ORIGINAL ARTICLE

The Role of DRE in the Diagnosis of Prostate Carcinoma

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Summary

DRE has been used as a diagnostic and screening tool for prostate cancer for decades. However these are based on Western data and its local applicability has yet to be verified. We held a Prostate Health Awareness Week in August 1998 and a total of 2086 men were screened. All men aged 50 years old and above were included for the study. The subjects were evaluated on DRE findings, PSA levels and if indicated a TRUS-guided biopsy results. We concluded that DRE per se might have limited role in the screening of prostate cancer in Malaysia. Screening using DRE and PSA combined are still recognized as the most cost-effective means. Neither DRE nor PSA alone has high enough specificity for diagnosis of prostate cancer cases. Combining DRE and PSA will definitely increase the specificity significantly.

Key Words: DRE, PSA, Screening, Diagnosis, Prostate cancer

Introduction

DRE has been used in the diagnosis and screening for prostate cancer for many decades and its importance has been well established[1]. Sensitivity and specificity of DRE for the detection of prostate cancer, range from 69% to 89% and 84% to 98% respectively in the peer review literature[2,3,4,5] Catalona *et al*[6] has reported a positive predictive value of 21.4%. The American Cancer Society recognizes the role of DRE in screening by recommending an annual DRE on all men above 50 years. The role of DRE in prostate cancer diagnosis in Malaysia has been largely been based upon these data from developed countries. The incidence has been reported to be lower in the Asian population as compared with the United States or United Kingdom. Thus, the role of DRE in the diagnosis of carcinoma of prostate might be different from what we have perceived this far.

Objective

To evaluate the role of digital rectal examination in the diagnosis of prostate carcinoma in a volunteer based Malaysian population.

Materials and Methods

A Prostate Health Awareness Campaign was held from 3rd to 8th of August 1998 at the Urology Clinic of Kuala Lumpur Hospital. All male subjects above the age of 50 were encouraged to attend. Information was disseminated through various mass media and leaflets. All the subjects who attended the clinic were requested to undergo a detailed clinical evaluation including a serum PSA determination (Abbot Axsymm) and digital rectal examination (DRE). DRE findings were categorized as normal including benign enlargement (DRE = 0), asymmetrical enlargement (DRE = 1), indurated (DRE =2) and suspicious of cancer (DRE=3).

Subsequently, a TRUS guided biopsy of the prostate was done on any patients with either an abnormal DRE, raised PSA>4ng/ml or fPSA/ tPSA ratio of <0.01. (Note: There is a possibility of the presence of verification bias as DRE has also been used to select subjects for verification)

Inclusion Criteria

1. All volunteers aged of 50 years and above.
2. All volunteers in the Federal Territory or State of Selangor.
3. All volunteers who are Chinese, Malays or Indians.
4. All volunteers had DRE and PSA done and if indicated a TRUS-guided biopsy.

Exclusion Criteria

1. Subjects with prostate diseases, bladder tumor, bladder stone, urethral stricture or trauma to the lower urinary tract.

Analysis: Statistical tests used included the chi-squared, analysis of variance and rank correlation tests.

Results

Demographic Data

Out of the total of 2086 men who attended the prostate health awareness week, 1346 men were included in this study. (The rest were excluded because they did not fulfil the inclusion criteria or fell into the exclusion criteria). There were 243 (18.0%) Malays, 627 (46.6%) Chinese and 476 (35.4%) Indians. The racial distribution of the subjects is shown in Table I.

Racial Distribution

The racial distribution and the type of DRE findings are shown in Figure 1 and Figure 2. There was no statistical difference among the races in term of DRE findings.

