a complete handover to receive anesthesia care by another clinician ($n = 908$) or no handover of anesthesia care ($n = 909$). None of the participating institutions used a standardized handover protocol.

MAIN OUTCOMES AND MEASURES

The primary outcome was a 30-day composite of all-cause mortality, hospital readmission, or serious postoperative complications. There were 19 secondary outcomes, including the components of the primary composite, along with intensive care unit and hospital lengths of stay.

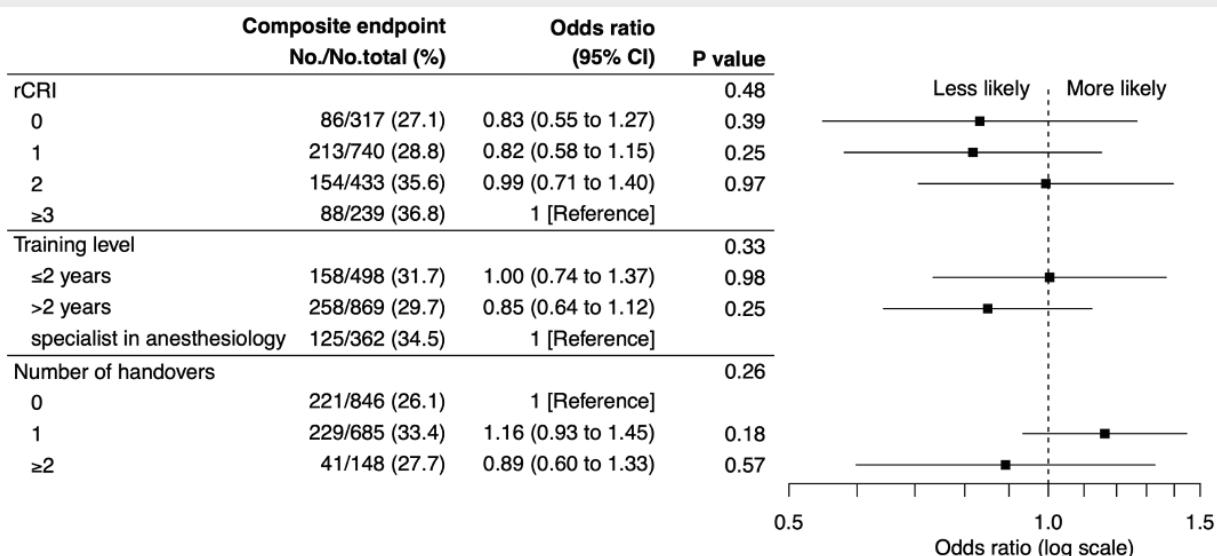
RESULTS

Among 1817 randomized patients, 1772 (98%; mean age, 66 [SD, 12] years; 997 men [56%]; and 1717 [97%] with an American Society of Anesthesiologists physical status of 3) completed the trial. The median total duration of anesthesia was 267 minutes (IQR, 206-351 minutes), and the median time from start of anesthesia to first handover was 144 minutes in the handover group (IQR, 105-213 minutes). The composite primary outcome occurred in 268 of 891 patients (30%) in the handover group and in 284 of 881 (33%) in the no handover group (absolute risk difference [RD], -2.5%; 95% CI, -6.8% to 1.9%; odds ratio [OR], 0.89; 95% CI, 0.72 to 1.10; $P = .27$). Nineteen of 889 patients (2.1%)

in the handover group and 30 of 873 (3.4%) in the no handover group experienced all-cause 30-day mortality (absolute RD, -1.3%; 95% CI, -2.8% to 0.2%; OR, 0.61; 95% CI, 0.34 to 1.10; $P = .11$); 115 of 888 (13%) vs 136 of 872 (16%) were readmitted to the hospital (absolute RD, -2.7%; 95% CI, -5.9% to 0.6%; OR, 0.80; 95% CI, 0.61 to 1.05; $P = .12$); and 195 of 890 (22%) vs 189 of 874 (22%) experienced serious postoperative complications (absolute RD, 0.3%; 95% CI, -3.6% to 4.1%; odds ratio, 1.02; 95% CI, 0.81 to 1.28; $P = .91$). None of the 19 prespecified secondary end points differed significantly.

CONCLUSIONS AND RELEVANCE

Among adults undergoing extended surgical procedures, there was no significant difference between the patients randomized to receive handover of anesthesia care from one clinician to another, compared with the no handover group, in the composite primary outcome of mortality, readmission, or serious postoperative complications within 30 days.



Patients were randomized assigned to intraoperative handovers of anesthesia care or not. Handovers did not significantly worsen the composite primary outcomes of serious complications. rCRI = revised cardiac risk index.

Published Full Papers

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