ORIGINAL PAPER

Chlorhexidine versus standard dressings after major urologic surgery: a pilot randomized controlled trial

Jakub Frydrych[1], Bartosz Ros[2], Anna K. Czech[1,3], Oleksandr Sydoruk[2], Mateusz Keska[2], Ilie Lastovetskyi[2], Marcin Chlosta[1], Aldona Olechowska-Jarzab[4], Piotr L. Chlosta[1,3]

[1]Department of Urology and Urological Oncology, University Hospital in Krakow, Poland
[2]Students' Scientific Group of Urology, Jagiellonian University Medical College, Krakow, Poland
[3]Department of Urology, Jagiellonian University Medical College, Krakow, Poland
[4]Department of Microbiology, University Hospital in Krakow, Poland

Citation: Frydrych J, Ros B, Czech AK, et al. Chlorhexidine versus standard dressings after major urologic surgery: a pilot randomized controlled trial. Cent European J Urol. 2026; doi: 10.5173/ceju.2026.0086

Article history
Submitted: Mar. 10, 2026
Accepted: Jul. 8, 2026
Published online: Sep. 12, 2026

Corresponding author
Jakub Frydrych
Department of Urology and Urological Oncology, University Hospital in Krakow,
2 Jakubowskiego St.,
30-688 Krakow, Poland
frydrych.jf@gmail.com

Introduction Chlorhexidine-impregnated dressings may reduce surgical site infections (SSIs). However, randomized evidence in major urologic surgery is lacking. In addition, baseline SSI incidence in this population remains insufficiently defined, limiting the design of adequately powered trials. This pilot randomized controlled trial aimed to estimate short-term SSI incidence after major urologic surgery and evaluate the feasibility of comparing chlorhexidine-based and standard dressings for SSI prevention.

Material and methods This single-center pilot randomized controlled trial was conducted at a tertiary university hospital between March and December 2024. Adult patients undergoing elective major urologic surgery with an expected incision length ≥10 cm were randomized to chlorhexidine-impregnated (Bactigras®) or standard sterile gauze dressings until postoperative day (POD) 5. Feasibility endpoints included recruitment rate, protocol adherence, and completeness of follow-up at POD14. The exploratory clinical endpoint was SSI within 14 days. Secondary outcomes comprised wound dehiscence, non-purulent exudate, and local skin irritation.

Results Eighty-nine patients were randomized; 79 were included in the final analysis (39 chlorhexidine, 40 gauze). Follow-up exceeded 95%. Overall, the 14-day SSI incidence was 3.8% (3/79 patients). SSI occurred in 2/39 patients (5.1%) in the chlorhexidine group and 1/40 (2.5%) in the gauze group. Wound dehiscence occurred in 1.3%, non-purulent exudate in 15.2%, and skin irritation in 3.8%, with no clear between-group differences.

Conclusions In this pilot study, early SSI incidence after major urologic surgery was low, with no clear differences between chlorhexidine and gauze dressings. The study demonstrated the feasibility of a randomized comparison and informs the design of future studies.

Key Words: surgical site infection ‹› wound dressing ‹› chlorhexidine ‹› urologic surgery ‹› randomized controlled trial ‹› pilot study

INTRODUCTION

Surgical site infection (SSI) rates have significantly decreased over the past few decades [1, 2]. This decline can be attributed to enhanced pre- and postoperative care, improved surgical techniques, and rigorous infection-control measures. Nevertheless, SSIs remain a well-recognized contributor to postoperative morbidity and mortality [3]. Numerous strategies exist to reduce SSI rates, including perioperative antibiotic prophylaxis, skin antisepsis, and postoperative wound management [4, 5].

While sterile gauze dressings are traditionally considered the standard of care in postoperative wound management, a wide variety of alternative dressing types are commercially available [6]. Among these are dressings with antimicrobial properties, such as chlorhexidine-based products. Chlorhexidine

is a broad-spectrum biocide known for its activity against a wide range of microorganisms [7]. Consequently, the application of chlorhexidine-based wound dressings could theoretically contribute to further reductions in SSI rates.

To date, no randomized controlled trial has compared standard sterile gauze dressings with chlorhexidine-based dressings in the context of major urologic surgery, particularly procedures involving large incisions. In addition, reliable epidemiological data on the baseline incidence of SSI in this specific surgical population are limited.

