

PMC91

REPORTING QUALITY OF DOUBLE-BLIND RANDOMIZED CONTROLLED TRIALS AND ITS ASSOCIATION WITH THE FUNDING AGENCY

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OBJECTIVE: To assess the reporting quality of double-blind randomized controlled trials (RCTs) published in the New England Journal of Medicine (NEJM) using Jadad scale and to examine the relationship between funding source and quality of reporting. **METHODS:** Medline database was searched for RCTs. Search was limited to RCTs published in the last five years in the NEJM and performed on humans. Quality of reporting was assessed using the Jadad scale (1 to 5). The analysis was limited only to the double-blind RCTs assessing drug or vaccine based intervention. **RESULTS:** A total of 207 double-blind trials out of 489 RCTs were assessed for reporting quality. Median (mean) Jadad score was 4 (3.8). The proportion of trials with Jadad score 5 was 20.8% whereas 5.8% trials received a Jadad score of 2. None of the trials received a Jadad score of 1. Method of randomization and concealment of allocation was adequate in 35.3% and 47.8% trials, respectively. Method of blinding was adequate in 51.2% of trials. A total of 89.4% trials reported details of follow-up and reasons for withdrawal. The quality of reporting was good (Jadad score = 3) in 94.2% studies. Year-wise analysis showed that 100%, 91%, 91%, 94% and 96% studies were of good reporting quality in the year 2004, 2005, 2006, 2007, and 2008, respectively. A Jadad score of 5 was received by 41% (9 out of 22) government sponsored trials as compared to only 14% (15 out of 107) trials sponsored by industry. **CONCLUSION:** There is a scope for further improvement in reporting of method for randomization, concealment of allocation and method of blinding. Influence of funding agency on the quality of reporting could be analyzed further.

CANCER – Clinical Outcomes Studies

PCNI

TIME DELAY OF OCCURRENCE OF SECONDARY MALIGNANT TUMORS AFTER PRIMARY BREAST CANCER IN THE FEMALE POPULATION OF HUNGARY BETWEEN 2003 AND 2007Gazdag L¹, Boncz I¹, Farkasné JE¹, Bódis J², Németh K¹, Kornya L¹, Vránics I¹, Gabara K¹, Kriszbacher I²¹University of Pécs, Pécs, Hungary, ²University of Pécs, Pécs, Hungary

OBJECTIVES: The purpose of this study was to determine the time delay from the diagnosis of primary breast cancer to the appearance of secondary tumors affecting other organs in Hungary. **METHODS:** Data were collected from the nationwide financing database of the National Health Insurance Fund Administration (OEP). The subject of the observation aimed female patients treated in hospitals with primary breast tumor (BNO: C5000-C5090, D0570, D0590) between the period of January 1, 2002 and December 31, 2002. We examined the time delay between the diagnosis of primary breast cancer in 2002 and its secondary malignancies in the following 5 years. **RESULTS:** In 2002, a total of 7548 patients were treated in hospitals with malignant primary breast tumor. Between 2003 and 2007 2870 primary breast tumor patients attended in hospitals with tumor disorders affected any other organs. In the following five years after the occurrence of primary breast tumors, secondary malignant tumors affecting other organs were occurred in 21.32% of the patients. The five most often appeared malignant diseases in the examined period were: malignant tumors in the bones and bone marrow were diagnosed 29.0 months, malignant tumor in the lung 34.4 months, malignant tumor in the lymph gland 20.3 months, malignant tumor of the liver 29.7 months and malignant tumor in the brain and dural tumor 32.3 months after the occurrence of primary breast tumors. **CONCLUSIONS:** In the following five years other malignant tumors were occurred in one fifth of the primary breast tumor patients. For the diagnoses of the five most often secondary tumors 29.1 months, or 2.4 years were needed. In consideration to all occurred secondary tumors in case of the whole population this value is on the average 35.2 months or 2.9 years.

PCN2

THE FREQUENCY OF OCCURRENCE OF SECONDARY MALIGNANT TUMORS EVOLVING ON THE FIELD OF PRIMARY BREAST CANCER IN THE FEMALE POPULATION OF HUNGARY BETWEEN 2003 AND 2007Gazdag L¹, Boncz I¹, Farkasné JE¹, Bódis J², Németh K¹, Kornya L¹, Vránics I¹, Gabara K¹, Kriszbacher I²¹University of Pécs, Pécs, Hungary, ²University of Pécs, Pécs, Hungary

OBJECTIVES: The purpose of this study was to determine the frequency of occurrence of secondary tumors affecting other organs in case of patients suffering from tumor located in any fields of the breast. **METHODS:** Data were collected from the financing database of the National Health Insurance Fund Administration (OEP). The subject of the observation aimed female patients treated in hospitals with primary breast tumor (BNO: C5000-C5090, D0570, D0590) between the period of January 1, 2002 and December 31, 2002. Accordingly we examined the frequency of occurrence of secondary tumors evolving after occurrence of the primary tumor in the following 5 years (2003–2007). **RESULTS:** In 2002, a total of 10,378 patients (21,418 cases) were treated with malignant breast tumor. 2,870 primary breast tumor patients attended in hospitals with tumor disorders in any organs between 2003 and 2007. The first five malignant diseases appeared the most often in the examined period were: malignant tumors in the bones and bone marrow in 298 patients, malignant tumor in the lung in 212 patients, malignant tumor in the lymph gland in 186 cases, malignant tumor of the liver in 182 cases and malignant brain and dural tumor in 151 cases. The fre-

quency of occurrence of these tumors projected on 10,000 primary breast tumors is the following: malignant tumors in the bones and bone marrow in 395 patients, malignant tumor in the lung in 281 patients, malignant tumor in the lymph gland in 246 cases, malignant tumor of the liver in 241 cases and malignant brain and dural tumor in 200 cases. **CONCLUSIONS:** In the following 5 years of the primary breast tumor diseases other malignant tumors affecting other organs were evolved in 21.32% of the patients. In 26.67% of the patients no secondary tumors were evolved, but the primary tumor needed further treatment.

