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THE RETROSPECTIVE RE-EVALUATION OF RESULTS OF SYSTEMATIC PROSTATE BIOPSY AS A SELECTIVE CRITERIA FOR FOCAL THERAPY IN BLACK AMERICANS MEN OF HAITIAN DESCENT

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Introduction & Objectives: In spite of introduction of novel techniques of advanced imaging-guided prostate biopsy such a fusion MRI-TRUS or transperineal template mapping biopsy, many institutions and practices still use a systemic 12 core- biopsy for final diagnosis and shared decision-making of treatment strategy for prostate cancer (PCa). The limited data from literature revealed that PCa affects Afro-Caribbean cohort of males are susceptible to development of PCa more frequently than men of other races or ethnic groups. Therefore, the aim of this study to re-evaluate a clinical application of focal therapy versus traditionally used a whole gland in unique population for PCa development of Haitian descent in large metropolitan area of North Miami. These men underwent PSA screening followed by transrectal ultrasound (TRUS)-guided systematic prostate needle biopsy (PNB).

Materials and Methods: We reviewed TRUS- guided PNB records from the Bladder Health and Reconstructive Urology Institute in Miramar, FL and Aventura, FL, from 4/2012 to 10/2014, when 135 men were tissue diagnosed with PCa after prostate biopsy Data were analyzed for correlation of age, PSA, TRUS volume, clinical stage, and pathological findings. The decision to proceed with TRUS-PNB included three indications: (1) PSA elevation > 4.0 ng/mL; (2) Rising PSA within the normal range of 0.0-4.0 ng/mL and short PSA doubling time less than 12 months; (3) suspicious prostate digital rectal examination (DRE) with palpable nodule(s).

Results: The cancer detection rate for cancer was as 135 of 396 (34.1%) men. Mean TRUS prostate volumes for PCa was 37.8 ± 4.5 ml. The prostate volume was not correlated with PSA in PCa group. In PCa group, the Gleason Score (GS) of 6, GS of 7 and GS of >7 accounted for 45.2% (n=61), 43.0% (n=58) and 11.9% (n=16), respectively. The distribution of the mean numbers of positive cores was as following : 3.4 ± 1.5 for GS of 6 group, 6.7 ± 1.9 for GS of 7 and 10.2 ± 2.1 for GS >7 group while the percent of positive cores were 4.7 ± 1.6 , 21.3 ± 3.1 and 41.9 ± 4.9 in these groups, respectively ($p < .001$). The GS distribution in PCa proven cores was as following: score 6, 7 and >7 accounted for 45.2% (n=61) , 43.0% (n=58) and 11.9 (n=16), respectively.

The most important findings were that the total PSA still remains a gold standard to distinguish histologically aggressiveness of PCa using GS. For instance, the mean PSA values for GS of 6 was 9.2 ± 2.9 ng/ml, and GS of 7- 10.4 ± 4.1 ng/ml and GS >7 – 13.3 ± 10.3 ng/ml, respectively ($p < .05$). The correlation analysis demonstrated that the GS was associated with PSA, number of positive cores, percent of positive cores, perineural invasion, and clinical stage (Table 2). The highest Spearman coefficient was revealed reflecting a strong correlation between percent/number of positive cores and GS. Ultimately, an absolute majority of diagnosed PCa cases represented a low risk disease in 49 (36.3%) patients, intermediate risk- in 59 (43.7%) and high risk – in 28 (20.7%) men, respectively, according to D'Amico definition. These data suggested a worldwide trend to over-diagnose a low-risk disease with its potential over-treatment.

Re-evaluation of pathology findings demonstrated a presence of unifocal lesions in 26 of 61 men with Gleason score of 6, in 3 of 58 – Gleason score of 7 and 0 of 28 patients with Gleason score of 8-10, respectively. In total, the rate of unifocal lesions in a whole cohort was 29 of 135 (21.4%) men. The unilateral lesion occurred in 45 of 61 men with Gleason score of 6, in 8 of 58 men with Gleason score of 7 and 0 of 28 patients with Gleason score of 8-10, respectively. In total, the rate of unilateral lesions in a whole cohort was as 54 of 135 (40.0%). These data can potentially change a treatment approach towards organ-sparing procedure. For instance, traditionally only 34 of 61 low-risk patients underwent active surveillance while other 27 men from this group and all patients (84) with intermediate- and high-risk underwent a whole gland therapy such a radical prostatectomy or radiation therapy. The percentage proportion was for active surveillance as of 25,2% while for a

whole gland therapy – 74.8%, respectively. With more wide implementation of a focal therapy approach 12 men with Gleason 6 and 13 patients with Gleason score 7 (mostly 3+4) could be eligible for unifocal or hemi-ablation.

Conclusion: Our study on re-evaluation of systematic PNB even in high-risk population of African American of Haitian descent can drastically change a treatment landscape of PCa towards unifocal or unilateral ablation instead of a whole gland therapy in 25 of 135 (18.5%) men with all benefits of focal therapy approach including an attractive balance between cancer control and better quality of life issues.