

17. 研究結果の発表

主たる公表論文は英文誌に投稿する。

プロトコールで規定された主たる解析と最終解析以外の発表に際しては、事前に効果・安全性評価委員会の承認を得ることが必要である。ただし、研究代表者または研究事務局による、研究のエンドポイントの解析結果を含まない、研究の紹介目的の学会・論文(総説)発表、および登録終了後の、患者背景の分布や安全性データの学会・論文発表については、効果・安全性評価委員会の承認は不要であり、研究グループ代表者および JCOG データセンター長の了承を得て行うことができる。

原則として、研究結果の主たる公表論文の著者は筆頭を研究事務局とし、以下、研究代表者、データセンターの統計担当(公表のための解析を行った時点での担当者 1 名)、放射線治療研究事務局、グループ代表者の順とする。それ以下は、論文の投稿規定による制限に従って、登録数の多い順に施設研究責任者または施設コーディネーターを施設毎に選び共著者とする。

すべての共著者は投稿前に論文内容を review し、発表内容に合意した者のみとする。内容に関して、議論にても合意が得られない場合、研究代表者はグループ代表者の了承の上で、その研究者を共著者に含めないことができる。

学会発表は複数回に及ぶ可能性があるため、研究事務局、研究代表者、登録の多い施設の研究責任者または施設コーディネーターの中から、持ち回りで発表を行うこととする。発表者は研究代表者がグループ代表者の了承を得て決定する。ただし、学会発表に際しては、発表準備および発表内容について研究事務局が責任を持ち、原則としてデータセンターとの連絡は研究事務局が行う。研究事務局以外の発表者が、研究事務局と JCOG データセンター長の了承なく、直接データセンターから集計・解析結果を受け取ることはできない。

18. 参考文献

1. <http://ganjoho.ncc.go.jp/professional/statistics/statistics.html>
2. 日本乳癌学会編:臨床・病理 乳癌取り扱い規約[第16版].金原出版 2008.
3. Early Breast cancer trialists' Collaborative Group. Effects of radiotherapy and surgery in early breast cancer. An overview of randomized trials. *N Engl J Med* 1995; 333:1444-55.
4. Voogd AC, Nielsen M, Peterse JL, Blichert-Toft M, Bartelink H, Overgaard M, et al. Differences in risk factors for local and distant recurrence after breast-conserving therapy or mastectomy for stage I and II breast cancer: Pooled results of two large European randomized trials.*J Clin Oncol* 2001;19:1688-1697.
5. 日本乳癌学会編:乳癌診療ガイドライン. 2.外科療法 金原出版 2008
6. Carter CL, Allen C, Henson DE. Relation of tumor size, Relation of tumor size, and survival in 24,740 breast cancer cases. *Cancer* 1989; 63:181-7.
7. Goldhirsch A, Wood WC, Gelber RD, Coates AS, Thurlimann B, Senn H-J and Panel members. Progress and promise: highlights of the international expert consensus on the primary therapy of early breast cancer 2007. *Ann Oncol* 2007; 18: 1133-44.
8. Ernster VL, Barclay J, Kerlikowske K, Wilkie H, Ballard-Barbash R. Mortality among women with ductal carcinoma in situ of the breast in the population-based surveillance. Epidemiology and end results program. *Arch Intern Med* 2000;160:953-8
9. http://www.nccn.org/professionals/physician_gls/PDF/breast.pdf
10. 厚生労働科学研究費補助金「がん臨床研究事業」標準的な乳房温存療法の実施要項の研究班編:乳房温存療法ガイドライン<医療者向け>. 金原出版 2005
11. Fisher B, Anderson S, Bryant J, Margolese RG, Deutsch M, Fisher ER, et al. Twenty-year follow-up of a randomized trial comparing total mastectomy, lumpectomy, and lumpectomy plus irradiation for the treatment of invasive breast cancer. *N Engl J Med* 2002; 347: 1233-41.
12. Ohsumi S, Sakamoto G, Takashima S, Koyama H, Shin E, Suemasu K, et al. Long-term results of breast-conserving treatment for early-stage breast cancer in Japanese women from multicenter investigation. *Jpn J Clin Oncol* 2003; 33: 61-7.
13. Veronesi U, Paganelli G, Viale G, Luini A, Zurrida S, Galimberti V, et al. A randomized comparison of sentinel-node biopsy with routine axillary dissection in breast cancer. *N Engl J Med* 2003; 349:546-53.
14. Bartelink H, Horiot J-C, Poortmans P, Struikmans H, Van den Bogaert W, Barillot I, et al. Recurrence rates after treatment of breast cancer with standard radiotherapy with or without additional radiation. *N Engl J Med* 2001; 345:1378-87.
15. Malmstrom P, Holmberg L, Anderson H, Mattsson J, Jonsson P-E, Tennvall-Nittby L, et al. Breast conservation surgery, with and without radiotherapy, in women with lymph node-negative breast cancer: a randomized clinical trial in a population with access to public mammography screening. *Eur J cancer* 2003; 39:1690-7.
16. Liljegren G, Holmberg L, Bergh J, Lindgren A, Tabar L, Nordgren HO, et al. 10-year results after sector resection with or without postoperative radiotherapy for stage I breast cancer: a randomized trial. *J Clin Oncol* 1999; 17: 2326-33.
17. Renton SC, Gazet JC, Ford HT, Corbishley C, Sutcliffe R. The importance of the resection margin in conservative surgery for breast cancer. *Eur J Surg Oncol* 1996; 22:17-22.
18. Veronesi U, Salvadori B, Luini A, Greco M, Saccozi R, del Vecchio M, et al. Breast conservation is a safe method in patients with small cancer of the breast. Long-term results of three randomized trials on 1,973 patients. *Eur J Cancer* 1995; 31: 1574-9.
19. Forrest AP, Stewart HJ, Everington D, Prescott RJ, McArdle CS, Harnett AN, et al. Randomized controlled trial of conservation therapy for breast cancer: 6-year analysis of Scottish trial. *Lancet* 1996; 348: 708-13.
20. Clark RM, Whelan T, Levine M, Roberts R, Willan A, McCulloch P, et al. Randomized clinical trial of breast irradiation following lumpectomy and axillary dissection for node-negative breast cancer: an update. *J Natl Cancer Inst* 1996; 88: 1659-64.
21. Early Breast Cancer Trialists' Collaborative Group. Favourable and unfavourable effects on long-term survival

