Cost-effectiveness of non-invasive assessment in the Dutch breast cancer screening program versus usual care: A randomized controlled trial

Johanna M. Timmers, PhD,[1] Johanna A. Damen, MSc,[1,2] Ruud M. Pijnappel, MD, PhD,[1,3] André L. Verbeek, MD, PhD,[1,2] Gerard J. den Heeten, MD, PhD,[1,4] Eddy M. Adang, PhD,[2] Mireille J. Broeders, PhD[1,2]

ABSTRACT

OBJECTIVE: Increased recall rates in the Dutch breast cancer screening program call for a new assessment strategy aiming to reduce unnecessary costs and anxiety. Diagnostic work-up (usual care) includes multidisciplinary hospital assessment and is similar for all recalled women, regardless of the radiologist's suspicion of breast cancer. This is similar in many Canadian settings. We developed a novel assessment strategy that offers women with a low suspicion of breast cancer a quick and non-invasive assessment by a screening radiologist (intervention). We compared these two strategies in a cost-effectiveness analysis based on a randomized controlled trial: multicentre randomized controlled trial (MASS trial, Netherlands National Trial Register: NTR1480).

METHODS: Participants were enrolled between August 2010 and December 2012 and were randomly assigned to either the intervention or control group (allocation ratio 2:1). Fourteen assessment centres participated in the study. Questionnaires were used to record quality of life (EuroQol-5D), health care use and costs after recall.

RESULTS: Our study comprised 366 women, of whom 288 were randomly assigned to the intervention group and 88 to the control group. The mean difference in cost was €153/CAD $226 (95% confidence interval €107-199/CAD $158-294, $p<0.001$). We found no significant differences in quality of life. The bootstrapped incremental cost-effectiveness ratios in the cost-effectiveness plane showed that the intervention was the efficient, cost-saving modality.

CONCLUSION: Our data show the benefits of tailoring diagnostic assessment to the screening radiologist's suspicion of breast cancer. Scenarios of implementing such a strategy in the Dutch screening or health care system are currently being discussed with various stakeholders.

KEY WORDS: Cost-benefit analysis; breast neoplasms; early detection of cancer

La traduction du résumé se trouve à la fin de l'article.

Can J Public Health 2014;105(5):e342-e347.

Breast cancer is the most commonly diagnosed cancer among women in the Netherlands and Canada, 14,296 and 23,800 new invasive cancer cases respectively occurring in 2012.[1-3] Early detection through mammographic screening combined with adequate treatment remains the best strategy for reducing deaths from breast cancer.[4] Both the Netherlands and Canada offer organized service screening programs, inviting women aged 50-74 (the Netherlands) and 50-69 (Canada) for a biennial mammographic screening examination. Some provincial programs in Canada also include women outside this age group.[3] In the case of an abnormal screening mammogram, the woman is recalled for full hospital assessment by a multidisciplinary breast cancer team. Further diagnostic assessment is not included in the Dutch screening program.[5] This is similar to the situation in most of Canada, where the woman's health care providers or screening program arrange the required assessment in hospitals.[3] There is no prior stratification for assessment type according to the screening radiologist's suspicion of breast cancer.

The Dutch screening program is currently undergoing rapid change. First, the number of women invited to screening is growing, mainly as a result of the ageing population and post-war baby-boomers. The number of women reaching the age of 50, the eligible age for screening, has increased by 31%, from 96,000 in 1990 to 126,000 in 2012, and is projected to increase by a further 4%, to 131,000, in 2020.[6] Second, because of this increase in screening numbers combined with the effect of a lower threshold for recall and the switch to digital mammography, we have observed an overall increase in the number of recalled women.[7] The absolute number of recalls has tripled from 6,773 in 2000 to 21,128 in 2011. The recall rate has doubled from 9 to 21 per 1,000.[7]

Author Affiliations

1. Dutch Reference Centre for Screening, Nijmegen, the Netherlands
2. Department for Health Evidence, Radboud University Medical Center, Radboud, the Netherlands
3. Department of Radiology, University Medical Centre, Utrecht, the Netherlands
4. Department of Radiology, Academic Medical Centre, University of Amsterdam, Amsterdam, the Netherlands

Correspondence: Johanna M. Timmers, Dutch Reference Centre for Screening, PO Box 6873, 6503 GJ Nijmegen, the Netherlands, Tel: +31(024)-7600650, E-mail: j.timmers@lrcb.nl

Acknowledgements: This study was supported by a grant from the Dutch Organization for Health Research and Development (ZonMw). ZonMw had no influence on the study design, collection of data, data analysis, interpretation, writing of the manuscript or the decision to submit the manuscript for publication. We thank all participating women for taking the time to complete our questionnaires during a most distressing period. We also acknowledge all screening radiologists, research assistants, assessment centres and hospitals for their valuable contribution to this study.

