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Evaluation of Clinical and Radiological Tumour Response during Neo-Adjuvant Breast Cancer Chemotherapy at Yalgado Ouedraogo University Hospital

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Abstract

Background: Neoadjuvant chemotherapy (NAC) is one of the treatment options for breast cancer. Its aim is to significantly reduce the size of the tumour in preparation for surgery. The aim of this work is to analyze the conditions of clinical and radiological evaluation of NAC at the Yalgado Ouédraogo University Hospital (CHUYO). **Patients and Methods:** This was a descriptive cross-sectional study based on the medical records of patients followed up in the cancer department of the CHUYO from 1 January 2013 to 31 December 2021. All patients followed for histologically proven, non-metastatic breast cancer and having received at least one course of NAC were included in this study. The variables were related to the socio-demographic characteristics of the patients, the indications, the protocols of NAC and the sequences of evaluation of the tumour response (clinical, radiological and anatomopathological). **Results:** We collected 105 cases. The average age of the patients concerned was 44 years. The most frequent histological type was non-specific invasive carcinoma in 97.1% of cases. Immunohistochemically, triple-negative patients accounted for 51.4%. At the initial stage, all patients underwent clinical exploration. Clinical measurement of the tumour was performed in 70.5% of cases. The radiological size of the tumour was determined by ultrasound in

59.1% of cases. One patient had a breast MRI. Thirty-one patients were lost to follow-up after the initial evaluation. At mid-term and at the end of treatment, clinical tumour size was performed in 38.6% and 45.6% of cases respectively. There was no breast imaging performed at mid- and end-of-treatment. CT scans were performed in all cases at baseline, mid-term and end of treatment for extension assessment but did not mention the breast tumour. The tumour response rate was not recorded. **Conclusion:** Clinical assessment of tumour response is almost always empirical and not quantified. Medical imaging examinations are prescribed sparingly so as not to compromise the regularity of treatment and patient assessment.

Keywords

Tumour Response, Neoadjuvant Chemotherapy, Breast Imaging, Burkina Faso

1. Introduction

Breast cancer is a public health problem. More than 2.2 million cases of breast cancer were reported in 2020, making it the number one cancer in the world [1]. In addition, it is the leading cause of cancer death in women. In sub-Saharan Africa, half of the women who die from breast cancer are under 50 years old [2]. In Burkina Faso, as in several African countries, the incidence was 1927 new cases in 2020, with a mortality rate of [2].

The treatment of breast cancer involves several complementary means including chemotherapy which can be neoadjuvant, adjuvant or palliative. Neoadjuvant chemotherapy (NAC) aims to significantly reduce the size of the tumour for conservative surgical treatment or to reduce the early spread of tumour cells, known as micrometastases, which are present in 30% - 90% of breast cancers [3]. This treatment is essential in locally advanced breast cancer and carcinomatous mastitis that are initially inoperable [4].

The evaluation of tumour response is of major importance in the therapeutic strategy. In developed countries, the means of assessment include, in addition to clinical examination, radiological investigations such as conventional breast morphology imaging, functional imaging with diffusion magnetic resonance imaging (MRI) and positron emission tomography (PET). In resource-limited countries, these means are often not available.

In Burkina Faso, where breast cancers are often diagnosed at a late stage, neoadjuvant chemotherapy is frequently prescribed and therefore occupies an important place in the therapeutic strategy. In this context of scarce resources and lack of universal health coverage, the evaluation of this treatment is a real challenge. The resources it requires are often not available and accessible to patients. No study has specifically looked at the state of tumour response assessment in our context. In order to improve the management of breast cancer by providing a basis for advocacy for improved NAC practices, we conducted this study with

the objective of analysing the conditions for clinical and radiological evaluation of NAC at the Yalgado Ouédraogo University Hospital (CHUYO).

2. Patients and Methods

This was a descriptive cross-sectional study based on medical records of patients followed up in the cancer department of the CHUYO for histologically confirmed breast cancer, from 1 January 2013 to 31 December 2021.

All patients with confirmed, non-metastatic breast cancer who received at least one course of neoadjuvant chemotherapy during the study period were included in the study.

Patients with non-metastatic breast cancer whose records did not include information on the assessment of tumour response and patients who were lost to follow-up before the first course of neoadjuvant chemotherapy were not included.

