

## Executive Summary

### 1. Purpose

After the FDA approval of robot surgery in the year of 2000, robot surgeries have been actively performed, and the surgeries have been performed in many diseases by showing its surgical cases to reach more than 13,000 cases in Korea after its approval by KFDA in 2005. But it is necessary to evaluate the effectiveness and safety of robot surgeries compared to other comparative surgical procedures considering its issues on high cost and monopoly. To prevent the abuse of performing indiscreet DaVinci surgeries for unverified indications and to perform correct medical examination by considering clinical characteristics of patients rather than the convenience of investigator, the present study aimed to perform health technology assessment study regard on the safety and effectiveness of robot surgeries by reflecting the national status of Korea to provide correct information to general people and to provide evidences that are necessary for the establishment of political action to decision makers.

### 2. Methods

#### 1) Current status of robot surgery

The present study was performed by reviewing the studies, reports and presentation data published along with the cooperation of a robot surgery company.

#### 2) Safety and effectiveness assessment of robot surgery

For the evaluation of studies related to the safety and effectiveness of robot surgery, 3 databases and 5 Korean local databases were reviewed.

The present study was performed by subjecting all robot surgeries. Robotic surgery studies compared with laparoscopy of open surgery were selected, and non-comparative studies were excluded. No limitation was set on the study period and language. The study was progressed by allowing two researchers to select a study report independently. Two researchers independently selected studies for inclusion, and a researcher performed the extraction for selected study by using a standardized data extraction form, and the extracted result was complemented by the other researcher. Analysis was performed by using RevMan 5.0, and the estimated effect value for variable was described by using the continuous variable of mean difference (MD), and the risk ratio was performed if the variable was a binary variable.

### 3) Questionnaire for subjected robot surgery performers

Web-based questionnaire survey was performed by subjecting 184 robot surgery performing surgeons in 24 hospitals. Through the survey, the opinions of medical specialists who performed robot surgeries were investigated and the status for the robot surgeries in Korea was understood by performing the questionnaire survey to the robot surgery experienced medical specialists.

### 4) Robot surgery from sociocultural perspective

To figure out the content and volume of information regard on the DaVinci robot surgery that could be gathered from current media, the related news articles posted on the media were reviewed and classified to confirm its reported frequency based on the type of main content. To understand the types of DaVinci robot surgery related information that is required by the Korean society, the main stories posted on the online communities formed by patients, patient families and medical specialists who are directly related to the surgeries were reviewed and those stories were classified for the arrangement of

major contents.

#### 5) Robot surgery from economical perspective

Through the study reviews for the studies that discussed about the economical perspective of robot surgeries, the evaluation for robot surgery out of Korea from the economical perspective was figured out, and the surgical costs for robot surgeries in Korea were investigated.

### 3. Results

#### 1) Current status of robot surgeries

The results of investigating robot surgeries revealed that Korea was registered as the 5th largest nation holding the robot surgical equipments in the world based on October, 2010. The system owned by each million population was investigated to be the 3rd largest country in the world. After the KFDA approval in the year of 2005, the overall robot surgery performance cases were estimated to be 13,700 cases within the nation based on October, 2010. In addition, health technology assessment reports were reviewed and the robot surgery evaluation results in foreign nations were figured out and sorted.

#### 2) Evaluation of safety and effectiveness of robot surgeries

A systematic study review was performed to select total 171 study articles. Since the interventional surgeries that were discussed at the 171 studies were so various, the types of the surgeries were classified into 19 groups, and only 7 study articles were suggested to be the studies that could be used to perform an actual quantitative analysis (meta-analysis). The meta-analysis performed interventional surgeries were the prostatectomy, hysterectomy and nephrectomy. Due to the difference of subjected patient groups and limited volume

of the studies, only a qualitative study was performed for other surgeries.

Initially, the result that was acquired by performing systematic reviews on prostatectomy by comparing the robot and open surgery revealed that hospitalized period, bleeding volume and transfused blood volume were found to be significantly low in robot surgery, and the comparison of robot surgery and laparoscopic surgery revealed to show significantly low hospitalized period and bleeding volume, but it was difficult to determine the effectiveness of robot surgery due to the low consistency of reviewed results with low evidence level, and no difference was observed compared to laparoscopic surgeries by using currently available evidences from the aspects of survival rate, relapse rate and occurrence of serious side effects.

The evidences for the safety and effectiveness of robot surgeries for other organs other than prostatectomy were found to be insufficient.

As a whole, it was difficult to withdraw a conclusion through the systematic reviews due to heterogeneity between the studies by the characteristics of surgeons, variance of result variables and by the difference of result definition. Since the studies performed by subjecting cancer patients were prevalent type of the surgery, the effectiveness of the surgery could be verified by observing relapse rate and long term death rate of the patients, but it was difficult to make a conclusion under the current status since the long term follow up studies were rarely performed with the scarcity of studies that reviewed the recurrence and death rates.

Therefore, since various studies are currently performed as of now, it is necessary to put more attention on the future study results. To determine the effects of robot surgeries, it is considered to be necessary to perform long term follow up studies and to perform highly qualitative studies equipped with standardized research design.

### 3) Questionnaire investigation for the robot surgery surgeons

In the questionnaires formed with total 18 items, 74 surgeons responded by showing 40.2% of response rate. The present questionnaire investigation can have its importance as the first study that was performed to investigate the acknowledgement of robot surgery and current status of the surgery by subjecting robot surgery performing surgeons within the nation. The surgeons performing robot surgeries considered robot surgery level as the excellent one. As the background of introducing robot surgeries, provision of good quality of health service and consideration of hospital image were investigated to be the most commonly considered reasons. As the major determinants of deciding the performance of DaVinci surgery, patients' economical burden was the most commonly selected reason, and the monopoly and high cost problem were pointed out as the largest problems as the obstacles of spreading robot surgeries. Considering from the aspects, the economical aspect of robot surgery is considered to be a large consideration in Korea other than clinical effectiveness and safety of robot surgeries. Through the analyses of using the current status investigation, the robot surgeries was most commonly found to be performed in the surgeries of prostate gland, kidney, and thyroid gland, which showed a slight gap from the evidence amount of the study mainly published out of Korea.

