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Comparing the effectiveness of digital rectal examination, prostate specific antigen, and TRUS guided prostate biopsy, in the detection of prostate cancer

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ABSTRACT

Introduction: Prostate cancer has been the most common malignancy in men accounting for one fourth of cancers. Use of Trans rectal ultrasonography (TRUS) in men with an abnormal PSA and/or digital rectal examination acting as a guide to direct prostate biopsies will lead to decrease in number of early deaths

Materials and Methods: It is a prospective observational study.All the patients attending the Urology Out patient Department with a suspicion of Ca prostate from clinical signs and symptoms were clinically evaluated using Digital Rectal Examination and screened for serum PSA levels. All the patients in whom abnormality was detected on DRE and/or an elevated serum PSA level were included in the study and TRUS biopsy was done. The statistical analysis was executed by SPSS version 20 continuous variables were analyzed with student t -test.

Results: The present study includes 95 men in whom abnormality detected in DRE or in the levels of serum PSA.10 core biopsy was done in 53 patients and 16 core biopsy was done in 42 patients. Among the total number of patients subjected to TRUS guided prostate biopsy either 10 core or 16 core, 31 patients detected with prostatic adenocarcinoma which accounts for 32.6%, 12 patients had High grade PIN accounting for 12.62%, 30 patients (31.57%) detected with fibroadenoleiomyomatous hyper plasia , 5 patients had fibroadenoleiomyomatous hyperplasia with chronic prostatitis which is 5.20% and chronic prostatitis is found in 15 patients attributing to 15.78%.

Conclusion: Cancer detection rate with abnormalities in PSA alone was found to be 15% while it was 70% when both DRE and PSA showed abnormal results which is significantly higher. It shows that both DRE and PSA has to be considered while estimating the cancer rate. Detection rate with 16 core TRUS guided biopsy is 54.76% which is significantly (P value 0.0037) higher than that of 10 core biopsy (15.09 %).

1. Introduction

As per American Cancer Society 2008, Prostate cancer has been the most common malignancy in U.S. Asia records lowest yearly incidence with 1.9 cases per 100,000 in China while the highest is seen in African-Americans with a rate of 249 cases per 100,000.[1] Selective use of Trans rectal ultrasonography (TRUS) in men based on abnormal PSA or digital rectal examination will help in early detection of cancer with reduced mortality.[2] Discrete nodule or a diffuse hardness of the prostate in DRE forms an absolute indication for prostate biopsy irrespective of PSA levels. But DRE itself has certain limitations leading to under staging of the cancer as except for posterior and lateral aspects of prostate, other sites are not accessible. The sensitivity (18 - 68%) of diagnosing cancer prostate using DRE thus found to be very

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less.[3]

Prostate gland biopsy involves obtaining cancerous tissue to diagnose the cancer. Advent of Trans rectal ultrasound (TRUS) has greatly increased the diagnostic accuracy of biopsy. Screening for prostate specific antigen (PSA) levels has guided for selective application of trans rectal ultrasound and prostate biopsy. Still blind biopsy is in practice in some centers due to lack of resources. The foundation for gold standard protocol TRUS guided biopsies has been laid by Hodge et al involving 6 systematic sextant.[4] Because of high false-negative rate (15% to 31%) associated with this procedure several clinicians switched on to different regimens which can prevent missing clinically significant tumors.[5,6] This procedure involves more extensive sampling of the gland concentrating more on the far lateral aspects of the peripheral zone of the prostate increasing the cancer yield.[7] Here in this study, we used 16 core biopsy in a subset of our study population and compared it with 10 core biopsy applied in another subset.

2. Materials and Methods

The study was conducted at a tertiary care Hospital over a period of two years. The study group includes patients who were above 50 years and presenting to urology OPD with symptoms and signs of obstructive uropathy. All were screened clinically using DRE and evaluated for serum PSA levels. Those who have abnormal DRE and /or raised PSA are considered for TRUS guided biopsy for confirming the diagnosis of cancer prostate. An informed consent was taken for the procedure from all the subjects.

