Urinary incontinence and quality of life in ageing community dwelling men: Long-term outcomes of the Concord Health and Ageing in Men Project (CHAMP) study

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Statement of originality

This is to certify that to the best of my knowledge; the content of this thesis is my own work. This thesis has not been submitted for any degree or other purposes.

I certify that the intellectual content of this thesis is the product of my own work and that all the assistance received in preparing this thesis and sources have been acknowledged.

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As supervisor for the candidature upon which this thesis is based, I can confirm that the authorship attribution statements above are correct.

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Abstract

Introduction and aims:

Urinary incontinence (UI) in both men and women is a common health problem in the ageing population. Estimates of UI prevalence for men is between 4.5 – 21%. UI can be a debilitating condition with significant impact on overall health and wellbeing. Particularly in its severe forms, UI can predispose to increased falls and fractures. In this study we aim to evaluate the long term changes in UI and its impact on Quality of life (QOL) in older men.

Methods:

Data was collected from the Concord Health and Ageing in Men Project (CHAMP), a population-based study of community-dwelling Australian men aged 70 years or older living in a defined geographical area in Sydney. In total 1705 men were included in the study. Participants were assessed at baseline, 2,5,8 and 11 years follow-up with clinical assessments and self-completed questionnaires. Urinary symptoms, continence, QOL and functional data was extracted from the CHAMP database including the International Prostate Symptom Score (IPSS), International Consultation on Incontinence Questionnaire- urinary incontinence short form (ICIQ) and 12-item Short Form survey (SF-12).

Results:

The results in this study showed a clear trend in older community dwelling men that the prevalence of UI increases over time, 14.8% (247 of 1674) at baseline and increasing to 22.8% (102 from 447) at 11 years follow-up. Furthermore, the severity of UI increased over the study period as demonstrated by the rising ICIQ scores and pad per day (PPD) usage. A negative impact of UI on the SF-12 score was seen across both physical/mental health component scores (PCS and MCS) . However, the impact on PCS longitudinally was greater than the impact seen on MCS.

Conclusion:

The results from the CHAMP study showed that UI is a common condition in our older male Australian population and affected more than 1 in 8 individuals in our cohort of 1705 men. The prevalence and severity of this condition

increased over time significantly and it had a persistent negative impact on QOL.

Acknowledgements

First and foremost, I would like to thank my Mphil Supervisor Professor Lewis Chan, who has been immensely supportive from the very beginning of this higher degree. I have learnt much along the way, particularly in the field of male urinary incontinence. My clinical practice has also improved from the knowledge gained through the completion of this thesis.

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My gratitude also extends to Kate Milledge, for all the assistance provided with the data extraction from the CHAMP database and for the guidance provided.

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Abbreviations

AUS	Artificial Urinary Sphincter
BOO	Bladder Outlet Obstruction
BPE	Benign Prostatic Enlargement
CFA	Continence Foundation Australia
CHAMP	Concord Health and Ageing in Men Project
COPD	Chronic Obstructive Pulmonary disease
CPD	Continuing Professional Development
EQ-VAS	EuroQOL Visual Analogue Scale
GP	General Practitioner
IBS	Irritable Bowel Syndrome
ICIQ	International Consultation on Incontinence Questionnaire- urinary incontinence short form
ICS	International Continence Society
IPSS	International Prostate Symptom Score
LUTS	Lower Urinary Tract Symptoms
MCS	Mental component score
OAB	Overactive Bladder
OR	Odds Ratio
PBS	Pharmaceutical Benefits Scheme
PCS	Physical Component score
PPD	Pad per day
PVR	Post Void Residual
Qmax	Peak flow

QOL	Quality of Life
RP	Radical prostatectomy
SF-12	12-item Short Form survey
TURP	TransUrethral Resection of Prostate
T2DM	Type 2 Diabetes Mellitus
UI	Urinary incontinence

Chapter 1: Introduction and Background

Urinary incontinence (UI) in both men and women is a common health problem in the older population, UI is defined by the International Continence Society (ICS) as "the involuntary loss of urine" [1]. The reported prevalence ranges for UI vary greatly. This is likely due in part to the lack of a universally agreed upon standard definition of what is urinary incontinence. Definitions used in previously published large cohort studies include leakage of urine greater than 25% of the time, any difficulty controlling bladder and any urinary leakage [2-4]. Obviously, any inadvertent leakage of urine constitutes an incontinence episode but when assessing incontinence as a chronic condition, it is important to identify those patients with clinically significant incontinence.

UI in ageing community dwelling men and its impact has become an increasingly prominent issue in developed countries such as Australia that have observed an increase in the older population[5]. Although several studies have sought to describe the impact of urinary symptoms and UI on QOL[4, 6-13],very few prospective longitudinal studies exist that have investigated outcomes in this population group[14, 15]. Furthermore, to date there remains few widely available and utilised primary interventions available to clinicians for prevention of UI in ageing men[16, 17]. The secondary impacts of UI such as falls, can also be devastating for patients and lead to serious morbidity.

CHAMP study overview

The Concord Health and Ageing in Men Project (CHAMP) is a population-based study of 1705 older, community-dwelling Australian men and currently has over 10 years follow-up. CHAMP was funded by the National Health and Medical Research Council and the Ageing and Alzheimer's Research Foundation. The study was approved by the Concord Hospital Human Research Ethics Committee and data collection commenced in 2005[18].

Participants were identified from the New South Wales electoral role and letters explaining the nature of the study were sent to their addresses. Men aged over 70 years living in the community and not residents of a nursing home or aged

care facility were recruited. The participation rate in the study was 47%, which is not dissimilar to the rates of participation seen in similar studies conducted in Australia[15, 19]. The main goals of this cohort study were to investigate common disease processes and issues in the older male population, such as falls, mobility, urinary function, bone strength, oral health and QOL changes.

CHAMP urinary data includes standardised questionnaires on lower urinary tract symptoms (LUTS), UI, QOL as well as functional data including urinary flow study and residual urine assessment. The International Prostatic Symptom Score (IPSS) was used as the LUTS questionnaire, the International Consultation on Incontinence Questionnaire- Short Form (ICIQ) assessed UI and the 12-item Short Form survey (SF 12) assessed QOL parameters[20-22]. Kwong et al reported the baseline UI data of the CHAMP cohort in 2010[6]. This study will build on this initial work and report UI and QOL changes in the CHAMP cohort over 11 years and investigate the impact of prostate cancer and benign prostatic enlargement (BPE) treatment in this same group of ageing men.

In the CHAMP cohort a self-reported clinical diagnosis of BPE had been made in over one third of men at study entry and just under 1 in 5 (302) men had undergone surgery for LUTS at baseline. These men were treated in an era where medical therapy for LUTS such as uro-selective alpha blockers or 5 Alpha reductase inhibitors were not widely used as these medications were not available on the Pharmaceutical Benefits Scheme (PBS). As such transurethral resection of prostate (TURP) was the predominant surgical procedure for LUTS management in men who failed conservative therapy. Data including urinary symptoms and post-void residual urine data collected in the CHAMP study have been reported by Noguchi et al[12].

Urinary incontinence overview

There are different types of UI, and the aetiology is complex and multifactorial. Broadly speaking, UI can be categorised into stress, urge, mixed and overflow incontinence. There are also rarer forms of incontinence such as giggle incontinence, but this typically afflicts younger females. Stress incontinence describes the involuntary loss of urine that occurs secondary to increases in abdomino-pelvic compartment pressure that overwhelm the usual continence mechanisms that primarily rely on the urinary sphincter muscle groups and the

pelvic floor musculature. Urge incontinence relates to the involuntary leakage of urine soon after the sudden and compelling sensation of requiring to void. Mixed incontinence combines elements of both stress and urge incontinence. Overflow incontinence is a form of UI that is seen mostly in men and is essentially in itself a symptom of urinary retention. In this type of UI, involuntary loss of urine occurs once bladder capacity is exceeded, and the usual continence mechanisms are overwhelmed.

Estimates of UI prevalence in older women vary from 13.1 - 37%[23-25], for men the rate is lower and between 4.5 - 21%[3, 4, 6, 7, 10, 13-15, 25-28]. The higher rates of incontinence amongst women (particularly stress incontinence) are not unexpected. The impact and trauma from childbirth on the pelvic floor musculature, in addition to anatomical differences, likely account for the discrepancy in prevalence of UI between the sexes. One of the largest studies (included 9965 men) was conducted in the United States of America utilising national survey data. In this study the prevalence of UI in men was 17% and UI was defined as difficulty controlling the bladder in the last 12 months[3].

Multiple anatomical and physiological systems are required to maintain continence. Briefly, normal bladder filling and urine storage requires relaxation and adequate compliance of the detrusor muscle and activation of the urethral sphincter. Normal voiding requires appropriate contraction of the detrusor muscle and simultaneous relaxation of the urethral sphincter. Incontinence can occur due to abnormalities in either bladder filling or voiding. Pathological findings that can contribute to incontinence include, overactivity of the detrusor muscle, poor compliance and urethral sphincter deficiency.

