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Randomized Control Trial; In cases of extra-peritoneal approach of either laparoscopic radical prostatectomy or robotic assisted laparoscopic radical prostatectomy. Is routine cystography necessary?

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Abstract

Objective: To evaluate the necessity of routine cystography prior to removal of urinary catheter after postoperative day 7 in prostate cancer patients, who underwent, either extraperitoneal laparoscopic radical prostatectomy (ELRP), or extraperitoneal robotic assisted laparoscopic radical prostatectomy (ERALRP).

Materials and Methods: Between May 2008 and March 2009. Patients who underwent either ELRP or ERALRP will be randomized into 2 groups by sealed envelops. In control group, patients will be evaluated by cystography at postoperative day 7. In study group, urethral catheter will be removed on postoperative day 7 without cystography. Patients of both groups will be discharged and followed up at postoperative day 14 and 28 for evaluation by ultrasound, IPSS and clinical symptoms.

Results: This study enrolls total 70 patients who underwent either ELRP or ERALRP. There were 35 patients in control group and 35 patients in study group. 4 of 35 patients were found to have contrast leakage during cystography. There was no other significant difference of clinical symptoms, IPSS between both groups. But, there was significant difference of catheterization time. ($p < 0.05$).

Conclusions: Routine cystography on postoperative day 7 seems to be not beneficial to the patients underwent extraperitoneal approach for both laparoscopic radical prostatectomy and robotic assisted laparoscopic radical prostatectomy.

Keywords: prostatic neoplasm, cystography, laparoscopic radical prostatectomy,

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Introduction

Prostate cancer is the most common non-cutaneous cancer and the second-leading cause of death from cancer in men in the United States [1]. Since the introduction of PSA testing, the incidence of local-regional disease has increased, whereas the incidence of metastatic disease has decreased [2].

Nonpalpable cancers (AJCC clinical stage T1c) now account for 75% of newly diagnosed disease [3]. Concomitant with these changes, the percentage of men treated for clinically localized disease with radical prostatectomy increased substantially [4].

Radical prostatectomy is the gold standard for treatment of localized disease. Open radical prostatectomy has been accepted as one of the standard treatments in clinically localized prostate cancer for many decades [5]. In recent years, the laparoscopic and robotic assisted radical prostatectomy has been developed as another approach to performing the operation. It may be associated with less bleeding, better visualization, less postoperative pain, and shorter convalescence than the standard open approach.

Laparoscopic prostatectomy can be performed through a transperitoneal or extraperitoneal approach.

Early catheter removal at 3-4 days has been attempted in open prostatectomy series [6] but acute urinary retention occurred in 19.3% of patients. In laparoscopic radical prostatectomy, early catheter removal has been attempted. However, acute urinary retention [7] also occurred in 10.4% of patients.

Removal of the catheter before 7 days is associated with a 15% to 20% risk of urinary retention. So, at postoperative day 7, cystography will be done for evaluation of vesicourethral anastomosis. If it has no contrast extravasation, a catheter will be removed. In cases of extravasation of contrast, a catheter will be retained for some days.

So, in Siriraj Hospital, routine cystography is done at postoperative day 7. If contrast extravasation is not shown, a catheter will be removed. But if it shows contrast extravasation, catheter will be retained.

At present time, our center has prostate cancer patients who underwent laparoscopic radical prostatectomy and robotic assisted laparoscopic radical prostatectomy, totally more than 700 cases in few years, ago. Because of improved laparoscopic surgical technique and more experiences, numbers of patients who have anastomotic contrast extravasation decrease, and other complications after catheter removal such as fever, gross hematuria, acute urinary retention are not severe. Almost of patients will be discharged without catheter in postoperative day 7, so the necessaries of cystography should be evaluated.

Materials and Methods

In this study, patients who underwent either extraperitoneal laparoscopic radical prostatectomy (ELRP) or extraperitoneal robotic assisted laparoscopic radical prostatectomy (ERALRP) will be randomized in 2 groups by sealed envelops.

The protocol was reviewed and approved by Siriraj Ethics Committee.