The present pilot randomized controlled trial was designed to generate preliminary data to inform the design of a future definitive study. Its objectives were to estimate the short-term incidence of SSIs following major urologic surgery, evaluate recruitment and follow-up feasibility, and assess adherence to dressing protocols. Exploratory analyses compared chlorhexidine-based versus standard gauze dressings with regard to early wound outcomes within 14 days after surgery.

MATERIAL AND METHODS

Study design and participants

This single-center, stratified, parallel-group pilot randomized controlled trial was conducted at a tertiary-care university hospital from March to December 2024 under a Students' Scientific Group grant with predefined duration. Adult patients scheduled for elective urologic procedures with an expected incision length of at least 10 cm were eligible. Exclusion criteria included anticipated smaller incision length and participation in another interventional trial.

Randomization and allocation concealment

Randomization was stratified by anticipated opening of the urinary tract during surgery (yes/no) and performed in permuted blocks using a computer-generated list prepared by an investigator not involved in patient care. Allocation was disclosed to the surgical team on the morning of surgery by a second investigator to maintain concealment. Due to the visually distinct appearance of the two dressing types, blinding of patients and clinical staff was not feasible. Wound assessments were performed by clinicians who were aware of group allocation.

Interventions

Patients assigned to Group A received chlorhexidine-impregnated paraffin tulle dressings containing 0.5% chlorhexidine acetate (Bactigras®, Smith & Nephew). The dressing was applied immediately after skin closure as a single layer covering the entire length of the surgical incision. A secondary sterile adhesive dressing was placed over the Bactigras® to secure the application. Dressings were changed daily until postoperative day 5 (POD5). Daily dressing replacement reflected routine institutional postoperative wound-care practice and was incorporated into the study protocol to standardize wound management during the early postoperative period. In accordance with the manufacturer's instructions, wounds were not cleaned with soap or other anionic antiseptics. Group B received standard sterile gauze dressings. Wound care followed institutional protocol and included routine antiseptic cleansing of the incision (e.g., octenidine-based solution) prior to application of a new sterile gauze dressing. Patients discharged before POD5 were instructed in home dressing changes. All other aspects of perioperative care, including antibiotic prophylaxis, followed institutional protocols and were identical in both groups. If allergic reaction or other dressing-related adverse events were observed, the study dressing was discontinued, and further wound management was conducted according to standard clinical practice.

Perioperative care and antibiotic prophylaxis

Patients with preoperative positive urine cultures received targeted antibiotic therapy for at least 48 hours before surgery. All patients underwent standard preoperative skin preparation, including hair removal and antiseptic body washing on the morning of surgery. Perioperative antibiotic prophylaxis was administered according to institutional guidelines. Decisions regarding continuation or initiation of postoperative antibiotic therapy were at the discretion of the operating surgeon and were not standardized by the study protocol. Wound assessment was performed continuously during hospital stay until discharge and at a follow-up visit on postoperative day 14 (POD14). If an in-person visit was not possible, patients were assessed via telephone or video consultation.

Outcome measures

Feasibility outcomes included recruitment rate over the study period, adherence to the assigned dressing protocol until POD5, and completeness of wound assessment at POD14 (in-person or teleconsultation). The exploratory clinical outcome was the incidence of SSI occurring within 14 postoperative days.

SSI was assessed according to the CDC/NHSN Surgical Site Infection event criteria (superficial incisional, deep incisional, and organ/space), defined as infection involving the incision or operated organ/space with purulent drainage, positive microbiological findings from an aseptically obtained specimen, deliberate opening of the incision with local signs of infection and antimicrobial treatment, or physician diagnosis of SSI. Because follow-up in this pilot study was predefined to POD14, only SSIs presenting within this early postoperative window were captured, rather than the full NHSN surveillance period (typically 30 days for most procedures) [9]. Secondary outcomes included wound dehiscence, non-purulent exudate, and skin irritation suggestive of hypersensitivity or intolerance.

Statistical analysis

As this was a pilot study, no formal sample-size calculation was performed. Statistical analyses were primarily descriptive and exploratory. Baseline characteristics and perioperative variables were summarized using descriptive statistics. Categorical variables were compared using the chi-square test or Fisher's exact test, and continuous variables using the t-test or Mann–Whitney U test, depending on data distribution. A p-value <0.05 was considered statistically significant. Analysis was conducted using Statistica 13.3 (TIBCO Software Inc.).

