Breast cancer pathology reporting in the Indian context: Need for introspection

A breast cancer pathology report is a sacrosanct document upon which all other treatment decisions are made, and pathologic evaluation dictates the use of potentially curable therapy. An incorrect pathologic diagnosis may lead to negative outcomes as serious as failure to treat a potentially curable case of breast cancer or the provision of unnecessary surgery, chemotherapy, and radiation.

The optimal management of breast cancer requires a multidisciplinary team composed of surgeons, medical oncologists, radiologists, and pathologists who determine a diagnosis and treatment plan by consensus.[1]

On the international front, practice guidelines, policy statements, and quality assurance programs have been developed in an effort to standardize and improve breast pathology practice.[2-4] Nonetheless, concerns remain universal with respect to the adequacy of specimen handling, pathology reporting, laboratory testing, personnel training, and quality control.

Currently, there are significant practice variations in breast pathology in India that most likely affect diagnostic accuracy and compromise observed patient outcomes. Our challenge is to determine how to ensure that breast pathology practices meet or exceed acceptable standards throughout India.

Areas of particular interest and concerns include but are not limited to:
• Specimen transport, handling and pathology reporting
• Pathology training and personnel
• Quality assurance programs, particularly for ER, PR, and HER2 testing and other markers as the science evolves.

SPECIMEN TRANSPORT, HANDLING, AND PATHOLOGY REPORTING

Appropriate specimen handling, fixation, and processing are crucial but these processes are not uniform throughout India. For example, the practice of specimen orientation and prompt specimen transport to pathologist by the surgeon is critical in order for the pathologist to adequately assess the margin status and achieve optimum fixation for several downstream investigations.

It would be prudent for pathologists to adopt a concerted approach in tandem with surgeons to establish good practices and a robust quality chain, which would also include other stakeholders as nursing staff, residents, and laboratory technologists.[5]

Accurate pathology diagnosis and the provision of prognostically significant information are important to ensure that patients are managed appropriately. A standard set of data from each patient, using the same terminology and diagnostic criteria, is essential to achieve these objectives. Minimum dataset reporting formats aim to encourage the use of common terminology and definitions of breast diseases and methods of classifying breast cancer. The value of structured reports with all core items over text-based, narrative, traditional histopathology reports is well proven.[6]

PATHOLOGY TRAINING AND PERSONNEL

Continuing medical education (CME) programs hold promise to improve performance in breast pathology. The provision of CME credits provides an incentive for participation.

Specialized training in breast pathology exists in few academic institutions; however, anatomic site-wise subspecialty surgical pathology practice is generally lacking in a majority of centers in India due to various reasons, predominantly administrative and logistic ones.

Association of Medical Histotechnologists of India (AMHI), established in the year 2014, provides an educational platform for the technical staff working in surgical pathology and immunohistochemistry. AMHI conducts its meetings regularly in various parts of India, addresses basic issues related to...
fixation, processing and fosters interaction among members of the technical fraternity.

QUALITY ASSURANCE PROGRAMS FOR BIOMARKER STUDIES

There is a need for a national quality assurance program for common procedures, such as ER, PR, and HER2 testing and other markers as the science evolves. It is well documented that the false-positive rate for HER2 testing is unacceptably high in laboratories that do a small volume of HER2 testing or that do not use automated staining.

Potential problems with immunohistochemistry (IHC) testing that may lead to interlaboratory discordance include the use of a diverse set of reagents (antibodies), different detection systems, different methods of scoring, and different cut-offs.[7]

THE NEED OF THE HOUR

What is needed at the current time is a more comprehensive evaluation of the issues raised here so that a plan of action can be created. The common thread connecting these issues is an apparent lack of uniform practices throughout the country.

The efforts to ensure uniformity in various steps from tissue acquisition to final diagnostic reports are underway in India.

In India, the National Accreditation Board for Testing and Calibration Laboratories (NABL) provides a third-party assessment of the technical competence of testing in medical laboratories. Similarly, many laboratories participate in CAP’s laboratory accreditation program. However, both NABL and CAP audits are voluntary and not mandatory exercises. Moreover, ensuring quality is a costly proposition.

In this context, great strides made by the National Cancer Grid (NCG), so far, are commendable. The NCG is a network of major cancer centers, research institutes, patient groups, and charitable institutions across India with the mandate of establishing uniform standards of patient care for prevention, diagnosis, and treatment of cancer, providing specialized training and education in oncology and facilitating collaborative basic, translational and clinical research in cancer.[9]

Under the aegis of NCG, adopting a “back to basics approach,” a series of workshops are being conducted in medical colleges across the length and breadth of our country on grossing and minimum dataset reporting for common cancers with emphasis on optimum fixation and processing. This initiative is aimed at sensitizing young postgraduates and faculty in surgery and pathology to the basic burning issues. In addition, an external quality assurance scheme (EQAS) is also being run under the aegis of NCG for biomarker estimation using IHC and molecular techniques. The EQA serves to investigate consistency in biomarker estimation among participating laboratories and also acts as an educational tool.

Thus, the need of the hour is to introspect, change our mindset and introduce simple preventive and corrective measures to improve our routine practices. High-quality, complete, clear, and consistent cancer pathology reports are important not only for contemporary oncological practice but also for cancer registries, epidemiologists, health policymakers, and researchers involved in translational medicine.

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