



# Utility of a Urinary Exosome Biomarker to Predict csPCa following Negative MRI



Elizabeth P. Kwenda<sup>1</sup>, Brianna Nguyen<sup>1</sup>, Rani Ashouri<sup>1</sup>, Nickolas Davies<sup>1</sup>, Padraic O'Malley<sup>1</sup>, Li-Ming Su<sup>1</sup>, Sanoj Punnen<sup>2</sup>, Paul Crispen<sup>1</sup>, Wayne G. Brisbane<sup>3</sup>  
<sup>1</sup>University of Florida College of Medicine, Department of Urology, <sup>2</sup>University of Miami, Desai Sethi Urology Institute, UCLA Health, Department of Urology

## INTRODUCTION

- In the setting of an elevated PSA, the NCCN, AUA and EUA guidelines recommend obtaining an MRI prior to biopsy. It is unclear if biopsy can be avoided in the setting of negative MRI.
- Some report the false negative rate for MRI to be as high 20-30% indicating a need for further risk stratification if biopsy is to be avoided.<sup>1</sup>
- ExoDx (Exosome Dx, Waltham MA) is a urine-based exosome-gene expression assay that provides a risk score to discriminate the presence of csPCA.
- It has been shown that a negative MRI + negative ExoDx (score < 15.6) excludes 92% of prostate cancer.<sup>2</sup> It is unclear of the significance of scores > 15.6 in the setting of a negative MRI.

**We hypothesized that an ExoDx score >30 would predict clinically significant prostate cancer (csPCa) in the setting of a negative MRI.**

## METHODS

- We performed a retrospective analysis of men undergoing transperineal prostate biopsy at the University of Florida between 9/2021 - 4/2022 (IRB 202200022).
- Our cohort included men with clinical concern for prostate cancer, with pre-biopsy MRI. Men with  $\geq$ PI-RADS 3 lesion on MRI underwent biopsy.
- Men with a negative MRI, were counseled on biopsy, or additional biomarker testing with ExoDx. Men with an ExoDx score > 15.6 underwent biopsy.
- The primary endpoint was presence of csPCa at biopsy. Statistical tests were performed using Pandas 1.0.3.

