

Original Article

Cost-effective analysis and budget comparison of laparoscopic radical prostatectomy and robotic-assisted radical prostatectomy for prostate cancer treatment in a health insurance system in Thailand

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Keywords:

Prostate cancer, cost-effectiveness, laparoscopic radical prostatectomy, robotassisted laparoscopic radical prostatectomy

Abstract

Objectives: To compare the total medical cost and post-operative quality of life between laparoscopic radical prostatectomy (LRP) and robotic-assisted laparoscopic radical prostatectomy (RALP) and to discuss the cost differences of each approach.

Materials and Methods: Data were retrospectively reviewed from patients diagnosed with prostate cancer and who underwent LRP (n=68) or RALP (n=104) during a 36-month period. The prostate cancers of all patients were classified as low, intermediate, or high risk. Patient variables, inpatient hospital charges, outpatient total medical costs within 24 months and post-operative quality of life were compared.

Results: The baseline patient characteristics were similar between each group. Rates of positive margins and the need for further cancer treatment were correlated with the burden of disease (highest in the high risk group). The RALP inpatient hospital charges were higher in all risk groups. However, the mean total outpatient hospital charges were comparable. The RALP group demonstrated a trend towards better sexual-related quality of life in all risk groups. However, urinary incontinence, urinary-related, bowel-related, vitality-related quality of life were not significantly different between LRP and RALP.

Conclusion: From the payer's perspective, RALP costs are higher than LRP costs. The clinical and quality of life benefits associated with RALP may not convert into a net savings of total medical costs within 24 months after surgery.

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Introduction

Prostate cancer is one of the emerging healthcare burdens in Thailand¹ and is the fourth most common cancer in males. However, the trend toward early stage presentation due to public awareness and PSA screening now means that early stage prostate cancer can be cured by radical prostatectomy. In the last decade, laparoscopic radical prostatectomy (LRP) and robotic-assisted laparoscopic radical prostatectomy (RALP) have become the dominant surgical approaches due to the benefits of minimally invasive surgery.

LRP has been performed in many large university or tertiary hospitals; however, this procedure has a steep learning curve for surgeons and several technological limitations, including the use of two-dimensional imaging, restrictive movement of the surgical instrument, and a long operative time². The first generation of the "Da Vinci System" was a robotic surgical device designed by Intuitive Surgical Inc. (Sunnyvale, CA, USA) in 1995. The machine consisted of robotic arms that could move freely. The surgeon remained seated at a console unit and had a 3D high-definition view of the surgical field³.

In Thailand, RALP was introduced in 2007. Since then, it has gradually become a more favored surgical approach both for surgeons and patients. This may be the result of aggressive marketing by the surgical robot manufacturer and the hospital⁴, and the eagerness of patients for new technology that claimed superior results. However, robotic systems come with a hefty price, and their high cost has led authorities into a reimbursement program and insurance companies to question their clinical value.

There is a large volume of evidence to indicate that the most consistent perioperative clinical benefits of RALP over LRP are lower blood loss, fewer transfusions, and a shorter length of stay^{5,6}. However, the available data are insufficient to draw conclusions regarding the effect of cancerrelated outcomes, complications, and quality of life⁷. Therefore, whether the benefits of RALP can outweigh its higher costs remain unclear.

Previous studies in this area usually compare the costs of LRP and RALP using theoretical economic modeling or they address only the costs of the procedure but exclude most of the costs associated with surgical complications, side effects, and cancer-related outcomes^{4,7-9}. The aim of the present study was to determine whether the extra cost of RALP can decrease the total expenditure of medical care and result in a better post-operative quality of life in real-world practice. We sub-classified our patients into prostate cancer risk groups and compared the results between each surgical approach in terms of clinical outcomes, total medical costs, and post-operative quality of life.

