

**Research Project RP09-03**

# Retropubic radical prostatectomy versus robot-assisted laparoscopic radical prostatectomy: a cost-effectiveness analysis

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## **Introduction**

The author is studying at the Department of Public Health, Aarhus University, Denmark. This research plan is the thesis at the education of Health Science in association with the Department of Urology at Aarhus University Hospital Skejby. The fundamental basis of the study is the introduction of new medical technology within urology. The study consists of two items: a health economic and individual epidemiological part where last-mentioned is to be considered as a sub-study to clarify the effect of data in the health economic analysis.

Prostate cancer is the second most frequent cancer among men in Denmark with 3000 new cases per year (1). Patients with localized prostate cancer are offered curative treatment with radical prostatectomy (2). At Aarhus University Hospital Skejby this procedure is performed as retropubic radikal prostatectomy (RRP) and robot-assisted laparoscopic radical prostatectomy (RALP). In 2004 RALP was introduced as a new medical technology at the Department of Urology in Aarhus.

A radical prostatectomy should ideally combine a safe radical tumour extirpation with preserved urinary continence and erectile function (3). The question whether the robot-assisted laparoscopic technique improves the chances of reaching these goals is under debate (4-7). Meanwhile, the cost-effectiveness of the new technique remains an issue (8).

The robot-assisted laparoscopic radical prostatectomy (RALP) is associated with high peroperative costs (9-11). The equipment is expensive and the operating time is, at least during the learning period, longer than in radical retropubic prostatectomy (RRP). It is a hope that these costs will be outweighed by savings due to shorter postoperative hospital care, reduced number of blood transfusions, less need for postoperative analgesics, shorter sick leave, and less risk of recurrence (9;10;12-14).

The total costs for radical prostatectomy is not estimated for a societal viewpoint. The economic studies comparing costs between RRP and RALP are estimated hospital costs only. The studies are cohort studies based on non-homogeneous groups of patients (9-11). The differences in clinical, functional, and oncology outcome may be explained by the study design and the shorter time of follow-up on long-term effects for RALP. [referencer mangler] In prioritising the resources in the healthcare system a cost-effectiveness analyses based on homogeneous groups of patients is desirable.

## **The purpose and hypotheses**

### ***Health economic part***

*The purpose:* To make a cost-effectiveness analysis and a cost-utility analysis of RRP versus RALP

### ***Individual epidemiological part***

*The purpose:* To examine whether there is a difference in chance of reaching a successful operation after RRP and RALP.

A successful operation is defined as attaining a radical operation (postoperative PSA <) with following urinary continence and erectile function.

*Hypothesis I:* The chance of attaining postoperative PSA < 0.2 ng/ml is expected to be 7% higher for RALP compared to RRP (14).

*Hypotese II:* The chance of attaining urinary continence is expected to be 8% higher for RALP compared to RRP (3).

*Hypotese III:* The chance of attaining erectile function is expected to be 10% higher for RALP compared to RRP (3).

## **Material and method**

*Design:* Historical cohort study

*Ethical committee:* The study is approved by the local ethical committee (j.nr: 20000299) and registered at Danish Data Protection Agency (j.nr: 2002-41-2640). The study belongs under Prostata Cancer-projektet (PC-database) at the Department of Urology, Aarhus University Hospital Skejby.

*Study population:* 228 men operated radical prostatectomy at the Department of Urology, Aarhus University Skejby during January 1st 2004 until December 31st 2007. A number of 152 patients are operated RRP (RRP group) and 76 patients are operated RALP (RALP group).

*Follow-up:* Each patient is observed from day of operation until one year postoperative. Concerning sick leave, all the patients are followed 1½ year postoperative.

Economic data of resources is to the extent possible based on year 2007.

*Criteria of inclusion:* Patients between the age of 50-69 years with clinical T-stage T1-T2, and operated RRP and RALP at the Department of Urology at Aarhus University Skejby during January 1st 2004 and December 31st 2007.

*Criteria of exclusion:* Patients with T stage T3 are excluded because these patients are in greater risk of postoperative urinary incontinence and recurrence. There is also a tendency toward selection to RRP among patients with T3. Patients operated between July 1st and December 31st 2007 and a consecutive sick leave of > 365 days is excluded because of follow-up < 1½ year.

*Selection of homogeneous groups of patients:* For every two patients operated RRP one patient operated RALP is selected. The groups of patients are chosen as the best match between age and The D'Amico Risk Classification of Prostate Cancer (riskdAmico):

riskdAmico	PSA (ng/ml)		T stage		Gleason score
low	< 10	and	≤ cT2	and	≤ 6
medium	10-20	or	cT2b	or	7
high	> 20	or	cT2c bilat	or	> 7

The difference in age is maximum 5 years. The patients are divided into groups of age: 50-54, 55-59, 60-64, and 65-69 years. For every patient operated RALP two patients operated RRP with same classification of riskdAmico and group of age is selected.

