

# EVALUATION OF PACEYCUFF AS A NOVEL TREATMENT FOR MALE STRESS URINARY INCONTINENCE: THE FIRST UK EXPERIENCE

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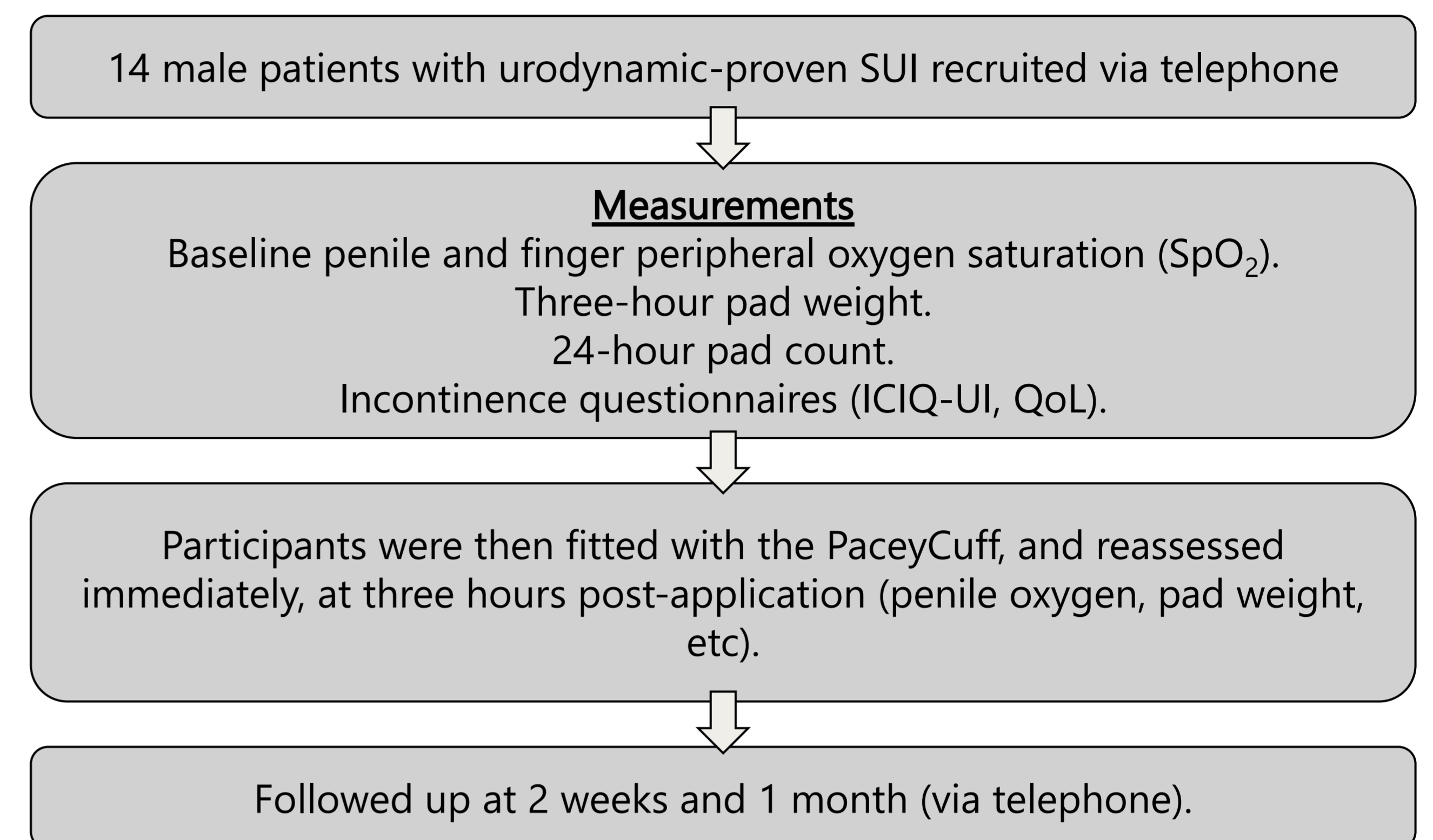
## INTRODUCTION