Materials and Methods

The study was conducted in a single institute, Ramathibodi Hospital, which is a tertiary referral center for prostate cancer in Thailand. LRP was performed in all cases by the intraperitoneal approach with various laparoscopic instruments from different manufacturers. RALP was all performed by intraperitoneal approach with the three-arm da Vinci Si HD surgical system model SS3000 (Intuitive Surgical, Inc., Sunnyvale, CA, USA). In our study, no patient underwent Retzius-sparing prostatectomy. All three surgeons (Sangkum P, Kongchareonsombat W, and Kijvikai K) performed both operations and were specialized in the field of prostate cancer treatment, with experience beyond the initial learning curve. All surgeons have successfully performed a nerve-sparing dissection, which is usually done as an interfascial dissection. The decision whether to perform LRP or RALP, the nerve sparing dissection and pelvic lymphadenectomy depended on the surgeon who operated on each case. The decision of any given post-operative treatment (e.g. radiation therapy, chemotherapy, androgen deprivation therapy (ADT) or other medicine were dependent on the decision of the individual surgeon.

Data were retrospectively reviewed from 238 patients who were diagnosed with prostate cancer and underwent radical prostatectomy between January 2013 and December 2015. Initially, 14 patients were excluded because they had undergone open radical prostatectomy. In addition, 9 patients in the LRP group and 15 patients in the RALP group were lost to follow up during the 24 month follow-up period and were excluded from the study. Another 28 patients in the RALP group were excluded because of the use of discounted promotion instruments from the robotic manufacturer. These exclusions resulted in a total of 68 patients remaining in the LRP group



and 104 patients in the RALP group (Figure 1). All patients were then sub-classified in terms of their prostate cancer risk as low risk (including the NCCN very low and low risk), intermediate risk, and high risk (including the NCCN high and very high risk) groups based on preoperative PSA level and Gleason score from preoperative biopsy results¹⁰.

Baseline patient characteristics and postoperative variables, such as preoperative PSA, total hospital stay, positive margin rate, and biochemical recurrence within 24 months, were collected separately for each risk group from the information system of the hospital.

Direct costs were used in this study to estimate the cost effectiveness because they are associated with hospitalization and subsequent treatments which represent major expenditures. We used hospital charges to represent the direct medical costs. Hospital charges gave the advantage of accuracy and objective values, but they may have incorporated direct costs and profit margins⁴. Indirect costs were highly varied due to many factors and we were unable to determine objective values; therefore, we omitted the effects of indirect costs under the assumption that no significant differences existed in terms of the opportunity costs of work loss or reduced productivity. The cost components associated with hospital care were more feasibly represented by the costs from a payer's perspective.

We examined the total medical costs by using all hospital charges from the surgical admission

period to the end of the 24-month period following the prostate cancer surgery. Notably, the costs of adjuvant or salvage radiation therapy, chemotherapy, androgen deprivation therapy (ADT), and surgical consequential treatment (e.g. re-operation due to complications, cystoscopy, and urethral dilatation) were included. No patient in our study underwent any male sling procedure after prostatectomy. We did not include the cost of preoperative hormonal treatment in the analysis. The cost was discounted at an annual rate of 3.5%.

Following radical prostatectomy, the patients either entered surveillance or received adjuvant treatment. Adjuvant treatment (RT or ADT) were usually given to men at high risk of cancer recurrence¹⁰. Both RT and ADT can cause significant side effects which affect urinary, sexual, bowel, or hormonal quality of life. Recovery from prostatectomy could be complicated by bladder neck contracture, urinary incontinence, and sexual dysfunction¹⁰. We compared the quality of life between each approach using the expanded prostate cancer index composite for clinical practice (EPIC-CP), which specifically measures 5 prostate cancer-related quality of life items. This questionnaire enabled real-time and point-of-care scoring¹¹. Cross-sectional data were collected at a time beyond the 24 month period after prostate surgery. A higher score indicated greater impairment of quality of life. Scores out of 12 in each domain and total scores out of 60 were used to compare each surgical approach.

