Indian Consensus on the management of Locally Advanced Breast Cancer : THE GULMARG DECLARATION

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THE GULMARG DECLARATION

10 October 2015, Gulmarg, KASHMIR, INDIA

MOTIVE

•Incidence of breast cancer in India and mortality rate are rising

•WHO estimated national incidence rate in 2015 - 1,55,000 (63%LABC=77,000)

•Five year survival of Stage I is 87%, Stage III is 50%

Serious issue of preventable deaths

OUR CONCERN

•To initiate a relevant debate among policy-planners, opinion-builders, cancer-care providers, cancer-medicine manufacturers and, information disseminators

•In the spirit of evidence-based scientific temperament and genuine public-private partnership that culminates in a consensus

•The motive was and remains *"to help decrease the mortality rates among Indian women suffering from Locally Advanced Breast Cancer by helping formulate a National Cancer Policy*. "

TACTICS

•***The Gulmarg Declaration*** is a consensus document on guidelines for the management of Indian patients of Locally Advanced Breast Cancer and was the result of an intensive one-day workshop.

•This focused event was held on Saturday, 10th October 2015 at The Khyber, Gulmarg

•Drew the participation of eminent breast cancer experts and managers from public and private sectors across India.

•A day of intensive brain-storming sessions and presentations culminated in the consensus document for qualitatively enhanced oncology practice and, for adoption into India's National Cancer Control Initiative.

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DIAGNOSIS & STAGING WORKUP OF LABC IN INDIA

Definition of LABC: More than 5 cm of primary tumour, with clinically positive node in the axilla, or skin or chest wall abnormality. However, individualization is necessary.

RADIOLOGICAL IMAGING

- **Bilateral mammogram: Level 1 evidence. Done irrespective of age**
- **Ultrasound Breast and axilla: Complimentary and case based. Good for directing biopsy for primary and axilla**
- **Contrast Breast MRI: Level 2B evidence. Select cases of Breast Conservation Surgery may require.**

HISTOPATHOLOGICAL DIAGNOSIS

- **Biopsy, ER/PR/Her2neu markers: Level 1 evidence**
- **Ki67 index: Not required**

STAGING WORKUP

- **CECT Chest and Abdomen: Level 1 evidence**
- **PET-CT: Level 2 evidence. Data from AIIMS is encouraging but needs confirmation**
- **PET-MRI: Level 3. Not ready for use yet**

NEOADJUVANT THERAPIES FOR LABC

CHEMOTHERAPY FOR TRIPLE NEGATIVE LABC

- Anthracyclines and Taxanes should be incorporated into the treatment.
- For a carrier of BRCA mutation/s, platinum to be added

TREATMENT OF HER2 POSITIVE LABC

- Taxane with Anti Her2 therapy is considered important to achieve optimal down-staging
- Dual targeted therapy is not routinely recommended except cases with ER negative disease
- Anthracyclines should be incorporated into the treatment and should be administered in a sequential fashion and not concurrently with the anti-Her2 treatment

NEOADJUVANT ENDOCRINE THERAPY FOR HORMONE RECEPTOR POSITIVE LABC

- Anthracycline and Taxanes should be considered as standard treatment for hormone positive LABC
- Neoadjuvant endocrine therapy alone to be considered in select cases (age, co morbidity, performance status, tumour grade and patient preference).

CHEMOTHERAPY FOR HER 2 NEGATIVE LABC

- Systemic treatment is the preferred initial treatment for all LABC.
- Anthracyclines and Taxanes to be considered standard regime
- pCR is an endpoint worthwhile aiming for as it has prognostic value and is valued by both doctors and patients
- As far as possible all 6 cycles of chemotherapy cycles should be completed pre operatively

