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ORIGINAL ARTICLE

Diagnostic Accuracy of Doppler Ultrasound in Diagnosis of Prostatic Neoplastic Etiology Recognizing Histopathology as the Gold Standard

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ABSTRACT

Objective: To utilize histopathology as the gold standard, ascertain the diagnostic accuracy of doppler ultrasound in the detection of prostatic neoplasm utilizing histopathology as gold standard.

Methodology: Study was conducted at the Radiology Department Rawalpindi Medical University from 20th September 2021 to 19th February 2022. A cross-sectional descriptive type, consisting of 157 male patients aged between 50 to 80 years with elevated prostatic serum antigen (PSA) and prostatomegaly on trans-abdominal ultrasonography. Patients, who have previously been diagnosed with prostate cancer, took chemotherapy for primary or secondary cancers and h/o radiation therapy were excluded. Trans-abdominal gray-scale and doppler ultrasound examinations were performed and gray-scale trans rectal ultrasound (TRUS) was performed on patients with inconclusive trans-abdominal ultrasound. Representative photos with any focal lesions were recorded. Biopsy was performed with TRUS or transurethral resection of prostate (TURP) and follow up with biopsy report.

Results: 80 (True Positive) of the 88 individuals with Doppler USG positivity for prostate cancer had the disease, while only 8 (False Positive) did not, according to histopathology. Among 69 patients who tested negative for Doppler USG, 13 (False Negative) had prostate cancer on histology, while 56 (True Negative) did not. Sensitivity, specificity, positive predictive value, negative predictive value, and diagnostic accuracy of conjunct Doppler USG on prostatic lesion was calculated as 86.02 percent, 87.50 percent, 90.91 percent, 81.16 percent, and 86.62 percent, respectively, using histopathology as the gold standard.

Conclusion: Doppler ultrasound is the non-invasive modality of preference with excellent diagnostic accuracy for identifying prostate cancer.

Keywords: Doppler Ultrasound; Prostate Cancer; Sensitivity

Authors' Contribution:
[1,2]Conception; Literature research; manuscript design and drafting; [3,4]Critical analysis and manuscript review; [4,5]Data analysis; Manuscript Editing.

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Introduction

Prostatic malignancy is the prevalent most cancer in US and Europe accounting for second leading cause of oncological deaths in men after bronchogenic carcinoma.[1]According to Globocan cancer statistics 2018, in men prostatic cancer is most occurring cancer in 12 regions of the world with an incidence of 13.5 % and a mortality rate of 6.7%.[2] In Pakistan prostatic cancer is less frequent than in west having an incidence of 2.6 % and a prevalence rate of 6.7%.[3]

The second most frequent cancer among Americans is prostate cancer.During 2019, prostate cancer accounted for 224,733 newly identified cases across the United Stateswith incidence of111.6 per 100,000 people and there were almost 31,636 fatalities from the disease accounting for 18.4 deaths per 100,000 people.[1]

"Diagnostic trio" of transrectal ultrasound, digital rectal examination (DRE), and serum prostate-specific antigen (PSA) level is used to identify prostate neoplasm (TRUS). Previous studies have demonstrated that using all three of these tests together increases the detection of a tumour.[4] Worldwide, several protocols and screening exams are employed for its early detection. The main technique for assessing the prostate has always been the digital rectal examination. The digital rectal examination (DRE) has a 77.7% accuracy rate for detecting cancer whereas serum prostate specific antigen (PSA) has a diagnostic accuracy of 44.7%.[5] According to estimates, transrectal ultrasound (TRUS), shear wave elastography (SWE), contrast enhanced ultrasound (CEUS), and multiparametric ultrasound (mpUS) has sensitivity of 55%, 73%, 70%, and 74%, respectively, while the specificity was 61%, 78.2%, 62%, and 59%, respectively, mpUS providing high sensitivity and specificity rates in detection of prostatic cancer.[6]

