Short Communication

National guidelines for management of breast cancer: for enforcement or persuasion?


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Abstract

Despite the effort undertaken by different health institutes in Sudan during the last years, to promote clinical practice guidelines for management of breast cancer, there is limited effect on changing physicians' behavior. Little is known or discussed about the real process and factors involved in changing physician practices in response to these guidelines. This article is giving historical background on the development of breast management guidelines, factors behind the limited effect of guidelines and discusses the way forward.

Keywords: Breast cancer, guidelines, Sudan.

Introduction

Breast cancer is the commonest site specific malignancy affecting women and the most common cause of cancer mortality in women worldwide and constitutes a major public health issue globally. The global incidence increased from 641,000 cases in 1980 to 1,643,000 cases in 2010, an annual rate of increase of 3·1%. Breast cancer killed 425,000 women in 2010, of whom 68,000 were aged 15-49 years in developing countries. It is the commonest site specific malignancy affecting women and the most common cause of cancer mortality in women worldwide(1,2,3,4,5), but the incidence and mortality rates vary internationally by more than 5-fold. Generally, the highest incidence rates are found in Switzerland, U.S. whites, Italy, and many other European countries, whereas low rates are found in Africa, Asia, and South America. Regional patterns in mortality rates are generally similar to the incidence patterns, although U.S. whites, Hispanics, and Asian-Pacific Islanders and Australia have relatively low rates, whereas U.S. blacks and Trinidad and Tobago have the highest rates(6).

Breast cancer accounted for about one-fifth of all cancer patients treated in Sudan and is the most frequent site-specific malignancy seen at both Radiation and Isotopes Center in Khartoum (RICK) (20%, i.e. 2,084/10,410 recorded cancer patients during the period 1967-1984) and National Cancer Institute of University of Gezira (NCI-UG) (19%, i.e. 1,009/5,236 recorded cancer patients during the period 1999-2008)(7-13). Similar frequencies were observed across different studies during the period 1935-2006 (16%,

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This may partly reflect awareness bias, as breast masses or ulcerated lesions are readily evident to the patients themselves, as well as hospitalization bias, given the presence of radiotherapy facilities at RICK and NCI-UG\(^{(14)}\).

A total of 78% of Sudanese breast cancer patients have stage III or IV disease (TNM classification) when they first seek medical treatment\(^{(7,11)}\). Treatment often involves multiple modalities, including surgery, radiotherapy, chemotherapy and hormone therapy, but in advanced stages has markedly diminished chance of success\(^{(15,16)}\). This article discusses the history of management of breast cancer in Sudan and factors behind the limited effect of existed guidelines on changing physician's behavior.

**Breast combined clinic- Gezira region- 2002**

In the year 2002, a group of specialists working in the Institute of Nuclear Medicine, Molecular Biology and Oncology now known as National Cancer Institute (NCI) University of Gezira, Wad Medani Teaching Hospital and Faculty of Medicine University of Gezira has decided to form a multidisciplinary team for management of breast cancer. The team included surgeons, oncologists, pathologists, social worker and a nurse; later a radiologist joined the team.

In the year 2004, the group felt the need for unifying guidelines of managing breast cancer in the Gezira region because of the huge variation in management of cases reviewed during the weekly meeting in the combined clinic. These variations included:

- Mastectomy versus breast conserving surgery; most of the cases during the first years were managed by mastectomy even in the presence of small peripheral tumours and patient's preference.
- Axillary management; in many cases axillary management was inadequate (either no axillary clearance or only few nodes axillary sampling) for axillary staging leading to failure of accurate prognosis estimation to enable proper tailoring of adjuvant treatment.
- Clear and safe resection margins; there was no agreement on what is an acceptable clear margin.
- Fine needle cytology and tissue biopsy; in many cases mastectomy was performed based exclusively on fine needle cytology.
- Specimen orientation/information; in many cases specimen sent without proper orientation and lacking tumour and patient's details.
- Histopathology reports; in most of cases, these reports were not structured and were lacking necessary information to guide further surgical and post operative management.
- Immuno-histochemistry; no immuno-histochemistry evaluation of ER and PR status and Her2 expression for the majority of patients.
- Patient's risk assessment; there was no uniformity among oncologists in assessing prognostic index of patients to guide post operative adjuvant management.
- Multidisciplinary approach; the existence of multidisciplinary team to review cases and draw management outlines were not known outside Gezira region.

**First workshop on breast cancer management-Gezira region**

In the same year-2004, a workshop was held at Faculty of Medicine-University of Gezira in collaboration with the Centre for Development of Medical Education. Invitation to all surgeons, pathologists, radiologists, and many other doctors who are involved in managing breast cancer from the region had been sent. Several papers were presented during the plenary session. These papers had discussed many aspects of breast cancer including presentation of different guidelines and protocols from different countries. A thorough discussion was then held to finalize guidelines.
for management of breast cancer in the Gezira region. Selected members of the workshop then wrote up the document and titled it as suggested Gezira protocol for management of breast cancer.