The aetiology and pathophysiology of male urinary symptoms and incontinence is complex and multifaceted. This is especially important when considering that patients often present with mixed UI rather than pure stress, urge or overflow incontinence. UI can also be transient or chronic depending on the underlying cause (urinary tract infection for example may cause urge incontinence that improves with antibiotic treatment). For the purposes of this study and for clarity, we will focus on chronic and persistent UI and discuss the different forms of UI as separate pathologies.

Urge related UI is the commonest type of UI in men and is amenable to pharmacotherapy[13-15, 25, 26]. Commonly seen causes of persistent urge UI include, idiopathic or neurogenic bladder overactivity, and overactive bladder secondary to benign prostatic obstruction. Neurological conditions such as stroke, Parkinson's disease, multiple sclerosis and dementia etc.) are responsible for a significant proportion of patients with UI, with up to 24% of men post stroke at 12 months reporting new urinary incontinence[29].

Urological/iatrogenic causes are also responsible for a significant proportion of UI in men. Post radical prostatectomy incontinence is one of the main causes of stress UI in this group, with multiple studies reporting on the incidence and treatments available[30-33]. Stress UI post-surgical treatment of BPH is rare, with less than 0.5% of patients reporting incontinence post trans-urethral resection and UI post simple prostatectomy a rare occurrence[34, 35].Although estimates vary, approximately 9-16% of men undergoing radical prostatectomy (RP) for prostate cancer will continue to report UI 12 months following surgery[36-38]. UI following RP can occur due to the disruption of the external urethral sphincter (Rhadosphincter), the bladder neck ('internal') sphincter, the periurethral supporting structures and innervation of the bladder. UI continues to remain a very common issue post RP, despite advances in surgical technique and the increasing utilisation of robotic surgery[39-41]. Risk factors for developing post RP incontinence include older age, short pre/post operative membranous urethral length, radiotherapy treatment, non-nerve sparing RP and pre-existing UI[42-47]. Less common causes of UI in older men include traumatic urethral/ pelvic floor injuries and adult epispadias. Overflow incontinence is another form of incontinence with a plethora of causes. They include BPE, urethral stricture, severe phimosis, bladder neck contracture/stenosis and detrusor underactivity with the commonest being chronic urinary retention related to bladder outlet obstruction from prostatomegaly.

Impact of Urinary Incontinence on QOL

UI can be a debilitating condition with significant impact on overall health and wellbeing. Particularly in its severe forms, UI can predispose to increased falls and fractures[12, 48]. Additionally, there are often negative impacts on quality of life (QOL) and the social life of UI sufferers[6, 7, 9-11, 13]. There is often a perceived stigma surrounding UI and patients are often embarrassed to seek help from healthcare providers and suffer in silence. In one study involving over a

thousand participants with UI, less than 40% sought treatment from their primary care physician for their UI [49]. As such, the burden of disease associated with UI on the community is therefore likely to be far greater than previously predicted. The economic impact of UI has also been evaluated and projected costs to the Australian economy in 2010 from the loss of productivity alone associated with UI are estimated at greater than $35 billion[50]. Given the prevalence of UI and its significant economic, social and health impacts, knowledge regarding the longitudinal changes of UI would be useful for governments and healthcare providers.

Multiple cross-sectional studies assessing prevalence of UI have also demonstrated the negative impact of UI on QOL. A Korean study of almost 6000 men demonstrated an age adjusted prevalence of UI of 5.5% and significantly worse QOL in the UI group. QOL was measured using the EuroQOL Visual Analogue Scale (EQ-VAS). The mixed UI group was associated with worse QOL outcomes when compared to both the pure stress and urge incontinence groups[4].

Kwong et al reported on the results of the CHAMP cohort at baseline and found for men age greater than 70 the prevalence of UI was 14.8%[6]. The investigators utilised the SF-12 tool to assess QOL. In both the physical and mental component scores (PCS and MCS) a negative impact was seen in the UI group. Not surprisingly, as frequency of incontinence episodes increased, the PCS decreased. Also, men with UI reported poorer general health when compared to continent men.

Few prospective longitudinal studies exist on the issue of male UI and only one longitudinal study conducted in Sweden, investigated UI and QOL[14, 15]. In the Swedish study, more than 7763 men were given postal questionnaires assessing UI, LUTS and QOL, a small subset of these patients (3.3%) was assessed in an outpatient clinic with history taking and physical examination. The cohort was then followed up at 11-years with another postal questionnaire, 3257 responded. The study assessed UI in in 2586 men and revealed that the rate of UI increased from 4.5% to 10.5% over the study period and that QOL outcomes were poorer in the UI group. The QOL tool utilised on this study was a validated visual analogue scale. Interestingly, in this study participants included nursing home

residents, and no difference was found between rates of UI between community dwelling men and those in residential care.

Patients with UI are at higher risk of suffering from falls and subsequently fractures[12, 48, 51]. Falls are an extremely common issue in older people, with 30-40% of participants in a community-based population reporting at least one fall in the last year [52, 53]. Falls in the acute setting can lead to serious morbidity and mortality in the long term they are associated with worsening general decline and functional status and can reduce the independence with activities of daily living. Therefore, it is reasonable to assume that treatment of UI may reduce the risk of falls in older people and spare patients from their devastating consequences. The link between falls and UI in the CHAMP cohort was investigated previously by Noguchi et al. Multivariate analysis demonstrated patients with urge UI were twice as likely to report a fall within the last 4 months. Patients with other forms of UI did not demonstrate an increased risk of falls and interestingly patients with urge symptoms without UI were not at an increased risk of falls[12].

Whilst there is a wealth of data on oncological outcomes in men who have undergone radical prostatectomy and radiotherapy for prostate cancer, there is very little longitudinal data on the impact these treatments have UI and QOL in this cohort [54-57]. The CHAMP cohort provides an ideal opportunity to report on these outcomes in the 275 (16.1%) men diagnosed with prostate cancer. At baseline 214 men (12.6%) were diagnosed, whilst 61 men (3.6%) were diagnosed during the study period. Of these men, 33% underwent radiation treatment, 38% had surgery, 30% androgen deprivation therapy alone or in combination with surgery or radiation and 9% had no treatment/observation only.

Treatment of Urinary incontinence

Treatment of UI depends on the suspected underlying aetiology. Conservative measures include bladder retraining, timed voiding, pelvic floor exercises, limiting caffeine intake and ceasing diuretics. Weight loss has also been shown to improve UI in both men and women[58]. Although these measures should generally be considered as first line therapy, they are more effective in patients

with mild symptoms. Patients are also less likely to see a significant response to conservative measures in the setting of severe UI[59].

As previously mentioned, pharmacological agents can be utilised to treat UI. If UI is thought to be related to an overactive bladder secondary to bladder outlet obstruction from an enlarged prostate, pharmacotherapy for prostatic obstruction such as alpha receptor blockers and 5-alpha reductase inhibitors are often utilised [60, 61]. Urge related UI secondary to detrusor overactivity can also be managed pharmacologically with multiple available agents including anti-muscarinics and Beta-3- adrenergic receptor agonists. In more severe cases intravesical botulinum injections can be utilised with good effect, although repeat administration is often required to maintain results[62-64]. An important consideration in the older patient is that anti-muscarinics can exacerbate pre-existing cognitive impairment and are associated with a side effect profile that may be unacceptable to many patients. Beta-3- adrenergic receptor agonists are generally better tolerated by patients but can increase systolic blood pressure which requires monitoring.

For patients post RP who report persistent stress UI greater than 12 months and have failed conservative measures such as pelvic floor physiotherapy and pharmacotherapy, surgical interventions can be considered. Surgical interventions include the use of bulking agents, slings and artificial urinary sphincters (AUS). Factors that impact the decision making when considering these surgical options include patient preference, manual dexterity of the patient, severity of incontinence and fitness for surgery. For comorbid patients with mild incontinence, bulking agents are an attractive option as they can be injected via a trans-urethral approach to improve coaptation of the urethra. Relatively well patients with moderate incontinence (pad weight <400g/day) can be considered for a sling procedure which has been shown to provide durable improvement in continence with long term follow-up. There are a variety of slings available, the commonest is a trans-obturator sling which provides ‘dynamic compression’ of the urethra during exertion episodes such as coughing or Valsalva, in addition to passive compression of the urethra[32]. The AUS provides continence through circumferential compression of the urethra by the cuff of the prosthesis. The AUS provides excellent continence outcomes for patients with severe incontinence (pad weight >400/day) and can be placed in patients who have failed previous surgery for UI such as sling procedures and ongoing UI. The main drawback of the AUS, however, is that it requires the

patient to have sufficient manual dexterity and cognitive function to operate the pump of the device to allow voiding to occur. In appropriately selected patients both the urethral sling and AUS are effective treatment options and lead to high patient satisfaction rates[65].