## RESULTS

Figure 1: Study Workflow

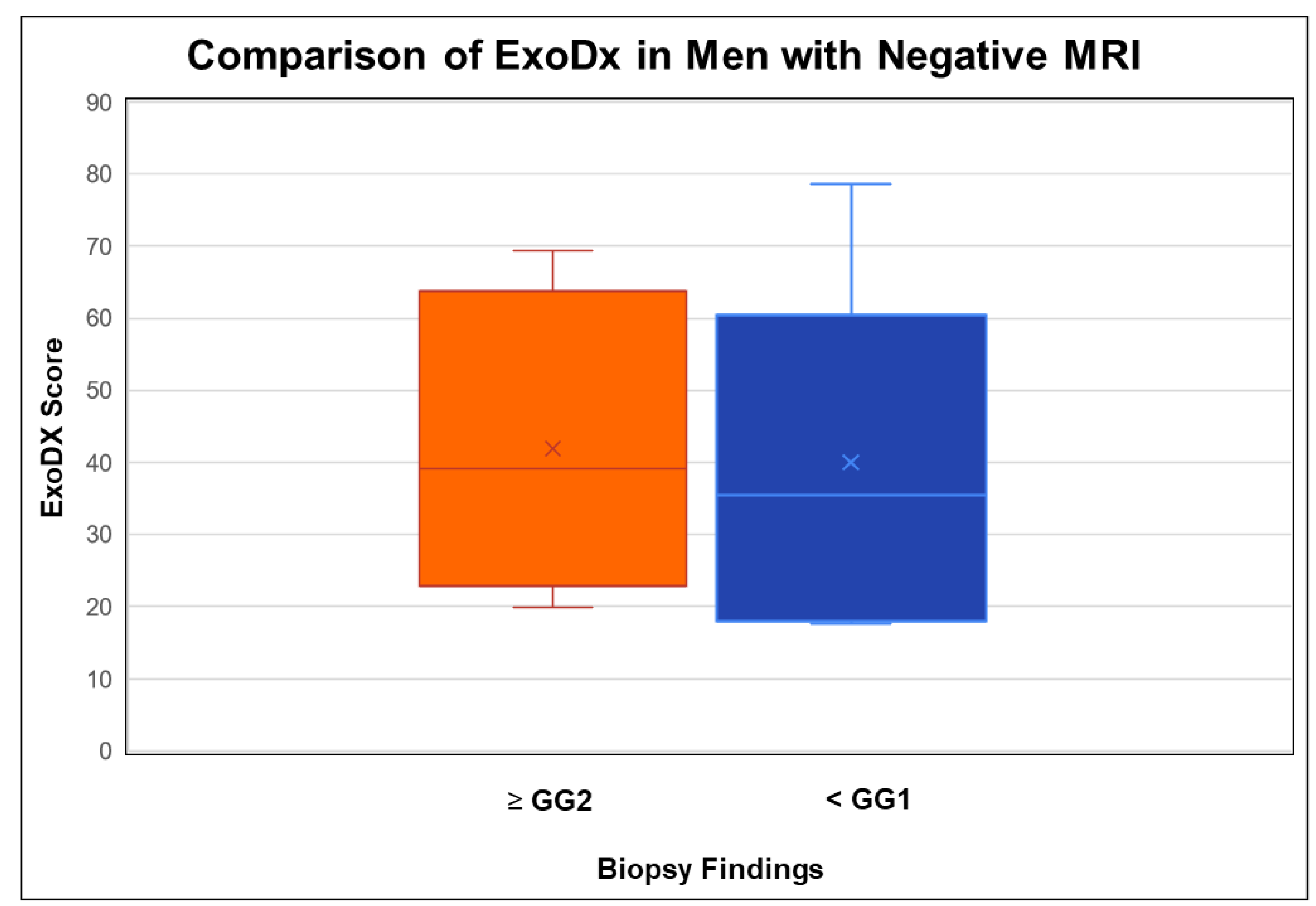
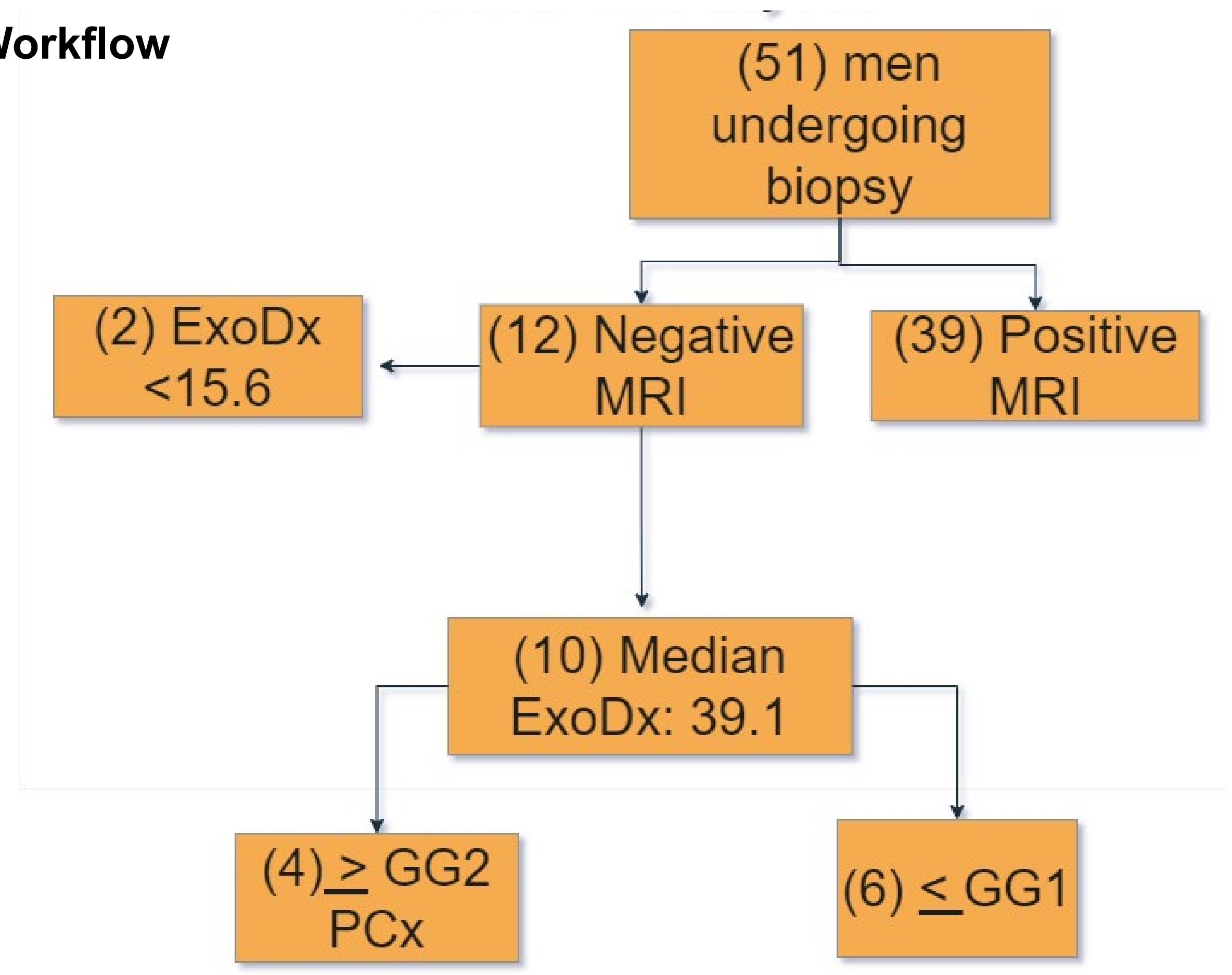


