

Curriculum Vitae

October 1, 2017

Name: Shiro Tanaka

Current position: Professor

Department of Clinical Biostatistics,
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Date of birth: Aug 29, 1979

Birth place: Osaka, Japan

Education: Ph.D. in Biostatistics from University of Tokyo (2008)

Adviser: Yutaka Matsuyama

Dissertation title: “Evaluation of surrogate endpoints via principal stratification with an application to advanced prostate cancer trial data”

Past academic positions:

Assistant professor, Department of Clinical Trial Design & Management, Translational Research Center, Kyoto University Hospital (April 2008 to Nov 2012)

Senior lecturer, Department of Pharmacoepidemiology, Graduate School of Medicine and Public Health, Kyoto University (Dec 2012 to March 2014)

Associate professor, Department of Pharmacoepidemiology, Graduate School of Medicine and Public Health, Kyoto University (March 2014 to January 2017)

Visiting scholar, Department of Epidemiology, Gillings School of Global Public Health, The University of North Carolina at Chapel Hill (Nov 2016 to June 2017)

Teaching:

Clinical Trial (2 credits), Statistical Methods in Clinical Trials (1 credits), Data management for Clinical Research (1 credit), Development Strategy Plan & Regulatory Affairs of Drugs and Medical Devices (2 credits), Seminar in Study Design I (1 credit), Seminar in Study Design II (1 credit), Special Seminar in Study Design I (1 credit), Special Seminar in Study Design II (1 credit), Statistics for Medical Science, Business and Policy (2 credits)

Advisory responsibilities:

Advisory expert for the Pharmaceutical and Medical Devices Agency (2013 to present)

Professional societies:

Japanese Society for Pharmacoepidemiology, Councilor (2013 to present)
Japan Society of Metabolism and Clinical Nutrition, Councilor (2013 to present)
The Biometric Society of Japan, Member
American Statistical Association, Member
Japan Osteoporosis Society, Member
Japan Society of Nutrition and Food Sciences, Member
The Japanese Society of Psychiatry and Neurology, Member

Editorial responsibilities:

Journal of Japan Society of Nutrition and Food Sciences, Editor (2010 to 2014)
Psychiatry and Clinical Neurosciences, Editor (2012 to present)
Journal of Orthopaedic Science, Editor (2017 to present)

Awards:

Japan Osteoporosis Society. The 5th Morii Award (2010)
American Diabetes Association's 72nd Scientific Sessions. Young Investigator Travel Grant (2012)
Japan Osteoporosis Society. The 11th Kenkyu-Shourei Award (2012)
Japan Osteoporosis Society. The 7th Morii Award (2012)
Japanese Society of Applied Statistics. Best Paper Award (2015)
The Institute of Statistical Mathematics. The 3th Fujita Award (2015)
Kyoto University. Best Teacher Award (2015)

Publication**Original contribution****2017**

1. Bhoo-Pathy NT, Inaida S, **Tanaka S**, Taib NA, Yip CH, Saad M, Kawakami K, Bhoo-Pathy N. Impact of adjuvant chemotherapy on survival of women with T1N0M0, hormone receptor negative breast cancer. *Cancer Epidemiol.* 2017 Mar 31;48:56-61.
2. Chen H, Shinzawa M, Tokumasu H, **Tanaka S**, Kawakami K. Short sleep and risk of proteinuria in 3-year-olds in Japan: a population-based cohort study. *Sleep Med* 2017, in press.

