5189 POSTER

Microarray Based Determination of ER, PR and HER2 Receptor Status Compared to Local IHC/FISH Assessment in 641 Patients

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Background: The level of estrogen receptor (ER), progesterone receptor (PR) and HER2 expression is predictive for prognosis and/or treatment response in breast cancer patients. However, differences in fixation and IHC and subjective interpretation can substantially affect the accuracy and reproducibility of the results. The commercially available TargetPrint test measures the mRNA expression level of ER, PR and HER2 and provides an objective and standardized alternative to IHC. This study compares results from the microarray-based TargetPrint with IHC and FISH generated by local standard procedures.
Material and Methods: Prospective tumour samples were collected for 641 patients diagnosed with breast cancer stage I to IV between 02/08 and 08/10. The mRNA level of ER, PR and HER2 (TargetPrint) was assessed in a central laboratory (Agendia BV, Amsterdam) in fresh tumour samples submitted from 13 hospitals in Europe, 2 in New Zealand and 1 in Japan. The results of the IHC/FISH assessments performed according to the local standards at the hospitals were compared to the quantitative gene expression readouts.
Results: Of the 641 samples, HER2 IHC/FISH assessment was unknown for 12 samples and for one sample ER/PR IHC assessment was unknown. Median age of these patients was 60 years. Comparison of IHC and gene expression read out by TargetPrint showed a concordance of 95% for ER; 82% for PR and 92% for HER2.
Conclusion: Microarray based readout of ER, PR and HER2 status using TargetPrint is highly comparable to local IHC and FISH analysis over 600 analyzed samples in various hospitals.

5190 POSTER

Feasibility of Home-adapted Aerobic Exercise Training on Peak Oxygen Consumption and Fatigue in Breast Cancer Patients During Adjuvant Chemotherapy

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Background: Breast cancer chemotherapy may cause unfavorable changes in fatigue and physical functioning. Few interventions have been shown to prevent these declines and physical exercise has been identified as a potential intervention to cancer-related fatigue and cardiopulmonary function. A feasibility study examining the effects of a 12-week adapted home-based aerobic exercise program on fatigue severity scale, physical function, and functional capacity in breast cancer patients receiving adjuvant chemotherapy.
Material and Methods: Using a single-group design, 33 patients with predominantly stage II breast cancer performed 3 home ambulatory aerobic walking sessions per week at 50−60% of the exercise heart rate for 12 weeks. Participants exercised for the duration of their chemotherapy, beginning in the days following the 3rd cycle and ending after chemotherapy. A measure of functional capacity was determined using an incremental cardiopulmonary exercise test with measurement of peak oxygen consumption (VO2peak). Six-minutes walking test (6MWT) was performed as a measure of physical function. The revised Piper fatigue Scale (PFS) was used to measure self-reported fatigue.
Results: Nine-patients (27.3%) either did not perform the walking exercise program or did less than half of it, and only 24 patients (72.7%) completed all study procedures. Intention-to-treat analysis indicated that VO2peak performed before and after home exercise program increased significantly 2.21 mL/kg-1/min-1 ($P < 0.001$). PFS score and 6MWT increased but no significantly by 0.4 points and 3 meters, respectively. There was no side effect attributable to the walking exercise program.
Conclusions: In cancer patients receiving adjuvant chemotherapy, home-based adapted exercise program is feasible and associated with significant improvements in VO2peak, with no significant effect on fatigue score. Results of this pilot study provide positive preliminary evidence that original home-based exercise during adjuvant treatment may be physiological beneficial for breast cancer patients and did not worsen fatigue scores during the trial. Further work and larger randomized trials are necessary.

5191 POSTER

Clinical Characteristics of Breast Cancer in Young Patients

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Background: Breast cancer in young women is common in Algeria, the national survey found an incidence of 9000 new cases per year and the average age is 48 years.
The objective of the study is to provide the clinical and histological profile of breast cancer in young patients.
The retrospective study over a period of 6 years, 238 patients with an age inferior or equal to 35 years.
Materials and Methods: Between January 1st, 2005 and December 31st, 2010, 238 patients were treated with age inferior or equal to 35 years.
Have to give: age of puberty, notion of taking an oral contraception, history of cancer in the family, reason for consultation, presence or absence distant metastases.
The following parameters were evaluated: BMI, histology of tumour, the number of metastasis lymph nodes, the grade SBR, hormonal receptor and HER 2/ neu.
Results: Age of the menstruation >12 years is 72.9%, 39% single, notion of taking an oral contraception 39%, cancer in the family 23.1%, BMI >30 is 19.7%, reason for consultation was represented by a nodule breast self examination 89.9%, T3 is 60%, stage 4 is 19.9% (13.4% metastatic bone, 6.7% metastatic liver), the most common histological type is ductal carcinoma, the lymph node status: positive 69.8%, negative 30.2%; positive hormonal receptors 56%, negative hormonal receptor 26%, HER2+ 30.6%.
Conclusions: In our department, the young patients affected by breast cancer have: BMI >30 with high percentage, the large tumour, the lymph node metastasis, and high percentage of oestrogen receptor and progesterone receptor positive tumours.

