Section: Miscellaneous

Original Research Article

SERUM CEA, CA-125 AND TOTAL PSA PROFILES AMONG HIGH-RISK RURAL ADULTS IN NORTH MAHARASHTRA: A CROSS-SECTIONAL STUDY

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ABSTRACT

Background: Serum tumor markers are useful for monitoring selected malignancies, but their value for screening people without a known cancer diagnosis is limited by low specificity and false-positive results. Evidence from rural Indian populations with common cancer risk factors is scarce. **Objectives:** To describe serum carcinoembryonic antigen (CEA), cancer antigen 125 (CA-125) and total prostate-specific antigen (PSA) concentrations in high-risk rural adults from North Maharashtra and to examine the distribution of study-defined borderline elevations across demographic and risk-factor groups.

Materials and Methods: This cross-sectional study included 100 rural adults aged 20 years or older with at least one cancer risk factor, including tobacco use, alcohol consumption or family history of malignancy. Individuals with known malignancy, ongoing cancer treatment or follow-up, and pregnant women were excluded. CEA was measured in all participants, CA-125 in 44 women and total PSA in 36 men older than 40 years using automated chemiluminescence immunoassays on the Mindray CL-960i platform. Results were classified using prespecified descriptive categories. Associations were assessed using Fisher exact or chi-square tests, as appropriate.

Results: The cohort comprised 56 men and 44 women; mean age was 45.8 ± 13.2 years. Tobacco exposure was present in 62%, alcohol consumption in 36% and a family history of malignancy in 8%. Borderline elevations were observed for CEA in 12/100 participants (12.0%; 95% confidence interval [CI], 7.0%-19.8%), CA-125 in 5/44 women (11.4%; 95% CI, 5.0%-24.0%) and total PSA in 3/36 eligible men (8.3%; 95% CI, 2.9%-21.8%). No participant had a value in the study-defined marked-elevation category. Borderline CEA was more frequent in participants older than 60 years than in those aged 60 years or younger (35.3% vs 7.2%; odds ratio 7.00, 95% CI 1.92-25.58; p=0.005). The higher proportion among tobacco users did not reach statistical significance (16.1% vs 5.3%; p=0.125).

Conclusion: Most tumor-marker values were within the selected reference categories. Borderline results were relatively common and were not diagnostic of malignancy. CEA, CA-125 and total PSA should not be used as standalone community screening tests; abnormal results require repeat testing, clinical correlation and organ-specific evaluation. Serum tumor markers should be used to complement—not replace—clinical assessment and established organ-specific screening. In rural practice, the most useful response to a borderline result is verification, evaluation for benign causes, symptom-directed examination and a clear referral pathway.

Keywords: CA-125; carcinoembryonic antigen; chemiluminescence immunoassay; prostate-specific antigen; rural health; tumor markers.

INTRODUCTION

Cancer remains a major global health problem. GLOBOCAN 2022 estimated close to 20 million new cancer cases and 9.7 million cancer deaths worldwide in 2022.[1] In India, the National Cancer Registry Programme estimated 1,461,427 incident cancer cases in 2022 and projected a continuing rise in burden.[2] Tobacco-related malignancies form an important preventable component of this burden, and rural populations may experience delayed diagnosis because of limited awareness, financial constraints, restricted access to screening and delayed referral [3,4]

Tumor markers are molecules produced by neoplastic cells or by the host in response to a tumor. In established oncology practice, serum markers may support diagnosis in selected clinical contexts, provide prognostic information, monitor response to treatment and assist in detecting recurrence. Most commonly used serum markers, however, do not have sufficient sensitivity or specificity for population screening, and an isolated abnormal result cannot confirm malignancy.[5-7]

