General introduction

FUNCTIONAL PELVIC FLOOR DISORDERS

Symptoms related to the dysfunction of the pelvic floor can disrupt dramatically the lives of the men and women who are affected by it. In clinical practice, functional disorders are conditions impairing the normal function and are not primarily due to a mechanical disorder or anatomical abnormality. Symptoms relating to dysfunction of the pelvic floor include involuntary loss of urine, pelvic organ prolapse, inability to control the passage of stool or flatus, and sexual dysfunction.

A few of the most commons symptoms are described:

Urinary incontinence: The loss of bladder control leading to persistent involuntary urine leakage is a symptom caused by underlying physical problems or changes, for instance after treatment of prostate cancer; an obstruction (e.g. enlarged prostate or tumor) hindering the normal flow of urine; aging of the bladder muscle resulting in a decrease of the bladder's capacity to store urine; damage of the supporting pelvic floor muscles (e.g. due to childbirth or surgery); or spinal injury (e.g. spinal cord injury, multiple sclerosis) interfering with nerve signals involved in bladder control. Different types of urinary incontinence can be distinguished, that is: stress urinary incontinence with symptoms of occasionally leaking of urine upon elevated abdominal pressure (for instance during coughing or sneezing); urge urinary incontinence with symptoms of having suddenly a strong urge to urinate leading to involuntarily urine loss; or a variation of both (mixed urinary incontinence).

Pelvic floor disorders: A weakening of the muscles and ligaments supporting women's pelvic organs – including uterus, vagina, bladder, small bowel or rectum – can lead to vaginal bulging due to sliding of these organs (prolapse). Pelvic floor disorders are seen usually years after childbirth, hysterectomy, menopause, or any combination of the above. Conditions associated with pelvic floor disorders include underactive bladder, obstructed urination or urinary incontinence, constipation, obstructed defecation or fecal incontinence, and sensation of prolapse (e.g. feeling of heaviness).

Fecal incontinence: The inability to control bowel movements can cause stool (feces) to leak from the rectum unexpectedly. Fecal incontinence ranges from an occasional leakage of stool while passing gas to a complete loss of bowel control. Common causes include diarrhea, constipation, and muscle or nerve damage of the anal sphincter. The muscle or nerve damage may be associated with aging, vaginal child delivery, pelvic surgery or spinal trauma.

Sexual dysfunction: Problems in any phase of the sexual response cycle, which consists of desire, excitement, sensation of orgasm and satisfaction,[1] can cause sexual dysfunction. In both men and women the origin of sexual dysfunction can be physical

(e.g. erectile dysfunction or ejaculation problems, pelvic floor disorders), psychological (e.g. stress, anxiety, past sexual trauma), or both.

Although above described functional disorders of the pelvic floor are as a rule not life-threatening, they often limit daily activities and may significantly influence physical, psychological, and social well-being of the affected individuals.[2] In the general population - depending on age, etiology, and the definition used - urinary incontinence affects approximately 30% to 60% of women and up to 29% of men[3,4], prolapse approximately 4-15% of women[3], and fecal incontinence up to 15% of both men and women[5]. Based on the considerable prevalence and clinical consequences, functional disorders of the pelvic floor are a serious health problem.

COMPONENTS OF ADEQUATE PATIENT CARE

Outcomes are fundamental measures of success in health care to provide for adequate patient care. When evaluating the efficacy of patient care for those with pelvic floor dysfunction, studies focused on measurable (objective of semi-objective) symptoms are useful to estimate disease burden and the effect of medical interventions. Examples of such *traditional outcome measures* are parameters obtained from urodynamic studies, voiding diaries and ultrasound results. *Patient reported outcome measures* (PROMs) are often standardized, validated questionnaires which are completed by patients to measure their perception of their functional well-being and health status.[6] PROMs represent patient's health-related quality of life (HRQOL), and provide as such another dimension of the efficacy of various treatment modalities than traditional outcome measures. Moreover, PROMs could assist to manage patient expectation and improve patient satisfaction.[7] Consequently, PROMs can be used to support shared decision-making, communication, and appropriate evaluation of individual treatment success. As physicians tend to assess superior valuation to traditional outcome measures - whereas patients tend to evaluate higher importance to the impact of symptoms on quality of life[8] - the use of PROMs has the potential to narrow the gap between the clinician's and patient's view of clinical reality and help tailor treatment plans to meet the patient's personal preferences and needs[9].

Considering that generic HRQOL measures lack sensitivity to the unique aspects of a specific disease[10,11], disease-specific HRQOL measures are regarded to be more applicable in capturing the impact of a particular disease. Suitable disease-specific PROMs have been developed and are currently recommended by the International Continence Society.[12] However, these measure tend to be English, and a measure that is valid and reliable for a particular language and culture may not prove so when used in a different population.[13] The reliability, validity, and responsiveness of a measure for

the population of interest can be assessed by testing its psychometric measurement properties.[14] So far, short, practical, and validated Dutch PROMs evaluating HRQOL of men and women with functional disorders of the pelvic floor are lacking.

Another essential contribution to adequate patient care is *evidence based medicine*. Evidence based medicine is the "conscientious, explicit and judicious use of current best evidence in making decisions about the care of individual patients".[15] To address a specific research or clinical question, systematic reviews collects all evidence according to pre-specified eligibility criteria using systematic methods to minimize bias. By integrating individual clinical expertise with the best available external clinical evidence from systematic research clinical practice guidelines can be developed. To optimize treatment and promote more uniform approaches to specific aspects of patient care, evidence based guidelines are required. An example of such evidence based guidelines is the European Association of Urology (EAU) Guidelines on Neuro-Urology.[16]

AIMS OF THIS THESIS

This thesis focuses on evaluating functional disorders of the urogenital tract in men and women, using traditional outcome measures along with PROMs. In this thesis, we aim to:

1. Evaluate the urodynamic changes in patients treated with Adjustable Continence Therapy for men (ProACT) for post-prostatectomy incontinence and to explore the clinical and urodynamic preimplantation parameters as predictors of clinical outcome.
2. Develop linguistically adapted and psychometrically adequate PROMs for assessing symptom distress and HRQOL of urogenital functional disorders in Dutch.
3. Assess the effectiveness of different surgical therapies for the treatment of functional bladder outlet obstruction in adults with neurogenic bladder dysfunction.
4. Compose Dutch multidisciplinary guidelines consisting of guiding decisions and criteria regarding diagnosis, management, and treatment in patients with neurogenic bladder.

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