

AMED 生物統計家育成支援事業 京都大学臨床統計家育成コース
聴講コース「臨床研究者のための生物統計学」 文献一覧

第 1 回 なぜランダム化が必要なのか?

Breast International Group (BIG) 1-98 Collaborative Group. A comparison of letrozole and tamoxifen in postmenopausal women with early breast cancer. *New England Journal of Medicine* 2005; 353: 2747-2757. (<https://www.nejm.org/doi/full/10.1056/NEJMoa052258>)

Buyse M. Randomized designs for early trials of new cancer treatments—an overview. *Drug Information Journal* 2000; 34: 387-96.

(<https://journals.sagepub.com/doi/pdf/10.1177/009286150003400207>)

Fisher RA. 実験計画法. 森北出版, 1971.

Furukawa TA, Akechi T, Shimodera S, et al. Strategic use of new generation antidepressants for depression: SUN(^_^)D study protocol. *Trials*. 2011; 12: 116.

(<https://trialsjournal.biomedcentral.com/articles/10.1186/1745-6215-12-116>)

O'Rourke PP, Crone RK, Vacanti JP, et al. Extracorporeal membrane oxygenation and conventional medical therapy in neonates with persistent pulmonary hypertension of the newborn: a prospective randomized study. *Pediatrics* 1989; 84: 957-963.

(<https://pediatrics.aappublications.org/content/84/6/957>)

Steering Committee of the Physicians' Health Study Research Group. Final report on the aspirin component of the ongoing Physicians' Health Study. *New England Journal of Medicine* 1989; 321: 129-135. (<https://www.nejm.org/doi/full/10.1056/NEJM198907203210301>)

田中司朗, 田中佐智子. 短期集中! オオサンショウウオ先生の医療統計セミナー論文読解レベルアップ 30. 羊土社, 2016.

第 2 回 リスクの指標と治療効果の指標

Connolly, Ezekowitz MD, Yusuf F, et al. Dabigatran versus warfarin in patients with atrial fibrillation. *New England Journal of Medicine* 2009; 361: 1139-1151.

(<https://www.nejm.org/doi/full/10.1056/NEJMoa0905561>)

Dobson AJ. 一般化線形モデル入門 原著第 2 版. 共立出版, 2008.

Gordis L. 疫学—医学的研究と実践のサイエンス—. メディカルサイエンスインターナショナル, 2010.

Rothman KJ. ロスマンの疫学—科学的思考への誘い—. 篠原出版新社, 2013

佐藤俊哉. 宇宙怪人しまりす医療統計を学ぶ. 岩波科学ライブラリー114, 2005.

田中司朗, 田中佐智子. 短期集中! オオサンショウウオ先生の医療統計セミナー論文読解レベルアップ 30. 羊土社, 2016.

Tsuda T, Tokinobu A, Yamamoto E, et al. Thyroid cancer detection by ultrasound among

residents ages 18 years and younger in Fukushima, Japan: 2011 to 2014. *Epidemiology* 2016; 27: 316-322.

(https://journals.lww.com/epidem/Fulltext/2016/05000/Thyroid_Cancer_Detection_by_Ultrasonound_Among.3.aspx)

第3回 仮説検定とP値の誤解

American Statistical Association. Statement on Statistical Significance and P-Values. March 7, 2016. (<https://www.amstat.org/newsroom/pressreleases/P-ValueStatement.pdf>)

エコチル調査コアセンター. エコチル調査における結果のとりまとめに関するガイダンス Ver.2.1. 2015年7月31日. (<http://www.env.go.jp/chemi/ceh/outline/data.html>)

Greenland S, Senn S, Rothman KJ, et al. Statistical tests, P values, confidence intervals, and power: A guide to misinterpretations. *European Journal of Epidemiology* 2016; 31: 337-350. (<https://link.springer.com/article/10.1007/s10654-016-0149-3>)

Hiatt WR, Fowkes FGR, Heizer G, et al. Ticagrelor versus clopidogrel in symptomatic peripheral artery disease. *New England Journal of Medicine* 2017; 376: 32-40. (<https://www.nejm.org/doi/full/10.1056/NEJMoa1611688>)

Rothman KJ, Greenland S, Lash TL. *Modern Epidemiology*, 3rd ed. Lippincott, Williams & Wilkins, 2008.

佐藤俊哉. 宇宙怪人しまりす 医療統計を学ぶ 検定の巻. 岩波科学ライブラリー194, 2012.