The aims of the thesis

1. To evaluate long-term changes in UI in older community dwelling men and impact on QOL.
2. To evaluate long-term changes in urinary symptoms, UI and QOL in a subgroup of participants diagnosed with prostate cancer.
3. To evaluate long-term changes in urinary symptoms, UI and QOL in a subgroup of participants diagnosed with BPE.

Chapter 3: Methodology

Introduction

Data was collected from the Concord Health and Ageing in Men Project (CHAMP), a population-based study of community-dwelling Australian men aged 70 years or older living in a defined geographical area in Sydney. In total 1705 men were included in the study[18]. The majority of men were identified on the electoral roll and agreed to participate in the study (n=1511). A further 194 men who heard about the study from brochures and resided in the same geographical region directly volunteered to participate. The inclusion/exclusion criteria were the same for both groups. Men living in residential care were excluded.

CHAMP study procedures

At baseline, 2 and 5 years, men completed an extensive self-administered questionnaire prior to attending Concord Hospital for a study clinic visit. The questions covered multiple domains including demographic characteristics, history of diagnosed medical conditions (including diabetes, previous stroke, Parkinson's Disease, epilepsy, prostate cancer), LUTS and UI. LUTS and UI data was collected via the International Prostate Symptom Score (IPSS) and the International Consultation on Incontinence Questionnaire (ICIQ). QOL was assessed mainly through collecting data related to the 12 items Short Form Health survey (SF-12). The definition of UI utilised in the CHAMP study was inadvertent leakage of urine on two occasions or more per week.

During scheduled clinic visits, uroflowmetry was performed and post-void residual urine volume (PVR) measured using BladderScan (Verathon, Inc., Bothell, WA). The uroflow graphs were examined by urologists to screen for anomalies. Peak flow rate was analysed only when the voided volume was 150 ml and over. The self-administered questionnaire and clinical assessments were repeated at 2 and 5-year follow-up visits and questionnaire data obtained at 8

and 11 years. These follow up periods corresponded to “waves” 1-5 in the study.

Current Study Methodology

For the purposes of this thesis, urinary symptoms, continence, QOL and functional data was extracted from the CHAMP database including IPSS, ICIQ, SF-12 questionnaires at baseline, 2, 5, 8 and 11 years.

The IPSS is a validated questionnaire tool that is composed of seven questions related to voiding symptoms that cumulatively provide a score from 0-35 and include an eighth question related to urinary function and QOL[66]. Rather than a diagnostic tool, the main role of the IPSS is to assess severity of symptoms from bladder outlet obstruction (BOO). This scoring system also can be utilised to provide quantitative results that provide objective evidence of the impact of treatment.

The ICIQ is another validated questionnaire tool and is primarily utilised to assess the severity of UI and its impact on QOL[20]. The questionnaire is composed of four separate questions that assesses the frequency, volume, cause of UI and its impact on QOL. After participants complete the questionnaire a total score from 0-21 is generated. The main benefit of including both these scoring systems in our study is that they both provide valuable quantitative information on the impact of UI on QOL. Further questions related to prostate disease were also extracted including data collected on diagnosis of prostate enlargement, prostate cancer and any treatments that patients may have had for these conditions.

A dedicated QOL questionnaire tool was included in the self-administered questionnaire of the CHAMP study. The SF-12 is one of the most widely used, reliable and validated tools to assess QOL[67, 68]. The questionnaire is split between physical and mental components scores (PCS and MCS) that together

provide scores between 0-100. A standardised score of 50 is then generated through a series of recommended algorithms[69]. Lower scores correspond to a decrease in perceived QOL. The SF-12 has previously been assessed at baseline in this cohort with separate analysis of the PCS and MCS. These scores will be further analysed longitudinally in this study to assess the impact of UI on QOL over time.

Random data audits were performed by the author. This was done by reviewing 10% of the hardcopy CHAMP files and cross checking with the electronic database to confirm validity of the urinary data extracted for the purposes of this study. No discrepancy was identified throughout the data audit process. The functional data (uroflow and residual urine) had previously been audited during previous studies.

Data Analysis plan

Descriptive statistics followed by linear regression models were fitted to the data. We assessed the urinary symptoms (IPSS), prevalence and severity of incontinence (ICIQ and pads per day usage) and QOL (SF-12) in the whole cohort at baseline, 2, 5, 8 and 11 years follow-ups. We then modelled each wave of data using generalised linear regression model for binomial outcomes. confounders such as relevant co-morbidities, diagnosis of prostate cancer or BPE were also included in the models to identify important correlations between them and rates of UI.

We conducted a further subgroup analysis of urinary symptoms, continence and QOL in men with either a prostate cancer or BPE diagnosis at baseline, 2, 5, 8 and 11 years. We fitted similar models. QOL analysis was also performed by utilising data from the SF-12. We quantified SF-12 scores from the questionnaire using standard methodology described previously[69]. The physical and mental health questionnaires underwent imputation of missing values through multiple imputation, involving 50 iterations. Further descriptive QOL analysis was performed on the specific QOL components of the IPSS and utilising the ICIQ questionnaires. All analyses were performed using R statistical software version 4.3.1 (R core team, Vienna, Austria, 2023)[70].

Chapter 4: Results

Baseline characteristics

The overall study sample in CHAMP consisted of 1705 men aged 70 to 97 years old with a mean age of 76.9 years. At baseline, over one-third of men (n=619) reported they had an enlarged prostate and 10% of men (n=183) had a diagnosis of prostate cancer. Comorbidity was as follows 18.5% were diagnosed with type 2 diabetes mellitus (T2DM), 8.5% reported a previous stroke, 2.4% reported a diagnosis of dementia and 1.9% reported a diagnosis of Parkinson's disease.

The number of participants available for follow-up during the study period at 2, 5, 8 and 11 years were 1367, 958, 781 and 457 respectively (**Figure.1**). The mean age of the cohort at 2, 5, 8 and 11 years was 79, 81.4, 84.1 and 87.2 respectively.

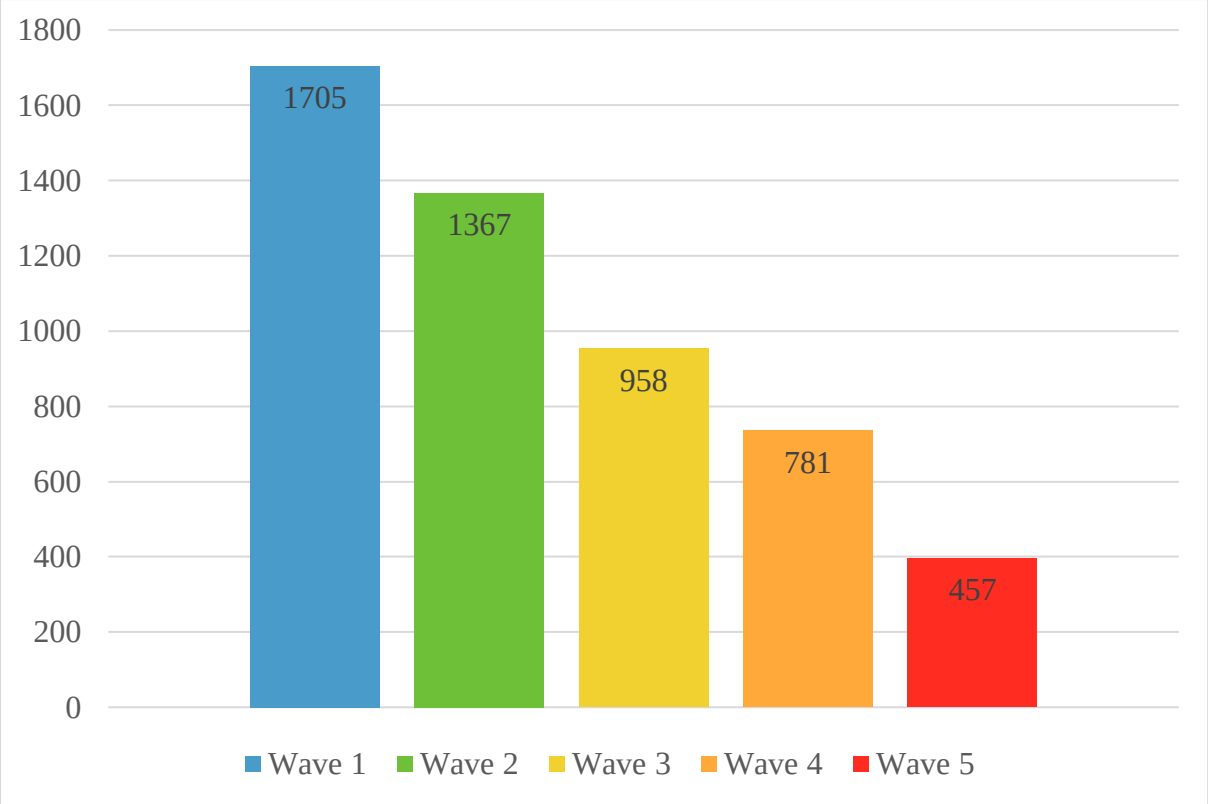

***Figure 1**. Participants available for follow-up longitudinally.*

**Wave 1= baseline, Wave 2= 2 years, Wave 3=5 years, Wave 4= 8 years, Wave 5= 11 years*

Prevalence and severity of UI

Prevalence of UI (defined as 2 episodes of urinary leakage in the last 4 weeks) for the total cohort was 14.8% at baseline, 15.1% at 2 years, 17.6% at 5 years, 23.2% at 8 years and 22.8% at 11 years (**Figure. 2**) . At baseline the prevalence of UI increased from 12.0% in the 70-74 years age group to 26.3% in the 85-89 years age group. Interestingly, the rate of UI decreased in the >90 age group to 16.3%. The severity of incontinence also increased over time as seen with increasing pad usage reported. At baseline 16.2% of incontinent men reported using at least 1 Pad per day (PPD) (**Table. 1**), this increased to 45.6% at 11 years (**Table. 2**). Urinary symptoms and bother were more common in men with UI, at baseline 69.2% of incontinent men reported an IPSS score of moderate to severe, compared to only 31.0% of continent men (**Table. 3**). At 11 years, 67.9% of incontinent men reported moderate to severe IPSS scores, compared to 32.7% of continent men (**Table. 4**).