Table I
Racial Distribution of the Sample

	Malay	Chinese	Indian	Total
Sample Size	243	627	476	1346
Range (Age)	50 - 80	50 - 91	50 - 81	50 - 91
Mean (Age)	59.84	60.51	59.68	60.09
Standard Deviation	6.9736	7.0542	6.34	6.8027

(Of Mean Age)
p = 0.2764

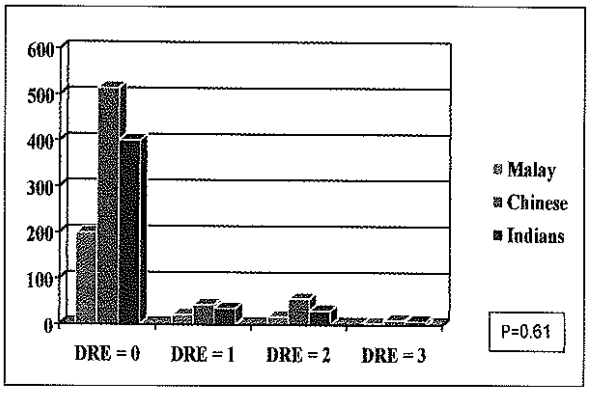

Fig. 1: Racial distribution according to DRE findings.

N.B. DRE=0: normal DRE
DRE=1: asymmetrical enlargement
DRE=2: indurated prostate
DRE=3: prostate suspicious of cancer

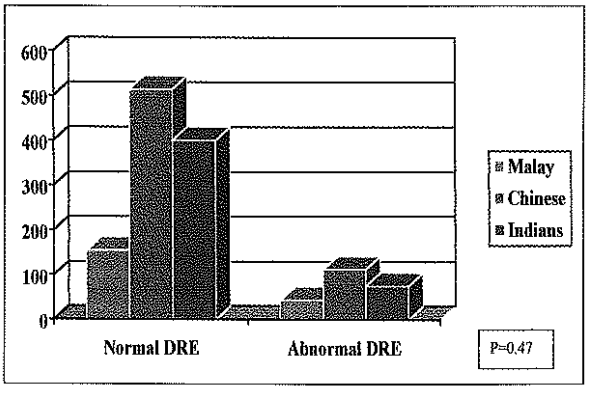

Fig. 2: Racial distribution of DRE normality.

Age and DRE Findings

Results revealed that there is a statistical significant difference in the DRE findings amongst the different age groups. The base is denser in those with normal DRE as opposed to those with abnormal DRE. Thus, DRE abnormalities increase with increasing age group.

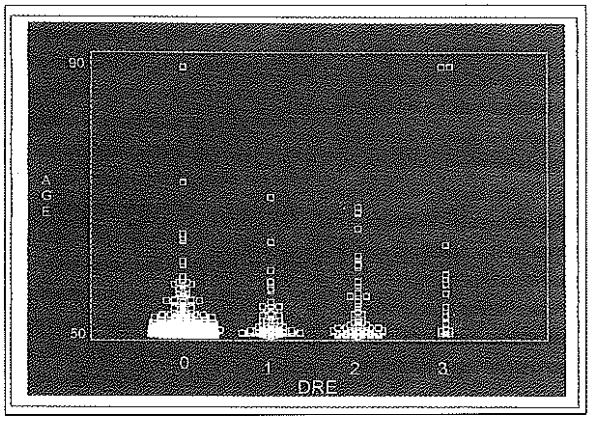

Fig. 3: Age Distribution of Different DRE Findings.

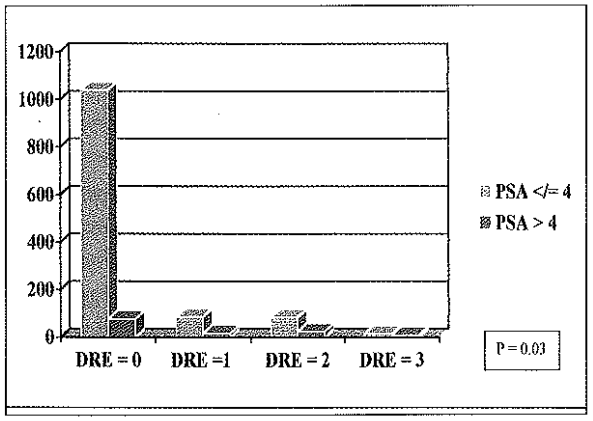

Fig. 4a: Relationship between DRE findings and PSA levels.