佐藤俊哉. 検定の考え方. 安原・佐藤・平山編, 薬学倫理・医薬品開発・臨床研究・医療統計学. 中山書店, 2017.

Wasserstein RL, Lazar NA. The ASA's statement on p-values: context, process, and purpose. *The American Statistician* 2016; 70: 129-133. (佐藤俊哉 訳. 統計的有意性とP値に関するASA声明. 2017, <https://www.biometrics.gr.jp/news/all/ASA.pdf>)

第4回 生存時間解析の基礎

Austin PC, Lee DS, Fine JP. Introduction to the Analysis of Survival Data in the Presence of Competing Risks. *Circulation* 2016; 133: 601-609. (<https://www.ahajournals.org/doi/10.1161/CIRCULATIONAHA.115.017719>)

Collett D. (宮岡悦良 監訳, グラクソ・スミスクライン株式会社バイオメディカルデータサイエンス部訳) 医療統計のための生存時間データ解析原著第2版. 共立出版, 2013.

Hosmer D, May S, Lemeshow S. (五所正彦 監訳) 生存時間解析入門原書第2版. 東京大学出版会, 2016.

Kleinbaum D, Klein M. (神田英一郎, 藤井朋子訳) エモリー大学クラインバウム教授の生

存時間解析. サイエンティスト社, 2015.

Marcovecchio ML, Chiesa ST, Bond S, et al., for the AdDIT Study Group. ACE inhibitors and statins in adolescents with type 1 diabetes. *New England Journal of Medicine* 2017; 377: 1733-1745. (<https://www.nejm.org/doi/full/10.1056/NEJMoa1703518>)

Oakes D, Peterson DR. Survival methods: additional topics. *Circulation* 2008; 117: 2949-2955. (<https://www.ahajournals.org/doi/10.1161/CIRCULATIONAHA.107.700377>)

大橋靖雄, 浜田知久馬. 生存時間解析—SASによる生物統計. 東京大学出版会, 1995.

大橋靖雄, 浜田知久馬, 魚住龍史. 生存時間解析応用編—SASによる生物統計. 東京大学出版会, 2016.

Rao SR, Schoenfeld DA. Survival methods. *Circulation* 2007; 115: 109-113.

(<https://www.ahajournals.org/doi/10.1161/CIRCULATIONAHA.106.614859>)

第5回 メタアナリシス

Connolly, Ezekowitz MD, Yusuf F, et al. Dabigatran versus warfarin in patients with atrial fibrillation. *New England Journal of Medicine* 2009; 361: 1139-1151.

(<https://www.nejm.org/doi/full/10.1056/NEJMoa0905561>)

Guan J, Tanaka S, Kawakami K. Anticonvulsants or antidepressants in combination pharmacotherapy for treatment of neuropathic pain in cancer patients: a systematic review and meta-analysis. *Clinical Journal of Pain* 2016; 32: 719-725.

(https://journals.lww.com/clinicalpain/Fulltext/2016/08000/Anticonvulsants_or_Antidepressants_in_Combination.11.aspx)

Higgins JP, Altman DG, Gøtzsche PC, et al. The Cochrane Collaboration's tool for assessing risk of bias in randomised trials. *British Medical Journal* 2011; 343: d5928.

(<https://www.bmj.com/content/343/bmj.d5928>)

Iijima K, Sako M, Nozu K, et al. Rituximab for childhood-onset, complicated, frequently relapsing nephrotic syndrome or steroid-dependent nephrotic syndrome: a multicentre, double-blind, randomised, placebo-controlled trial. *Lancet* 2014; 384: 1273-1281.

([https://www.thelancet.com/journals/lancet/article/PIIS0140-6736\(14\)60541-9/fulltext](https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(14)60541-9/fulltext))

Ruff CT, Giugliano RP, Braunwald E, et al. Comparison of the efficacy and safety of new oral anticoagulants with warfarin in patients with atrial fibrillation: a meta-analysis of randomised trials. *Lancet* 2014; 383: 955-962.

([https://www.thelancet.com/journals/lancet/article/PIIS0140-6736\(13\)62343-0/fulltext](https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(13)62343-0/fulltext))

Turner EH, Matthews AM, Linardatos E, et al. Selective publication of antidepressant trials and its influence on apparent efficacy. *New England Journal of Medicine* 2008; 358:252-260.

(<https://www.nejm.org/doi/full/10.1056/NEJMsa065779>)

UMIN 臨床試験登録システム(<http://www.umin.ac.jp/ctr/index-j.htm>).

