Annual Report (2024)

ACTR AME Clinical Trials Review

Insights committed to advancing clinical trials from bench to bedside and practice

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AME Publishing Company

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Outline of the Report

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1. Basic Information

- Launched in Jun. 2023
- ISSN 3005-6152
- Open access & Peer-review
- Published bimonthly since launch

- Concentrating on reviews of the most essential clinical trials from Phase 1 up to Phase 4, in an effort to advance the understanding, reflection, and translation of clinical trials.

- Dedicated to sharing insights of the key opinion leaders to stimulate thought and discussion on all aspects of clinical trials, including but not limited to the design, conduct, analysis, regulation and ethics.

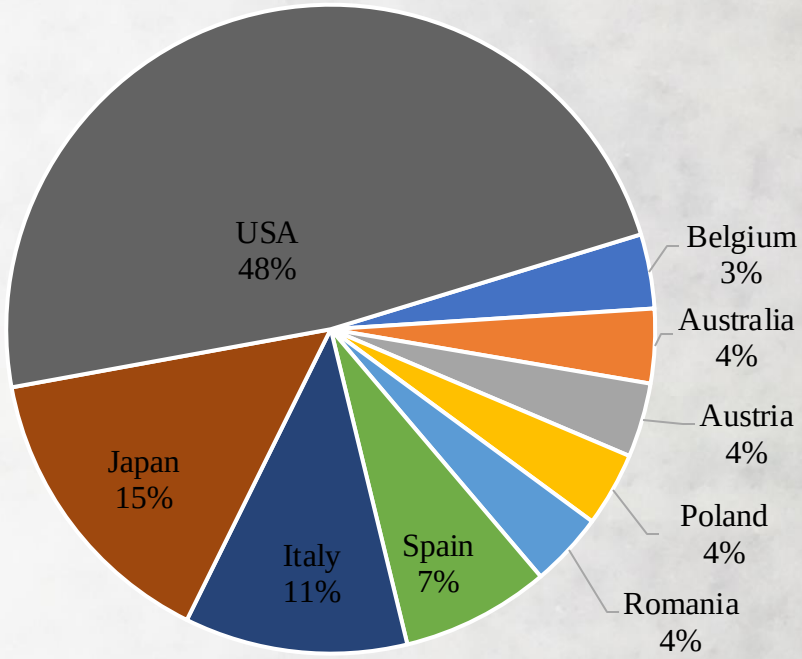
2. Editor-in-Chief

Kaiping Zhang, PhD, MPH

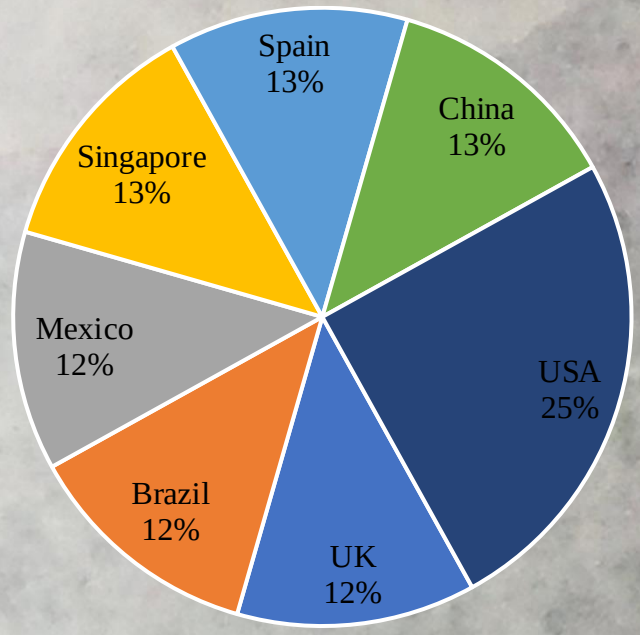
Dr. Kaiping Zhang is the Academic Director of AME Publishing Company. She holds a PhD in Pharmacology from Harbin Medical University and an MPH from the Imperial College of London. Since joining AME Publishing Company in 2017, she has established and led the Academic Development Department, which oversees the quality and impact of academic works. She is responsible for enhancing the peer review standards and conducting editorial in-house reviews of manuscripts. She also has been engaging prominent professionals to offer insightful comments on key clinical trials. Her academic interests include transparency and objectivity in academic research, global public health, and publishing paradigm. She has authored or co-authored over 20 peer-reviewed articles and four books on these topics.

3. Geographical Distributions of Editorial Team

27 International Advisory Board members and **13** Section Editors come from **14** countries. Among them, USA has the largest number, followed by Japan, Italy, Spain, UK, Poland, Singapore, Mexico, Austria, Australia, Brazil, etc.