In control group, patients will be evaluated by cystography at postoperative day 7. The cystography is taken under fluoroscopic control. The bladder is filled with contrast agent 25 cc in normal saline 125 cc until the patient felt a sense of fullness and slight discomfort. If contrast extravasation is not shown, a catheter will be removed. But if it shows contrast extravasation, a catheter will be retained.

In study group, catheter will be removed in postoperative day 7 without cystography.

Inclusion criteria includes localized prostate cancer patients who underwent either ELRP or

ERALRP, which surgical technique of vesicourethral anastomosis is interrupted suture by using polyglactin 2/0 for 6 stitches. All operations were done by single surgeon (Srinualnad S).

Exclusion criteria includes prostate cancer patients who underwent either ELRP or ERALRP which have proved urinary leakage from surgical drain(Cr from content > 10 times of serum Cr), rectal injury, ureteric injury, enlarge prostate gland (>100 g).

Patients in both groups will be discharged and followed up at postoperative day 14 and 28.

At postoperative day 14, both groups will be evaluated pelvic collection by transabdominal ultrasound, other complications such as fever, gross hematuria, acute urinary retention will be evaluated at the same time.

At postoperative day 28, IPSS score and incontinent will be evaluated, the patients will be asked for using pads /day.

Outcome is overall complications within 1 month after operation compared between both groups of patients.

Statistical analysis

Data was evaluated by Chi-square test, Fisher exact test and Unpaired t-test.

Body temperature, IPSS and number of diapers were evaluated by Unpaired t-test.

Hematuria, acute urinary retention and pelvic collection were evaluated by Fisher exact test.

Catheterization time was evaluated by Chi-square test for trend.

Sample size was calculated by using equation formula for test equivalence.

In this research, it must be at least 35 patients each groups for detection difference of catheterization time.

Results

In 10 months, this study enrolls total 70 patients who underwent either extraperitoneal laparoscopic radical prostatectomy (ELRP) or extraperitoneal robotic assisted laparoscopic radical prostatectomy (ERALRP) in Siriraj Hospital.

28 patients (40%) who underwent extraperitoneal laparoscopic radical prostatectomy (ELRP)

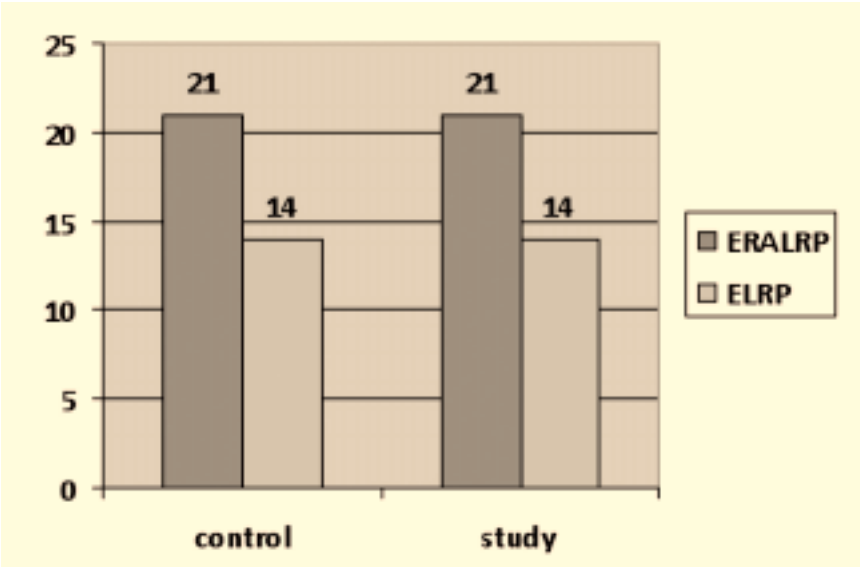

Figure 1 *Show type of operation*

and 42 patients (60%) who underwent or extra-peritoneal robotic assisted laparoscopic radical prostatectomy (ERALRP).

35 patients (50%) in control group and 35 patients (50%) in study group.

Demographic data was shown as table 1.

There were some complications such as 1 rectal injury (1.4%) which was repaired by simple suture and continued laparoscopic prostatectomy, but the patient was excluded from the study. One patient was proved urinary leakage from surgical drain and was excluded from study. One patient had post-operative pulmonary embolism and be treated by intravenous heparin, and clinical improve in few days, later and was included in the research.

