Examination of necessity for pelvic drain placement after robot-assisted radical prostatectomy

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Abstract

Purpose

Radical prostatectomy is the gold standard treatment for clinically localised prostate cancer. Pelvic drain (PD) placement is commonly performed after RARP to prevent the formation of urinary cysts, pelvic hematomas and lymphoceles that would require further treatment. RARP has been reported to have few perioperative complications, and the need for PD placement is not clear. This study aimed to assess the need for PD placement after robot-assisted radical prostatectomy (RARP).

Method

This retrospective uncontrolled before-after study analysed the effect of PD placement on postoperative complications in patients who underwent RARP between May 2009 and April 2018.

Results

All patients prior to October 1, 2016 had a PD placed; those after did not. Of the 308 study patients, 231 received a PD (PD group) and 77 did not (ND group). The incidence of ileus, urinary tract infection and anastomotic leak did not differ significantly between the groups; nor did the incidence of asymptomatic and symptomatic lymphocele at 2 weeks and 1 year after surgery. Multivariate analysis showed that lymph node dissection is a predictor of asymptomatic lymphocele development two weeks after surgery.

Conclusion

PD placement is not necessary after RARP. Future large-scale studies are required to identify patients that would benefit from PD placement.

Introduction

Prostate cancer is the most common cancer and second leading cause of cancer-related mortality in men (1). Radical prostatectomy (RP) is the gold standard treatment for clinically localised prostate cancer (2). In addition to open radical prostatectomy (ORP) and laparoscopic radical prostatectomy, robot-assisted RP (RARP) has become widely used in recent years and is often the first choice of treatment (3, 4). Pelvic drain (PD) placement is commonly performed after RARP to prevent the formation of urinary cysts, pelvic hematomas and lymphoceles that would require further treatment. RARP has the same oncological outcome as ORP (5–7) and is associated with shorter operation time and length of hospital stay, less bleeding and higher rate of erectile function improvement (7–10). This raises a question regarding the need for routine pelvic drainage after RARP. After experiencing two cases of ileus that may have been due to PD placement, we have not been placing PDs. Here, we present an uncontrolled before-after study that examined outcome of PD placement, focusing on prevention of lymphoceles and other complications.

Materials And Methods
This study was approved by the Medical Ethics Committee of our University. We retrospectively reviewed the charts of all patients who underwent transperitoneal RARP at our University Hospital between May 2009 and April 2018 to record and analyse relevant data. PDs were routinely placed in all patients prior to October 1, 2016; they were not placed afterward. RARP was performed in 308 patients during the study period. The PD group was comprised of 231 patients and the no PD (ND) group was comprised of 77.

Preoperative evaluation included digital rectal examination, transrectal ultrasonography, measurement of serum prostate specific antigen (PSA) level and 10–12-core systematic prostate biopsies for cancer detection; cancer staging was conducted using computerised tomography (CT), magnetic resonance imaging (MRI) and bone scintigraphy. CT or MRI was performed approximately 2 weeks and 1 year after RARP to evaluate the presence of pelvic fluid retention. The need for and extent of lymph node dissection and use of nerve-sparing technique were at the discretion of the attending surgeon.

The collected medical data included age, body mass index (BMI), serum PSA level, prostate volume (PV), prostate biopsy pathology, clinical stage, imaging findings and surgical details. Pelvic fluid retention was determined using triaxial ellipsoid approximation. Complications were graded according to the extended Clavien–Dindo system: asymptomatic lymphocele was classified as grade 1 and symptomatic lymphocele was classified as grade ≥ 3 (11).

Statistical analyses were performed using SPSS software version 17.0 (IBM Corp., Armonk, NY, USA) and Prism software version 5 (GraphPad Software, San Diego, CA, USA). The chi-square and Mann–Whitney U tests were used to compare data between groups. Binomial logistic regression was used for multivariate analyses. P < 0.05 was considered significant.