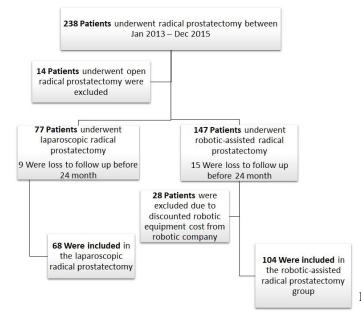
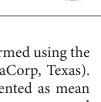


Figure 1. Patient classification.



Statistical analysis was performed using the Stata program version 14.1 (StataCorp, Texas). Quantitative variables were presented as mean ± standard deviation and data were compared between groups with the Independent t-test. Categorical variables were presented as numbers (percentage, %) and data were compared between groups with the Fisher's exact test. A p-value < 0.05 was considered statistically significant.

Results

In all risk groups, each surgical approach had similar pre-operative baseline characteristics. The mean age of patients in all risk groups ranged from 65 to 69 years. The mean PSA level was lowest in the low risk group $(7.00 \pm 1.97 \text{ ng/}$ ml) and highest $(36.00 \pm 23.40 \text{ ng/ml})$ in the high risk group.

Between LRP and RALP, the comparisons of post-operative variables for all three risk groups showed no statistically significant differences in terms of total hospital stay, rate of neurovascular preservation, rate of positive margins, and the need for further cancer treatment (RT or ADT) (Table 1). After the follow-up period of up to 24 months from the prostate cancer surgery, the rate of biochemical recurrence was also similar between the LRP and RALP groups. (Biochemical recurrence was defined as undetectable PSA after radical prostatectomy with subsequent detectable PSA that increased in 2 or more determinations¹⁰.)

A majority of patients were enrolled in the civil servant medical benefit scheme (CSMBS) (56.72% in the LRP group and 56.31% in the RALP group). The fewest patients in this study were

Table 1. Baseline patient characteristics and post-operative variables. (Classified based on prostate cancer risk-groups)

Patient risk group/ patient characteristic	Low risk group			Intermediate risk group			High risk group		
	LRP	RALP	P-value**	LRP	RALP	P-value**	LRP	RALP	P-value**
Number of patients: n (%)	10 (40.0)	15 (60.0)	-	32 (41.0)	46 (59.0)	-	25 (37.3)	42 (62.7)	-
Age (years): mean \pm SD ∂	68.7±6.3	67.0±4.7	0.501	67.2±7.3	66.8±6.6	0.806	67.2±5.1	65.9±6.9	0.413
Preoperative PSA level (ng/ml): mean \pm SD Δ	7.0±2.6	7.0±1.4	0.995	10.3±3.6	10.1±3.8	0.796	33.7±27.5	37.4±20.5	0.571
Total hospital stay (days): mean \pm SD Π	7.2±1.5	7.9±3.3	0.558	6.7±2.9	7.0±2.4	0.525	7.0±2.6	7.9±2.6	0.155
Neurovascular Preservation: $n (\%) \Sigma$	4 (40.0)	8 (53.3)	0.688	10 (31.3)	21 (45.7)	0.244	3 (12.0)	1 (2.4)	0.143
Positive Margin of prostate specimen: n (%) ∞	2 (20.0)	1 (6.7)	0.543	10 (31.3)	21 (45.7)	0.244	14 (56.0)	18 (42.9)	0.324
Need for further cancer treatment: $n (\%) \int$	3 (30.0)	4 (26.7)	1.000	9 (28.1)	11 (23.9)	0.793	15 (60.0)	25 (59.5)	1.000
Radiation therapy: n (%) "	2 (20.0)	1 (6.7)	0.543	5 (15.6)	3 (6.5)	0.262	9 (36.0)	13 (31.0)	0.789
ADT: n (%) ⁻	3 (30.0)	3 (20.0)	0.653	9 (28.1)	11 (23.9)	0.793	15 (60.0)	23 (54.8)	0.800
Biochemical recurrence within 24 months: n (%) [‡]	3 (30.0)	1 (6.7)	0.267	5 (15.6)	13 (28.3)	0.276	9 (36.0)	15 (35.7)	1.000

^{*}Patients were classified based on NCCN guidelines risk-group (Version 2.2016),

NCCN criteria from very low and low risk were combined and labelled as "low risk group",

NCCN criteria from intermediate risk was labelled as "intermediate risk group"

NCCN criteria from high and very high risk were labelled as "high risk group".

