

# Feasibility of using the ARES™ Device to Measure Sleep Parameters in Men with Asymptomatic Prostate Cancer Before as well as at 3 and 6 Months after Starting Androgen Deprivation Therapy

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## Background

Approximately 50% of men diagnosed with Prostate Cancer (PCa) will be on androgen deprivation therapy (ADT) at some point in their lives.

It is estimated that there were approximately 600,000 men in North America on ADT (Smith, 2007). Men with localized and even metastatic hormone sensitive prostate cancer may live for many years, often without symptoms.

It is therefore very important to define and treat outcomes related to ADT that could otherwise affect longevity. These include:

- Increased risk of osteoporosis
- Increased risk of cardiovascular events
- Weight gain
- Insulin Resistance
- Hot flashes
- Fatigue

Hot flashes often occur or are worse at night and might cause awakening. Although some evidence links ADT to poor quality sleep, little research has rigorously assessed the impact of ADT on most sleep parameters.

**This study assessed the feasibility of using the ARES™ device to measure sleep parameters of PCa patients who are on ADT.**

## Methods

- Men with no symptomatic distant metastases who were about to start ADT were eligible.
- Participants wore the ARES™ device for 2 consecutive nights at baseline, before starting ADT, and at 3- and 6- months after starting ADT.
- The following questionnaires were administered at each study time points:

- *Hot Flash Related Daily Interference Scale (HFRDIS)*
- *Pittsburgh Sleep Quality Index (PSQI)*
- *Modified Expanded Prostate Cancer Index Composite (EPIC)*
- *Health and Lifestyle Questionnaire (HQL)*

