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

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Abstract

Objective

To evaluate

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Methods

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Show Purpose

the Department of Urology, Aarhus University Hospital, Skejby from 1 January 2004 to 31 December 2007, were included.

The RALP and RRP patients were matched 1:2 on the basis of age and the D'Amico Risk Classification of Prostate Cancer; 77 RALP and 154 RRP.

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 effect of measure

Conclusion

RALP wa be to each ro



Keywords

Robotics

retropubic

Prostate cancer is in the western world the most frequent malignant disease in urology. Due to the introduction of new diagnostic tools, the incidence increases rapidly with the consequence of heavy stress on the economical burden in public healthcare. Most new 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 2008^{4,5}. 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 RRP^{1,8,9} although no randomised controlled trial has ever been

carried out comparing RALP and RRP. The aim of this study was to compare the surgical procedure of RALP and RRP. Three hundred and thirty patients were randomised to higher or lower cost of RALP. The expected outcome was that the economic burden of RALP would be lower than RRP. The results of the study are available in the full text. RRP is more expensive than RALP. This study compares RALP and RRP.



Economic evaluation

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 evaluation¹¹. 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 performed alongside a retrospective cohort-control study and with the aim of comparing the incremental cost-utility ratio (ICUR) of RALP compared to RRP. The effectiveness of RALP compared to RRP was determined in a one-way sensitivity analysis. The results of the sensitivity analysis are presented in Table 1.

Clinical outcome

The study included 100 prostate cancer patients who were treated at the University Hospital, Skejby from 2005 to 2010. The patients were divided into two groups: RALP (n=50) and RRP (n=50). The RALP group consisted of 27 patients who were included in the conclusion of 77 RALPs.



Patients with stage cT3 disease were excluded because of the higher risk of urinary 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 follow-up visits at 3, 6, and 12 months postoperatively. The short form health survey SF-36 was f

Costs

The value of the study was estimated in

Table 1.



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The life expectancy of patients with prostate cancer is estimated to be 12.5 years, which is reduced by 3% to 12.1 years in patients with prostate cancer treated with the da Vinci

be €380,135 using the standard annualisation method¹¹. 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

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

Result

There were 100 patients in the RALP group and 100 patients in the RRP group who were to be treated with RP. The mean age was 62.2 years (range 45–80 years) and the mean preoperative T2 signal intensity was 93.5% (range 78–100%). The mean PS was 2.0 (range 1–3).

The outcome was compared between the two groups. The difference in favour of RALP was significant (p = 0.02). The percentage of patients who were able to walk without crutches was 7% in the RALP group and 20% in the RRP group. The percentage of patients who were able to function without medication was 20% in the RALP group and 10% in the RRP group.



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 statistical 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.

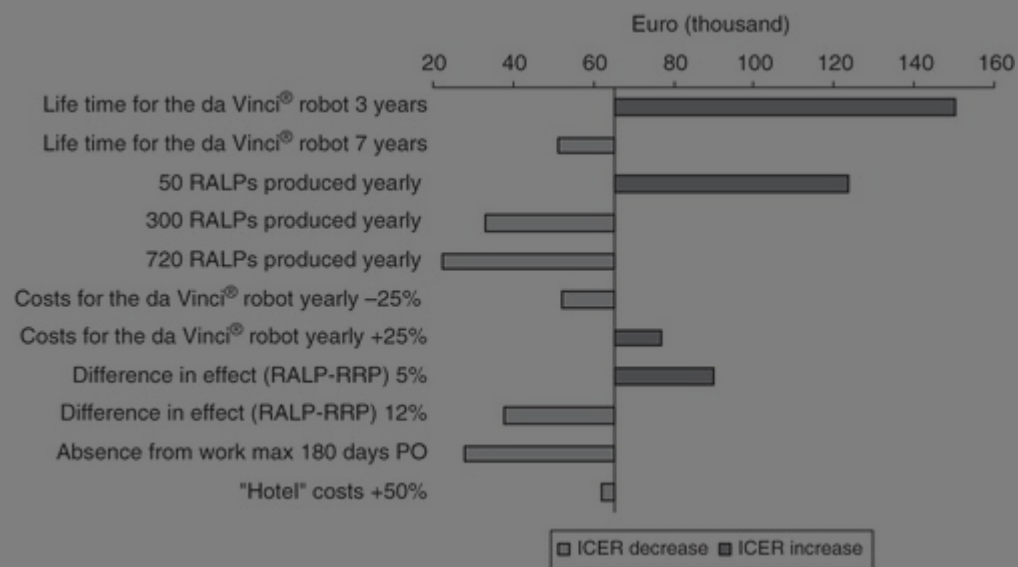


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radical prostatectomy. The ICER was estimated assuming 70 RALP were performed annually with the costs for the da Vinci distributed between 110 robot-assisted procedures yearly and a life time for the da Vinci robot of 5 years. A successful treatment 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 evaluation¹¹.

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 RRP^{1,8,9}. 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 outcomes²⁸. 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.

Two previous cost studies included the fixed costs for da Vinci basing the calculations on 300 RALP procedures yearly and a lifetime for the da Vinci robot of 7 years^{3,7}. Additionally, the annual purchase and the maintenance costs for the da Vinci robot in the two studies were estimated to be lower; €807,800 and €72,629, respectively^{3,7}. In our study the purchase was estimated to €1.4 million while the maintenance was €120,100 per year. Consequently, the costs for RALP are higher in our study.

Only one of the previous cost studies had made a sensitivity analysis showing that the costs for RALP are volume dependent where an increased volume of RALP demonstrates a lower cost per procedure. Our sensitivity analysis shows that the costs for RALP increase with the number of procedures performed. This is due to the fact that the da Vinci robot is a fixed cost and the number of procedures performed is limited. The effectiveness of RALP compared to RRP. Furthermore, the maintenance costs for the da Vinci robot may be higher in our study due to the fact that the da Vinci robot is used for all capacity of the da Vinci robot. The effectiveness of RALP compared to RRP may be higher in our study due to the fact that the da Vinci robot is used for all capacity of the da Vinci robot. The effectiveness of RALP compared to RRP may be higher in our study due to the fact that the da Vinci robot is used for all capacity of the da Vinci robot.



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

No declaration of funding is to be declared.

Declaration of financial/other relationships

No financial or other financial relationship is to be declared.

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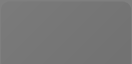
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