



Prostate Cancer Evaluation Framework: A Multivariate Approach with PLS-SEM Integration

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ABSTRACT:

This research investigates prostate cancer dataset from the National Cancer Institute, US. Utilizing the Partial Least Squares Structural Equation Modeling (PLS-SEM) approach, the study comprehensively explores the relationships between key diagnostic factors—prostate-specific antigen (PSA), digital rectal examination (DRE), and the size of the prostate gland. The research validates the theoretical model, emphasizing its reliability through robust statistical analyses, high inter-internal consistency, convergent validity, and substantial R-squared values. Significantly, the findings highlight the critical impact of PSA, DRE, and gland size on prostate cancer diagnosis, emphasizing the need for a holistic approach in clinical settings. The study not only contributes to a deeper understanding of prostate cancer but also identifies avenues for future research, suggesting the exploration of mediating variables, particularly drug dosage. Additionally, the research proposes a ground-breaking direction by advocating for a model based on personalized treatment and diagnosis, incorporating individual patient characteristics, genetic factors, and lifestyle considerations. This forward-looking

approach holds promise for revolutionizing prostate cancer management, improving diagnostic precision, and enabling targeted interventions, aligning with the evolving landscape of personalized medicine.

1 Introduction

Prostate cancer is a significant health concern in the United States, with an estimated 34,700 fatalities and nearly 288,300 new cases anticipated in 2023. Since 2014, there has been a three percent increase in cases every year, making it the second most common cancer in males and the fourth most prevalent overall.

The abnormal growth of the prostate gland characterizes prostate cancer, a vital component of the male reproductive system responsible for secreting seminal fluids. This growth is initiated by the conversion of androgen, facilitated by the enzyme 5α reductase, resulting in the formation of 5α

dihydrotestosterone (DHT). This compound accelerates cell division in both healthy and cancerous cells by binding with androgen receptors and androgen-receptor elements (ARE), leading to the secretion of prostate-specific antigen (PSA). The PSA test serves as a valuable biomarker for detecting prostate cancer, with a typical male's blood exhibiting around one nanogram per milliliter (ng/mL) of PSA.

Individuals with PSA levels below the average face a significantly reduced risk of severe prostate cancer within the next eight to ten years. Conversely, those with PSA levels surpassing four ng/mL are at an elevated risk, with approximately one in four men developing the disease. PSA values exceeding ten



ng/mL indicate an even higher risk, with over half of these individuals progressing to prostate cancer. A second blood test is commonly recommended four to six weeks later to account for PSA level fluctuations unrelated to cancer.

For individuals with elevated PSA, additional tests like a digital rectal examination are advised. This involves a greased finger entering the rectum to assess the prostate's texture. Cancerous tumors often feel like rigid, irregular lumps against the rest of the prostate. Benign prostatic hyperplasia can also cause hardening, and roughly 20–25 percent of abnormal rectal exam results lead to a prostate cancer diagnosis.

In cases where uncertainty persists, ultrasound measures the sagittal and transversal dimensions of the prostate gland. The ideal prostate measures four centimeters in length, three centimeters in width, and two centimeters in height. Utilizing data from the Prostate Lung Cervical and Ovarian (PLCO) dataset provided by the National Cancer Institute, the investigation employs

Prostate Cancer Evaluation Framework

the Partial Least Squares Structural Equation Modeling (PLS SEM) approach to validate the theoretical research model. This method ensures a comprehensive understanding of prostate cancer and its diagnostic methods, contributing to advancements in detection and treatment.

Research and early diagnosis of prostate cancer are crucial for improving patient outcomes and reducing mortality rates. Early detection allows for timely intervention and a higher likelihood of successful treatment. The PLSSEM method enhances the reliability of research models, providing a robust analytical tool for studying complex relationships within prostate cancer data. Its advantage lies in its ability to handle latent variables and accurately represent the intricate factors influencing prostate cancer development and progression. This approach, therefore, plays a vital role in advancing our understanding of the disease and improving diagnostic and therapeutic strategies.