The required information was collected from medical records, surgical and pathological registers.

The study variables were related to patient socio-demographic characteristics, indications for ANC, ANC protocols and tumour response assessment sequences.

The reference sequence, the one routinely recommended for ANC assessment, was as follows:

- Initial assessment (clinical, radiological, pathological);
- A mid-term evaluation of the NAC, after the 3ème or 4ème treatment, (clinical, radiological);
- An end-of-NAC assessment (clinical and radiological);
- A postoperative evaluation (clinical and anatomopathological) for patients operated on after the NAC.

The variables used to assess the completeness and regularity of the different assessments were as follows (Figure 1):

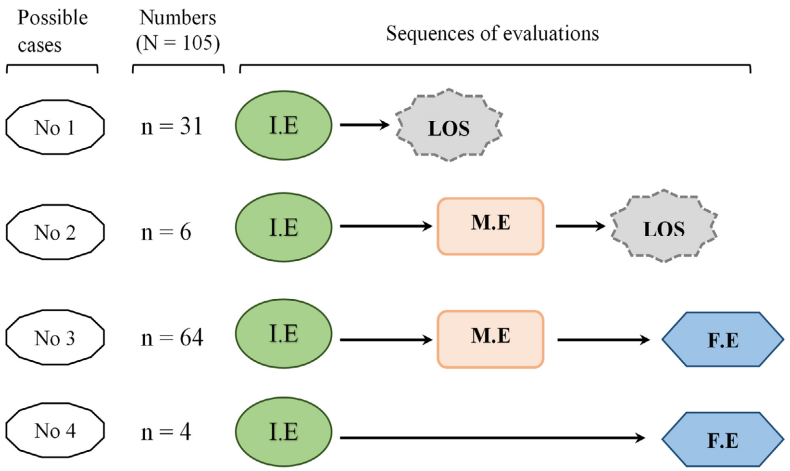

Figure 1. Overview of the different assessments. *I.E.* = Initial evaluation; M.E. = Mid-term evaluation; F.E = Final Evaluation; LOS = Lost to view.

- For the initial assessment, this was the mention or not of the following information in the documents consulted:
  - Clinical data: tumour size, local extension of the tumour, lymph node status;
  - Pathological data: histological type, histopronostic grade SBR, molecular classification;
  - Radiological data :
    - Tumour size, multifocality on mammography and breast ultrasound ;
    - Breast Magnetic Resonance Imaging (MRI) data
    - Secondary distant localizations on thoracic-abdominal-pelvic CT scan, bone scan.
- For mid-term and end-of-treatment evaluation: the means used (clinical examination, paraclinical examinations), tumour response, response of other lesions, appearance of new lesions and overall response;
- For evaluation after surgery: tumour size of the mastectomy specimen, histological type of the tumour and SBR grade, number of nodes removed, number of invaded nodes and Sataloff classification [5].

Quantitative variables were described by means, standard deviation, 1st 2ème and 3ème quartile and their extremes. Qualitative variables were described by proportions.

Ethical considerations were addressed by anonymizing all data collected from patient files. We presented the study protocol to the Yalgado Ouédraogo University Hospital's management and obtained a written approval.

We used the following operational definitions:

- Assessment: An assessment is a qualitative and/or quantitative evaluation of the tumour.
- Mid-term evaluation: This is an evaluation after the 3rd or 4th treatment according to the 6 or 8 treatment protocols respectively.
- End-of-treatment assessment: This is the assessment of the evaluation made after the last course of neoadjuvant chemotherapy.
- Clinical tumour size: This is the size of the tumour as measured and reported by the clinician following a physical examination.

3. Results

We collected 105 cases meeting the inclusion criteria. The characteristics of the patients included in the study are summarised in **Table 1**.

3.1. Initial Assessment

All patients underwent an initial assessment. The evaluation included a positive diagnosis and a diagnosis of extension. Nonspecific infiltrating carcinoma was the most common type (97.1%). Thirty-five patients had additional immunohistochemical analysis. Triple-negative molecular type was the most common (51.4%).

Local extension: All patients underwent a clinical breast examination (**Table 2**). Tumour size was specified in 70.5% of cases (n = 74) and lymph node status

Table 1. Characteristics of patients from the files reviewed.