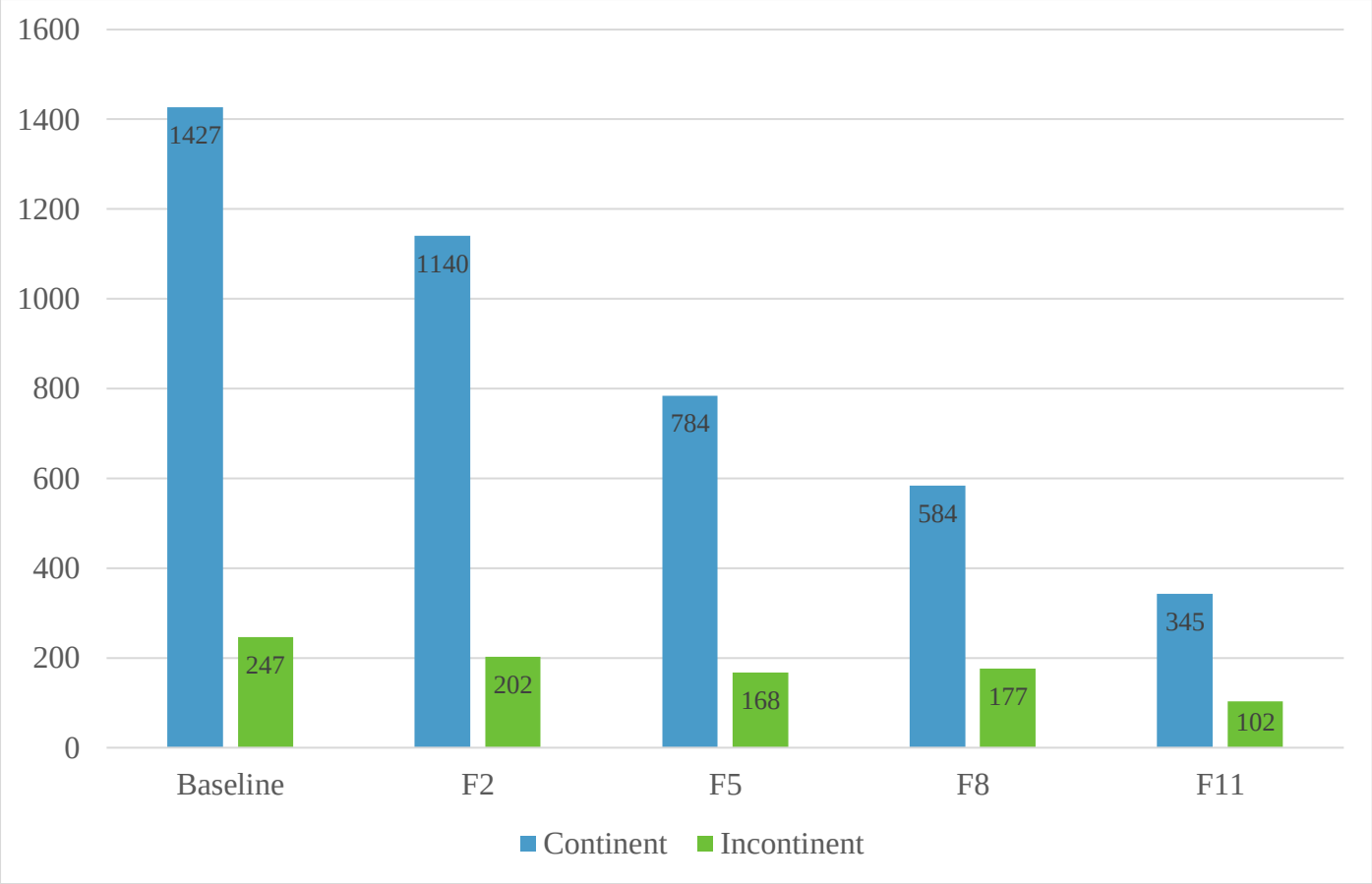

***Figure 2**. Longitudinal prevalence of UI.*

Table 1: Use of pads at baseline across groups (n=1,674).

Group	Use of pads (S3Q13) N (%)		
	Full cohort	Continent (n = 1,427)	Incontinent (n = 247)
No pads	1,621 (96.8)	1,414 (99.1)	207 (83.8)
1 pad per day	39 (2.3)	12 (0.8)	27 (10.9)
2 pads per day	8 (0.5)	1 (0.1)	7 (2.8)
3 or more pads per day	6 (0.4)	0 (0.0)	6 (2.4)

Table 2: Use of pads at F11 across groups (n=446).

Group	Use of pads (S3Q13) N (%)		
	Full cohort	Continent (n = 343)	Incontinent (n = 103)

No pads	380 (85.2)	324 (94.5)	56 (54.4)
1 pad per day	40 (9.0)	15 (4.4)	25 (24.3)
2 pads per day	14 (3.1)	4 (1.2)	10 (9.7)
3 or more pads per day	12 (2.7)	0 (0.0)	12 (11.7)

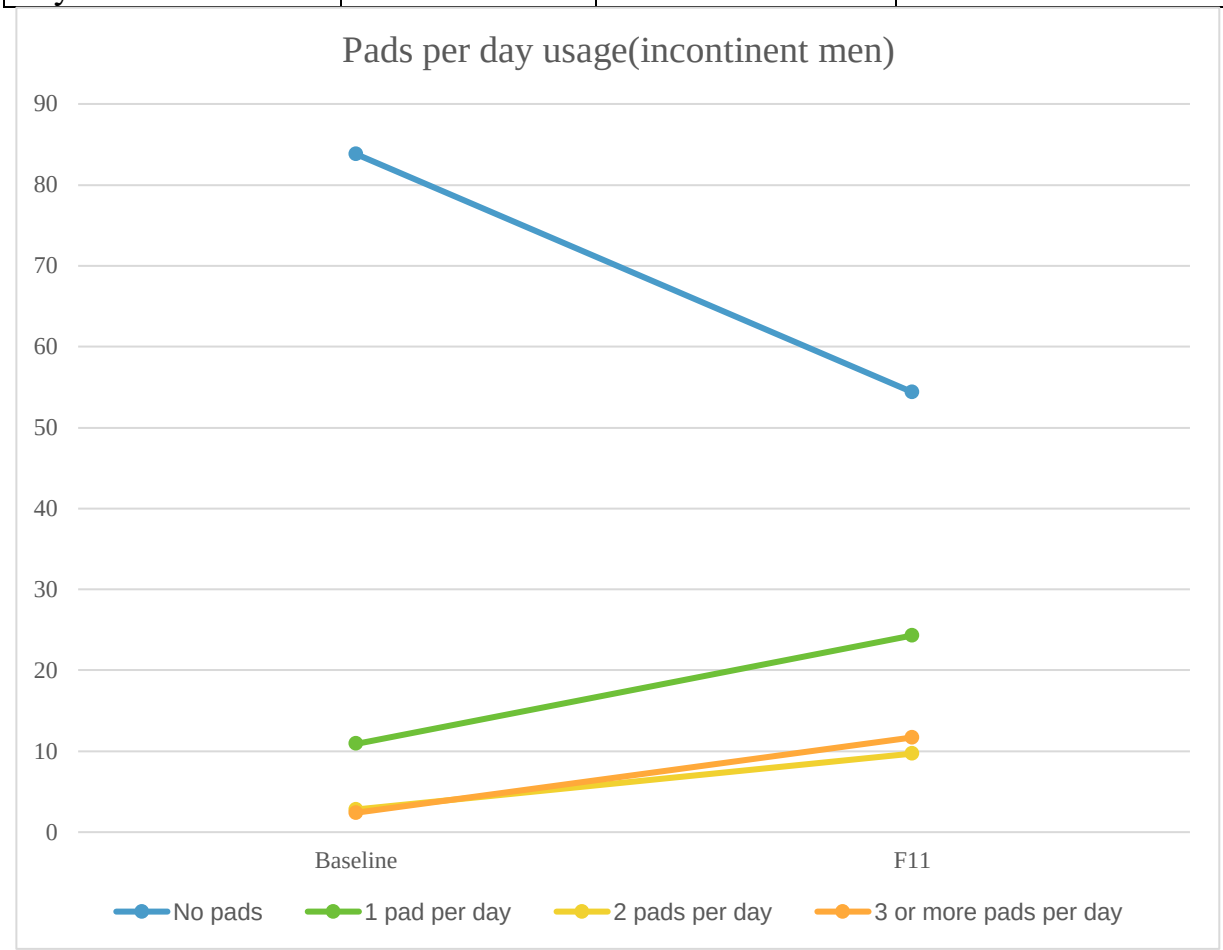

Figure 3. Summary of tables 1,2.