**Results**

RARP was performed in 308 patients during the study period. The PD group was comprised of 231 patients and the no PD (ND) group was comprised of 77. Table 1 shows the patient characteristics of the groups. The median age at time of surgery was significantly lower in the PD group than the ND group (66 years and 68 years, respectively; p = 0.007). Furthermore, the median preoperative PSA level was significantly lower in the PD group than the ND group (6.8 ng/mL and 5.8 ng/mL, respectively, p = 0.03). There were no significant differences between the two groups in median BMI, biopsy Gleason score (GS), clinical stage, D'Amico risk classification, history of abdominal surgery, proportion of patients receiving neoadjuvant androgen deprivation therapy, or median estimated PV.
| Variable                                | PD   | ND   | P  |
|-----------------------------------------|------|------|----|
| Number of patients                      | 231  | 77   |    |
| Median age at surgery, years (range)    | 66   | 68   | 0.007 |
| Median BMI, kg/m² (range)               | 23.6 | 23.5 | 0.73 |
| Preoperative PSA level, ng/mL (range)   | 6.8  | 5.8  | 0.03 |
| Biopsy GS (%)                           |      |      | 0.81 |
| ≤ 6                                     | 75 (32.5) | 22 (28.6) |    |
| 7                                       | 104 (45)  | 37 (48.1)  |    |
| ≥ 8                                     | 52 (22.5) | 18 (23.4)  |    |
| Clinical stage (%)                      |      |      | 1   |
| ≤ T2                                    | 219 (94.8) | 73 (94.8) |    |
| ≥ T3                                    | 12 (5.2)  | 4 (5.2)   |    |
| D’amico risk classification (%)         |      |      | 0.98 |
| Low                                    | 62 (26.8) | 21 (27.3) |    |
| Intermediate                            | 91 (39.4) | 31 (40.3) |    |
| High                                   | 78 (33.8) | 25 (32.5) |    |
| History of abdominal surgery (%)        |      |      | 0.6 |
| +                                      | 94 (40.7) | 34 (44.2) |    |
| -                                      | 137 (59.3) | 43 (55.8) |    |
| Neoadjuvant ADT (%)                     |      |      | 0.12 |
| +                                      | 46 (19.9) | 9 (11.7)  |    |
| -                                      | 185 (80.1) | 68 (88.3) |    |

PD: pelvic drain; ND: no pelvic drain; BMI: body mass index; PSA: prostate specific antigen; GS: Gleason score; ADT: androgen deprivation therapy; PV: prostate volume
Table 2 shows the perioperative and pathological outcomes of the two groups. The PD group had a significantly higher proportion of patients who underwent pelvic lymph node dissection (PLND) (48.1% vs. 24.7%, \( p < 0.001 \)) and higher median estimated blood loss (100 mL vs. 80 mL, \( p = 0.03 \)). The median length of hospital stay was significantly longer in the PD group (6.8 days vs. 5.8 days, \( p < 0.001 \)). There were no significant differences between the two groups in median operation time, pathological GS, pathological stage, median volume of resected prostate, median length of urinary catheter placement period, or proportion of patients who underwent nerve-sparing surgery, received a complete resection, or had extraprostatic extension. The incidence of complications, including ileus, urinary tract infection (UTI) with fever and anastomotic leak, did not significantly differ between the two groups; nor did the incidence of asymptomatic and symptomatic lymphocele at 2 weeks and 1 year after surgery.
| Variable                                      | PD     | ND     | P     |
|----------------------------------------------|--------|--------|-------|
| Number of patients                           | 231    | 77     | 0.3   |
| Median operating time, minute (range)        | 234 (138–398) | 239 (177–352) | 0.3   |
| Median console time, minute (range)          | 180 (102–350) | 176 (123–306) | 0.74  |
| Median estimated blood loss, mL (range)      | 100 (0-1350) | 80 (0-510) | 0.03  |
| Pathological GS (%)                          |        |        | 0.045 |
| No malignancy                                | 10 (4.3) | 1 (1.3) |       |
| ≤ 6                                          | 58 (25.1) | 11 (14.3) |       |
| 7                                            | 126 (54.5) | 58 (75.3) |       |
| ≥ 8                                          | 17 (7.4) | 7 (9.1) |       |
| Unknown                                      | 20 (8.7) | 0 (0)  |       |
| Pathological stage (%)                       |        |        | 0.18  |
| ≤ T2                                         | 191 (82.7) | 58 (75.3) |       |
| ≥ T3                                         | 40 (17.3) | 19 (24.7) |       |
| Pelvic lymph node dissection (%)              |        |        | < 0.001 |
| None                                         | 120 (51.9) | 58 (75.3) |       |
| Limited or extended                          | 111 (48.1) | 19 (24.7) |       |
| Nerve sparing (%)                            |        |        | 0.22  |
| None                                         | 42 (18.2) | 9 (11.7) |       |
| Limited or bilateral                         | 189 (91.8) | 68 (88.3) |       |
| Median hospital stay, days (range)           | 15 (9–48) | 12 (9–25) | < 0.001 |
| RM                                           |        |        | 0.062 |
| 0                                            | 194 (84.0) | 57 (74.0) |       |
| 1                                            | 37 (16.0) | 20 (26.0) |       |