3. Fuji H, Hatano E, Iguchi K, Yamanaka K, Yoh T, Ikeno Y, Seo S, Taura K, Yasuchika K, **Tanaka S**, Ishii H, Kobayashi M, Ueno K, Uemoto S. Phase I clinical trial of olprinone in liver surgery. *Surg Today*. 2017 Aug;47(8):918-27.
4. Fujihara K, Igarashi R, Matsunaga S, Matsubayashi Y, Yamada T, Yokoyama H, **Tanaka S**, Shimano H, Maegawa H, Yamazaki K, Kawai K, Sone H. Comparison of baseline characteristics and clinical course in Japanese patients with type 2 diabetes among whom different types of oral hypoglycemic agents were chosen by diabetes specialists as initial monotherapy (JDDM 42). *Medicine (Baltimore)*. 2017 Feb;96(7):e6122.
5. Furukawa TA, Weitz ES, **Tanaka S**, Hollon SD, Hofmann SG, Andersson G, Twisk J, DeRubeis RJ, Dimidjian S, Hegerl U, Mergl R, Jarrett RB, Vittengl JR, Watanabe N, Cuijpers P. Initial severity of depression and efficacy of cognitive-behaviour therapy: An individual-participant data meta-analysis of pill-placebo-controlled trials. *Br J Psychiatry*. 2017 Mar;210(3):190-6.
6. Hiroi S, Sugano K, **Tanaka S**, Kawakami K. Impact of health insurance coverage for Helicobacter pylori gastritis on the trends in eradication therapy in Japan: retrospective observational study and simulation study based on real-world data. *BMJ Open*. 2017 Jul 31;7(7):e015855.
7. Horikawa C, Yoshimura Y, Kamada C, **Tanaka S**, Tanaka S, Matsunaga S, Hanyu O, Araki A, Ito H, Tanaka A, Ohashi Y, Akanuma Y, Sone H. Is the proportion of carbohydrate intake associated with the incidence of diabetes complications?: analysis of the Japan Diabetes Complications Study. *Nutrients* 2017 Feb 6;9(2).
8. Imai T, **Tanaka S**, Kawakami K, Miyazaki T, Hagino H, Shiraki M for the A-TOP research group. Health state utility values and patient-reported outcomes before and after vertebral and non-vertebral fractures in an osteoporosis clinical trial. *Osteoporos Int*. 2017 Jun;28(6):1893-901.
9. Imanaka T, Sato I, **Tanaka S**, Kawakami K. Predictive factors for the placebo effect in clinical trials for dry eye: A pooled analysis of three clinical trials. *Br J Ophthalmol* 2017, in press.
10. Iwasaku M, Shinzawa M, **Tanaka S**, Kimachi K, Kawakami K. Clinical characteristics of adrenal crisis in adult population with and without predisposing chronic adrenal insufficiency: a retrospective cohort study. *BMC Endocr Disord*. 2017 Sep 11;17(1):58.
11. Kimura T, Takeuchi M, Imai T, **Tanaka S**, Kawakami K; Neonatal Research Network of Japan. Neurodevelopment at 3 years in neonates born by vaginal delivery versus Cesarean section at <26 weeks of gestation: Retrospective analysis of a nationwide registry in Japan. *Neonatology*. 2017 Jul 14;112(3):258-66.
12. Kinoshita T, Tokumasu H, **Tanaka S**, Kramer A, Kawakami K. Policy implementation for methicillin-resistant *Staphylococcus aureus* in seven European countries: a comparative

analysis from 1999 to 2015. *J Mark Access Health Policy*. 2017 Jul 26;5(1):1351293.

13. Kodama S, Fujihara K, Ishiguro H, Horikawa C, Ohara N, Yachi Y, **Tanaka S**, Shimano H, Kato K, Hanyu O, Sone H. Unstable body weight and incident type 2 diabetes mellitus - A meta-analysis. *J Diabetes Investig*. 2017 Jul;8(4):501-9.
14. Kodama S, Fujihara K, Ishiguro H, Horikawa C, Ohara N, Yachi Y, **Tanaka S**, Shimano H, Kato K, Hanyu O, Sone H. Quantitative relationship between cumulative risk alleles based on genome-wide association studies and type 2 diabetes mellitus: A systematic review and meta-analysis. *J Epidemiol*. 2017, published online.
15. Matsunaga S, **Tanaka S**, Fujihara K, Hanyu O, Haneda M, Nakamura J, Akanuma Y, Ohashi Y, Yamada N, Sone H. Association between all-cause mortality and severity of depressive symptoms in patients with type 2 diabetes: analysis from the Japan Diabetes Complications Study (JDCS). *J Psychosom Res*. 2017 Aug;99:34-9.
16. Minakata K, **Tanaka S**, Tamura N, Yanagi S, Ohkawa Y, Okonogi S, Kaneko T, Usui A, Abe T, Shimamoto M, Takahara Y, Yamanaka K, Yaku H, Sakata R. Comparison of long-term outcomes between mechanical and bioprosthetic valves in the aortic position: a propensity score analysis. *Circ J* 2017, in press.
17. Miyamoto Y, Shinzawa M, **Tanaka S**, Tanaka-Mizuno S, Kawakami K. Perioperative steroid use for tonsillectomy and its association with reoperation for post-tonsillectomy hemorrhage: a retrospective cohort study. *Anesthesia & Analgesia* 2017, in press.
18. Moritake H, **Tanaka S**, Nakayama H, Miyamura T, Iwamoto S, Shimada A, Terui K, Saito A, Shiba N, Hayashi Y, Tomizawa D, Taga T, Goto H, Hasegawa D, Horibe K, Mizutani S, Adachi S. Outcome of relapsed core binding factor acute myeloid leukemia in children: A result from the Japanese Pediatric Leukemia/Lymphoma Study Group (JPLSG) AML-05R study. *Pediatr Blood Cancer*. 2017 Oct;64(10).
19. Moriya T, **Tanaka S**, Sone H, Ishibashi S, Matsunaga S, Ohashi Y, Akanuma Y, Haneda M, Katayama S. Patients with type 2 diabetes having higher glomerular filtration rate showed rapid renal function decline followed by impaired glomerular filtration rate: Japan Diabetes Complications Study. *J Diabetes Complications*. 2017 Feb;31(2):473-8.
20. Nakayama H, Tomizawa D, **Tanaka S**, Iwamoto S, Shimada A, Saito A, Yamashita Y, Moritake H, Terui K, Taga T, Matsuo H, Kosaka Y, Koh K, Hosoi H, Kurosawa H, Isoyama K, Horibe K, Mizutani S, Adachi S. Fludarabine, cytarabine, G-CSF and idarubicin for children with relapsed AML. *Pediatrics Int* 2017, in press.
21. Nakayama N, Imanaka Y, Okuno Y, Kato G, Kuroda T, Goto R, **Tanaka S**, Tamura H, Fukuhara S, Fukuma S, Muto M, Yanagita M, Yamamoto Y, on behalf of BiDAME. Analysis of the evidence-practice gap to facilitate proper medical care for the elderly: Investigation, using Databases, of Utilization Measures for National Database of Health Insurance Claims and