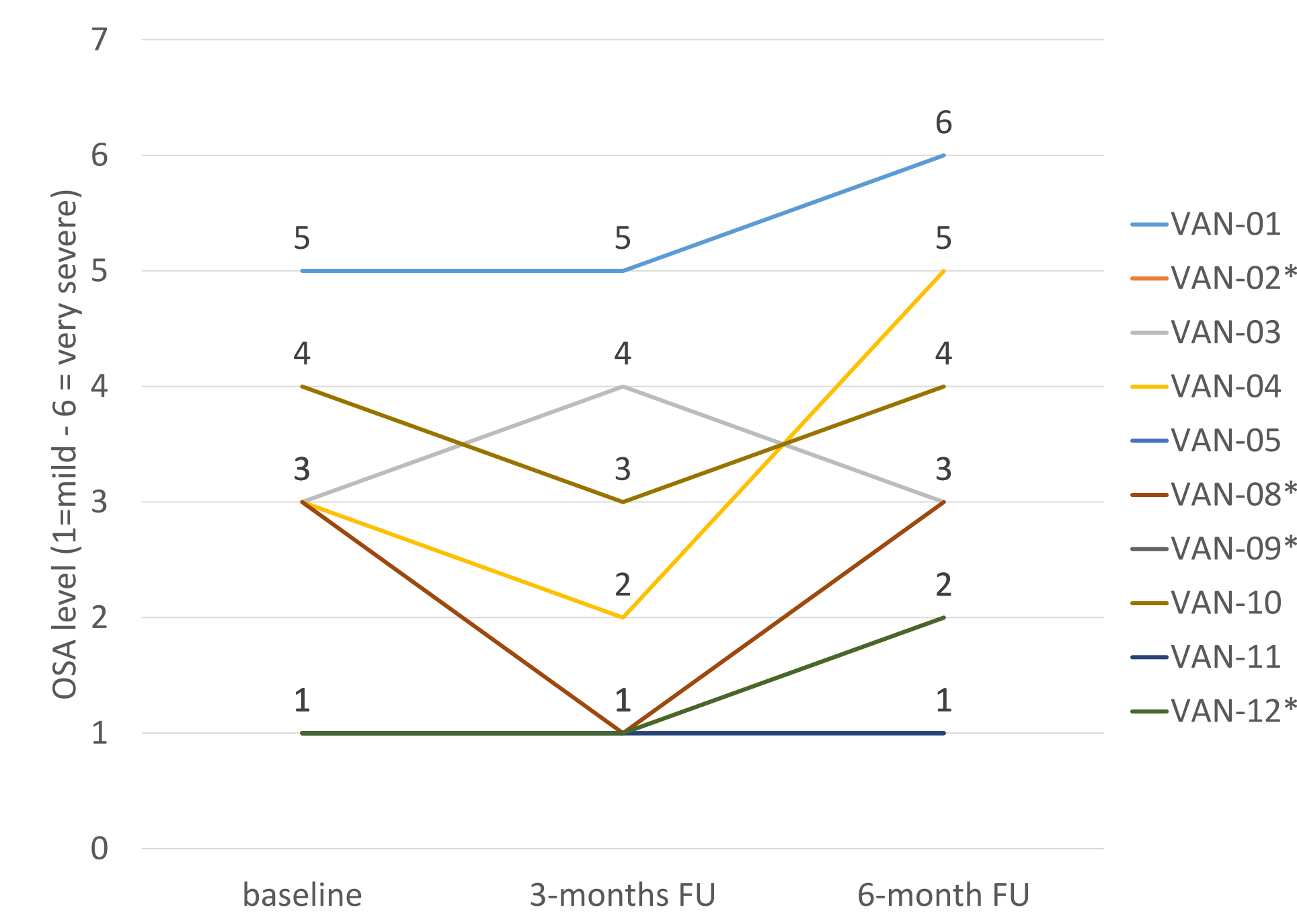
## Results: Patient Demographics

Table 1: Demographics summary, n=12

Mean age at baseline (SD)	72.3 (6.96)	Mean age at diagnosis (SD)	66.4 (8.72)
Gleason Score at diagnosis (%)		Education Level	
3+4=7	16.7%	Graduate/Professional Degree	50% (6/12)
4+3=7	41.67%	College	8.33% (1/12)
4+4=8	16.67%	Some College	16.67% (2/12)
3+5=8, or 4+5=9	8.33%	High School/Technical Diploma	25% (3/12)
5+5=10	8.33%	Race	
Treatment (%)		Retired	White/Caucasian
Radical Prostatectomy	66.67%	Full-time job	Aboriginal
EBRT	41.67%	Part-time job	Middle Eastern/Arab
Neo-Adj Chemo / TURP	16.67%	Income bracket	
Had ADT before Study?		\$10,000-\$30,000	33.33% (4/12)
Yes	41.67%	\$30,000-\$100,000	25% (3/12)
No	58.33%	Above \$100,000	41.67% (5/12)