Table 3: IPSS score at baseline across groups (n=1,674).

Group	IPSS scores N (%)		
	Full cohort	Continent (n = 1,427)	Incontinent (n = 247)
Mild (0-7)	1,060 (63.3)	984 (69.0)	76 (30.8)
Moderate (8-19)	482 (28.8)	373 (26.1)	109 (44.1)
Severe (20-35)	132 (7.9)	70 (4.9)	62 (25.1)

Table 4: IPSS score at F11 across groups (n=446).

Group	IPSS scores N (%)		
	Full cohort	Continent (n = 343)	Incontinent (n = 103)
Mild (0-7)	264 (59.2)	231 (67.3)	33 (32.0)
Moderate (8-19)	141 (31.6)	97 (28.3)	44 (42.7)
Severe (20-35)	41 (9.2)	15 (4.4)	26 (25.2)

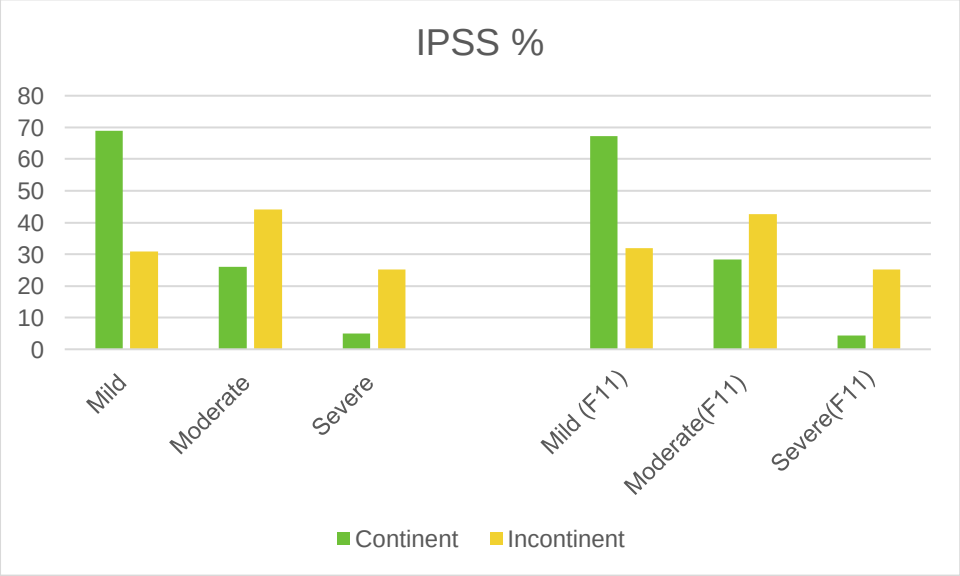

Figure 4 Summary of tables 3,4.

Risk factors for UI

At baseline men with prostate cancer reported higher rates of UI compared to men without prostate cancer, 22.9% and 13.6% respectively. Similarly, at baseline men with BPE reported higher rates of UI compared to men without BPE, 20.8% and 10.8% respectively. Results from longitudinal logistic regression analysis demonstrate several risk factors for UI. BPE, prostate cancer and several medical comorbidities (Stroke, dementia, Parkinson's disease, T2DM). At baseline, men with BPE had increased odds of reporting UI, with Odds ratio (OR) of 2.04 (1.52 - 2.7, $p<0.001$). Although this trend persisted at 8 year follow-up, OR 1.2 (0.81 – 1.79, $p= 0.347$), this was not statistically significant.

Similarly, men diagnosed with prostate cancer at baseline had increased odds of reporting UI, OR 1.72(1.15 – 2.5, $p=0.007$) and this also persisted at long term follow-up, OR 1.54 (0.84 – 2.86, $p=0.147$), although this was not statistically significant. Relevant comorbidities are also associated with UI at baseline, OR 1.56 (1.15 – 2.08, $p=0.004$) and this trend continued at long term follow-up, OR 1.56 (1.09 – 2.22, $p=0.013$).

Impact of UI on QOL- ICIQ and IPSS data

There was a noticeable increase in the severity of UI and its negative QOL impact over time, with 71.2% of incontinent men reporting at least moderate UI as scored on the ICIQ at baseline (**Table. 5**), compared to 88.3% at 11 years (**Table. 6**). Given the significant weighting of the QOL item in the ICIQ, these results not only provide information regarding the severity of UI but also an indication of its impact on QOL. When analysing the data from the IPSS QOL question at baseline, 32.8% of incontinent men reported being mostly unsatisfied or worse, compared to only 7.4% of continent men (**Table. 7**). By 11 years, 29.5% of incontinent men reported being mostly unsatisfied or worse, compared to only 6.2% of continent men (**Table. 8).**

The SF-12 data also confirms the negative impact of UI on QOL. At baseline there was a significantly lower PCS score in the incontinent group when compared to continent men, 41.94 vs 46.03 respectively. MCS scores similarly demonstrated a negative impact from UI, with a score of 55.39 in the continent group vs 52.74 in the incontinent group (**Table. 9).** These trends continued during the subsequent follow-up waves. Data from the SF-12 was available until 8 years follow-up and showed a PCS score of 43.97 and 39.69 in the continent and incontinent groups respectively. MCS scores at 8 years were 55.65 and 52.25 in the continent and incontinent groups respectively (**Table**. **10**).

Table 5: ICIQ score at baseline across groups (n=1,674).

Group	ICIQ scores N (%)		
	Full cohort	Continent (n = 1,427)	Incontinent (n = 247)
Slight (1-5)	1,470 (87.8)	1,399 (98.0)	71 (28.7)
Moderate (6-12)	179 (10.7)	25 (1.8)	154 (62.3)
Severe (13-18)	25 (1.5)	3 (0.2)	22 (8.9)

Table 6: ICIQ score at F11 across groups (n=446).

Group	ICIQ scores N (%)		
	Full cohort	Continent (n = 343)	Incontinent (n = 103)
Slight (1-5)	341 (76.5)	329 (95.9)	12 (11.7)
Moderate (6-12)	81 (18.2)	13 (3.8)	68 (66.0)
Severe (13-18)	21 (4.7)	1 (0.3)	20 (19.4)
Very severe (19-21)	3 (0.7)	0 (0.0)	3 (2.9)

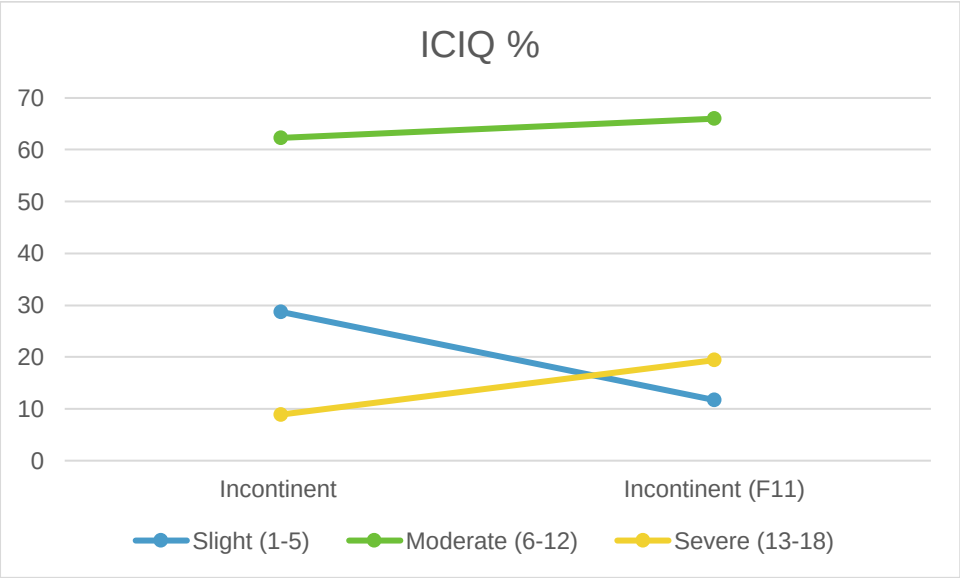

Figure 5 Summary of tables 5/6.