GS: Gleason score; RM: resection margin; EPE: extraprostatic extension; PV: prostate volume
| Variable                                      | PD       | ND       | P  |
|----------------------------------------------|----------|----------|----|
| EPE                                          |          |          | 0.19 |
| 0                                            | 199 (86.1) | 62 (80.5) |    |
| 1                                            | 29 (12.6)  | 15 (19.5) |    |
| X                                            | 3 (1.3)   | 0 (0)    |    |
| Median removed PV, ml (range)                | 37 (15–87) | 38 (18–113) | 0.3 |
| Ileus (%)                                     | 8 (3.5)  | 1 (1.3)  | 0.46 |
| Febrile urinary tract infection (%)           | 3 (1.3)  | 0 (0)    | 0.58 |
| Anastomotic leak (%)                          | 10 (4.3) | 4 (5.2)  | 0.76 |
| Median urinary catheter placement period, day (range) | 7 (5–41) | 7 (6–21) | 0.055 |
| Average liquid storage for 2 weeks after surgery, ml (range) | 8.9 (0-229) | 10.9 (0-210) | 0.55 |
| Average liquid storage for 1 year after surgery, ml (range) | 1.4 (0-232) | 0 | n.d. |
| Asymptomatic lymphocele for 2 weeks after surgery (%) | 29 (12.6%) | 12 (15.6%) | 0.56 |
| Asymptomatic lymphocele for 1 year after surgery (%) | 3 (1.3%) | 0 | n.d. |
| Symptomatic lymphocele (%)                    | 1 (0.4%) | 0 | n.d. |

GS: Gleason score; RM: resection margin; EPE: extraprostatic extension; PV: prostate volume

Table 3 shows the results of the univariate and multivariate analyses for predictors of asymptomatic lymphocele 2 weeks after surgery. Significant univariate predictors included BMI < 25 kg/m² (p = 0.04), biopsy GS ≥ 8 (p = 0.03), pelvic lymph node dissection (p < 0.001) and pathological GS ≥ 8 (p = 0.03). In the multivariate analyses, the only significant independent predictor was pelvic lymph node dissection (p < 0.001).
Table 3
Analyses for prediction of asymptomatic lymphocele for 2 weeks after surgery

|                                | Univariable analysis |                                      | Multivariable analysis |                                      |
|--------------------------------|----------------------|---------------------------------------|------------------------|---------------------------------------|
|                                | P        | Odds ratio* | P        | Odds ratio* |
| age (≥ 70 vs < 70 years)        | 0.83    | 0.94        |          |            |
| BMI (≥ 25 vs < 25 kg/m2)        | 0.09    | 0.57        | 0.08    | 0.55        |
| PSA (≥ 10 vs < 10 ng/ml)        | 0.71    | 1.14        |          |            |
| Prostate volume (≥ 30 vs < 30 ml) | 0.52    | 0.81        |          |            |
| Biopsy GS (≥ 8 vs < 8)          | 0.1     | 1.65        | 0.351    | 1.37        |
| Clinical stage (≥ cT3 vs < cT3) | 0.72    | 0.79        |          |            |
| Neoadjuvant ADT (yes vs no)     | 0.41    | 0.73        |          |            |
| D'Amico's risk classification (high vs low, intermediate) | 0.4 | 1.27 |          |            |
| History of abdominal surgery (yes vs no) | 0.46 | 0.81 |          |            |
| Operating time (≥ 240 vs < 240 minutes) | 0.28 | 1.35 |          |            |
| Console time (≥ 180 vs < 180 minutes) | 0.37 | 1.28 |          |            |
| Bleeding volume (≥ 150 vs < 150 ml) | 0.08 | 1.63 | 0.054 | 1.75 |
| Nerve sparing (yes vs no)       | 0.6     | 1.22        |          |            |
| Lymph node dissection (yes vs no) | 0.001 | 2.47        | 0.016 | 2.08        |
| Pathological GS (≥ 8 vs < 8)    | 0.07    | 2.27        |          |            |

BMI: body mass index; PSA: prostate specific antigen; ADT: androgen deprivation therapy; GS: Gleason score

*The odd ratio was described using the latter in parentheses as a reference.
| Pathological stage (≥ pT3 vs < pT3) | 0.34 | 1.38 |
| Pelvic drain (yes vs no) | 0.58 | 0.84 |
| Drainage volume the day before drain removal (≥ 100 vs < 100 ml) | 0.9 | 1.05 |

BMI: body mass index; PSA: prostate specific antigen; ADT: androgen deprivation therapy; GS: Gleason score

*The odd ratio was described using the latter in parentheses as a reference.