Trus imaging of prostate is done simultaneously in both longitudinal and transverse planes. Prostate volume has been calculated by measuring prostate in different dimensions of transverse, antero-posterior and longitudinal. Prostate Specific Antigen Density (PSAD) is calculated by dividing PSA by prostate volume. This is useful in further evaluating the prostate cancer rather than levels of PSA alone. All hypo echoic lesions in the PZ are considered for biopsy material. But this may lead to missing some of the cases because 39% of all cancers are isoechoic and up to 1% may be of hyperechoic on conventional gray-scale TRUS as studied by Shinohara et al, 1989. Instrument used by us was BK medical Ultrasound machine 10 using Trans rectal probe of 7.-12 MHZ with 2 planes of side firing and end firing. Biopsy gun with 18 G needle is used for tissue biopsy. 53 patients have undergone 10 core biopsy and 42 patients were selected for 16 core biopsy.

2.1. Core biopsy sites

6 samples from the traditional sextant regions and 2 cores from each of the lateral regions (peripheral zones}

2.2. Core biopsy sites

In addition to the 10 sites as above, tissue is collected from 2 mid regions one each from 2 periphery zones and 2 mid regions and 2 base regions one each from 2 para median regions.

The statistical analysis was executed by Graph pad prism software USA Version-5. The data is summarized in tabular form. Continuous data was presented as mean and standard deviation and Student t test was used to study variation between the two groups. Categorical data was presented in the form of absolute numbers and percentage was used to compare between different groups. Probability (p) value of less than 0.05 was considered as statistically significant.

3. Results

Table 1 shows the comparison of demographic characteristics between the study groups of 10 core biopsy and 16 core biopsy.53 men underwent 10 core biopsy and 42 men underwent 16 core biopsy.From table1, it can be seen that there is no significant difference in the demographic characteristics between the two groups that is with respect to age, weight, height, BMI or diabetes.

Table 2 shows the detection range of cancer among the different age groups. Out of 95 patients, 31 patients found to have prostate cancer and the age range was between 50-80 years. The cancer detection rate increased with increasing age and that the maximum number of cancer detection is seen in the age group of 61-70.

Table 3 shows cancer detection rate among patients with normal DRE. Out of 95 patients, 51 men showed normal DRE that is no nodule was detected on DRE and with elevated PSA alone.Out of 51 men, 8 men had showed evidence of malignancy on biopsy with a cancer detection rate of 15.68% and the cancer detection rate increased with increased levels of PSA with a rate of 5 men in the group with PSA levels >20ng/ml which accounts to 27.77%.

Table 4 shows 44 men had abnormal DRE that is a nodule was detected (46.3%), and among the 44, 23 men had evidence of malignancy with a cancer detection rate of 52.27 %. All the 44 patients with nodule had elevated serum PSA level and the cancer detected rate increased with increased PSA levels with maximum number of cancers (20) detected in the group with PSA levels> 20ng/ml. which amounts to 80%.

Table 5 shows all the 95 patients had serum PSA level of more than 4ng/ml. Three groups were formed based on PSA levels. Among these three groups, maximum number of cancers were detected in group 3 with PSA >20ng/ml. Out of 44 men with PSA > 20ng/ml, 26 cancers were detected (54.54 %). It shows the cancer detection rate increased significantly with increasing serum PSA levels. ($p<0.0013$)

From Table 6, 8 cancers were detected in 53 patients who underwent 10-core biopsy compared to 23 cancers

in 42 patients subjected to 16 core biopsy. Also 16 core with PSA> 20 ng/ml had overall detection rate high (70%) compared with that of 10 core biopsy with PSA> 20 ng/ml (27%). There was no statistical significance in detection of cancer among patients who underwent 10 core biopsy with rising PSA levels (P>0.09) when compared with 16-core biopsy which show significant increase in cancer detection rate with increasing PSA levels (P= 0.002)

