by treatment modality, we found a 2.2 fold increase for irradiated patients (95% CI: 1.4–3.6) compared to non-irradiated patients. For non-irradiated patients, cardiovascular mortality was significantly decreased (SMR=0.5; 95% CI: 0.3–0.8) in comparison to the general population, indicating that the risk profile for breast cancer may be protective against CVD. A healthier life style after breast cancer may also play a role. The radiation-related risk increased especially after more than 10 years follow-up, and even more for patients treated before age 45 (SMR=2.6; 95% CI: 1.4–4.5). Analysis by laterality showed for the internal mammary chain field similarly increased CVD mortality for left and right side (SMR=2.1; 95% CI: 1.2–3.7) against no RT; for the chest wall field, irradiation on the left side revealed a significantly increased CVD mortality against no radiation (SMR=2.5; 95% CI: 1.1–6.4); compared to radiation to the right chest wall the risk was 1.6 fold increased, though not significantly. During the EORTC BCC4 conference results will be presented for the entire cohort of 7600 patients, including 1900 patients treated by breast conserving therapy.

292 ORAL

Cardiac safety analysis of the first stage of NSABP B-31, a randomized trial comparing the safety and efficacy of doxorubicin and cyclophosphamide (AC) followed by paclitaxel (T) to that of AC followed by paclitaxel plus trastuzumab (TH) in patients (pts) with operable, node-positive (N+), HER-2 overexpressing breast cancer (HER2+BC)

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Background: NSABP B-31 is a randomized Phase III trial comparing the safety and efficacy of AC followed by T with AC followed by TH, in the adjuvant treatment of pts with operable, N+, HER2+BC. The pivotal trial of H in pts with metastatic breast cancer demonstrated that concurrent H improved efficacy of chemotherapy (increased response rate and overall survival), but resulted in an increased frequency of congestive heart failure (CHF). To minimize risk of cardiotoxicity for women participating in B-31, a program for close monitoring of protocol defined cardiac events (CE) with planned, formal interim safety analyses was incorporated into the trial.

Methods: Women with N+, HER2+BC, free of cardiac disease, and with normal left ventricular ejection fraction (LVEF) assessed by MUGA scan were eligible. In both arms, MUGA scans were repeated post-AC, 6, 9 and 18 months following randomization. Initiation of H required post-AC LVEF $\geqslant$ the lower limit of normal and a $\leqslant$15 point percentage drop from baseline. If pts developed symptoms or findings of possible CHF, H was held if being given, MUGA was obtained and pts underwent physician-directed evaluation. Copies of reports of MUGA scans and evaluation records were received centrally, blinded as to specifics of cancer therapy and forwarded for review by members of an external Cardiac Advisory Panel, who determined if protocol criteria for CE had been met.

Results of 6 and 9 month MUGA scans were used to guide H therapy, and strict criteria for temporarily holding or discontinuing H based on MUGA results in asymptomatic pts were incorporated into the protocol.

Formal comparisons of the frequency of CE in the 2 arms were planned after 200, 600 and 1000 evaluable pts began post-AC therapy and had been followed for an additional 6 months. Early stopping rules were specified in the protocol to protect against the possibility of excessive cardiotoxicity. Results of the 1st and 2nd interim analyses were reviewed by the Data Monitoring Committee, and accrual was allowed to continue.

Results: The final planned cardiac safety analysis is being completed and results will be available for presentation in 3/04.

293 POSTER HIGHLIGHT

Locally placed catheter with anesthesia pump after mastectomy significantly reduces postoperative opioid medication with up to 68.4%

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Objective: Postoperative pain management is increasingly important especially in cancer patients. We evaluated the use of a temporarily placed thin catheter with continuously application of local anesthetic postoperatively (ON~Q by I-Flow-Corp., Lake Forrest, CA, USA) vs. without regarding postoperative need for opioids until discharge from hospital.

