A Multicenter, Prospective, Non-randomized Study Evaluating Surgical Hand Preparation between Double-Gloving and Single-Gloving for Preventing Postoperative Infection in Robotic and Laparoscopic Minimally Invasive Surgeries

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Purpose: This study aimed to analyze a feasible and suitable surgical precautionary preparatory technique. The techniques of double-gloving with hygienic hand wash (DH) and single-gloving with surgical hand wash (SS) were compared for their ability to prevent postoperative infection in robotic and laparoscopic minimally invasive surgeries.

Materials and Methods: A prospective, non-randomized, multicenter study was conducted between January 2016 and June 2020. We divided the robotic and laparoscopic cases into two groups: DH and SS. Data on infectious outcomes were collected. Propensity score matching was performed to control for operative characteristics between the two groups. The primary endpoint was the presence of fever and surgical site infections (SSIs) indicating postoperative infection.

Results: Among four medical centers, seven surgeons were allocated to either the DH or the SS group. A total of 221 and 251 patients underwent DH and SS, respectively. Propensity score matching, which included 171 cases from each group, showed that the incidence of fever during hospitalization was significantly lower in the DH group than that in the SS group (11.7% vs. 23.4%, $p = 0.007$). Multivariable analysis revealed that DH was associated with a reduced odds ratio for developing postoperative fever during hospitalization (risk ratio: 0.49, $p = 0.043$). No differences were found in SSI before and after hospitalization between the two groups.

Conclusion: DH resulted in less postoperative fever and had a comparable effect in preventing SSIs. This procedure could be an alternative to the SS protocol in some minimally invasive surgeries.

Keywords: assistive devices; hand washing; laparoscopy; surgical site infection endoscopes

INTRODUCTION

Several urological surgeries have shifted from open to robotic or laparoscopic surgeries. Therefore, while we face fewer challenges, such as postoperative infections, the practices to mitigate these postoperative complications remain largely unchanged. Surgical site infections (SSIs) are crucial problems known to be associated with prolonged hospital stay, increased mortality, and disfiguring scars[(1)]. Appropriate hand washing and surgical gloving as part of the presurgical preparation have been researched. However, the duration wherein surgeons are in contact with the patients is reducing. Therefore, modification of this protocol may benefit the current surgical trends.

Prevention of postoperative infection is essential and is at par with other desirable surgical outcomes. Using an appropriate antiseptic agent to perform preoperative surgical scrub is recommended by the Society for Healthcare Epidemiology of America[(2)]. Semmelweis et al. first reported on the utility of preoperative hand washing in 1847. Although the conventional surgical scrub has been performed for decades, it has disadvantages; it is time-consuming and may cause skin damage or allergic reactions[(3)]. In the 2000s, some studies supported hand rubs using alcohol components[(4,5)]. Regarding antiseptics, Oriel BS et al. have reported that chlorhexidine gluconate aqueous scrubs and alcohol-based rubs were preferred over povidone-iodine[(6)]. However, the most appropriate antiseptic remains a controversial topic owing to contradictory results and the impossibility of randomized trials due to ethical reasons.

Double-gloving reportedly has lower incidence of pinhole micropunctures during surgery than single-gloving [(7)]. Moreover, double-gloving has been reported as a

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Table 1. Preoperative characteristics of cases underwent robotic-assisted and/or laparoscopic urological surgeries