Carcinoembryonic antigen (CEA) is used mainly in the surveillance and treatment monitoring of colorectal cancer. Mild elevation can occur with tobacco exposure and several benign gastrointestinal, hepatic and inflammatory conditions.[8,9] Cancer antigen 125 (CA-125) is used primarily to monitor epithelial ovarian cancer, but it may increase during menstruation, pregnancy and benign gynecological or inflammatory disorders. Screening with CA-125 in asymptomatic average-risk women has not demonstrated a mortality benefit and can lead to false-positive investigations [10,11]. Total prostate-specific antigen (PSA) may be elevated in prostate cancer, benign prostatic hyperplasia, prostatitis, urinary infection and after prostatic manipulation. Consequently, PSA testing requires age, symptoms, individual risk and patient preferences to be considered.[12-14]

Blood-based investigations appear attractive in resource-constrained settings because they are accessible and minimally invasive. Nevertheless, applying tumor markers outside their validated indications may lead to anxiety, repeat testing and unnecessary referrals. Data describing tumor-marker distributions in rural adults with common cancer risk factors are limited in North Maharashtra. This study therefore aimed to describe serum CEA, CA-125 and total PSA concentrations in a risk-factor-enriched rural cohort and to examine the distribution of study-defined borderline elevations across demographic and risk-factor groups. The study was not designed to estimate diagnostic sensitivity, specificity or predictive value for cancer.

MATERIALS AND METHODS

Study design and setting

This cross-sectional observational study enrolled adults from rural areas of North Maharashtra. Laboratory investigations were performed in the Department of Biochemistry, Government Medical College, Jalgaon. The study period was [July 2025 to Dec 2025]. The manuscript was structured in accordance with the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) recommendations.

Participants and eligibility

A feasibility sample of 100 adults was included. Participants were eligible if they were aged 20 years or older, were permanent residents of a rural area of North Maharashtra, and had at least one prespecified cancer risk factor: tobacco exposure, alcohol consumption or family history of malignancy. Tobacco exposure included smoking and smokeless forms. Participants were excluded if they had a known malignancy, were receiving or had follow-up for cancer treatment, were pregnant, or declined written informed consent.

Data collection

A structured questionnaire was used to record age, sex, residence, tobacco exposure, alcohol consumption, family history of malignancy and relevant clinical complaints. Gastrointestinal symptoms, gynecological symptoms in women, and urinary or prostatic symptoms in men were recorded when present. No validated composite cancer-risk score was used; the term “high risk” in this manuscript refers to the presence of at least one of the prespecified risk factors.

Sample collection and laboratory analysis

Venous blood was collected under aseptic precautions, allowed to clot and centrifuged to separate serum. Serum CEA, CA-125 and total PSA were measured using automated chemiluminescence immunoassay technology on the Mindray CL-960i analyzer with manufacturer-supplied reagents, calibrators and quality-control materials [15,16]. Internal quality control was performed before sample analysis in accordance with routine laboratory procedures [17]. CEA was measured in all 100 participants. CA-125 was interpreted among the 44 women, and total PSA was interpreted among 36 men older than 40 years.

Sr. No.	Test	Laboratory Kit Lot No.	Kit Expiry	Calibrator Lot No.	QC High Lot No.	QC Low Lot No.
1	CEA	2025070111	28/02/2027	2025070111	2025120111	2025120111
2	CA-125	20250500112	28/02/2027	2025070111	2025120111	2025120111
3	(tPSA)	20250400112	28/02/2027	2025090111	2025120111	2025120111

Outcome definitions

For uniform descriptive reporting, CEA was categorized as normal (<5.0 ng/mL), borderline (5.0-10.0 ng/mL) or marked (>10.0 ng/mL); CA-125 as normal (<35 U/mL), borderline (35-65 U/mL) or marked (>65 U/mL); and total PSA as normal (<4.0 ng/mL), borderline (4.0-10.0 ng/mL) or marked (>10.0 ng/mL). These were study-defined analytical categories based on the laboratory protocol and were not diagnostic thresholds for malignancy. Smoking status, age, symptoms and other clinical factors were considered when interpreting individual results.