Conflict of Interest: None to declare.

In the same period, the number of screen-detected breast cancers almost doubled, from 3,036 to 6,108 (detection rate increased from 4.9 to 6.2 per 1,000).[7] An adverse consequence of these increased recall rates is the disproportional increase in false-positive recalls, from 3,737 to 15,021, leading to a decrease in the positive predictive value after recall from 44% to 29%.[7] The majority of the women classified with false-positive screening mammography received only additional clinical mammography and/or ultrasound examination.[8]

Although mainly an intentional strategy, this larger number of recalls leads to an emotional burden for the women involved and a financial burden on the health care system. We developed an alternative assessment strategy aiming to reduce unnecessary delays in assessment, costs and anxiety. For the same reasons, similar strategies have been implemented in some provincial mammography screening programs in Canada.[9] In this strategy, women with a low suspicion of malignancy (approximately 50% of all recalls) are assessed separately along a quick assessment route of non-invasive imaging by a screening radiologist. The aim of this study is to determine, by means of a multicentre randomized controlled trial, whether this alternative strategy is cost-effective compared with the usual care of recall to general practitioner (GP) and full hospital assessment.

METHODS

Setting

The Dutch breast cancer screening program is one of the longest running population-based programs in the world.[10] In short, women aged 50-75 are invited for a screening examination every two years.[11,12] Currently, approximately 1 million Dutch women (80% of eligible) participate in the national program each year.[7] Screening examinations are independently read by two qualified screening radiologists, who must reach consensus about recall for further diagnostic assessment. Digital mammography was introduced into the screening program and was fully implemented in 2010. Diagnostic work-up is not included in the Dutch screening program. In the case of an abnormal screening mammogram, the woman is recalled to her general practitioner and hospital for further assessment.

To standardize and classify recalls according to the radiologist's suspicion of breast cancer, the Breast Imaging Reporting and Data System (BI-RADS) of the American College of Radiology is used in the Dutch screening program.[13-15] According to these guidelines, a negative screening examination is one that is negative or has benign findings (BI-RADS categories 1 and 2). A positive screening examination is one for which recall is required (BI-RADS categories 0, 4 and 5).[14] A BI-RADS code 0 indicates that the screening radiologist needs more information to determine whether recall is necessary, for instance, in the case of possible superimposed images. BI-RADS 4 or 5 indicates a suspicious or highly suspicious abnormality respectively.[15]

Participants

Only women who were screened and recalled to the GP and hospital with a BI-RADS 0 were eligible for participation in our trial. We did not include women with a relatively high suspicion of breast cancer (BI-RADS 4 or 5). These women need to be recalled directly to the GP and hospital for full assessment, as they are likely to undergo invasive biopsy procedures. We excluded women who did not understand the Dutch language, as well as women who were in a state of diminished responsibility or mentally disabled. Participants could leave the study at any time without any consequences.

Study design

We used a multicentre randomized controlled trial design to compare two strategies for recall and assessment within the Dutch breast cancer screening program. Women assigned to the intervention group (IG) received quick, non-invasive assessment (additional mammographic views and/or ultrasound examination) in the screening setting. Women assigned to the control group (CG) received the usual care of recall to the GP and assessment in hospital by the multidisciplinary breast cancer team (recruitment target: 2,580, allocation ratio 2:1). The trial is called the MASS trial: Modified Assessment of Recalled Women in Service Screening (registered in the Dutch National Trial Register, NTR1480). The study was approved by the medical ethics committees of all participating centres.

Intervention

Women were assessed in 14 participating centres, including several diagnostic centres and hospitals, where screening radiologists work. Because of practical and financial limitations, we were not able to set up assessment centres within the organizational framework of the screening program. Our local research assistants contacted the women recalled with BI-RADS 0 to provide information on the MASS trial, discuss participation and answer any questions regarding the trial. In addition, the GPs were informed in advance. After completing the informed consent procedure, the research assistants randomly assigned the participants to either the CG or IG. In the case of the CG, women were advised to contact their GP to arrange diagnostic work-up by the multidisciplinary breast cancer team (usual care). In the case of the IG, work-up was arranged in an assessment centre where women were seen by a screening radiologist who directly discussed the test results. This is not necessarily the case in the regular diagnostic setting. There were two possible outcomes: the result was either benign (re-invitation in two years), or a biopsy was required, including a visit to a multidisciplinary breast cancer team.

Outcome parameters

This economic evaluation is based on the general principles of a cost-effectiveness analysis (CEA). It is furthermore conducted from a health care perspective, alongside the randomized clinical trial (results concerning other outcome measures are to be reported elsewhere) and is based on intention to treat. The following outcome measures are considered informative for this economic evaluation: patient costs and health-related quality of life (QOL) converted into quality-adjusted life years (QALYs).