5192 POSTER

Breast Conserving Therapy − Morbidity and Cosmetic Outcome in DBCG Protocols TM-'89, -'99 and -'01

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Background: Based on large international and national clinical trials comparing mastectomy and BCT (Breast Conserving Therapy = Breast Conserving Surgery + Radiotherapy), Danish Breast Cancer Cooperative Group (DBCG) introduced BCT as a standard treatment in Denmark in 1990. Since then no evaluations have been performed to ensure good cosmetic outcome and low levels of adverse reactions in Danish patients. This study was designed to evaluate these issues.
Material and Methods: A total of 214 patients treated with BCT according to the DBCG protocols from 1989 to 2002 participated in a single follow-up visit, comprising an interview, a clinical examination, clinical photos and completion of a questionnaire. Patients were divided into 3 treatment-groups: no adjuvant treatment, chemotherapy and anti-hormone therapy. Data were analyzed using univariate logistic regression.
Results: Mean follow-up time was 12.3 (range 7 to 20) years. Moderate to severe fibrosis was found in 49 patients (23%). Other adverse reactions (telangiectasia, oedema, dyspigmentation) of moderate to severe degree were found in 55 patients (26%). Fibrosis was more common in those who received chemotherapy (OR 2.6 $p = 0.02$), were current smokers (OR 2.4 $p = 0.02$) or had large breasts (bra cup size $\geqslant$ C; OR 3.2 $p = 0.001$).
Patients with a satisfactory cosmetic outcome, when assessed by a clinician, were characterized by small tumours ($\leqslant$2 cm; OR 3.7 $p = 0.001$), small to medium breasts (bra cup size <C; OR 1.9 $p = 0.02$), no adverse reactions to radiotherapy (excluding fibrosis; OR 4.4) and no obesity at follow-up (BMI < 30; OR = 7.2 $p < 0.0005$). Fifty percent of patients scored 'Good' 'Excellent' when assessed by a clinician compared to 88% when reported by the patients themselves.
Patients were more likely to be satisfied with their own cosmetic outcome if they were younger (<50 years; OR 3.2 $p = 0.03$), had no postoperative complications (OR 3.4 $p = 0.02$), had no fibrosis (OR 6.4 $p < 0.0005$) or had no more than one positive lymph node in the axilla (OR 3.6 $p = 0.01$).
Conclusions: It is important to do long-term investigations of patient-morbidity and cosmetic outcome when a treatment has been applied as

a standard to attain the best results. With a mean follow-up time of 12.3 years the 214 patients in this study treated with BCT according to the DBCG protocol exhibited low levels of moderate to severe fibrosis and high levels of satisfaction with the cosmetic outcome.

5193 POSTER

Invasive Ductal Breast Cancer. Correlation Between Tumour Size in Physical Examination, Mammography, Magnetic Resonance and Pathological Anatomy

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Background: The most frequent indication of magnetic resonance in breast cancer is the evaluation of tumoral extension. Several studies suggest that mammography and ultrasound underestimate tumour size. With our study, we try to analyze the correlation between the tumour size of invasive ductal carcinomas in physical examination, mammography, magnetic resonance and pathological anatomy.
Material and Methods: We review the 290 magnetic resonance made in our Radiology Department from 1st January 2009 to 1st September 2010. 56 of them were applied as complementary study before surgery of suspected lesions of breast cancer. We excluded lobular carcinoma and in situ ductal carcinoma. We made an analysis of paired test, and then a hypothesis test for equal sample testing, supported by an analysis of power curves. The paired test analysed were physical examination (PE) − mammography − magnetic resonance (MR) − pathological anatomy (PA).
Results: A 100% of the patients were women, with an average of age of 54.1 years old. A 42.8% of them were premenopausal. The averages of tumour size were: 18.3 mm in PE; 18.8 mm in mammography; 25.3 mm in MR and 24.8 mm in PA. The correlation between the tumour size in PE and PA is not statistically significant ($p = 0.05$, 95% CI 11.07; 1.93), and also between the mammography and the PA ($p = 0.05$, 95% CI 10.69; 1.47). The correlation between tumour size in mammography and MR is statistically significant ($p = 0.05$, 95% CI −9.83; −3.26), and also between MR and PA ($p = 0.05$, 95% CI −3.31; 4.25). We analysed the relation between clinical tumour size by MR and pathological size, and in a 25% of the cases, the clinical and the pathological stage were different. The pathological one was more advance in a 57.1% of them.
Conclusion: In our series, the mammography underestimate the tumour size, with no correlation with the pathological tumour size. However, there is a good correlation between the tumour size in magnetic resonance and the pathological size. The MR is the most reliable imaging technique to optimize the surgical and oncological treatment in patients with breast cancer.