- Stress urinary incontinence (SUI) is a distressing condition that significantly impacts the quality of life for many men, with rising prevalence due to an ageing population.
- Commonly associated to prostate cancer and bladder outlet obstruction (BOO), SUI often occurs post-operatively.
- Implantable urological continence devices provide life-changing relief for patients with post-operative incontinence.
- However, long waiting lists and an ageing population prevent some from having surgery, leaving them wet in incontinence pads.
- Penile clamp devices offer a simpler, externally worn option to reduce incontinence, but traditional clamps can only be worn for 3 hours due to the risk of penile ischaemia.
- The PaceyCuff is a new type of penile clamp designed to maintain blood flow while providing continence and can be worn for 24 hours.

## METHODOLOGY

AIMS:

To evaluate the efficacy, safety, and patient satisfaction associated with the use of the PaceyCuff to manage male SUI



## RESULTS

- The average age of the 14 participants was 75 years. The youngest participant was 62 years, while the oldest was 82 years.
- Participants reported generally good tolerance of the device, with an average pain score of 1.9/10 and only 2 minor adverse events (skin abrasion, transient pain).
- A statistical analysis was carried out using ANOVA two-factor without replication. The p-value for overall urine loss pre- and post-intervention was 0.014, indicating a statistically significant reduction.
- For the International Consultation on Incontinence Questionnaire (ICIQ) scores, the p-value was <0.0001, reflecting a highly significant improvement in patient-reported incontinence symptoms.
- Additionally, the Quality of Life (QoL) score showed a statistically significant improvement, with a p-value of 0.0045, demonstrating positive impacts on patients' well-being post-treatment.