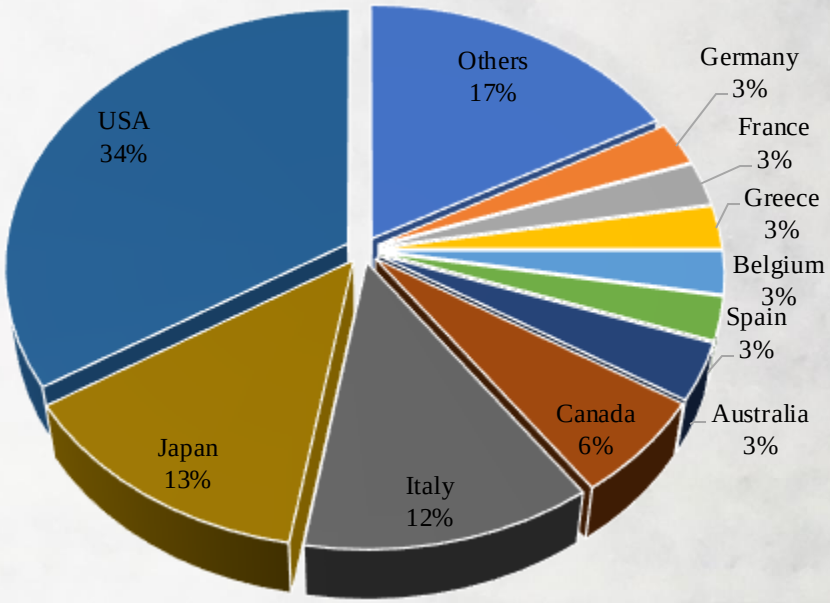


International Advisory Board



Section Editors

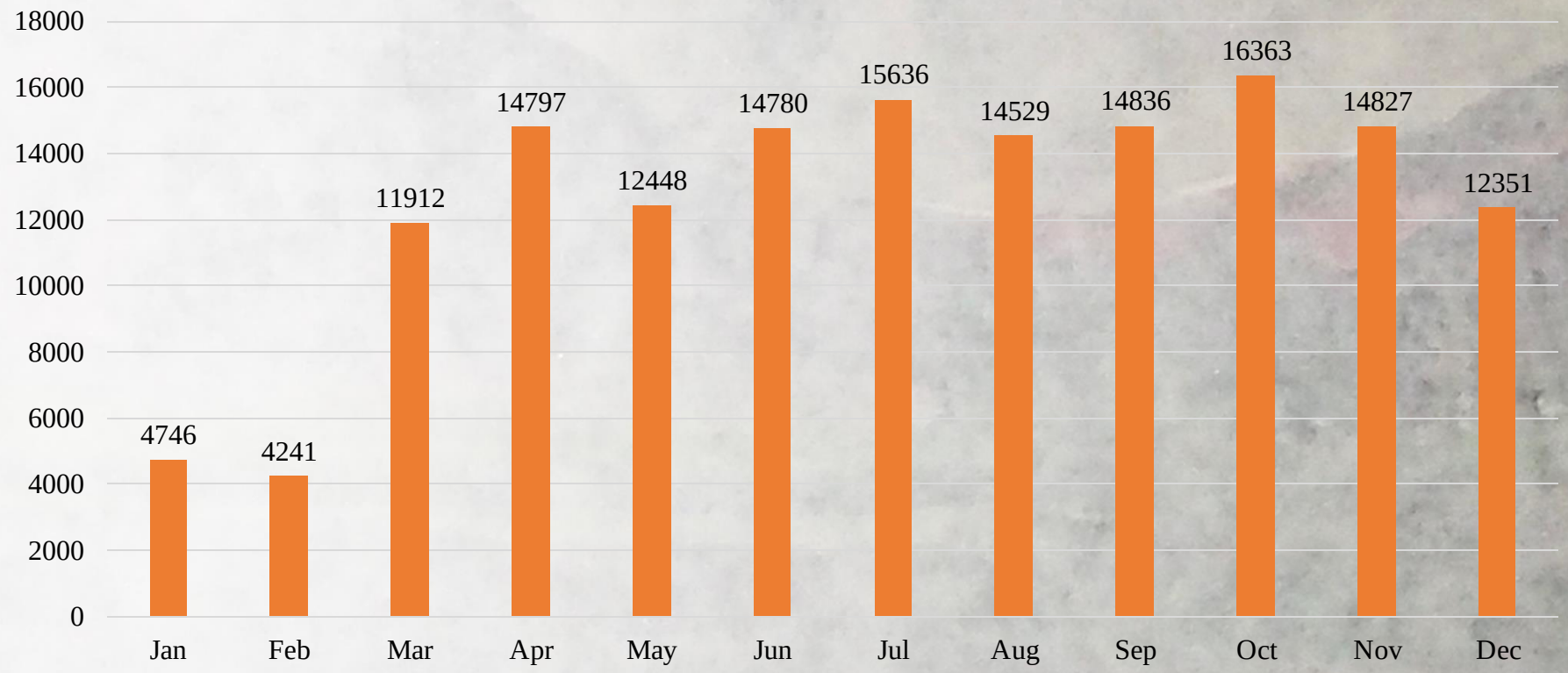
4. International Diversity of Corresponding Authors