Method: Retrospective analysis from 1/97–12/01 of all mastectomies (n=49) at Fayette Medical Center, Alabama, USA, regarding use of postoperative pain medication with ON~Q pain management pump with continuously Sensorcaine 0.25% application for approx. 72 h (n=22) vs. control group without pain pump (n=27). Different pain medication was standardized in dose equivalents (DE) and statistically analyzed.

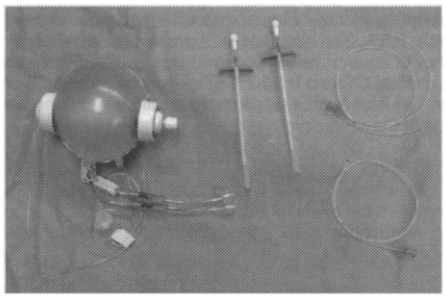

Fig. 1. ON~Q continuous local anesthetic pump with y-shaped catheter.

Results: Patient statistics in the ON~Q vs. control group was age 66.9 vs. 66.7 years, sex 22 female vs. 26 female and 1 male, weight 147 vs. 158 pounds. The procedures performed were modified radical mastectomy 17 vs. 24, simple mastectomy 3 vs. 3 and simple mastectomy with nodes 2 vs. 0. Patients with no need of postoperative pain medication were 18.2% vs. 3.7% ($p<0.001$), no use of pain medication after postoperative day 1 68% vs. 11% ($p<0.001$), total opioid usage in dose equivalents 1.25 vs. 3.36 DE (−62.8%) ($p=0.016$), opioid usage day 1 0.645 vs. 1.82 DE (−64.6%) ($p=0.016$), opioid usage day 2 0.236 vs. 0.748 DE (−68.4%) ($p=0.011$), length of stay 2.35 vs. 2.93 days ($p=0.13$), and postoperative stay in PACU 38.4 vs. 43.3 min ($p=0.13$).

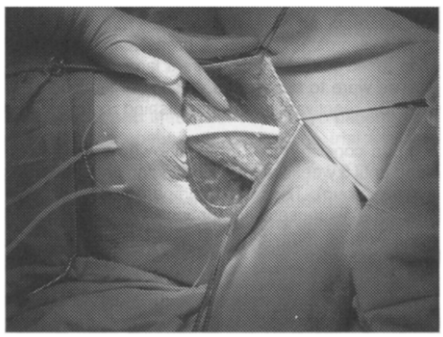

Fig. 2. Intraoperative placement of ON~Q pain pump after mastectomy.

Conclusion: Use of an ON~Q pain management pump could significantly reduce or even eliminate postoperative need for analgesics and reduce the absolute amount of opioid DE used postoperatively up to 68.4%. Length of PACU time (−10.7%) and hospital stay (−19.7%) were also reduced with use of the ON~Q. OR time for placement of catheter and pump is only slightly increased, but no complication occurred and patient's feedback is excellent.

294 POSTER HIGHLIGHT

Factors influencing the amenorrhea caused by anthracycline chemotherapy regimens in premenopausal breast cancer patients

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Amenorrhea secondary to the non-anthracycline chemotherapy (CT) regimens in premenopausal breast cancer patients has been well defined. Less information exists on an anthracycline-induced amenorrhea.

In the aim to get insight into the anthracycline-indiced amenorrhea, the hospital records of 152 premenopausal early breast cancer patients were checked. All patients have been treated with anthracycline-based chemotherapy (FAC or FEC) within five clinical studies: two international multicentric randomized, and three institutional studies. They received 4 cycles of FEC60, either pre- or postoperatively (n=31), or 6–10 cycles of FAC50, either postoperatively (n=102), or pre- and postoperatively (n=19). In total, amenorrhea occurred in 47%, and dismenorrhea in additional 9% pts. The frequency of amenorrhea was related strongly to the age of pts: in the age groups <=35, 36–40, 41–45 and >45 it reached 9%, 24%, 59% and 80.5%, respectively. In the same time the frequency of dismenorrhea decreased with age from 15% to 5%. The beginning of amenorrhea