Factor		All cases DH group (n=221)	All cases SS group (n=251)	*p* value	Matched cases by propensity score DH group (n=171)	Matched cases by propensity score SS group (n=171)	*p* value	SD
age	y.o	67.4	66.6	0.43	70.0	69.0	0.520	0.001
male sex (%)		138 (62.4)	183 (72.9)	0.018	119 (69.6)	111 (64.9)	0.420	0.074
BMI	kg/m^2	23.7	23.8	0.81	24.1	23.3	0.493	0.026
Infection risk (%)		45 (20.4)	45 (18.0)	0.56	31 (18.1)	32 (18.7)	1	0.015
preop ABx use (%)		6 (2.7)	3 (1.2)	0.32	5 (2.9)	2 (1.2)	0.448	0.12
preop pyuria (%)		34 (15.4)	51 (20.3)	0.19	31 (18.1)	27 (15.8)	0.666	0.062
bacteriuria (%)		10 (4.5)	13 (5.1)	0.50	10 (5.8)	7 (4.1)	0.208	0.20
Type of procedure (%)	LRP, RARP	61 (27.6), 36 (16.3)	55 (21.9), 57 (22.7)	NA	48 (28.1), 34 (19.9)	44 (25.7), 30 (17.5)	0.995	0.13
	LPN, RAPN	5 (2.3), 3 (1.4)	6 (2.4), 2 (0.8)		4 (2.3), 1 (0.6)	4 (2.3), 2 (1.2)		
	LRA, LRN	9 (4.1), 45 (20.4)	16 (6.4), 67 (26.7)		6 (3.5), 37 (21.6)	9 (5.3), 39 (22.8)		
	LSC	52 (23.5)	40 (15.9)		34 (19.9)	36 (21.1)		
	LPDCP, LUCE	5 (2.3), 5 (2.3)	4 (1.6), 4 (1.6)		4 (2.3), 3 (1.8)	4 (2.3),3 (1.8)		

DH, double-gloving with hygienic hand wash; SS, single-gloving with surgical hand wash; SD, standardized difference; BMI, body mass index; preop, preoperative; ABx, antibiotics; y.o, years old; LRP, laparoscopic radical prostatectomy; RARP, robotic-assisted laparoscopic radical prostatectomy; LPN, laparoscopic partial nephrectomy; RAPN, robotic-assisted laparoscopic partial nephrectomy; LRA, laparoscopic radical adrenalectomy; LRN, laparoscopic radical nephrectomy; LSC, laparoscopic sacral colpopexy; LPDCP, laparoscopic peritoneal dialysis catheter placement; LUCE, laparoscopic urachal cyst excision; NA, not applicable.

useful method for preventing surgical cross-infection [7]. However, the World Health Organization has stated that double-gloving is not formally recommended because of the lack of evidence on its role in reducing the risk of SSI[8]. The effectiveness of double-gloving over single-gloving remains undetermined; overall, the ideal methods of handwashing and the number of glove pairs surgeons should wear remain unclear.

We focused on the necessity and efficiency of handwashing and gloving for urologic robotic or laparoscopic surgeries as most of these procedures are clean or clean-contaminated operations. In this study, we compared the effectiveness of double-gloving with hygienic hand wash (DH) and single-gloving with surgical hand wash (SS) in preventing postoperative infection in robotic and laparoscopic minimally invasive surgeries.

PATIENTS AND METHODS

Study design and patient population

This was a multicenter, prospective cohort study that included patients who underwent urologic robotic or laparoscopic minimally invasive surgery at the Nagoya City University Hospital, Nagoya City East Medical Center, Daido Clinic and Hospital, and Gamagori City Hospital between January 2017 and June 2020. **Figure 1** elaborates the study protocol. The following procedures were selected as minimally invasive surgeries with only small incisions, defined as <4 cm for ports involving extraction of removed organs: laparoscopic radical prostatectomy (LRP), robotic-assisted LRP (RARP), laparoscopic partial nephrectomy (LPN), robot-assisted LPN, laparoscopic radical adrenalectomy, laparoscopic radical nephrectomy, laparoscopic sacral colpopexy, laparoscopic peritoneal dialysis catheter placement, and laparoscopic urachal cyst excision. We excluded any robotic or laparoscopic surgery requiring additional incisions for an open procedure, such as nephroureterectomy and total cystectomy.

All urologists who participated in this study were allocated to the DH and the SS groups (n=7 each) based on their preference and capability for double-gloving. The allocation was determined owing to their flexibility for altering their surgical hand antiseptic protocol. The two groups had similar proportions of residents, fellows, and attending physicians. At the time of surgery, all presurgical preparation was standardized among surgeons according to their assigned group. The patients were allocated to two groups (the DH group and the SS group) according to the surgery they would be underwent. Randomization of the patients was not conducted because the allocation of the patients depended on the surgeries.