Corresponding authors of **112** articles published in 2024 come from **25** countries. Among them, the most number from USA and Japan, followed by Italy, Canada, Australia, etc.

5. Website Pageviews (Results by month)

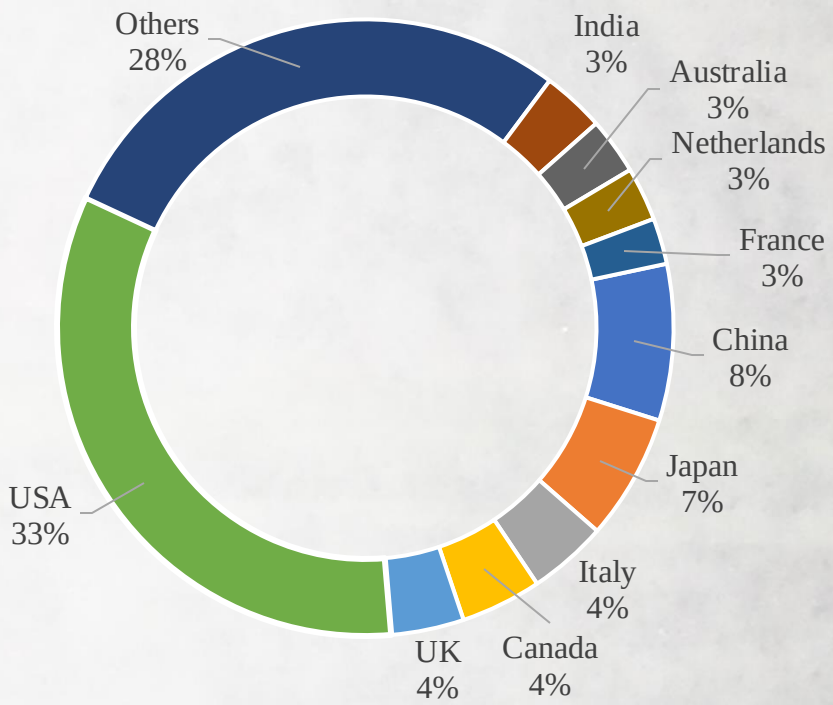
Pageviews of ACTR from Google Analytics in 2024 reached **151,466** in total. Especially, it reaches its highest point in October with **16,363**.



Note: Data collected from Google Analytics on Jan. 3, 2025

6. Website Visits in 2024

In 2024, ACTR website received **17,463** visitors from 143 regions and countries, with the majority from USA, followed by China, Japan, Canada, etc.



No.	Country	Users
1	USA	5811
2	China	1432
3	Japan	1150
4	Canada	741
5	Italy	723
6	UK	668
7	India	571
8	Australia	519
9	Netherlands	491
10	France	421

Note: Data collected from Google Analytics on Jan. 3, 2025

7. Most Read Articles Published in 2024 (Top 10)

No.	Pub. Time	Article Title	Corresponding Author	Pageviews
1	Aug 2024	Xaluritamig: a first step towards a new target, new mechanism for metastatic prostate cancer	Evan Y. Yu	1243
2	Jun 2024	The Butterfly effect—will the MARIPOSA-2 study alter the trajectory of EGFR mutated non-small cell lung cancer (NSCLC)	Aaron C. Tan	1030
3	Apr 2024	ADAURA: redefining the role of target therapy in resectable lung adenocarcinoma	Andrés F. Cardon	964
4	Jun 2024	KEYNOTE-189 5-years update: setting a backbone for the next generation clinical research in advanced non-squamous non-small cell lung cancer without oncogenic addiction	Paolo Bironzo	744
5	Apr 2024	Is osimertinib effective as 2nd line treatment in T790M-negative EGFR mutant NSCLC?	Panagiota Economopoulou	738