DRE and PSA

Both figures 4 (a) and (b) reveal that the proportion of patients with PSA levels of 4ng/ml or less decreases as the DRE abnormality increases. Figure 5 will further put the above statement in a better perspective.

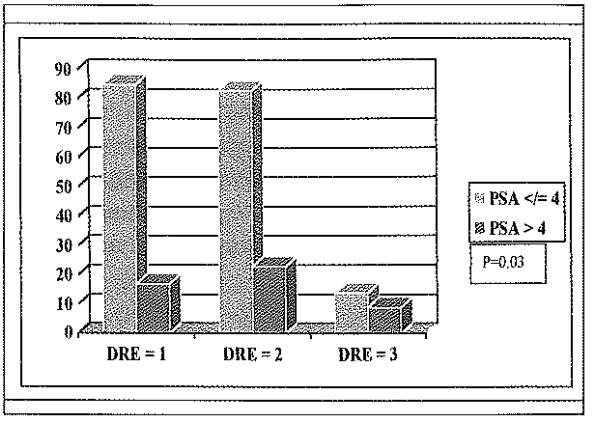

Fig. 4b: Relationship between abnormal DRE findings and PSA levels.

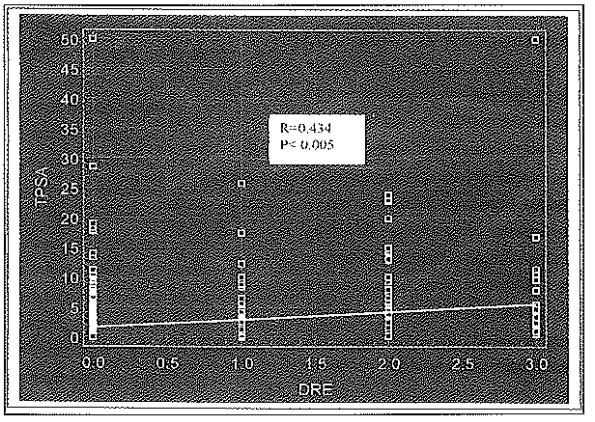

Fig. 5: Relationship between Total PSA level and DRE findings.

There is a direct correlation between DRE abnormalities with PSA level. As the degree of DRE increases from 0 to 3, the PSA levels also increase correspondingly.

Biopsy Rate

Table II shows the various sub-groups of patients for whom TRUS guided biopsy was indicated. Out of a total, there were 59 Malays (19.0%), 155 Chinese (50.1%) and 95 Indians (30.8%). Out of a total of 309 patients for whom TRUS guided

biopsy was indicated but, only a total of 153, 29 Malays (19.0%), 87 Chinese (56.8%) and 37 Indians (24.2%) underwent the TRUS Biopsy. Overall biopsy rate was 49.5%.

Figure 6 shows the HPE results of the patients according to DRE findings. Carcinoma is found even in patients with a normal DRE as shown in Table IV.

Table II
Categories of Patients Requiring Biopsy

	Malay	Chinese	Indian
DRE = 0	15	43	18
DRE = 1	22	44	36
DRE = 2	18	57	31
DRE = 3	4	11	8
Total	59	155	93

P = 0.5

Table III
Biopsy Rate among the 3 Races

	Malay	Chinese	Indian
Biopsy Done	29	87	37
Biopsy Indicated	59	155	93
Biopsy Rate	49.2%	56.1%	39.8%

p>0.05

Table IV
Presence or Absence of Prostate Cancer in Relation to DRE Findings

	Ca P+ve	Ca P-ve
DRE +ve	6	85
DRE -ve	2	60

There was no difference in the biopsy rates among the three different races. (Table III)

The sensitivity of DRE for the diagnosis of prostatic carcinoma is 75%(95% CI) and its specificity is 41.7%(95% CI). The positive predictive value is 6.67%.

