

Breast-conserving therapy

As systemic therapy becomes more effective, the use of NAC has increased, enabling more patients to potentially undergo breast-conserving therapy (BCT). There are many questions, however, that remain unanswered. While NAC has been shown to increase the rate of BCT in clinical trials²⁹, it is unknown how NAC is being used to improve the use of BCT in general community practice and what the surgical outcomes (including margins and re-excision rates) are for BCS after NAC compared to primary BCS. In **chapter 5** we, therefore, analyzed national trends in the use of BCS after NAC in early breast cancer and the surgical outcomes after NAC in the Netherlands.

Axillary lymph-node management

In **chapter 6**, we investigate the implementation process in the Netherlands of omitting ALND in cT1-2N0M0 sentinel node-positive breast cancer patients after the publication of the ACOSOG-Z0011 and AMAROS trial. Previously, performing an axillary lymph node dissection (ALND) was the standard of care for all non-metastatic breast cancer patients. However, this treatment is associated with significant long-term problems such as pain, arm swelling (lymphedema), restricted shoulder movement, and sensory changes in the arm and hand.^{30,31} In the early nineties, sentinel lymph node biopsy (SLNB) was introduced as an accurate and less invasive axillary staging procedure, omitting the need for an axillary lymph node dissection in cT1-2N0M0 sentinel node-negative breast cancer patients.^{32,33} The additional value of ALND in cT1-2N0M0 breast cancer patients with 1-2 detected *positive* sentinel lymph nodes was further questioned in two important randomized controlled trials; the ACOSOG-Z0011 trial and the AMAROS trial. The main objective of ACOSOG Z0011 was to compare locoregional recurrence-free survival for these patient population managed with or without ALND and no axillary irradiation.³⁴ The AMAROS trial evaluated whether regional control was comparable between ALND and axillary radiation therapy in cT1-2N0M0 breast cancer patients with a positive sentinel lymph node.³⁵ The results of these trials indicate that in case of a positive sentinel node, both ALND and axillary radiotherapy provide excellent and comparable axillary control in terms of disease-free and overall survival. This is illustrated by the 2012 Dutch breast cancer guideline, suggesting omission of ALND in cT1-2N0 breast cancer patients with a maximum of two positive sentinel nodes treated with breast-conserving treatment and adjuvant systemic therapy.

II. Quality assurance in breast implant surgery

Breast implants are used routinely for purposes of breast reconstruction and breast augmentation. Since the introduction five decades ago, problems with a variety of breast implants have emerged with direct consequences for the patients' health. Plastic surgeons worldwide reacted through campaigning for auditing on long-term implant quality, surgeon performance and institutional outcomes in implant registries. Especially, the Poly Implant Prothèse (PIP) crisis^{36,37} and more recent reports on breast implant-associated anaplastic large cell lymphoma^{38,39} have raised awareness of the need for long-term follow-up and clinical registries for long-term safety reasons. Various reports e.g. by the European Union, the FDA and other stakeholders, stress the importance of a well-organized clinical registry including epidemiological data to assess the appropriateness and effectiveness of a specified clinical issue, whether it is an implantable device or care pathway.⁴⁰

The Dutch Breast Implant Registry (DBIR)

In the Netherlands, an estimated 30.000 implants are inserted annually. As an initiative of the Association of Plastic Surgeons of the Netherlands (NVPC), the Dutch Breast Implants Registry (DBIR) was instituted in April 2015, as a nation-wide audit to monitor breast implant quality and complications, independently from the industry. The main purpose of the DBIR is to enable benchmarking between hospitals and surgeons and to develop a 'track-and-trace system' with the implants and patients. Since the start of the DBIR in April 2015, all board-certified plastic surgeons are required to register their implants in the system and thousands of implants have been registered. Since 2016 registry of all sorts of medical implants is being required by the Dutch Health Inspectorate.

The dataset of the DBIR is based on the dataset constructed by the international Collaboration of Breast Registry Activities (ICOBRA).⁴¹ Patient data including indication for surgery, unique and descriptive implant data, operation details and data regarding surgical technique. Also, the reasons for revision or explantations are collected.

Chapter 7 gives an overview of which numbers and types of implants, patients and interventions have been registered in the Netherlands since April 2015.

The International Collaboration of Breast Registry Activities (ICOBRA)

In 2012, the International Collaboration of Breast Registry Activities (ICOBRA) was founded by the Australian Society of Plastic Surgeons to improve breast device registries by sharing datasets and connecting organizations from various countries all over the world.⁴¹ The members of ICOBRA include national plastic surgery societies or multidisciplinary breast implant registries of several countries, including Australia, Austria, Canada, France, Germany, Ireland, Italy, the Netherlands, New Zealand, South Africa, the United Kingdom, and the United States. Each country has an independent registry, but all are using largely similar datasets. Harmonization of data points and data definitions is key in order to compare and pool data from registries. Pooling is crucial to amplify the data and reduce the time needed to identify implants performing well and those associated with higher rates of adverse events, such as anaplastic lymphoma or capsular contraction. We, therefore, set out to identify and define an internationally agreed minimum core set of data points to be used by all breast device registries globally (**chapter 8**).