Note: Data collected from ACTR's website on Jan. 3, 2025

7. Most Read Articles Published in 2024 (Top 10)

No.	Pub. Time	Article Title	Corresponding Author	Pageviews
6	Feb 2024	Immunotherapy as first-line treatment in locally advanced/metastatic and previously untreated squamous cell lung cancer: which advances?	Alfonso Fiorelli	621
7	Jun 2024	Induction therapy for acute myeloid leukemia: still nothing beyond 7+3?	Daniela Damian	575
8	Mar 2024	Neoadjuvant osimertinib: a promising therapeutic option for locally advanced EGFR-mutant lung adenocarcinoma	Masaaki Sato	548
9	Jan 2024	Utilization of pharmacokinetics in the dosing of pembrolizumab in non-small cell lung cancer	Lauren Tagliaferro Epler	587
10	Jun 2024	Hyperthermic intraperitoneal chemotherapy in colorectal cancer: is COLOPEC just another brick in the wall?	Sebastian Stintzing	552

Note: Data collected from ACTR's website on Jan. 3, 2025

8. Interviews with Outstanding Authors (2024)

In 2024, hundreds of authors shared their insights on clinical trials in our journal. Their articles published with us have received very well feedback in the field and stimulate a lot of discussions and new insights among the peers. Hereby, we would like to highlight some of our outstanding authors who have been making immense efforts in their research fields, with a brief interview of their unique perspectives and insightful views as authors.

Toyoaki Hida (IAB member)

Dr. Toyoaki Hida, MD, PhD, is the Director of Lung Cancer Center at Central Japan International Medical Center, Japan. He spent 2 years in the Biomarkers and Prevention Research Branch of the National Cancer Institute, Maryland. Thereafter, he joined Aichi Cancer Center's Thoracic Oncology unit in 1996. At Aichi Cancer Center, he was Director of Thoracic Oncology from 2005, and vice president from 2018.

His primary interests are translational medicine in the field of non-small cell lung cancer. In the first period of his career, his work focused on the studies on lung cancer pathogenesis, and then on the personalized cancer therapy using molecular target agents, immune-checkpoint inhibitors, and antibody-drug conjugates.

Dr. Hida emphasized that clinical trials play a crucial role in determining the clinical value of expected treatments. Good clinical trials may need the key elements such as appropriate trial population, adequate sample size, adherence to allocated trial intervention, trustworthy capture of data, monitoring emerging information on benefits and toxicities, thorough follow-up, and appropriate statistical analysis.

When discussing the interpretation of clinical trial results, Dr. Hida provided an in-depth example from the field of non-small cell lung cancer (NSCLC). Durvalumab sequentially administered after platinum-based CRT is the

Savvas Lampridis (Section Editor)

Dr. Savvas Lampridis is a cardiothoracic surgeon at the 424 General Military Hospital in Greece, where he serves as a Major in the Army Medical Corps, and is also a Researcher at Imperial College London, UK. His clinical and research interests include minimally invasive surgery, thoracic trauma, translational cardiovascular medicine, surgical education, and health policy. He trained in Greece and the UK, including at the Royal Brompton Hospital and University College London Hospitals, and worked at Guy's Hospital and Hammersmith Hospital in London. Dr. Lampridis completed master's degrees in Translational Cardiovascular Medicine and Health Policy and Planning, both with Distinction. He is a member of the Royal College of Surgeons of Edinburgh and the European Association for Cardio-Thoracic Surgery, where he serves on the Solitary Pulmonary Nodules Task Force. He holds positions on editorial boards of several peer-reviewed journals, has guest-edited multiple special issues, and has reviewed more than 1,000

Joseph Dux

Dr. Joseph Dux specializes in breast surgery and breast cancer patient care, with a particular focus on oncoplastic surgery and tailored surgical approaches for patients. His clinical expertise spans all aspects breast cancer care, including surgery and collaboration with medical and radiation oncology teams to pr comprehensive, patient-centered treatments. On the research front, Dr. Dux is dedicated to improving di imaging and advancing methodologies to enhance the precision and effectiveness of breast cancer diag and therapies. He is also actively pioneering innovations in breast cancer surgery and exploring novel s approaches to improve outcomes for a broad range of patients. Learn more about him on LinkedIn.

A good clinical trial, according to Dr. Dux, starts with identifying the real, practical questions that clinician every day. These questions should be relevant and address challenges that impact patient care. It's also to include a diverse patient population, covering all ages and races. For instance, breast cancer studies focus on older-postmenopausal patients, which can leave younger populations underrepresented. A mo inclusive approach ensures that the findings apply broadly and benefit everyone.