The protocol of antibiotic prophylaxis was based on the Japanese guidelines for the prevention of perioperative infections in the urological field[9]. Surgical procedures were classified according to the Center for Disease Control and Prevention wound classification[10]. As antibiotic prophylaxis, the patients who underwent LPN, RAPN, LRA, LRN, LSC, LPDCP, and LUCE defined as clean (class I) were administrated 1st cephalosporins/penicillins with Beta(ß)-lactamase inhibitor (BLI) and the patients who underwent LRP and RARP defined as clean-contaminated (class II) 1st or 2nd cephalosporins/penicillins with BLI.

This study was conducted with the approval of the Institutional Review Board of the Nagoya City University Hospital (#60-20-0090) and followed the tenets set by the Declaration of Helsinki. All patients provided their verbal and opt-out informed consent for study participation.

Endpoints, data collection, and adjustment

The primary endpoint was the presence of fever and SSI, indicating postoperative infection. The secondary endpoints included influence on shorter operation time, less blood loss, shorter duration of antibiotics after the surgeries, presence of pyuria, shorter duration of hospital stay, and changes in serum inflammatory markers.

We obtained clinical data for each patient, including age, sex, body mass index (BMI), infection risk, use of preoperative antibiotics, presence of preoperative pyuria, and presence of bacteriuria. Infection risk was defined as meeting at least one of the following conditions: obesity (BMI >30), diabetes mellitus, use of steroids, and receiving dialysis. Furthermore, we collected intraoperative data, including operation time and estimated blood loss, as well as postoperative data during hospitalization, including duration of antibiotic use, use of additional antibiotics, number of antipyretics/analgesics use, fever (defined as temperature $\geq$ 38°C) during hospitalization, serum examination data at postoperative day (POD) 1, presence of SSI, and duration of hospital stay. The Southampton wound scoring system

Table 2. Comparison of perioperative factors related to postoperative infection between the two antisepsis protocols.

Factor	units	All cases DH group(n=221)	SS group(n=251)	*p* value	Matched cases by propensity score DH group(n=171)	SS group(n=171)	*p* value	SD
Intra- and postoperative factors during hospitalization								
operation time	min	164 [135, 199]	197 [156, 246]	< 0.001	174 [146, 216]	174 [149, 210]	0.946	0.009
estimate blood loss	mL	50 [10, 250]	100 [10, 284]	0.045	51 [10, 250]	99 [10, 245]	0.725	0.082
duration of ABx use	days	3.0 [2.0, 3.0]	2.0 [2.0, 3.0]	0.031	3.0 [2.0, 3.0]	2.0 [2.0, 3.0]	0.064	0.077
additional ABx use (%)		20 (9.1)	43 (17.1)	0.014	19 (11.1)	32 (18.7)	0.068	0.20
fever during hospitalization (%)		27 (12.2)	64 (25.5)	<0.001	20 (11.7)	40 (23.4)	0.007	
WBC at pod1	/μL	8300 [6900, 10180]	8600 [7063, 10400]	0.467	8280 [6935, 10500]	8450 [7078, 10200]	0.923	
CRP at pod1	mg/L	2.40 [1.62, 3.75]	2.88 [1.60, 4.22]	0.154	2.47 [1.62, 3.90]	2.51 [1.52, 3.90]	0.873	
SSI during hospitalization (%)		1 (0.5)	2 (0.8)	1	1 (0.6)	2 (1.0)	1	
hospital stay	days	7.0 [4.0, 9.3]	8.0 [6.0, 10.0]	0.043	8.00 [5.0, 10.0]	7.00 [5.0, 10.0]	0.633	
Postoperative factors after discharge from hospital								
fever at 1 month (%)		1 (0.5)	2 (0.8)	1	1 (0.6)	1 (0.6)	1	
SSI at 1 month (%)		4 (1.8)	1 (0.4)	0.191	3 (1.8)	1 (0.6)	0.371	
pyuria at 1month (%)		33 (14.9)	36 (14.3)	0.418	26 (21.8)	27 (21.3)	1	
WBC at 1 month	/μL	5920 [4900, 6928]	5800 [4800, 6800]	0.275	5950 [4863, 7003]	5700[4800, 6730]	0.113	
CRP at 1 month	mg/L	0.10 [0.05, 0.38]	0.10 [0.04, 0.30]	0.535	0.10 [0.05, 0.31]	0.08 [0.04, 0.20]	0.270	

