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Original Article

Role of contrast enhanced spectral mammography in predicting pathological response of locally advanced breast cancer post neo-adjuvant chemotherapy

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ABSTRACT

Objective: To evaluate the accuracy of CESM technique in predicting the final pathological response and residual tumor size post NAC in LABC.

Patients and methods: This study was prospectively carried on 21 female patients diagnosed with stage II and III breast cancer. CESM was done at the end of last cycle of chemotherapy and before definitive surgery.

Results: The sensitivity, specificity, negative predictive value (NPV), positive predictive value (PPV), false negative and false positive of the CESM were assessed by comparing the enhancement of the residual lesions and their size post neoadjuvant chemotherapy (NAC) with the final pathological response and residual tumor size in the MD Anderson system. The specificity of the CESM in predicting the tumor response to NAC in this initial study is 91%, sensitivity was 40% and the NPV and PPV were 80% and 62.5% respectively. The sensitivity of this technique for complete response detection was 100% with a specificity 83% and lowered sensitivity in detecting chemoresistant tumors (33.3%).

Conclusion: CESM is an emerging easy technique that can predict the final pathologic tumor response after NAC especially complete response acting as a good negative technique.

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1. Introduction

Before the introduction of the neo-adjuvant chemotherapy as a standard of care for locally advanced breast cancer, the surgical treatment available for stage 2 and stage 3 operable breast cancers was mastectomy [1]. Neo-adjuvant chemotherapy allowed for down staging of the tumor then performance of more conservative surgeries [2], also it has allowed assessment of the chemotherapy response in vivo which correlates with the clinical outcome [3]. The tumor response to NAC influences surgical planning in the form of mastectomy or breast conserving surgery and even omitting surgery in complete responders as have been suggested recently [4].

Accurate prediction of pathological response to neo-adjuvant chemotherapy with down staging in locally advanced breast tumors as well as estimation of the residual tumor size are critical elements in determining if the patient is a good candidate for breast conservative surgery or not [5].

The complete clinical response if it corresponds to a complete pathological response represents a good prognostic indicator. The use of dual block targeted therapy anti her2 trastuzumab and pertuzumab and tailored chemotherapy regimen according to the hormonal receptor status allowed for an increase in the rate of complete pathological response [6].

Clinical as well as radiological and pathologic methods are used to assess the tumor response to NAC; clinical by comparing the size of the mass pre and during and post the course of the

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chemotherapy [7], radiological using the RECIST criteria (Response Evaluation Criteria In Solid Tumors) [8] and pathological using the MD Anderson and Miller Payne systems [9].

All the available radiological methods have their limitations in predicting the final pathologic response. Mammography and complementary US are the routine methods in our center to assess the response post NAC in locally advanced breast cancer. CESM is an emerging technique that has proved to be an accurate tool in breast cancer diagnosis. The technique relies on the assessment of the vascularity of the tumor where the non-ionic iodine based contrast material injected during mammography is only taken by the viable cancer cells [10].

Different patterns of enhancement that forms images derived from subtraction of dual exposures of low and high X-rays energies are obtained [10]. In this study we investigated the use and the feasibility of the CESM as a method for assessment of chemotherapy response in a sample of locally advanced breast cancer patients. The clinical and radiological findings are compared to the final pathologic diagnosis.

2. Patients and methods

This is a prospective case series performed for 21 patients who attended the outpatient surgical and oncology clinics and diagnosed by biopsy as locally advanced breast cancer (stage II and III) at the National Cancer Institute, Cairo University.

3. Patients' selection criteria

Inclusion criteria: locally advanced breast cancer cases scheduled for neo-adjuvant chemotherapy including T3, T4 and N1, N2 or N3 nodal disease (stages II or III).

Exclusion criteria: stage IV metastatic breast cancer, contraindications for neo-adjuvant chemotherapy or to the administration of iodine contrast agent, pregnancy, and known BRCA mutation.

