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Original Article

The incidence of urologic complications requiring urologic procedure in radical hysterectomy and difference between abdominal radical hysterectomy and laparoscopic radical hysterectomy

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Synopsis
Previous studies have been insufficient to detect clinically significant difference in urologic complications between abdominal radical hysterectomy (ARH) and laparoscopic radical hysterectomy (LRH). It is clinically more

ABSTRACT

Objective: To evaluate the incidence of urologic complications requiring a urologic procedure during the perioperative period and compare the differences between abdominal radical hysterectomy (ARH) and laparoscopic radical hysterectomy (LRH).
Methods: We identified all Korean women who underwent radical hysterectomy (RH) between January 2006 and December 2019 using the National Health Insurance Service database. Complications requiring surgical intervention-based urologic procedures between ARH and LRH were investigated.
Results: A total of 12,068 patients were classified into the ARH group and 8,837 patients were classified into the LRH group. Urologic complications requiring urologic procedures occurred in 1,546 of 20,905 patients (7.40%) who underwent RH. The most common urologic procedure was double-J insertion (R326, 5.18%), followed by bladder repair (R3550, 0.90%). There was no significant difference in urologic complications requiring urologic procedures between the ARH and LRH groups (odds ratio [OR]=1.027; 95% confidence interval [CI]=0.925–1.141; p=0.612). The incidence of bladder repair (R3550) was significantly higher in patients who underwent LRH (OR=1.620; 95% CI=1.220–2.171; p<0.001). Urologic complications requiring urologic procedures were statistically higher in the LRH group during the first half (OR=1.446; 95% CI=1.240–1.685; p<0.001), but more in the ARH group during the second half (OR=0.696; 95% CI=0.602–0.804; p<0.001) of the study period.
Conclusion: There was no difference of urologic complications between ARH and LRH with regard to urologic procedures. The incidence of urologic procedures decreases with time in patients who underwent LRH.

Keywords: Uterine Cervical Neoplasm; Hysterectomy; Laparoscopy; Intraoperative Complications; Postoperative Complications; Big Data; Urologic Surgical Procedures

important to evaluate urologic complications that require urologic procedures rather than urologic complications alone. The incidence of urologic complications requiring urologic procedures related to radical hysterectomy was evaluated using data from the National Health Insurance Service. There was no difference in urologic complications between ARH and LRH.

Conflict of Interest
No potential conflict of interest relevant to this article was reported.

Author Contributions
Conceptualization: H.J.H.; Data curation: K.H., J.H.J.; Formal analysis: H.J.H.; Methodology: J.H.J.; Writing - original draft: H.J.H.; Writing - review & editing: K.H., K.B.W., H.J.H.

INTRODUCTION

Uterine cervical cancer is the fourth leading cause of cancer-related deaths among women [1]. Radical hysterectomy (RH) with bilateral pelvic lymph node dissection (LND) with or without para-aortic LND has been the preferred mode of treatment in women with early cervical cancer. Urinary tract injury is the most common and important complication of RH. Several urologic complications can occur after RH. RH requires processing of ureteral tunnel dissection in the cardinal ligament and freeing the ureter from the anterior parametrium after periureteral tissue dissection, which could increase the incidence of urinary tract injuries compared with simple hysterectomy [2].

RH can be performed via an open approach or using a laparoscopic/robotic approach. In the Laparoscopic Approach to Cervical Cancer (LACC) trial [3], the recurrence rate was higher in minimally invasive RH, including laparoscopic RH (LRH) and robotic RH (RRH), than abdominal RH (ARH). The use of LRH has continued to decrease since the LACC trial. However, whether there is a difference in surgery-related complications, including urinary tract injuries, between the patients who undergo ARH and those who undergo LRH still remains controversial. Although many studies have reported the incidence of perioperative urologic complications after RH, previous studies were limited in detecting the exact urologic complications owing to their retrospective nature and small sample size. Most retrospective studies [4-8] indicated that LRH and ARH did not show any difference in urologic complications. However, a meta-analysis [9,10] showed that the incidence of urologic complications was higher in LRH. Meta-analysis increases statistical power by integrating each study, but it is limited by data quality and heterogeneity among studies. Hwang et al. [11] analyzed perioperative urologic complications after RH using nation-wide population data; because the study was retrospective in nature and conducted based on the diagnostic code, the incidence rate may be underestimated than the actual case. It is clinically more important to evaluate urologic complications requiring urologic procedures rather than urologic complications alone.