Data collection and statistical analyses

Participating women completed a questionnaire at two time points. The first questionnaire had to be completed directly after they had received the results of the positive screening examination but before further assessment (T1). The second questionnaire was sent

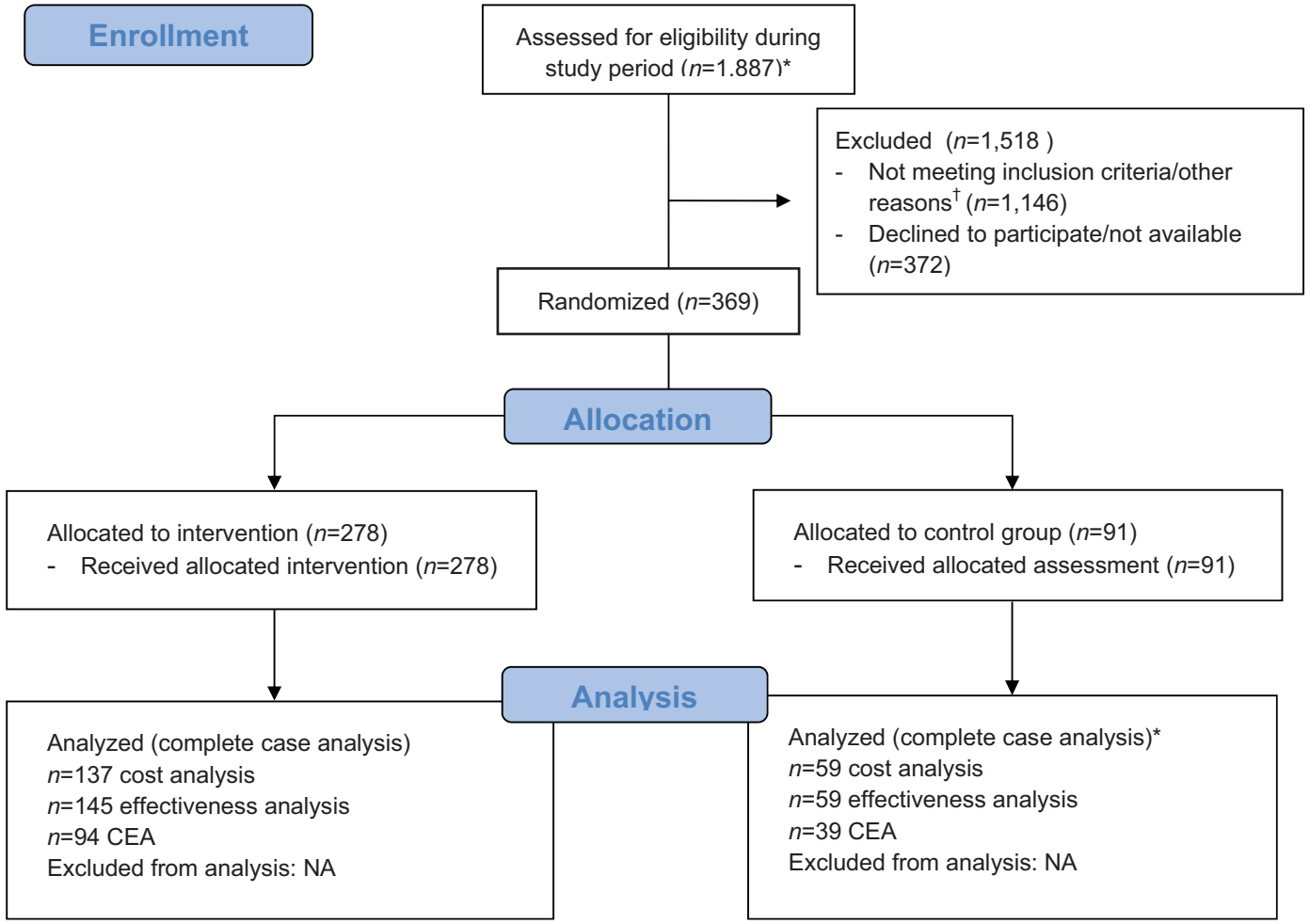

Figure 1. MASS trial flow diagram, including all participants who were randomly assigned and received treatment and whose data were analyzed for the primary outcome
* Original recruitment target: 2,580.
† Exclusion criteria included, for instance, not being able to understand the Dutch language, personnel shortage at the screening organizations or no quick assessment appointments available at the assessment centres.
‡ Final diagnostic results are available from patient records, but we did not receive all questionnaires.
CA=cost-effectiveness analysis.

after completion of the diagnostic process (T2). These questionnaires were used to measure quality of life (EQ-5D)[16] and baseline characteristics. A self-report diary was used to determine waiting time, health care use and, subsequently, costs. Cost prices were determined for all assessment procedures.[17] We indexed the cost prices using the consumer price index from Statistics Netherlands.[18] Costs were converted to Canadian dollars (2014 exchange rate: 1 EUR=1.48 CAD). All women in the CG and upgraded women in the IG visited the GP and multidisciplinary breast cancer team.