Specific Health Checkups of Japan (NDB). Environ Health Prev Med 2017;22:51.

22. Noma H, **Tanaka S**. Analysis of case-cohort designs with binary outcomes: Improving efficiency using whole-cohort auxiliary information. Stat Method Med Res 2017;26(2):691-706.
23. Noma H, **Tanaka S**, Matsui S, Cipriani A, Furukawa TA. Quantifying indirect evidence in network meta-analysis. Stat Med 2017; 36(6):917-27.
24. Ogawa Y, Furukawa TA, Takeshima N, Hayasaka Y, Atkinson LZ, **Tanaka S**, Cipriani A, Salanti G. Efficacy of antidepressants over placebo is similar in two-armed versus three- or more-armed randomized placebo-controlled trials. Int Clin Psychopharmacol 2017, in press.
25. Okuda Y, Taura K, Yoshino K, Ikeno Y, Nishio T, Yamamoto G, Tanabe K, Koyama Y, Hatano E, **Tanaka S**, Uemoto S. Usefulness of mac-2 binding protein glycosylation isomer for prediction of posthepatectomy liver failure in patients with hepatocellular carcinoma. Ann Surg. 2017 Jun;265(6):1201-8.
26. Ono F, **Tanaka S**, Nakao YM, Kawakami K. Utilization of anticoagulant and antiplatelet agents among patients with atrial fibrillation undergoing percutaneous coronary intervention—A retrospective cohort study using a nationwide claims database in Japan—. Circ J 2017, in press.
27. Shinzawa M, **Tanaka S**, Tokumasu H, Takada D, Tsukamoto T, Yanagita M, Kawakami K. Maternal smoking during pregnancy, household smoking after the child's birth, and childhood proteinuria at age 3 years. Clin J Am Soc Nephrol. 2017 Feb 7;12(2):253-60.
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29. **Tanaka S**. Simulation study of confounder selection procedures using the Hoffman's collapsibility test. Biostat Biometrics Open Acc J 2017;2(3):555590.
30. **Tanaka S**, Matsuyama Y, Ohashi Y. Validation of surrogate endpoints in cancer clinical trials via principal stratification with an application to a prostate cancer trial. Stat Med. 2017 Aug 30;36(19):2963-77.
31. **Tanaka S**, Miyazaki T, Uemura Y, Miyakawa N, Gorai I, Nakamura T, Fukunaga M, Ohashi Y, Ohta H, Mori S, Hagino H, Hosoi T, Sugimoto T, Itoi E, Orimo H, Shiraki M. Comparison of concurrent treatment with vitamin K2 and risedronate compared to risedronate alone in patients with osteoporosis: Japanese Osteoporosis Intervention Trial-03 (JOINT-03). J Bone Miner Metab. 2017 Jul;35(4):385-95.
32. Tomizawa D, **Tanaka S**, Kondo T, Hashii Y, Arai Y, Kudo K, Taga T, Fukuda T, Goto H, Inagaki J, Koh K, Ohashi K, Ozawa Y, Inoue M, Kato K, Tanaka J, Atsuta Y, Adachi S, Ishida

