

# Better Clinical Practice Could Overcome Patient-Related Risk Factors of Vascular Surgical Site Infections

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**SAGE**

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## Abstract

**Purpose:** To clarify the current status of surgical site infection (SSI) during endovascular aortic repair and to define risk factors for SSI among the patients who underwent thoracic or abdominal stent-graft repair through a groin incision. **Methods:** Between 2006 and 2013, data were collected from 1604 patients (mean age 75.2±9.5 years; 1282 men) with 2799 groin incisions for transfemoral access during aortic stent-graft procedures. SSIs were classified as superficial or deep (both occurring within 30 days) or organ/space infections (occurring within 1 year after surgery) according to the Centers for Disease Control and Prevention guidelines. Strategies in place for minimizing SSIs were (1) employing oblique groin incisions, (2) covering the incision with saline-soaked gauze, (3) irrigating the incision thoroughly with saline per layer, and (4) using absorbable sutures. **Results:** Overall incidence of SSI was 0.4% (6 patients). The majority of SSIs were late-onset prosthetic graft infections (5, 0.3%). Five of the 6 were successfully treated with conservative therapy; one patient died of sepsis. Univariate analysis showed additional therapy (eg, coil embolization) with a stent-graft procedure was a risk factor for SSI. **Conclusion:** Appropriate antibiotic administration, oblique groin incision, meticulous operative technique, protection against airborne infection during the operation, and closed dressings may avert vascular wound SSIs.

## Keywords

abdominal aortic aneurysm, thoracic aortic aneurysm, endovascular aneurysm repair, thoracic endovascular aortic repair, endograft, infection, stent-graft

## Introduction

Stent-graft procedures have facilitated remarkable progress in the treatment of aneurysms, with their less invasiveness and better short-term outcomes compared with conventional open repairs. In the past 2 decades, the procedure has superseded open surgery, achieving favorable clinical outcomes with improvements in endovascular devices.<sup>1,2</sup> Surgical site infection (SSI) is one of the major adverse events in cardiovascular and endovascular surgery, representing a serious health concern.<sup>3</sup> Several procedure- and patient-related factors, such as groin incision and diabetes, are known to contribute to the development of SSI.<sup>4</sup>

During endovascular aortic repairs, most stent-grafts require a 3- to 6-cm skin incision in the groin for insertion, and patient comorbidities are generally not modifiable. Accordingly, the current strategies for prophylaxis of vascular SSI may be suboptimal.<sup>5-14</sup> We propose a user-friendly protocol for prevention of SSI in endograft operations on the basis of the analysis of more than 1600 patients.

## Methods

### Stent-Graft Procedures

This clinical study was conducted in a high-volume vascular center in which more than 700 arterial surgeries are performed annually. Between July 2006 and June 2013, 2002 of these surgeries were endovascular aortic repairs. These included 584 thoracic endovascular aortic repairs (TEVAR), 90 branched/fenestrated endovascular aneurysm repairs (b-EVAR), and 1328 EVARs for abdominal aortic aneurysm. Forty-two cases involved simultaneous TEVAR and EVAR. In general, TEVAR required a unilateral groin incision,

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whereas b-EVAR or EVAR was performed via bilateral groin incisions. Excluded from this population were 372 patients undergoing percutaneous EVAR, a transiliac or transaortic approach owing to poor access, additional reconstruction of the cervical vessels, or chimney procedures. Twenty-six patients with infectious aneurysm were also excluded. This analysis thus included 1604 patients (mean age  $75.2 \pm 9.5$  years; 1282 men) with 2799 groin incisions for transfemoral access during the initial procedure. The type of stent-grafts included Zenith (Cook Medical, Bloomington, IN, USA;  $n=402$ ), Excluder (W. L. Gore & Associates, Flagstaff, AZ, USA;  $n=717$ ), Talent (Medtronic CardioVascular, Santa Rosa, CA, USA;  $n=5$ ), Endurant (Medtronic CardioVascular,  $n=116$ ), TAG (W. L. Gore & Associates,  $n=279$ ), Talent-Thoracic (Medtronic CardioVascular,  $n=40$ ), TX2 (Cook Medical,  $n=58$ ), and Valiant (Medtronic CardioVascular,  $n=28$ ).