^{**}Boldfaced p-value denote statistical significance (p-value < 0.05)

[∂] Age at the time of surgery

Δ Preoperative PSA level within 3 months

 $[\]Pi$ count from the day of admission until the day of hospital discharge within operation visit

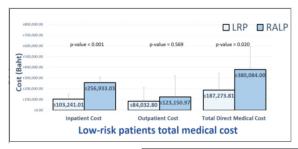
 $[\]Sigma$ the decision whether to perform neurovascular preservation was based on the surgeon

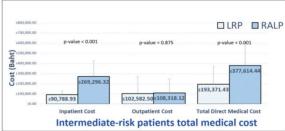
[∞] positive margin from the final pathologic specimen

f the rate of patient need to receive radiation therapy and androgen deprivation therapy within 24 months post-operative period ** including both adjuvant and salvage RT

Androgen Deprivation Therapy (ADT) included any forms of medical or surgical therapy that aim to block the effects of androgens ‡ Biochemical recurrence defined as undetectable PSA after radical prostatectomy with subsequent detectable PSA that increase on 2 or more determinations







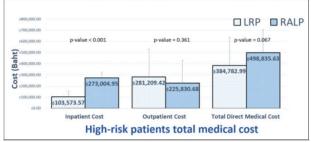


Figure 2. Total medical cost comparison between LRP and RALP

enrolled in the social security scheme (SSS) (5.97% in the LRP group and 0.97% in the RALP group).

The da Vinci Si HD surgical system model SS3000 was purchased in 2013 at a cost of approximately 52.5 million baht (1.75 million US dollars, in 2013). However, in our cost analysis, we used the section of "medical equipment and medical procedures cost" in the hospital bills to represent the divided cost of purchasing both laparoscopic and robotic systems. These costs were consistent for each surgical approach (22,500\$\mathbb{B}\$ in LRP and 105,000\$\mathbb{B}\$ in RALP). Calculating the true costs of system purchasing and maintenance was troublesome and potentially inaccurate when included in the analysis.

We observed that the risk group had no impact on the inpatient hospital charges. In the LRP cohort, the mean inpatient hospital charges were 103,241.01\$, 90,788.93\$, and 103,573.57\$ for the low, intermediate, and high risk groups, respectively. In the RALP cohort, the inpatient hospital charges were 256,933.03\, 269,296.32\, and 273,004.95\$ for the low, intermediate, and high risk groups, respectively (Figure 2). The RALP inpatient hospital charges were significantly higher for all risk groups (with p < 0.001). The higher costs of RALP could be explained by the "prosthesis devices cost," which represents the apportioned cost of disposable instruments per case. In the LRP cohort, the mean expenditure in this section was 32,052.75\, compared to 146,467.65**B** in the RALP cohort.

The mean total outpatient hospital charges

between each surgical approach showed no statistically significant difference. Nonetheless, we observed that, in the high risk group, the mean outpatient cost was lower in the RALP than in the LRP cohort, although the difference was not statistically significant (281,209.42\$ in LRP vs. 225,830.68\$ in RALP; p = 0.361).

The quality of life assessment, determined by the EPIC-CP scores, demonstrated comparable quality of life domains within the risk groups. Urinary irritation, urinary incontinence, bowel symptoms, and hormonal symptoms domains did not differ between the LRP and RALP cohorts (Figure 3).