Characteristics	Frequency	Percentage (%)
Residence (N = 105)		
Urban	68	64.8
Rural	37	35.2
Tumour histology (N = 105)		
NSIC	102	97.1
Carcinomatous mastitis	2	1.9
ILC	1	1.0
SBR grade (N = 105)		
1	18	16.8
2	78	74.3
3	9	8.9
The T category of TNM (N = 105)		
T3	27	25.7
T4a	5	4.8
T4b	14	13.3
T4c	7	6.7
T4d	52	49.5
UICC classification (N = 105)		
IIIA	77	73.3
IIIB	23	21.9
IIIC	5	4.8
Molecular subtype (N = 35)		
Luminal A	5	14.3
Luminal B	9	25.7
Her2 enriched	3	8.6
Triple negative	18	51.4
NAC Protocols (N = 105)		
4 AC60 + 4 Paclitaxel hebd.	55	52.4
4 AC60 + 4 Docetaxel	29	27.6
3 AC60 + 3 Paclitaxel hebd.	2	1.9
3 AC60 + 3 Docetaxel	11	10.5
6 FAC60	8	7.6
Number of cures received (N = 105)		
≤5	30	28.6

Continued

6 - 8	72	68.6
≥9	3	2.8

NSIC: Non-Specific Invasive Cancer; ILC: Invasive Lobular Carcinoma; NAC: Neo Adjuvant Chemotherapy.

Table 2. Distribution of patients according to clinical assessment parameters specified in medical records (n = 105).

Clinical parameters	Specified	%	Not specified	%
Tumour size	74	70.5	31	29.5
Lymph node status	105	100.0	0	0.0
Review of other equipment	105	100.0	0	0.0

in 100% of cases. Breast ultrasound was performed in 62 patients, *i.e.* 59.1% of cases. Multifocality was mentioned in nine patients, *i.e.* 14.5% of cases. Breast MRI was performed in one patient.

Lymph node extension of the tumour. Tumours classified as N1 in the TNM classification were the most frequent (66.7%), followed by N2 (19%) and N3 (4.8%). Cases classified as N0 represented 9.5% (n = 10).

Distant extension: All patients underwent TAP CT and did not show secondary lesions on the supra- and subphrenic levels as required by the inclusion criteria.

3.2. Mid-Term Evaluation

Thirty-one patients, or 30% of the sample, were lost to follow-up before the mid-term evaluation and 69 patients (66.7%) received a mid-term evaluation (Table 3). Tumour size was specified in 38.6% (n = 27), lymph node status in 91.4% (n = 64), tumour response in 98.6% (n = 69). Thoracic-abdominal-pelvic CT scans were performed in 69 patients at mid-term. No patients had breast ultrasound or breast MRI.

Tumour response was reported in the records without quantification of response rates. Thus, there were no cases of complete remission. Partial remission was noted in 56.5% of cases (n = 39) and tumour stability in 27.6% of cases (n = 19). Progression was noted in 15.9% of cases (n = 11). It was locoregional in 3 patients and metastatic in 8 patients. At this stage, one patient underwent surgery and 68 continued chemotherapy.

3.3. Final Evaluation

Sixty-eight patients (64.8%) received an end-of-treatment assessment (Table 4). Of these patients, four (5.9%) did not receive a mid-term evaluation.

At the end of the course, tumour size was mentioned in 45.6% of cases (n = 31), lymph node status in 88.2% (n = 60), tumour response in 100% of cases. The tumour response rate was not mentioned in any case.

Table 3. Distribution of patients according to the parameters of the mid-term clinical evaluation, specified in the medical records (n = 70).

Clinical parameters	Specified	%	Not specified	%
Tumour size	27	38.6	43	61.4
Lymph node status	64	91.4	6	8.6
Tumour response	69	98.6	1	1.4
Tumour response rate	0	0.0	70	100.0

Table 4. Distribution of patients according to end-of-course clinical assessment parameters specified in medical records (n = 68).

Clinical parameters	Specified	%	Not specified	%
Tumour size	31	45.6	37	54.4
Lymph node status	60	88.2	8	11.8
Tumour response	68	100.0	0	0.0
Tumour response rate	0	0.0	68	100.0

All 68 patients underwent a PET scan. In no case did it specify the tumour size. Remission was complete in 1 case (1.5%), partial in 50 cases (73.5%). Stability was noted in 4 cases (5.9% of cases). There was metastatic tumour progression in 19.1% of cases (n = 13).