DH, double-gloving with hygienic hand wash; SS, single-gloving with surgical hand wash; SD, Standardized difference; ABx, antibiotics; #, number; WBC, white blood cell; pod; postoperative day; CRP, C-reactive protein; SSI, surgical site infection.

was used to evaluate SSI (**Supplementary Table 1**)[11]. Grade II or higher in the Southampton wound scoring system was defined as SSI. Postoperative data after hospital discharge, presence of fever, SSI, pyuria, and serum examination data were collected at the clinical visit 1 month after the surgeries. All clinical data were collected prospectively.

To mitigate case-collection bias due to the different surgeon groups, propensity score matching was performed to adjust for the differences in the patients who were assigned specific method for washing hands and wearing gloves. We matched age, sex, BMI, rate of infection risks, rate of preoperative pyuria, duration of antibiotics use, types of operations, and operation time using a logistic regression model.

Interventions: hand wash technique

In the DH group, hand washing and gloving were performed according to the following protocol: (1) one pump of a non-medicated soap was applied followed by gentle rubbing of the fingertips to the arms for at least 1 min without using brushes, sponges, or nail tips and then rinsed with non-sterile water; (2) the hands and arms were dried with non-medicated towels/paper; and (3) double-gloving was performed after drying.

In the SS group, hand washing was performed by the hand rubbing technique. Hand rubbing was performed according to the following protocol: (1) the hands were washed using non-medicated soap and warm water for at least 1 min without using brushes, sponges, or nail tips; (2) the hands and arms were wiped with non-medicated towels/paper; (3) alcohol-based hand rubs were used for both the hands and arms; (4) the hands were air-dried; and (5) single gloves were worn.

For both groups, we utilized similar latex gloves for each institution, and no obligation for using gloves for either inner or outer set was implemented.

Sample size calculation

The overall rate of postoperative infection in robotic or laparoscopic urological surgeries was estimated to be 3% according to a previous report[12]. These surgeries were conducted using SS. We set the rate of SSIs with DH as 5.5% because it seemed higher than single-gloving with surgical hand antisepsis due to the increased risk of infection with normal hand wash procedures. We calculated the sample size for a non-inferiority test using a statistical power of 80%, double-sided analysis, alpha value of 5%, and a non-inferiority limit of 3%. Based on these settings, the minimum required number of samples for each group was calculated as 211 using the EZR software (R Project, Vienna, Austria)[13].

Statistical analysis

Continuous normally distributed variables are presented as mean ± standard deviation, whereas non-normally distributed variables are presented as median (25% and 75% interquartile range). Categorical variables are presented as numbers in each group (percentage within each group). For continuous variables, the normality and homogeneity of each variable were assessed and Student's or Welch's t-test was performed according to the homoscedasticity. For non-parametric variables, Mann–Whitney U test was used. Categorical variables were compared using Fisher's exact test. Propensity score matching was used to achieve a balance between the two groups. A minimally sufficient set of confounders were selected by literature research and using a causal directed acyclic graph (Supplemental figure 1). Propensity scores were calculated using a logistic regression model including age, sex, BMI, rate of infection risk, rate of preoperative pyuria, duration of antibiotics use, types of operations, and operation time. Patients were matched by a matching ratio of 1:1 based on the propensity score with a standard caliper width of 0.02. A Standardized differences (SD) between groups for all covariates were analyzed. SD value less than 0.2 refers to not statistically significant difference. Multivariable modified Poisson regression analysis was performed to estimate the risk ratio (RR) and confidence interval (CI) for postoperative fever and SSI. The covariates were selected based on previous reports which were associated with postoperative fever and SSI.[2,3,12]. Differences were considered statistically significant at alpha value of < 0.05. All statistical analyses were performed using the EZR software.

