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Original Research

Evaluating Tumour Marker Utilization in a Rural Tertiary Care Teaching Hospital: Insights from a Clinical Laboratory Audit in the Konkan Region

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Introduction: Tumour markers are biochemical entities used to aid in diagnosis, prognostication, and therapeutic monitoring of malignancies. However, their utility in rural healthcare settings remains underexplored. This study aimed to audit the utilization patterns of tumour marker assays in a rural tertiary care hospital, evaluate their appropriateness in clinical context, identify potential misuse, and propose actionable recommendations for rational test ordering.

Materials and Methods: A retrospective audit was conducted on 477 patients over two years (June 2021–June 2023) in the Central Clinical Laboratory of BKL Walawalkar Hospital. Data were analyzed by sex, departmental origin (IPD/OPD), type of tumour marker ordered, and clinical relevance as per established guidelines. Tumour markers included PSA, CEA, CA-125, CA 19-9, AFP, and B-HCG.

Results: Females constituted 54.1% of the cohort. PSA (21.3%) and CEA (21%) were the most commonly ordered tests. CA-125 and B-HCG were largely requisitioned by OB-GYN departments. A mismatch was observed between test ordering patterns and guideline-based indications in several instances, particularly for PSA and CEA, with evidence of redundant or non-indicated requisitions from departments with low oncology involvement.

Conclusions: While tumour markers are indispensable tools in oncology, this audit reveals significant gaps in their utilization, especially in departments lacking direct oncologic focus. The findings underscore the need for institutional guidelines, education on appropriate test use, and periodic audits to promote diagnostic stewardship in resource-limited rural settings.

Introduction

Tumour markers are endogenous biochemical substances commonly proteins, glycoproteins, or hormones that are either secreted by malignant cells or produced by host tissues in response to neoplastic transformation. They play a pivotal role in the oncological landscape by aiding in the diagnosis, staging, therapeutic monitoring, and prognostication of cancer. The clinical utility of tumour markers, however, is often tempered by their limited specificity and sensitivity, especially when used in isolation without correlation to radiologic or histopathological data [1].

The proliferation of immunoassay technologies has facilitated widespread availability of tumour marker tests, leading to their increasing incorporation into routine clinical practice. Nevertheless, this accessibility has also engendered a propensity for indiscriminate ordering of these assays, frequently without adherence to evidence- based guidelines. This is particularly problematic in resource-limited settings where the burden of cost and diagnostic uncertainty is compounded [2].

The National Academy of Clinical Biochemistry (NACB) and other global organizations have issued directives emphasizing the prudent use of tumour markers, particularly recommending their application in monitoring disease progression or therapeutic efficacy rather than for primary diagnosis [3]. Despite these recommendations, widespread misuse continues, often driven by a lack of awareness or over-reliance on laboratory data in the absence of definitive clinical findings.

In rural healthcare systems, where diagnostic imaging and histological services are often constrained by logistical and financial barriers, tumour markers may serve as preliminary indicators of malignancy. As such, understanding the patterns of their utilization becomes essential to enhancing diagnostic stewardship and ensuring the rational use of limited resources [4].

This study was conducted to systematically audit the utilization of tumour marker assays within a rural tertiary care teaching hospital, to evaluate current practices, identify potential gaps in appropriateness of test requisition, and ultimately contribute towards the formulation of standardized guidelines tailored to such settings.

Materials and Methods

Study Design

This observational, retrospective audit was conducted in the Department of Biochemistry at BKL Walawalkar Rural Medical College and Hospital, encompassing all tumour marker assays performed between June 2021 and June 2023.

Sample Population

The study population included 477 patients, irrespective of age or clinical diagnosis, for whom any of the following tumour marker tests were ordered: Prostate-Specific Antigen (PSA), Carcinoembryonic Antigen (CEA), Cancer Antigen 125 (CA-125), Cancer Antigen 19.9 (CA 19-9), Alpha-fetoprotein (AFP), and Beta-Human Chorionic Gonadotropin (B-HCG).

Data Acquisition

Data were extracted from laboratory information systems and included demographic variables (age, sex), origin of request (IPD/OPD), departmental affiliation, and tumour marker values.

Analytical Procedure

Venous blood specimens (5 mL) were collected and centrifuged at 3500 rpm for 10 minutes. Serum aliquots were subjected to chemiluminescent microparticle immunoassay (CMIA) using the Abbott Architect i1000SR platform.

Reference Intervals

PSA: 1–4 ng/ml; CEA: 0–2.5 ng/ml; CA-125: 0–35 U/ml; CA 19-9: 0–37 U/ml; AFP: 0–40 ng/ml; B-HCG: 0–5 mIU/ml (female), 0–2 mIU/ml (male).

Statistical Analysis

Data were analysed for distribution patterns, mean values, standard deviations, and ward-specific requisition frequencies using descriptive statistics.

Results

Among the 477 subjects, female patients (n=258; 54.1%) slightly outnumbered males (n=219; 45.9%).

Test Frequency

PSA (21.3%) and CEA (21%) were the most frequently requisitioned tumour markers, followed by CA-125 (19.3%), CA 19-9 (14.7%), B-HCG (13%), and AFP (10.9%).

Departmental Trends

The Outpatient Department contributed the highest proportion of test requisitions (20.3%), followed by Female Surgery Ward (16.8%) and Female Medicine Ward (16.6%).

Marker-Specific Observations

• PSA tests were predominantly ordered for male inpatients, particularly from the Internal Medicine and Surgical wards.

• CA-125 and B-HCG were primarily utilized for female patients, notably from Obstetrics and Gynaecology.

• CEA and CA 19-9 were distributed across multiple wards, reflecting their use in gastrointestinal and general oncological assessments.