In evaluating the positive and negative results of a clinical trial, Dr. Dux thinks both positive and negative

Zhonghua Sun

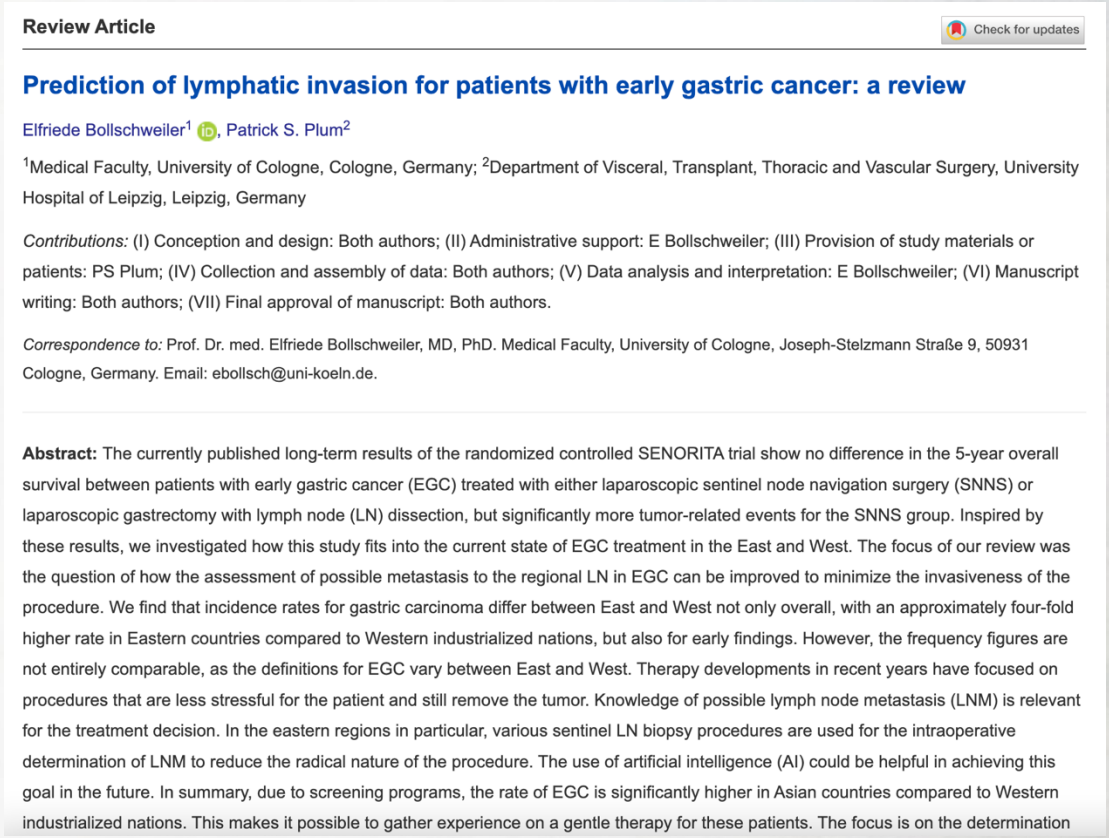
Dr. Sun is a John Curtin Distinguished Professor in medical imaging at Curtin Medical School, Curtin University, Australia. His research interests include 3D image processing and visualization in cardiovascular disease, mainly focusing on the use of 3D printing, virtual reality and mixed reality, and AI technologies in enhancing the diagnosis of coronary artery disease. His research projects involve the development of Generative AI tools in improving diagnostic assessment of calcified coronary plaques, and the development of personalized 3D printed models for medical education and clinical training. Learn more about him here.

A good clinical trial design, according to Dr. Sun, includes innovative ideas, feasible study design, and reasonable sample size that allows for robust conclusions. This foundation is essential for translating positive results into clinical practice, which directly benefits patient care and outcomes. Instead, negative results often stem from challenges in recruiting patients and following up on clinical outcomes, which can hinder the progress of a trial.

Dr. Sun is actively engaged in the field of clinical trials, with a particular focus on the innovative use of AI models in assisting the diagnosis of coronary artery disease This cutting-edge application of artificial intelligence has the

9. Published Reviews in 2024

We have already published two reviews in the August and December issues.