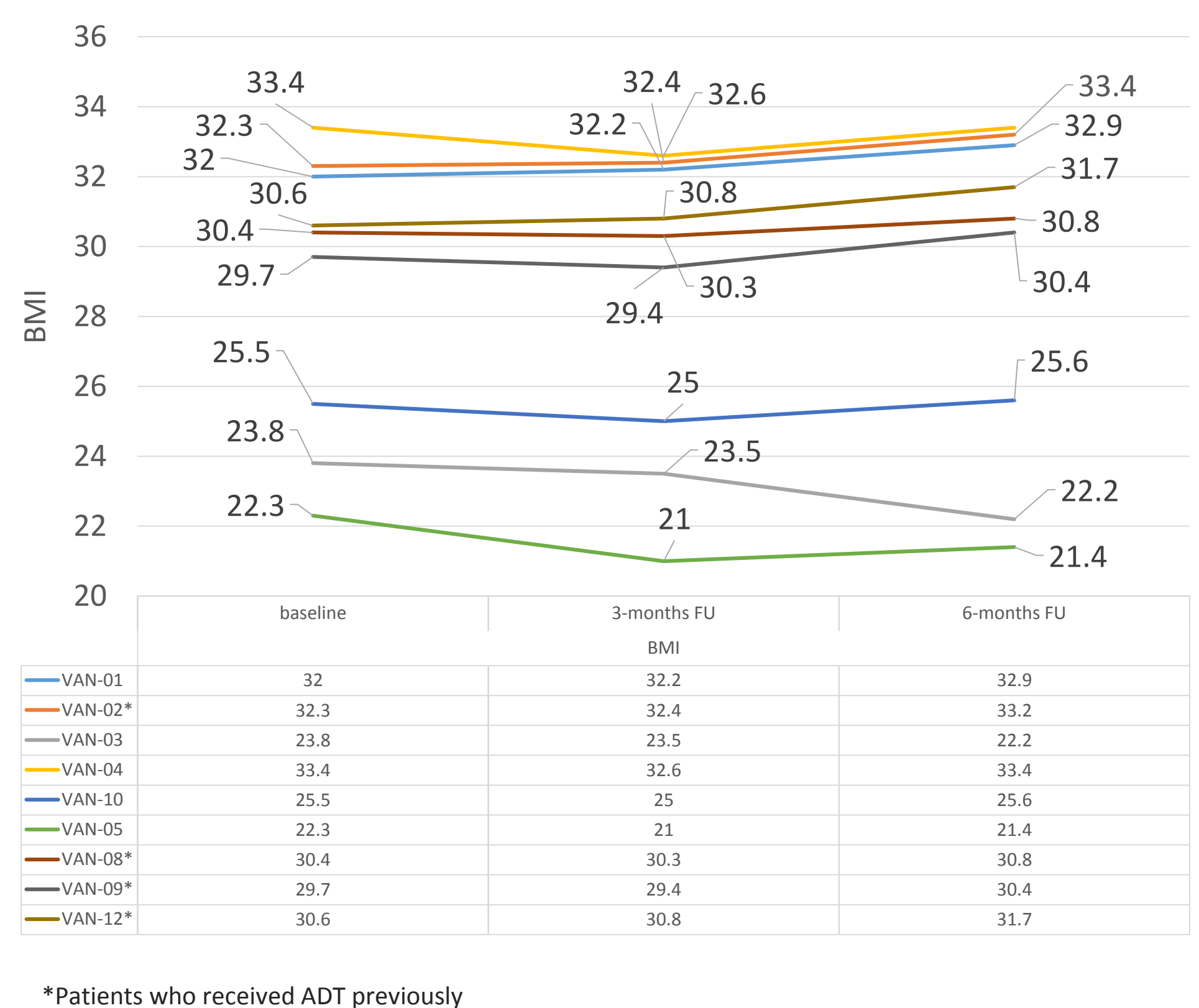
## Results: Sleep and Morphometric measures

