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Seo Y[1], Sim K[1], Park E[2], Huh J[1], Park J[3]
1. *Busan veterans hospital, Korea,* ***2.*** *Busan Baptist Hospital, Korea,* ***3.*** *Busan St. Mary medical center, Korea.*

THE EFFICACY OF EARLY ARTIFICIAL SPHINCTER INSERTION FOR THE TREATMENT OF INCONTINENCE AFTER RADICAL PROSTATECTOMY.

Hypothesis / aims of study
After radical prostatectomy, Incontinence is common complication and urinary artificial sphincter is currently the gold standard treatment. But usually, the patient should be waited for 6 to 12 month after operation until the symptom improved. This complication generates important deterioration in the quality of life and 1 year is too long for just waiting. We retrospectively reviewed for the efficacy and the satisfaction of patients who had early artificial urinary sphincter insertion.

Study design, materials and methods
From March 2007 to December 2010, 13 patients with post-prostatectomy incontinence were enrolled on this study. Those patients had severe incontinence symptom, they used more than 2 pads per day after 1 month later from laparoscopic radical prostatectomy. Also all of them would like to take artificial urinary sphincter insertion. We divided early operation group (N= 6) and delayed operation group (N= 7). We got informed consent form all patient. We performed early sphincter placement after 3 month for early operation group. For delayed operation group, we operated after 1 year's waiting. Two patients among them exclude from the study. Because one of the patient improved incontinence to wet less than 1 pad per day and the other patient did not want to get the operation despite of severe incontinence. After artificial urinary sphincter insertion, continence was assessed 24 hours after catheter removal. Monthly follow up visits were done. After 3 months later we assessed recovery as the number of pads needed per day and checked patients satisfaction. Questionnaire was conducted to determine patient's satisfaction.

Results
There were no other statistically significant differences between two groups, including mean age (68.2 years, range 59 to 71), mean follow up (duration 16.3 months), median preoperative quality of life index (4, range 2 to 6), mean preoperative pads daily (4.5 ± 2.4) and mean preoperative Valsalva leak point pressure (45.7 ± 19.3 cmH_2O). There was no significant complication on early operation group, except one patient had to remove implant due to infection and reinsert after 6 months. According to delayed group date, if sphincter insertion delayed to one year, one of six patients (16.7%) might be improved, but it was not complete dry.
In the early operation group, the mean postoperative pads daily was 0.6, mean quality of life index 1. In the delayed operation group, the mean postoperative pads daily was 0.8, mean quality of life index 1. There were no other statistically significant differences. In the early operation group, all patients reported satisfaction with the artificial urinary sphincter and 83.3% stated that they would recommend or had recommended the artificial urinary sphincter to the other patients. In retrospect, 100% of the patients would have the artificial urinary sphincter placed again. But for the delayed operation group, satisfaction with the artificial urinary sphincter was 80% and 60% stated that they would recommend or had recommended the artificial urinary sphincter to the others. In retrospect, 80% of the patients would have the artificial urinary sphincter placed again, and all patients would like to take operation earlier.

Interpretation of results
Due to the improvement of surgical techniques like laparoscopy and robotic surgery, incontinence after radical prostatectomy was decreased. It was reported about 20% before, but it was 5-10% nowadays. Most patients with incontinence, got continence within one or two months, but severe cases were not got continence till after 3 month. Most of the severe cases continued incontinence even after 1 year. It is very long period to wait for artificial urinary sphincter insertion. About 3 months later from laparoscopic or robotic radical prostatectomy, the patient who use two or more pad per day, early artificial urinary sphincter insertion was recommended and it resulted good outcome and high satisfaction of patients.

Concluding message
The satisfaction of patients with the artificial urinary sphincter for post-prostatectomy incontinence is uniformly high. Although postoperative continence was not 100%, relative improvement in continence was the most significant factor affecting patient perceived outcome. Therefore early artificial urinary sphincter insertion was recommended for the patients who use two or more pads per day. It brings good outcome and high satisfaction of the patients. It need to multicenter study for developing guideline of early artificial urinary sphincter insertion.

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Is this a clinical trial?	**Yes**
Is this study registered in a public clinical trials registry?	**No**
Is this a Randomised Controlled Trial (RCT)?	**No**
What were the subjects in the study?	**HUMAN**
Was this study approved by an ethics committee?	**No**
This study did not require ethics committee approval because	**This study is concerned with only time of treatment, the treatment method is same.**
Was the Declaration of Helsinki followed?	**Yes**
Was informed consent obtained from the patients?	**Yes**