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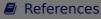
A short-term cost-effectiveness study comparing robot-assisted laparoscopic and open retropubic radical prostatectomy

Lena Hohwü, Michael Borre, Lars Ehlers & Knud Venborg Pedersen

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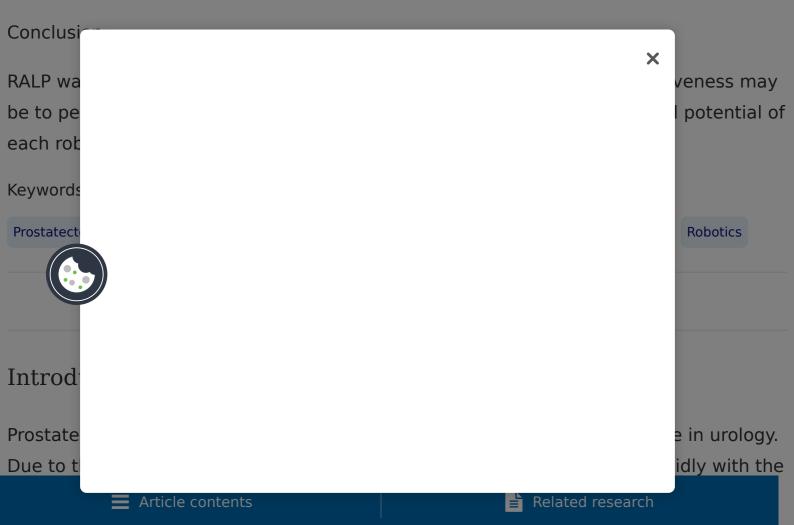
An economic evaluation was made to estimate direct costs of the first postoperative year and an incremental cost-effectiveness ratio (ICER) per successful surgical treatment and per quality-adjusted life-year (QALY). A successful RP was defined as: no residual cancer (PSA <0.2 ng/ml, preserved urinary continence and erectile function. A one-way sensitivity analysis was made to investigate the impact of changing one variable at a time.

Results:

The ICER per extra successful treatment was €64,343 using RALP. For indirect costs, the ICER per extra successful treatment was €13,514 using RALP. The difference in effectiveness between RALP and RRP procedures was 7% in favour of RALP. In the present study no QALY was gained 1 year after RALP, however this result is uncertain due to a high degree of missing data. The sensitivity analysis did not change the results noticeably.

Limitations:

The study was limited by the design resulting in a low percentage of information on the effect of medication for erectile dysfunction and only short-term quality of life was measured at 1 year postoperatively.



cases are feasible for curative treatment such as surgery or radiotherapy. The traditional surgical method, retropubic radical prostatectomy (RRP) has been replaced in the last decade by a computer-assisted methodology – robot-assisted laparoscopic prostatectomy (RALP) – because of its expected better outcome. The cost of RALP is more than twice the cost of RRP. It therefore is relevant and urgent to compare the two methodologies from a cost-effectiveness perspective.

The increased use of RALP from 1% in 2001 to 40% in 2006 has opened up a debate concerning prioritisation of the economic resources between RALP and RRP which is related to the purchase and maintenance of the operative equipment for RALP1–3. As in other countries, the use of RALP in Denmark has expanded rapidly. The incidence of prostate cancer was 136 per 100,000 men and the disease specific mortality 19.5 per 100,000 patients in Denmark in 20084,5. At Aarhus University Hospital, Skejby, RRP has been performed as a standard procedure since 1997 and is still a common methodology; RALP was introduced in 2005 using the da Vinci system.

RALP is normally considered as a more costly 2, 3, 6, 7 and marginally more effective procedure compared to RRP1, 8, 9 although no randomised controlled trial has ever been carried out to compare the efficacy, safety and costs of the two alternative surgical procedures. A study by Schroeck et al. found that patients who underwent RALP were three to four times more likely to be regretful and dissatisfied compared to patients

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A health economic evaluation was performed alongside a retrospective cohort-control study of prostate cancer patients treated with radical prostatectomy and followed 1 year postoperatively. The incremental cost-effectiveness ratio (ICER), i.e. the extra costs of RALP compared to RRP divided by the extra gained patient outcome from RALP compared to RRP, was calculated according to international guidelines on health economic evaluation 11. The ICER was calculated from a societal perspective, i.e. all costs were included. All prices were quoted in euros, 2008 prices, and exclusive of value added tax (VAT).