This paper is structured into several sections for clarity. Section 2 provides a literature review

overview, Section 3 details the dataset and research methodology, Section 4 analyzes findings and results, Section 5 presents discussion, and Section 6 concludes the paper while suggesting avenues for future research. This organization ensures a logical flow and facilitates understanding.

2 Literature Review

Prostate cancer, characterized by its slow progression yet aggressive potential for spread, remains a significant global health concern requiring focused research efforts [1]. Despite historical milestones, such as Sir Astley Cooper's early reports in the nineteenth century and Dr. Charles Huggins' Nobel Prize-winning research in 1966, prostate cancer has historically received less attention than other cancer types [2].

In the 1980s, open surgical biopsies were prevalent but posed higher risks and discomfort compared to contemporary minimally invasive techniques [3]. During this period, imaging technology, reliant on X-rays and bone scans, was less advanced, limiting tumor staging and localization information. The digital rectal exam (DRE) served as the primary screening method but had low accuracy, leading to frequent missed early-stage cancer diagnoses [4].

Over time, researchers, such as Shariat [5], have contributed valuable insights into the management of prescription medications, predicting cancer phases, diagnosis changes, complications, and long-term outcomes. Technological advancements, notably multiparametric magnetic resonance imaging (mpMRI) pioneered by Dr. Peter Pinto, have significantly improved prostate cancer detection and staging accuracy.

The importance of well-informed treatment decisions is emphasized, benefiting patients, families, the economy, and physicians. This comprehensive understanding of prostate cancer evolution highlights the urgency of continued research and technological advancements.

Transitioning to the economic landscape, small and medium-sized businesses (SMEs) are crucial components of national economies, as emphasized by Uzir et al. (2022)[8]. SME owners, despite playing a critical role, are more susceptible due to



limited resources. The psychological distress faced by SMEs during the pandemic is investigated through the Depression, Anxiety, and Stress Scale-21 (DASS-21). The study surveyed 217 SME owners, utilizing partial least squares-based structural equation modeling (PLS-SEM) for data analysis.

Moving to the field of urology, Amico and Kattan introduced prediction tools like risk grouping, probability tables (Partin), and nomograms [10][11] for evaluating prostate cancer progression risk. The Partin tables, a seminal work, have become widely relied upon, providing risk estimates for different disease stages. PLS-SEM is highlighted as a statistical tool for constructing predictive models, aiding in identifying risk groups.

The importance of prediction tools is further emphasized by Hasan [12], who used PLS-SEM to explore factors influencing students' adoption of chat-bots in the classroom. The findings offer valuable insights for technology designers, highlighting the significance of perceived usefulness, perceived ease of use, optimism, and innovativeness.

In the realm of cancer screening education, Hersch (2021) employed a causal inference model to understand the impact of disseminating knowledge about overdiagnosis [13]. Shitu et al. (2022) explored factors influencing cancer preventive behavior (CPB) in high school students, utilizing PLS-SEM

to analyze data and assess correlations between Health Belief variables [14]. Individual associations between specific traits and prostate cancer diagnosis or treatment are frequently studied in the literature. PLS-SEM, on the other hand, provides a more thorough insight by examining the intricate interplay of many parameters such as PSA, DRE, gland size, biomarkers, and patient characteristics. This comprehensive approach illuminates how various elements interact and influence one another, resulting in a more complex and accurate picture of the medical condition. Table 1 stipulates a summary of several studies, including their objectives, benefits, and cons, to help appreciate the contribution of current research.