Mostly patients having elevated PSA levels, prostate cancer may be isoechoic (30 to 40 %) and hence occult at Gray-scale sonographic examination, leading to false-negative transrectal ultrasonography-guided biopsies.[6, 7]

In addition, a large number of hypoechoic peripheral zone (PZ) lesions identified by sonography are benign upon histological inspection.[6] Transrectal colour Doppler sonography can show neoplastic and aggressive lesions without a corresponding Gray-scale aberration, according to the findings of a recent study.[6, 7]

Traditional greyscale ultrasound imaging is said to be less sensitive than colour doppler ultrasonography (CDU). However, given that there is evidence that adding Colour Doppler Ultrasound boosts Positive Predictive Value, but sensitivity reduces for the detection of malignant prostate lesion as already mentioned, its use may be restricted in the clinical environment.[4, 6, 7] Furthermore, it can be challenging to detect blood flow in microscopic malignant lesions.

According to research by Jawli et al. sensitivity of mpUS is higher in the detection PCa in PZ by an average of 73.5%, while in TZ, it is low by an average of 48.3. The average specificity of mpUS in PZ was 65.8%, and in TZ was 77.16%, Doppler ultrasound in suspicious areas increased the likelihood of prostate cancer diagnosis compared to randomized grayscale systematic biopsy.[6, 7]

Rationale of my study is that since metastatic prostate cancer carries a poor prognosis, the most effective way to reduce disease-related morbidity and mortality is early detection. Currently, mpMRI remains the predominant imaging modality for the clinical assessment of prostate cancer, and no comparable standardized scoring system exists for multiparametric ultrasound. However, ultrasound continues to play a crucial role in prostate cancer imaging owing to its affordability, wide availability, real-time capability, absence of ionizing radiation, and ongoing advances in ultrasound technology. This study evaluated the diagnostic efficacy of colour Doppler sonography to that of TRUS-guided biopsy or prostatectomy reports, using histopathological report as the gold standard.

Methodology

Descriptive cross-sectional validation study was conducted at Department of Diagnostic Radiology (Benazir Bhutto Hospital, Rawalpindi) from September 20th, 2021 to February 19th, 2022. WHO sample size calculator was used to calculate sample size, taking global prevalence of prostatic cancer as 260 per 100,00 (26%).[8] Utilizing consecutive non-probability technique, taking confidence level to be 95%, with 12% margin of error, sample size was

calculated to be 157. Here, value of sensitivity and specificity was taken as 81% and 68% respectively.[7]

The inclusion criteria were all patients with raised PSA with prostatomegaly on transabdominal ultrasound with age in the range of 50 to 80 years.

The exclusion criteria were the patients having history of prior irradiation for cancer or who took chemotherapy for primary or secondary cancers and already proven histopathology.

The Hospital Ethical Committee gave its clearance before this investigation was started. All patients who met the aforementioned eligibility requirements were enrolled in the trial, and an informed written consent was formally acquired from all the outpatients and inpatients admitted in urology department in order to participate in the study. An Esoate Ultrasound Machine (Model #mylab7 Italy) equipped with a 5.0-MHz broadband curvilinear and 7.0-MHz endoluminal probe was used to assess 157 patients. All included patients with raised PSA levels underwent trans-abdominal colour doppler examinations. Focal, diffuse or peripheral colour flow within the prostate gland is considered as positive for prostatic malignancy. Except for the inconclusive trans-abdominal investigation, Gray-scale TRUS of the whole prostate gland and seminal vesicles was not performed. Representative ultrasound images depicting focal lesions were printed for documentation. TRUS or TURP assisted biopsy was performed, and a biopsy report was then generated. Then, histology and Doppler ultrasound were linked.