### 4) Robot surgeries from sociocultural perspective

For the evaluation of DaVinci robot surgery from sociocultural perspective, 260 related news articles and 60 online posted comments were reviewed. As the results of reviewing the related news articles, the health institution and surgery advertising news overwhelmingly occupied the articles, which were followed by the articles that described about the detailed surgical procedures and expected effects of DaVinci robot surgery to specific indications as the level of surgical advertisement.

Under the circumstances without satisfactory levels of good qualitative individual studies regard on the effectiveness and safety of DaVinci robot surgery, promotional new articles about the achievement of surgeons in a specific hospital, that could be misunderstood as the objective information about the DaVinci robot surgery were commonly circulated. Therefore, it is considered that the information between the scientific evidence of DaVinci robot surgery and the information circulated through the current media has a gap. Very little information regard on merits and demerits of robot surgeries that were compared with previous surgical procedures and the cost effectiveness of the surgery was available. So, it is considered that the related information on the current development status and future plan for the robot surgery has to be actively provided from related government officials, academic societies and from industries.

#### 5) Robot surgeries from economical perspectives

At the time of reviewing the studies that were performed out of Korea, the cost difference between the cases of applying and not applying robot surgeries in various surgical techniques, the use of robot surgeries required to spend more than 1,600 US dollars (6% of surgery related expenditure) based on the year of 2007. To the extent of considering the payment for the purchase of a robot system, more than 3,200 US dollars that is estimated to take up 13% of the surgery related expenditure was required. To figure out the expenditure of robot surgery in Korea, each hospital homepage survey and questionnaire survey were performed. But the surgical cost for each organ was only allowed to be estimated as the expenditure range. Although there was a difference by the application of surgical methods, the approximated cost of robot surgery was ranged to be 500-1,200 million won. Considering the fact that the insurance payment for the conventional standard surgeries was

allowed, especially considering the health insurance deductible payment of 5%, the cost of robot surgery that was imposed onto a patient was relatively large one compared to conventional surgeries.

#### **4. Discussion and Conclusion**

Although the present study can have a significance of performing systematic reviews including quantitative analyses for all surgical methods of using robot surgeries, the present study was limited by the difficulties of eliminating heterogeneity and by the rarity of study articles that discussed about result variables that can be used to determine the safety and effectiveness of the surgery. In addition, although the present study can have its significance as the first study that reviewed the acknowledgment survey for robot surgery by subjecting surgeons who perform the surgery and as the first study that attempted to figure out the current status of robot surgery within the nation, it was limited by the depreciating representativeness and preciseness of the study.

However, the present study evaluated robot surgeries from various perspectives, since the evidences for safety and effectiveness of robot surgery compared to conventional surgeries were difficult to have, the study can suggest the following contents regard on the robot surgeries in Korea.

Robot surgeries were still expensive surgery compared to conventional surgeries and it showed a large gap from the aspect of patient's burden for its expense since the surgeries were not covered by insurance payment, but when the surgeries were evaluated from the currently acquired evidences, the claimed evidences for the significantly large cost effectiveness of the treatment were found to be low.

Even without the enough accumulation of evidences for robot

surgeries, the performance of robot surgeries in Korea have been performed frequently compared to nations. If robot surgeries are introduced in Korea without full discretion, it can be economically burdensome to general people and can have harmful effects on the health of general people. Therefore, the related medical staffs have to select a surgical method in an objective and neutral attitude by considering the clinical characteristics of a subjected patient who will receive a surgery and precise information has to be delivered to the patients to help them in selecting appropriate surgical procedures.

For the correct settlement of robot surgeries in Korea, it is necessary to provide a precise information regard on robot surgery through the merit and demerit evaluation performed with currently performed comparative surgical procedures. For that purpose, the performances of clinical studies that are equipped with standardized clinical research design are considered to be necessary. Especially for the robot surgery field that is actively performed, but with limited clinical studies that can help in determining its effectiveness, the provision of surgical evidences by performing clinical researches are urgently necessary. In addition, robot surgeries should not be used as a competitive approach between hospitals. If it is an absolutely necessary health technology, the introduction has to be made regionally, and impractical competition has to be avoided by placing upper and lower limits of robot surgical system introduction cost and surgical cost of the surgery.

In case of the surgery that is performed widely with sufficient amount of evidences (prostatectomy), a guideline has to be established to determine which type of patients will be benefited by the performance of the surgery. In case of newly developing robot surgeries with less sufficient amount of evidences, it is considered that the surgeries have to be performed under well-designed clinical study plan rather than indiscreetly performing the surgeries by the patients' expenses to reduce the cost of patients' burden and to



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accumulate evidences for the surgeries. Especially, since the studies that are progressed with the result variables that can correctly determine the effectiveness and safety of the surgery are limited, it is considered to perform high quality clinical studies by setting appropriate result variables for each indication. Also, based on the corresponding results, the cost effectiveness of the surgery has to be evaluated with comparative surgical procedures to provide the evidences for general people to select more economically desirable surgical procedure. Other educational program and quality management program within medical institutions that are related with robot surgeries have to be improved and the DaVinci system has to be continuously supplemented and developed to meet the characteristics of established indications to have its meaning in introducing robot surgeries in Korea.