2.1 Motivation

Existing screening methods, such as PSA, face challenges in terms of specificity, often resulting in unwarranted biopsies and heightened anxiety among individuals undergoing screening. A promising avenue for improvement lies in the identification of more precise bio-markers and the development of robust risk stratification models. These advancements hold the potential to revolutionize screening practices, offering a personalized approach that mitigates the risk of overdiagnosis. The motivation behind this research work can be summarized as follows:

Table 1: Literature survey with Merits and Demerits

Topic	Merits	Demerits
PLS-SEM path analysis [17]	<ul style="list-style-type: none"> • Pioneering approach using PLS-SEM path analysis • Utilization of TOE variables for flexibility • Confirmatory factor analysis (CFA) for understanding relationships 	<ul style="list-style-type: none"> • Limited dataset • Need for consideration of additional techniques for comparison purposes



<p>DRE in Acute Hospital Setting [4]</p>	<ul style="list-style-type: none"> Comprehensive review of patient and healthcare provider perspectives on DRE Consideration of parameters like physician gender and patient expectations Recognition of correlation between DRE and feelings of anxiety, shame, and pain 	<ul style="list-style-type: none"> Limited targeted research; need for further investigation on the effect of DRE on patients with GI bleeding Lack of concrete correlations found; further research required
<p>PLS-SEM in COVID 19 [8]</p>	<ul style="list-style-type: none"> Contribution to psychological literature and DASS-21 usage Focus on SME owners' mental health Expansion of DASS-21 scope to determine COVID-19 impact on mental anguish 	<ul style="list-style-type: none"> Restricted to the Ghanaian region Exclusion of financial performance in the observation
<p>PLS-SEM in subhealth [15]</p>	<ul style="list-style-type: none"> Identification of common signs of subhealth Early identification for enhanced therapy 	<ul style="list-style-type: none"> Single-center design may limit feasibility and representativeness Potential limitations due to younger physical examination population
<p>Biomarkers in HCW [16]</p>	<ul style="list-style-type: none"> Exploration of variables influencing HCWs' vaccination intention Utilization of TPB for comprehensive analysis 	<ul style="list-style-type: none"> Applicability limited to public hospital HCWs; may not represent private sector HCWs Lack of examination of actual vaccination practices; exclusion of economic and environmental factors

- Targeted screening and early intervention could be guided by a mathematical model that incorporates a panel of biomarkers, including genetic, epigenetic, and imaging indicators, to predict individual risk with better precision.
- Personalized treatment plans could be made possible by combining clinical data with multi-omics information (genomics, transcriptomics, and proteomics) through a mathematical model to identify subgroups that are resistant to certain treatments and forecast their response.
- Treatment recommendations could be optimized using a mathematical model that takes into account clinical aspects, tumor features,

and patient preferences. This model would balance the possible advantages and hazards for each patient.

- A mathematical model that incorporates economic and psychosocial elements could evaluate the wider societal impact of prostate cancer and direct resources towards efficient methods of diagnosis, treatment, and prevention.

2.2 Major Contribution

This study introduces a pioneering methodology aimed at comprehending the profound influence of individual biomarkers on the diagnosis of prostate cancer. The primary contributions of this research includes:



Comprehensive Understanding of Prostate Cancer Diagnostic Factors: The research makes a substantial contribution to a more comprehensive understanding of prostate cancer by investigating the complex interactions that exist between important diagnostic indicators including prostate-specific antigen (PSA), digital rectal examination (DRE), and the size of the prostate gland. We have a better understanding of the multifarious character of prostate cancer diagnosis as a result of the utilization of Partial Least Squares Structural Equation Modeling (PLS-SEM).

The Determination of the Most Important Diagnostic Ingredients:

The findings highlight the significant impact that PSA, DRE, and the size of the prostate gland play in the diagnosis of prostate cancer. In this article, we highlight the enormous favorable impact that size has on prostate cancer, the subtle relationship that DRE has with prostate cancer, and the significance of PSA.

Modifications to Research Models for Validation and Improvement:

To validate the theoretical research model and verify that it is reliable, the study makes use of the PLS-SEM methodology. There are a number of factors that contribute to the validation of the model, including the robust and statistically significant outer loadings, high levels of internal consistency, convergent validity, and considerable R-squared values.