In the sexual symptoms domain, RALP showed a consistent trend towards a better post-operative quality of life assessment. Nonetheless, combining all the quality of life domains did not reveal a statistically significant difference. We presumed that the incremental cost-effectiveness ratio cannot further contribute to the quality of life analysis in this scenario.

Discussion

Our study did not observe any clinically significant benefits of RALP. Previous studies on this topic have demonstrated inconsistent results. For example, a review by Caceres et al. suggested that RALP may be associated with a reduced incidence of sexual dysfunction (22–85%, median 61%) when compared with LRP, when the rates of positive surgical margins are similar¹¹. Similarly, the meta-analysis by Ficarra et al. of 37 comparative studies between open retropubic

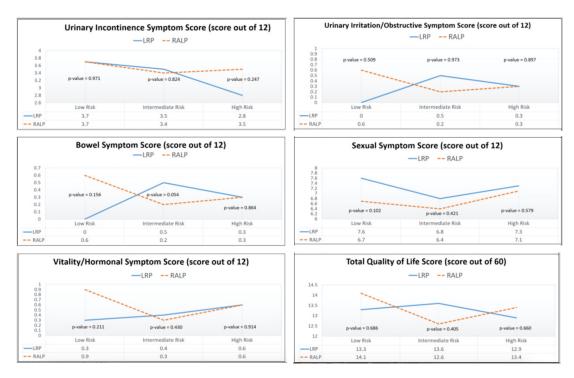


Figure 3. Prostate cancer related quality of life comparison between LRP and RALP.

radical prostatectomy (RRP), LRP, and RALP compared functional and oncologic outcomes, surgical complications, time to continence, potency rate, quality of life and cancer recurrence. Their analysis showed no differences in functional outcomes or in oncologic outcomes⁵.

Our data must be viewed with some caution because we focused solely on the outcomes of the post-operative period and did not include the perioperative period outcomes. We cannot draw a conclusion that RALP had no clinical benefits in any manner. Some previous studies reported that the rate of perioperative morbidity was lower for RALP than for LRP. For example, the systematic review conducted by Ramsay et al. demonstrated that RALP had a lower rate of major adverse events, such as blood transfusion and organ injury. These researchers also predicted a probability of a positive margin of 17.6% following RALP, compared with 23.6% following LRP⁷.

Some advantages of robotic surgery may not be measurable based on their clinical endpoints. For example, it is claimed that robotic surgery improves visualization, facilitates dissection and suturing, reduces the technical complexity, and shortens the learning curve when compared with traditional LRP. However, there is only limited evidence to confirmed these benefits or the impact of robotic surgery on clinical and economic outcomes. For this reason, our cost-effectiveness

analysis had to be based principally on costs.

The high cost of RALP has been recognized since its introduction, and previous studies have explored the cost differences between LRP and RALP. For example, Bolenz et al. compared 643 consecutive radical prostatectomy operations (262 RALP, 220 LRP, and 161 RRP) and found a significantly higher median direct cost for RALP than for either LRP or RRP. The higher cost was predominantly due to the increased costs of surgical supplies and operation rooms.

In our study, we observed that the risk grouping did not have any impact on the inpatient hospital charges. In both the LRP and RALP cohorts, the low risk groups had similar mean inpatient costs to those observed for the high risk groups. This finding could reflect the fact that a majority of the expenditure was the fixed costs of each procedure and that the additional surgical or medical expenditures did not differ significantly among the risk groups. The fixed cost was largely due to the cost of purchasing the system and the cost of disposable surgical instruments, in agreement with previous studies^{4,9,13,14}. The costs of drugs, blood transfusions, laboratory tests, doctors' fees, and anesthesia had a negligible impact on the total inpatient cost. We concluded that any benefits from RALP cannot be converted into net savings in terms of inpatient costs.