- of radiotherapy for early breast cancer: an overview of the randomized trials. *Lancet* 2000; 355: 1757–70.
22. Early Breast Cancer Trialists' Group. Effects of radiotherapy and of differences in the extent of surgery for early breast cancer on local recurrence and 15-year survival: an overview of the randomized trials. *Lancet* 2005; 366: 2087–106.
 23. 日本乳癌学会編: 乳癌診療ガイドライン. 3.放射線療法 金原出版 2008
 24. 日本乳癌学会編: 乳癌診療ガイドライン. 1.薬物療法 金原出版 2007
 25. National Institute of health Consensus Development Panel. National Institutes of Health Consensus Development Conference statement: adjuvant therapy for breast cancer, November 1–3, 2000. *N Natl Cancer Inst* 2001; 93:979–89.
 26. ATAC trialists' group. Results of the ATAC (arimidex, tamoxifen, alone or in combination) trial after completion of 5 years' adjuvant treatment for breast cancer. *Lancet* 2005; 365: 60–2.
 27. Dorr W, Bertmann S, Herrmann T. Radiation induced lung reactions in breast cancer therapy. Modulating factors and consequential effects. *Strahlen Onkol* 2005; 181: 567–73.
 28. Harris EER, Christensen VJ, Hwang W-T, Fox K, Solin LJ. Impact of concurrent versus sequential tamoxifen with radiation therapy in early-stage breast cancer patients undergoing breast conservation treatment. *J Clin Oncol* 2005; 23:11–6.
 29. Pierce LJ, Hutchins LF, Green SR, Lew DL, Gralow JR, Livingston RB, et al. Sequencing of tamoxifen and radiotherapy after breast-conserving surgery in early-stage breast cancer. *J Clin Oncol* 2005; 23:198–203.
 30. Japanese Breast Cancer Society. Results of Questionnaires Concerning Breast Cancer Surgery in Japan 1980–2003. *Breast Cancer* 2005 12:1–2.
 31. Froud PJ, Mates D, Jackson JSH, Phillips N, Andersen S, Jackson SM, et al. Effect of time interval between breast-conserving surgery and radiation therapy on ipsilateral breast recurrence. *Int J Radiat Oncol Biol Phys* 2000; 46:363–72
 32. Olivotto IA, Weir LM, Kim-Sing C, Bajdik CD, Trevisan CH, Doll CM, et al. Late cosmetic results of short fractionation for breast conservation. *Radiother Oncol* 1996; 41: 7–13.
 33. Shelley W, Brundage M, Hayter C, Paszat L, Zhou S, Mackillop W. A shorter fractionation schedule for postlumpectomy breast cancer patients. *Int J Radiat Oncol Biol Phys* 2000; 47:1219–28
 34. Ash DV, Benson EA, Sainsbury JR, Round C, Head C. Seven-year follow-up on 334 patients treated by breast conserving surgery and short course radical postoperative radiotherapy: a report of the Yorkshire Breast Cancer Group. *Clin Oncol* 1995; 7: 93–6.
 35. Whelan T, MacKenzie R, Julian J, Levine M, Shelly W, Grimard L, et al. Randomized trial of breast irradiation schedules after lumpectomy for women with lymph node-negative breast cancer. *J Natl Cancer Inst* 2002; 94:1143–50.
 36. 釋舎竜司、吉田賢史、平塚純一、今城吉成、園尾博司. 当院における乳房温存術後の放射線療法: 42.56Gy/16fr 照射法の初期検討。2006; 日医放 supplement 第 65 回学術集会抄録集 306.
 37. 今井敦, 加賀美芳和, 角美奈子, 伊藤芳紀, 藤本直子, 池田恢, 他. 乳房温存療法での短期放射線治療の安全性と有効性についての研究-有害事象等について -. *J Jpn Soc Ther Radiol Oncol* 2005; 17 Supplement: 156
 38. Yarnord J, Ashton A, Bliss J, Homewood J, Harper C, Hanson J, et al. Fractionation sensitivity and dose response of late adverse effects in the breast after radiotherapy for early breast cancer: long-term results of a randomized trial. *Raiother Oncol* 2005; 75:9–17.
 39. Van Limbergen E, Rijnders A, van der Schueren E, van der Shaueren E, Lerut T, Christiaens R. Cosmetic evaluation of breast conserving treatment for mammary cancer. 2. A quantitative analysis of the influence of radiation dose, fractionation schedules and surgical treatment techniques on cosmetic results. *Radiother Oncol* 1989; 16: 253–67.
 40. Kurtz JM. The clinical radiobiology of breast cancer radiotherapy. *Radiother Oncol* 2005; 75: 6–8.
 41. Steel GG, Deacon JM, Duchese GM. The dose-rate effect in human tumour cells. *Radiother Oncol* 1987; 9: 299–310.
 42. Williams MV, Denekamp J, Fowler JF. A review of α/β ratios for experimental tumours: Implications for clinical studies of altered fractionation. *Int J Radiat Oncol Biol Phys* 1985; 11: 87–96.