- H. Allogeneic hematopoietic stem cell transplantation for adolescents and young adults with acute myeloid leukemia. Biol Blood Marrow Transplant. 2017 Sep;23(9):1515-22.
- 33. Urano T, Shiraki M, Kuroda T, **Tanaka S**, Uenishi K, Inoue S. Preventive effects of raloxifene treatment on age-related weight loss in postmenopausal women. J Bone Miner Metab. 2017 Jan;35(1):108-13.
 - 34. Urano T, Shiraki M, Kuroda T, **Tanaka S**, Uenishi K, Inoue S. Bisphosphonates prevent age-related weight loss in Japanese postmenopausal women. J Bone Miner Metab 2017, in press.
 - 35. Urano T, Shiraki M, Kuroda T, **Tanaka S**, Urano F, Uenishi K, Inoue S. Low serum osteocalcin concentration is associated with incident type 2 diabetes mellitus in Japanese women. J Bone Miner Metab 2017, in press.
 - 36. Wilunda C, **Tanaka S**, Esamai F, Kawakami K. Prenatal anemia control and anemia in children aged 6-23 months in sub-Saharan Africa. Matern Child Nutr. 2017 Jul;13(3).
 - 37. Wilunda C, Yoshida S, Blangiardo M, Betran AP, **Tanaka S**, Kawakami K. Caesarean delivery and anaemia risk in children in 45 low- and middle-income countries. Matern Child Nutr. 2017, in press.
 - 38. Yonekura H, Ide K, Seto K, Kawasaki Y, **Tanaka S**, Nahara I, Takeda C, Kawakami K. Preoperative pulmonary function tests before low-risk surgery in Japan: a retrospective cohort study using a claims database. J Anesth 2017, in press.

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- 39. Fujihara K, Hanyu O, Heianza Y, Suzuki A, Yamada T, Yokoyama H, **Tanaka S**, Yagyu H, Shimano H, Atsunori A, Yamazaki K, Kawai K, Sone H. Comparison of clinical characteristics in patients with type 2 diabetes among whom different antihyperglycemic agents were prescribed as monotherapy or combination therapy by diabetes specialists (JDDM 35). J Diabetes Investig. 2016 Mar;7(2):260-9.
- 40. 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. Clin J Pain. 2016 Aug;32(8):719-25.
- 41. Heianza Y, Hara S, Saito K, Tsuji H, **Tanaka S**, Kodama S, Kobayashi T, Arase Y, Sone H. Assessment of kidney dysfunction with cystatin C- and creatinine-based estimated glomerular filtration rate and predicting type 2 diabetes: Toranomon Hospital Health Management Center Study 21. Diabetes Res Clin Pract. 2016 Mar;113:60-8.
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- 43. Kanematsu A, Higuchi Y, **Tanaka S**, Hashimoto T, Nojima M, Yamamoto S. Multivariate

analysis of the factors associated with sexual intercourse, marriage, and paternity of hypospadias patients. *J Sex Med.* 2016 Oct;13(10):1488-95.