In postoperative day 7, no immediate compli-cation was happened after remove urethral catheter in both groups. All patients can be discharged to home.

In Control group, 4 patients were found to have contrast leakage during cystography. At postoperative day 14, repeat cystography was done. It showed no contrast leakage. Urethral catheter was removed.

In postoperative day 14, the results showed 2 patients had fever, 1 patient had gross hematuria but none had urinary retention. Transabdominal ultrasound was done and shown right paravesical collection in one patient, size 4x5 cm. Conservative management was done and no clinical significance in later stage, as Table 2.

In postoperative day 28. As shown in Table 3, it shows mean number of diapers, IPSS, and cathe-terization time. There is no other significant difference of clinical symptoms, IPSS between both groups. But, there is significant difference of catheterization time. ($p < 0.05$)

Discussions

Extraperitoneal laparoscopic radical pros-tatectomy is feasible option of treatment for patients

Table 1 *Demographic data*

Mean ± SD	Control	Study	P
Age (years)	64.7 ± 1.4	63.9 ± 1.3	NS
PSA (ng/dl)	24.5 ± 8.8	19 ± 5.3	NS
Weight of prostate gland (g)	44.5 ± 3.2	40.9 ± 2.7	NS
Blood loss (ml)	510 ± 87.8	451.4 ± 53.2	NS
Operative time (min)	168.7 ± 9.3	167 ± 10.9	NS

Table 2 *Postoperative day 14*

Complications	Control	Study	P
Fever	0	2 (0.06%)	NS
Hematuria	1 (0.03%)	1 (0.03%)	NS
AUR	1 (0.03%)	0	NS
Pelvic collection	0	1 (0.03%)	NS

Table 3 *Postoperative day 28.*

Mean ± SD	Control	Study	P
Number of diapers (pads/day)	2.69 ± 0.3	2.32 ± 0.3	0.419
IPSS	15.97 ± 1.0	15.96 ± 1.3	0.996
Catheter time (days)	7.8 ± 0.4	7 ± 0.0	0.041

with localized prostate cancer. There is no doubt that patients can gain the benefit of a minimally invasive procedure.

In Thailand, Nualyong et al firstly reported transperitoneal laparoscopic radical prostatectomy [8]. Subsequently, there was a report of extraperitoneal approach. Extraperitoneal laparoscopic radical prostatectomy is as good as open retropubic radical prostatectomy [9]. Patients who undergo extraperitoneal laparoscopic radical prostatectomy have a lower chance of getting transfusion with equal oncological outcomes and quality of life to those undergoing open radical prostatectomy in the early postoperative period [9].

It is our belief that cystography is not useful because of improved laparoscopic surgical technique and more experiences, numbers of patients who have anastomotic contrast extravasation decrease, and other complications after catheter removal such as fever, gross hematuria, acute urinary retention are not severe. Furthermore, if cystography is not done, it will reduce cost of hospitalization.

In this study, the authors use double blind randomized control trial to evaluate the necessity of routine cystography prior to removal of urinary catheter after postoperative day 7 in prostate cancer patients, who underwent, either extraperitoneal laparoscopic radical prostatectomy (ELRP), or extraperitoneal robotic assisted laparoscopic radical prostatectomy (ERALRP).

In Control group (Patients with cystography) the average catheterization time was significantly longer than in the Study group (7.8±0.4 days in Control group and 7±0.0 days in Study group, $p < 0.05$). But, there was no other significant difference of clinical symptoms, IPSS, complications such as fever, acute urinary retention, incontinence, hematuria and pelvic collection between both groups.

This means that cystography is unintentionally prolonged urethral catheterization time. Therefore this should be abandoned in a straight forward care of urethrovesical anastomosis during ELRP or ERALRP.

The result of such a study depends on the skill and experience of surgeon in each institute. However, long-term follow up is needed to evaluate the patients' quality of life including incontinence.

Conclusions

Routine cystography on postoperative day 7 seems to be not beneficial to the patients underwent extraperitoneal approach for both laparoscopic radical prostatectomy and robotic assisted laparoscopic radical prostatectomy.

Conflict of interest

None declared

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