Graph 1: OSA Level changes using the ARES™ device, n=10



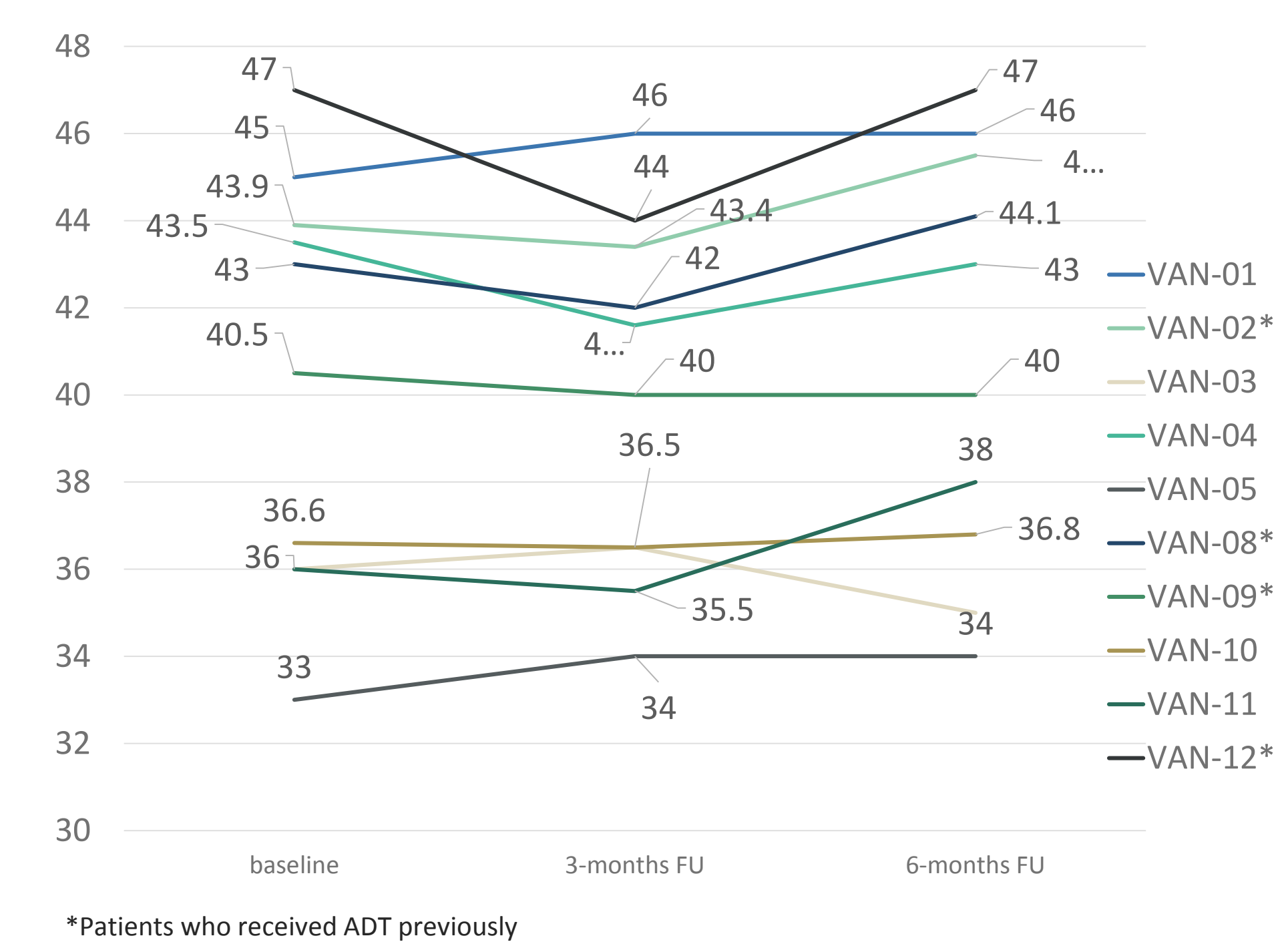
For 10/12 study participants, obstructive sleep apnea (OSA) was mild (5), moderate (2), moderate-severe (1), and severe (2). After 6 months, OSA measures were worse in 4 men (upward trend) and stayed the same in 7.

Graph 2: BMI changes, n=10



BMI increased a median of 2.85 kg/m<sup>2</sup> from baseline to 6-months follow up.