Figure 2: ExoDx in Men with Negative MRI There was not a significant difference in the ExoDx score between the two groups, median 39.1; 35.5 and IQR = 23.8;34.2 respectively; p = 0.90010

## DISCUSSION

- Within our cohort of 51 men undergoing biopsy, 24% had a negative MRI. Among these men, ExoDx >15.6 was seen in 10 men with a median score of 39.1.
- Greater than GG2 prostate cancer was identified in 40% of the cohort. However, this was not statically significant

### LIMITATIONS

- Limited size of cohort
- Average age of patients in sample (66)
- Institution is a tertiary care center; with many patients being referred once presence of cancer is confirmed

## CONCLUSIONS

- ExoDx was historically validated in an imaging naïve cohort.<sup>3</sup> Prior retrospective evaluation of double negative MRI + ExoDx virtually excludes csPCa.<sup>2</sup>
- Within our data, there was no identified ExoDx score useful for delineating prostate cancer vs no prostate cancer
- Future studies should seek to build upon the current literature using large scale databases to better asses the utility of ExoDx in this setting .

## REFERENCES

1. Ahmed HU, El-Shater Bosaily A, Brown LC, et al: Diagnostic accuracy of multi-parametric MRI and TRUS biopsy in prostate cancer (PROMIS): a paired validating confirmatory study. Lancet 2017; **389**: 815–822. Available at: <https://pubmed.ncbi.nlm.nih.gov/28110982/>, accessed Jan 7, 2023.
2. de la Calle CM, Fasulo V, Cowan JE, et al: Clinical Utility of 4Kscore®, ExosomeDx™ and Magnetic Resonance Imaging for the Early Detection of High Grade Prostate Cancer. J Urol 2021; **205**: 452–460. Available at: <https://pubmed.ncbi.nlm.nih.gov/32897802/>, accessed Jan 7, 2023.
3. McKiernan J, Donovan MJ, O’Neill V, et al: A Novel Urine Exosome Gene Expression Assay to Predict High-grade Prostate Cancer at Initial Biopsy. JAMA Oncol 2016; **2**: 882–889. Available at: <https://pubmed.ncbi.nlm.nih.gov/27032035/>, accessed Jan 7, 2023.