REFERENCES

1. Institute of Medicine Committee on Quality of Health Care in America. *Crossing the Quality Chasm: a New Health System for the 21st Century*. National Academies Press, National Academy of Sciences: Washington, 2011.
2. Donabedian, A. Quality of care: problems of measurement. II. Some issues in evaluating the quality of nursing care. *Am J Public Health Nations Health* 1969;59(10):1833-6.
3. Donabedian, A. The quality of care. How can it be assessed? *JAMA* 1988;260(12):1743-8.
4. Van Leersum NJ, Snijders HS, Henneman D, et al. The Dutch surgical colorectal audit. *Eur J Surg Oncol* 2013;39(10):1063-70.
5. Khuri SF, Daley J, Henderson W, et al. The Department of Veterans Affairs' NSQIP Peer-Controlled Program for the Measurement and Enhancement of the Quality of Surgical Care. *Ann of Surg* 1998;228(4):491-504.
6. Dreyer NA, Garner S. Registries for Robust Evidence. *JAMA* 2009;302(7):790-1.
7. The Dutch Institute for Clinical Auditing. Available at: <http://www.ichom.org/others/building-national-outcomes-registries-in-the-netherlands-dica/>
8. Jochems A, Schouwenburg MG, Leeneman B, et al. Dutch Melanoma Treatment Registry: quality assurance in the care of patients with metastatic melanoma in the Netherlands. *Eur J Cancer* 2017;72:156-165.
9. Ferlay J, Soerjomataram I, Dikshit R, et al. Cancer incidence and mortality worldwide: Sources, methods and major patterns in GLOBOCAN 2012. *Int J Cancer* 2015 Mar 1;136(5):359-86.
10. Netherlands Cancer Registry. Available at: <http://www.cijfersoverkanker.nl> [TNM 6th ed. 2003-2009].
11. Dutch national breast cancer guideline. Available at: <http://www.oncoline.nl/mam-macarcinoom> [Version 2.0, 2012].
12. van Bommel ACM, Spronk PER, Peeters MTFDV, et al. Clinical Auditing as an Instrument for Quality Improvement in Breast Cancer Care in the Netherlands: The National NABON Breast Cancer Audit. *J Surg Oncol* 2016;(June):1-7.
13. Vriens IJH, Keymeulen K, Lobbes MBI, et al. Breast magnetic resonance imaging use in patients undergoing neoadjuvant chemotherapy is associated with less mastectomies in large ductal cancers but not in lobular cancers. *Eur J Cancer* 2017;81:74-80.
14. Schreuder K, Bommel ACM Van, Ligt KM De, Maduro JH. Hospital organizational factors affect the use of immediate breast reconstruction after mastectomy for breast cancer in the Netherlands. *The Breast* 2017;34:96-102.
15. van Bommel AC, Mureau MA, Schreuder K, et al. Large variation between hospitals in immediate breast reconstruction rates after mastectomy for breast cancer in the. *Br J Plast Surg* 2017;70(2):215-21.
16. Spronk PER, van Bommel ACM, Sieseling S, et al. Variation in use of neoadjuvant chemotherapy in patients with stage III breast cancer: results of the Dutch national breast cancer audit. *The Breast* 2017;36:34-38.
17. Harris JR. *Diseases of the breast*. Philadelphia: Lippincott; 1995.
18. Fisher B, Brown A, Mamounas E, et al. Effect of preoperative chemotherapy on local-regional disease in women with operable breast cancer: findings from National Surgical Adjuvant Breast and Bowel Project B-18. *J Clin Oncol* 1997;15(7):2483-93.