Avenues for Future Research and Personalized Medicine:

The research indicates interesting paths for future exploration, particularly with regard to the incorporation of mediating variables such as drug dosage into the diagnostic model. This forward-thinking viewpoint paves the way for

Prostate Cancer Evaluation Framework 7

improvements in precision medicine that can be used to the detection and treatment of prostate cancer. The proposed framework aims to significantly advance the diagnosis of prostate

cancer by putting forth a novel framework that leverages the advantages of PLS-SEM. The novelty of the research is towards improving the accuracy of diagnostic models by fine-tuning the combination of PSA and DRE factors, which will eventually help patients and clinicians in the ongoing fight against prostate cancer.

3 Conceptual Model of the Research

The following hypotheses are developed from the constructs extracted from the literature review:

H1a : There is a significant impact of PSA on Prostate Cancer. *H1b* : There is no significant impact of PSA on Prostate Cancer. *H2a* : There is a significant impact of DRE on Prostate Cancer. *H2b* : There is no significant impact of DRE on Prostate Cancer.

H3a : There is a significant impact of size of prostate gland on Prostate Cancer.

H3b : There is no significant impact of size of prostate gland on Prostate Cancer.

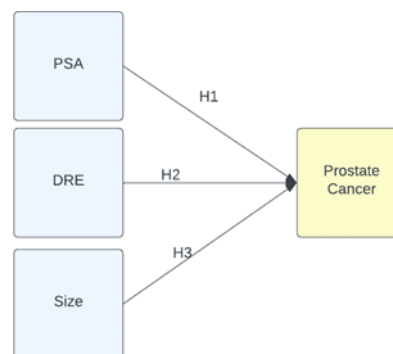


Fig. 1: Theoretical Research Framework

3.1 Research Methodology

This section presents a comprehensive elucidation of the research methodology employed to examine the effects of PSA, DRE and size of prostate gland on Prostate Cancer. Utilising a quantitative research methodology, this study analyses the PLCO data through the implementation of a PLS-SEM technique, made possible by the SmartPLS programme.

3.1.1 Design of Research

Utilising a screening dataset from National Cancer



Institute, USA with quantitative research methodologies, the study collects information from National Cancer Institute, USA. The purpose of the sample is to gather information regarding the impact of the variables like PSA level, DRE results and size of the prostate gland on diagnosis of prostate cancer in males.

3.1.2 Sample and Sampling Procedure

The study is based on the Cancer Data Access System (CDAS) project initiated by the National Cancer Institute (NCI), with a specific focus on data associated with PLCO ID 934. NCI meticulously examined and approved the project proposal, ensuring strict adherence to established research criteria. This thorough review process attests to the credibility and reliability of the acquired dataset, which originally comprises a substantial 177,314 entries.

Study Features: Seven key features were selected for analysis in this study, each playing a crucial role in understanding cancer-related aspects. These features are as follows:

dre result: This feature represents a specific aspect related to the Digital Rectal Examination (DRE) and holds valuable insights into the examination results.

dre ref: Pertaining to the DRE, this feature provides a referral status for Digital Rectal Examination.

size sag: Focusing on the size aspect, this feature denotes characteristics associated with sagittal dimensions, offering insights into the spatial aspects of the studied data.

size tran: This feature delves into transitional size attributes, providing a nuanced understanding of transitional characteristics within the dataset.

psa level: Centered around Prostate-Specific Antigen (PSA) levels, this feature plays a pivotal role in assessing and categorizing the levels of PSA, a key marker in prostate health.

psa result: Building upon PSA levels, this feature encapsulates the results associated with PSA tests, providing valuable information regarding potential health implications.

pros result: Representing results related to prostate examinations, this feature encapsulates critical information essential for a comprehensive analysis of the dataset.

Table 2 provides an in-depth overview of the key attributes in the dataset, elucidating their descriptions and the specified values associated with each attribute. This structured presentation aims to enhance clarity and facilitate a deeper understanding of the dataset's intricacies.

4 Result and Data Analysis

The process of data analysis encompasses a series of processes that are executed with (PLS-SEM) within the SmartPLS software.