43. Matthews JHL, Meeker BE, Chapman JD. Response of human tumor cell lines in vitro to fractionated irradiation. *Int J Radiat Biol Oncol Phys* 1989; 16: 133-138.
44. Yamada Y, Ackerman I, Franssen E, MacKenzie RG, Thomas G. Does the dose fractionation schedule influence local control of adjuvant radiotherapy for early stage breast cancer? *Int J Radiat Oncol Biol Phys* 1999; 44: 99-104.
45. Owen JR, Ashton A, Bliss JM, Homewood J, Harper C, Hanson J, et al. Effect of radiotherapy fraction size on tumour control in patients with early-stage breast cancer after local tumour excision: long-term results of a randomized trial. *Lancet Oncol* 2006; 7: 467-71.
46. Anscher MS, Jones P, Prosnitz LR, Blackstock W, Herbert M, Reddick R, et al. Local failure and margin status in early-stage breast carcinoma treated with conservation surgery and radiation therapy. *Ann Surg* 1993; 218: 22-8
47. Park CC, Mitsumori M, Nixon A, Recht A, Connolly J, Gelman R, et al. Outcome at 8 years after breast-conserving surgery and radiation therapy for invasive breast cancer: influence of margin status and systemic therapy on local recurrence. *J Clin Oncol* 2000; 18:1668-75.
48. Karasawa K, Mitsumori M, Yamauchi C, Gomi K, Kataoka M, Uematsu T, et al. Treatment outcome of breast-conserving therapy in patients with positive or close resection margins: Japanese multi survey for radiation dose effect. *Breast Cancer* 2005; 12: 91-8.
49. Romestaing P, Lehingue Y, Carrie C, Coquard R, Mantbarbon X, Ardiet J-M, et al. Role of a 10Gy Boost in the conservative treatment of early breast cancer: Results of a randomized clinical trial in Lyon, France. *J Clin Oncol* 1997; 15: 963-8.
50. Bartelink H, Horiot J-C, Poortmans PM, Struinkmans H, Van den Bogaert W, Fourquet A, et al. Impact of a higher radiation dose on local control and survival in breast-conserving therapy of early breast cancer: 10-year results of the randomized boost versus no boost EORTC 22881-10882 trial. *J Clin Oncol* 2007; 25: 3259-65.
51. Pierce SM, Recht A, Lingos TI, Abner A, Vicini F, Silver B, et al. Long-term radiation complications following conservative surgery (CS) and radiation therapy (RT) in patients with early stage breast cancer. *Int J Radiat Oncol Biol Phys* 1992; 23:915-23.
52. LENT SOMA Tables: Radiother Oncol 1995;35: 17-60.
53. <http://www.jcog.jp>: 有害事象共通用語規準 v3.0 日本語訳 JCOG/JSCO 版—2007年3月8日
54. Olivetto IA, Rose MA, Osteen RT, Love S, Cady B, Silver B, et al. Late cosmetic outcome after conservative surgery and radiotherapy: analysis of causes of cosmetic failure, *Int J Radiat Oncol Phys* 1989; 17:747-53.
55. Winchester DP, Cox JD: Standards for breast-conservation treatment. *CA Cancer J Clin* 1992; 42:134-162.
56. The STRAT Trial Group: The UK Standardisation of Breast Radiotherapy (START) Trial B of radiotherapy hypofractionation for treatment of early breast cancer: a randomized trial. *Lancet* 2008; 1098-107.
57. Smith I, Proctor M, Gelber RD, Guillaume S, Feireislova A, Dowsett M, et al: 2-year follow-up trastuzumab after adjuvant chemotherapy in HER2-positive breast cancer: a randomized controlled trial. *Lancet* 2007;369: 29-36.
58. Vicini FA, Goldstein NS, Pass H, Lestin L: Use of pathologic factors to assist in establishing adequacy of excision before radiotherapy in patients treated with breast-conserving therapy. *Int J Radiat Oncol Biol Phys* 2004, 60; 86-94.
59. Rakha EA, EL-Sayed ME, Lee AHS, Elston CW, Grainge MJ, Hodi Z, et al.: Prognostic significance of Nottingham histologic grade in invasive breast cancer. *J Clin Oncol* 2008; 26; 3153-3158.
60. Solin LJ, Fowbe BL, Schultz DJ, et al: The significance of the pathology margins of the tumor excision on the outcome of patients treated with definitive irradiation for early stage breast cancer. *Int J Radiat Oncol Biol Phys* 1991, 21: 279-990.
61. Mitsumori M, Hiraoka M, Negoro Y, Yamauchi C, Shikama N, Sasaki S, et al: The patterns of care study for breast-conserving therapy in Japan: analysis of process survey from 1995 to 1997. *Int J Radiat Oncol Biol Phys*. 2005, 62: 1048-1054.
62. Wratten C, Kilmurray J, Nash S, Seldon M, Hamilton CS, O'Brien P, et al: Fatigue during breast radiotherapy and its relationship to biological factors. *Int J Radiat Oncol Biol Phys*. 2004, 59: 160-167.
63. Back M, Guerrieri M, Warten C, Steigler A: Impact of radiation therapy on acute toxicity in breast