19. Fisher B, Bryant J, Wolmark N, et al. Effect of preoperative chemotherapy on the outcome of women with operable breast cancer. *J Clin Oncol* 1998;16(8):2672–85.
20. Wolmark N, Wang J, Mamounas E, et al. Preoperative chemotherapy in patients with operable breast cancer: nine-year results from National Surgical Adjuvant Breast and Bowel Project B-18. *J Natl Cancer Inst Monogr* 2001;30:96–102.
21. Heys SD, Hutcheon AW, Sarkar TK, et al. Neoadjuvant docetaxel in breast cancer: 3-year survival results from the Aberdeen trial. *Clin Breast Cancer* 2002;3:69–74.
22. Cortazar P, Zhang L, Untch M, et al. Pathological complete response and long-term clinical benefit in breast cancer: the CTNeoBC pooled analysis. *Lancet* 2014;384(9938):164–172.
23. Holmes D, Colfry A, Czerniecki B, Dickson-Witmer D, Francisco Espinel C, Feldman E, Gallagher K, Greenup R, Herrmann V, Kuerer H, Malik M, Manahan E, O'Neill J, Patel M, Sebastian M, Wheeler A KR. Performance and Practice Guideline for the Use of Neoadjuvant Systemic Therapy in the Management of Breast Cancer. *Ann Surg Oncol* 2015;10:3184–90.
24. Cardoso F, Costa A, Norton L, et al. ESO-ESMO 2nd international consensus for advanced breast cancer (ABC2). *Breast* 2014;23:489–502.
25. Roses DF, Brooks AD, Harris MN, Shapiro RL, Mitnick J: Complications of level I and II axillary dissections in the treatment of carcinoma of the breast. *Ann Surg* 1999, 230(2):194–201.
26. Mansel RE, Fallowfield L, Kissin M, Goyal A, Newcombe RG, Dixon JM, et al: Randomized multicenter trial of sentinel node biopsy versus standard axillary treatment in operable breast cancer: the ALMANAC Trial. *J Natl Cancer Inst* 2006, 98(9):599–609.
27. Krag DN, Anderson SJ, Julian TB, et al. Sentinel-lymph-node resection compared with conventional axillary-lymph-node dissection in clinically node-negative patients with breast cancer : overall survival findings from the NSABP B-32 randomized phase 3 trial. *Lancet Oncol* 2010;9:27–33.
28. Veronisa U, Viale G, Paganelli G, et al. Sentinel lymph node biopsy in breast cancer- ten-year results of a randomized controlled study. *Ann Surg* 2010;251(4):595-600.
29. Giuliano AE, Ballman KV, McCall L, et al. Effect of axillary dissection vs no axillary dissection on 10-year overall survival among women with invasive breast cancer and sentinel node metastasis: the ACOSOG Z0011 Randomized Clinical Trial. *JAMA* 2017;318(10):918-926.
30. Donker M, van Tienhoven G, Straver ME, et al. Radiotherapy or surgery of the axilla after a positive sentinel node in breast cancer (EORTC 10981-22023 AMAROS)-a randomized, multicentre, open-label, phase 3 non-inferiority trial. *Lancet Oncol* 2014;15(12):1303-1030.
31. Boughey JC, Peintinger F, Meric-bernstam F, et al. Impact of Preoperative Versus Postoperative Chemotherapy on the Extent and Number of Surgical Procedures in Patients Treated in Randomized Clinical Trials for Breast Cancer. *Ann Surg* 2006;244(3):464-70.
32. Beck N, Busweiler LAD, Schouwenburg MG, et al. Factors contributing to variation in the use of multimodality treatment in patients with gastric cancer: a Dutch population-based study. *Eur J Surg Oncol* 2018;44(2):260-267.
33. Johansson N, Jakobsson N, Svensson M. Regional variation in health care utilization in Sweden – the importance of demand

- side factors. *BMC Health Services Research* 2018;18(1):403.
34. Skinner J. Causes and consequences of regional variations in health care. In: Pauly MV, Barros PP, McGuire TG, editors. *Handbook of health economics*, vol. 2. London: Elsevier Science; 2012.
 35. Cutler D, Skinner J, Stern AD, et al. Physician beliefs and patient preferences: a new look at regional variation in health care spending, Harvard Business School Working Paper; 2015. p15-090.
 36. Santé, A.F.d.s.s.d.p.d., *Situation update on checking procedures performed by the health authorities on Poly Implant Prothèse Company*. 2011.
 37. Keogh, B. Poly Implant Prothèse (PIP) breast implants: final report of the Expert Group. 2012, Department of Health, NHS Medical Directorate: Leeds, the UK.
 38. Doren EL, Miranda RN, Selber JC, et al. U.S. epidemiology of breast implant-associated anaplastic large cell lymphoma. *Plast Reconstr Surg*. 2017;139(5):1042–1050.
 39. de Jong D, Vasmel WL, de Boer JP et al. Breast implants and the risk of anaplastic large-cell lymphoma in the breast. *JAMA Oncol* 2018;4(3):335-341.
 40. McLaughlin JK, Lipworth L, Murphy DK, et al. The safety of silicone gel-filled breast implants: a review of the epidemiologic evidence. *Ann of Plastic Surgery* 2007;59(5):569-580.
 41. Cooter RD, Barker S, Carroll SM, et al. International Importance of Robust Breast Device Registries. *Plast Reconstr Surg* 2015;135(2):330-6.