PCN3

THE FEASIBILITY AND COST OF EARLY DETECTION OF PROSTATE CANCER IN GASTROENTEROLOGY UNITSShafran-Tikva S¹, Lysy J¹, Goldin E¹, Greenberg D²¹Hadassah University Medical Center, Ein Kerem, Jerusalem, Israel, ²Ben-Gurion University of the Negev, Beer-Sheva, Israel

OBJECTIVES: The American Cancer Society suggests that men over the age of 50 should have their PSA level checked and undergo a rectal examination for early detection of prostate cancer. However, rectal examinations are infrequently performed by family physicians in Israel. Palpation of the prostate gland can be performed during routine rectal examination of patients arriving at gastroenterology units for lower digestive system examinations and serve as an additional tier in the early detection of prostate cancer. We evaluated the cost and feasibility of routine rectal examinations for early detection of prostate cancer in a gastroenterology unit, and follow-up by family physician. **METHODS:** Our study population included a convenience sample of 554 males (age 50–79) arriving at Hadassah Ein-Kerem Medical Center in Israel. During the rectal examination, the gastroenterologist estimated the size, structure and texture of the prostate gland. Patients with suspected pathological results were referred to their family physician for further examinations. We assessed the costs of the screening and follow-up program using the Ministry of Health price list. These costs included the costs of family physician and urologist consultations, PSA test, rectal ultrasound, and biopsy. **RESULTS:** In 145 of patients (26.1%), the gastroenterologist found a pathological mass in the prostate gland and they were referred to their family physicians. Of the 134 patients who went to their family physician, 58 (43.3%) remained for observation and monitoring and 76 (56.7%) were referred to urologists for further examination. Three patients were diagnosed with prostate cancer. The total cost of the screening and follow-up was \$25 per patient and the cost per a prostate cancer detected was approximately \$5000. **CONCLUSIONS:** Our screening model is applicable, efficient, easy to implement and can be introduced with minimal investment of resources. Further studies are needed to examine the long-term cost-effectiveness of such a screening program.

PCN5

GAINS ASSOCIATED WITH CLINICAL EXAMS AND MAMMOGRAPHIC SCREENING FOR WOMEN ABOVE 40 YEARS OF AGECaleffi M¹, Boscatti FHG², Ribeiro RA¹, Bedin Junior A¹, Duarte Filho D¹, Muranaka AH³, Weber B¹¹Hospital Moinhos de Vento, Porto Alegre, RS, Brazil, ²Universidade de São Paulo, São Paulo, SP, Brazil, ³Universidade Federal de São Paulo, São Paulo, SP, Brazil

OBJECTIVES: In Brazil, according to the National Cancer Institute (INCA, 2005), approximately 50% of all breast cancer (BC) diagnosis point to advanced cases at the time of first presentation (stages III and IV), which results in a maximal 5 year survival rate of 36% for these women (The Susan G. Komen Breast Cancer Foundation). It is supposed that this mortality could be reduced through an improvement of public breast health care to encourage early detection of breast lesions for the population. Hence, the Associação Hospitalar Moinhos de Vento started a partnership with Health Secretary of Porto Alegre (capital of Rio Grande do Sul State) to perform a study to measure the impact of annual clinical examinations together with mammography for underserved women over 40 years old. **METHODS:** A total of 9,218 women aged between 40 and 69 year old, living in a delimited geographic area connected to 18 Health Care Units of Porto Alegre are being studied; BC risk factors are also being assessed. For these, yearly clinical examinations and screening mammograms are performed. The analysis is related to the first four years of the project. Its results are compared against INCA epidemiologic data. **RESULTS:** Among the searched universe, 50 women have been diagnosed for BC. Comparing the cancer staging of these women at diagnosis with INCA data for the same region, we have: stage 0 (16% VS 6.7%), stage I (38% VS 20.6%), stage II (32% VS 45%), stage III (10% VS 20%) and stage IV (4% VS 7.7%), respectively. **CONCLUSIONS:** The study showed that the annual screening associated with preventive mammography for women above 40 year old increased their likelihood of an early diagnosis of BC, thus yielding them a better survival and cure prognostic. Therefore, the national adoption of this protocol could reduce the high mortality associated with this neoplasia.

PCN6

USING PREDICTIVE MODELS TO ANALYZE LUNG CANCER DATA

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OBJECTIVES: The purpose of this study is to examine the relationship between patient outcomes and conditions of the patients undergoing different treatments for lung cancer and to estimate the population burden, the cost of cancer, and to examine treatment choice in clinical decision-making. **METHODS:** Lung Cancer data were extracted from the Medstat MarketScan Database based on ICD9 diagnosis codes.