44. Kodama S, Fujihara K, Ishiguro H, Horikawa C, Ohara N, Yachi Y, **Tanaka S**, Shimano H, Kato K, Hanyu O, Sone H. Meta-analytic research on the relationship between cumulative risk alleles and risk of type 2 diabetes mellitus. *Diabetes Metab Res Rev.* 2016 Feb;32(2):178-86.
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46. Kumagai M, Marui A, Tabata Y, Takeda T, Yamamoto M, Yonezawa A, **Tanaka S**, Yanagi S, Ito-Ihara T, Ikeda T, Murayama T, Teramukai T, Katsura T, Matsubara K, Kawakami K, Yokode M, Shimizu A, Sakata R. Safety and efficacy of sustained release of basic fibroblast growth factor using gelatin hydrogel in patients with critical limb ischemia. *Heart Vessels* 2016 May;31(5):713-21.
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48. Miyake KK, Nakamoto Y, Mikami Y, **Tanaka S**, Higashi T, Tadamura E, Saga T, Minami S, Togashi K. The predictive value of preoperative 18F-fluorodeoxyglucose PET for postoperative recurrence in patients with localized primary gastrointestinal stromal tumour. *Eur Radiol.* 2016 Dec;26(12):4664-74.
49. Nishio T, Taura K, Koyama Y, Tanabe K, Yamamoto G, Okuda Y, Ikeno Y, Seo S, Yasuchika K, Hatano E, Okajima H, Kaido T, **Tanaka S**, Uemoto S. Prediction of posthepatectomy liver failure based on liver stiffness measurement in patients with hepatocellular carcinoma. *Surgery.* 2016 Feb;159(2):399-408.
50. Sato A, Hamada S, Urashima Y, **Tanaka S**, Okamoto H, Kawakami K. The effect of false-positive results on subsequent participation in chest X-ray screening for lung cancer. *J Epidemiol.* 2016 Dec 5;26(12):646-53.
51. **Tanaka S**, Hagino H, Ishizuka A, Miyazaki T, Yamamoto T, Hosoi T. Validation study of claims-based definitions of suspected atypical femoral fractures using clinical information. *Jpn Pharmacoepidemiol* 2016; 21(1): 13-9.
52. **Tanaka S**, Tanaka S, Iimuro S, Ishibashi S, Yamashita H, Moriya T, Katayama S, Akanuma Y, Ohashi Y, Yamada N, Araki A, Ito H, Sone H; Japan Diabetes Complications Study Group. Maximum BMI and microvascular complications in a cohort of Japanese patients with type 2

diabetes: the Japan Diabetes Complications Study. *J Diabetes Complications*. 2016 Jul;30(5):790-7.

53. Umeda K, Adachi S, **Tanaka S**, Miki M, Okada K, Hashii Y, Inoue M, Cho Y, Koh K, Goto H, Kajiwara R, Hyakuna N, Kato K, Morio T, Yabe H; Inherited Disease Working Group of the Japan Society for Hematopoietic Cell Transplantation. Comparison of second transplantation and donor lymphocyte infusion for donor mixed chimerism after allogeneic stem cell transplantation for nonmalignant diseases. *Pediatr Blood Cancer*. 2016 Dec;63(12):2221-9.
54. Wilunda C, **Tanaka S**, Putoto G, Tsegaye A, Kawakami K. Evaluation of a maternal health care project in South West Shoa Zone, Ethiopia: before-and-after comparison. *Reprod Health*. 2016 Aug 20;13(1):95.
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2015

56. Furukawa TA, Levine SZ, **Tanaka S**, Goldberg T, Samara M, Davis JM, Cipriani A, Leucht S. Initial severity and efficacy of antipsychotics for schizophrenia: Individual participant level analyses of six placebo-controlled studies. *JAMA Psychiatry*. 2015;72(1):14-2.
57. Guidance Development Review Committee, Working Group for Clinical Studies of Cancer Immunotherapy Working Group for Effector Cell Therapy, Working Group for CMC/Non-clinical Studies, Working Group for Cancer Vaccines and Adjuvants, Working Group for Anti-immune Checkpoint Therapy and Comprehensive Cancer Immunotherapy, and **Biostatistics Subcommittee**. 2015 Guidance on cancer immunotherapy development in early-phase clinical studies. *Cancer Sci* 2015 December; 106(12): 1761-71.
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60. Himoto Y, Fujimoto K, Kido A, Baba T, **Tanaka S**, Morisawa N, Koyasu S, Konishi I, Togashi K. Pretreatment mean apparent diffusion coefficient is significantly correlated with event-free survival in patients with FIGO stages Ib to IIIb cervical cancer. *Int J Gynecological Cancer* 2015 Jul;25(6):1079-85.
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- resection criteria in patients with hepatocellular carcinoma in terms of the incidence of posthepatectomy liver failure and long-term prognosis. *Dig Surg* 2015;32:344-51.
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 - 64. Marui A, Kimura T, Nishiwaki N, Komiya T, Hanyu M, Shiomi H, Tanaka S, Sakata R; CREDO-Kyoto PCI/CABG Registry Cohort-2 Investigators. Three-year outcomes after percutaneous coronary intervention and coronary artery bypass grafting in patients with heart failure: from the CREDO-Kyoto percutaneous coronary intervention/coronary artery bypass graft registry cohort-2. *Eur J Cardiothorac Surg*. 2015 Feb;47(2):316-21.
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