Bioethical standards

The study was conducted in accordance with the Declaration of Helsinki and Good Clinical Practice guidelines. The study protocol was reviewed and approved by the Bioethics Committee of the Jagiellonian University (approval no. 1072.6120.151.2023). Written informed consent was obtained from all participants before enrollment. The trial was conducted and reported in accordance with the CONSORT 2010 statement and its extension for pilot and feasibility trials [8].

RESULTS

Feasibility outcomes

Recruitment and trial procedures were completed within the planned 9-month funding period, confirming the overall feasibility of the study design. A total of 196 patients were assessed for eligibility, of whom 89 were enrolled and randomized. The most common reasons for ineligibility were minimally invasive procedures and incision length <10 cm. The CONSORT flow diagram of patient recruitment and allocation is presented in Figure 1.
All eligible patients consented to participation and were randomized according to the pre-specified allocation sequence, with no protocol deviations related to randomization. Adherence to the assigned dressing protocol was 100%, and no crossover between groups occurred. Follow-up at POD14 was completed for all participants except one patient who was transferred to the intensive care unit on POD1 and subsequently lost to follow-up. All predefined feasibility criteria were met.

Clinical outcomes

Eighty-nine patients were randomized. Eighty patients with an incision length ≥10 cm received the allocated dressing according to protocol, and 79 completed follow-up and were included in the final analysis (39 in the chlorhexidine group and 40 in the gauze group) (Figure 1).
Baseline demographic and clinical characteristics of the study groups are presented in Table 1. The median age of participants was 67 years (interquartile range 58–72), and nearly three-quarters were male. Obesity (BMI >30 kg/m^2) was present

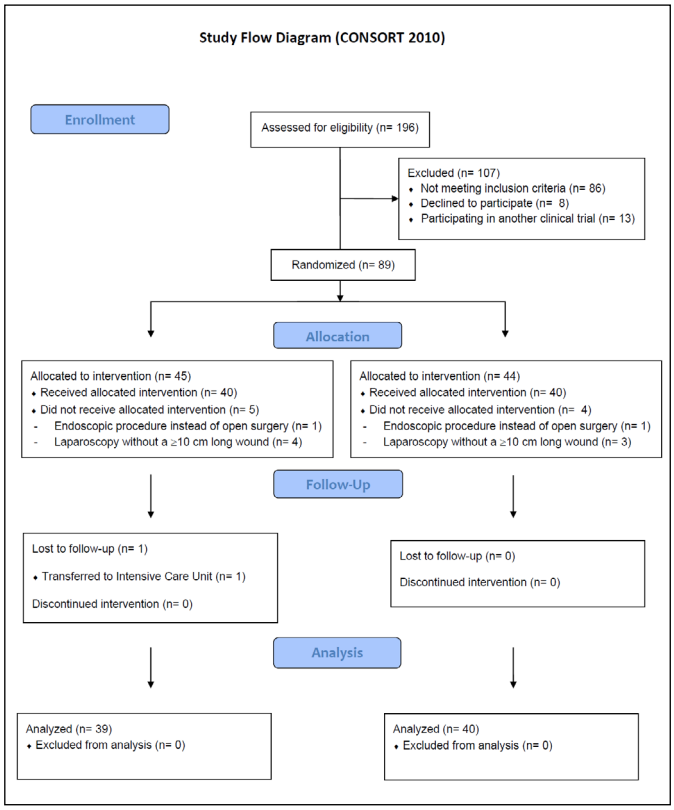

Figure 1. *CONSORT flow diagram of patient enrollment, randomization, and follow-up.*

in approximately one-quarter of patients, and diabetes mellitus in one-third. Preoperative positive urine cultures were identified in 41.8% of patients, all of whom received targeted antibiotic therapy before surgery.

Most operations were performed via an open approach (69.6%), while laparoscopic and mixed approaches accounted for 13.9% and 16.5%, respectively. In half of the procedures, the urinary tract was opened. Clean and clean-contaminated wounds predominated (95%), and the majority were closed with sutures. A detailed list of surgical procedures is provided in Suppl. Table 1. All patients received perioperative antibiotic prophylaxis. Postoperative antibiotic therapy was administered in 97.5% of cases, and 79.7% of patients continued oral antibiotics after discharge. Indications for extended antibiotic therapy included preoperative bacteriuria, urinary tract opening during surgery, and surgeon discretion based on intraoperative findings; formal duration data were not systematically collected in this pilot study.