Therefore, the objective of this study was to determine the incidence of urologic complications requiring urologic procedures related to RH and compare the differences between ARH and LRH using data from the National Health Insurance Service (NHIS).

MATERIALS AND METHODS

1. Study design and data source

This study was a retrospective observational study. We obtained the data of cervical cancer patients from the health insurance data filed for medical claim, which was extracted from the NHIS database (approval No. NHIS-2020-1-393). The Korean national healthcare system is applied to the entire population. The National Health Insurance (NHI) data is a public and centralized database containing all medical records, except for the procedures not covered by insurance, such as cosmetic or robotic surgery. The health information, including health screening, demographic variables, patient diagnosis, treatment, surgical history, prescription drugs, and mortality, of the entire population is coded and registered in this database. However, the NHI data does not include medical records such as cancer stage and laboratory results [12]. Disease codes are standardized according to the Korea Standard Classification of Disease-6 (KCD-6), which is a modification of the International Classification of Disease

and Related Health Problems, 10th edition, suited to Korean medical circumstances. Health Insurance Review & Assessment Service annually released procedure and operation codes.

2. Study population and variables

All Korean women who were diagnosed with uterine cervical cancer and underwent RH and pelvic or pelvic/para-aortic LND were identified from the NHIS database between January 2006 and December 2019. Newly diagnosed cervical cancer and type of RH was defined using disease codes listed in the claim data. KCD-6 code for uterine cervical cancer (C53: C530, C531, C538, C539) and operation codes (R 4154: RH and pelvic LND, R4155: RH and pelvic/para-aortic LND), respectively. The patients were categorized under the following age groups: <30, 31–40, 41–50, 51–60, 61–70, and >70 years.

Material cost code billed for laparoscopic surgery (N0031001) was used to identify the patients who underwent LRH. Because LRH was selected based on the code, and patients who switched from laparoscopy to laparotomy were classified as those who underwent LRH. The patients who were diagnosed with cervical cancer and underwent RRH were excluded because NHI did not cover the cost of robotic surgeries in South Korea.

Urologic procedures included the following: double-J insertion (R3262: cystoscopic, R3263: percutaneous, R3264: operative), ureteroneocystostomy (R3151: simple, R3153: with ureteral tailoring, R3154: using bladder flap), percutaneous nephrostomy (R3321), vesicovaginal fistula (VVF) repair (RA 164), ureteral dilatation (R3190: transurethral ureteral balloon dilatation, R3191: transurethral ureteral dilatation with balloon, R3192: percutaneous ureteral dilatation), bladder repair (R3550), end-to-end ureteroureterostomy (R3180). All urologic procedures during surgery and within 1 month after surgery were counted. VVF repair (RA 164) was counted for 1 month. Urologic procedures were used to estimate urologic complications related to RH (**Fig. 1**).

3. Statistical analysis

Categorical variables were expressed as numbers and percentages. Clinical characteristics for categorical variables were compared using the χ^2 test. All tests were 2-sided, and p-values of