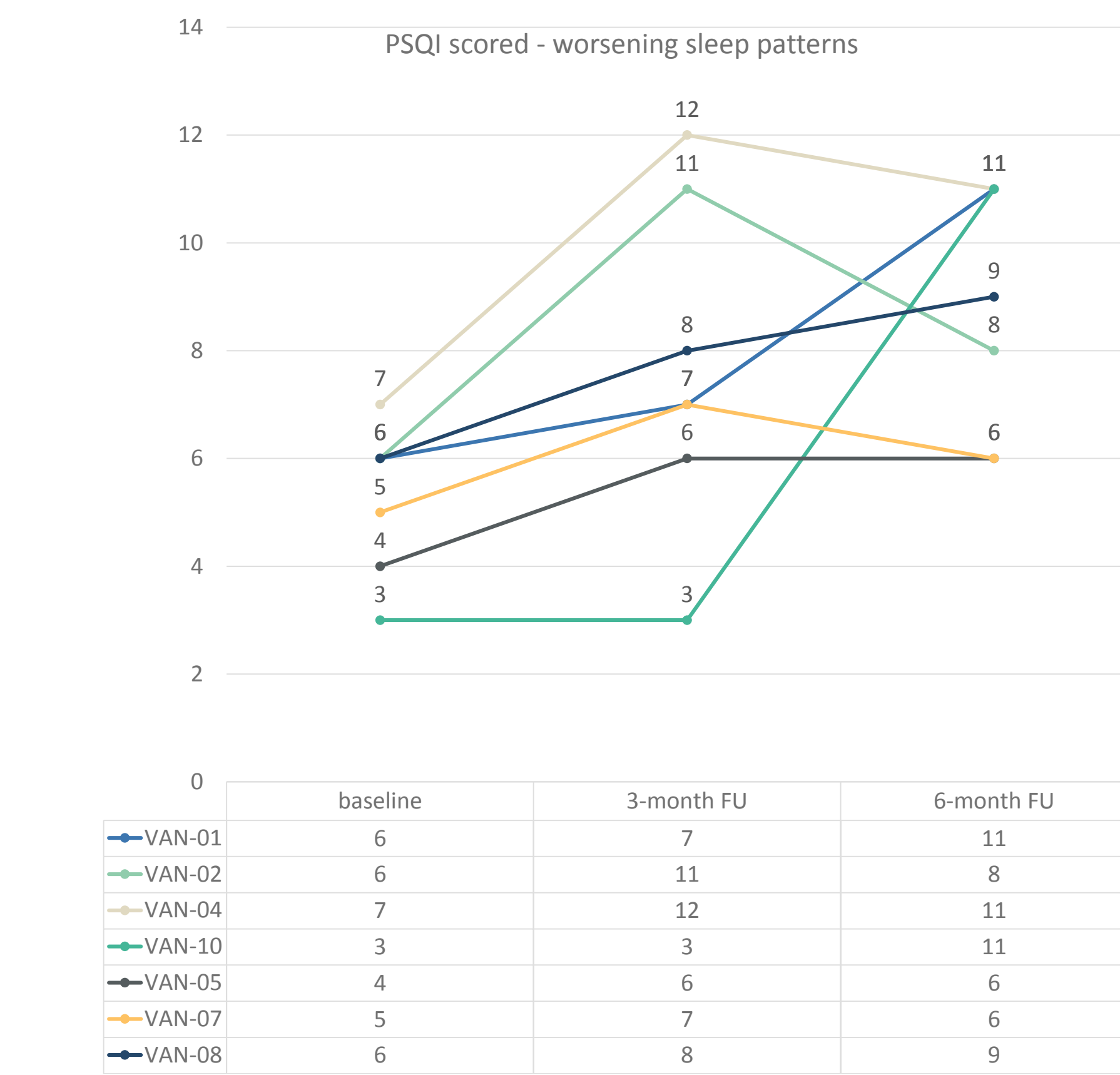
Graph 3: Waist circumference changes, n=10



Of 10 baseline assessments, the waist circumference increased in 7 patients by a median of 0.4 inches at 6-months follow up.

