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Original article

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

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evaluation – Prostatic neoplasm – Retropubic –
RoboticsAccepted: 5 May 2011; published online: 23 May 2011
Citation: J Med Econ 2011; 14:403–09**Abstract****Objective:**

To evaluate cost effectiveness and cost utility comparing robot-assisted laparoscopic prostatectomy (RALP) versus retropubic radical prostatectomy (RRP).

Methods:

In a retrospective cohort study a total of 231 men between the age of 50 and 69 years and with clinically localised prostate cancer underwent radical prostatectomy (RP) at 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 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.

Conclusion:

RALP was more effective and more costly. A way to improve the cost effectiveness may be to perform RALP at fewer high volume urology centres and utilise the full potential of each robot.

Introduction

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 RALP^{1–3}. 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 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 undergoing RRP. According to Schroeck *et al.* this result could be attributed to higher expectations of RALP¹⁰. It is important for decision-makers to be informed about the economic consequences and effects of introducing a new medical technology such as RALP. This information is limited and is often supplied by the manufacturer. To our knowledge, no economic evaluation of radical prostatectomy comparing RALP and RRP is available. Unfortunately, it is therefore not yet clarified which alternative of RALP and RRP is most cost effective.

This study aimed at evaluating short-term cost effectiveness and cost utility comparing RALP and RRP, respectively in a group of matched patients.

Methods

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 made to estimate ICER per successful operation with and without indirect costs (absence from work) using the human capital method¹¹. A cost-utility analysis was made to estimate ICER per QALY.

The effects of changes in selected costs and clinical parameters were examined in a one-way sensitivity analysis and independently illustrated in a Tornado chart.

Clinical study

The study cohort consisted of 231 men between 50 and 69 years with prostate cancer stages cT1–T2 undergoing RP at the Department of Urology, Aarhus University Hospital, Skejby from 1 January 2004 to 31 December 2007.

The RALP and RRP patients were matched 1:2 on the basis of age within 5-year groups and the D'Amico Risk Classification of Prostate Cancer¹³; this resulted in inclusion of 77 consecutive RALPs with clinical localised cancer cT1–T2 and 154 matching RRP, respectively. In total, 356 eligible patients underwent RP (271 RRP and 85 RALP). 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 filled in at baseline and 1 year postoperatively.

Costs

The valuation of costs components included in the economic evaluation is listed in Table 1.

The life time of the da Vinci robot was assumed to be 5 years and depreciated by 3% to estimate the annual costs¹¹. The replacement cost (purchase price) of the da Vinci robot was estimated to be €1.4 million²⁵ with an equivalent annual cost calculated to 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. Statistical significance was considered when $p < 0.05$.

Results

There existed a reasonable selection of patients with a larger tumour burden who were to be treated operatively. Patients in the two groups were of equal age (mean age of 62.2 years for RALP and RRP) and risk groups (RALP vs. RRP: patients with preoperative T2 93.5 vs. 94.8%, patients with preoperative Gleason score <7 71.4 vs. 68.8%, and mean PSA 11.6 ng/ml vs. 14.4 ng/ml).

The outcome measures used in the economic evaluation are shown in Table 2. The difference between the RALP and the RRP procedures for successful treatment was 7% in favour of RALP ($p = 0.3$). More RRP patients reported postoperative erectile function compared to RALP patients. On the other hand, prescriptions for erectile medication were more common among the RALP patients (Table 2).

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

Table 1. Assessment of cost components in the economic evaluation.

	Euro	Ref.
Fixed costs per da Vinci procedure yearly*	3,456	
Equipment costs per operation:		
RALP	1,884	[14]
RRP	316	[14]
Average hourly rate:		
Surgeon	63	[15]
Specialist registrar, urology	43	[15]
Anaesthesiologist	61	[15]
RN at operation and recovery ward	28	[15]
RN at anaesthesiology ward	29	[15]
‘Hotel’ – costs per day†	281	[16]
Blood transfusion each	135	[17]
Outpatient visit per visit (mean)	267	[18]
Re-admission at hospital per day (mean)	892	[18]
Consultation at GP‡	33	[19]
Pad each	0.5	[20,21]
Absence from work per day	186	[22]
Home visit by community nurse, per hour	67	[23]
Medical treatment, erectile dysfunction:		
Injection Caverject, each§	20	[24]
Injection Invicorp, each	20	[24]
Tablet viagra, each	12	[24]
Tablet cialis, each	13	[24]
Tablet Levitra, each¶	11	[24]
Treatment, recurrence:		
Tablet Casodex 150 mg apiece	16	[24]
Profylax mammae radiation therapy	380	[16]
Radiation therapy, 39 fractions	29,678	[16]

