Participation in study improves treatment strategies and individual patient care in the participating centres

The ADEBAR study is a prospective multicenter phase III study which aims to assess whether high-risk breast carcinoma patients (>= 4 axillary lymph nodes affected) will profit from a sequential anthracycline-docetaxel regime (E90C_D: 4 cycles of epirubicin [E] 90 mg/m(2) KOF plus cyclophosphamide [C] 600 mg/m(2) KOF q21 d, followed by 4 cycles of docetaxel [D] loo mg/m(2) KOF q21 d) rather than a standard chemotherapy with anthracyclines (F120C: 6 cycles E-60 mg/m(2) KOF d 1 + 8, 5-fluorouracil 500 mg/m(2) KOF d 1 + 8 and C 75 mg/m(2) KOF d 1 - 14, q28d). With more than 198 actively recruited centers and a median inclusion of 33 patients/month, up until the conclusion of the study the ADEBAR study was the study with the highest recruitment in Germany for this range of indications. Method: Using a standardized questionnaire the participating centers were asked to confirm to what extent therapy and patient care were influenced by participation in the ADEBAR study. The questionnaire consisted of 5 questions: earlier inclusion of patients in the same tumor stages in studies; the type of chemotherapy formerly received by comparable patients outside of the study; changes in the intensity of medical care since participation in the ADEBAR study; increase in information through participation in the study and changes
in the overall quality of medical care. Results: A total of 51% (n = 98) of the questionnaires were returned. Three of the returned questionnaires were excluded from the analysis as the answers to the questions were incomplete. In the year prior to the commencement of the ADEBAR study 63.2% of the participating centers had not included their high-risk patients in clinical studies. Prior to participation in the ADEBAR protocol, the therapy administered to 44.2% of patients with the same indications - usually CMF, EC/CMF or 4 x EC - was inadequate according to the current state of knowledge. 59% of the centers noted that the intensity of their care of patients had increased through participation in the study, independently of the amount of increased attention given for study purposes. Through participation in the research network with its regular flow of information through the newsletter, meetings of study groups, etc., 80% noted an improvement in the extent of their knowledge about breast carcinoma. In addition, 31.6% of the centers confirmed that since the beginning of the study the general quality of the medical care had improved. Conclusion: The results of the survey show that both doctors and patients can profit from participation in clinical studies as these are accompanied by an optimization of decisions concerning therapy and of patient care.