

Executive Summary

□ Background

Since the introduction of the first robotic platform in 2005, urology, which accounts for 33.4% of all robotic surgeries, is the fastest growing sector of robotic surgery in South Korea. Among these surgeries, robot-assisted radical prostatectomy (RARP) is most frequently used for patients with prostate cancer. Further, the application of RARP is expected to increase owing to its various advantages. According to a systematic review (SR) published in 2012 (Ficarra et al, 2012), RARP was superior in terms of functional outcomes such as the urinary incontinence recovery rate and potency recovery rates compared to conventional surgeries (laparoscopic radical prostatectomy [LRP] and open radical prostatectomy [ORP]). In addition, an SR (Lee et al. 2014), undertaken in 2003 at our research institute, showed that RARP was superior not only in terms of functional outcomes, but also in terms of safety, and was associated with improved immediate postoperative outcomes such as estimated blood loss. However, the cost-effectiveness of RARP remains under debate owing to high medical costs compared to that of conventional surgery.

The Korean government is currently extending coverage for four major diseases that incur high medical expenditure, and robotic surgery is included in the expanding health insurance benefit plan. However, no studies have reported an economic evaluation in Korea of Robotic surgery in prostate cancer using Korea data, and the provision to extend coverage for robotic surgery is under debate.

□ Objective

To provide fundamental data for instituting the national health policy, this study evaluated the clinical efficacy and cost-effectiveness of RARP compared to that for LRP and ORP for localized prostate cancer in South Korea.

□ Methods

To evaluate the clinical efficacy and safety of the surgical modalities (RARP, LRP, and ORP), first, we retrospectively reviewed the clinical data of 864 consecutive patients with prostate cancer who had undergone RP between January 2010 and December 2011 at 5 tertiary hospitals in South Korea, regardless of the modality.

Second, we assessed quality of life in terms of the state of health after RP. The quality of life of 393 normal men was measured mainly using Time-Trade-Off. The survey was based on a scenario that describes the state of health in detail and considers the surgical methods, short-term adverse effects following RP, disease-specific status, and additional treatments 1 year after RP.

Third, we analyzed total medical expenses, including postoperative insured and non-insured amounts for 682 of the aforementioned 864 patients.

Finally, we used the decision tree model to compare expected costs and quality-adjusted life years (QALYs) for RARP and LRP or ORP as per the Korean Healthcare system perspectives during the one-year horizon. We retrospectively reviewed a cohort of patients with localized prostate cancer to identify transition probabilities and costs. The status of health depended on the absence of evidence of disease, biochemical, metastasis, death, or major complications. A discount rate of 5% was applied to the cost and QALYs. The incremental cost-effectiveness ratios of RARP compared to that of LRP or ORP were calculated.

□ Results

- With a threshold value of 30.5 million KRW, the cost-effectiveness analysis of different RP procedures showed that RARP was not cost-effective when compared to existing surgical procedures.
- The effectiveness may not have offset the costs, since there was no profound difference in effectiveness between the different RP procedures, whereas RARP was significantly more expensive than its alternatives.

I. Retrospective cohort study

Total 864 patients met the inclusion criteria of our study. Of 864 patients, 559 patients underwent RARP, 170 patients underwent LRP, and 135 patients underwent ORP. In perioperative outcomes, Patients treated with RARP had less operation time and high rate of treating pelvic lymphadenectomy and nerve sparing techniques compare to conventional surgery. In oncological outcomes, the positive surgical margins (PSM) rate was the lowest in patients who underwent LRP, but there was no significant differences in biochemical recurrence rate (BCR) according to modalities. In safety outcomes, the complication rates were the lowest in the patients who underwent RARP. In functional outcomes, RARP showed the highest urinary incontinence recovery rate, with 89.4% and 92.5% of the patients showing complete continence recovery by the 3-month and 3-year follow-up periods, respectively.

Cox proportional hazards regression looking at predictors of urinary incontinence recovery are shown that there was difference in the probability of recovery between RARP and LRP

There was statistically significant differences in patients characteristics such as age, ASA class, prostate volume, clinical stage, so patients were matched based upon the covariates.

Total 864 patients, only 269 patients were matched. Of them, 133 patients

underwent RARP, 68 patients underwent LRP, and 68 patients underwent ORP. In perioperative outcomes, Patients treated with RARP had less operation time and high rate of treating pelvic lymphadenectomy and nerve sparing techniques compare to conventional surgery. In oncological outcomes, there were no significant differences in BCR, and PSM according to modalities. In functional outcomes, RARP showed the highest urinary incontinence recovery rate, with 88.7% and 95.3% of the patients showing complete continence recovery by the 3-month and 3-year follow-up periods, respectively.

Cox proportional hazards regression looking at predictors of urinary incontinence recovery are shown that there was difference in the probability of recovery between RARP and LRP.