Postoperative wound outcomes are summarized in Table 2. Overall, the 14-day SSI incidence was 3.8% (3/79 patients). SSI occurred in 2/39 patients (5.1%) in the chlorhexidine group and 1/40 (2.5%)

Table 1. *Baseline demographic and clinical characteristics of the study groups*

Variable	Total	Group A Chlorhexidine dressing n = 39 (49.4%)	Group B Regular dressing n = 40 (50.6%)
Age, median (IQR)	67 (58-72)	68 (57-72)	66.5 (58-72.5)
Male sex, n (%)	59 (74.7)	30 (76.9)	29 (72.5)
BMI > 30 kg/m2, n (%)	21 (26.6)	10 (25.6)	11 (27.5)
Diabetes mellitus, n (%)	25 (31.6)	14 (35.9)	11 (27.5)
Smoking status			
Current smoker n (%)	12 (15.2)	5 (12.8)	7 (17.5)
Former smoker, n (%)	33 (41.8)	16 (41)	17 (42.5)
Positive urine culture before surgery, n (%)	33 (41.8)	17 (43.6)	16 (40)
Surgical approach, n (%)			
Open	55 (69.6)	30 (76.9)	25 (62.5)
Laparoscopic	11 (13.9)	4 (10.3)	7 (17.5)
Mixed	13 (16.5)	5 (12.8)	8 (20)
Urinary tract opened during surgery – yes, n (%)	40 (50.6)	20 (51.3)	20 (50)
Wound type, n (%)			
Clean	39 (49.4)	19 (48.7)	20 (50)
Clean contaminated	36 (45.6)	17 (43.6)	19 (47.5)
Contaminated	4 (5.1)	3 (7.7)	1 (2.5)
Skin closure, n (%)			
Sutures	60 (75.9)	29 (74.4)	31 (77.5)
Staples	19 (24.1)	10 (25.6)	9 (22.5)
Perioperative antibiotic prophylaxis administered, n (%)	79 (100)	39 (100)	40 (100)
Extended antibiotic therapy (>single prophylactic dose), n (%)	77 (97.5)	39 (100)	38 (95)
Oral antibiotic after discharge, n (%)	63 (79.7)	30 (76.9)	33 (82.5)

BMI – body mass index; IQR – interquartile range

Table 2. *Postoperative wound outcomes*

Variable	Total (n = 79)	Group A Chlorhexidine dressing (n = 39)	Group B Regular dressing (n = 40)	Univariate analysis p-value
Surgical site infection, n (%)	3 (3.8)	2 (5.1)	1 (2.5)	0.5
Wound dehiscence, n (%)	1 (1.3)	0	1 (2.5)	0.24
Wound exudate (non-purulent), n (%)	12 (15.2)	6 (15.4)	6 (15)	0.96
Skin irritation, n (%)	3 (3.8)	2 (5.1)	1 (2.5)	0.56

in the gauze group. Given the very small number of events, between-group comparisons should be interpreted descriptively. The single case of wound dehiscence occurred in the gauze group. Non-purulent exudate was observed in 15.2% of patients, and mild local skin irritation in 3.8%, with similar frequencies across groups. No allergic reactions or serious wound-related adverse events were reported.

DISCUSSION

This pilot randomized controlled trial evaluated the use of chlorhexidine-based versus standard gauze dressings after major urologic surgery. The study demonstrated that randomization, dressing protocol implementation, and short-term follow-up were feasible within a time-limited funding period.

Importantly, the trial provides a contemporary estimate of SSI incidence in large-incision urologic procedures – approximately 4% within 14 days. The low incidence may reflect modern surgical standards, effective perioperative antibiotic use, and a predominance of clean or clean-contaminated wounds. Nonetheless, no clear difference between dressing types was observed, suggesting that if there is any advantage of chlorhexidine-impregnated dressings, it is likely modest in this context.

The high rate of postoperative antibiotic use in this cohort warrants specific comment. Nearly all patients received extended antibiotic therapy, and approximately 80% continued oral antibiotics after discharge. This pattern likely reflects the complexity of procedures performed at a tertiary referral center, the high proportion of patients with preoperative bacteriuria, urinary tract opening during surgery, and the discretionary nature of postoperative antibiotic decisions in this clinical setting. Such extensive antibiotic exposure likely reduced baseline SSI risk and may have obscured any differential effect attributable to dressing type. Furthermore, these prescribing patterns may limit the external validity of the observed SSI incidence relative to contemporary SSI-prevention strategies, which generally favor more restrictive postoperative antibiotic use. Standardization of perioperative antibiotic protocols would therefore represent an important design element of future definitive trials.