The EQ-5D consisted of five questions covering the dimensions of mobility, self-care, usual activities, pain/discomfort and anxiety/depression. Each dimension had three levels: no problems, some problems and extreme problems.[16] The answers to the five questions were converted into a single value, named the EQ-5D index,[16] which was used to calculate QALYs.[19] Differences in QALYs between T1 and T2 were determined at the patient level by using the trapezium rule[20] (adding the patient-based EQ-5D index scores at T1 and T2 then dividing them by 2 and multiplying by the patient-specific waiting time between T1 and T2). This provided average difference scores at the patient level. The difference scores were compared between the IG and CG: (EQ-5D index at T2–EQ-5D index at T1) * (waiting time/365).

A cost-effectiveness (CE) plane was constructed displaying the difference in costs (y axis) and difference in effects (x axis). Every point in the CE plane represents a bootstrapped incremental cost-effectiveness ratio (ICER): the ratio of the change in costs of the CG compared with the IG to the change in the effects of the IG. The CE plane shows the uncertainty (by bootstrapping of the original dataset) surrounding the difference in costs and the difference in effects. Furthermore, a cost-effectiveness acceptability curve (CEAC) is presented to determine the probability of cost-effectiveness given a certain threshold (willingness to pay for a QALY).

Absolute numbers and percentages are reported as well as mean or median values, including the 95% confidence intervals (95% CI). A general linear model was built to analyze differences in EQ-5D and costs between the CG and IG, with baseline EQ-5D value as covariate. Differences in EQ-5D index scores within the two groups at T1 and T2 were identified using non-parametric tests for related samples. Bootstrap sampling (1,000 samples) was performed for the cost analysis and CEA. Analyses were performed using SPSS (IBM, version 20; SPSS, Chicago, IL, USA) and Microsoft Office Excel 2007

to calculate the CE plane and CEAC. The allocation sequence was determined by a written script in Microsoft Office Access 2007. Data were analyzed from a complete case scenario.

RESULTS

Study group

Between August 2010 and December 2012, 1,887 women were screened and recalled with a BI-RADS 0 at the participating screening centres (see Figure 1).

A total of 372 women were contacted but were not available or declined to participate for various reasons, including: preferred to be seen by the GP first (35%); personal reasons, such as travel distance and not being able to understand the Dutch language (65%). Furthermore, a total of 1,146 women were excluded from participating because of personnel shortage; recall on a Friday and inability to guarantee quick assessment as outpatient clinics are closed during the weekends; travel distance to the assessment centre; and GP advice against participation (35%, 20%, 10% and 10% respectively). Other reasons were too many BI-RADS 0 women recalled to schedule assessment appointments, national holidays and mentally disabled (total 25%).

Ultimately, 369 women (mean age of 57, range 49-75) participated in the MASS trial, of whom 91 were randomly assigned to the control arm and 278 to the intervention arm of the trial. We collected 337 questionnaires (92%), 91 in the CG and 246 in the IG. Not all questions were completed by all women, therefore the total number of complete questionnaires varied per analysis (costs and effects, CEA). In the CG, the number of complete questionnaires was 59 (65%) for the cost analysis and effectiveness analysis and 39 (44%) for the CEA. In the IG, the number of complete questionnaires was 137 (56%), 145 (59%) and 94 (38%) for the cost analysis, effectiveness analysis and CEA respectively. See also Figure 1 for the flow diagram.[21] Baseline characteristics are shown in Table 1.

Table 1. Baseline characteristics of 336 women participating in the control group (CG) or intervention group (IG) of the MASS trial

	CG	IG
N	91	245
Age, mean (range)	57 (49-75)	57 (49-75)
Children (yes), *n* (%)	68 (74.7)	189 (77.1)
Age at having first child, mean (range)	26 (20-37)	26 (16-41)
Median number (range) of children	2 (0-6)	2 (0-5)
Missing, *n* (%)	4 (4.4)	19 (7.8)
Physical activity, yes,* *n* (%)	50 (54.9)	139 (56.7)
Missing	5 (5.5)	21 (8.6)
BMI (kg/m^2), mean (range)	26.12 (17.9-42.2)	26.6 (17.6-56.2)
Education level, *n* (%)		
Low (primary/secondary school)	8 (8.8)	21 (8.6)
Medium (professional education)	58 (63.7)	156 (63.7)
High (≥higher professional education)	21 (23.1)	48 (19.6)
Missing	4 (4.4)	20 (8.2)
Breast cancer in family, *n* (%)	35 (40.2)	53 (21.6)
Missing	4 (4.4)	23 (9.4)
Employed, *n* (%)	28 (30.8)	78 (31.7)
Missing	30 (33.0)	94 (38.4)
Income, *n* (%)		
Low (€0-1500)	26 (28.6)	66 (26.8)
Medium (€1501-2500)	11 (12.1)	24 (9.8)
High (>€2500)	1 (1.1)	4 (1.6)
Considered private	5 (5.5)	15 (6.1)
Missing	48 (52.7)	136 (5.5)

* 30 minutes of physical activity for a minimum of 5 days per week.