第6回 この臨床試験できますか？

Chapman PB, Hauschild A, Robert C, et al., for the BRIM-3 Study Group. Improved Survival with vemurafenib in melanoma with BRAF V600E mutation. *New England Journal of Medicine* 2011; 364: 2507-2516. (<https://www.nejm.org/doi/full/10.1056/NEJMoa1103782>)

Department of Health and Human Services Food and Drug Administration (FDA). Guidance for Industry. Expedited programs for serious conditions-drug and biologics. 2014. (<http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM358301.pdf>)

Emanuel EJ, Wendler D, Grady C. What makes clinical research ethical? *Journal of the American Medical Association* 2000; 283: 2701-2711. (<https://jamanetwork.com/journals/jama/fullarticle/192740>)

FINAL REPORT of the Tuskegee Syphilis Study Ad Hoc Advisory. (<https://biotech.law.lsu.edu/cphl/history/reports/tuskegee/tuskegee.htm>)

Flaherty KT, Hennig M, Lee SJ, et al. Surrogate endpoints for overall survival in metastatic melanoma: a meta-analysis of randomised controlled trials. *Lancet Oncology* 2014; 15: 297-304. ([https://www.thelancet.com/journals/lanonc/article/PIIS1470-2045\(14\)70007-5/fulltext](https://www.thelancet.com/journals/lanonc/article/PIIS1470-2045(14)70007-5/fulltext))

Freedman B. Equipoise and the ethics of clinical research. *New England Journal of Medicine* 1987; 317: 141-145. (<https://www.nejm.org/doi/full/10.1056/NEJM198707163170304>)

加藤尚武. 現代倫理学入門. 講談社学術文庫, 1997.

國頭英夫. Vemurafenib の臨床試験の妥当性、特に crossover の禁止についての考察. *腫瘍内科* 2012; 9: 562-572.

Sharma MR, Schilsky RL. Role of randomized phase III trials in an era of effective targeted therapies. *Nature Reviews Clinical Oncology* 2012; 9: 208-214. (<https://www.nature.com/articles/nrclinonc.2011.190>)

McArthur GA, Chapman PB, Robert C, et al. Safety and efficacy of vemurafenib in BRAF(V600E) and BRAF(V600K) mutation-positive melanoma (BRIM-3): extended follow-up of a phase 3, randomised, open-label study. *Lancet Oncology* 2014; 15: 323-332. ([https://www.thelancet.com/journals/lanonc/article/PIIS1470-2045\(14\)70012-9/fulltext](https://www.thelancet.com/journals/lanonc/article/PIIS1470-2045(14)70012-9/fulltext))

Miller FG, Joffe S. Equipoise and the dilemma of randomized clinical trials. *New England Journal of Medicine* 2011; 364: 476-480. (<https://www.nejm.org/doi/full/10.1056/NEJMs1011301>)

佐藤恵子. 実地臨床につながる臨床試験の倫理的要素. *産婦人科の実際* 2014; 63: 2031-2040.

世界医師会. ヘルシンキ宣言. (<http://www.med.or.jp/wma/helsinki.html>)

第7回 データマネジメントとは

Niimi M, Yamamoto S, Fukuda H, et al. The influence of handling censored data on estimating progression-free survival in cancer clinical trials (JCOG9913-A). Japanese Journal of Clinical Oncology 2002; 32: 19-26. (<https://academic.oup.com/jjco/article/32/1/19/869041>)

Rondel RK, Varly SA, Webb CF, eds. Clinical Data Management, 2nd ed. Wiley, 2000.

第8回 ランダム化ができないとき

Greenland S. Concepts of validity in epidemiologic research. In Detels R, et al., eds., The Oxford Textbook of Public Health, Vol. 2, Oxford University Press, 1997.

Hartzema AG, Porta MS, Tilson HH, Rogers AS. Adverse drug events: Identification and attribution. Drug Intelligence & Clinical Pharmacy 1987; 21: 915-920.

(<https://journals.sagepub.com/doi/pdf/10.1177/106002808702101114>)

Lash TL, Fox MP, MacLehose RF, et al. Good practices for quantitative bias analysis. International Journal of Epidemiology 2014; 43: 1969-1985.

(<https://academic.oup.com/ije/article/43/6/1969/705764>)

Medical Research Council. Streptomycin treatment of pulmonary tuberculosis. British Medical Journal 1948; 2: 762-782. (<https://www.bmj.com/content/2/4582/769>)

佐藤俊哉. 宇宙怪人しまりす 医療統計を学ぶ 検定の巻. 岩波科学ライブラリー194, 2012.