Table 7: IPSS quality of life score at baseline across groups (n=1,674).

Group	IPSS quality of life score (S3Q8) N (%)		
	Full cohort	Continent (n = 1,427)	Incontinent (n = 247)
Delighted	228 (13.6)	225 (15.8)	3 (1.2)
Pleased	482 (28.8)	458 (32.1)	24 (9.7)
Mostly satisfied	517 (30.9)	449 (31.5)	68 (27.5)
Mixed	260 (15.5)	189 (13.2)	71 (28.7)
Mostly unsatisfied	98 (5.9)	62 (4.3)	36 (14.6)
Unhappy	74 (4.4)	35 (2.5)	39 (15.8)
Terrible	15 (0.9)	9 (0.6)	6 (2.4)

Table 8: IPSS quality of life score at F11 across groups (n=446).

Group	IPSS quality of life score (S3Q8) N (%)		
	Full cohort	Continent (n = 343)	Incontinent (n = 103)
Delighted	51 (11.4)	48 (14.0)	3 (2.9)
Pleased	122 (27.4)	112 (32.7)	10 (9.7)
Mostly satisfied	153 (34.3)	123 (35.9)	30 (29.1)
Mixed	69 (15.5)	39 (11.4)	30 (29.1)
Mostly unsatisfied	20 (4.5)	13 (3.8)	7 (6.8)
Unhappy	23 (5.2)	4 (1.2)	19 (18.4)
Terrible	8 (1.8)	4 (1.2)	4 (3.9)

Table 9: SF-12 score at baseline across groups (n=1,650).

SPF-12	Mean (SD)		
	Full cohort	Continent (n = 1,409)	Incontinent (n = 241)
PCS	45.43 (10.02)	46.03 (9.91)	41.94 (9.93)
MCS	55.00 (8.16)	55.39 (8.02)	52.74 (8.59)

Table 10: SF-12 score at F8 across groups (n=758).

SPF-12	Mean (SD)		
	Full cohort	Continent (n = 583)	Incontinent (n = 175)
PCS	42.98 (10.48)	43.97 (10.27)	39.69 (10.53)
MCS	54.86 (8.67)	55.65 (8.02)	52.25 (10.14)

Impact of BPE on UI and urinary symptoms

IPSS scores in the BPE group were significantly higher when compared to those without BPE, with moderate to severe IPSS scores of 49.2% and 28.8% respectively (**Table. 11**). This trend persisted over time with 51.8% of men with BPE reporting moderate to severe IPSS scores, when compared to only 36.4% of men without BPE (**Table. 12**). Additionally, the IPSS QOL question revealed 16% of men with BPE were mostly unsatisfied or worse, compared to only 8.1% of men without BPE (**Table. 13**). Again, this trend continued longitudinally and at 11 years 16.6% of men with BPE were mostly unsatisfied or worse, compared to 9.3% of men without BPE (**Table. 14**). ICIQ scores at baseline in men with BPE were elevated compared to men without BPE. 21.3% of men with BPE reported moderate to very severe ICIQ scores, compared to 12.8% of men without BPE (**Table. 15)**. At 11 years, 39.5% of men with BPE reported moderated to very severe ICIQ scores, compared to 25.6% of men without BPE (**Table. 16**).

Table 11: IPSS score at baseline across groups (n=1,656).

IPSS scores	N (%)		
	Full cohort	BPE (n = 662)	None (n = 1,034)
Mild (0-7)	1,052 (63.5)	316 (50.8)	736 (71.2)
Moderate (8-19)	473 (28.6)	229 (36.8)	244 (23.6)
Severe (20-35)	131 (7.9)	77 (12.4)	54 (5.2)

Table 22: IPSS score at F11 across groups (n=446).

IPSS scores	N (%)		
	Full cohort	BPE (n = 114)	None (n = 332)
Mild (0-7)	266 (59.6)	55 (48.2)	211 (63.6)
Moderate (8-19)	140 (31.4)	44 (38.6)	96 (28.9)
Severe (20-35)	40 (9.0)	15 (13.2)	25 (7.5)

Table 13: IPSS quality of life score at baseline across groups (n=1,656).

IPSS quality of life score (S3Q8)	N (%)		
	Full cohort	BPE (n = 662)	None (n = 1,034)
Delighted	229 (13.8)	66 (10.6)	163 (15.8)
Pleased	479 (28.9)	132 (21.2)	347 (33.6)
Mostly satisfied	508 (30.7)	194 (31.2)	314 (30.4)
Mixed	256 (15.5)	130 (20.9)	126 (12.2)
Mostly unsatisfied	98 (5.9)	50 (8.0)	48 (4.6)
Unhappy	71 (4.3)	40 (6.4)	31 (3.0)
Terrible	15 (0.9)	10 (1.6)	5 (0.5)

Table 14: IPSS quality of life score at F11 across groups (n=446).

IPSS quality of life score (S3Q8)	N (%)		
	Full cohort	BPE (n = 114)	None (n = 332)
Delighted	55 (12.3)	7 (6.1)	48 (14.5)
Pleased	121 (27.1)	24 (21.1)	97 (29.2)
Mostly satisfied	151 (33.9)	35 (30.7)	116 (34.9)
Mixed	69 (15.5)	29 (25.4)	40 (12.0)
Mostly unsatisfied	20 (4.5)	9 (7.9)	11 (3.3)
Unhappy	22 (4.9)	7 (6.1)	15 (4.5)
Terrible	8 (1.8)	3 (2.6)	5 (1.5)

Table 15: ICIQ score at baseline across groups (n=1,656).

ICIQ scores	N (%)		
	Full cohort	BPE (n = 662)	None (n = 1,034)
Slight (1-5)	1,390 (83.9)	489 (78.6)	901 (87.1)
Moderate (6-12)	230 (13.9)	117 (18.8)	113 (10.9)
Severe (13-18)	28 (1.7)	12 (1.9)	16 (1.5)
Very Severe (≥ 19)	8 (0.5)	4 (0.6)	4 (0.4)

Table 16: ICIQ score at F11 across groups (n=446).

ICIQ scores	N (%)		
	Full cohort	BPE (n = 114)	None (n = 332)
Slight (1-5)	316 (70.9)	69 (60.5)	247 (74.4)
Moderate (6-12)	99 (22.2)	32 (28.1)	67 (20.2)
Severe (13-18)	24 (5.4)	10 (8.8)	14 (4.2)
Very severe (19-21)	7 (1.6)	3 (2.6)	4 (1.2)

Chapter 5: Discussion

Introduction

The results in this study showed a clear trend in older community dwelling men that the prevalence of UI increases over time, 14.8% at baseline and increasing to 22.8% at 11 years follow-up. Furthermore, the severity of UI increased over the study period as demonstrated by the rising ICIQ scores and PPD usage. However, when compared to the most similar study in the literature (conducted by Malmsten et al), a significantly lower UI prevalence was seen at both baseline and 11-year follow-up, 4.5% and 10.5% respectively[14]. Reasons for this included baseline population demographic differences. In that cohort, of the men for which data was available to assess UI. 83.9% of men at baseline were aged 70 years or less. This represents a significantly younger population compared to CHAMP, where the median age was 76.9 years at baseline.

Comparison between the CHAMP cohort and the study by Malmsten et al is difficult due to the differences in study design. Malmsten et al collected data on participants based on year of birth with the age cohorts spread by 5-year intervals. Nonetheless, post age-stratification of the baseline cohort, the prevalence of UI was lower than in the CHAMP cohort. With 5.6-7.8% of men aged 70 and 75 reporting UI, compared to 12% of men in the CHAMP cohort in the 70-74 age bracket. Interestingly, at 11 years follow-up participants aged 71 and 76 reported higher rates of UI, 12.4 and 14.9% respectively, which were similar to the UI prevalence rate in the CHAMP cohort in this age bracket. Although not a complete explanation for the discrepancy in UI prevalence within the study by Malmsten et al, the older cohort at baseline was relatively small with only 251 men aged 70 and 116 aged 75. This was in in contrast to the 355 and 322 men, aged 71 and 76 respectively in CHAMP.

In previous cross sectional studies, older patients reported higher rates of UI and this was in keeping with findings of our study, where 12% of men in the 70-74 age bracket reported UI, compared to 26.3% of men in the 85-89 age bracket[4, 6, 14, 24-27]. However, a lower rate of UI prevalence was seen in the >90 age group (16.3%). There are several possible explanations for this, recognising that the sample size in this age bracket was much smaller than other age groups and hence the results may not be representative and generalisable. Another, perhaps more interesting explanation may be the “survivor effect”. This describes an

unexpected phenomenon where an older cohort fares better compared to a younger one when assessing a particular health related outcome, in this case UI. Potentially, the participants that have survived well beyond the mean life expectancy have done so as they are healthier individuals and may demonstrate superior physiology when compared to their younger peers. Although, to substantiate this claim one would have to assess other markers of general health such as frailty and mobility and assess if similar trends exist.