Cost-effectiveness

The cost prices of assessment procedures upon recall and assessment after recall are displayed in Table 2. Bootstrap sampling showed an average cost per woman of €320/CAD $473 in the CG group (95% CI €290-350/CAD $429-518) and €119/CAD $176 in the IG group (95% CI €104-137/CAD $153-202)). The mean difference between the two groups is €153/CAD $226 (95% CI €107-199/CAD $158-294, $p<0.001$). Quality of life, measured as mean EQ-5D index scores, is presented in Figure 2. The EQ-5D index for the CG was 0.89 at T1 and 0.91 at T2 ($p=0.270$). The EQ-5D in the IG was higher at T2 than at T1 (0.89 vs. 0.85, $p=0,001$). Bootstrap sampling showed a mean value for QALY in the CG group of 0.00010215 (95% CI –0.00039113-0.00055709) and 0.00035836 (95% CI 0.00013354-0.00060058) in the IG (statistically not significant). Figure 3 presents 1,000 bootstrapped ICERs in the CE plane. This CE plane shows that the intervention is the efficient modality, as it saves costs at equal effectiveness. As shown in the acceptability curve (Figure 4), the probability of having a cost-effective intervention strategy approaches 100%.

DISCUSSION

This is the first paper that addresses the cost-effectiveness of different recall and assessment strategies for women with a low suspicion of breast cancer (BI-RADS 0) in a centrally organized breast cancer screening program. We adopted a multicentre randomized controlled trial design in which women were assigned to either the control group of usual care (e.g., full hospital assessment by GP and multidisciplinary breast cancer team) or the intervention group of quick, non-invasive assessment in screening. We found a mean difference in cost between the two groups of €153/ CAD $226 (95% CI €107-199/CAD $158-294, $p<0.001$) and no significant differences in effects (EQ-5D). The analyses showed that the intervention is the efficient, i.e., cost-saving, modality.

There are no other studies that specifically determine the cost-effectiveness of different recall and assessment strategies. This may be explained by the fact that the majority of screening programs choose to incorporate further assessment of women with a positive screening. For that reason, alternative recall and assessment strategies are not objects of research in these countries, in contrast to the Netherlands, where assessment is not part of the screening program. We could not identify any cost-effectiveness studies from Canada, one of the very few countries that has an assessment policy in most provinces resembling the Dutch situation. We did find a Canadian study by Borugian et al. that compared time intervals for patients who were assessed through a fast-track route, i.e., direct referral to diagnostic imaging without a visit to the GP first.[9] They found that the time interval from recall to diagnosis for the fast-track route was reduced by more than half. We also found one study, by Blane et al., that addressed further assessment of women who were assigned a BI-RADS code 0 (defined as an incomplete screening examination).[22] However, the focus in this study was not cost-effectiveness but, rather, the costs of achieving high patient compliance afterwards. It did show that, with a work flow similar to that of our intervention, it is possible to achieve 99.5% compliance with additional diagnostic imaging at small additional costs (¢6 per screening patient). These results are of interest because they support the feasibility of our approach. A recent study by Sherman et al. evaluated the psychological effects of a streamlined breast assessment clinic for low-risk women.[23] However, they did

Table 2. Costs of diagnostic assessment after recall for both the control group (CG) and intervention group (IG)

	Costs per procedure*	CG (*n*=59)		IG (*n*=137)	
	€ (CAD)†	*N* (%)	Cost € (CAD)†	*N* (%)	Cost € (CAD)†
General practitioner‡	30 (44)	59 (100)	1770 (2,619)	–	0
Breast cancer team§	184 (272)	59 (100)	10,856 (16,066)	–	0
Mammography	45 (66)	48 (81)	2160 (3,197)	107 (78)	4815 (7,126)
Breast ultrasonography	42 (62)	42 (71)	1764 (2,610)	99 (72)	4158 (6,153)
Histological or cytological biopsy procedure	149 (220)	20 (34)	2980 (4,410)	30 (22)	4470 (6,615)
Breast magnetic resonance imaging	198 (293)	5 (8)	990 (1,465)	15 (11)	2970 (4,395)
Average cost per woman		€320/CAD $473 (95% CI €290-350/CAD $429-518)		€119/CAD $176 (95% CI €104-137/CAD $153-202))	

* Cost per procedure (2013) using the consumer price index[18] for indexation.
† 2014 exchange rate 1 EUR=CAD 1.48.
‡ For all CG participants and IG participants who were upgraded for further assessment.
§ Breast cancer team consists of a multidisciplinary meeting (€140), surgeon or nurse practitioner (€24) and a breast cancer nurse (€20).