The results of this study were similar to those reported previously in medical technology assessment reports(HIQA 2011; NETSCC 2012) and SR (Ficarra et al, 2012) that the postoperative and functional outcomes were superior in the RARP group. However, potency recovery rates could not be confirmed in this retrospective cohort analysis owing to the lack of written medical records. While, BCR rates results, which were similar to those reported in international SR (Ficarra, 2012; Novara, 2012) and HTA reports published between 2011 and 2012 (HIQA 2011; NETSCC 2012), were different compared to our results that there was no significant differences according to modalities. SR from the Korean Institute for Health and Medical Research reported that the rate of BCR of prostate cancer was significantly lower in the patients who underwent RARP. The surgical techniques and treatment outcomes of RARP have been improving constantly; however, by limiting the analysis to patients who underwent RP between 2010 and 2011, the study may have failed to reflect the improvement in surgical outcomes. Moreover, recent international publications report surgical outcomes from physicians who had performed > 5,000 RARP procedures. In contrast, RARP techniques were still under development in Korea at 2010~2011.

II. Quality of Life

According to a study that analyzed a target of 303 men for meeting logical consistency of the survey, the utility values are as follows. First, health status after surgery showed that the utility value reduced greatly in patients who underwent open radical prostatectomy (ORP) than in those who underwent LRP. The utility value was reduced by approximately 9.5 and 2.9 days per year, respectively, for ORP and LRP compared to that for RARP. Second, the utility value based on adverse effects after RP indicated that erectile dysfunction caused a greater reduction in efficacy than urinary incontinence. Owing to erectile dysfunction and urinary incontinence, efficacy reduced to approximately 34 and 25.2 days per year, respectively, in comparison to health state without adverse effects. Finally, the utility values were arranged in order from the highest to the lowest based on the state of health 1 year after RP as follows: no evidence of disease (0.826), biochemical recurrence (0.421-0.692), and metastasis (0.129-0.269). Further, according to additional treatment for recurrence, utility values were arranged in order from the highest to the lowest as follows: no treatment (0.692), radiation with/without hormone replacement therapy for a specific period (0.547), and lifelong hormone therapy (0.421). In addition, depending on the need for additional treatment for metastasis, utility values were arranged as follows: initial-stage (0.269) > terminal-stage (0.129).

III. Cost Analysis

The data of 682 patients were collected using medical chart review in order to estimate total medical costs, including amounts covered with and without National Health Insurance. The medical costs of RP procedures, which included costs of the operation and postoperative management for 1 year, were the highest for the RARP group at 18 million South Korean Won (KRW), followed by approximately 8.4 million KRW for LRP and 6.2 million KRW for ORP. The cost of RARP was two-fold more expensive than the conventional surgeries, LRP and ORP. The cost of surgery accounted for the

majority of the medical expenses incurred in the first year after RP. There was no significant difference between the costs, except for the cost of surgery. National Health Insurance did not cover 85.0% of the expenses in the RARP group, which had the highest proportion, followed by LRP, and ORP.

IV. Cost-utility Analysis

The economic efficiency of different surgical procedures for RP was measured using a decision-analysis model built over 1year, based on the perspective of the health insurance system. The cost-utility analysis results for the different surgical procedures were expressed in different incremental cost-effectiveness ratios as follows: 44,338,406 KRW for LRP over ORP; 132,507,255 KRW for RARP over ORP; and 252,141,944 KRW for RARP over LRP. In other words, considering the threshold value of 30.50 million KRW proposed by Hoon et al., RARP could not be considered as a cost-effective alternative, when compared to other surgeries. Although the utility value and RARP cost were confirmed as sensitive variables through one-way sensitivity analysis, the outcome did not affect the basic analysis, which demonstrated that RARP was not cost-effective. Moreover, multi-way sensitivity analysis demonstrated similar outcomes to those of the basic analysis.

Meanwhile, the threshold analysis to confirm the impact of surgery costs on cost-effectiveness demonstrated that LRP could be a more cost-effective alternative compared to ORP if costs for the LRP were to be reduced by 700,000 KRW. Similarly, RARP could be a cost-effective alternative to ORP or LRP if the costs could be reduced by approximately 9 million KRW, or 8.3 million KRW, respectively. In the present study, cost-effectiveness analysis of ORP over LRP, ORP over RARP, and LRP over RARP showed that the cost difference between the alternatives was significant at 2.3-12 million KRW, while the differences in the quality of life after 1year was non-significant at 0.04-0.09.

Specifically, due to large expenses and small differences in effectiveness,

costly surgical treatments can be considered cost-effective only if the costs are reduced to levels similar to or marginally higher than those of the alternatives. However, the findings of the present study should be interpreted with caution, because our results were interpreted using data from a one-year period.

□ Conclusions

This study analyzed the economic effectiveness of RARP for prostate cancer. Because the coverage plan was introduced for four severe diseases, RARP has become increasingly popular after its introduction in 2005. With a threshold value of 30.5 million KRW, the cost-effectiveness analysis of different RP procedures showed that RARP was not cost-effective when compared to existing surgical procedures. RARP could be cost-effective if the expenses could be reduced by 8.3-9 million KRW within the first year of RARP use.

The effectiveness may not have offset the costs, since there was no profound difference in effectiveness between the different RP procedures, whereas RARP was significantly more expensive than its alternatives. Moreover, while RARP was validated through cohort analysis and quality of life analysis and was shown to be more effective than conventional procedures, the functional index excluded factors such as survival. The results of the present study should be interpreted with caution as short-term data were used for cost-effectiveness analysis and a retrospective research design was used to assess the efficacy. Based on the results of our study, long-term prospective studies are necessary to yield superior results.

Key words

Prostate cancer, Robotic surgery, Robot-assisted radical prostatectomy, Cost-effectiveness