Table 3. Multivariable analysis for surgical outcomes related to postoperative infection among various parameters.

Modified Poisson regression model	fever during hospitalization RR (95% CI)	*p* value	fever at 1 month RR (95% CI)	*p* value	SSI during hospitalization RR (95% CI)	*p* value	SSI at 1 month RR (95% CI)	*p* value
bacteriuria	1.66 (0.65-4.24)	0.29	1.30 x10-8 (0.00-Inf)	1.00	6.11 x10-8 (0.00-Inf)	1.00	1.32x10-8 (0.00-Inf)	1.00
estimate blood loss	1.00 (1.00-1.00)	0.93	1.00 (1.00-1.00)	0.99	1.00 (0.99-1.01)	0.88	1.00 (0.99-1.01)	0.76
Preop ABx use	1.46 x10-7 (0-Inf)	0.99	2.68 x10-8 (0.00-Inf)	1.00	1.11x10-7 (0.00-Inf)	1.00	3.52x10-8 (0.00-Inf)	1.00
DH group	0.49 (0.24-0.98)	0.043	1.78x108 (0.00-Inf)	1.00	2.47x10-8 (0.00-Inf)	1.00	1.77x108 (0.00-Inf)	1.00

DH, double-gloving with hygienic hand wash; ABx, antibiotics; SSI, surgical site infection; RR, risk ratio; CI, confidence interval.

RESULTS

Patient characteristics

Among the 472 patients included in this prospective cohort, 221 and 251 patients underwent DH and SS, respectively. **Table 1** summarizes the patient characteristics of the two groups. No significant differences were noted in age, BMI, infection risk, preoperative antibiotic use, and preoperative pyuria. The proportion of male patients and the rate of preoperative bacteriuria were higher in the SS group than in the DH group.

In propensity score matching, age, sex, BMI, rate of infection risk, rate of preoperative pyuria, duration of antibiotics use, types of operations, and operation time were matched (**Table 1,2**). The data of a total of 342 patients were analyzed, and each group included 171 patients.

Intra- and postoperative factors related to postoperative infection during hospitalization