Two outcome measures were used: (1) a successful surgical treatment and (2) quality-adjusted life-years (QALY). Successful radical prostatectomy was defined as no residual cancer (prostate-specific antigen (PSA) <0.2 ng/ml), urinary continence and erectile function with or without medical treatment. To estimate QALY within the first postoperative year, the SF-36 score was translated to SF-6D using Brazier's algorithm12. The patients were asked to fill out a SF-36 questionnaire at baseline and 1 year postoperatively. SF-36 is a generic, but not a preference-based instrument and, thus, needs to be 'translated' into utility-weights to be used to calculate gained QALYs. The difference in the derived utility-weight between baseline and 1 year constitutes the gained QALYs for each group.

A cost-effectiveness analysis was made to estimate ICER per successful operation with and with thod11. A X cost-util ined in a The effe one-way t. Clinica The s ate cancer sity Hospital, stage Skejby f The RAL ear groups clusion of 77 and the RPs, consecu ALP). respecti

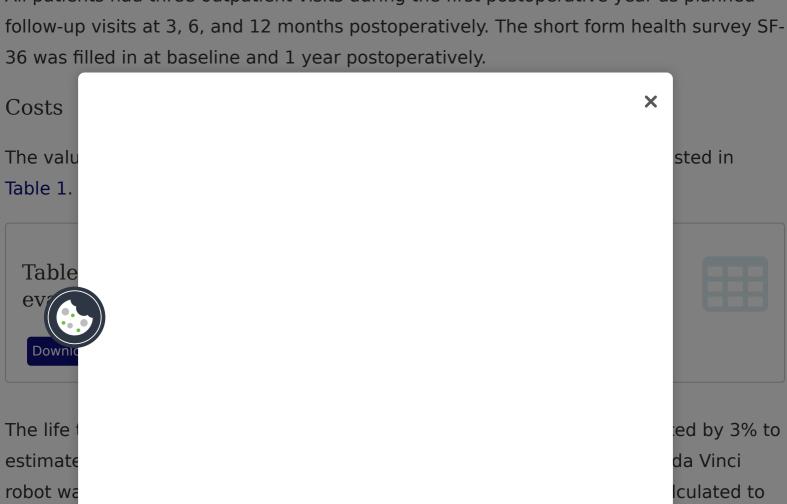
incontinence and recurrence postoperatively and were mainly assigned to the open procedure.

The power was calculated to be 23% based on the study population of 231 men and the minimum relevant difference for a successful surgical treatment of 7% between the two groups of patients.

All patients were followed prospectively according to department procedures for the Prostate Cancer project. Each patient was observed from day of surgery to 1 year postoperatively where differences in side-effects were assumed to be steady state. Long-term follow-up of the oncological outcome was desirable but was outside the scope of this study.

The in-hospital data were collected from the medical journals. Data on general practitioner consultations, acute hospital admissions were collected from the Danish National Registry of Patients at the Danish National Board of Health and from the Health Service Registry, Central Denmark Region. Data on absence from work was taken from The Sickness Absence Registry at the Ministry of Employment.

All patients had three outpatient visits during the first postoperative year as planned 36 was filled in at baseline and 1 year postoperatively.



be €380,135 using the standard annualisation method 11. Maintenance costs were estimated to be €120,100 per year25.

It was assumed that 70 RALP procedures were performed annually based on the level of activity in 2008 at our department. The costs for da Vinci were distributed between a total of 110 robot-assisted procedures yearly (70 RALP plus 40 different procedures performed with the same equipment).

The cost of managing side-effects during the first postoperative year by consultations in hospital and primary care as well as the cost of urinary pads and medical drugs were all included in the total cost calculations for both RALP and RRP.

The use of staff resources (nurses and supporting personnel) was estimated by interview. Data concerning sick leave after RP was observed for 1½ years based on previous experiences26.

The study was approved by the local ethical committee and the Danish Data Protection agency was informed.

Statistics

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The two groups of patients were compared using descriptive statistics, tested with ttest, χ^2 -test or the non-parametric Wilcoxon rank-sum (Mann-Whitney) test as appropri

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Table 2. Effects used in the economic evaluation based on matched* groups of patients and estimated at 1 year postoperatively.



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No QALY was gained for RALP patients 1 year postoperatively (Table 2). The majority of RRP patients filled in the SF-36 both at baseline and at 12 months postoperatively compared to RALP, 74.7% versus 33.8%, respectively (Table 2).

The mean costs per patient and the estimated ICER are presented in Table 3. The mean costs per RALP procedure were twice the costs of RRP 1 year postoperatively.

Concerning the mean indirect costs per patient, there was no statistically significance between the two groups of patients (Table 3).

Table 3. Mean costs, effects, and incremental cost-effectiveness ratio per successful operation 1 year postoperatively. The parameters are calculated as direct costs and indirect costs (direct costs including absences from work), respectively.



