[A health technology assessment of the effectiveness and safety of robot surgery]
Shin C, Lee Y, Suh H, Chang B, Park J, Son H, Yang J, Oh S

Record Status
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Citation

Authors' objectives
After the FDA (Food and Drug Administration) approval of robot surgery in the year 2000, robot surgeries have been actively performed, and these surgeries have been performed for many diseases, with robot surgical cases reaching more than 13,000 in Korea after its approval by the KFDA (Korea Food and Drug Administration) in 2005. However, it is necessary to evaluate the effectiveness and safety of robot surgeries compared to other comparable surgical procedures, considering the issues of high costs and the monopoly situation in robot surgery. To prevent the abuse of discreet DaVinci surgeries being performed for unverified indications and to perform correct medical examinations by considering the clinical characteristics of patients rather than the convenience of investigators, the present study was done with the goal of performing a health technology assessment study with regard to the safety and effectiveness of robot surgeries by reflecting the national status of Korea in order to provide correct information to the general population and to provide evidence that is necessary for the establishment of policies by decision-makers.

Authors' conclusions
Robot surgeries were still an expensive form of surgery compared to conventional surgeries and there was a large gap from the aspect of the patient’s financial burden since the surgeries were not covered by insurance payment, but when the surgeries were evaluated from the currently acquired evidence, the claimed evidence for the significantly large cost effectiveness of the treatment was found to be low. Even without enough accumulation of evidence for the benefits of robot surgeries, the performance of robot surgeries in Korea has been performed frequently compared to most other nations. If robot surgeries are introduced in Korea without certain considerations, it can be economically burdensome to the general population, and it can have harmful effects on their health. Therefore, the related medical staff should select a surgical method in an objective and neutral manner by considering the clinical characteristics of the patient who will receive the surgery, and precise information has to be delivered to the patients to help them select the appropriate surgical procedures. For the correct settlement of robot surgeries in Korea, it is necessary to provide precise information regarding robot surgery through a merit and demerit evaluation that is done with currently performed comparative surgical procedures. For that purpose, the performance of clinical studies that are equipped with a standardized clinical research design is considered to be necessary. Especially for robot surgery fields which are being actively performed but with limited clinical studies that can help in determining its effectiveness, the provision of surgical evidence by performing clinical research is relatively urgent. 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 setting upper and lower limits for the costs of introducing a robot surgical system and the surgical cost of the surgery. In the case of surgery that is performed widely with a sufficient amount of evidence (e.g. prostatectomy), a guideline has to be established to determine which type of patients will be benefited by the performance of the surgery. In the case of newly developing robot surgeries with less evidence supporting their use, the surgeries should be performed under a well-designed clinical study plan rather than be indiscriminantly performed at the patients’ expense, in order to reduce the cost of the patients’ financial burden and to accumulate evidence for the benefits of the surgeries. Especially, since the studies that have been carried out with the result variables that can correctly determine the effectiveness and safety of the surgery are limited, high quality clinical studies should be performed 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 the comparable surgical procedures to provide evidence for the general population to help them select a more economically desirable surgical procedure.
Other educational programs and quality management programs 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 the established indications in order to properly introduce robot surgeries in Korea.

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**Address for correspondence**
National Evidence-based Healthcare Collaborating Agency (NECA), Changkyung B/D 9F, Wonnam-dong 28-7, Jongnogu, Seoul, South Korea Email: hta_neca@neca.re.kr

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