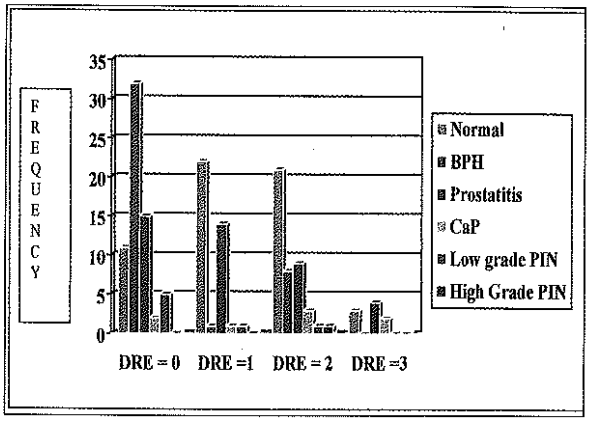

Fig. 6: Relationship between DRE findings and final histopathology.

Figure 7 and Figure 8 further sub-divide the HPE findings and DRE findings with normal and abnormal PSA.

In this group of patients, the sensitivity of DRE is still 75% (CI 95%) but its specificity and positive predictive value increased to 60.7% (CI 95%) and 14.6% respectively.

There was no prostate carcinoma detected in this group of patients.

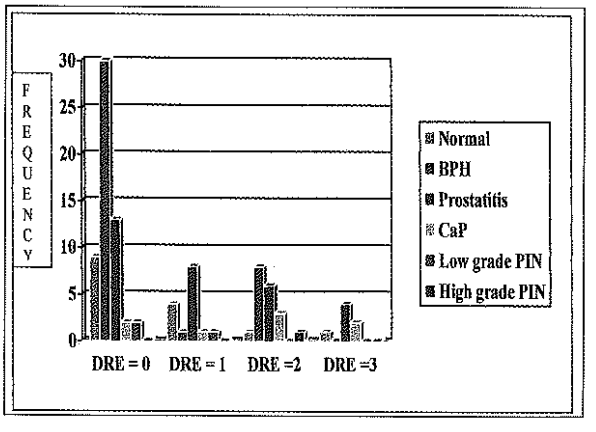

Fig. 7: Relationship between DRE findings (for those with PSA>4ng/ml) and final histopathology.

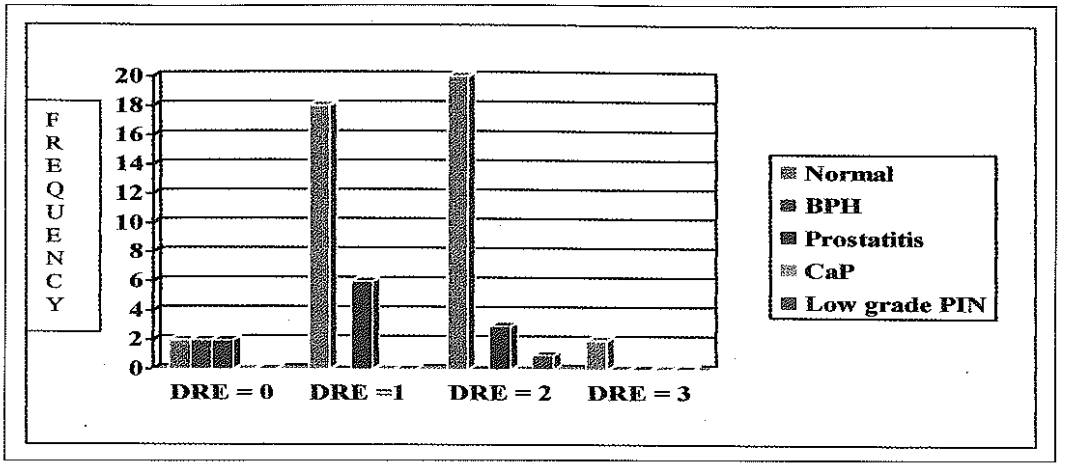

Fig. 8: Relationship between DRE findings (for those with PSA </= 4ng/ml) and final histopathology.