Review Article

Check for updates

Prediction of lymphatic invasion for patients with early gastric cancer: a review

Elfriede Bollschweiler[1], Patrick S. Plum[2]

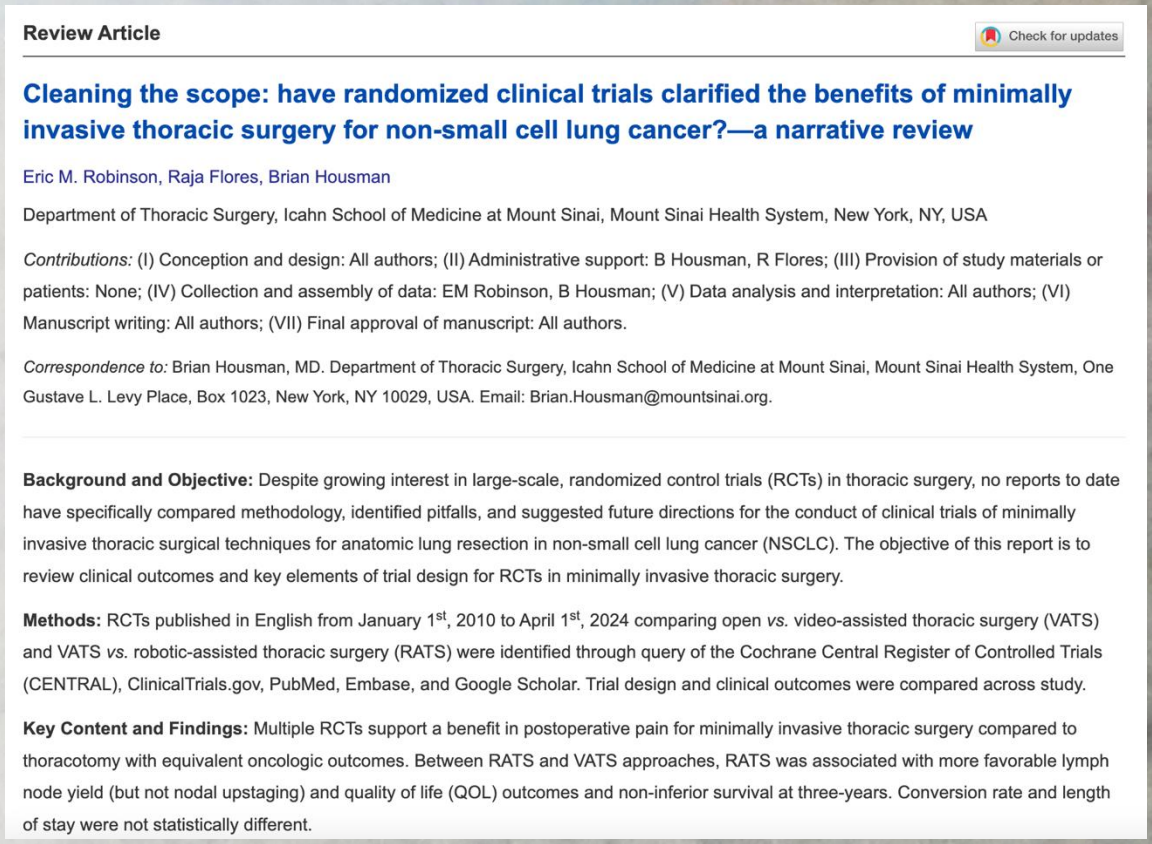
[1]Medical Faculty, University of Cologne, Cologne, Germany; [2]Department of Visceral, Transplant, Thoracic and Vascular Surgery, University Hospital of Leipzig, Leipzig, Germany

Contributions: (I) Conception and design: Both authors; (II) Administrative support: E Bollschweiler; (III) Provision of study materials or patients: PS Plum; (IV) Collection and assembly of data: Both authors; (V) Data analysis and interpretation: E Bollschweiler; (VI) Manuscript writing: Both authors; (VII) Final approval of manuscript: Both authors.

Correspondence to: Prof. Dr. med. Elfriede Bollschweiler, MD, PhD. Medical Faculty, University of Cologne, Joseph-Stelzmann Straße 9, 50931 Cologne, Germany. Email: ebollsch@uni-koeln.de.