The clinical heterogeneity of included procedures is an important consideration. Operations ranged from relatively straightforward nephrectomy to complex reconstructive procedures such as continent urinary diversion and ureteral repair, which differ substantially in operative complexity, contamination risk, urinary tract exposure, and expected SSI rates. Although stratification by urinary tract opening partially addressed this variability, it does not fully account for the range of wound contamination profiles across procedures. Future trials should consider stratifying by procedure type or focusing on a more homogeneous high-risk cohort to improve statistical power and clinical interpretability.

Evidence regarding chlorhexidine's role in SSI prevention is mixed. Randomized trials and meta-analyses have demonstrated that chlorhexidine–alcohol skin antisepsis is superior or non-inferior to povidone–iodine for preoperative skin preparation, with a reduction in SSI risk in some settings [10, 11]. However, this benefit relates primarily to preoperative skin antisepsis rather than to postoperative wound dressings. Recent urology-specific reviews emphasize that current evidence and guideline recommendations predominantly support chlorhexidine use for skin antisepsis across urologic procedures, while data supporting routine use of chlorhexidine-impregnated dressings after primary wound closure remain limited [12].

Most high-quality evidence supporting chlorhexidine-impregnated dressings originates from studies on central venous catheter exit sites, where randomized trials and meta-analyses consistently demonstrate reductions in catheter-related bloodstream and exit-site infections [13, 14]. These findings, however, relate to percutaneous device management and cannot be directly extrapolated to closed surgical incisions.

Consistently, major surgical and infection-control guidelines endorse alcohol-based skin antisepsis but do not recommend routine use of chlorhexidine-impregnated dressings after primary wound closure, citing insufficient or inconsistent clinical evidence [5].

In contrast, evidence supporting the use of advanced or antiseptic postoperative dressings for primarily closed surgical wounds remains inconsistent. A systematic review and meta-analysis of randomized trials did not demonstrate a significant reduction in SSI rates compared with standard dressings [15]. These findings are consistent with the results of the present pilot study, in which no clinically relevant differences in early wound outcomes were observed between groups.

Experimental data suggest that prolonged or repeated exposure to chlorhexidine may exert cytotoxic effects on healing tissues; however, the clinical relevance of these findings for short-term use on closed surgical wounds remains uncertain [16].

Limitations of this pilot study include the small

sample size, single-center design, short follow-up period, and the potential confounding effect of extended postoperative antibiotic use. An important limitation is that postoperative wound-care protocols were not fully identical between groups. In accordance with manufacturer recommendations for Bactigras®, soap and other anionic antiseptics were avoided in the chlorhexidine group, and standard postoperative wound-care practices may not have been fully equivalent between groups. These pragmatic differences in postoperative wound management may nevertheless have introduced confounding and limit attribution of outcomes solely to dressing type. In addition, the study was unblinded, and outcome assessors were aware of treatment allocation. Although SSI diagnosis was based on predefined clinical criteria, lack of blinding may have influenced assessment of subjective wound findings such as exudate or mild skin irritation. Standard CDC surveillance definitions use a 30-day follow-up window for most procedures; therefore, late-presenting SSIs may have been underreported in this feasibility-focused trial [9]. Strengths include the randomized design, high protocol adherence, pragmatic implementation, and reporting in accordance with the CONSORT extension for pilot and feasibility trials.

CONCLUSIONS

The observed early postoperative SSI incidence within 14 days after major urologic surgery was low. Under the conditions of this pilot study, no clear differences in SSI incidence or other early wound outcomes were observed between chlorhexidine-based and standard gauze dressings. This pilot randomized controlled trial confirmed the feasibility and safety of a randomized comparison of chlorhexidine-based and standard gauze dressings and provides preliminary data to inform the design and sample-size estimation of future definitive multicenter studies, particularly those focusing on higher-risk patient populations and standardized perioperative protocols.

CONFLICT OF INTEREST

The authors declare no conflict of interest.

FUNDING

The study was supported by a Students' Scientific Grant from the Jagiellonian University Medical College.

ETHICS APPROVAL STATEMENT

The study protocol was reviewed and approved by the Bioethics Committee of the Jagiellonian University (approval no. 1072.6120.151.2023).