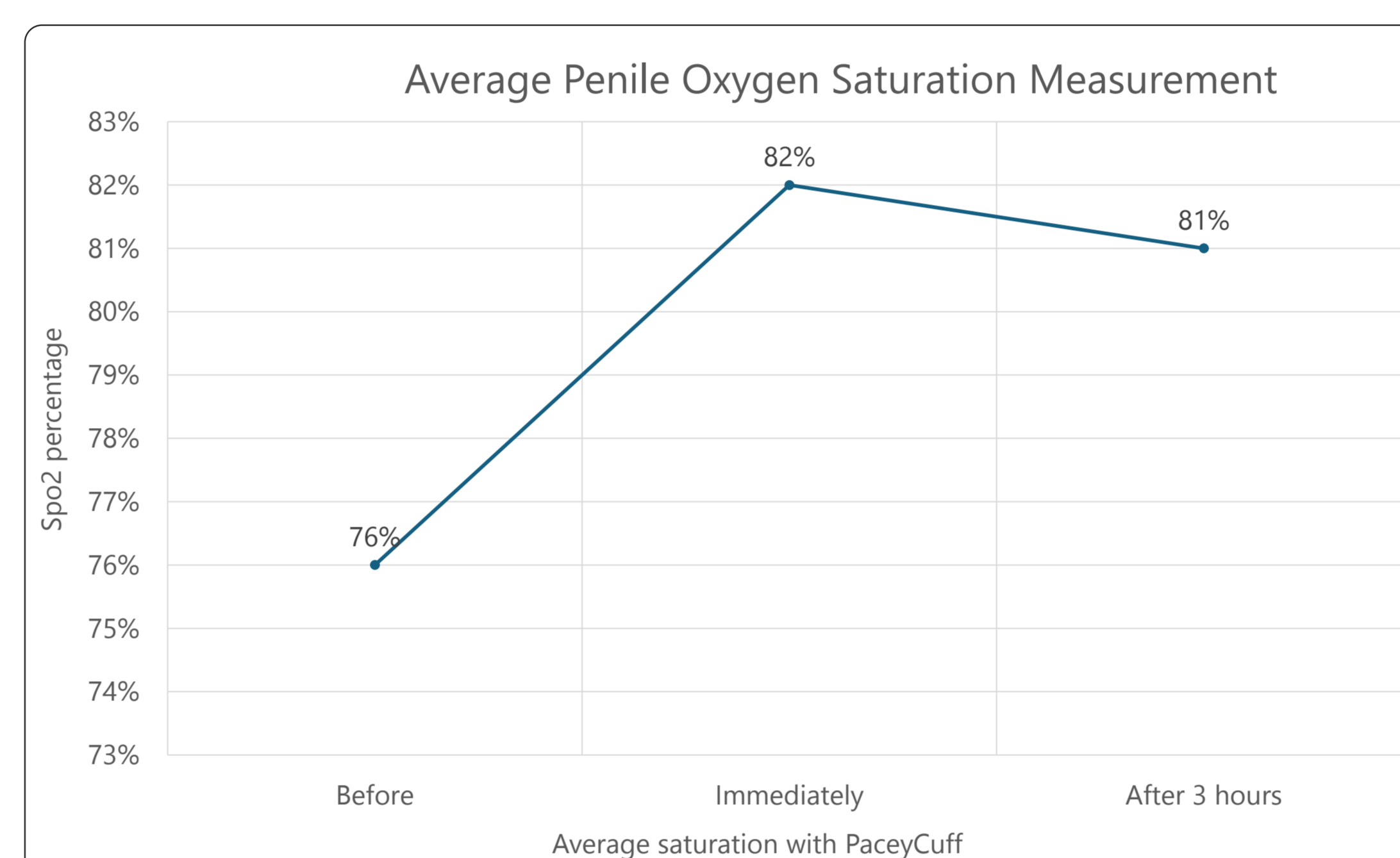


Figure 1: shows the average penile oxygen saturation measurement

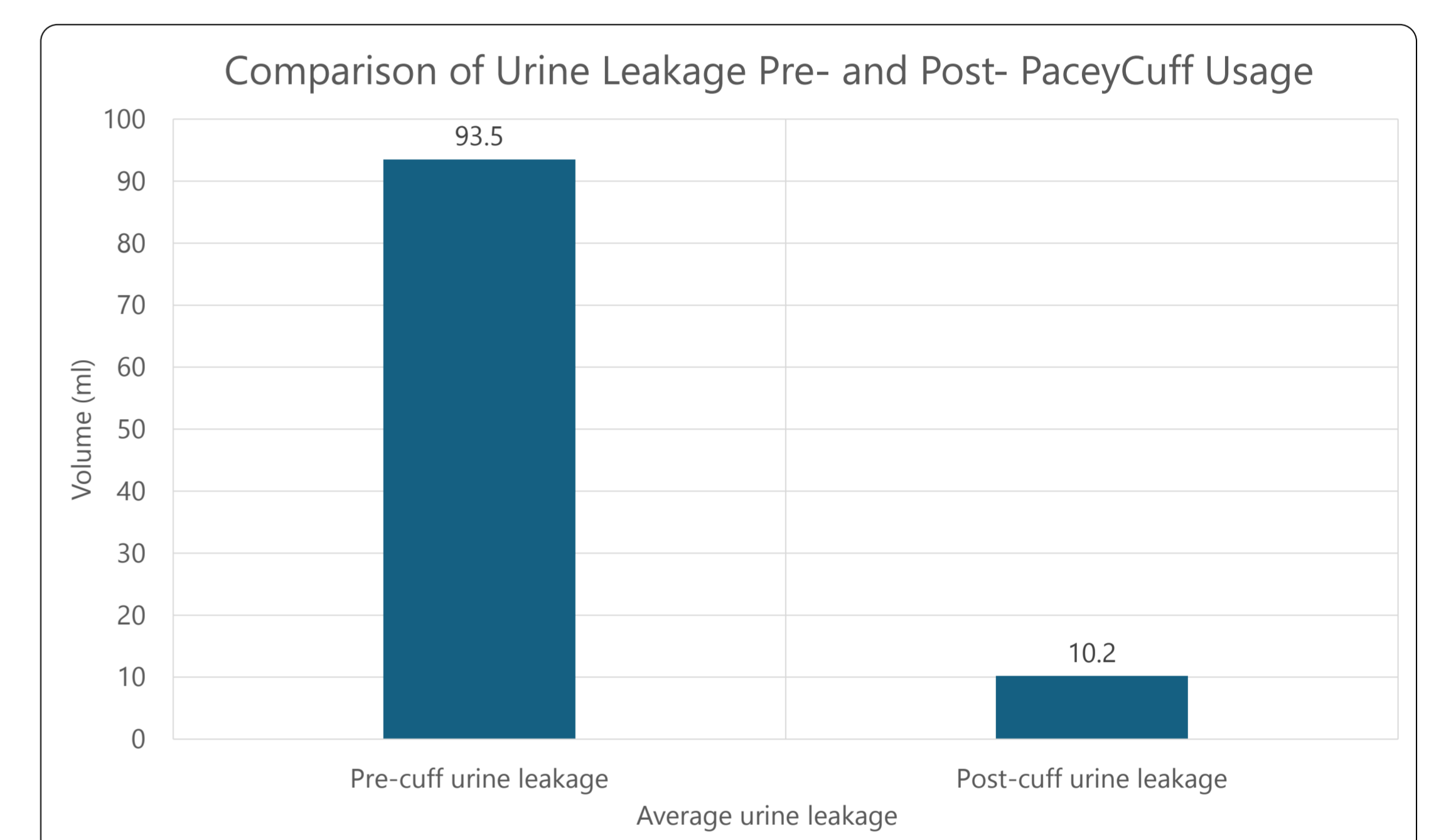


Figure 2: shows comparison of urine leakage pre- and post-PaceyCuff usage

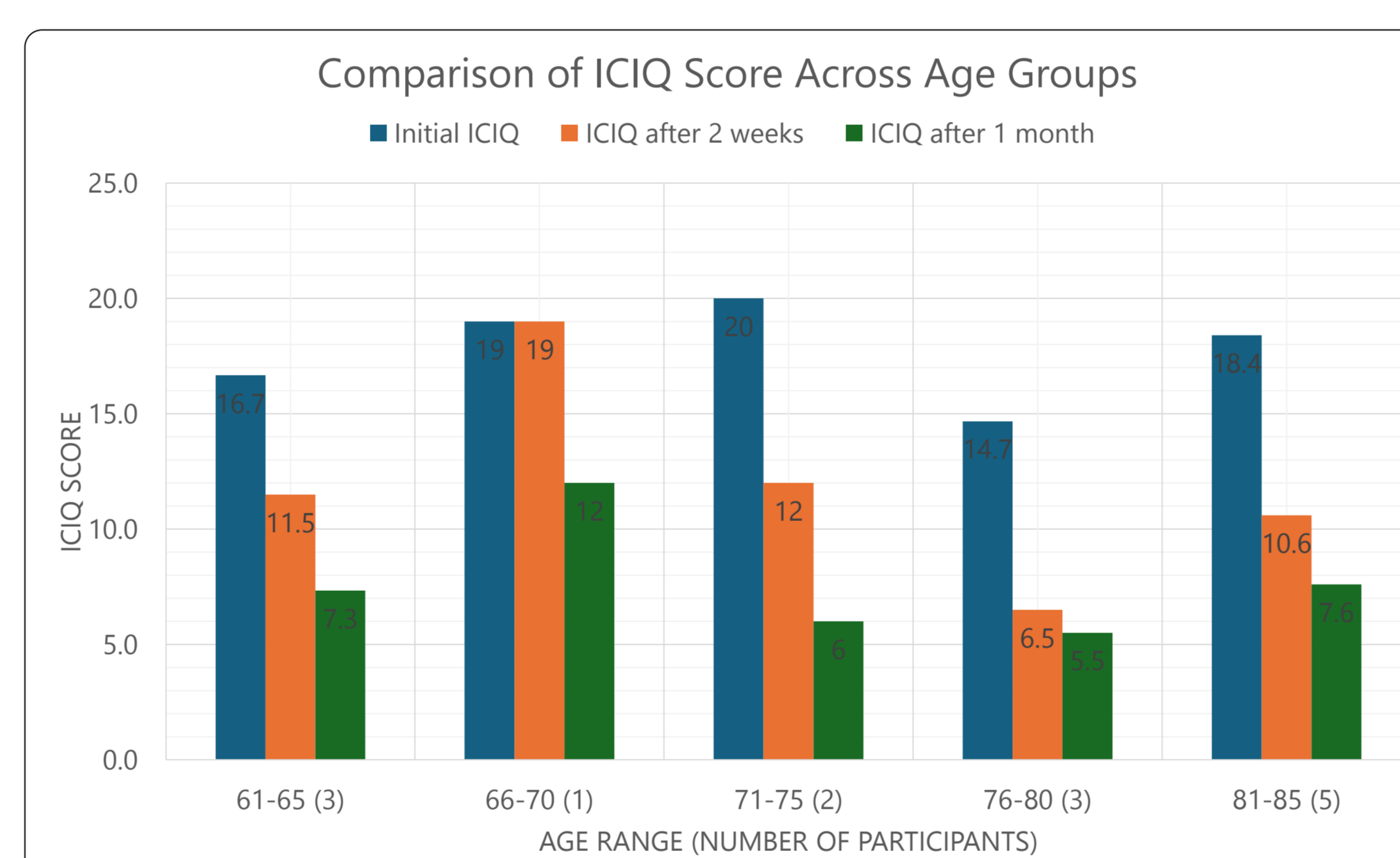


Figure 3: shows the comparison of ICIQ score across age groups over time

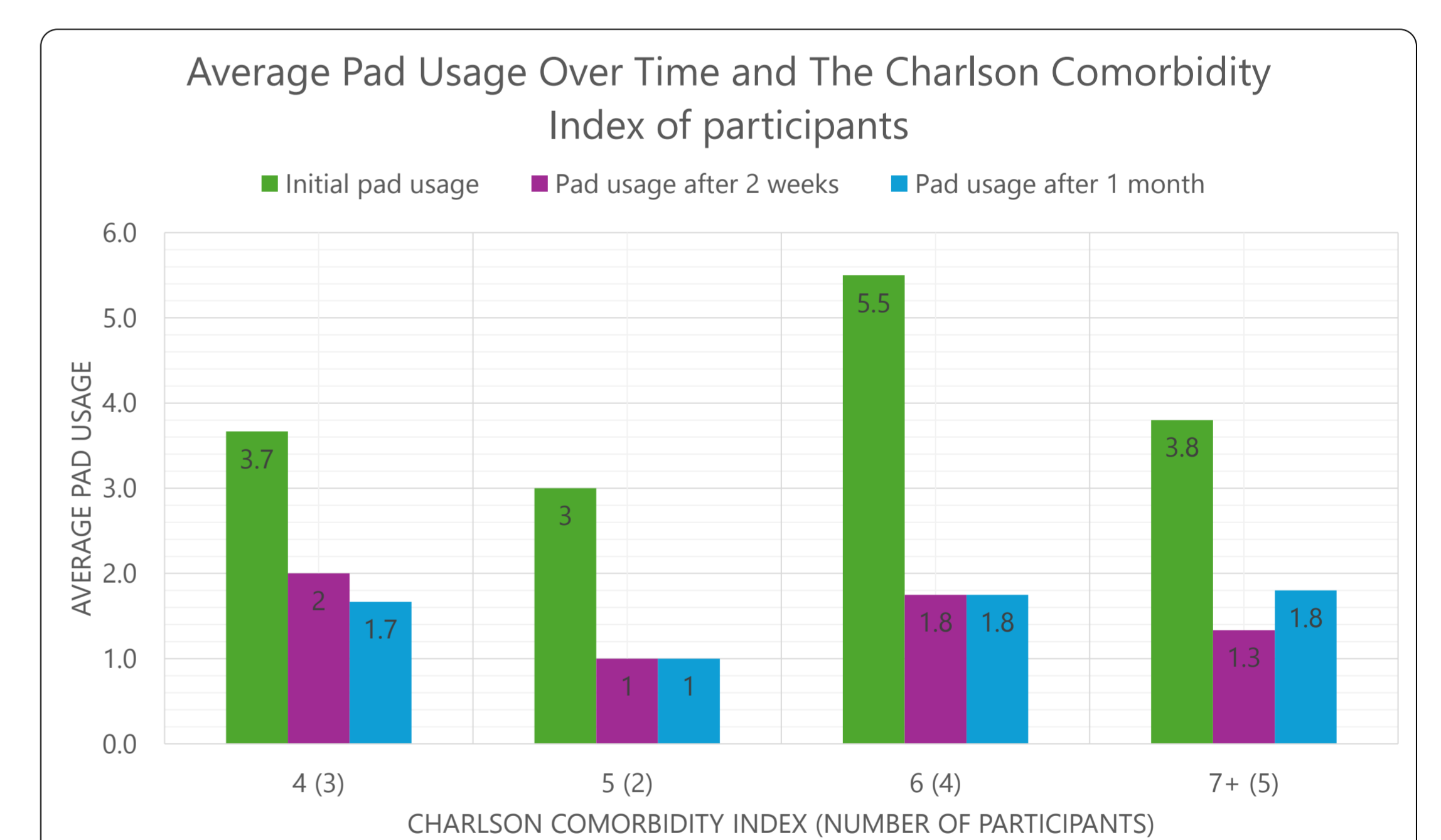


Figure 4: shows the average pad usage over time and the Charlson Comorbidity Index

## DISCUSSION

The findings above show a significant reduction in urine leakage with PaceyCuff use, demonstrating its effectiveness in reducing urinary incontinence (UI) and improving ICIQ scores, particularly in patient's post-prostate surgery. Similarly, studies done in Sweden, Jula et al., (2024) and Canada, BC Medical Journal (2018) also support these findings. Although the PaceyCuff does not completely eliminate incontinence, it greatly reduces leakage, as shown by improvements in ICIQ subcategories, with most patients reporting less frequent and smaller amounts of leakage.

Participants experienced reduced pad usage (from 4 to 1.6 after two weeks), and those with a Charlson Comorbidity Index (CCI) of 6-9, who are typically unfit for surgery, saw the most significant improvements in ICIQ scores, dropping from 18.6 to 7.4 after one month. Patients with lower CCI scores also saw marked improvements, reinforcing the PaceyCuff's role as a non-invasive, effective option for high-risk patients. However, some patients reported only mild improvements in quality of life despite the reduction in leakage, indicating that residual UI can still impact satisfaction. Tolerance with the PaceyCuff was generally good, with an average pain score of 1.9/10 and only two minor adverse events.

This study emphasises the PaceyCuff's potential as a key management tool for UI in patients unfit for invasive procedures due to comorbidities.

## CONCLUSION

For the first time in the UK, the PaceyCuff represents a novel approach to managing male SUI.

- Demonstrating efficacy and tolerability, including in surgically unfit patients, providing a solution for incontinence both day and night without risking penile tissue ischaemia.
- PaceyCuff achieved a 89% decrease in 3 hour pad weight with no decrease in penile oxygen levels.
- Improved continence, QoL, and high patient satisfaction, coupled with minimal side effects, highlight its potential as a valuable treatment option.
- Further larger-scale, long-term studies are warranted to confirm these findings.