Abstract: The currently published long-term results of the randomized controlled SENORITA trial show no difference in the 5-year overall survival between patients with early gastric cancer (EGC) treated with either laparoscopic sentinel node navigation surgery (SNNS) or laparoscopic gastrectomy with lymph node (LN) dissection, but significantly more tumor-related events for the SNNS group. Inspired by these results, we investigated how this study fits into the current state of EGC treatment in the East and West. The focus of our review was the question of how the assessment of possible metastasis to the regional LN in EGC can be improved to minimize the invasiveness of the procedure. We find that incidence rates for gastric carcinoma differ between East and West not only overall, with an approximately four-fold higher rate in Eastern countries compared to Western industrialized nations, but also for early findings. However, the frequency figures are not entirely comparable, as the definitions for EGC vary between East and West. Therapy developments in recent years have focused on procedures that are less stressful for the patient and still remove the tumor. Knowledge of possible lymph node metastasis (LNM) is relevant for the treatment decision. In the eastern regions in particular, various sentinel LN biopsy procedures are used for the intraoperative determination of LNM to reduce the radical nature of the procedure. The use of artificial intelligence (AI) could be helpful in achieving this goal in the future. In summary, due to screening programs, the rate of EGC is significantly higher in Asian countries compared to Western industrialized nations. This makes it possible to gather experience on a gentle therapy for these patients. The focus is on the determination

Link: https://actr.amegroups.org/article/view/9749/html



Review Article

Check for updates

Cleaning the scope: have randomized clinical trials clarified the benefits of minimally invasive thoracic surgery for non-small cell lung cancer?—a narrative review

Eric M. Robinson, Raja Flores, Brian Housman

Department of Thoracic Surgery, Icahn School of Medicine at Mount Sinai, Mount Sinai Health System, New York, NY, USA

Contributions: (I) Conception and design: All authors; (II) Administrative support: B Housman, R Flores; (III) Provision of study materials or patients: None; (IV) Collection and assembly of data: EM Robinson, B Housman; (V) Data analysis and interpretation: All authors; (VI) Manuscript writing: All authors; (VII) Final approval of manuscript: All authors.

Correspondence to: Brian Housman, MD. Department of Thoracic Surgery, Icahn School of Medicine at Mount Sinai, Mount Sinai Health System, One Gustave L. Levy Place, Box 1023, New York, NY 10029, USA. Email: Brian.Housman@mountsinai.org.

Background and Objective: Despite growing interest in large-scale, randomized control trials (RCTs) in thoracic surgery, no reports to date have specifically compared methodology, identified pitfalls, and suggested future directions for the conduct of clinical trials of minimally invasive thoracic surgical techniques for anatomic lung resection in non-small cell lung cancer (NSCLC). The objective of this report is to review clinical outcomes and key elements of trial design for RCTs in minimally invasive thoracic surgery.

Methods: RCTs published in English from January 1st, 2010 to April 1st, 2024 comparing open *vs.* video-assisted thoracic surgery (VATS) and VATS *vs.* robotic-assisted thoracic surgery (RATS) were identified through query of the Cochrane Central Register of Controlled Trials (CENTRAL), ClinicalTrials.gov, PubMed, Embase, and Google Scholar. Trial design and clinical outcomes were compared across study.

Key Content and Findings: Multiple RCTs support a benefit in postoperative pain for minimally invasive thoracic surgery compared to thoracotomy with equivalent oncologic outcomes. Between RATS and VATS approaches, RATS was associated with more favorable lymph node yield (but not nodal upstaging) and quality of life (QOL) outcomes and non-inferior survival at three-years. Conversion rate and length of stay were not statistically different.

Link: https://actr.amegroups.org/article/view/10215/html

10. Upcoming Reviews

Leading Author	Affiliation	Topic
Guido Marcucci	Department of Hematology and Hematopoietic Cell Transplantation, Duarte, California, USA	The latest clinical trial advances and addressing these critical controversies in treatment strategies for TP53-mutated AML
Giuseppe Cardillo	Unit of Thoracic Surgery, Azienda Ospedaliera San Camillo Forlanini, Rome, Italy	The latest clinical trial advances on whether chest tube aspiration or water sealing should be performed for pleural air leaks after lung cancer surgery
Joel W. Neal	Division of Oncology, Department of Medicine, Stanford University, Stanford, CA, USA	The clinical trial advances on targeted therapy for NSCLC
Carolina Schinke	Myeloma Center, University of Arkansas for Medical Science, Little Rock, Arkansas, USA	MRD in multiple myeloma
Tanios S. Bekaii-Saab	Division of Hematology and Oncology, Mayo Clinic, AZ, USA	The progress of clinical studies on the TNT of LARC
Grace K. Dy	Roswell Park Comprehensive Cancer Center, Buffalo, NY, USA	First-line treatment strategies and potential prognostic factors in patients with KRAS G12C mutated non-small cell lung cancer
Jason M. Ali	Department of Cardiothoracic Surgery, Royal Papworth Hospital, Cambridge, UK	Dual Antiplatelet Therapy – the missing key after Coronary Artery Bypass Graft surgery?
Takehiro Uemura	Department of Respiratory Medicine, Allergy and Clinical Immunology, Nagoya City University Graduate School of Medical Sciences, Mizuho-ku, Nagoya, Japan	Emerging clinical trials and their potential impact on the future of lung cancer care

11. Upcoming commentaries

A batch of articles commenting on key clinical trials will be online soon. Hereby, we would like to highlight some of them.