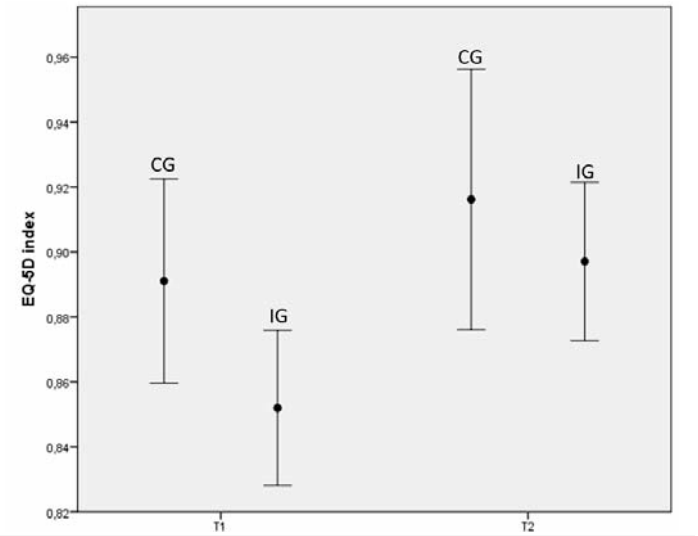

Figure 2. Dutch index scores (mean±95% CI) of the EQ-5D for the control group (CG) and intervention group (IG) at T1 (directly after the women were told that their screening examination was positive but before the assessment in the hospital) and T2 (after completion of the diagnostic process)

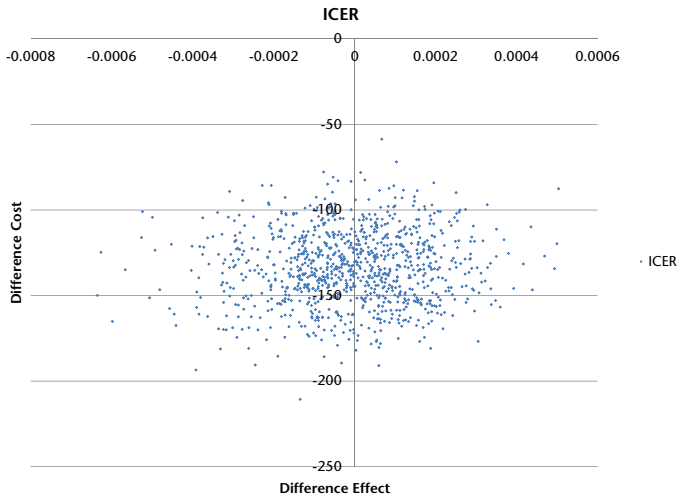

Figure 3. Cost-effectiveness plane. Scatter plot showing 1,000 bootstrapped incremental cost-effectiveness ratios (ICERs) from the trial data (expressed as cost [€] and differences in effects [EQ-5D])

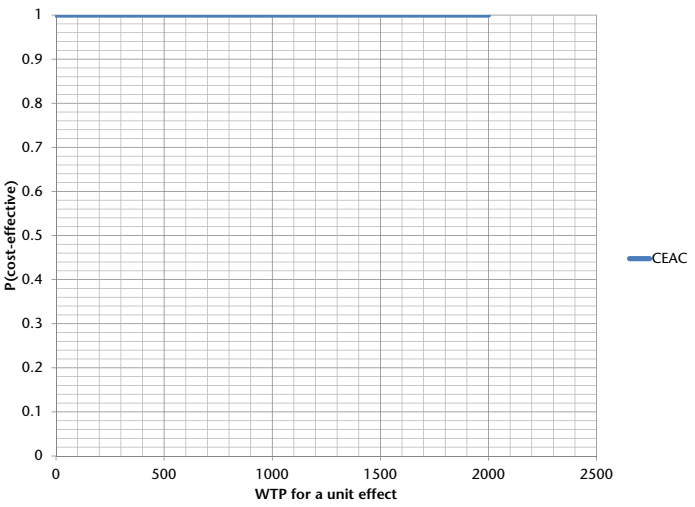

Figure 4. Cost-effectiveness acceptability curve showing the probability that the intervention is cost-effective

not use the BI-RADS to establish the women's suspicion of breast cancer or perform a CEA.