*Power (individual epidemiological part):* The power is estimated from the minimal relevant difference (MIREDIF) between the groups of patients attained a radical operation (postoperative PSA < 0.2 ng/ml). If the power is 80% (1-β), MIREDIF 7% and level of significant 5% it is necessary to test a total of 706 patients - 353 patients in each group. The power is estimated to 23% if based on available material for PC-project (76 RALP and 152 PPR).

*Data collection, health economic part:*

- Inpatient and outpatient costs (The Danish Casemix system, The National Board of Health)
- Stay at hospital and readmission (The Danish National Patient Registry)
- Gross pay per day to estimate costs at sick leave (Statistics Denmark)
- Licence if still using > 2 pads per day at 1½ month postoperative (data is to be collected in the medical record)
- One-off licence to medical support of erectile dysfunction (data is to be collected in the medical record)
- Weeks of sick pay postoperative (DREAM-register)
- The questionnaire SF-36 at baseline and 12 month postoperative to estimate QALY (questionnaires are to be entered in EpiData).
- Aarhus University Hospital Skejby:
  - salary, overhead, “hotel”-costs (Department of Economy)
  - use of utility at operation (a central department at the hospital)
  - resources of staff during operation and recovery room (Department of Anaesthesia)
  - costs of operation and resources of staff during operation (Department of Urology)
  - purchase costs, depreciation, operating costs, and maintenance of the robot (Department of Urology)
  - accounting reports (Department of Economy, Department of Urology)

*Data collection, individual epidemiological part:*

- Medical record: age (years), pre- and postoperative T stage (T1-T3), pre- and postoperative Gleason score (1-10), PSA (ng/ml), stay at hospital (days), postoperative complications (%), positive margin (%). Information available in the PC-database.
- Questionnaire at baseline-3-6-12-month postoperative: Lower Urinary Tract Symptoms (yes/no), erectile dysfunction (nothing, little, a lot). Information available in the PC-database.
- Operation time (min) (data is to be collected in the medical record)

Data in PC-database is dichotomised:

- Urinary incontinence is redefined to urinary continence and classified yes/no:
  - yes = no use of absorbent pad (or one security pad) per day, and no = use of more than one pad per day
- Erectile dysfunction is redefined to potency and classified yes/no:
  - yes = potency with or without medical support, and no = erectile dysfunction
- Information on attained radical operation is defined at PSA and classified yes/no:
  - yes =  $PSA \leq 0,2$  ng/ml, and no =  $PSA > 0,2$  ng/ml

*Exposure:* RALP and RRP (dichotomy variable)

*Effects (health economical part):* 1) per expected successful operation and 2) per quality adjusted life-years (QALY).

*Outcome (individual epidemiological part):* successful operation yes/no (dichotomy variable).

*Potential confounders (individual epidemiological part):* positive margin, postoperative complications, experience of the surgery.

*Central selected parameters to sensitivity analysis (health economic part):* costs of operation, length of hospital stay.

*Decision tree (health economical part):*

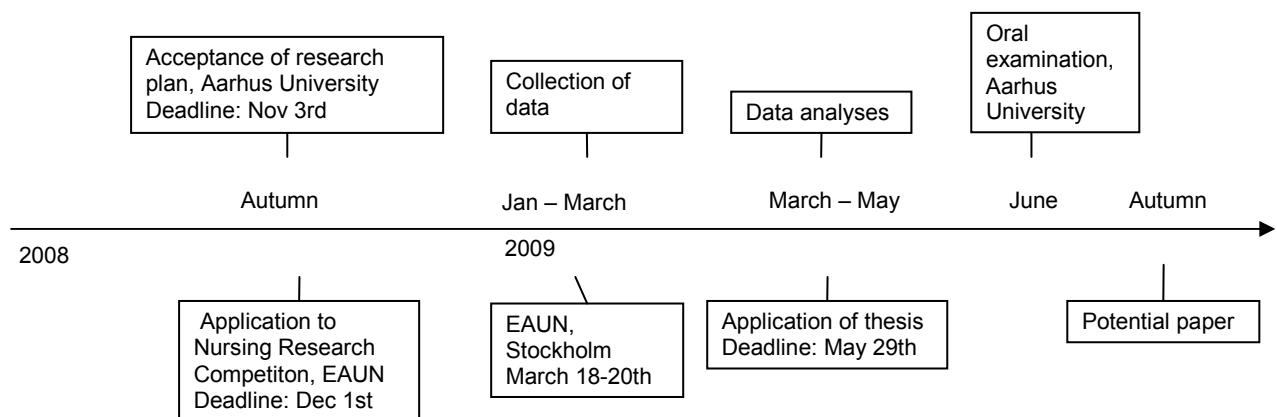
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*Statistic analysis:*

In the health economic part two cost-effectiveness analyses will be done to estimate incremental cost-effectiveness ratio (ICER) per successful operation; one base case-model during stay at hospital and another model of analysis including indirect costs (sick leave). A cost-utility analysis is made to estimate costs per QALY. A one-way and multiway sensitivity analysis is undertaken in order to investigate the impact on study results. The Human Capital method will be used for indirect costs (15). All the costs are based on patient level data.