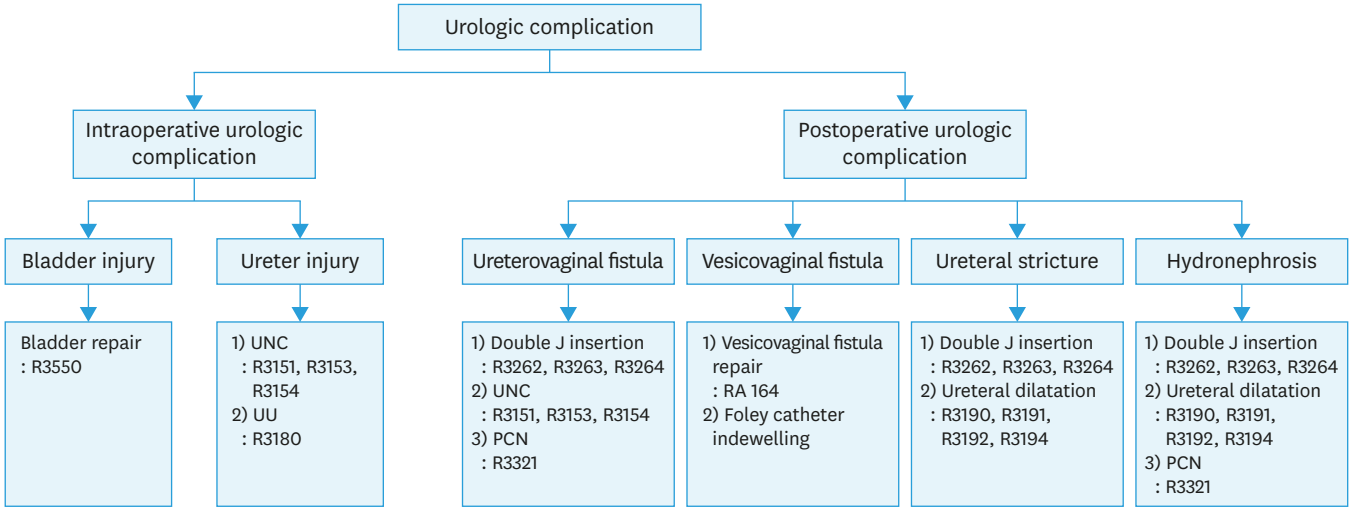

Fig. 1. Schematic association between urologic complications and related urologic procedures.
PCN, percutaneous nephrostomy; UNC, ureteroneocystostomy; UU, ureteroureterostomy.

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<0.05 were considered statistically significant. Odds ratio (OR) and 95% confidence interval (CI) were used to estimate the incidence of urologic procedures and compare LRH with ARH. Statistical analysis was performed using Microsoft Excel (2016) and MedCalc Statistical Software version 19.4 (MedCalc Software Ltd., Ostend, Belgium; http://www.medcalc.org;2020).

4. Ethics statement

The study was reviewed and approved by the Institutional Review Board of International St. Mary's Hospital, Catholic Kwandong University College of Medicine, Incheon, Republic of Korea (IS20EISI0040). We did not have to obtain informed consent from all subjects because this study used the secondary data of NHIS.

RESULTS

A total of 58,156 patients were diagnosed and hospitalized for uterine cervical cancer during the study period. We identified 20,905 patients with uterine cervical cancer who underwent RH; of them, 12,068 patients underwent ARH and 8,837 patients underwent LRH. The number of patients in the ARH group was higher than that in the LRH group (p<0.001). **Fig. 2** shows a change in the population with uterine cervical cancer who underwent RH in South Korea between 2006 and 2019. The total number of patients undergoing RH tends to decrease as time passes. The proportion of patients undergoing LRH increased from 2006 to 2017 and decreased after 2018 (LACC trial) compared with that of patients undergoing ARH. LRH/ARH ratio exceeded one since 2012 and fell below one in 2019. **Fig. S1** shows the age distribution among patients who underwent RH. The most common age group is 41–50 years (33.39%), followed by 50–60 years (24.6%) and 31–40 (20.23%). More patients aged <40 years underwent LRH than those aged >40 years.