**Discussion**

PD placement after RP has previously been considered necessary (12). However, RP has changed significantly in recent years with the introduction of robot-assisted surgery. The reported incidence of post-RARP anastomotic leakage ranges between 0.1% and 6.7% (13–15) and the incidence of symptomatic lymphocele in patients undergoing RARP with extended pelvic lymph node dissection ranges between 1.2% and 5% (16–19). This study found similar anastomotic leak and symptomatic lymphocele rates (4.5% and 0.3%, respectively). In addition, the incidence of complications, such as ileus, UTI, anastomotic leakage and asymptomatic and symptomatic lymphocele did not differ according to PD placement, suggesting that routine PD placement is not necessary during RARP. Furthermore, the length of hospital stay was significantly shorter in the ND group.

We also found that lymph node dissection was the only significant independent predictor of postoperative asymptomatic lymphocele development. Previous reports have shown that lymphocele incidence increases after extended pelvic lymph node dissection and with the number of lymph nodes removed (20–24). Although PDs are placed to prevent lymphoceles, their absence did not predict asymptomatic lymphocele development two weeks after surgery in this study. A previous systematic review and meta-analysis reported that PD placement after RARP with extended pelvic lymph node dissection does not prevent symptomatic lymphocele or postoperative complications (25), which also suggests that PD placement after RARP is not required. However, PD placement cannot be deemed unnecessary in all cases. PD placement may still be beneficial in patients undergoing extended pelvic lymph node dissection and those who are administered perioperative prophylactic low-molecular-weight heparin.

This study has several limitations. The sample size may have been too small to determine significant differences between groups. In addition, the proportion of patients who underwent lymph node dissection and median intraoperative blood loss significantly differed between the two study groups. Larger
prospective studies and data from patients of other ethnic backgrounds are needed to confirm our findings. Future studies may indicate more clearly those patients who would benefit from PD placement.

**Conclusion**

PD placement after RARP did not affect the incidence of postoperative lymphocele development. Lack of a PD did not predict development of asymptomatic lymphocele two weeks after surgery. Future large-scale studies are required to identify patients that would benefit from PD placement.

**Declarations**

_Declarations_  
Not applicable

**Funding**

There was no funding support for this study.

**Conflicts of Interest**

All Authors declare that there are no potential conflicts of interest relevant to this article

**Availability of data and material**

The datasets of this study are available at the Department of Integrative Cancer Therapy and Urology, Kanazawa University Graduate School of Medical Science, Ishikawa, Japan.

**Ethics approval**

This study was approved by Medical Ethics Committee of Kanazawa University (No. 2016-328).

**Author contributions**

H.I. and Y.K. designed the experiments. H.I., T.M., R.N., T.M., Y.K., H.Y., M.I., S.K. and T.K. collected clinical data. H.I., Y.K., T.K., K.S., K.I. and A.M. analyzed the data. H.I., Y.K. and A.M. drafted and revised the manuscript. All authors read and approved the final version of the manuscript

**References**

1. Siegel RL, Miller KD, Jemal A. Cancer statistics, 2019. CA: a cancer journal for clinicians. 2019;69(1):7-34.

2. Mottet N, Bellmunt J, Bolla M, Briers E, Cumberbatch MG, De Santis M, et al. EAU-ESTRO-SIOG Guidelines on Prostate Cancer. Part 1: Screening, Diagnosis, and Local Treatment with Curative
3. Basto M, Sathianathen N, Te Marvelde L, Ryan S, Goad J, Lawrentschuk N, et al. Patterns-of-care and health economic analysis of robot-assisted radical prostatectomy in the Australian public health system. BJU international. 2016;117(6):930-9.

4. Hu JC, Gu X, Lipsitz SR, Barry MJ, D’Amico AV, Weinberg AC, et al. Comparative effectiveness of minimally invasive vs open radical prostatectomy. Jama. 2009;302(14):1557-64.

5. Hu JC, O’Malley P, Chughtai B, Isaacs A, Mao J, Wright JD, et al. Comparative Effectiveness of Cancer Control and Survival after Robot-Assisted versus Open Radical Prostatectomy. The Journal of urology. 2017;197(1):115-21.

6. Okegawa T, Omura S, Samejima M, Ninomiya N, Taguchi S, Nakamura Y, et al. Laparoscopic radical prostatectomy versus robot-assisted radical prostatectomy: comparison of oncological outcomes at a single center. Prostate international. 2020;8(1):16-21.

7. Yaxley JW, Coughlin GD, Chambers SK, Occhipinti S, Samaratunga H, Zajdlewicz L, et al. Robot-assisted laparoscopic prostatectomy versus open radical retropubic prostatectomy: early outcomes from a randomised controlled phase 3 study. Lancet (London, England). 2016;388(10049):1057-66.