Statistical analysis

Categorical variables were summarized as numbers and percentages. Continuous variables were summarized using mean ± standard deviation, median and range. Wilson 95% confidence intervals (CIs) were calculated for the proportion of participants with borderline values. Associations between borderline CEA and age or risk factors were examined using Fisher exact tests; odds ratios (ORs) with 95% CIs were calculated for binary comparisons. Age-stratified CA-125 and PSA findings were considered descriptive because of the small subgroup sizes. A two-sided p value <0.05 was considered statistically significant. Statistical software and version: [SPSS].

Ethical considerations

The study was approved by the Institutional Ethics Committee of Government Medical College, Jalgaon (GMCJ/ IEC/104/2025). Written informed consent was obtained from all participants. Confidentiality was maintained, and participants with abnormal results were advised clinical evaluation and appropriate follow-up.

RESULTS

Participant characteristics

The study included 100 rural adults: 56 men and 44 women. Age ranged from 20 to 72 years; mean age was 45.8 ± 13.2 years and median age was 46 years. Forty-five participants were aged 41-60 years, 38 were aged 20-40 years and 17 were older than 60 years. Tobacco exposure was the most common risk factor (62%), followed by alcohol consumption (36%) and family history of malignancy (8%). Twenty-eight participants had more than one risk factor. [Table 1]

Table 1: Demographic and risk-factor profile of the study participants

Characteristic	Value*
Age, years	45.8 ± 13.2; median 46; range 20-72
Age 20-40 years	38 (38.0)
Age 41-60 years	45 (45.0)
Age >60 years	17 (17.0)
Male sex	56 (56.0)
Female sex	44 (44.0)
Tobacco exposure, any form	62 (62.0)
Smoking tobacco	24 (24.0)
Smokeless tobacco	38 (38.0)
Alcohol consumption	36 (36.0)
Family history of malignancy	8 (8.0)
More than one risk factor	28 (28.0)
Tobacco plus alcohol	25 (25.0)

**Values are n (%) unless otherwise stated.*

Distribution of tumor-marker concentrations

CEA was measured in all participants, CA-125 in 44 women and total PSA in 36 men older than 40 years. Most values were within the study-defined normal category. Borderline values were found in 12.0% for CEA, 11.4% for CA-125 and 8.3% for total PSA. No participant had a result in the study-defined marked-elevation category. [Table 2 and Figure 1]

Table 2: Distribution of serum CEA, CA-125 and total PSA

Marker	Tested	Mean ± SD	Median	Range	Normal n (%)	Borderline n (%)	95% CI, %	Marked n
CEA	100	3.1 ± 1.8	2.7	0.6-9.8 ng/mL	88 (88.0)	12 (12.0)	7.0-19.8	0
CA-125	44 women	18.6 ± 9.4	16.5	5.4-52.0 U/mL	39 (88.6)	5 (11.4)	5.0-24.0	0
Total PSA	36 men >40 y	1.9 ± 1.0	1.6	0.3-4.8 ng/mL	33 (91.7)	3 (8.3)	2.9-21.8	0

CEA: carcinoembryonic antigen; CA-125: cancer antigen 125; PSA: prostate-specific antigen; CI: confidence interval. Categories were study-defined and were not diagnostic of malignancy.

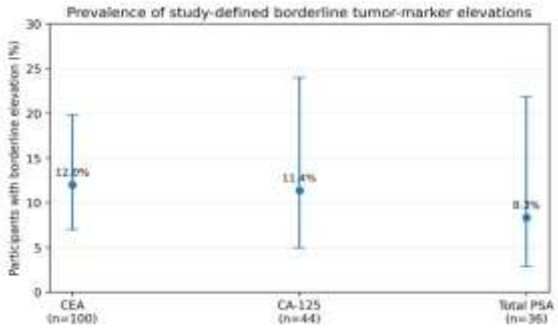

Figure 1. Prevalence of study-defined borderline tumor-marker elevations. Points show proportions and error bars show Wilson 95% confidence intervals. Denominators differed by marker: CEA, n=100; CA-125, n=44 women; total PSA, n=36 men older than 40 years