The important features of the first document are the following:
1. The editors of the document stated that these guidelines were in use in the NCI and Wad Medani Teaching Hospital.
2. In the assessment of breast lesion; double assessment was chosen instead of triple assessment which is the international standard (due to unavailability of breast imaging facility in Gezira area).
3. TNM staging system was adopted instead of Manchester's which was used by many doctors in the region.
4. Standard investigations for staging were recommended for all invasive breast lesions (included liver and renal profile, complete blood count, chest radiograph, ultrasound scan for the abdomen and bone scan).
5. The document listed the indications for total mastectomy and emphasized the need for tissue biopsy before operation.
6. Indications for breast conservation surgery with safe resection margins- (5-10 mms) have been stated.
7. Surgical management of the axilla (clearance of level I and II) with both total mastectomy and breast conserving surgery was suggested as mandatory procedure.
8. Nottingham's Prognostic Index (NPI) score and estrogen/progesterone receptors status were suggested to guide adjuvant chemotherapy and hormonal therapy respectively.
9. Indications for postoperative radiotherapy were listed.
10. Management of local recurrence and /or metastatic disease which include second/third line chemotherapy, hormonal therapy, indication for radiotherapy and possibility of surgery were stated.
11. Locally advanced disease/disease in elderly patients who are not fit for operation were stated and management outline were mentioned.
12. Follow-up recommendation after completion of treatment was made.
13. Male breast cancer and cancer during pregnancy were mentioned and recommendation of management has been stated.
14. Specimen orientation and clinical information were considered duty of the surgeons toward pathology.
15. Minimum information that must be mentioned in the histopathology report was listed.
16. Some benign breast diseases and tumours were mentioned.
17. Recommendation for breast cancer prevention and cancer registry were made.

Later during year 2004, a booklet of the suggested Gezira protocol was published and distributed to doctors in Gezira and nearby regions. Although there is no evidence based data on the improvement that has been achieved since the publication of this document, the general impression of the practicing doctors in the combined clinic, where most of breast cancer cases from Gezira region end, was that the suggested protocol has impacted positively on the general management of breast cancer.

Second workshop on breast cancer management guidelines-Gezira region
The success of the first workshop and the development of suggested Gezira protocol have encouraged the doctors in NCI and Wad Medani teaching hospital to organize another workshop in the year 2006 for updating the protocol and to include as many doctors as possible from all over Sudan. The invitation included official medical organizations and bodies, such as Sudan Medical Council, Association of Surgeons and the Sudanese Medical Specialization Board.
Indeed, many senior surgeons, pathologists, oncologists and radiologists from Khartoum and other regions of Sudan had attended and contributed to the discussion of management problems. Although the content and guidelines has not changed markedly, the layout and organization of content and name of the protocol had changed. Below are the major changes that the new document in 2006 had:
1. The name became Gezira guidelines for management of breast cancer.
2. In the section of diagnosis, triple assessment has been adopted as the standard after introduction of mammography service in Gezira.
3. In the treatment section, treatment according to TNM stage of disease was chosen as the new layout of guidelines.
4. Guidelines for surgical operation-mastectomy, breast conservative, axillary clearance as well as sentinel lymph node biopsy and breast reconstruction were included.
5. Guidelines on specimen labeling, clinical data and minimal information in reporting histopathology were stated in the document.
6. Management of phylloides tumor was included.
7. Guidelines on breast radiotherapy planning and doses as well as chemotherapy regimens and doses were included.

The final document included all the amendments and corrections was published and distributed all over Sudan.

Federal Ministry of health effort- 2010
In the year 2010, doctors involved in developing Gezira guidelines encouraged Federal Ministry of Health, through the Consultative Council for Cancer and Radiotherapy, to sponsor a workshop in Khartoum to develop national guidelines for proper management of breast cancer. The workshop was held in Khartoum in early 2010 and many doctors-surgeons, radiologists, pathologists, oncologists, plastic surgeons, clinical pharmacists form all over Sudan were invited. A thorough discussion and consensus on points of diversity has been made. The final document included all the guidelines on management of breast cancer has been edited and reviewed. Unfortunately, it took almost two years for this document to be published and distributed. The name which was chosen for this new version of the guidelines is protocols for management of breast cancer. This document has been arranged into different chapters, each one contains guidelines in one aspect of breast cancer management.
   • Chapter I contains guidelines for diagnosis and staging.
   • Chapter II contains guidelines for management of early breast cancer.
   • Chapter III contains guidelines for management of locally advanced breast cancer.
   • Chapter IV contains guidelines for management of metastatic and refractory breast cancer.
   • Chapter V contains treatment details (Nottingham prognostic index, male breast cancer, radiotherapy, chemotherapy, hormonal therapy).

This document of breast cancer protocol is to be reviewed in the year 2013.

The challenges and the way forward
Although many practicing doctors who are actively involved in the management of breast cancer are currently aware of these 3 documents or at least of the last one, still the variation in management is there and reflects major deviation from the national/international guidelines. This can be explained by the following reasons:
1. Limited facilities for diagnosis of breast cancer. Triple assessment cannot be done in most parts of the country because of limited number of mammography machines, and existence of few radiologists. Most of the diagnostic
facilities and trained personnel are in the capital.

2. Histopathology facilities limitation. The extreme shortage of pathologists and laboratory technician is a major issue that hindering proper diagnosis.

3. The persons who are involved in breast cancer management have different educational bases. For example surgeons who are among the first medical specialists to meet patients are very much different in their training and exposure to such conditions.

4. The majority of surgeons are not specialized in certain branch of surgery and they practice general surgery and few of them are interested in breast surgery.

5. Extreme shortage of well trained oncologists, radiotherapy units and chemotherapeutic agents.

6. Above all there is very little number of combined breast clinic where the multimodalities management of breast cancer is applied.

7. There is no enforcement of management guidelines.

The way forward
Although it is realistically difficult for the Federal Ministry of Health to enforce guidelines and change behavior of physicians, the continuous efforts mentioned previously to change the practice are plausible and should be encouraged by the ministry to go further and to persuade many others to adopt and apply these guidelines. Basic and essential requirement supply that includes diagnostic facilities e.g. mammography machine, and trained personnel are the pillars for guidelines implementation. The supply of these requirements is the obligation of the Ministry of Health and it has to strive to make them available for physicians who care for breast cancer patients.

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