Urologic procedures were administered to 1,546 of 20,905 patients (7.4%) who underwent either ARH or LRH. There was no difference in complications requiring urologic procedures between the ARH and LRH groups (p=0.612). The most common urologic procedure was double-J insertion (R326: 5.18%), followed by bladder repair (R3550: 0.90%), percutaneous nephrostomy (R3321: 0.49%), and ureteroneocystostomy (R315: 0.40%). The proportion of patients who received double-J insertion via a cystoscopic approach was 86.15%. When

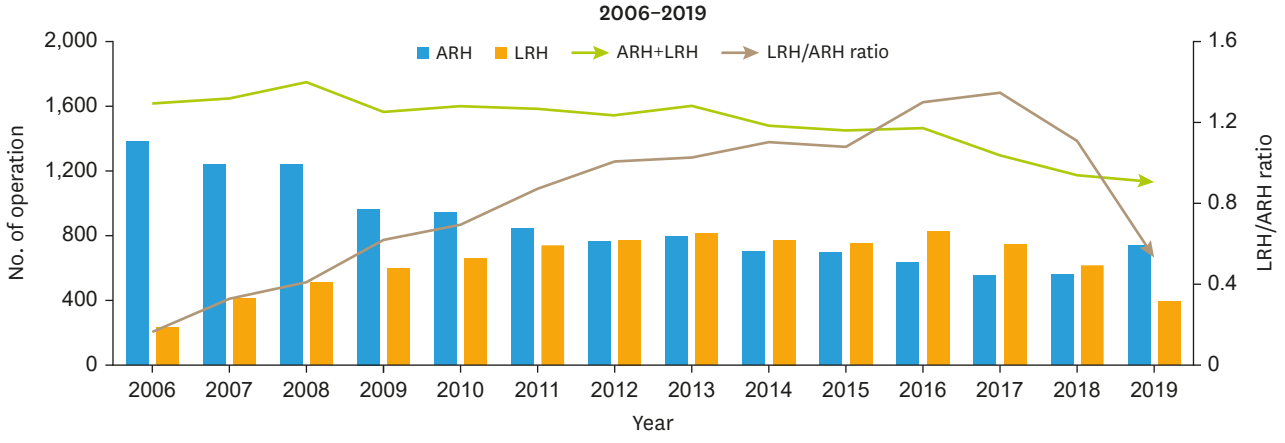

Fig. 2. LRH/ARH ratio and the annual number of patients who underwent radical hysterectomy between 2006 and 2019.
ARH, abdominal radical hysterectomy; LRH, laparoscopic radical hysterectomy.

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Table 1. Urologic procedure related to radical hysterectomy (n=20,905)

Urologic procedure	ARH (n=12,068)	LRH (n=8,837)	Total (n=20,905)	OR*	95% CI	p-value
Double-J insertion (R326)	620 (5.14)	463 (5.24)	1,083 (5.18)	1.021	0.902–1.155	0.743
Cystoscopic ureteral stent indwelling (R3262)	521 (4.32)	412 (4.66)	933 (4.46)	1.084	0.950–1.237	0.233
Percutaneous (R3263)	25 (0.21)	22 (0.25)	47 (0.22)	1.202	0.667–2.134	0.529
Operative (R3264)	45 (0.37)	12 (0.14)	57 (0.27)	0.363	0.192–0.687	0.002
Ureteroneocystostomy (R315)	55 (0.46)	28 (0.32)	83 (0.40)	0.695	0.441–1.096	0.118
Simple (R3151)	47 (0.39)	23 (0.26)	70 (0.33)	0.667	0.405–1.010	0.113
Ureteral tailoring (R3153)	2 (0.02)	1 (0.01)	3 (0.01)	0.683	0.062–7.531	0.755
Using bladder flap (R3154)	6 (0.05)	4 (0.05)	10 (0.05)	0.910	0.257–3.227	0.884
Percutaneous nephrostomy (R3321)	62 (0.51)	41 (0.46)	103 (0.49)	0.903	0.608–1.341	0.612
Ureteral dilatation (R319)	6 (0.05)	3 (0.03)	9 (0.04)	0.683	0.171–2.731	0.589
With balloon (R3191)	2 (0.02)	1 (0.01)	3 (0.01)	0.683	0.062–7.531	0.755
With percutaneous (R3192)	1 (0.01)	2 (0.02)	3 (0.01)	2.732	0.248–30.131	0.412
Vesicovaginal fistula (RA164)†	2 (0.02)	2 (0.02)	4 (0.02)	1.366	0.192–9.697	0.755
Bladder repair (R3550)	86 (0.71)	102 (1.15)	188 (0.90)	1.620	1.220–2.171	<0.001
Ureteroureterostomy (R3180)	52 (0.43)	24 (0.27)	76 (0.36)	0.629	0.388–1.022	0.061
Total	883 (7.32)	663 (7.50)	1,546 (7.40)	1.027	0.925–1.141	0.612