*Based on 110 operations yearly; †Stay at the ward: all costs and gross salary including pay supplement; ‡Fee for a consultation of 10 min; §Average price of 10 and 20 µg; ¶Average price of 5, 10 and 20 µg. RALP, robot-assisted laparoscopic radical prostatectomy; RRP, retropubic radical prostatectomy; RN, registered nurse; GP, general practitioner.

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

	RALP	RRP	Difference†	p-value
Effects				
Number of patients	77	154		
PSA <0.2 ng/ml‡; n (%)	73 (94.8)	133 (86.4)		0.05§
Urinary continence (0–1 pad per day)‡; n (%)	67 (87)	108 (70)		
Erectile function with or without medication‡; n (%)	31 (40.3)	68 (44.2)		
Prescriptions used for erectile dysfunction¶; n (%)	27 (35.1)	38 (24.7)		
Successful treatment**, n (%)				
Number of patients	77	154		
Yes	26 (34)	42 (27)	7%	0.30††
No	51 (66)	112 (73)		
QALY				
Number of patients (%)	26 (33.8)	115 (74.7)		
Gain of QALY‡‡ [95% CI]	0.0103 [–0.2895 to 0.3100]	0.0116 [–0.3272 to 0.3727]	–0.0065	

*Matched on preoperative age, PSA, T-stage and Gleason score; †Difference: effect (RALP) – effect (RRP); ‡1 year postoperatively; § χ^2 -test; ¶Registered from a public database of health service at Central Denmark Region; **No residual cancer (PSA <0.2 ng/ml), urinary continence and erectile function with or without medication; ††Unpaired *t*-test; ‡‡Mean gain.

QALY, quality-adjusted life-years; PSA, prostate-specific antigen; RALP, robot-assisted laparoscopic radical prostatectomy; RRP, retropubic radical prostatectomy.

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.

	RALP (n = 77)			RRP (n = 154)			ICER (€)
	Mean (€)	95% CI	Effect* (%)	Mean (€)	95% CI	Effect* (%)	per successful operation*
Direct costs	8,369	[7,742–9,320]	34	3,863	[3,437–4,478]	27	64,343
Indirect costs	13,411	[11,320–17,264]	34	12,465	[9,611–15,318]	27	13,514

*Patients with the outcome measure 'Successful operation' (No residual cancer (PSA <0.2 ng/ml), urinary continence and erectile function with or without medication).

€, euro; RALP, robot-assisted laparoscopic prostatectomy; RRP, retropubic radical prostatectomy; CI, confidence interval, non-parametric bootstrap; PSA, prostate-specific antigen.

was no statistically significance between the two groups of patients (Table 3).

The ICER for direct costs was €64,343 per extra successful treatment using RALP (Table 3). Since no QALY was gained in favour of RALP it was not possible to estimate the ICER per QALY.

Figure 1 illustrates the impact of selected parameters on the estimated ICER of €64,343 per successful RALP procedure. The ICER decreased when increasing the effectiveness of RALP or with higher utilisation of the da Vinci robot. The costs of RALP would still be higher compared to RRP when the production of RALP was set at 720 annually – this would be equivalent to three RALPs per day, 5 days a week for 48 weeks per year (Figure 1).

Discussion

The ICER per extra successful procedure was €64,343 using RALP 1 year postoperatively with a production of 70 RALPs per year and the fixed costs for the da Vinci robot distributed on 110 robot-assisted procedures

annually. The more costly RALP procedure was also found to be more effective than RRP. Thus, the assessment of cost effectiveness was not clear per successful RALP procedure. Regarding QALY, RALP procedures were not considered cost effective because the cost were higher and at the same time the procedure was less effective compared to RRP. The selected parameters in the sensitivity analysis did not independently change the results noticeable and our economic evaluation was assessed to be robust to the cost data.