We found no significant differences in effects using the EQ-5D, a standardized instrument that measures health outcome and is widely applied in cost-effectiveness analyses.[16] The EQ-5D is not specifically designed to measure the psychological consequences for women who are recalled, and it is likely that it is not sensitive enough to detect differences.

The main strength of our study was our multicentre randomized controlled trial design, in which participants were allocated at random to the intervention and control group, thereby ensuring that participants in both study arms were similar in all respects except exposure to our intervention. Second, we conducted our trial at 14 assessment centres, covering both rural and urban areas, which eliminated demographic bias. Third, in this study we were able to collect data on cost and quality of life, which are not routinely collected in the screening program. Fourth, though the EQ-5D is not specifically designed for use in mammography screening, this could be seen as a strength, since it measures the impact of recall on general QOL. The fact that QOL after final assessment is higher than immediately following recall indicates some sensitivity of the EQ-5D in the screening setting. We chose to approach our missing data by means of a complete case analysis whereby we omitted women with missing data on one or more variables of the questionnaires measuring costs and effects. The effect part and the cost part of our questionnaire were completed by 204 and 197 women respectively. Included in the CEA were all participants who completed both parts (*n*=133). We considered

imputation of missing values and checked whether there were differences in characteristics between the participants who did or did not complete the questionnaires. We found no differences between the two groups in age, diagnosis of breast cancer, educational level, body mass index and randomization result (data not shown). The results of our analysis showed that imputation would be at random and would therefore not add power or decrease bias in our study.

The findings from our multicentre randomized controlled trial showed that the alternative strategy of separately assessing BI-RADS 0 women (low suspicion of breast cancer) along a quick, non-invasive assessment route is a cost-effective one. Such a strategy is relatively easy to implement. The results of our study have initiated discussions in the Netherlands among various stakeholders, including radiographers, screening radiologists, GPs, policy-makers, hospital managers, screening organizations and government. We found that our so called "BI-RADS 0 pathway" (quick assessment by screening radiologists in hospital or diagnostic centres) appeared to be pragmatic and relatively easy to implement in daily clinical practice. An expert group has been formed comprising all stakeholders to discuss several options for the implementation of a BI-RADS 0 pathway, taking into account several issues, such as women's travel distance, number of visits to the assessment centre and a new reimbursement scheme.

REFERENCES

1. Statistics Netherlands. Access to StatLine: Make your own tables. 2010/12/01/ 2010. Available at: http://www.cbs.nl/nl-NL/menu/cijfers/statline/zelf-tabellen-maken/default.htm (Accessed October 1, 2014).
2. Canadian Cancer Society, Statistics Canada. Canadian Cancer Statistics 2013. Toronto, ON, 2013.
3. Canadian Partnership Against Cancer. Organized Breast Cancer Screening Programs in Canada: Report on Program Performance in 2007 and 2008. Toronto, 2013.
4. The benefits and harms of breast cancer screening: An independent review. *Lancet* 2012;380(9855):1778-86.
5. Nationaal Borstkanker Overleg Nederland. National Guideline "Breast Cancer". Amsterdam, 2011.
6. Statistics Netherlands. Population Pyramid - Age composition in the Netherlands. 2012. Available at: http://www.cbs.nl/nl-nl/menu/themas/ bevolking/cijfers/extra/piramide-fx.htm (Accessed August 1, 2012).
7. National Evaluation Team for Breast Cancer Screening. National evaluation of breast cancer screening in the Netherlands (1990-2011/2012), thirteenth evaluation report. Rotterdam: NETB, 2014.
8. Timmers JM, den Heeten GJ, Adang EM, Otten JD, Verbeek AL, Broeders MJ. Dutch digital breast cancer screening: Implications for breast cancer care. *Eur J Public Health* Epub 2011 Dec 8..
9. Borugian MJ, Kan L, Chu CC, Ceballos K, Gelmon KA, Gordon PB, et al. Facilitated "fast track" referral reduces time from abnormal screening mammogram to diagnosis. *Can J Public Health* 2008;99(4):252-56.
10. Holland R, Rijken HJ, Hendriks JH. The Dutch population-based mammography screening: 30-years experience. *Breast Care* 2007;2:12-18.
11. Otten JD, van Dijck JA, Peer PG, Straatman H, Verbeek AL, Mravunac M, et al. Long term breast cancer screening in Nijmegen, The Netherlands: The nine rounds from 1975-92. *J Epidemiol Community Health* 1996;50(3):353-58.
12. Fracheboud J, de Koning HJ, Boer R, Groenewoud JH, Verbeek AL, Broeders MJ, et al. Nationwide breast cancer screening programme fully implemented in The Netherlands. *Breast* 2001;10(1):6-11.
13. American College of Radiology. ACR practice guideline for the performance of screening and diagnostic mammography (2008). Preston, VA, 2008.
14. American College of Radiology. ACR BI-RADS®-Mammography: Breast Imaging Reporting and Data System, Breast Imaging Atlas. Preston, 2003.
15. Timmers JM, van Doorne-Nagtegaal HJ, Zonderland HM, van Tinteren H, Visser O, Verbeek AL, et al. The Breast Imaging Reporting and Data System (BI-RADS) in the Dutch breast cancer screening programme: Its role as an assessment and stratification tool. *Eur Radiol* 2012;22(8):5.
16. EuroQol Group. EuroQol-a new facility for the measurement of health-related quality of life. *Health Policy* 1990;16(3):9.
17. The Social and Economic Council of the Netherlands. Costs and benefits of healthcare renewal, 2006. Available at: http://www.seo.nl/uploads/media/ 916_Kosten_en_baten_van_zorgvernieuwing.pdf (Accessed October 6, 2014).
18. Statistics Netherlands. Statline, consumer price index. 2013. Available at: http://statline.cbs.nl/StatWeb/publication/?VW=T&DM=SLNL&PA=71311ned &D1=0-1,4-5&D2=0&D3=a&HD=080521-1622&HDR=G1,T&STB=G2 (Accessed June 20, 2013).
19. Lamers LM, Stalmeier PF, McDonnell J, Krabbe PF, van Busschbach JJ. [Measuring the quality of life in economic evaluations: the Dutch EQ-5D tariff]. *Ned Tijdschr Geneeskd* 2005;149(28):1574-78.
20. Atkinson KE. *An Introduction to Numerical Analysis*, 2nd ed. New York: John Wiley & Sons, 1989.
21. Moher D, Hopewell S, Schulz KF, Montori V, Gotzsche PC, Devereaux PJ, et al. CONSORT 2010 explanation and elaboration: Updated guidelines for reporting parallel group randomised trials. *Int J Surg* 2012;10(1):28-55.
22. Blane CE, Pinsky RW, Joe AI, Pichan AE, Blajan MR, Helvie MA. Costs of achieving high patient compliance after recall from screening mammography. *AJR Am J Roentgenol* 2007;188(4):894-96.
23. Sherman KA, Winch CJ, Borecky N, Boyages J. Psychological distress and streamlined BreastScreen follow-up assessment versus standard assessment. *Med J Aust* 2013;199(9):599-603.