Severity of UI

A strength of this study was that multiple urinary symptoms tools were utilised to assess the severity of UI. The available data from CHAMP regarding the severity of UI allows investigators to more accurately identify the prevalence of clinically significant UI. To illustrate the importance of this data, the UI prevalence of the CHAMP cohort at baseline was 14.8%, however 83.8% of these men reported requiring zero pads, suggesting that the majority of incontinent men had relatively mild UI. Additionally, the pad usage increased over time, which is in keeping with the increasing severity of UI seen in the ICIQ scores.

Despite the very low pad usage amongst incontinent men at baseline, 71.2% of incontinent men reported moderate or worse ICIQ scores. Possible explanations for this discrepancy firstly include that men may feel embarrassed to wear pads, and a proportion suffer with their UI without the appropriate use of incontinence aids such as pads. Secondly, the discrepancy can potentially be explained by particiapnts in the study confusing post micturition dribbling(which is a common complaint) and incontinence.

Impact of BPE/Prostate cancer and Comorbidities on UI

Multivariate analysis using longitudinal logistical regression revealed several risk factors for UI. These included prostate cancer, BPE, medical comorbidities (CVA, Parkinson's disease, dementia and T2DM) and age. This confirms the results in previously published studies that have also found significant correlations between these risk factors and UI [26, 27, 71]. There are cohort studies that have assessed IPSS scores longitudinally and established this tool as a predictor of likelihood to require intervention for BPE[72]. In our study we confirmed the higher rate of UI amongst men with BPE but also the negative

impact of their urinary symptoms and UI on QOL. Both the ICIQ and IPSS QOL scores were worse for men who reported BPE, and this impact persisted over the course of the study period. An important consideration when interpreting the results regarding BPE and its impact, are that the individuals in this group self-reported the diagnosis. However, considering the question participants were asked, "Has a clinician ever told you that you have an enlarged prostate?" One could argue that given the large number of the cohort that the BPE group in our study accurately represents men with BPE. Additionally, the results of the IPSS are significantly higher in the BPE group, confirming the likely presence of BPE. In further studies on this cohort, we plan to assess the impact of BPE treatment on the rates of UI and QOL.

There were too few patients with prostate cancer at subsequent follow-up periods for significant analysis to be conducted (prostate cancer at 8-year follow up, n=56). However, analysis based on the 183 men with prostate cancer identified at baseline showed cancer to be a significant risk factor for UI.

The importance of recognising comorbidities as risk factors is that they can better guide treatment options and UI prevention programs. For example, urge UI secondary to neurological disorders may be amenable to pharmacotherapy such as anticholinergics or mirabegron. Similarly, patients with a history of T2DM (particularly those with poorly controlled disease) and UI may benefit from improved blood glucose level control. Additionally, the treatment of these underlying disease processes can often be optimised with oral agents. These agents are usually inexpensive and in combination with other conservative measures can provide significant relief for patients suffering from UI.

QOL and urinary incontinence

The results from the various QOL tools (IPSS QOL question, ICIQ and SF-12) provide an understanding of the impact of UI on QOL from different perspectives. They all suggest a negative impact of UI on QOL that persists over time. Although the main outcomes of the ICIQ and IPSS questionnaires are to assess urinary symptoms and UI, the SF-12 is a validated tool widely utilised in the assessment of QOL[67, 68]. A negative impact of UI on the SF-12 score was seen across both physical and mental health (PCS and MCS) domains. However, the impact on PCS longitudinally was greater than the impact seen on MCS. To better appreciate the significance of the SF-12 data, Kwong et al

compared the impact of UI on QOL with other health conditions. They found that regarding the PCS, UI had a greater negative impact compared to men reporting musculoskeletal pain and recurrent urinary tract infection. Additionally, the QOL impact from UI on the MCS was greater than chronic obstructive pulmonary disease (COPD), angina and irritable bowel syndrome (IBS).

Despite the worsening severity of incontinence over time, the SF-12 scores remained relatively stable. A possible explanation for this is that patients suffering from ongoing incontinence are likely to require treatment and management over time and conservative treatment strategies such as modifications to toileting routines and appropriate continence appliances can significantly improve QOL. For some patients, a gradual worsening of their incontinence may not require a significant change in their daily routines or management strategies. For example, an individual that usually requires 1 pad/day to manage their incontinence, may not be particularly bothered at the prospects of needing to increase this to 2 pads/day over the course of years compared to an individual who has become newly incontinent and must come to terms with the impact of incontinence on their daily living. Another potential explanation could be that as individuals age, other health issues may be the source of primary concern and the main cause driving negative impacts on QOL.

Need for resource allocation, education and prevention strategies.

The results from this study have demonstrated the impact of UI in community over an extended period and reinforces the need for measures to reduce the burden of UI to both the QOL of older community dwelling men and the cost burden to the community. There is a pressing need to address the common issue of UI, given that the Australian population is ageing[19, 50]. Multiple cost-benefit analyses have previously been conducted both locally and internationally that have demonstrated the cost effectiveness of managing chronic disease in the primary health care, when compared to inpatient hospital treatment[73, 74]. The Australian government has also recognised this and committed to new investments in primary healthcare as outlined by the *Future focused primary health care: Australia's Primary Health Care 10 Year Plan 2022-2032*, submitted by the health minister in March 2022[75].

General practitioners (GPs) that form the backbone of primary healthcare in the Australian context, have previously raised concerns regarding the allocation of funding in primary healthcare. Of 34% of total health expenditure being allocated to primary healthcare, only 4.2-6.8% is allocated to GP services[76]. However, despite the small percentage of funding provided to GPs, patients with UI along with presentations for other chronic conditions often initially present to GPs for treatment and subsequent ongoing management. In this context, it is important that the healthcare system adequately support GPs and other allied health professionals such as community nurses to appropriately manage UI in the community. Aside from ensuring funding is adequately provided, education of primary healthcare providers is vitally important in ensuring proper diagnosis and timely management. In Australia, GPs and community nurses are required to accumulate a minimum amount of Continuing Professional Development Points (CPD) each year to maintain their registration. Given the scope of this study and the complexity associated with UI and the multiple possible aetiologies, it is necessary to ensure the education provided to primary care providers is sufficient to meet the needs of this growing health issue. One of the most notable organisations providing continence specific training and education is the Continence Foundation of Australia (CFA). In addition to providing clinicians with access to training modules specific for their needs, annual conferences and education days are held that further promote the need for education regarding UI and its management[77].

For a significant proportion of older patients with UI, due to the underlying complex aetiology driving their UI, attempts to resolve their continence concerns may not be achievable. For example, a commonly seen patient with UI may present with mild dementia, multiple comorbidities and obesity. In our experience, although the normal investigation and management strategies can be utilised, there may be little improvement in their UI and the focus of care often shifts to assisting the patient/carers with appropriate management strategies. These measures include providing patients and their families with education to manage continence aids and logistical support. Education and ongoing support are largely provided by allied health staff such as continence nurse specialists and community nursing services. Multiple benefits of these services have been identified not only from a cost effectiveness perspective to the overall healthcare budget and to UI sufferers but also to caregivers of individuals with UI. Estimates from a study from the Netherlands assessing the overall cost

savings associated with the introduction of a continence nursing program in general practice are up to 500 million Australian dollars. This demonstrates the important role primary healthcare providers play in managing UI in community dwelling individuals with UI[78].

Strengths/Limitations of the study

This study addresses a gap in knowledge as demonstrated by the lack of longitudinal prospective studies available investigating UI in community dwelling men. The few studies that have assessed UI in men over time conducted surveys of all men rather than those residing in the community and one of them did not assess the impact of UI on QOL[14, 15]. Additionally, the study by Malmsten et al that did assess the impact of UI on QOL, only assessed 4.6% (260 men) of the respondents in clinic at baseline, rather than the whole cohort. The CHAMP study conducted on a large cohort of community dwelling men assessed the entirety of the cohort by questionnaires and in a clinic setting at baseline, 2 and 5 years follow-up.

There were some limitations of our study, and this included the small number of prostate cancer patients over the follow up period. There were 183 patients diagnosed at baseline and prostate cancer was identified as a significant risk factor for UI. However, due to the decreasing number of participants in this subgroup over the study period, meaningful conclusions regarding the longitudinal changes of UI in CHAMP participants with prostate cancer were not possible. A strength of CHAMP is that data collection on the multiple domains included in the study was conducted by investigators in a clinic setting in addition to self-completed questionnaires for all participants. However, in a study of this magnitude it was impractical to repeatedly assess patients individually in a clinic setting and urological function assessments with flow rate and PVR were conducted at baseline, 2 and 5 years follow-up only. The natural history of PVR and urine flow rates were previously published by Noguchi et al[79]. Knowledge of these parameters at the longer follow up waves would complement the findings of this study.