CEA according to age and risk factors

Borderline CEA increased across age groups: 1 of 38 participants aged 20-40 years (2.6%), 5 of 45 aged 41-60 years (11.1%) and 6 of 17 older than 60 years (35.3%). Participants older than 60 years had sevenfold higher odds of borderline CEA than those aged 60 years or younger (OR 7.00, 95% CI 1.92-25.58; p=0.005). Borderline CEA was more frequent among tobacco users than non-users (16.1% vs 5.3%), but this difference was not statistically significant (p=0.125). Associations with alcohol use and family history were also not statistically significant. [Table 3]

Table 3: Borderline CEA according to age and selected risk factors

Comparison	Exposed/older group	Reference group	OR (95% CI)	p value*
Age >60 years	6/17 (35.3)	6/83 (7.2)†	7.00 (1.92-25.58)	0.005
Tobacco exposure	10/62 (16.1)	2/38 (5.3)	3.46 (0.72-16.75)	0.125
Alcohol consumption	6/36 (16.7)	6/64 (9.4)	1.93 (0.57-6.51)	0.342
Family history of malignancy	2/8 (25.0)	10/92 (10.9)	2.73 (0.48-15.41)	0.245

Fisher exact test. †Participants aged 60 years or younger. OR: odds ratio; CI: confidence interval.

Age-stratified CA-125 and total PSA findings

Among women, borderline CA-125 was observed in 1 of 20 aged 20-40 years, 3 of 19 aged 41-60 years and 1 of 5 older than 60 years. Among eligible men, borderline total PSA was absent in those aged 41-50 years and was present in one participant in each older age stratum. Because the subgroup sizes were small and clinical diagnoses were not systematically available, these patterns were interpreted descriptively. [Table 4]

Table 4: Age-stratified CA-125 and total PSA categories

Marker	Age group	Tested, n	Normal n (%)	Borderline n (%)
CA-125	20-40 years	20	19 (95.0)	1 (5.0)
CA-125	41-60 years	19	16 (84.2)	3 (15.8)
CA-125	>60 years	5	4 (80.0)	1 (20.0)
Total PSA	41-50 years	12	12 (100.0)	0 (0.0)
Total PSA	51-60 years	13	12 (92.3)	1 (7.7)
Total PSA	61-70 years	8	7 (87.5)	1 (12.5)
Total PSA	>70 years	3	2 (66.7)	1 (33.3)

DISCUSSION

This cross-sectional study described serum CEA, CA-125 and total PSA concentrations in 100 rural adults selected for common cancer risk factors. Most results were within the study-defined reference categories, while approximately one in ten participants tested for each marker had a borderline value. No value was in the marked-elevation category. The principal association was an increase in borderline CEA with advancing age; the apparent excess among tobacco users was imprecise and did not reach statistical significance.

The findings reinforce the limited specificity of serum tumor markers outside established oncology indications. CEA is valuable for monitoring colorectal cancer, but it is not recommended for population screening because early cancers may have normal CEA and benign conditions may produce mild elevation.[8,9] The age association observed in this cohort may reflect cumulative exposure, comorbidity or age-related inflammatory and hepatic factors. Tobacco exposure is also a recognized cause of higher CEA concentrations. Although the point estimate for tobacco exposure suggested higher odds of a borderline result, the wide confidence interval and non-significant p value indicate that the magnitude of this association cannot be estimated reliably from the present sample.

CA-125 was borderline in 11.4% of women. CA-125 is expressed by tissues derived from coelomic epithelium and may rise in menstruation, pregnancy, endometriosis, leiomyoma, pelvic inflammation, liver disease and other non-malignant states [10]. Randomized screening evidence and guideline assessments do not support CA-125, alone or with ultrasonography, as a routine screening test in asymptomatic average-risk women because it does not reduce ovarian-cancer mortality and may lead to false-positive surgery.[11,18] The current study did not include systematic pelvic imaging, gynecological diagnosis or follow-up, so the cause and clinical

significance of the borderline results cannot be determined.