From Table 7, it is seen that among 95 men, 10 core biopsy was done in 53 patients and 16 core biopsy was done among 42 men. Out of 53 men subjected to10 core biopsy, 8 were detected with cancer, whereas among 42 men who had undergone 16-core biopsy group, 23 had cancer. Detection of Ca prostate was found to be more in patients who underwent 16 core biopsy as compared to 10 core biopsy which is statistically highly significant (p=0.001)

From Table 8, it can be seen that the number of patients with abnormal DRE were equal (22) in both 10- core and 16-core groups. Among 22 patients with abnormal DRE in 10- core biopsy group, 6 patients were found to have ca prostate, whereas 17 patients were found to have ca prostate, among 22 patients with abnormal DRE in 16- core group. This shows a significant increase in the cancer detection rate with abnormal DRE (p=0.002) than in normal DRE when compared both for 10-core and 16-core.

4. Discussion

Prostate cancer is one of the most common causes of cancer among men. Cancerous tissue has to be obtained from the prostate gland during biopsy which is the gold standard investigation for detecting cancer. Trans rectal ultrasound which is ultrasound guided biopsy has revolutionized prostate biopsy techniques. The diagnostic accuracy of biopsy has been enormously increased with the advent of TRUS. Screening of prostate specific antigen (PSA) has aided in the increased detection of prostate cancer in adjunct with trans rectal ultrasound and prostate biopsy. Though TRUS biopsy of prostate has become a commonly performed urological procedure in most of the places still it is not widely available. Digital rectal examination helps in clinical detection of prostate cancer and any abnormality detected in DRE is an absolute indication for prostate biopsy. In a study by Richie et al, it was shown that abnormal DRE alone has been found in 18% of patients with prostate cancer. According to this study irrespective of PSA levels, a firm to hard nodule or a diffusely firm prostate should prompt biopsy.[8] Contrary to this, in 1998, a study by Schroder et al reported that DRE has a poor predictive value in the detection of prostate cancer. They also suggested that it should be replaced with a more sensitive test.[9] Since that time of proposal by this study, DRE has been abandoned as a screening tool by the European Randomized Study of Screening for Prostate Cancer.[10] However, a study by Carvalhal et al suggested that DRE can be performed in men with a PSA level of more than or equal to 1.0 ng/ml. Because they have observed in their study that initial prostate biopsy revealed prostate cancer in an appreciable proportion (14% to 30%) of patients with a suspicious DRE and a PSA of 1 to 4 ng/ml.[11]

In the studies prior to this that is until 1991, biopsies were performed only for abnormalities on digital rectal examination but not for PSA abnormalities alone.[12] After 1991, studies started to consider abnormal PSA as a sole indication for biopsy.[13] After introduction of PSA as a sole indication for prostate biopsy, then started the debate about whether the patients with PSA at levels between 4 to 10 ng/ml should undergo biopsy regardless of DRE or ultrasound status. In 1992, a study showed that the cancer detection rate was 5.5% for patients with PSA levels of 4 to10 ng/ml. and normal digital rectal examination.[14] But recent studies have found that the cancer detection rate is increased to 20% to 30% for patients with a PSA of 4 to 10 ng./m1.[15,16] Henceforth serum PSA greater than 4.0 ng./ml. alone is considered to be an indication for biopsy. Recently some other studies have shown that indications for prostate biopsy was PSA level of 2.5 to 4.0 ng/ml. Because of this some investigators proposed to decrease the PSA cut offs to enhance prostate cancer detection.[17] Some other studies such as the one by Catalona et al has also found the cancer detection rate to be 73 of 332 men (22%) with cut off PSA levels of 2.6 to 4.0 ng./m1.[18] Similarly Smith et al reported that in men with PSA levels of 2.6 to 4.0 ng./m1, an overall cancer detection rate was found to be 27%. It was also shown that with an initial PSA of 2.5 to 4.0 ng./ml, prostate cancer may be detected within 3 to 5 years in 13% to 20% of men. Approximately 80% of patients with cancer have clinically significant aggressive characteristics at PSA levels of 2.5 to 4.0 ng/ml.[19–21]