Logistic regression is used in the individual epidemiological part to estimate the odds ratio of attained successful operation, adjusted for potential confounders. McNemar's test is made to test whether there is the same share of patients attaining PSA < 0,2 ng/ml, urinary continence and potency between the groups of patients at 3-6-12 month postoperative. Statistic analyses are performed in software program Stata® release 10 and EpiBasic (16). A p-value of < 0.05 is considered as statistically significant.

## Timetable



## Participants in the project

Lena Hohwü, stud.scient.san, RN (primary responsibility)\*

Lars Ehlers cand.eocon, ph.d, associated professor (thesis supervisor)\*

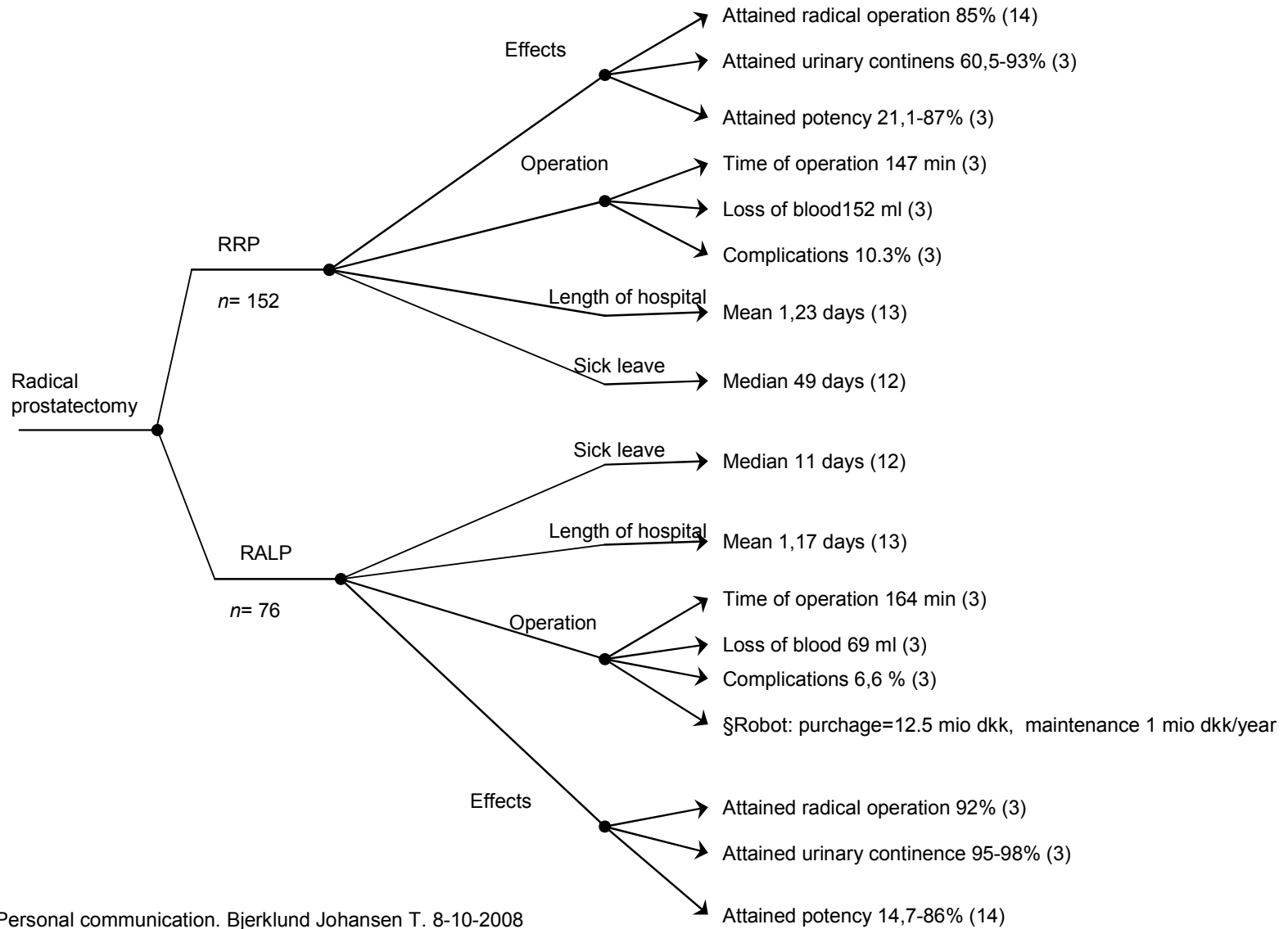
Knud Venborg Pedersen, chief surgeon, med.dr (clinical supervisor)\*

Michael Borre, chief surgeon, ph.d, dr.med (PC-database)\*

Jakob Hjort, Datamanagement, Central region of Denmark (DREAM-register)

\* Authors to a potential paper with Lena Hohwü as main author.

## Attachment. Health economic model



§RefType: Personal communication. Bjerklund Johansen T. 8-10-2008

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Ref Type: Unpublished Work



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