Total PSA was borderline in 8.3% of men older than 40 years. PSA is organ-specific rather than cancer-specific, and elevations can occur with benign prostatic enlargement, prostatitis, infection and recent instrumentation.[12] Prostate-cancer screening trials have shown a small or uncertain mortality benefit accompanied by overdiagnosis and treatment-related harms.[13,14,19] Therefore, a single PSA value should not be interpreted in isolation. Age, urinary symptoms, family history, repeat testing, digital rectal examination and urological assessment are relevant when deciding whether further investigation is required.

The analytical platform allowed standardized automated measurement with calibration and internal quality control. Analytical reliability, however, does not overcome limitations in clinical specificity. Reference intervals and decision limits can differ between platforms and populations, and the "borderline" bands used in this study were descriptive categories rather than validated diagnostic thresholds. This distinction is especially important in rural outreach settings, where an abnormal laboratory report may cause anxiety or trigger costly investigations.

The rural context remains clinically relevant. Community cancer-control activities should prioritize interventions with established benefit: tobacco cessation, oral visual examination in tobacco users, cervical-cancer screening, breast awareness and clinical assessment, symptom recognition, and timely referral. Serum tumor markers may occasionally assist evaluation after clinical assessment, but they should not replace organ-specific screening pathways. The absence of markedly elevated values in this small cohort also cannot exclude occult cancer because sensitivity was not evaluated.

The study contributes local descriptive data but should not be interpreted as a validation of a multi-marker screening panel. A stronger future design would prospectively enroll a larger cohort, use predefined organ-specific eligibility criteria, record symptoms and benign comorbidities, repeat abnormal tests, and link marker values to imaging, specialist assessment, histopathology and longitudinal outcomes. Such a design would permit estimation of sensitivity, specificity, predictive values, referral yield and cost-effectiveness.

Strengths and Limitations

This study addressed a rural, risk-factor-enriched population and used a standardized automated chemiluminescence platform with routine quality control. It also reported sex-appropriate marker subgroups and emphasized clinical interpretation rather than labeling borderline results as cancer.

Important limitations include the small feasibility sample, cross-sectional design, absence of a comparison group and possible selection bias. "High risk" was defined by the presence of at least one broad risk factor rather than a validated cancer-risk model. CA-125 and PSA analyses were based on small sex- and age-specific subgroups. Symptoms, benign diseases and recent procedures were not systematically linked to each marker result. Abnormal findings were not uniformly correlated with repeat testing, imaging, specialist examination, histopathology or long-term outcomes. Therefore, the study could not estimate cancer-detection rate, sensitivity, specificity, predictive value or mortality benefit. Assay-specific reference intervals and pre-analytical details should be confirmed from the original laboratory records.

CONCLUSION

In this cross-sectional sample of high-risk rural adults from North Maharashtra, most serum CEA, CA-125 and total PSA values were within the study-defined normal categories. Borderline elevations occurred in approximately 8%-12% of tested participants and were more frequent for CEA in adults older than 60 years. No result was in the marked-elevation category. These findings illustrate the nonspecific nature of isolated tumor-marker abnormalities and do not support CEA, CA-125 or total PSA as standalone community screening tests. Borderline or persistent abnormalities should prompt repeat testing and targeted clinical evaluation rather than an immediate diagnosis of malignancy.

Clinical Significance

Serum tumor markers should be used to complement—not replace—clinical assessment and established organ-specific screening. In rural practice, the most useful response to a borderline result is verification, evaluation for benign causes, symptom-directed examination and a clear referral pathway.

Declarations

Ethics approval and consent to participate: Approved by the Institutional Ethics Committee of Government Medical College, Jalgaon (GMCJ/IEC/104/2025). Written informed consent was obtained from all participants.

Consent for publication: Not applicable; no identifiable participant information is presented.

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Data availability: De-identified data may be made available by the corresponding author on reasonable request, subject to institutional and ethics approval.

Author contributions: RDB: investigation, participant interaction, data collection, literature review and writing—original draft. VP: clinical guidance, supervision and writing—review and editing. RKJ: conceptualization, laboratory supervision, biochemical analysis, formal analysis, interpretation and writing—review and editing. All

authors reviewed and approved the final manuscript and agree to be accountable for the work.

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