8. Antonelli A, Palumbo C, Noale M, Porreca A, Maggi S, Simeone C, et al. Impact of Surgical Approach on Patient-Reported Outcomes after Radical Prostatectomy: A Propensity Score-Weighted Analysis from a Multicenter, Prospective, Observational Study (The Pros-IT CNR Study). Urologia internationalis. 2019;103(1):8-18.

9. Nyberg M, Hugosson J, Wiklund P, Sjoberg D, Wilderang U, Carlsson SV, et al. Functional and Oncologic Outcomes Between Open and Robotic Radical Prostatectomy at 24-month Follow-up in the Swedish LAPPRO Trial. European urology oncology. 2018;1(5):353-60.

10. Yun JE, Lee NR, Kwak C, Rha KH, Seo SI, Hong SH, et al. Clinical outcomes and costs of robotic surgery in prostate cancer: a multiinstitutional study in Korea. Prostate international. 2019;7(1):19-24.

11. Katayama H, Kurokawa Y, Nakamura K, Ito H, Kanemitsu Y, Masuda N, et al. Extended Clavien-Dindo classification of surgical complications: Japan Clinical Oncology Group postoperative complications criteria. Surg Today. 2016;46(6):668-85.

12. Walsh PC. Anatomic radical prostatectomy: evolution of the surgical technique. The Journal of urology. 1998;160(6 Pt 2):2418-24.

13. Jacobsen A, Berg KD, Iversen P, Brasso K, Roder MA. Anastomotic complications after robot-assisted laparoscopic and open radical prostatectomy. Scand J Urol. 2016;50(4):274-9.

14. Novara G, Ficarra V, Rosen RC, Artibani W, Costello A, Eastham JA, et al. Systematic review and meta-analysis of perioperative outcomes and complications after robot-assisted radical prostatectomy. European urology. 2012;62(3):431-52.

15. Ou YC, Yang CK, Chang KS, Wang J, Hung SW, Tung MC, et al. Prevention and Management of Complications During Robotic-assisted Laparoscopic Radical Prostatectomy Following...
16. Agarwal PK, Sammon J, Bhandari A, Dabaja A, Diaz M, Dusik-Fenton S, et al. Safety profile of robot-assisted radical prostatectomy: a standardized report of complications in 3317 patients. European urology. 2011;59(5):684-98.

17. Fischer B, Engel N, Fehr JL, John H. Complications of robotic assisted radical prostatectomy. World journal of urology. 2008;26(6):595-602.

18. GB DIP, Grande P, Mordasini L, Danuser H, Mattei A. Safety and Efficacy of Robot-assisted Radical Prostatectomy in a Low-volume Center: A 6-year Single-surgeon Experience. Anticancer research. 2016;36(8):4201-7.

19. Keskin MS, Argun OB, Obek C, Tufek I, Tuna MB, Mourmouris P, et al. The incidence and sequela of lymphocele formation after robot-assisted extended pelvic lymph node dissection. BJU international. 2016;118(1):127-31.

20. Capitanio U, Pellucchi F, Gallina A, Briganti A, Suardi N, Salonia A, et al. How can we predict lymphorrhoea and clinically significant lymphocelees after radical prostatectomy and pelvic lymphadenectomy? Clinical implications. BJU international. 2011;107(7):1095-101.

21. Gotto GT, Yunis LH, Guillonneau B, Touijer K, Eastham JA, Scardino PT, et al. Predictors of symptomatic lymphocele after radical prostatectomy and bilateral pelvic lymph node dissection. International journal of urology : official journal of the Japanese Urological Association. 2011;18(4):291-6.

22. Musch M, Klevecka V, Roggenbuck U, Kroepfl D. Complications of pelvic lymphadenectomy in 1,380 patients undergoing radical retropubic prostatectomy between 1993 and 2006. The Journal of urology. 2008;179(3):923-8; discussion 8-9.

23. Naselli A, Andreatta R, Introini C, Fontana V, Puppo P. Predictors of symptomatic lymphocele after lymph node excision and radical prostatectomy. Urology. 2010;75(3):630-5.

24. Seetharam Bhat KR, Onol F, Rogers T, Ganapathi HP, Moschovas M, Roof S, et al. Can we predict who will need lymphocele drainage following robot assisted laparoscopic prostatectomy (RALP)? J Robot Surg. 2019.

25. Zhong W, Roberts M, Saad J, Thangasamy I, Arianayagam R, Sathianathen N, et al. A systematic review and meta-analysis of pelvic drain insertion after robot-assisted radical prostatectomy. J Endourol. 2020.