The influences of anatomical changes of urethra and urethral sfincter on stress urinary incontinence and erectile dysfunction after a laparoscopic radical prostatectomy with 2D and 3D ultrasound

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To detect the differences in the length of the urethra in healthy volunteers and in men after laparoscopic radical prostatectomy.To detect the degree of erectiel dysfunction before and after laparoscopic radical prostatectomy.To detect the cause of...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Urethral disorders (excl calculi)
Study type	Observational invasive

Summary

ID

NL-OMON39932

Source
ToetsingOnline

Brief title
anatomical changes after a laparoscopic radical prostatectomy

Condition

- Urethral disorders (excl calculi)

Synonym
erectyle dysfunction, stress urinary incontinence

Research involving

Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: anatomy, erectile dysfunction, laparoscopic radical prostatectomy, stress urinary incontinence

Outcome measures

Primary outcome

To detect the cause of stress urinary incontinence and erectyle dysfunction

after laparoscopic radical prostatectomy.

Secondary outcome

NA

Study description

Background summary

Radical prostatectomy (RP) is one of the treatments of organ confined prostate cancer . Stress urinary incontinence (SUI) and Erectyle Dysfunction(ED) could be a consequence of this treatment . SUI is the complaint of involuntary loss of urine on effort or physical exertion (e.g. sporting activities), or on sneezing and coughing . In literature, the incidence of early SUI after a RP varies from 0.8 % - 87 %. This wide range indicates the difficulty involved in the accurate assessment of urinary control after RP. The precise aetiology of post-prostatectomy urinary incontinence (UI) has not been completely understood until now. Dysfunction of the bladder neck as well as intra operative damage of the nerves and sphincter may play a causative role. In this regard, damage of the urethral sphincter can result not only from direct muscle damage but also from damage of the neuronal innervation .
Several predictors of post-prostatectomy UI have been investigated, such as age, prostate volume, disease stage, body weight, co morbidities, history of previous lower urinary tract dysfunctions, surgical techniques and urine loss ratio. Nevertheless, few of these studies reached a high level of evidence.

The incidence of erectile dysfunction after radical prostatectomy varies wide in literature. They range from 11% to over 90% patients with good erectile function postoperative. One meta-analysis shows an overall erectile function rate of 58% after radical prostatectomy, but also states that most data does not meet the strict criteria for reporting erectile dysfunction. The discrepancy in al these results is following Mulhall because of a wide variety in study populations, population demographics, means of data acquisition, variability in questionnaires, temporal considerations, baseline erectile dysfunction status, defining adequate erectile dysfunction and the concepts of quality and consistency of erections used in literature.This makes it difficult for urologists to counsel patients correctly about their postoperative sexual functioning and could cause false expectations.

Study objective

To detect the differences in the length of the urethra in healthy volunteers and in men after laparoscopic radical prostatectomy.
To detect the degree of erectiel dysfunction before and after laparoscopic radical prostatectomy.
To detect the cause of stressincontinence and erectyle dysfunction after laparoscopic radical prostatectomy.

Study design

This study concerns a longitudinal study in which patientes diagnosed with local prostate cancer and who will have a laparoscopic radical prostatectomy will be followed before and 2 years after the laparoscopic radical prostatectomy.

This study will consist of 3 parts.

1) 3D Ultra sound. Before surgery patients will have once a 3D ultrasound examination of the anal canal. In this manner the thickness of the musculus levator ani and the diafragm urogenitalis can be detected just like the functionig of the urethral sfincter complex. Postoperative: This examination will be repaeted at 6 months, 1 year and 2 years postoperativeliy to observe the anatomical changes.
2) Questionairres with the use of validated questionairres: the KIngs Health Questionairre, the International Index of Erectile dysfunction, the Pelvic Floor Inventories Leiden (PeLFis), in order to map the sfincter function en erectyle function
3) In the dissecting room 3 laparoscopic radical prostatectomies will be performed, in order to study the anatomical changes thouroughly.

Of great importance is the analyzing of the relationship resection margin in relation to the nervus levator ani and the autonom nervus system.

Also the anatomical changes after a laparoscopic radical prostatectomy will be studied

We hypothesized that there will be a relationship between the length of the urethra preoperative and postoperative after a LARP. an earlier study showed that the incidence of SUI is 42% after a LARP with a follow up of one year Logistic regression analysis showed that 78 patients are needed to reach a power of 80 % with p of < 0.05 to detect a difference in having incontinence between 42% for the mean length of the urethral sphincter and 57.9% if the length of the urethral sphincter is a standard deviation lower. this difference will be a ODDs ratio of 1.90 per SD Dit verschil komt overeen met een odds ratio van 1.90 per SD decrease of the length of the urethral sfincter.

Study burden and risks

NA

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Patients before and after laparoscopic radical prostatectomy

Exclusion criteria

neurological diseases, radiotherapy

Study design

Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	02-09-2013
Enrollment:	80
Type:	Actual

Medical products/devices used

Generic name:	Ultra sound
Registration:	Yes - CE outside intended use

Ethics review

Approved WMO Date:	27-03-2013
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
	metc-ldd@lumc.nl

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL41702.058.12