### Definition of SSI

The definition of SSI followed the guidelines of the Centers for Disease Control and Prevention (CDC), the Society for Healthcare Epidemiology of America, and the Infectious Disease Society of America.<sup>5,6</sup> SSIs were classified as superficial, deep, and organ/space infections. Superficial SSIs involved the skin or subcutaneous tissue of the incision, whereas deep SSIs involved the fascia and muscle layer. The diagnosis of superficial and deep SSIs was based on visual inspection, blood test, and computed tomography (CT). Superficial and deep infections were regarded as SSIs if they occurred within 30 days postoperatively. According to the 1999 CDC surveillance guidelines,<sup>5</sup> organ/space SSIs were also defined as infections of the endograft or aneurysms that occurred within 1 year after surgery. Confirmation of organ/space SSIs requires air trapping, characteristic inflammatory changes, or presence of fluid around the endograft on CT scan, and also an abnormal accumulation of gallium on scintigraphy.

### Procedures for Minimizing SSI

All procedures were performed in a class 10,000 operating room equipped with a flat panel detector [Innova (GE Medical Systems, Milwaukee, WI, USA) or Artis Zeego (Siemens Medical Solutions, Malvern, PA, USA)] or portable C-arm (OEC9800; GE Medical Systems). Skin preparations, such as washing with antiseptic solutions, were not carried out, whereas skin sterilization was completed using povidone iodine in the area between the navel and the thigh. The operative area was covered with a sterile drape that visualizes only the groin site. Electric shavers were used as needed just before a groin incision. With regard to groin incision and closure, our strategies against SSI were (1) employing oblique groin incisions along the Langer line;

(2) covering the incision with saline-soaked gauze throughout the stent-graft procedure to avoid infection by airborne bacteria; (3) carefully irrigating the incision with  $\sim 250$  mL saline per layer including the femoral fascia, subcutaneous tissue, and subdermal fascia on closure; and (4) using absorbable sutures to close each layer (Figure 1). The endograft was prepared immediately prior to insertion into the operative field to avoid attachment of airborne bacteria. Skin closure strip and film dressings were used to reinforce the wound during the postoperative period, and the dressing tape was removed 48 hours after surgery.

In addition to wound management, there was a well established protocol for SSI prevention.<sup>7,8</sup> Antibiotic administration was started from 1 hour before skin incision, with an additional infusion of antibiotics every 3 hours in order to maintain the minimum inhibitory concentration during surgery. In patients with renal dysfunction (creatinine  $>1.5$  mg/dL), antibiotics were administered in half quantities every 6 hours. Cephazolin (4 g/d) was routinely used for prophylaxis of SSIs due to gram-positive bacteria. Ampicillin/sulbactam (6 g/d) was used for patients with a cephalosporin allergy and fosfomycin (2 g/d) for those with a penicillin allergy.