SPSS 20.0 was used to examine the data that was collected. Quantitative variables including age, the length of the disease, and the size of the lesion were assessed by mean and standard deviation. Malignant prostatic lesion (present/absent) is a qualitative characteristic which was displayed as frequency and percentage. Using histopathology as the gold standard, a 2x2 table was deployed to determine the sensitivity, specificity, positive predictive value, negative predictive value, and diagnostic accuracy of doppler ultrasonography in identifying malignant prostatic lesions. Age, the length of the disease, and the size of the lesion, were effect modifiers hence results were stratified into groups and sub groups. Post-stratification diagnostic accuracy was calculated and a p-value of 0.05 was recognized as significant.

Ethical approval was taken from the Ethical Review Board of Rawalpindi Medical University (Ref No. RMU-ERC/09/500/21) on 17-09-2021

Results

Study participants consisting of 157 patients aged between 50 to 80 years, mean age being 64.78 ± 7.49 years. According to Table I, significant number 89 patients (56.69 %) were between the ages of 50 and 65. Similarly, the distribution of patients as per the lesion's size was also given in Table I. The average size of lesion was 19.78 mm ± 10.72 mm. Likewise, Figure 1 depicts the distribution of disease duration in the patients. The mean duration of illness is 10.0 ± 3.52 months.

Table I. Stratification of Prostatic Neoplasm, according to age and size of lesion according to age

Age (years)	No. of Patients
50-65	89 (56.69)
66-80	68 (43.31)
Total	157 (100.0)
Mean ± SD = 64.78 ± 7.49 years	
According to size of lesion	
Size of lesion (mm)	No. of Patients (%)
≤20	86 (54.78)
>20	71 (45.22)
Mean ± SD = 19.78 ± 10.72 mm	

Mean ± SD = 10.0 ± 3.52 months

Figure 1. Distribution of patients according to duration of disease (n=157)

Table II. Diagnostic accuracy of doppler ultrasound in diagnosing prostatic neoplasm, keeping histopathology as a gold standard

	Positive result on Histopathology (93)	**Negative result on Histopathology (64)**
Positive result on Doppler USG (88)	80 (True Positive)	08 (False Positive)
Negative result on Doppler USG (69)	13 (False Negative)	56 (True Negative)

As demonstrated in Table II, 88 (56.05%) individuals had a prostate cancer diagnosis that was supported by Doppler USG. In 93 (59.24%) cases, prostate cancer was found through histopathology, while no prostate cancer was found in 64 (40.76%) patients. 80 (True Positive) of the 88 individuals with Doppler USG positivity for prostate cancer had the disease, while only 8 (False Positive) did not, according to histopathology. 13 (False Negative) of the 69 Doppler USG negative patients had prostate cancer on histopathology. Prostate cancer was confirmed in some patients, while 56 were true negatives. Using histopathology as the gold standard, Doppler ultrasound achieved 86.02% sensitivity, 87.50% specificity, 90.91% PPV, 81.16% NPV, and an overall accuracy of 86.6. The p-value calculated after application of chi square test is 0.001 which represents the statistical significance of the association between Doppler ultrasonography findings and histopathology within each stratified group. It indicates a highly significant association, confirming that the diagnostic performance of Doppler USG is not due to chance.

Table III stratifies diagnostic accuracy of prostatic doppler according to age groups and Table IV stratifies diagnostic accuracy of prostatic doppler ultrasound according to duration of the disease and size of the lesion. The stratified analysis of diagnostic performance demonstrates that Doppler ultrasonography maintains a high level of reliability across all clinically relevant subgroups, supporting its utility as a dependable screening and diagnostic tool. The stable sensitivity and specificity observed in both younger (50–65 years) and older (66–80 years) patients suggest that age does not substantially impair the ability of Doppler USG to differentiate between diseased and non-diseased individuals. Notably, the slightly higher specificity in the older age group may reflect more advanced or clearer disease-related vascular changes, facilitating easier detection. Similarly, diagnostic performance remained strong regardless of symptom duration, with the highest accuracy seen in patients with disease lasting more than 12 months. This may be attributed to more established pathological changes in chronic cases, resulting in clearer Doppler findings. Importantly, the consistently high predictive values across subgroups further reinforce the clinical applicability of Doppler USG as a first-line, non-invasive, and cost-effective modality for early detection and assessment. For lesions ≤ 20 mm, Doppler USG achieved an accuracy of 84.88 % while for larger lesions demonstrated even higher specificity (92.31%) and accuracy (88.73 %). Overall, findings indicate slightly superior performance of Doppler ultrasound in cases of longer disease duration and larger lesions. The results support the integration of Doppler ultrasonography into routine diagnostic pathways, with reliable performance across diverse patient population