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SURGICAL OPTIONS IN LABC

- The surgeon's evaluation and documentation of the primary disease status at presentation, is essential.
- Primary surgery offered to a small subset of patients with resectable LABC, majority require neoadjuvant systemic treatment (NAST), followed by surgery.
- Periodic evaluations during NAST to assess response, and repeat imaging prior to definitive surgery. Final surgical options depend on primary disease status and response to NAST.
- Mastectomy is the mainstay of the treatment. Recent data suggest that BCS may be safely performed on carefully selected patients with equivalent or better outcomes in terms of DFS, OS
- THREE CRUCIAL INGREDIENTS FOR BCS INCLUDE
  - Careful evaluation and stringent patients selection
  - High quality pathological assessment to ensure negative surgical margins
  - BCS is followed by high quality radiation
- SURGICAL TREATMENT OF THE BREAST PRIMARY
  - Achieving excellent cosmetic result is important with oncoplastic techniques
- SURGICAL TREATMENT OF THE AXILLA
  - Level I and II axillary dissection, and level III in selected patients is recommended
  - Selected patients without axillary involvement at presentation prior to NAST, candidates for Sentinel Lymph Node or Axillary sampling
- BREAST RECONSTRUCTION
  - Feasible immediately following mastectomy or delayed till the completion of radiation therapy.
- PALLIATIVE SURGERY
  - Palliative mastectomy may be essential in patients with poor or no response to NAST, with appropriate skin cover / reconstruction

STANDARD RADIOTHERAPY TECHNIQUES LABC

- Linear accelerator is preferred over Cobalt 60.
- 3-dimensional conformal radiotherapy is a good option, but wherever possible, IMRT is to be preferred
- **USE OF IMAGE GUIDED RADIATION THERAPY (IGRT)**
  - Daily imaging is suggested for all breast cancer treatment, particularly for high precision techniques like IMRT or Volumetric Arc Therapy (VMAT) us suggested.
  - Volumetric Arc Therapy is preferred over IMRT
  - APBI is not the standard of care yet. But it can be practiced in select group of patients (Low risk: Over 50 years of age, T1N0, ER positive)
  - It has enough evidence, and is becoming standard of care. It can be adopted safely, especially in the Indian scenario.
- **RADIATION IN NODAL REGION POST BCS**
  - Node negative patients: radiation limited to the breast only.
  - High risk node negative: irradiate regional nodes in select groups (>2 cm, <10 lymph node removed with ER negative, grade III or lymphovascular invasion)
  - Node positive patients: regional nodal irradiation strongly considered over whole body irradiation

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- POST MASTECTOMY RADIATION THERAPY
  - Indicated for patients with tumor size more than 5 cm, 1-3 positive nodes with adverse pathological feature (close margins of <1mm, lymphovascular invasion, ER negative, grade III, inadequate lymph node dissection) and young age.
  - Standard option for patients with 1-2 sentinel node positive and no axillary dissection
  - Regional Nodal Irradiation warranted in inadequate nodal irradiation
  - Should include regional nodal irradiation to supra/infraclavicular region
  - Internal mammary node radiation if heavy axillary burden with PNE, inner or central quadrant tumors.
- RADIATION AFTER NEOADJUVANT THERAPY
  - Follow the staging before the neoadjuvant chemotherapy for radiotherapy.
- RADIATION IN POST-MENOPAUSAL AFTER BCS

  RT with hypo fractionated protocol considered
  - Expected survival is longer
  - Active life with minimal comorbid conditions.
  - Radiotherapy may be omitted after BCS
  - Women more than 70 years of age with ER positive, node negative or T1 disease.

ADJUVANT THERAPIES IN LABC STATE OF THE ART

- All treatment should be driven by the base line bio-markers (ER/PR/HER) and the quality of response to the initial chemotherapy.
- 'Good responders' should complete all courses of chemotherapy; go for adjuvant radiation therapy and adjuvant hormone therapy as per the receptor and menopausal status
- 'Slow responders' a change of chemotherapy may be considered based on the drugs received in the initial treatment. The alternative treatment for this group is to go for surgery and give the rest of chemo post surgery.
- Addition of platinum agent for young patient with BRCA mutation who is a slow responder to the initial treatment.
- One year of Trastuzumab continues to be the standard for Her2neu positive patients
- Adjuvant bisphosphonates should be considered for bone health particularly in post menopausal women who are receiving aromatase inhibitor and have a compromised bone health
- Follow up of patients, initially 3 monthly and then gradual prolongation of the follow up interval is recommendation.
- Follow up of patients, X Ray Chest, Ultrasound of abdomen and Mammograms should constitute the radiological work up. Routine use of CT scans/MRI/PET scans is discouraged. They should be used only when clearly indicated.

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IMPACT

The guidelines issued were adopted by
UNION MINISTRY OF HEALTH & FAMILY WELFARE In NATIONAL CANCER POLICY

Guidelines were distributed for compliance to
33 REGIONAL CANCER CENTERS & 108 STATE CANCER CENTERS

One hopes for optimum post treatment outcomes in LABC patients in India

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