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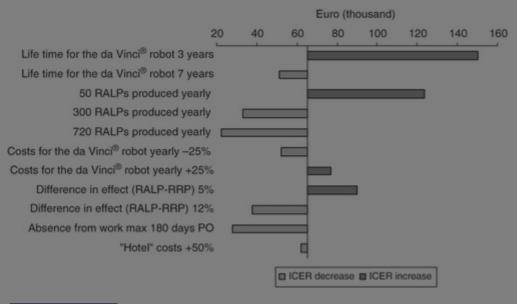
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radical prostatectomy. The ICER was estimated assuming 70 RALP were performed annually with the costs for the da Vinci distributed between 110 robot-assisted procedures yearly and a life time for the da Vinci robot of 5 years. A successful treatment was defined as no residual cancer (prostate-specific antigen <0.2 ng/ml), preserved urinary continence and erectile function 1 year postoperatively. RALP robot-assisted laparoscopic radical prostatectomy; RRP, retropubic radical prostatectomy; PSA prostate-specific antigen; PO, postoperatively; ICER, incremental cost-effectiveness ratio.



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comparing RALP and RRP procedures have estimated costs from a broad societal perspective with a similar high level of precision in costing. The results of previous economic studies are opaque because they are based on different cost models as well as non-clarified methods 2, 3, 6, 7. Minutely, the present study followed the internationally recommended methods for economic evaluation 11.

The study estimated incremental effectiveness and costs comparing RALP and RRP procedures. Estimating the success of the treatments we wanted an outcome measure that made a difference and included the potential benefits for RALP stated by the manufacture of the robotic system27. It is documented that there are no significant differences in continence, erectile function and biochemical progression-free survival between RALP and RRP1,8,9. Therefore, we consider the chosen outcome measure "successful treatment" useful in the discussion of priority of the economic resources between RALP and RRP procedures. The retrospective study design resulted in a low percentage of information on the effect of medication for erectile dysfunction at 1 year postoperatively. A greater share of RALP patients had used prescriptions for medicine for erectile dysfunction compared to RRP patients indicating that more RALP patients might have an erectile function than estimated in our study. Furthermore, two thirds of the RALP patients underwent nerve-sparing surgery compared to half of the patients operated RRP.

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in RRP patients indicating a higher risk at final pathology for patients undergoing RRP and that patients with lower tumour stage were predominantly selected to RALP. Secondly, QALY indicates a side-effect, and quality of life might be more crucial to patients operated by RALP compared with a quicker recovery of continence and erectile function. A randomised controlled trial with long-term follow-up of effectiveness and quality of life between RALP and RRP is therefore warranted along with standardised reporting of outcomes 28. At least better data on quality of life after RALP and RRP should be obtained.

We calculated the ICER per successful treatment with and without indirect costs. It is uncertain whether the decision makers find it relevant to include indirect costs. Furthermore, estimating absence from work is methodologically uncertain.

Only one of the previous cost studies had made a sensitivity analysis showing that the

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Conclu

It is uncertain whether the RALP procedure is cost effective. The incremental costs per extra successful procedure were €64,343. A long-term follow-up of the outcome measures and sick leave may intensify the assessment of the cost effectiveness between the two alternatives.

Transparency

Declaration of funding

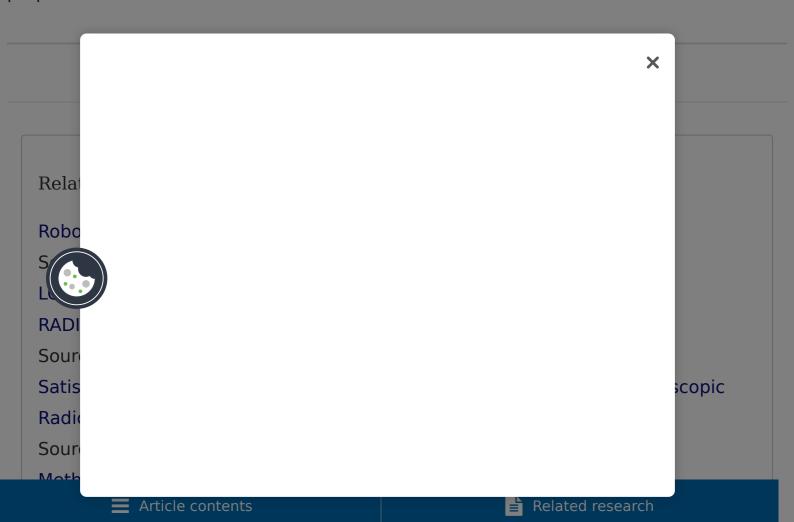
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Declaration of financial/other relationships

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