Table III: Stratification of Diagnostic Accuracy by Age of the Patient							
Stratification Group	**Positive on Histopathology (Disease +)**	**Negative on Histopathology (Disease –)**	**Sensitivity**	**Specificity**	**PPV**	**NPV**	**Diagnostic Accuracy**
Age 50-65 years (n=89)	TP = 43 FN = 07	FP = 06 TN = 33	86.0 %	84.62 %	87.76%	82.50%	85.39%
Age 66-80 years (n=68)	TP = 37 FN = 06	FP = 02 TN = 33	86.05 %	92.00%	94.87%	79.31%	88.24%

Table IV: Stratification of Diagnostic Accuracy by Duration of Disease & Size of the Lesion							
Stratification Group	**Positive on Histopathology (Disease +)**	**Negative on Histopathology (Disease –)**	**Sensitivity**	**Specificity**	**PPV**	**NPV**	**Diagnostic Accuracy**
Duration of Disease ≤12 months (n=133)	TP = 68 FN = 11	FP = 08 TN = 46	86.08 %	85.19%	89.47%	80.70%	85.71%
Duration of Disease > 12 months (n=24)	TP = 12 FN = 02	FP = 00 TN = 10	85.71 %	100.00%	100.00%	83.33%	91.6 %
Lesion Size ≤20 mm (n=86)	TP = 41 FN = 07	FP = 06 TN = 32	85.42%	84.21%	87.23%	82.05%	84.88%
Lesion Size ≤20 mm (n=71)	TP = 39 FN = 06	FP = 02 TN = 24	86.67%	92.31%	95.12%	80.0 %	88.73 %

Discussion

After declining for much of the late 2000s and early 2010s, prostate cancer incidence rates have increased for nearly a decade, with the diagnosis of distant-stage disease increasing in men of every age, including by nearly 3% annually in those younger than 55 years.[9] The observation of enhanced perfusion due to tumour neovascularity relative to rest of the prostatic tissue underlies the application of colour and power doppler ultrasonography (CDUS& PDUS) techniques in prostate malignancy assessment.[6] On Colour Doppler ultrasound, three distinct flow patterns i.e., diffuse intralesional flow, focused intralesional flow, and peripheral circumferential flow have been discovered to be related to prostatic malignant lesion, diffuse intralesional flow being the predominant prevalent appearance. Gray-scale ultrasound alone has been proven to be less specific and have a lower positive predictive value than Colour Doppler ultrasound, which has been demonstrated to detect more prostate tumours.[10] Particularly helpful in identifying isoechoic prostate tumours with enhanced vascularity is colour doppler ultrasonography.[10] Although prostate cancer detection rates have increased, CDUS has a restricted diagnostic accuracy since many cancers are still overlooked, and it has a low specificity because not all hyper vascular tumours and lesions are malignant.[7] I've carried out this research to see how well doppler ultrasound demonstrates diagnostic ability for prostatic lesions, when

validated against reference gold standard histopathological findings.

Cross-sectional descriptive study, consisting of 157 male patients aged between 50 to 80, mean age being 64.78 ± 7.49 years. The majority 89 patients (56.69%) were between the ages of 50 and 65 years. 80 (True Positive) of the 88 individuals with Doppler USG positivity for prostate cancer had the disease, while only 8 (False Positive) did not, according to histology. Among 69 patients who tested negative for Doppler USG, 13 (False Negative) had prostate cancer on histology, while 56 (True Negative) did not. Sensitivity, specificity, positive predictive value, negative predictive value, and diagnostic accuracy of conjunct Doppler USG on prostatic lesion was calculated as 86.02 percent, 87.50 percent, 90.91 percent, 81.16 percent, and 86.62 percent, respectively, using histopathology as the gold standard.