Surgery was indicated and performed in 55 patients (52.4% of cases) with an operability rate of 72.4%. For the 13 patients (19.1% of cases) with metastatic progression, a second line of chemotherapy was indicated. The remaining 36 patients (34.3% of cases) were considered lost to follow-up.

3.4. Pathological Evaluation of the Surgical Specimen

Histology of the surgical specimen was available for all operated patients. In the pathology report, the size of the tumour remnant, the number of nodes removed and the number of invaded nodes were mentioned in all cases. The Sataloff classification was specified in 44 reports (Table 5).

4. Discussion

Our study showed that the assessment of breast tumour response during neoadjuvant chemotherapy was mainly based on clinical examination in our setting. The prescribed NAC was discontinued in 1/3 of the cases, mainly between the start of the treatment and the mid-term evaluation. Only half of the patients were evaluated at mid-term and at the end of the treatment. No radiological exploration of the breast was performed at mid-term or at the end of the treatment. At the end of treatment, about one in two patients had surgery. The rest were either lost to follow-up or undergoing palliative chemotherapy.

Table 5. Distribution of patients according to the therapeutic effect obtained (n = 44).

Classification according to Sataloff	Frequency	Percentage (%)
TA; NA	1	2.3
TA; NB	4	9.1
TA; NC	0	0.0
TA; ND	0	0.0
TB; NA	0	0.0
TB; NB	7	15.9
TB; NC	18	40.9
TB; ND	0	0.0
TC; NA	0	0.0
TC; NB	4	9.1
TC; NC	3	6.8
TC; ND	7	15.9
Total	**44**	**100.0**

NAC was originally intended to improve locoregional control and survival in patients with high-risk cancers [6]. All patients who underwent NAC were classified as UICC stage III. High-risk patients (N+) represented 91.5% of the cases.

During this NAC, one third of the patients were lost to follow-up mainly between the initial work-up and the mid-term evaluation. This is probably due to the high cost of these investigations for a poor population. Indeed, the majority of patients were housewives and therefore on low incomes. The cost of cancer treatment and imaging studies combined with the poverty of the patients could explain this high attrition rate, in our context where there is no universal health coverage for the population. These wastage rates have also been noted by Takongmo *et al.* [7] in Cameroon. He mentioned a drop-out rate from neoadjuvant treatment at mid-term in 31.4% of cases. The causes were mainly related to the cost of the drugs and side effects.

Assessment of tumour response is both clinical and paraclinical. The gold standard for assessing tumour response is histology [8]. The aim is to identify factors that predict a good tumour response or recurrence after surgery and to objectively estimate the tumour response rate to treatment. Performing an evaluation during chemotherapy allows us to analyse the relevance of continuing a treatment that is not only costly but also not without side effects.

Tumour response or objective response is based on changes in the number and size of targets. The reliability of this assessment depends on the quality of the measurements made [9]. Pierga *et al.* [10] noted that the assessment of response by clinical examination could be relevant when done well, especially by the same clinician during successive assessments. The assessment of tumour re-

sponse was performed by clinical examination in our sample. A predominance of partial remission in more than half of the cases at mid and end of treatment was noted empirically. No radiological breast examinations were performed at mid- and end-of-treatment. There was no tumour response rate noted in the records.

However, a study by the Institut Curie showed that clinical assessment of tumour response may be insufficient. Factors such as obesity may lead to a poor estimate of tumour size. Also, during treatment, oedematous, necrotic or fibrous changes may lead to an overestimation of the size of the lesion. Conversely, the regression of inflammatory phenomena under NAC may also lead to an underestimation of the size of the underlying tumour [11].

The antitumour activity of anti-cancer drugs is assessed in vivo on objective criteria of tumour measurements. The first criteria were developed by the World Health Organization (WHO) in 1970. Currently, the Response Evaluation Criteria In Solid Tumors (RECIST), proposed in 1994, are used. They simplified the WHO criteria by using one-dimensional measures of tumour targets [12]. Four classes are noted: 1) complete response if the lesion is not visible, 2) partial regression if the measurement of the longest tumour axis is 30% smaller than the initial measurement; 3) progression if the tumour size increases by more than 20%; 4) stability if the tumour measures between +20% and −30%.