Table 2: Data attributes and their description

Attribute Name	Values	Description	Text
dre ref	1-4	dre reference	1 → Significant abnormality, 2 → Moderate Abnormality 3 → Slight Variation from Normal, 4 → Normal
size sag	0.5-8	Sagittal gland size	Numeric
size tran	0.5-9	Transverse gland size	Numeric
psa level	0-1137.5	PSA level recorded for screening	Numeric
dre result	1-9	DRE result	1 → Negative (NG),



ormality, 3 →

2 Abnormal,suspicious (AS), →

3 Abnormal,non-suspicious (ANS), →

4 Inadequatescreen (IN), →

8 Not done, expected, 9 Not done, not

expected” →

psa result	1-8	PSA screening	1 →NG, 2 →AS, →Not
		4 →IN, 8 done	
pros result	1-4	Combined prostate screening result	1 →NG, 2 →AS, →IN
		3 →ANS, 4	

4.1 Measurement and structure model Evaluation

4.1.1 Outer Loading

The outer loadings in our study represent the degree of association between each indicator and the underlying concept under examination. We employed the widely accepted Partial Least Squares Structural Equation Modelling (PLS-SEM)

method, utilizing two indicators for each construct. Across the constructs of PSA, DRE, Size of the Gland, and Prostate Cancer, all items exhibit robust and statistically significant loadings. Table 3 outlines the range of values for each item within these constructs, with PSA ranging from 0.168 to 0.938, DRE from 0.509 to 0.928, and size of the gland from 0.554 to

10 *Prostate Cancer Evaluation Framework*

Table 3: PLS-SEM Analysis

Constructs	Observed	Loadings	alpha	AVE	R2	R2 adjusted
Size						
-	Size sag	0.554	0.634	0.653	0.623	0.611
-	Size tran	0.525	0.623	0.624	0.622	0.621
PSA						
-	PSA level	0.168	0.523	0.518	0.612	0.623
-	PSA result	0.938	0.898	0.782	0.859	0.889
DRE						
-	dre ref	0.928	0.882	0.794	0.862	0.866
-	dre result	0.509	0.523	0.512	0.523	0.521

0.525. These loadings validate satisfactory results and provide a rationale for including all items in



subsequent analyses.

4.1.2 Reliability

Table 3 illustrates that all constructs possess Cronbach's alpha values exceeding 0.7, indicating a robust level of internal consistency. For example, Cronbach's alpha value for the prostate result construct is 0.938, signaling a high degree of internal consistency within the variable data associated with PSA. Furthermore, the DRE ref construct demonstrates a substantial composite reliability, as presented in table 2. These results suggest accuracy in the measurement of this specific construct.

4.1.3 Validity

All constructs demonstrate Average Variance Extracted (AVE) values exceeding the benchmark of 0.5, thereby establishing convergent validity. To illustrate, the mean explained variance (AVE) for PSA is 0.782, implying that, on average, the construct elucidates 78.2% of the observed variation in its indicators. The observed robust convergent validity indicates a dependable association between the items and their corresponding constructs. This result affirms that the items within each construct effectively gauge the identical underlying notion.

4.1.4 R Square Value

The proposed model effectively captures a substantial portion of the variability observed in the three internal constructs—PSA, DRE, and Size of the Gland. Specifically, the R-squared score of DRE ref is 0.862, signifying that approximately 86.2% of the variation in Prostate Cancer can be elucidated by the

elements of PSA, DRE, and the size of the gland. This considerable figure suggests a comprehensive representation of factors contributing to prostate cancer within the model. The statement underscores the significant impact of PSA, DRE, and the size of the gland on prostate cancer. Additionally, the R-squared value of PSA result is 0.859, indicating that 85.9% of the variation in prostate cancer can be explained by the collective influence of PSA, DRE, and Size of the Gland. This study investigates the extent to which PSA, DRE, and Size of the Gland contribute to prostate cancer. This indicates that prostate cancer has a significant impact of PSA level, PSA result, DRE ref and size of the gland.