Porta, M 編(日本疫学会訳). 疫学辞典第5版, 日本公衆衛生協会, 2010.

(https://jeaweb.jp/files/activities/jiten_rev20210818.pdf)

Taubes G. Epidemiology faces its limits. Science 1995; 269: 164-169.

(<http://science.sciencemag.org/content/269/5221/164>)

第9回 交絡とその調整

Greenland S. Concepts of validity in epidemiologic research. In Detels R, et al., eds., The Oxford Textbook of Public Health, Vol. 2, Oxford University Press, 1997.

Greenland S, Morgenstern H. Matching and efficiency in cohort studies. American Journal of Epidemiology 1990; 131: 151-159.

(<https://academic.oup.com/aje/article-abstract/131/1/151/90844?redirectedFrom=fulltext>)

Greenland S, Robins JM. Identifiability, exchangeability, and epidemiologic confounding. International Journal of Epidemiology 1986; 15: 413-419.

(<https://academic.oup.com/ije/article-abstract/15/3/413/658713?redirectedFrom=fulltext>)

Greenland S, Robins JM, Pearl J. Confounding and collapsibility in causal inference. Statistical Science 1999; 14: 29-46. (<https://projecteuclid.org/euclid.ss/1009211805>)

佐藤俊哉. 疫学研究における交絡と効果の修飾. 統計数理 1994; 42: 83-101.

(https://ismrepo.ism.ac.jp/?action=pages_view_main&active_action=repository_view_main_item_detail&item_id=32061&item_no=1&page_id=13&block_id=21)

佐藤俊哉. 宇宙怪人しまりす 医療統計を学ぶ 検定の巻. 岩波科学ライブラリー194, 2012.

佐藤俊哉, 松山裕. 交絡という不思議な現象と交絡を取りのぞく解析. 計量生物学 2011; 32: S35-S49.

(https://www.jstage.jst.go.jp/article/jjb/32/Special_Issue/32_Special_Issue_S35/article/-char/ja)

第10回 回帰モデルと傾向スコア

Fujii T, Sato T, Uchino S, Doi K, Iwami T, Kawamura T, on behalf of the JAKID study group.

Human atrial natriuretic peptide for acute kidney injury in adult critically ill patients: A multicenter prospective observational study. *Journal of Critical Care* 2019; 51: 229-235.

(<https://doi.org/10.1016/j.jcrc.2018.11.032>)

Joffe MM, Rosenbaum PR. Propensity scores. *American Journal of Epidemiology* 1999; 150: 327-333. (<https://academic.oup.com/aje/article/150/4/327/98791>)

Robins JM, Hernan MA, Brumback B. Marginal structural models and causal inference in epidemiology. *Epidemiology* 2000; 11: 550-560.

(https://journals.lww.com/epidem/Fulltext/2000/09000/Marginal_Structural_Models_and_Causal_Inference_in.11.aspx)

Rosenbaum PR, Rubin DB. The central role of propensity score in observational studies for causal effects. *Biometrika* 1983; 70: 41-55.

(https://www.jstor.org/stable/2335942?seq=1#metadata_info_tab_contents)

Sato T, Matsuyama Y. Marginal structural models as a tool for standardization. *Epidemiology* 2003; 14: 680-686.

(https://journals.lww.com/epidem/Fulltext/2003/11000/Marginal_Structural_Models_as_a_Tool_for.9.aspx)

佐藤俊哉. 疫学研究における交絡と効果の修飾. *統計数理* 1994; 42: 83-101.

(https://ismrepo.ism.ac.jp/?action=pages_view_main&active_action=repository_view_main_item_detail&item_id=32061&item_no=1&page_id=13&block_id=21)

佐藤俊哉. 宇宙怪人しまりす 医療統計を学ぶ 検定の巻. 岩波科学ライブラリー194, 2012.

佐藤俊哉, 松山裕. 交絡という不思議な現象と交絡を取りのぞく解析. 計量生物学 2011; 32: S35-S49.

(https://www.jstage.jst.go.jp/article/jjb/32/Special_Issue/32_Special_Issue_S35/article/-char/ja)

VanderWeele TJ, Ding P. Sensitivity analysis in observational research: Introducing the E-value. *Annals of Internal Medicine* 2017; 167: 268-274.
(<https://annals.org/aim/fullarticle/2643434/sensitivity-analysis-observational-research-introducing-e-value>)