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Vienna Nomogram Versus Standard Twelve Core Transrectal Ultrasound Guided Prostate Biopsy: Safety and Efficacy

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Abstract:

Introduction: The Vienna nomogram was developed to better identify the adequate number of prostatic cores that should be taken during transrectal prostatic biopsy for better detection of prostatic tumors, depending on the patient's age and the prostatic volume.

Aim of study: To compare the use of the Vienna nomogram in comparison to the standard 12-core transrectal ultrasound-guided biopsy of the prostate regarding the overall detection rate of cancer and complication rate.

Subjects and Methods: 100 patients were eligible for the study and randomized into two equal groups: group (A) who had core number determination using Vienna nomogram and group (B) who had (12) core TRUS prostatic biopsy

Results: The rate of detection of PCa in the Vietnam nomogram group vs. the 12 core TRUS groups was 15/50 (30%) vs. 14/50 (28%), respectively. The statistical difference was insignificant. There was a statistically significant percentage of hematuria in group A, with a p-value of 0.04. The hematuria was self-limited, and regarding other complications, there wasn't any statistically significant difference between the two study groups.

Conclusions: Using the Vienna nomogram for TRUS biopsy core number determination is a safe and efficient technique for the diagnosis of prostate cancer.

Keywords: Prostate; Vienna; nomogram; Cancer; Biopsy.

1. Introduction

Prostate cancer is one of the most important health-related issues worldwide. It is among the most common causes of cancer-related mortality in males [1].

The techniques used for prostate biopsy have been updated to improve the detection rate, allow for accurate estimation of the tumor burden, and guide surgical

planning; furthermore, the improvements applied to patient preparation before the biopsy enhanced tolerability and decreased the rates of major complications associated with transrectal prostate biopsy [2].

When a decision is made to perform a prostate biopsy, the 12-core TRUS prostate biopsy is considered the preferred and current standard of care technique [3].

Despite transrectal prostate biopsy, a standard minimally invasive technique to diagnose prostatic carcinoma, increasing the number of biopsy samples risks over diagnosing clinically insignificant prostate cancers, exposing the patient to the risk of complications, and decreasing the number of samples will lead to missing the detection of significant cancers [4].

Remzi et al. (2005) developed the Vienna nomogram to better identify the adequate prostatic core number that should be taken during prostatic biopsy to enhance the rate of detection depending on the patient's age and the prostatic size [5].

2. Subjects and methods

2.1. Subjects

From March 2022 until September 2022, this study was carried out prospectively on 100 patients fulfilling eligibility criteria. They were all suspected to have prostate cancer, and they were equally randomized into two groups and underwent a TRUS-guided prostatic biopsy using the Vienna nomogram as an indicator for core number determination in group A or 12 cores in group B.

Inclusion criteria

Elevated PSA level patients (between 2.5 to 10 ng/mL) and/or suspicious DRE.

Exclusion criteria

Patients who had prior prostate biopsy, recent urine retention or pelvic surgery, pelvic radiotherapy, and Patients who have a contraindication for transrectal prostatic biopsy (e.g. sever anal stenosis, acute prostatitis, immune-suppression and coagulopathy).

2.2. Study design

Prospective randomized clinical trial

2.3. Statistical Methods

The obtained data was coded to facilitate manipulation, entered into Microsoft Access, and analyzed with SPSS

software version 22 in Windows 7 (SPSS Inc., Chicago, USA). Using a descriptive Simple analysis of the qualitative data in the form of percentages and numbers and the arithmetic means as measurements of the central tendency, the standard deviation was used as a measure of dispersion of quantitative parametric data. And regarding quantitative parametric data: To compare quantitative measurements between two independent groups, a t-test was used. On the other hand, for qualitative data, the Chi square test was applied to compare two or more qualitative groups. The P-value of 0.05 was considered a statistically significant value.

3. Results

The overall PCa detection rate in the nomogram group vs. the 12 core TRUS groups was 15/50 (30%) vs. 14/50 (28%), respectively, as shown in **Table 1**. The table showed that there wasn't any significant statistical difference between the two groups regarding the cancer detection rate (*P >0.9*).

Table 1: Prostate cancer detection among study groups.

Variables	Vienna nomogram Group	12-core Group	*P-value*
Total Number of patients	50	50	-
Number of detected Patients with PCa	15 (30%)	14 (28%)	0.9

Regarding complications, as shown in **Table 2**, the table showed a higher statistically significant hematuria among group A with a p-value of 0.04. However, the hematuria was self-limited, and there wasn't any significant statistical difference with a p-value greater than 0.05 regarding other complications between the two groups.

Table 2: The complications between the two study groups.

Variables	Group (A) (N=50)		Group(B) (N=50)		P-value
	No.	%	No.	%	
Heamaturia	25	50%	14	28%	0.04
Bleeding per rectum	1	2%	2	4%	0.9
Hematospermia	13	26%	15	30%	0.8
Fever	2	4%	3	6%	0.9
Prostatitis	2	4%	3	6%	0.9
UTI	13	26%	14	28%	0.9
Epideio-orchitis	2	4%	3	6%	0.9
Urine retention	0	0%	0	0%	----
Sepsis	0	0%	0	0%	----
Vaso -vagal attack	0	0%	0	0%	----
Death	0	0%	0	0%	----

4. Discussion

The rate of PCa detection in our study was slightly elevated by using the Vienna nomogram versus the standard 12-core TRUS biopsy group (30% vs 28%) without any statistically significant difference (*P = 0.9*)

This result agreed with the study of Leitao et al., who conducted a prospective randomized study and revealed no statistically significant difference in total CDR among the Vienna nomogram and the 10-core groups. with a somewhat higher detection rate than the Vienna nomogram group (42.6% vs. 38.4%; *P = 0.301*) [2].

Regarding the complication rate between the two groups, there was a significantly higher percentage of hematuria in group A (50%) versus group B (28%), with a p-value of 0.04. but the hematuria was self-limited, and there wasn't any significant statistical difference *(P > 0.05*) regarding other complications (hematospermia, UTI, rectal bleeding, prostatitis, fever, epididymal-orchitis,

retention, sepsis, vaso-vagal attack, death) between the two groups.

Generally, the complication rates after TRUS prostate biopsy are low and this agrees with prior studies. In the prospective randomized trial that was carried out by Leucona and Hyens, they studied the complication rates in a prospective randomized trial that enrolled 303 patients, comparing the cancer detection rate and complication rate between the vieena nomogram group and the 8 core trus biopsy group. Patients who had a prostate volume > 50 mL had a significantly higher rate of complications in the Vienna nomogram group (average core number equals 14.4) than in the eight-core group (59.3% vs. 37.8%). These complications consisted mainly of self-limiting macroscopic hematuria, with no significant differences in tumor detection or complication rates between the two groups [6].

Conclusion: Using the Vienna nomogram for TRUS-guided prostatic biopsy is considered a safe and efficient technique for cancer detection, as is the standard 12-core TRUS prostate biopsy.

Ethical approval and consent to participate: The committee of Ethics in Fayoum university hospital & Faculty of Medicine approved this study and numbered M569 in its session 91 on 13-2-2022, all the participants were informed about the details of the procedure and the possible outcomes and drawbacks, with documented written informed consent.

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Conflicts of Interest: the authors declare no conflict of interest

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