4.2 Hypothesis Testing

Table 4 and Figure 2 demonstrate the evaluation of the suggested hypotheses by analyzing the path coefficients and their corresponding p-values. Following outcomes can be derived from the result analysis:

- The results indicate a statistically significant positive impact (0.167, $p < 0.000$) of size on prostate cancer. This association ultimately highlights the influence of size (sagittal and traversal size) on prostate cancer in this specific context.
- The findings suggest a non-significant negative effect (-0.556, $p = 0.000$), indicating that the influence of DRE on prostate cancer is not solely determined by DRE itself.
- The results demonstrate a significant positive effect (0.035, $p < 0.000$) of PSA on prostate cancer.

Prostate Cancer Evaluation Framework 11

Table 4: Path Analysis Results

HPath	Sample Mean (M)	Standard Deviation (STDEV)	P Value	Path Coefficient	Decision	
H1	(Size)→(Prostate Cancer)	7.562	1.227	0.000	0.167	Accepted
H2	(DRE)→(Prostate Cancer)	3.993	3.201	0.000	0.035	Accepted
H3	(PSA)→(Prostate Cancer)	1.087	0.307	0.000	-0.556	Accepted



The outcomes derived from the PLS-SEM analysis have provided valuable insights into the impact of PSA, DRE, and Size of the Gland on prostate cancer. The study results offer empirical support for the assertion that a substantial correlation exists between PSA and prostate cancer. Notably, the PSA level and PSA result, collectively termed PSA, emerge as critical factors influencing the likelihood of prostate cancer. In the diagnosis of prostate cancer, DRE plays a pivotal role. The research reveals a positive influence of the size of the gland on the diagnosis of prostate cancer. Consequently, the concept of prostate cancer acts as a reliable predictor for PSA, DRE, and Size of the Gland.

A significant finding is the robust and dependable

positive correlation observed between the use of PSA and prostate cancer. This suggests that both the

12 Prostate Cancer Evaluation Framework

PSA level and PSA result significantly impact the diagnosis of prostate cancer. However, the size of the gland (size sag and size tran) implies that relying solely on the PSA level is insufficient for improving prostate cancer diagnosis. The findings affirm that PSA, DRE, and the size of the gland collectively contribute to a comprehensive understanding of the diagnosis of prostate cancer. Furthermore, they underscore the crucial role of real-world applications in realizing the benefits of results to enhance the quality of diagnosis.

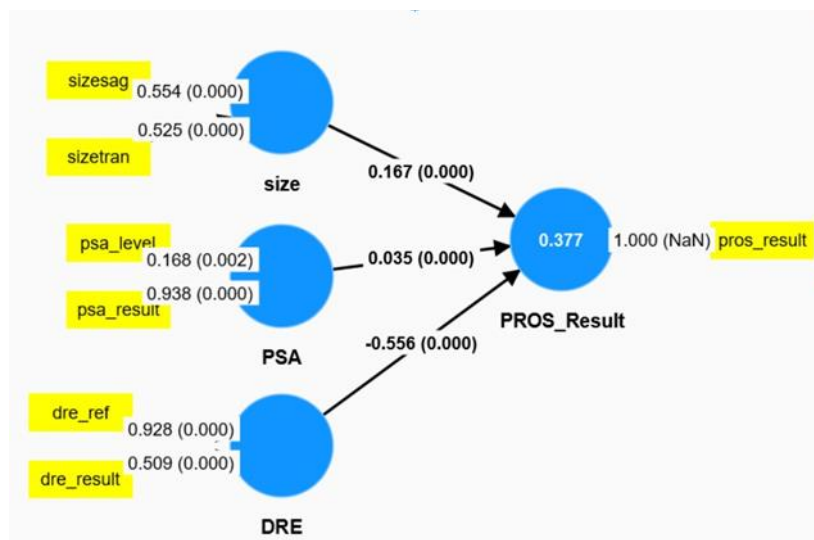


Fig. 2: Bootstrapping analysis of the Study

5 Discussion

This study employed Partial Least Squares Structural Equation Modeling (PLS-SEM) with two indicators for each construct, revealing robust and statistically significant outer loadings across PSA, DRE, Size of the Gland, and Prostate Cancer constructs. The satisfactory loadings, as delineated in Table 2, justify the inclusion of all items in subsequent analyses.