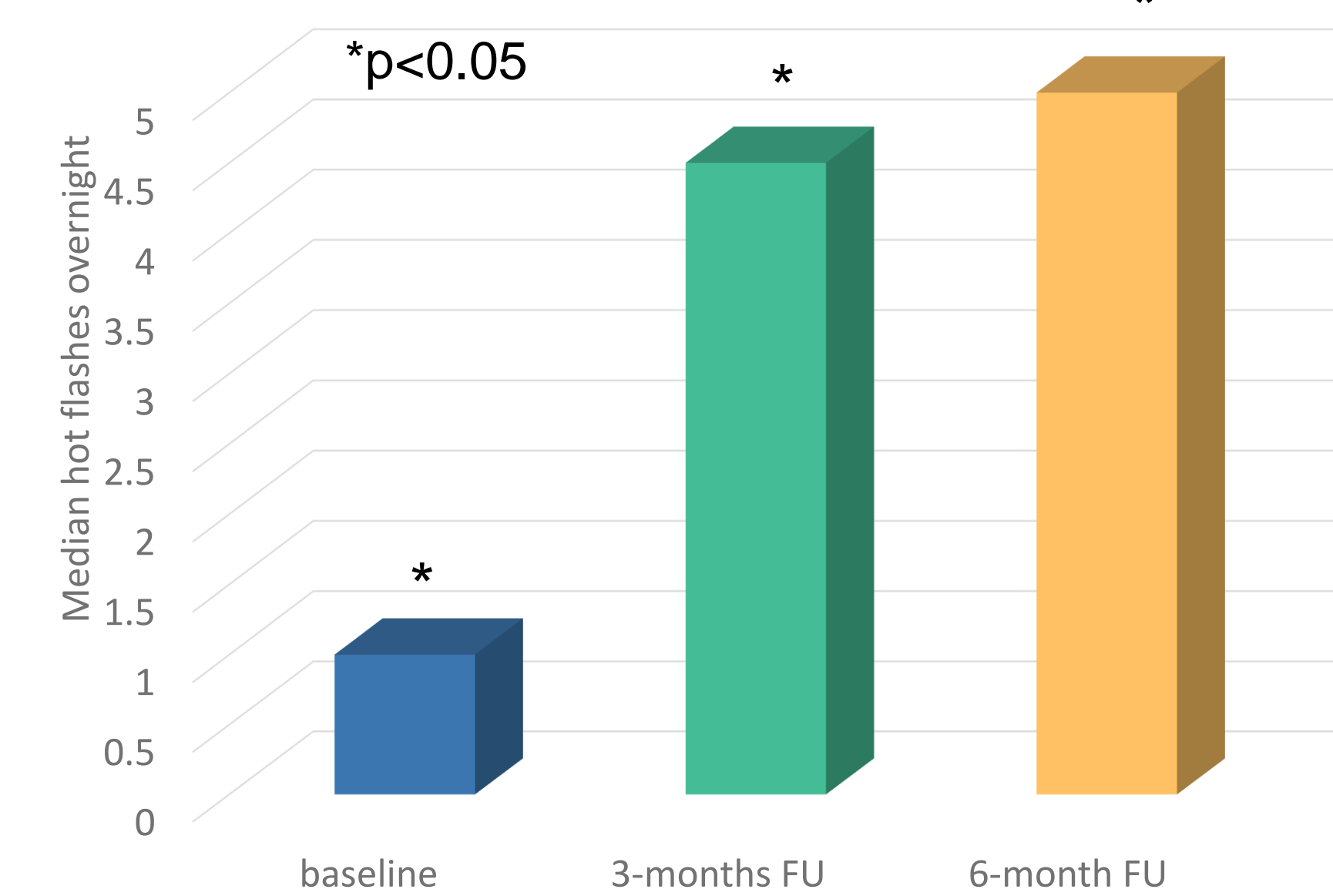
## Results: Patient reported symptoms

Graph 4. Pittsburgh Sleep Quality Index, n=12



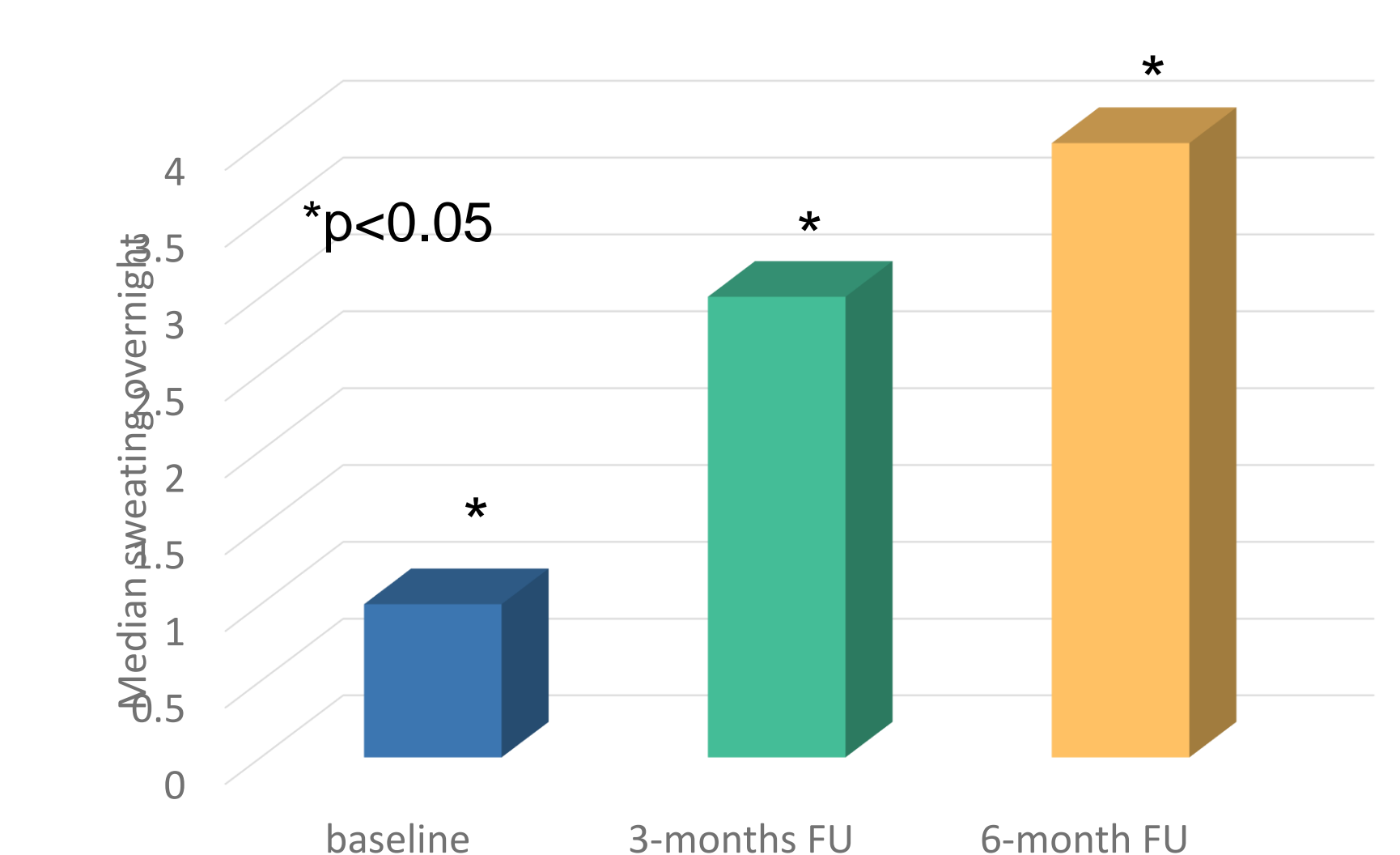
Graph 4 shows an upward trend for 7/12 participants who reported worsening sleep patterns after 6 months of ADT.