Values are presented as number (%).
ARH, abdominal radical hysterectomy; CI, confidence interval; LRH, laparoscopic radical hysterectomy; OR, odd ratio.
*OR for LRH compared to ARH; †Over a month after surgery.

analyzing each urologic procedure, the incidence of bladder repair (R3550) is significantly higher in patients who underwent LRH (OR=1.620; 95% CI=1.220–2.171; p<0.001), whereas the incidence of operative double-J insertion (R3264) is significantly higher in patients who underwent ARH (OR=2.75; 95% CI=1.456–5.208; p=0.002). No patients underwent VVF fistula repair (RA154) within a month after surgery. The details of urologic procedures are shown in **Table 1**.

Table 2 shows differences in the incidence of complications requiring urologic procedures according to age. Patients were classified as ≤40 years old and >40 years old. There was no significant difference in the overall incidence of urologic complications between ARH and LRH in the each age group. In the >40 age group, the incidence of bladder repair was higher (OR=1.751; 95% CI=1.274-2.405; p<0.001) in the LRH group. In the ≤40 age group, the incidence of double-J insertion using cystoscopy was higher (OR=1.353; 95% CI=1.005–1.823; p=0.047) in the LRH group. In the both group, operative double-J insertion was higher in the ARH group.

Table 2. OR of LRH for the risk of urologic procedures compared to ARH according to age (n=20,905)

Urologic procedure	Year of operation									
	≤40 yr					>40 yr				
	ARH	LRH	OR	95% CI	p-value	ARH	LRH	OR	95% CI	p-value
Double-J insertion (R326)	4.36	4.77	1.097	0.838–1.437	0.499	5.34	5.41	1.014	0.881–1.166	0.851
Cystoscopic ureteral stent indwelling (R3262)	3.21	4.30	1.353	1.005–1.823	0.047	4.61	4.79	1.042	0.898–1.209	0.587
Percutaneous (R3263)	0.24	0.13	0.536	0.134–2.146	0.378	0.20	0.29	1.473	0.779–2.784	0.233
Operative (R3264)	0.52	0.09	0.164	0.037–0.729	0.018	0.34	0.15	0.459	0.226–0.934	0.032
Ureteroneocystostomy (R315)	0.56	0.21	0.382	0.137–1.062	0.676	0.43	0.35	0.825	0.495–1.376	0.461
Simple (R3151)	0.48	0.21	0.446	0.157–1.268	0.130	0.37	0.28	0.756	0.428–1.136	0.336
Percutaneous nephrostomy (R3321)	0.20	0.26	1.289	0.393–4.228	0.676	0.60	0.54	0.903	0.592–1.377	0.473
Bladder repair (R3550)	0.59	0.77	1.290	0.649–2.566	0.468	0.74	1.29	1.751	1.274–2.405	<0.001
Ureteroureterostomy (R3180)	0.28	0.21	0.766	0.243–2.417	0.649	0.47	0.29	0.620	0.363–1.061	0.081
Total	5.99	6.21	10.4	0.823–1.315	0.742	7.58	7.89	1.044	0.928–1.175	0.473

Values are presented as percentage.
ARH, abdominal radical hysterectomy; CI, confidence interval; LRH, laparoscopic radical hysterectomy; OR, odd ratio.