Future directions

Whilst significant research and resources have been allocated to investigating UI in the female population[71, 80], there are far less studies conducted on the impact of UI on older men. Given the current trends in ageing of the Australian population, it is prudent to study the impact of UI in the older male population. Information gained from research into this field, can hopefully inform government bodies and health services in adequately preparing to manage the impact of UI in our community.

The impact of prostate cancer treatment on UI is well described in the literature, particularly post RP and post radiotherapy[39-42, 81, 82] although there is still a paucity of long term data on UI in this group. There is also scant data available on the natural history of urinary function in patients with prostate cancer that are managed with androgen deprivation therapy or with watchful waiting. This data would be of particular interest to urologists, as an important secondary outcome measure for prostate cancer treatment is long term continence post operatively. Investigating this issue further would allow clinicians to counsel patients regarding the impacts of locally advanced prostate cancer and the development of UI.

Data linkage with existing medical records available was not utilised in this study. However, depending on the completeness of readily accessible administrative registries, further important variables potentially associated with UI may be discovered. For example, ethnicity, socioeconomic status and level of education are all data points available from regularly conducted national censuses. Other sources of data that may yield important results include the national bowel cancer registry. There are multiple studies that have demonstrated the impact of bowel cancer treatment on urinary function and the development of UI[83-85].

Chapter 6: Conclusion

The results from the CHAMP study showed that UI is a common condition in our older male Australian population and affected more than 1 in 8 individuals in our cohort of 1705 men. The prevalence and severity of this condition increased over time significantly. Data on UI severity, urinary symptoms and QOL was collected utilising multiple validated questionnaire tools that included the IPSS, ICIQ and SF-12. To our knowledge this study is the largest and most comprehensive investigation into the longitudinal changes in UI in older community dwelling men and its impact on QOL.

Risk factors associated with UI included a history of neurological disorders (dementia, stroke and Parkinson's), T2DM, prostate cancer and BPE. Knowledge of these risk factors are important when considering elements for UI prevention programs and for treatment of patients with known UI. Current guidelines for the treatment of UI generally recommend an initial trial of conservative measures that are centered on lifestyle modifications and physiotherapy. Failing this, pharmaceutical agents can be considered, particularly in the setting of urge UI. Surgical options are less commonly utilised but do offer long term success and high rates of patient satisfaction in appropriate patients.

UI is a debilitating condition and there are significant negative impacts to patients' life. These include the social stigma associated with UI, increased risk of falls, cost burden to patients and healthcare systems and finally reduced QOL. The CHAMP QOL data as assessed by the SF-12, demonstrated a consistent and significant longitudinal negative impact both to the physical and mental components assessed. These results demonstrate the potential benefits that clinicians can provide to patient with effective treatment of UI. Additionally, there is significant improvement that can be achieved in the field of UI prevention. Simple measures that can be undertaken by clinicians are recognising and minimising risk factors. At a government level, health services can increase community awareness of UI in the older male population to reduce the stigma associated and encourage men to present earlier when symptoms are milder and perhaps more amenable to treatment. Appropriate funding to

primary healthcare providers is important to ensure appropriate investigation, diagnosis and management.

Accurate diagnosis of UI subtypes and an understanding of patient and institutional factors is important when counselling patients on the available treatment options and expected clinical course. Early inclusion of allied health services is critical, as theses healthcare providers often provide the necessary ancillary support required by patients. The SF-12 results in CHAMP highlighted that there is a negative mental health impact from UI and members of the allied health team are often the first healthcare providers that patients contact during times of increased stress or when overwhelmed.

In summary UI is a commonly reported issue by community dwelling older men and its prevalence and severity increases with age. There are significant negative impacts to the QOL of individuals with UI and this impact persisted over the study period, which indicates that older men do not become more accepting of their UI over time. Additionally, UI is associated with increased risk of falls which can themselves significantly further impact QOL[12, 48]. Well established risk factors of UI have previously been identified in published studies and the results of this study confirmed their significance[26, 27, 71]. Early identification and treatment of patients with UI and management of risk factors can reduce the severity of symptoms and impact to QOL. Increased awareness of the scale of UI as a healthcare issue is critical in reducing the stigma associated with it and improving the rate of men seeking treatment for this issue. Healthcare systems are also likely to realise significant economic benefits from improvements to primary care prevention programs.

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Conflict of interest- Nil identifiable conflict of interest.

Ethics approval- The CHAMP study was approved by the Concord Hospital Human Research Ethics Committee. All participants gave written informed consent.

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Appendix

International Prostate Symptom Score (I-PSS)

Patient Name: _____ **Date of birth:** _____ **Date completed** _____

In the past month:	Not at All	Less than 1 in 5 Times	Less than Half the Time	About Half the Time	More than Half the Time	Almost Always	Your score
1. Incomplete Emptying How often have you had the sensation of not emptying your bladder?	0	1	2	3	4	5	
2. Frequency How often have you had to urinate less than every two hours?	0	1	2	3	4	5	
3. Intermittency How often have you found you stopped and started again several times when you urinated?	0	1	2	3	4	5	
4. Urgency How often have you found it difficult to postpone urination?	0	1	2	3	4	5	
5. Weak Stream How often have you had a weak urinary stream?	0	1	2	3	4	5	
6. Straining How often have you had to strain to start urination?	0	1	2	3	4	5	
	None	**1 Time**	**2 Times**	**3 Times**	**4 Times**	**5 Times**	
7. Nocturia How many times did you typically get up at night to urinate?	0	1	2	3	4	5	
Total I-PSS Score							

Score: 1-7: *Mild* 8-19: *Moderate* 20-35: *Severe*

Quality of Life Due to Urinary Symptoms	Delighted	Pleased	Mostly Satisfied	Mixed	Mostly Dissatisfied	Unhappy	Terrible
If you were to spend the rest of your life with your urinary condition just the way it is now, how would you feel about that?	**0**	**1**	**2**	**3**	**4**	**5**	**6**

*__IPSS__ form, courtesy of Taneja, Yogesh & Ram, Priyatama et al. (2017). Comparison of Visual Prostate Symptom Score and International Prostate Symptom Score in the evaluation of men with Benign Prostatic Hyperplasia: A prospective study from Indian population. Prostate International. 5. 158-161. 10.1016/j.prnil.2017.04.004.

Scales	Items		Response categories
	No.	Contents (abridged)	
PCS-12	1	General health	Excellent/Very good/Good/Fair/Poor
	2	Moderate activities	Limited a lot/Limited a little/Not limited at all
	3	Climb several flights of stairs	Limited a lot/Limited a little/Not limited at all
	4	Accomplished less (physical)	Yes/No
	5	Limited in kind of work	Yes/No
	8	Pain - interference	Not at all/A little bit/Moderately/Quite a bit/Extremely
MCS-12	6	Accomplished less (emotional)	Yes/No
	7	Did work less careful	Yes/No
	9	Calm and peaceful	All of the time/Most of the time/A good bit of the time/Some of the time/A little of the time/None of the time
	10	Energy	All of the time/Most of the time/A good bit of the time/Some of the time/A little of the time/None of the time
	11	Downhearted and blue	All of the time/Most of the time/A good bit of the time/Some of the time/A little of the time/None of the time
	12	Social limitations - time	All of the time/Most of the time/Some of the time/A little of the time/None of the time

* **SF-12** items, courtesy of Hagell, Peter & Westergren, Albert. (2011). Measurement Properties of the SF-12 Health Survey in Parkinson's Disease. Journal of Parkinson's disease. 1. 185-96. 10.3233/JPD-2011-11026.

1 Please write in your date of birth: ☐☐ ☐☐ ☐☐ DAY MONTH YEAR

2 Are you *(tick one)*: Female ☐ Male ☐

3 How often do you leak urine? *(Tick one box)*

never ☐	0
about once a week or less often ☐	1
two or three times a week ☐	2
about once a day ☐	3
several times a day ☐	4
all the time ☐	5

4 We would like to know how much urine <u>you think</u> leaks.
How much urine do you <u>usually</u> leak (whether you wear protection or not)?
(Tick one box)

none ☐	0
a small amount ☐	2
a moderate amount ☐	4
a large amount ☐	6

5 Overall, how much does leaking urine interfere with your everyday life?
Please ring a number between 0 (not at all) and 10 (a great deal)

0 1 2 3 4 5 6 7 8 9 **10**
not at all a great deal

ICIQ score: sum scores 3+4+5 ☐☐

6 When does urine leak? *(Please tick all that apply to you)*

never – urine does not leak ☐	
leaks before you can get to the toilet ☐	
leaks when you cough or sneeze ☐	
leaks when you are asleep ☐	
leaks when you are physically active/exercising ☐	
leaks when you have finished urinating and are dressed ☐	
leaks for no obvious reason ☐	
leaks all the time ☐	

* **ICIQ**- UI short form, courtesy of Avery K et al. ICIQ: a brief and robust measure for evaluating the symptoms and impact of urinary incontinence. Neurourol.Urodyn. 2004; 23(4) :322-30