SUPPLEMENTARY MATERIAL

Suppl. Table 1. *Detailed list of surgical procedures*

No.	Surgical procedure	Total n (%)	Group A – chlorhexidine (n = 39) n (%)	Group B – standard (n = 40) n (%)
1	Nephrectomy	22 (27.8)	9 (23.1)	13 (32.5)
2	Radical cystectomy	13 (16.5)	6 (15.4)	7 (17.5)
3	Simple prostatectomy	10 (12.7)	4 (10.3)	6 (15.0)
4	Partial nephrectomy	9 (11.4)	5 (12.8)	4 (10.0)
5	Nephroureterectomy	9 (11.4)	2 (5.1)	7 (17.5)
6	Nephrectomy with IVC thrombus	5 (6.3)	3 (7.7)	2 (5.0)
7	Ureteral reconstruction	5 (6.3)	5 (12.8)	0 (0)
8	Retroperitoneal lymph node dissection	2 (2.5)	2 (5.1)	0 (0)
9	RCC recurrence in retroperitoneum	1 (1.3)	0 (0)	1 (2.5)
10	Other kidney surgery (benign)	1 (1.3)	1 (2.6)	0 (0)
11	Fistula repair	1 (1.3)	1 (2.6)	0 (0)
12	Continent pouch formation	1 (1.3)	1 (2.6)	0 (0)

IVC – inferior vena cava; RCC – renal cell carcinoma

References

1. Couris CM, Rabilloud M, Ecochard R, et al. Nine-year downward trends in surgical site infection rate in southeast France (1995–2003). J Hosp Infect. 2007; 67: 127-134.

2. Worth LJ, Bull AL, Spelman T, Brett J, Richards MJ. Diminishing surgical site infections in Australia: time trends and predictors. Infect Control Hosp Epidemiol. 2015; 36: 409-416.

3. Young PY, Khadaroo RG. Surgical site infections. Surg Clin North Am. 2014; 94: 1245-1264.

4. National Institute for Health and Care Excellence (NICE). Surgical Site Infections: Prevention and Treatment (NG125). Updated 2020.

5. Berríos-Torres SI, Umscheid CA, Bratzler DW, et al. Centers for Disease Control and Prevention guideline for the prevention of surgical site infection, 2017. JAMA Surg. 2017; 152: 784-791.

6. Sood A, Granick MS, Tomaselli NL. Wound dressings and comparative effectiveness data. Adv Wound Care (New Rochelle). 2014; 3: 511-529.

7. Seidelman JL, Mantyh CR, Anderson DJ. Surgical site infection prevention: a review. JAMA. 2023; 330: 651-662.

8. Eldridge SM, Chan CL, Campbell MJ, et al. CONSORT 2010 statement: extension to randomised pilot and feasibility trials. BMJ. 2016; 355: i5239.

9. National Healthcare Safety Network, Centers for Disease Control and Prevention. Surgical site infection (SSI) event. Available at: http://www.cdc.gov/nhsn/pdfs/pscmanual/9pscssicurrent.pdf. Published January 2017. Accessed December 2023.

10. Darouiche RO, Wall MJ Jr, Itani KM, et al. Chlorhexidine–alcohol versus povidone–iodine for surgical-site antisepsis. N Engl J Med. 2010; 362: 18-26.

11. Widmer AF, Atkinson A, Kuster SP, et al. Povidone iodine vs chlorhexidine gluconate in alcohol for preoperative skin antisepsis: a randomized clinical trial. JAMA. 2024; 332: 541-549.

12. Lynch NB, Badalato GM. Evidence-based skin antisepsis for urologic surgery: a narrative review. Urology. 2025; 205: 331-336.

13. Safdar N, O'Horo JC, Ghufran A, et al. Chlorhexidine-impregnated dressing for prevention of catheter-related bloodstream infection: a meta-analysis. Crit Care Med. 2014; 42: 1703-1713.

14. Puig-Asensio M, Marra AR, Childs CA, Kukla ME, Perencevich EN, Schweizer ML. Effectiveness of chlorhexidine dressings to prevent catheter-related bloodstream infections: a systematic review and meta-analysis. Infect Control Hosp Epidemiol. 2020; 41: 1383-1392.

15. Walter CJ, Dumville JC, Sharp CA, Page T. Systematic review and meta-analysis of wound dressings in the prevention of surgical site infection in surgical wounds healing by primary intention. Br J Surg. 2012; 99: 1185-1194.

16. Cheong JZA, Liu A, Rust CJ, et al. Robbing Peter to pay Paul: chlorhexidine gluconate demonstrates short-term efficacy and long-term cytotoxicity. Wound Repair Regen. 2022; 30: 451–461. ■