Graph 5. Median number of hot flashes experienced overnight - EPIC, n=12



In Graph 5, 8/12 participants reported a gradual increase in hot flashes overnight, from rarely or never, to once per day or more. The median values at each time point are displayed above and the difference was statistically significant over the study time-points.

Graph 6. Median sweating experienced overnight - EPIC, n=12



In Graph 6, 10 participants experienced gradual increase in sweating overnight from rarely or never to once per day and more. The median values at each time point are displayed above and the difference was statistically significant over the study time-points.

## Results: Exit interview data

- 10/12 study participants said that they did not like anything about the ARES™ device, but they were happy to wear it for this or any future research studies.
- 2/12 study participants said that they would not wear the device in the future for research.
- 1 study participant (VAN-06) refused to wear the study device after the baseline sleep study.
- 12/12 of the study participants expressed that they understood the instruction sheet that accompanied the ARES™ device and that it was easy to use.
- 2/12 study participants were happy with the research and PCSC team, and 1/12 asked about study results.

## Summary & Conclusions

- The ARES™ home sleep monitor device was reasonably tolerated by 10/12 men.
- More than half the patients experienced hot flashes and sweating that disturb sleep by questionnaire and by ARES™ monitoring.
- Weight gain (measured at study visits) was not associated with a deterioration in sleep parameters.
- While use of the ARES™ home sleep monitor device was feasible, recruitment to the study was work intensive and the goal of understanding the role of ADT on sleep quality may be better obtained with traditional sleep studies in a sleep laboratory.

## References

1. Smith MR. 2007. Androgen deprivation therapy for prostate cancer: new concepts and concerns. *Curr Opin Endocrinol Diabetes Obes* 14(3):247-254.
2. Wassersug RJ, Walker LM, Robinson JW. 2014. Androgen deprivation therapy: An essential guide for prostate cancer patients and their loved ones. New York: Demos Health.
3. Elliott S, Latini DM, Walker LM, Wassersug R, Robinson JW. 2010. Androgen deprivation therapy for prostate cancer: recommendations to improve patient and partner quality of life. *J Sex Med* 7(9):2996-3010.

## Acknowledgements

Financial support for the PCSC Program and its activities is provided from a number of government and non-government organizations and philanthropic donations.