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Table 3. OR of LRH for the risk of urologic procedures compared to ARH according to year of operation (n=20,905)

Urologic procedure	Year of operation									
	2006–2012					2013–2019				
	ARH	LRH	OR	95% CI	p-value	ARH	LRH	OR	95% CI	p-value
Double-J insertion (R326)	3.91	5.38	1.503	1.253–1.803	<0.001	7.08	5.13	0.710	0.600–0.841	0.001
Cystoscopic ureteral stent indwelling (R3262)	3.18	4.69	1.611	1.324–1.962	<0.001	6.11	4.64	0.747	0.625–0.894	0.001
Percutaneous (R3263)	0.18	0.41	2.324	1.117–4.836	0.024	0.26	0.12	0.475	0.178–1.268	0.137
Operative (R3264)	0.37	0.15	0.417	0.172–1.011	0.053	0.38	0.12	0.317	0.126–0.798	0.015
Ureteroneocystostomy (R315)	0.26	0.36	1.591	0.747–2.977	0.257	0.77	0.28	0.368	0.199–0.684	0.002
Simple (R3151)	0.24	0.23	1.011	0.454–2.252	0.979	0.62	0.28	0.458	0.242–0.868	0.017
Percutaneous nephrostomy (R3321)	0.45	0.66	1.597	0.954–2.673	0.075	0.62	0.31	0.491	0.263–0.917	0.026
Bladder repair (R3550)	0.49	1.12	2.487	1.599–3.870	<0.001	1.07	1.18	1.106	0.756–1.617	0.605
Ureteroureterostomy (R3180)	0.42	0.28	0.717	0.360–1.427	0.343	0.45	0.26	0.588	0.294–1.176	0.133
Total	5.52	7.80	1.446	1.240–1.685	<0.001	9.98	7.16	0.696	0.602–0.804	<0.001

Values are presented as percentage.
ARH, abdominal radical hysterectomy; CI, confidence interval; LRH, laparoscopic radical hysterectomy; OR, odd ratio.

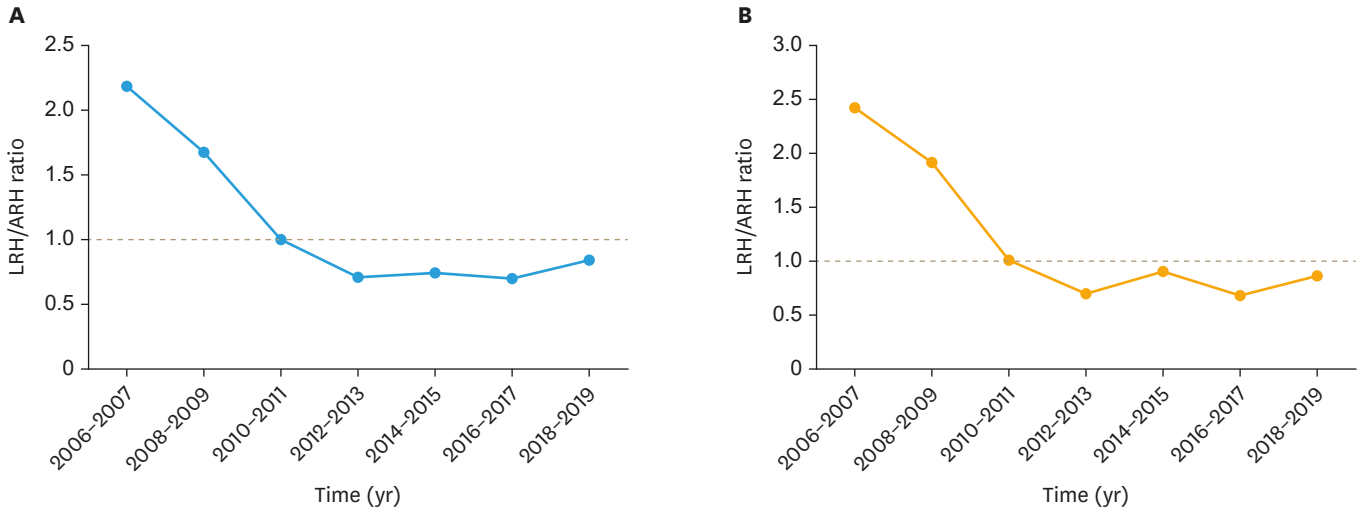

Fig. 3. The change in LRH/ARH ratio requiring urologic procedures. (A) Total urologic procedures and (B) cystoscopic ureteral stent indwelling.
ARH, abdominal radical hysterectomy; LRH, laparoscopic radical hysterectomy.