The present study is to our knowledge the first economic evaluation to look at marginal costs (i.e. all costs that vary between the two alternatives) as recommended by most guidelines for health economic evaluations. Additionally, no other cost studies 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.

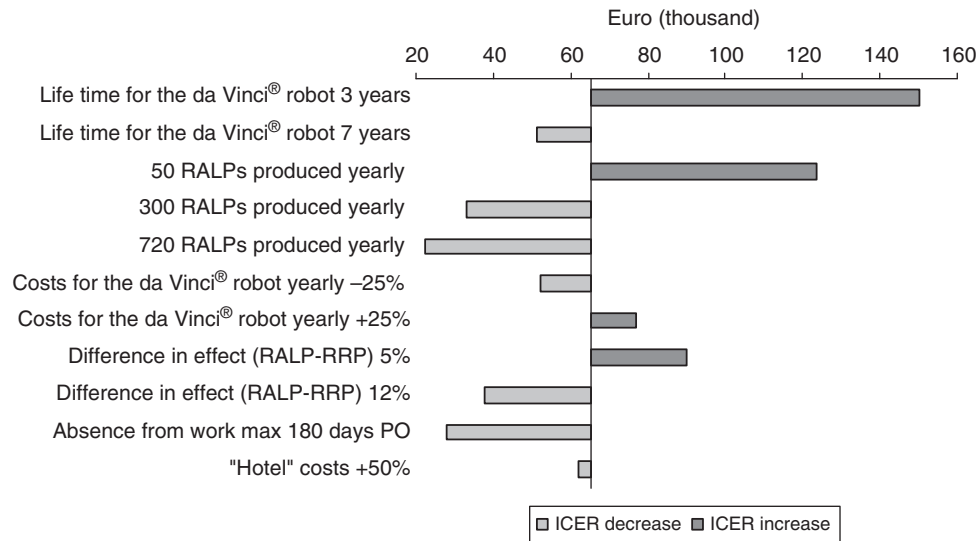


Figure 1. Impact of one-way sensitivity analysis with selected parameters on the estimated ICER of €64,343 per successful treatment using robot-assisted laparoscopic radical prostatectomy. The ICER was estimated assuming 70 RALP were performed annually with the costs for the da Vinci distributed between 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.

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.

Our study has some limitations regarding length of follow-up for costs and effectiveness. Only short-term quality of life was measured and should be followed by assessment of quality of life-years ahead. Of the patients who had completed the SF-36, only one in five underwent RALP. Both questionnaires were handed out at baseline, where the patient filled out the first copy. At 6 months follow-up visit the patient was reminded to bring along the completed second questionnaire for the 1 year outpatient control visit. The low percentage for

RALP patients filling in the second questionnaire may result in a biased estimate of QALY, if, for example, only the most dissatisfied RALP patients replied. On the other hand, the study by Schroeck *et al.* also found that patients who underwent RALP were most likely to be dissatisfied compared to RRP¹⁰.

Even though the patients included in the present study are matched selection bias is not eliminated. First of all, our matched study is not comparable to randomised controlled trials due to confounders such as unintended selection of procedure based on clinical T stages of disease and opportunity for nerve-sparing surgical technique. The clinical study in the present economic evaluation showed a higher share of recurrence 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 demonstrated a reduction of the costs for RALP⁷. Even though the present sensitivity analysis also showed that the costs for the RALP procedure decreased when increasing number of RALPs per week, it did not have influence of the assessment of cost effectiveness per successful treatment. Yet, even if RALP was used at the full capacity with three procedures per day, 5 days a week, the costs were still higher compared to RRP. Furthermore, the increased number of RALPs may decrease the life time of the da Vinci robot and the depreciation. The focus of improving the cost effectiveness may be to perform RALP at fewer centres with a high number of robot-assisted procedures, utilise the full potential of each robotic surgical system and increase the effectiveness of RALP.

Conclusions

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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