The substantial variability in marker levels underscores the heterogeneity of clinical presentations and the necessity for correlation with definitive diagnostic modalities.

Discussion

The present audit was designed not merely to document the frequency of tumour marker utilization, but to critically examine the appropriateness and contextual relevance of these assays within a rural tertiary care teaching hospital. This analytical lens is essential in settings where healthcare resources are finite, diagnostic modalities are constrained, and clinical decision-making is often influenced by accessibility rather than appropriateness. The findings of this study thus

provide valuable insights into both practical trends and systemic lapses in diagnostic stewardship [5].

The predominance of PSA (21.3%) and CEA (21%) in the test requisition profile is, at face value, consistent with their broad clinical applications in prostate and colorectal malignancies. However, deeper examination reveals that a substantial fraction of these requests originated from general outpatient clinics and departments lacking direct oncological focus. This pattern raises concerns regarding non-specific or exploratory testing, possibly undertaken in the absence of concrete clinical indications. As per guidelines established by the National Academy of Clinical Biochemistry (NACB) and European Group on Tumour Markers (EGTM), PSA and CEA assays are best reserved for monitoring confirmed malignancies or recurrence, not for indiscriminate screening, especially in asymptomatic populations without supporting clinical or radiologic evidence. Overuse in such contexts may contribute to false-positive interpretations, unnecessary anxiety, and downstream testing, thereby straining both the patient and the healthcare system [6, 7].

The ordering trends for CA-125 and B-HCG were more aligned with clinical expectations, predominantly issued by departments of Obstetrics and Gynaecology. CA-125, despite its known limitations in specificity particularly its elevation in benign gynaecological and inflammatory conditions remains a useful adjunct in the evaluation of suspected ovarian malignancies when used judiciously. Similarly, B-HCG retains diagnostic relevance in the detection of gestational trophoblastic neoplasia and germ cell tumours. However, even within these contexts, the high standard deviation observed in values (e.g., B-HCG: 433.56 ± 1177.09 mIU/ml) suggests a broad, possibly unfocused range of clinical scenarios prompting test requisition, which calls for further scrutiny [8].

CA 19-9 and AFP, while relevant to gastrointestinal and hepatic malignancies respectively, demonstrated considerable inter-assay variability and were requested across diverse departments with minimal oncologic specialization. These findings point toward heterogeneous and potentially non-guideline-based utilization, which may dilute the diagnostic utility of these assays. In particular, AFP showed a mean of 151.78 ng/ml with a standard deviation of 450.77, highlighting possible misuse in screening contexts rather than targeted follow-up or surveillance [9].

In resource-limited settings such as ours, where the diagnostic armamentarium is often circumscribed by financial and logistical barriers, tumour markers may be over-relied upon as surrogate diagnostic tools. This reliance, though understandable, can result in diagnostic misdirection, especially when serological assays are interpreted in isolation without corroborative imaging, histopathology, or clinical suspicion. Studies from other LMIC contexts have similarly reported indiscriminate use of tumour markers, often driven by clinician unfamiliarity with evolving recommendations and absence of institutional protocols.

Furthermore, the economic implications of such non-targeted testing must not be underestimated. Unnecessary tumour marker requisitions incur direct costs and may initiate cascades of additional diagnostic investigations, leading to increased patient burden without commensurate clinical benefit. Additionally, false positives can inadvertently delay accurate diagnosis, initiate inappropriate referrals, or cause unwarranted psychological distress.

The variability and at times non-conforming patterns of test requisition identified in this audit strongly suggest the absence of structured institutional policies governing tumour marker use. To bridge this gap, it is imperative to adopt a multi-pronged approach. This should include:

• Development of local requisition guidelines, harmonized with NACB and EGTM frameworks but contextualized for rural and resource-constrained realities.

• Mandatory requisition protocols, where clinicians must document the clinical indication and suspected diagnosis prior to assay approval.

• Interdisciplinary audit committees, comprising clinicians, biochemists, and hospital administrators, to periodically review requisition trends and provide targeted feedback.

• Capacity-building and continuing medical education (CME) initiatives aimed at sensitizing frontline healthcare providers on the appropriate role, limitations, and interpretation of tumour markers in clinical decision-making.

By linking audit-derived empirical data with guideline-based analysis, this study offers actionable insights into the disconnect between test utilization and clinical appropriateness, a phenomenon rarely studied in rural Indian healthcare contexts. It underscores the urgent need for institutional accountability and promotes evidence-based diagnostic practices to ensure efficient resource use and improved patient outcomes. Importantly, this work establishes a methodological framework for similar audits across comparable healthcare settings, with potential to contribute toward national policy-level discourse on laboratory governance and oncology diagnostics.

In conclusion, this study furnishes a comprehensive and critical evaluation of tumour marker utilization within a rural tertiary care environment, elucidating both the pragmatic reliance on serological diagnostics and the endemic lapses in test appropriateness. While the prominence of markers such as PSA, CEA and CA-125 aligns with their well-documented clinical utility, their requisition in contexts bereft of corresponding clinical justification reveals systemic vulnerabilities in diagnostic stewardship.

The findings underscore an exigent need for the formulation and implementation of institution-specific requisition protocols, underpinned by globally recognized guidelines and adapted to the local healthcare milieu. Furthermore, integrating mandatory requisition justification, routine audits, and interdisciplinary consensus-building into institutional practice can meaningfully recalibrate test utilization patterns.

By bridging the chasm between accessibility and appropriateness, the audit not only fulfills its stated objectives but also contributes substantively to the discourse on laboratory governance and evidence-based oncology diagnostics in underserved settings. The insights derived herein may serve as a template for analogous rural healthcare infrastructures seeking to harmonize diagnostic efficiency with clinical prudence.

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Conflict of Interest

None

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