underlying incidence (from year 0) was calculated. Late-stage breast cancers were defined as pT2-4.
Results: In year 1, the incidence ratio of late-stage breast cancers was 1.11 (95% CI 1.00-1.22). After decreasing to values next to unity in years 2 and 3, the ratio showed a weakly significant reduction in years 4 (0.91; 0.81-1.01) and 5 (0.88; 0.79-0.99). A significant and stable reduction was observed in years 6 (0.79; 0.70-0.90), 7 (0.77; 0.67-0.89), and 8 (0.79; 0.67-0.93).
Discussion: Starting from the 6th year of screening, the incidence of late-stage breast cancers decreased by slightly more than 20%. This observation predicts a mortality reduction and is consistent with the results of other evaluations from the same programmes.

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SURVIVAL OF WOMEN DIAGNOSED WITH COMPRESSION SYNDROME DUE TO BONE METASTASIS SECONDARY TO BREAST CANCER

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Introduction: 60% of breast cancer cases are diagnosed in advanced stages in Brazil. Metastases occur more often on bone structures, and axial skeleton is the most common. As a consequence, these women can develop radicular and/or spinal cord compression syndrome, highlighted by neurological changes below the spinal cord damage level, reflecting important functional loss.
Objective: To describe survival as well as clinical and demographic profile of women diagnosed with spinal cord compression syndrome following breast cancer.
Material and Methods: Study on survival of women diagnosed with compression syndrome at the Hospital of Cancer III from the Brazilian National Cancer Institute (INCA), between May 2006 and April 2007. Outcome was considered when death occurred and cases that did not evolve to compression syndrome until April 2010 were refused. Variables related to demographic and clinical features were collected. Descriptive analysis was carried out through measures of central and dispersion tendencies for continuous variables and absolute and relative frequencies for dichotomous variables. Survival analysis was carried out by the Kaplan-Meier method. The study was approved by INCA's Research and Ethics Committee.
Results: 36 cases were diagnosed with compression syndrome, 50% of which were spinal cord, 30% radicular and 20% both spinal cord and radicular. Average age at breast cancer diagnosis was 53 years old (DP 13.8) and 81% with staging equal to or higher than IIIA. Concomitantly to bone implant, metastasis was observed in the liver (28%), lungs (14%) and central nervous system (8.3%). Spinal cord compression occurred in the dorsal region (72%), cervical region (16%) and lumbar region (12%). Radicular compression was more likely to occur in the second (29%) and fifth (29%) lumbar vertebras. Median time between cancer diagnosis and bone metastasis was 17 months (0-167) and 30 months (0-167) until compression syndrome. Among palliative treatments, all underwent radiotherapy, 61% underwent chemotherapy, and 75%, bisphosphonates. The women were followed up after compression syndrome, in median, for 8 months (0-47). Death occurred in 92% of cases, in median, after 2 months (1-99) from bone metastasis diagnosis and nine months (0-47) after compression syndrome diagnosis.
Conclusion: The women studied were young and diagnosed with advanced breast cancer. Median time between cancer diagnosis and bone metastasis was 17 months and 30 months before compression syndrome. The women were followed up after compression syndrome, in median, for 8 months, and death occurred in 92% of cases. Survival was 22 months after bone metastasis diagnosis and nine months after radicular or spinal cord compression syndrome diagnosis.

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APPLICATION OF NEW METHODOLOGY TO ALLOW COMPARISON OF DURATION OF RESPONSE AND DURATION OF CLINICAL BENEFIT BETWEEN FULVESTRANT TREATMENT GROUPS IN THE CONFIRM TRIAL

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Background: Duration of response (DoR) and duration of clinical benefit (DoCB) are widely evaluated during randomised oncology trials and are important clinical measures that help to determine a drug's therapeutic value. These values are calculated using a subset of responding patients defined post-randomisation. As a result, the subset of patients who respond in a control arm may not be comparable with the subset in an experimental treatment arm in terms of important prognostic factors. Consequently, such comparisons may be prone to biases and may not reflect actual treatment effects. Attempts have been made to overcome these challenges and, using the methodology described by Ellis and colleagues (Ellis et al. Contemp Clin Trials 2008; 29(4): 456-465), we present a prospective analysis of DoR and DoCB between two fulvestrant (an oestrogen receptor antagonist indicated for the second-line treatment of postmenopausal women with endocrine-sensitive advanced breast cancer) treatment groups (500mg vs 250mg) from the double-blind, Phase III, COmparisoN of Faslodex In Recurrent or Metastatic breast cancer (CONFIRM) trial.
Methods: For each fulvestrant dose group, the objective response rate (ORR) was calculated out of all randomised patients with measurable disease at baseline while clinical benefit response rate (CBR) was calculated across all randomised patients. The resultant ORR and CBR were used to calculate the expected DoR (EDoR) and expected DoCB (EDoCB) for each fulvestrant dose group from randomisation to progression or death (from any cause). The ratios for EDoR and EDoCB ($EDoR_{500}/EDoR_{250}$ and $EDoCB_{500}/EDoCB_{250}$) were then calculated.
Results: The ORRs for fulvestrant 500mg and 250mg were 13.8% (33/240) and 14.6% (38/261), respectively (odds ratio: 0.94; 95% confidence interval [CI] 0.57-1.55, p=0.795). The EDoRs for fulvestrant 500mg and 250mg were 3.19 and 3.57 months, respectively. The ratio of EDoR between fulvestrant 500mg and 250mg was not statistically significant (0.89; 95% CI 0.48-1.67, p=0.724). The CBRs for fulvestrant 500mg and 250mg were 45.6% (165/362) and 39.6% (148/374), respectively (odds ratio: 1.28; 95% CI 0.95-1.71, p=0.100). The EDoCBs for fulvestrant 500mg and 250mg were 9.83 and 7.24 months, respectively. The EDoCB for fulvestrant 500mg was significantly improved compared with the EDoCB for fulvestrant 250mg (1.36; 95% CI 1.07-1.73, p=0.013).
Conclusion: Our analysis of EDoR and EDoCB showed that treatment with fulvestrant 500mg resulted in a statistically significant increase in EDoCB compared with fulvestrant 250mg in the CONFIRM trial. As far as we are aware, this is the first study of endocrine therapy in breast cancer to formally compare DoR and DoCB by prospectively applying the methodology of Ellis et al. This methodology provides an additional efficacy endpoint option for clinical studies where stabilisation of disease is a clinically relevant endpoint.