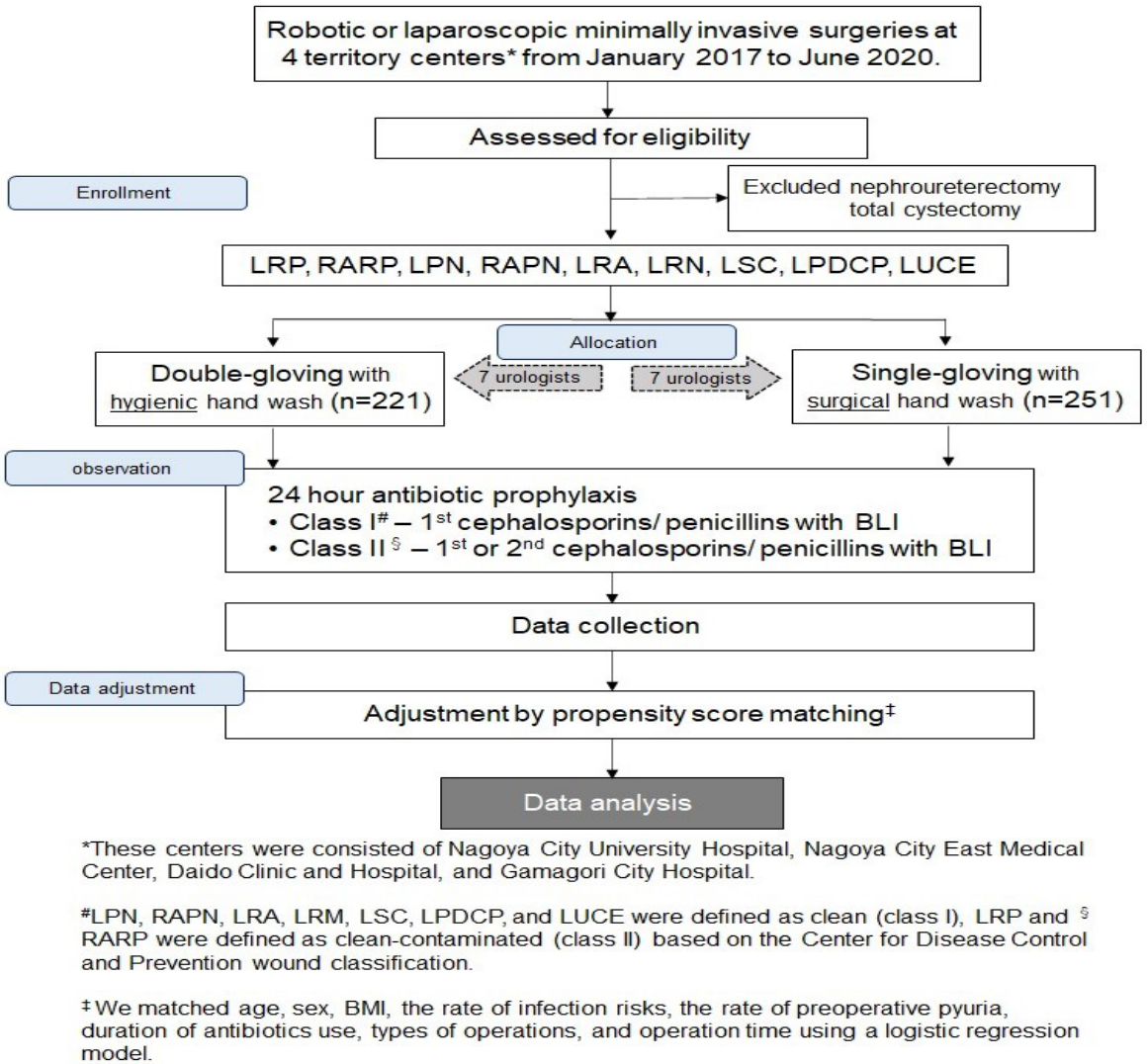

Figure 1. Protocol of this study

Intra- and postoperative outcomes during hospitalization are shown in **Table 2**. In the entire cohort population, the DH group had significantly shorter operation time, less estimated blood loss, lower percentage of additional antibiotic use, less fever during hospitalization, and shorter hospital stay than the SS group. The duration of antibiotic use was longer and number of antipyretics/analgesics used increased in the DH group than those in the SS group.

After propensity score matching, univariate analysis revealed that the incidence of fever during hospitalization was significantly lower in the DH group than in the SS group (11.7% vs 23.4%, $p = 0.007$). Other postoperative outcomes, including white blood cell (WBC) count and C-reactive protein (CRP) level at POD 1 and the SSI rate during hospitalization, were not significantly different between the two groups.

Postoperative factors related to postoperative infection after hospital discharge

Postoperative outcomes after discharge from the hospital in all cases and the propensity score-matched cases are also shown in Table 2. In both settings, the rates of fever, SSI, pyuria, WBC count, and CRP level 1 month postoperatively after discharge were not significantly different between the two groups.

Multivariable analyses for the factors associated with infectious surgical outcomes

Table 3 shows multivariable modified Poisson regression analysis revealing that DH decreased the RR for developing fever during hospitalization (RR =0.49, $p = 0.043$). No pre- or intraoperative factors were found to be associated with fever at 1 month and SSI during hospitalization or 1 month after the surgeries.

DISCUSSION

Our study demonstrated that infectious outcomes in DH were equivalent to or better than those in SS in urologic robotic/laparoscopic surgeries. Moreover, DH was associated with lower incidence of postoperative fever. These findings were obtained for all patients as well as propensity score-matched patients.