Diagnosis was done using the TNM staging system for breast cancer according to the AJCC cancer staging system (American Joint Committee on Cancer). A biopsy in the form of FNAC or true cut needle was done for diagnosis. Metastatic workup was done in the form of chest X-ray, abdominal US; CT and bone scan to detect distant metastasis.

An initial bilateral mammography and a complementary US with or without contrast were done to determine the site and size of the tumor. Preoperative skin tattooing was done to localize the tumor in case of complete response.

Treatment: Neo-adjuvant chemotherapy was given in the form of eight cycles, four cycles of adriamycin and cyclophosphamide followed by four cycles of taxenes. After the last course of chemotherapy, all selected patients underwent clinical response assessment as well as CESM and complementary US. The chemotherapy response was categorized into: complete response, partial response, progression of the disease, stable disease.

Definitive surgical treatment in the form of modified radical mastectomy or breast conservative surgery was done for the patients depending on the assessment of the clinical response to chemotherapy, the presence of preoperative tattooing and the patient's choice as well as the indications and contraindications for the breast conservative surgery.

CESM interpretation of response: interpretation was done using response evaluation criteria in solid tumors (RECIST) guide lines for evaluation of target lesions [8]:

- *Complete Response (CR):* complete resolution of all main lesions with reduced short axis of pathological lymph nodes to <10 mm.
- *Partial Response (PR):* At least a 30% decrease in the diameters of the main lesion.
- *Progressive Disease (PD):* At least a 20% increase in the diameters of main lesions as compared to the smallest sum diameters. The appearance of one or more new lesions is also considered progression.
- *Stable Disease (SD):* the lesion didn't reduce in size to meet with PR and didn't progress to be PD as compared to the smallest sum diameters of the original lesion.
- Contrast Agent:
- The contrast agent used was the non-ionic solution (iohexol, Omnipaque 300; Nycomed, Roskilde, Denmark) containing 300 mg of iodine per milliliter, which is commonly used for CT. In our study, we injected 1.5 ml/kg of the agent by hand over a period of approximately 1 min.
- Instrumentation:
- All images were acquired with a production system (Senobright; GE Medical Systems, Milwaukee, Wis). GE Healthcare's new Seno-Bright Contrast Enhanced Spectral Mammography (CESM) technology designed to allow the physician to image blood flow through angiography of the breast using a contrast agent and a dual energy acquisition technique.

3.1. Technique

This is consisted of high-energy and low-energy digital mammograms obtained after administration of iodinated contrast agent. An informed consent was obtained from all patients.

Bilateral conventional mammography both cranio-caudal and medio-lateral oblique views were taken. Contrast-enhanced digital mammographic procedure was performed in approximately 7–10 min. The lesions were analyzed by the radiologist for the presence, morphology, and pattern of enhancement of residual lesions after CTH.

The patterns of contrast enhancement of the residual tumors were interpreted as follows: Intense contrast enhancement denotes chemo-resistance (stable and progressive disease), faint uptake and homogenous background uptake denotes minimal residual disease and enhancement with reduced lesion size is considered partial response, no contrast uptake indicates complete therapeutic response.

3.2. Assessment of the pathology response

Interpretation of the pathology response was done by the pathologist using the MD Anderson system [9] for assessment of response post neo-adjuvant chemotherapy using the following parameters from pathologic examination in order to calculate Residual Cancer Burden (RCB);

1. The largest two dimensions (mms) of the residual tumor bed in the breast (largest tumor bed if multi-centric disease)
2. Submission of the entire largest cross-sectional area of the residual tumor bed for histologic mapping, with specific identification of those slides in the pathology report
   - If the residual tumor is large (i.e. largest diameter > 5 cm), then at least 5 representative cassettes from the largest cross-sectional area are sufficient, but should be identified in the original pathology report
     - o Histologic assessment of the percentage of the tumor bed area that contains carcinoma (all carcinoma, i.e. invasive and in situ).
   - To assess cellularity it is helpful to scan across the sections of tumor bed and then estimate the average cellularity from the different microscopic fields.

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