Table 3 shows the risk of urologic procedure based on the year of operation. It was divided into the first half (2006–2012) and second half (2013–2019) according to the year in which RH was performed. The proportion of urologic complications requiring urologic procedures was significantly higher in the LRH group during the first half (OR=1.446; 95% CI=1.240–1.685; p<0.001), but their proportion was even higher in the ARH group during the second half (OR=0.696; 95% CI=0.602–0.804; p<0.001). With regard to specific urologic procedures, the incidence of double-J insertion (OR=1.503; 95% CI=1.253–1.803; p<0.001) and bladder repair (OR=2.487; 95% CI=1.599–3.870; p<0.001) during the first half was higher in the LRH group. The incidence of double-J insertion (OR=0.710; 95% CI=0.600–0.841; p<0.001) and ureteroneocystostomy (OR=0.368; 95% CI=0.199–0.684; p<0.001) during the second half was higher in the ARH group. **Fig. 3** shows the LRH/ARH ratio for total urologic procedures and cystoscopic double-J insertion with time. Since 2012the LRH/ARH ratio decreased below 1.

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DISCUSSION

Previous studies that were conducted in a single hospital and focused on LRH-related perioperative complications reported that the incidence of urologic complications ranged from 4.40% to 6.85% [13,14]. According to large-scale comparative studies, which have been conducted on more than 200 patients and evaluated the perioperative complications related to RH, including ARH and LRH, the incidence of perioperative urologic complications ranged from 1.27% to 7.79% [4,5,7,15,16]. These studies are limited by their retrospective nature. One nation-based study reported that the incidence of urologic complications related to RH was 1.48% [11]. This figure may have been underestimated because the incidence was calculated based on the diagnostic code. To compensate for the drawback, we extracted data regarding urologic procedures from NHIS and investigated the incidence of urologic complications and attempted to determine the difference between ARH and LRH. It is possible to predict urologic complications based on urologic procedures. In the present study, the incidence of urologic complications requiring RH-related urologic procedures was 7.40%, which is relatively higher than those reported in previous population-based studies (1.48%–1.54%) [11,17].

When urologic complications are estimated through urologic procedures, urinary complications may be overestimated. Double-J ureteral stent indwelling is required during ureteroneocystostomy, ureteroureterostomy, and ureteral dilatation; hence, separately reporting the incidence of double-J ureteral stent indwelling becomes redundant. Considering these factors, the incidence of urologic complications decreases from 7.40% to 6.59%. Additionally, double-J ureteral stent indwelling can be performed before RH to prevent ureteral injury, which is associated with potential overestimation of its incidence. Contrastingly, even if urologic complications occur, urologic procedures are not required in all cases and can be cured spontaneously via conservative treatment such as Foley catheter insertion. The incidence of urologic procedures can be underestimated in such cases.

Urologic complications that are not conservatively treated and require a urologic procedure or surgery are clinically more significant. Specific urologic complications can be estimated via specific urologic procedures. As shown in **Fig. 1**, the incidence of bladder injury can be predicted by bladder repair (R3550). The incidence of ureter injury can be calculated as the sum of ureteroneocystostomy and ureteroureterostomy. From that point of view, bladder injury can be estimated as 0.90% (188 of 20,905) and ureter injury 0.76% (159 of 20,905). According to a study conducted by Hwang et al. [11] using the diagnostic code of NHIS., the incidence of bladder injury and ureter injury was 0.47% and 0.70%, respectively. It is noteworthy that the tendency to overlook the incidence of bladder injury was higher when data is extracted using diagnostic code. It can be explained that bladder repair can be performed by a gynecologic oncologist without any urologic consultation. Contrastingly, a minor injury of the ureter or bladder, such as electric or small injury, which can be treated with ureteral stent indwelling or with a combination of primary repair of the ureter and ureteral stent indwelling, may not have been included in the incidence of bladder or ureter injury requiring urologic procedures.