Hence in this study we compared the results of TRUS guided prostate biopsy in men suspected to have prostate cancer, based on DRE and/ or PSA. Out of 95 patients, 31(32%) had malignancy on TRUS guided biopsy. Prostate cancer is rarely diagnosed in men younger than 50 years old, accounting for only 2% of all cases. Median age at diagnosis is 68 years which is correlating with our study (66).[22] The study also found that at 85 years of age, the cumulative risk of prostate cancer ranges from 0.5% to 20% worldwide that is detection rate decreases in this age group which is also corresponding with our study as seen from Table 1.

As discussed earlier some of the studies have shown that abnormal DRE is an absolute indication for Prostate biopsy. But fair reproducibility of DRE result rests in the hands of few well experienced examiners. This leads to missing of a substantial proportion of early cancers.[23] But the detection also depends on PSA levels. It has been suggested that at PSA level of less than 3.0 ng/mL, the value of DRE for screening prostate cancer is limited. From various studies it has been found that overall the sensitivity of DRE ranges

Table 1: Showing demographic characteristics of study population

Demographic features	10 core Biopsy (n=53) Mean ±S.D	16 core Biopsy (n=42) Mean ±S.D	p-value
Age (years)	63.5 ± 9.02	64.3 ± 10.7	0.68
Weight (kg)	67.02 ± 14.2	65.3 ± 13.5	0.55
Height (cm)	162.5 ± 10.1	158.8 ± 11.1	0.09
BMI (kg/m^2)	25.3 ± 1.2	25.9 ± 4.7	0.51
Diabetes	20 (37.7%)	14(33.3%)	0.65

Table 2: Table showing age wise distribution and detection range of prostrate cancer

Age	No. of patients (95%)	No. of cancers (31)
51-60	30(26)	8
61-70	38(28)	11
71-80	22(45)	10
>80	5(40)	2

Table 3: Table showing cancer detection among patients with normal DRE and PSA levels

PSA	Without nodule	Cancer detection rate
4-10	14	1(7.1%)
10.1 -20	19	2(10.52%)
>20.1	18	5(27.77%)

Table 4: Table showing cancer detection rate among patients with abnormal DRE

PSA (ng/ml)	No. of patients with nodule	Cancer detection
4-10	9	2(22.22%)
10.1-20	10	1(10%)
>20.1	25	20(80%)

Table 5: Table showing cancer detection rate with increasing PSA levels

PSA (ng/ml)	No. of patients	No .of patients with cancer	P value
4-10	21	3(14.28)	
10.1-20	30	3(10)	< 0.0013
>20.1	44	24(54.54)	

Table 6: Table showing cancer detection in comparison with PSA in 10 core and 16 core biopsy

No. of core	Total no. of patients	PSA (ng/ml)	No. of patients	No. of cancers	Cancer detection rate	p-value
10	53	4-10	14(26.42%)	1	7%	0.09
		10.1-20	21(39.62%)	2	9.5%	
		>20.1	18(33.96%)	5	27.77%	
16	42	4-10	6(14.29%)	2	33.33%	0.02
		10.1-20	9(21.43%)	2	22.22%	
		>20.1	27(64.28%)	19	70.37%	

Table 7: Table showing overall cancer detection in the groups of 10-core and 16- core biopsy

No. of cores	Total number of patients	No. of patients with positive cancer	p-value
10-core	53	8 (15.68)	0.001
16- core	42	23 (54.76)	

Table 8: Table showing cancer detection rate in patients with normal versus abnormal DRE findings comparing the groups of 10-core and 16- core.

