

4. Need for Surgical training and validation.
5. Dedicated oncopathology divisions with frozen & cytology facilities are mandatory for SLNB program
6. High false negative SLN rate can lead to under treatment of patients
7. Long term oncologic out come in large randomized trials is yet to be proven

Indian Scenario:

Basically SLNB has evolved as an alternative staging tool for ALND in patients with node negative early breast cancer in the west. Seventy percent of breast cancer population in the west consist of screen detected node negative early breast cancer. This was possible because of the wide spread use of screening programs and public awareness campaigns held during the last three decades. Whereas, in India majority of breast cancer patients present with advanced stage disease and 60 to 70 % are node positive at presentation. We don't have a comprehensive screening program for early detection of breast cancer in India. Most of the breast cancer patients have no access to quality diagnostic and treatment facilities and currently primary level surgical mismanagement (under treatment) is prevalent in most parts of the country. Very few centers are following standard surgical guidelines. The media and physicians treating breast cancer should understand these issues and exercise caution before publicizing SLNB as a new surgical technique for managing breast cancer. If these relevant issues are not propagated by the Indian scientific community the potential for mismanagement of Indian breast cancer patients will be enormous.

In view of the issues discussed earlier, we would like to recommend that Indian surgeons treating breast cancer should offer ALND for all invasive breast cancer patients routinely. Academic surgical divisions and dedicated high volume breast centers should initiate SLNB program for training and validation only, till the long term results of large western randomized trials are available.

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ETHICAL GUIDELINES FOR BIOMEDICAL RESEARCH

The need for uniform ethical guidelines for research on human subjects is universally recognised. It has acquired a new sense of urgency as the critical issues in the area of biogenetic research involving human subjects have become acute. Apart from the mandatory *clinical trials* on new drugs, a number of *diagnostic procedures, therapeutic interventions and prevention measures* including the use of vaccines, are being introduced which involve human subjects. Further the advent of *new medical devices and radio-active materials* and therapeutic benefits of *recombinant DNA products* have added a new dimension to the ethical issues that need to be considered before evaluating these for their efficacy, utility and safety.

Any research using the human beings as subjects shall bear in

mind the following principles of : i) **essentiality**, (ii) **voluntariness**, **informed consent**, (iii) **non exploitation**, (iv) **privacy** and **confidentially**, (v) **precaution and risk minimisation**, (vi) **professional competence**, (vii) **accountability & transparency**, (viii) **maximisation of public interest** and **distributive justice** (ix) **institutional arrangements** (x) **public domain** (xi) **totality of responsibility** and (xii) **compliance**.

Recent advances in the field of **Assisted Reproductive technologies, organ transplantation, Human genome analysis, and gene therapy** promise unquestionable benefits to mankind. At the same time, they raise many questions of law and ethics, stimulating public interest and concern.

(Source : ICMR Publication 2000)