A mix of various modalities have been utilized to evaluate prostate gland and improve early detection of prostatic CA. A recent study applied automated calculation of prostatic serum antigen density calculation (PSAD) utilizing abdominal ultrasound (AUS) of the prostate and they proposed point -of-care ultrasound systems for use as triage step in prostatic cancer screening.[11]

A study by Lie et al observed that twelve-core systematic TRUS-guided biopsy remains the current gold standard for diagnosing prostate cancer in men with PSA levels >4.0 ng/mL, despite having limited sensitivity for cancer detection rate of only 27%–40.3% and the false-negative rate is also considerable, ranging from 17% to 21%. Although increasing the number of cores can improve the likelihood of detecting prostate cancer and provide a more accurate Gleason score assessment. Multiple ultrasound imaging modes combined with targeted-guided prostate biopsy can not only increase the detection rate of malignant lesions but also reduce the number of tissue punctures.[12]

Liu et al defined Doppler ultrasound criteria based on the vascularity of the prostate tissue and the presence of any abnormal vascular branches: regions showing increased vascularity or multiple atypical vascular branches relative to the surrounding normal prostate tissue were considered suspicious (positive), whereas areas with similar or decreased blood flow compared to adjacent normal tissue were interpreted as negative.[13]

The capability of using Doppler for prostatic malignant lesion detection has been studied, with varying degrees of success. Literature review demonstrated variable results. One study indicated that Doppler US was not beneficial for PCA identification when compared to sextant biopsy. [12] Doppler US had an excellent sensitivity and both targeted and systematic biopsy revealed low sensitivity (45%) and moderate specificity (74%) in detecting low-risk prostate cancer, indicating that PDUS effectively detected higher-grade cases in 96% of instances.[13]

Increased enhanced colour Doppler flow and higher Gleason grade not only suggests aggressive nature of the prostatic neoplasm but may predict recurrence of the tumour, hence USG colour doppler could be utilized for prostatic cancer diagnosis and prognosis. [13,14]

Our study had few limitations, one being that patients who underwent TRUS- guided biopsy were scanned with gray scale ultrasound only without the guidance of colour or power Doppler, so these lesions were analysed as whole without taking consideration of the lesion vascularity. Colour doppler is sensitive for detecting vascular lesions and neoplasm however unfortunately, some prostatic conditions like prostitis increases prostatic blood flow thus further limiting colour Doppler USG specificity. Another drawback is that the luminal diameter of micro vessels within the prostatic neoplastic lesion is less than 50 µm, the resolution of colour Doppler is roughly 1 mm, which restricts the detection of hyper vascular nodules.[15] Furthermore multiparametric MRI (mpMRI) and multiparametric ultrasound (mUS) both in

combination can be used as a triage test before first invasive prostatic biopsy.[16]

Despite these limitations, using colour Doppler in prostate cancer imaging is still debatable, and recent studies suggest colour and power doppler increases the sensitivity of the diagnosis when compared to grayscale ultrasound alone.[13,15] Incorporating color Doppler sonography into routine practice may enhance diagnostic accuracy and lesion targeting in prostate cancer assessment in conjunction with trans-rectal grey-scale sonography of the prostate gland. We also advise patients with PSA > 4 mg to undergo ultrasound-guided transrectal biopsy to rule out prostatic cancer.

Conclusion

Doppler ultrasound serves as the imaging method of choice, providing reliable, non-invasive, and accurate diagnosis of prostate cancer, according to the study's findings. Our results support that diagnostic accuracy is robust across different patient ages, disease duration and lesion sizes. We advise that doppler ultrasound be utilised routinely in all suspected cases of prostate cancer for an accurate assessment of prostate cancer when it is localised and therefore at a stage that may be treated.

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