	Normal DRE			Abnormal DRE		
	10-Core	16-core	p-value	10-core	16-core	p-value
Total no. of patients	31	20	0.06	22	22	0.002
No. of patients positive for cancer	2	6		6	17	

from 18 - 68% in diagnosing cancer prostate which is very wide. In our study out of total of 95 patients, DRE in the form of nodule and/or induration of the prostate has been noted in 44 patients. At the same time, All 44 patients also had elevated serum PSA. But cancer was diagnosed only in 31(70%) patients with abnormal DRE and PSA levels above 20ng/ml as seen from table 3.

In a study conducted in 1992, the cancer detection rate was found to be 5.5% for patients with PSA levels of 4-10ng/m1 and normal DRE. Recent data suggest that the current cancer detection rate is increased to 20-30% for patients with a PSA of same levels that is between 4-10ng/ml. This could be due to advanced biopsy techniques involving extended biopsy protocols. In our study one out of 14 patients with PSA level of 4-10ng/ml had cancer (7.1%). This may be explained by the small sample size considered for the study group and also the mild rise in PSA level might be due to high incidence of non-malignant pathologies in our population. At a PSA level of 4-10ng/ml and with abnormal DRE, the cancer detection rate in our study is found to be 22.2%. But there was no significant change in the cancer detection rate in patients with PSA level of 10.1-20ng/ml compared to 4-10ng/ml group. Elevated PSA levels in these cases again could be explained by the non-malignant pathologies contributing to elevated PSA.

Cancer detection rates greater than 70% has been associated with serum PSA levels greater than 20 ng/ml, and this extremely high level of PSA is uncommon in non-malignant conditions such as BPH or chronic prostatitis without concurrent cancer in the gland.[24–26] In our study, the cancer detection rate is found to be 54.5% in patients with PSA levels greater than 20.1ng/ml.

Even an initial biopsy significantly increases the likelihood of overall cancer detection with the implementation of extended patterns of prostate biopsy technique. The study by Eskew et al also advocated an extended pattern of prostate biopsy to enhance the cancer detection rate. With the extended pattern of additional cores of a 5 region biopsy, they could detect a statistically significant advantage of 35% greater cancer detection. More aggressive biopsy schemes with greater than 12 cores have reported an increased detection rate of additional 30%.[27]

Similar types of multiple in vivo studies have revealed that enhanced prostate cancer detection can be possible with increase in the number of prostate biopsies. But our study failed to show this phenomenon.[28–30] Eskew and Chan et al recently found that increased sampling of prostate biopsy through extended biopsy techniques appears to detect earlier stage cancer rather than increase in the detection of potentially insignificant tumors.[31,32]

In our study out of 53 patients who underwent 10-core biopsy, 8 cancers were detected. Whereas 23 cancers out of 42 patients have been diagnosed among patients subjected to 16 core biopsy. A 16 core biopsy with PSA> 20 ng/ml had overall high detection rate (70%) when compared with that of 10 core biopsy with PSA> 20 ng/ml (27%). On evaluation, it was found that there was no statistical significance in detection of cancer among patients who underwent 10 core biopsy with rising PSA levels (P>0.09). However, in the 16- core biopsy group, we found statistically significant difference in detection of cancer with rising PSA levels (P=0.002) On comparing two groups, cancer detection rate with rising PSA level was high in patients who underwent 16 core biopsy as compared to 10 core biopsy especially in patients with high PSA level of > 20 ng/ml in both groups.

5. Conclusion

DRE and serum PSA are efficient tools in diagnosing prostate Cancer. Cancer detection rate increases with increased abnormalities that are found in both DRE and PSA (70%) when compared to elevated PSA alone (15%). Detection rate with 16 core TRUS guided biopsy is significantly higher than 10 core biopsy (54. 76% vs. 15.09%).

6. Source of Funding

None.

7. Conflict of Interest

None.

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