- conservation therapy for early breast cancer. *Clin Oncol* 2004, 16: 12-16.
64. Whelan TJ, Levine M, Julian J, Kirkbride P, Skingley P: The effects of radiation therapy on Quality of life women with breast carcinoma. *Cancer* 2000, 88: 260-266.
 65. Lingos TI, Recht A, Vicini F, Abner A, Silver B, Harris JR: Radiation pneumonitis in breast cancer patients treated with conservative surgery and radiation therapy. *Int J Radiat Oncol Biol Phys.* 1999, 21: 355-360.
 66. Bosch AM, Kessells AG, Beets GL, Rupa JD, Koster D, van Engeleshoven JM, et al.: Preoperative estimation of the pathological breast tumor size by physical examination, mammography and ultrasound: a prospective study on 105 invasive tumors. *Eur J Radiol* 2003, 48:285-92.
 67. Snelling JD, Abdullah N, Brown G, King DM, Moskovic E, Gui GP. Measurement of tumour size in case selection for breast cancer therapy by clinical assessment and ultrasound. *Eur J Surg Oncol* 2004, 30:5-9.
 68. Kurtz JM, Jacquemier J, Amarlic R, Brandone H, Ayme Y, Hans D, et al. Breast-conserving therapy for macroscopically multiple cancers. *Ann Surg* 1990, 212:38-44.
 69. Wilson LD, Beinfield M, McKhann CF, Haffty BG. Conservative surgery and radiation in the treatment of synchronous ipsilateral breast cancers. *Cancer* 1993. 72:137-42.
 70. Leopold KA, Recht A, Schnitt SJ, et al. Results of conservative surgery and radiation therapy for multiple synchronous cancers of one breast. *Int J Radiat Oncol Biol Phys* 1989, 16:11-16.

19. 附表Appendix

- ・ 説明文書・同意書
- ・ 体表面積表
- ・ 毒性規準 (CTCAE v3.0)
- ・ CRF 一式