Received: February 9, 2014
Accepted: July 4, 2014

RÉSUMÉ

OBJECTIF : Les taux de rappel accrus dans le programme néerlandais de dépistage du cancer du sein requièrent une nouvelle stratégie d'évaluation des patientes pour réduire les coûts et l'anxiété inutiles. L'investigation diagnostique (les soins habituels) inclut une évaluation multidisciplinaire à l'hôpital; le processus est le même pour toutes les femmes rappelées, peu importe si le radiologiste soupçonne ou non un cancer du sein. Il en va de même dans de nombreux établissements au Canada. Nous avons élaboré une stratégie d'évaluation novatrice qui offre aux femmes pour lesquelles la présomption de cancer du sein est faible une évaluation rapide et non invasive par un médecin radiologiste (intervention). Nous avons comparé ces deux stratégies à la faveur d'une analyse coût-avantage fondée sur un essai comparatif randomisé multicentrique (essai MASS, registre national d'essais des Pays-Bas : NTR1480).

MÉTHODE : Les participantes ont été recrutées entre août 2010 et décembre 2012 et réparties de façon aléatoire entre le groupe d'intervention et un groupe témoin (ratio de répartition 2:1). Quatorze centres d'évaluation ont participé à l'étude. Des questionnaires ont été administrés pour enregistrer la qualité de vie (EuroQol-5D), l'utilisation des soins de santé et les coûts après le rappel.

RÉSULTATS : Notre étude comprenait 366 femmes, dont 288 ont été affectées de façon aléatoire au groupe d'intervention et 88 au groupe témoin. La différence moyenne de coût était de 153 €/226 $CAN (intervalle de confiance de 95 % : 107-199 €/158-294 $CAN, p<0,001). Nous n'avons trouvé aucune différence significative dans la qualité de vie. Les ratios coût-efficacité incrémentiels (selon la méthode bootstrap) indiquent que l'intervention est la méthode la plus efficiente et économique.

CONCLUSION : Nos données montrent les avantages d'adapter l'évaluation diagnostique selon que le médecin radiologiste qui effectue le dépistage soupçonne ou non un cancer du sein. On discute actuellement avec divers acteurs du milieu de scénarios de mise en œuvre d'une telle stratégie dans le système néerlandais de dépistage ou de soins de santé.

MOTS CLÉS : analyse coût-bénéfice; tumeurs du sein; dépistage précoce du cancer