Leading author	Affiliation	Comment on	Area of expertise/disease
Margarita Majem	Department of Medical Oncology, Hospital de la Santa Creu i Sant Pau, Barcelona, Spain	First-line cemiplimab monotherapy and continued cemiplimab beyond progression plus chemotherapy for advanced non-small-cell lung cancer with PD-L1 50% or more (EMPOWER-Lung 1): 35-month follow-up from a mutlicentre, open-label, randomised, phase 3 trial	Lung cancer
Claudia Parisi	Drug Development Department, International Center for Thoracic Cancers (CICT), Gustave Roussy, Villejuif, France	Translational insights and overall survival in the U31402-A-U102 study of patritumab deruxtecan (HER3-DXd) in EGFR-mutated NSCLC	
Fernando A. M. Herbella	Department of Surgery, Escola Paulista de Medicina, Federal University of Sao Paulo, Sao Paulo, Brazil	Multicentre randomized clinical trial on robot-assisted versus video-assisted thoracoscopic oesophagectomy (REVATE trial)	Esophageal and gastrointestinal cancer
Jane E Rogers	U.T. M.D. Anderson Cancer Center Pharmacy Clinical Programs, Houston, TX, USA	Perioperative chemotherapy with docetaxel plus oxaliplatin and S-1 (DOS) versus oxaliplatin plus S-1 (SOX) for the treatment of locally advanced gastric or gastro-esophageal junction adenocarcinoma (MATCH): an open-label, randomized, phase 2 clinical trial	
Xavier Thomas	Department of Clinical Hematology, Hospices Civils de Lyon, Centre Hospitalier Lyon-Sud, Pierre-Bénite Cedex, France	Menin Inhibition With Revumenib for KMT2A-Rearranged Relapsed or Refractory Acute Leukemia (AUGMENT-101)	Hematology
Monia Marchetti	Hematology Unit & Transplant Center, Azienza Ospedaliera Ss Antonio E Biagio E Cesare Arrigo, Alessandria, Italy	Iadademstat in combination with azacitidine in patients with newly diagnosed acute myeloid leukaemia (ALICE): an open-label, phase 2a dose-finding study	

11. Upcoming commentaries

Leading author	Affiliation	Comment on	Area of expertise/disease
Brian J Potter	Centre hospitalier de l'Université de Montréal (CHUM) Research Center and Cardiovascular Centre, Montreal, Québec, Canada	Aspirin Dosing for Secondary Prevention of Atherosclerotic Cardiovascular Disease in Male and Female Patients: A Secondary Analysis of the ADAPTABLE Randomized Clinical Trial	Cardiovascular Disease
Francesco Burzotta	Dipartimento di Scienze Cardiovascolari, Fondazione Policlinico Universitario A. Gemelli IRCCS, Rome, Italy	Optical coherence tomography-guided versus angiography-guided percutaneous coronary intervention for patients with complex lesions (OCCUPI): an investigator-initiated, multicentre, randomised, open-label, superiority trial in South Korea	
Tetsuya Ishikawa	Saitama Medical Center, Dokkyo Medical University, Koshigaya, Japan	Drug-coated balloon angioplasty with rescue stenting versus intended stenting for the treatment of patients with de novo coronary artery lesions (REC-CAGEFREE I): an open-label, randomised, non-inferiority trial	
Lorenzo Fornaro	Unit of Medical Oncology 2, Azienda Ospedaliero-Universitaria Pisana, Pisa, Italy	Multicenter phase I/II trial of gemcitabine, oxaliplatin and nab-paclitaxel as first-line treatment for patients with advanced biliary tract cancer	Hepatobiliary pancreatic Disease
Anna Weiss	Division of Surgical Oncology, Department of Surgery, University of Rochester Medical Center, Rochester, NY, USA	Omitting Axillary Dissection in Breast Cancer with Sentinel-Node Metastases	Breast cancer
Tomás Reinert	Irineu Boff Family Oncology Center, Nora Teixeira Hospital, Porto Alegre, Brazil	Final Results of RIGHT Choice: Ribociclib Plus Endocrine Therapy Versus Combination Chemotherapy in Premenopausal Women With Clinically Aggressive Hormone Receptor-Positive/Human Epidermal Growth Factor Receptor 2-Negative Advanced Breast Cancer	

12. About AME Publishing Company

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