By contrast, the outpatient costs, which were highest in the high risk group, directly varied according to risk groups. This finding could be explained by the add-on costs of adjuvant treatments, as well as the higher rate of biochemical recurrence. The outpatient costs did not show statistically significant differences between the LRP and RALP cohorts. In the high risk group, the mean outpatient cost was slightly lower for RALP than for LRP. Future studies could explore this point by performing a prospective study or by increasing the number of patients in the high risk group. We did not take into account the indirect costs because the mean age of the patients in our study was the mid to late sixties. We assumed that the majority of these patients were retired from work. Therefore, we focused solely on the total direct medical costs.

We observed no significant benefit of RALP in terms of prostate cancer-related quality of life. This result was similar to that of the previous study by Hohwu et al., which included readmissions and adjuvant treatments within the first post-prostatectomy year. They retrospectively matched 77 consecutive RALPs with 154 RRPs based on the D'Amico risk, and they concluded that RALP was more effective with regard to cancer removal, continence, and erectile function. However, the health economic evaluation did not show any quality of life (QALY) gain 1 year after RALP¹⁵. A study by Close et al. found a small margin of QALY benefit over 10 years, with a mean (95% CI) of 0.08 (0.01-0.15). They concluded that RALP costs may be offset by modest health gains that result from a lower risk of early harm and positive margins, if RALP is performed on >150 cases each year8.

In Thailand, the three major medical insurance schemes are: (1) the social security scheme (SSS) for private sector employees (16% of the total population), (2) the civil servant medical benefit scheme (CSMBS) for government employees as well as their families (8% of the total population), and (3) the universal health-care coverage scheme (UCS) (75% of the population). These facts complicated the cost-effective analysis from the Thailand health-care perspective when compared to developed countries, where most of the population is covered by compulsory health insurance and everyone has the right to the same benefits package and usually has equal access to prostate cancer treatment 16,17.

We acknowledge that cost of the procedures varies not only among institutions but also between centers and health care systems¹⁴. We conducted our study in a large teaching-university hospital (>1,000 beds). The findings in our study that a majority of patients had the CSMBS (56.72% in LRP group and 56.31% in RALP group) may reflect their privilege of having a free choice of public hospitals and reimbursement of almost all medical expenditures. By contrast, the patients with SSS had the least access to LRP and RALP (5.97% in LRP group and only 0.97% in RALP group) because they were limited by the contracted network and could only be reimbursed when they received their treatment within the network area. Although the data were not well collected, most of the patients in the SSS and the UCS received primary ADT (usually done by surgical castration) for the treatment of localized prostate cancer in provincial hospitals¹. There is clearly a lot of room for improvement.

Will RALP ever be cost effective? An increase in case volumes or even extension of the criteria for surgery may lead to lower charges, and this has been proposed as a way to increase cost effectiveness of RALP^{7,8}. The high cost of the robotic system may also change in the near future. Before 2012, the Intuitive surgical system held a market monopoly on robotic systems, so negotiating discounts or lowering the purchasing price was difficult¹⁸. The increasing competition among medical companies may lower the price. For example, the Revo-i robot by Meere Company (South Korea) had already been used for the Retzius-sparing RALP and data on 17 patients has been published; surgery cost cuts of 42 percent are expected^{19,20}. The new Versius robotic system, designed and built by CMR surgical (Cambridge, UK), is expected to be used on patients for the first time in 2019. We encourage surgeons to keep abreast of robotic technology, because the price may be affordable for mid-sized or provincial hospitals in the upcoming years.

Our study was limited by the retrospective data collection, which possibly imposed a recall bias in the quality of life assessment. The lack of patient randomization or propensity score matching of the patients is an area of improvement to consider in future studies.



Conclusion

From the payer's perspective, RALP costs, which are attributable to the robotic equipment and supplies, are higher when compared to LRP costs. The clinical and quality of life benefits associated with RALP may not convert into a net savings in terms of total medical costs within 24 months after surgery.

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Conflict of Interest

The authors declare no conflict of interest.

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