Prospective Registry for Patients Undergoing Surgery for Male Stress Urinary Incontinence in Multiple European Centres ("SATURN")

An initial report of the registry

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Section for Reconstructive Urology and Neuourology. Oslo University Hospital, Norway
Surgical treatment of male stress urinary incontinence in Oslo
Number of procedures in Oslo

Antall operert for PPI pr. år

AMS 800 AdVance

KDK 10

KDG70
Why a registry?

• Monitor results and quality of treatment
• Compare with international results
• Patient information
• Research

• Good quality data, prospectively collected, written consent
Why not make our own registry?
Study Protocol

Prospective Registry for Patients Undergoing Surgery for Male Stress Urinary Incontinence in Multiple European Centres

EAU-RF 2016-01

Study team

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Joni Kats, Clinical Project and Data Manager
Christien Caris, Clinical Project Manager
Joke van Egmond, Clinical Data Manager
Study Protocol

OBJECTIVES
Prospective pre-defined dataset male patients undergoing surgical treatment with medical devices (e.g., AUS, male slings) for stress urinary incontinence from multiple centres in Europe: evaluation short and long term efficacy, complications procedures, impact on Quality of Life.

Primary Objective and endpoint
Primary objective: is to evaluate cure rate of procedures at 5 years of study follow up.

Cure rate will be the main endpoint of the study, and is defined as urinary continence with no need for use of pads or the use of 1 light security pad.
Study Protocol

STUDY DESIGN

• Study participants
  - Planned number of participants: 1000
  - Follow-up duration: 10 years
  - Planned study period: 10 years

• Patient Inclusion Criteria
  - Male patients undergoing surgery for treatment of stress urinary incontinence with medical devices such as AUS or sling in a given centre.
  - Participant is willing and able to give informed consent for participation in the study and is able to complete the questionnaires.

• Centre Specific Inclusion Criteria
  - The centre is able to contribute consecutive patients.
STUDY DESIGN

• Study Assessments

• Pre-operative data (e.g., patient characteristics, Charlson co-morbidity index, 24 h pad test, urodynamic results)

• Per-operative data (e.g., details on surgery type of prosthesis, cuff size and location, pressure of regulating balloon, presence of double cuff, type of per-operative antibiotics, type of associated procedures (e.g. penile prosthesis), use of suprapubic or transurethral catheter or drain)

• Post-operative data (e.g., time of presence of suprapubic or transurethral catheter, presence of postoperative retention, scrotal hematoma, perineal or groin pain, hematuria, swelling or other problems)

• ICIQ UI Questionnaire SF and EQ-5D-5L questionnaires: 12 wks after surgery, year 1, yearly until tenth year
### Study Protocol

#### TIMELINES OF PATIENT CONTACT

<table>
<thead>
<tr>
<th>Activity</th>
<th>Baseline</th>
<th>Surgery</th>
<th>Week 6*</th>
<th>Week 12</th>
<th>Yearly**</th>
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<tbody>
<tr>
<td>Informed Consent</td>
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<td>Weight and length</td>
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<td>Medical history, Charlson Cormorbidity Index (CCI)</td>
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<tr>
<td>Medication use (anticoagulation, antibiotics) and use of antiseptic washings</td>
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<td>24 hours pad test (not compulsory)</td>
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<tr>
<td>Urodynamic investigation (if applicable)</td>
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<td>Cystoscopy</td>
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<tr>
<td>Surgery by AUS or male sling as per local practice</td>
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<tr>
<td>Activation of AUS (in case of AUS surgery)</td>
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<td>Questionnaires (ICIQ UI SF + EQ-5D-5L)</td>
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<td>Complications</td>
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How are we doing?

• 28 European centers participating
• Recruitment completed
• Included more than 1000 patients

• No data published yet
## Inclusion - Oslo

### Patient Inclusion per month

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<th>Jan</th>
<th>Feb</th>
<th>Mar</th>
<th>Apr</th>
<th>May</th>
<th>Jun</th>
<th>Jul</th>
<th>Aug</th>
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<td>4</td>
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<td>9</td>
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Lessons learned

• With lack of own registries, this is an option

• Inclusion is time consuming
• Involves several professions
• Make detailed routines
• Take time to educate study personell and clinicians
• Study nurse