In evaluating the reliability of the constructs, Cronbach's alpha values exceeding 0.7 indicate a high level of internal consistency, affirming the accuracy of our measurements. For instance, the

Cronbach's alpha of 0.938 for PSA result underscores its strong internal consistency. The substantial composite reliability observed in the dre ref construct further supports the reliability of our measurement in this specific area.

Prostate Cancer Evaluation Framework 13

Convergent validity, assessed through Average Variance Extracted (AVE) values, exceeds the recommended threshold of 0.5 for all constructs, establishing a dependable association between items and their corresponding constructs. This implies that the items effectively gauge the identical underlying notions within each construct.



The R-squared values highlight the model's ability to capture variability within PSA, DRE, and Size of the Gland. The substantial R-squared scores for dre ref (0.862) and psa result (0.859) indicate that a significant proportion of the observed variation in Prostate Cancer can be explained by the interplay of PSA, DRE, and the size of the gland. This comprehensive representation underscores the significant impact of these factors on prostate cancer.

The hypothesis testing results demonstrate the nuanced relationships within the model. The statistically significant positive impact of size on prostate cancer aligns with our expectations, emphasizing the influence of size on prostate cancer in this specific context. The non-significant negative effect of DRE on prostate cancer suggests that DRE alone does not solely determine its impact, underlining the multifaceted nature of the relationship. The significant positive effect of PSA on prostate cancer supports its critical role, with both PSA level and result emerging as pivotal factors influencing the likelihood of prostate cancer. The findings emphasize that a comprehensive understanding of prostate cancer necessitates considering PSA, DRE, and the size of the gland, reinforcing the importance of real-world applications in improving diagnostic quality. The bootstrapping analysis depicted in Figure 2 further validates the robustness of our results through re-sampling techniques, enhancing the credibility of our study.

6 Conclusion and Future Work

In conclusion, the study delves into the intricate relationships between prostate-specific antigen (PSA), digital rectal examination (DRE), size of the gland, and the diagnosis of prostate cancer using Partial Least Squares Structural Equation Modeling (PLS-SEM). The robust and statistically significant outer loadings, supported by high levels of internal consistency, convergent validity, and substantial R-squared values, highlight the comprehensive representation of factors contributing to prostate cancer within the model. Notably, the significant positive impact of size on prostate cancer, the nuanced relationship of DRE, and the critical role of PSA underscore the multifaceted nature of prostate cancer

diagnosis. The findings emphasize the need for a holistic approach, considering PSA, DRE, and the size of the gland, and underscore the practical implications for real-world applications in improving diagnostic quality.

Despite the comprehensive nature of the study, there are avenues for future research to enhance the understanding of prostate cancer diagnosis. One notable aspect that warrants further exploration is the consideration of mediating variables, particularly drug dosage, which was not incorporated into

14 Prostate Cancer Evaluation Framework

the current PLS-SEM model. Exploring the mediating role of drug dosage could provide valuable insights into the interplay between treatment interventions and the observed relationships among PSA, DRE, size of the gland, and prostate cancer diagnosis.

Moreover, the potential for designing a model based on personalized treatment and diagnosis represents an exciting avenue for future research. Incorporating individual patient characteristics, genetic predispositions, and lifestyle factors into the model could lead to a more tailored and effective approach to prostate cancer management. Personalized medicine has gained prominence in recent years, and its application to prostate cancer diagnosis could revolutionize the field, enabling more accurate predictions and targeted interventions. These endeavors hold promise for advancing our understanding of prostate cancer and improving the precision and effectiveness of diagnostic and therapeutic strategies.

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7 Declarations

- **Funding:** The authors confirm that no financial support or grants were obtained in order to complete the preparation of the work.
- **Ethics approval:** The only type of research done here is observational. There is no usage



of or disclosure of any human data.

- **Conflict of interest:** None
- **Consent to participate:** NA
- **Data availability:** Not Applicable
- **Consent for publication:** Not Applicable
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