These criteria can be used regardless of the imaging modality. Mammography, ultrasound and MRI are routinely used to assess tumour response during neoadjuvant chemotherapy [13]. Mammography is reliable when the breast is sparse and the tumour contours are visible. Breast ultrasound is best used to assess well-delineated tumours. It allows a clip to be placed within the tumour site before NAC, aiming to locate the tumour site if there is a complete response to imaging. It is much more efficient for axillary lymph node analysis: 30% - 50% of invaded lymph nodes are not clinically palpable and palpated lymph nodes may be inflammatory on histology. Magnetic resonance imaging allows an even more objective assessment of the size, the deep extension and also the multicentricity of the tumours [11]. When the reduction of the tumour is concentric, the patient may be subject to lumpectomy. However, if the reduction is fragmented, there is a risk of positive margins during lumpectomy. In our sample, only one patient out of 105 was able to benefit from this examination during the initial work-up but there was no control during or at the end of treatment. This modality is not functional in the public structures of our country and the cost of carrying out an examination represents five times the guaranteed minimum wage (XOF 30,684, *i.e.* $61) [14].

Currently, apart from the size criterion, functional imaging can be used to analyse information on the vascularisation, metabolism or viability of tumours. Changes in these parameters indicate response to treatment even before volume reduction [15]. These modalities are ultrasound-Doppler with contrast medium, dynamic CT or MRI, diffusion imaging, magnetic resonance spectroscopy, targeted imaging, PET-CT. These modalities are not available in our country.

CT-PET is routinely performed as part of the initial workup in the case of planned mastectomy to avoid overlooking a metastatic lesion. In the absence of MRI, which is not widely available and not very accessible in our context, the evaluation of tumour size under neoadjuvant chemotherapy could be carried out by CT-PET as part of the therapeutic surveillance, particularly for large tumours [16]. In our study, CT was performed in all patients before, during and at the end of neoadjuvant chemotherapy but no breast tumour measurements were performed.

Postoperatively, histology is the gold standard for assessing tumour response. There are several classifications used by pathologists, but the Sataloff classification has the advantage of assessing the neoadjuvant therapeutic response on breast tissue and lymph nodes. This classification is closer to reality as it takes into account cell viability [5]. However, it was not mentioned in all histopathology reports, limiting any comprehensive search for a clinico-histological correlation of tumour response after NAC.

In less than 1% of cases, there was a complete tumour and lymph node response. On postoperative histology, the therapeutic effect on the tumour was greater than 50% in most cases, associated with a lack of therapeutic effect and the presence of lymph node metastases. These results can be explained by the fact that patients are diagnosed at a late stage [17] [18]. Indeed, most of our patients started treatment at T4 N+ stage, with lymph node involvement present in 90.5% of cases. These elements, which are negative prognostic factors for tumour response, may have been associated with other unfavourable factors: a majority of "triple-negative" cases on immunohistochemistry, frequent in Africa and often defined as resistant to ANC. Poor compliance with treatment remains one of the factors of tumour non-response, whatever the treatment and the means of evaluation used: in fact, almost a third of the patients had not received the required number of treatments.

This study, despite its limitations, has highlighted a series of diagnostic, therapeutic and follow-up problems linked to the management of breast cancer in our country.

5. Conclusion

The use of NAC in our setting is motivated by advanced stages at diagnosis, with the aim of treating micro-metastatic disease early and facilitating possible surgery. Discontinuation and non-adherence to treatment are frequent. The evaluation of tumour response in ANC is a multifactorial challenge due to the limitations of the technical platform, the poverty of the population and the lack of universal health coverage. The clinical examination is the most widely used means of evaluation due to its accessibility. Paraclinical examinations are prescribed sparingly so as not to compromise the regularity of treatment for patients who often have to choose between honouring an assessment and buying anti-cancer drugs. The assessment of tumour response is therefore almost always

empirical and unquantified. It is therefore necessary to advocate for the accessibility of therapeutic and assessment means in order to optimise ANC in Burkina Faso. Ideally, however, prevention and early diagnosis measures would limit the use of this treatment.

Conflicts of Interest

The authors declare no conflicts of interest.

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