VVF is one of the most devastating postoperative complication after RH. Here, there were no cases of VVF. We believe that this may be owing to the inclusion of urologic procedures that were performed within 1 month of RH. VVF which are detected early can be treated with placing a Foley catheter in the bladder. VVF repair can be considered when conservative treatment fails.

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Although the timing of surgery remains controversial, it is a classical opinion to wait 3–6 months for allowing inflammatory reactions to subside. VVF is also detected late at approximately 1 month after RH. Small VVF can be treated with transvesical or transvaginal injection of glue via cystoscopy [18,19], which was not considered in this study. We detected four patients who underwent VVF repair within an expanded range approximately 1 month later.

When analyzed after being divided into first and second half, the incidence of urologic procedures was higher for LRH in the first half and for ARH in the second half. It is noteworthy that the incidence of urologic complications has decreased for LRH over time owing to improvements in surgical techniques, substantial experience, and development of energy devices. Continued technological advances, including the universalization of robotic surgery for minimally invasive LRH, have the potential to reduce urological complications in the future. NHIS data does not provide information on the stage of cancer patients. Based on previous studies [11,20] analyzed using NHIS data, all-cause mortality was higher for ARH, which indicates that the prevalence of advanced stages was higher in the ARH group. This can explain why there were more urologic complications requiring urologic procedures in relation to ARH in the second half of the study period. This also indicates that the incidence of urologic procedures in the LRH group may have been relatively underestimated in the first half of study period. Since the LACC trial (2018), LRH/ARH ratio has been decreasing. LRHs are often targeted in early patients less than 2 cm, which may have resulted in relatively more urologic complications in ARH. This time-series relevance is consistent with previous studies [9,10].

The current study has several limitations. First, an important limitation is that the NHIS database does not provide information on cancer stage. The stage of uterine cervical cancer may act as one of the most significant predisposing factors related to perioperative urologic complications [19]. There was no difference in urological complications requiring urological procedures between ARH and LRH, but the possibility of more urologic complications in patients who underwent LRH cannot be excluded when considered along with clinical staging analysis. However, according to the study conducted by Liu et al. [17] using big data, specific clinical stages did not affect urologic complications although urologic complications increased in the LRH group. The OR tended to increase with advanced stage, but without statistical significance. Second, because the analysis is based on urologic procedures, it is not accurately matched with specific urologic complications. Third, we did not evaluate demographic and clinical variables, including coexisting pelvic adhesion, previous operation history, obesity, presence of diabetes, and postoperative infection, which may affect urologic complications and procedures [2,21]. Fourth, the extent of surgery can be possible predisposing factors for urinary tract injury [2]. The group that underwent pelvic LND alone and the group that underwent para-aortic LND in addition to pelvic LND were not separately analyzed. We did not evaluate the effect of para-aortic LND on urologic complications. Fifth, robotic surgery for RH was not included in this study due to lack of information. A meta-analysis [22] demonstrated that there is no difference in perioperative urologic complications between RRH and LRH. However, no study has been conducted using population-based data. Finally, the urologic complications may differ according to hospital function, hospital location, and surgeon's experience [17,23], but these factors have not been considered in this study.

To the best of our knowledge, this is the first population-based study to evaluate the incidence of urologic complications and compare perioperative urologic procedures between ARH and LRH from the point of view of urologic procedures. This study overcomes the

drawbacks of meta-analysis that are conduced retrospectively or population-based studies conducted using diagnostic codes, which may result in an underestimation of perioperative complications. Here, in terms of urologic procedures, laparoscopic approach in RH was not a risk factor for general urologic complications. Among specific urologic complications, the incidence of bladder repair is significantly higher in patients who underwent LRH. We confirmed that urologic complications requiring urologic procedures has been decreasing over time in patients who underwent LRH. In the future, our finding should be verified by population-based studies after including information on clinical cancer staging.

SUPPLEMENTARY MATERIAL

Fig. S1

The incidence of ARH and LRH according to age distribution.

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