Table V
Presence or Absence of Prostate Cancer in Relation to DRE Findings (for those with PSA > 4 ng/ml)

	Ca P+ve	Ca P-ve
DRE +ve	6	35
DRE -ve	2	54

Table VI
Presence or Absence of Prostate Cancer in Relation to DRE Findings (for those with PSA </= 4 ng/ml)

	Ca P+ve	Ca P-ve
DRE +ve	0	50
DRE -ve	0	6

Discussion

The primary objective of this study was to evaluate the role of DRE in the diagnosis of prostate cancer in the Malaysian population. The low prevalence of prostate cancer in this country will have a major impact in the PPV of any diagnostic test for carcinoma of prostate. It is envisaged that the role of DRE could be different from that of what we have been practicing all this while. While the sensitivity and specificity might be unchanged, its PPV is related to the prevalence of the disease in the population[6].

The unique composition of the Malaysian population, which is comprised, of three major races allow us to investigate any differences in DRE findings amongst these three races. Whether the DRE abnormalities are significantly different amongst Indian as compared with the other two major races is answered by this study. There was no significant difference amongst the three different races in terms of DRE abnormalities.

The number of DRE abnormalities increased with age and this was statistically significant. Catalona *et al* elucidated a similar trend in his study on a screened population.

Grading of DRE Abnormalities

Although the DRE abnormalities classification used in this trial merely indicate different characteristic of the DRE findings, we have found the possibility that the DRE characteristic could be graded hierarchically from 0 to 3 that is from normal = 0 to suspicious of cancer = 3. This is evident from two significant findings from this study i.e.

a) The proportion of DRE abnormalities increases with age.
b) There is a definite correlation between severity of abnormalities with PSA level. However, the prevalence of carcinoma prostate is too low to prove the correlation between degree of DRE abnormalities with the proportion of carcinoma prostate in each group.

Biopsy Rate

Out of the 1346, 14.9% had indication for biopsy compared to Catalona's screened population of 26%[6]. But our compliance rate of 76% is higher than Brawer's[7] series of 58% and Catalona's 68%[6].

In Catalona's group, 15% of his screened population had abnormal DRE, whereas in our group 17% of screened population had abnormal DRE.

DRE and HPE

It is noted that carcinoma prostate was detected in all categories of DRE findings although the sensitivity of 75% falls within the range quoted in other studies, the specificity of 41.7% and PPV of 6.67% falls well below other western studies.

One would easily conclude that if the PSA level is less than 4ng/ml, even with any gross DRE abnormalities, a TRUS / biopsy is not indicated. The following is a conservative recommendation. A TRUS / guided biopsy is not indicated if the PSA is < 4ng/ml and DRE findings is not suspicious of cancer. Obviously this statement is derived from the fact that we had only two patients whose PSA was </=4ng/ml and DRE findings were suspicious of malignancy.

Conclusion

The low prevalence of prostate cancer amongst the three major races of the Malaysian population highlights the need for a revision of the role of DRE in the diagnosis of carcinoma of prostate.

The low sensitivity indicates that DRE alone is not a suitable as a screening tool for carcinoma of prostate. The low specificity further depreciates the role of DRE in the diagnosis of carcinoma of prostate. However, its role is enhanced when coupled with a PSA test, whereby if PSA is more than 4ng/ml, the specificity and PPV are increased to 60.7% and 14.6% respectively.

A more interesting finding is seen in the group where PSA is less than 4ng/ml. Even with abnormalities in DRE findings, no one was found to have carcinoma of prostate. Also, no one was found to have high grade PIN. In other words, this implies that in the presence of serum PSA level of <4ng/ml, the pickup rate for carcinoma prostate is very low.

Two pertinent conclusions on the role of DRE derived from this study are:-

1) DRE alone has limited role in the screening and diagnosis of carcinoma of prostate in the Malaysian population.
2) A TRUS guided biopsy is not indicated if the PSA is <4ng/ml and DRE findings is not suspicious of cancer.

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