5194 POSTER

Is the 21-gene Breast Cancer Test (Oncotype DX®) Good Value for Money?

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Background: The Oncotype DX® Breast Cancer Test (ODX) is a validated 21-gene assay that predicts 10 year risk of recurrence and the likelihood of benefit from adjuvant chemotherapy in early-stage, node-negative ER+ breast cancer. The cost-effectiveness of using ODX has been published in several countries but to date, there hasn't been any review of these studies.
Materials and Methods: The electronic database Pubmed and a selection of congress databases were searched using combinations of search terms designed to identify publications describing cost-effectiveness analyses of ODX in early stage breast cancer patients. Searches were limited to those published in the English language between January 2001 and April 2011. All records were screened for inclusion in the review.
Results: Five published health economics analyses and 1 abstract were identified. The studies were carried out in several countries (US (2), Canada, Japan, Israel and Hungary) and have used a Markov modelling approach based on data from a large multicentre trial (e.g. NSABP B-20) to make estimates of long-term outcomes, and assess the cost-effectiveness of using the ODX recurrence score in patients classified as having a high or low risk of distant recurrence using other methods of assessment. All studies were carried out in the perspective of the healthcare payer, and therefore did not consider broader costs to the patients and the society. Study comparators, costs, characteristics of the population receiving the test and impact of using the ODX results on treatment decisions were adapted to each individual country clinical practice explaining the large range of cost-effectiveness results from these studies. In the US, using ODX was shown to be cost-saving when in Canada, it was likely to be cost-effective (incremental cost-effectiveness ratio of $64,063 per QALY gained). Consistently across all five studies, use of ODX was projected to improve survival (where reported), quality-adjusted life expectancy and to reduce chemotherapy costs versus comparators.
Conclusions: Despite local adaption of the cost-effectiveness models, literature to date is consistently supporting the cost-effectiveness of using ODX in the various settings. Further analyses should be carried on to assess the budget impact of funding ODX and to include a broader perspective of the costs.

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Persistent Pain After Targeted Intraoperative Radiotherapy (TARGIT) or External Breast Radiotherapy for Breast Cancer − a Randomized Trial

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Background: Persistent pain following breast cancer treatment affects between 25−60% of patients depending on surgical and adjuvant treatment [1]. The pathophysiology of persistent pain is complex and includes several pre-, intra and postoperative risk factors for the development of persistent pain after breast cancer treatment (PPBCT). Radiotherapy has been shown to be a risk factor [2]. It raises the question whether intraoperative radiation therapy (IORT), with its smaller radiation field may reduce the development of PPBCT. IORT has been compared to external breast radiation therapy (EBRT) in terms of recurrence and survival, in the randomized non-inferiority study, TARGIT-A trial. Using data from this trial, the aim of this study was to compare these two treatments with regard to development of PPBCT.
Materials and Methods: A total of 281 patients enrolled between 2007 and 2010 in the TARGIT-A trial (NCT00983684) from the Copenhagen University Hospitals were identified in the local TARGIT database. Exclusion criteria: patients receiving axillary lymph clearence, patients with bilateral disease, recurrence, other cancer, and patients not treated according to protocol. A total of 245 questionnaires were sent out. The response rate was 98%. Two patients were excluded due to insufficient answers in the questionnaire, leaving 239 for final analysis. A detailed questionnaire from a large nationwide study on PPBCT [1] was used.
Results: Disease and demographic characteristics in the two groups were similar. Pain prevalence were 33.6% in the EBRT group and 24.6% in the IORT group, which did not reach statistical significance ($p = 0.124$). Pain intensity was similar, most patients experiencing light pain (NRS $\leqslant 3$). Patients in the IORT group reported more pain in other places outside the treatment area (40.6% in the IORT group and 27.7% in the EBRT group $p = 0.045$).
Conclusion: This first study to compare IORT and EBRT in terms of PPBCT, shows that treatment with IORT does not increase the risk of PPBCT, and provides support for the safety of IORT in terms of PPBCT. Any potential positive effect of IORT on PPBCT will require a larger study.

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Relevance of Breast Cancer Subtypes for Magnetic Resonance Imaging (MRI) Response Monitoring Neoadjuvant Chemotherapy (NAC)

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Background: Recently some authors have reported that changes in magnetic resonance imaging (MRI) during neoadjuvant chemotherapy (NAC)