There are reports regarding infectious outcomes in urology, which mainly concern postoperative SSI. SSI is a postoperative complication that occurs in 0.1%–50.4% of cases, and its occurrence rate varies based on the type of surgery and risk factors, such as reduced fitness, patient frailty, increased surgery duration, and surgical complexity[14]. In urologic cases, patients who underwent RARP showed a lower incidence of SSI and postoperative infections than patients who underwent radical retropubic prostatectomy[15,16]. The incidence of SSIs in minimally invasive urological surgery, including nephrectomy, nephrouretectomy, prostatectomy, and cystectomy, was reported to be less than that in open surgery[17]. In our study, partially because procedures were limited to minimally invasive urological surgeries, there were few cases of SSI. Postoperative fever is also a concern in clinical situations and is caused by various infectious and non-infectious etiologies. It is a common complication with incidence of 20%–90% in the postoperative period and may include serious infection resulting in sepsis if not correctly diagnosed[18]. Postoperative fever can prolong hospitalization and increase the mortality rate[18]. In our study, DH reduced the rate of postoperative fever. Reducing the incidence of fever after DH seemed to be beneficial for the patients. The present study resulted in a difference in terms of postoperative fever and there was not in terms of SSI. Nowadays, the cause of postoperative fever is considered as biological response to surgical invasion if the obvious source of infection was not pointed out. But antibiotic prophylaxis might mask the small infection leads to postoperative fever but does not lead to SSI.

Conflicting reports exist regarding ideal presurgical preparation, such as various methods of hand rubs. According to previous reports, alcohol-based rubbing yields better outcomes in terms of skin damage, microbial counts, and cost than traditional surgical scrubs[19]. However, the bacterial colony counts of the hands increased during an operation even though alcohol-based rubbing was performed[20]. It must be considered that changing methods of washing hand improves certain aspects of infection prevention; however, it is impossible to avoid bacterial colonization completely.

In addition, the number of gloves worn during presurgical preparation is important; according to previous studies, double-gloving tends to prevent blood-skin exposure and glove perforation[21,22]. In endourologic surgery, regular hand hygiene with double-gloving and surgical hand hygiene were reported to be effective in preventing endourological febrile urinary tract infections[23]. In our study, the effectiveness of DH in preventing the indications of infection was comparable to or even exceeded that of SS, particularly regarding postoperative fever. This suggests that double-gloving helps prevent infections regardless of the hand wash technique used. Regarding the cost, the preventive effect of double-gloving for healthcare workers in terms of perforation and bloodstains on the skin was reported as beneficial[24]. Moreover, a randomized trial conducted in non-sterile settings indicated that double-gloving could reduce contamination in an intraoperative environment[25]. Furthermore, double-gloving is effective in preventing hand contamination of healthcare workers when removing personal protective equipment[26]. Double-gloving was further reported to not influence tactile sensibility[27]. In summary, double-gloving seems to have several benefits in infection prevention for both patients and healthcare workers. However, its effect on surgical performance remains unknown.

Our study has some limitations. This was a non-randomized study, which might have resulted in a selection bias due to each surgeon's preference in gloving. Additionally, the operation time was statistically different between the two groups because of the study design. Consequently, the duration of surgery may influence the risk of postoperative infections. The overall results were highly generalized because various surgical procedures were simultaneously analyzed. Moreover, this multicenter study may have included unequal heterogeneity and diversity of cases among the sites. Thus, the different settings of the study design may have resulted in baseline differences. We conducted propensity score matching to minimize these biases; however, there were some differences, such as operative methods, surgical instruments, and operating room conditions, which were not controllable. Only measurable potential confounders were included in the model for estimating propensity scores, so we were not able to directly adjust for the effects of non-measurable potential confounders. The present study resulted in significantly shorter

operation time and less estimated blood loss in the DH group than those in the SS group. They were also uncontrollable factors because we were unable to adjust them before surgery. These factors were considered to affect infectious outcomes as confounding biases but we attempted to adjust these factors by propensity score matching. Finally, the type of gloves and the method of surgical hand wash differed between surgeons and cases. However, we believe that these different preoperative aspects might cause only small differences.

CONCLUSIONS

We found that double-gloving may result in reduced postoperative fever during hospitalization in robotic or laparoscopic urologic surgery regardless of omitting surgical hand hygiene. Given that other infectious outcomes were comparable between the DH and SS groups, DH is effective in preventing complications and could be an alternative to the current protocols in microincisional laparoscopic and robotic surgeries.

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CONFLICT OF INTEREST

The authors report no conflict of interest.

APPENDIX

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