### Risk Factor Analysis

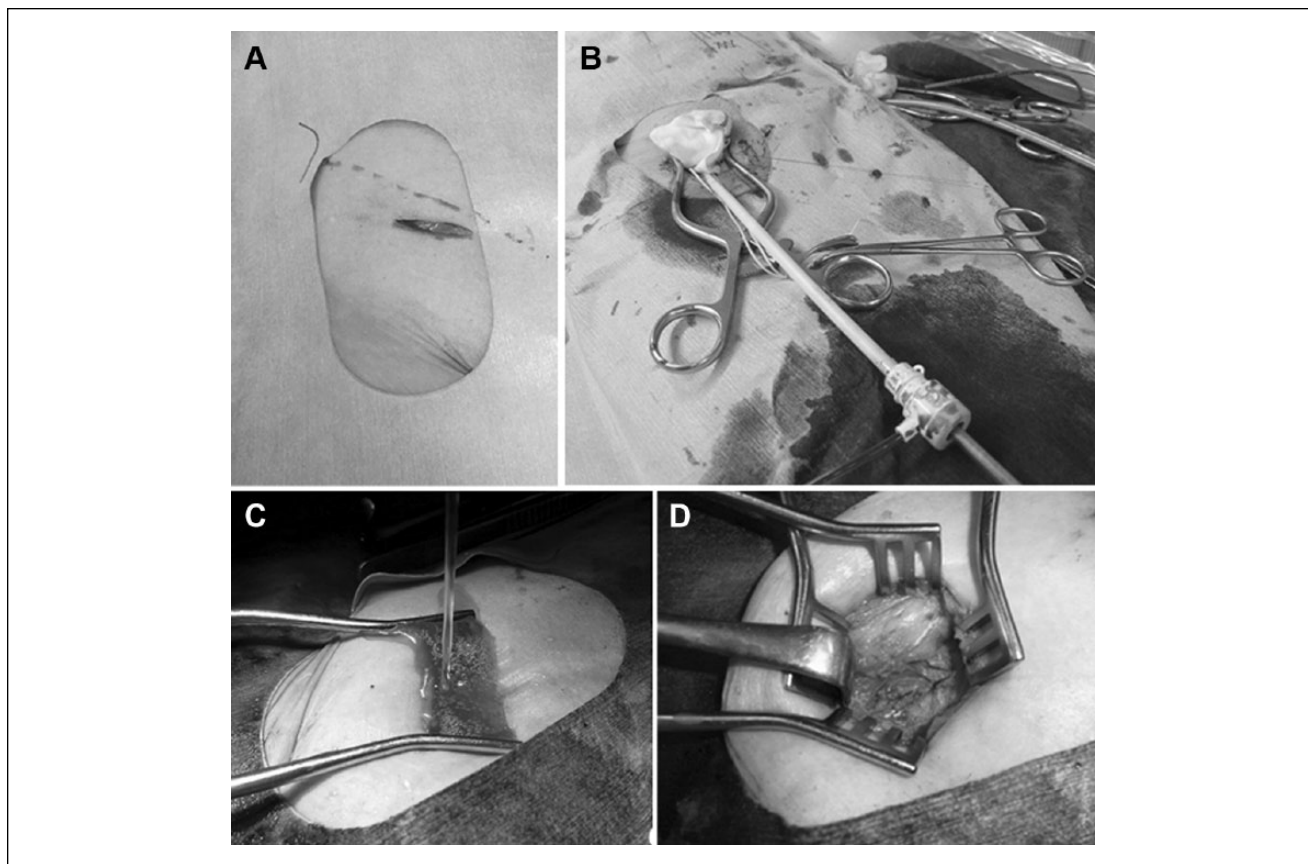
The length of hospital stay (LOS) before surgery, patient age, hypertension, hyperlipidemia, diabetes mellitus, coronary artery disease (CAD), cerebrovascular disease (CVD), chronic kidney disease (CKD), chronic obstructive pulmonary disease (COPD), body mass index (BMI)  $>25$  kg/m<sup>2</sup>, past history of smoking, use of steroids, aneurysm size, and the American Society of Anesthesiologists (ASA) classification were assessed as potential risk factors of SSI. Surgeon- and procedure-related potential risk factors included the length of wound incision, procedure time, estimated blood loss, volume of contrast agents during surgery, fluoroscopy time, and need for additional therapy, including coil embolization.

### Statistical Analysis

Continuous data are presented as the means  $\pm$  standard deviation; categorical data are given as the counts (percentage). Differences between groups were analyzed using the chi-square test for categorical variables and the *t* test for continuous variables. All analyses were performed using SPSS software (IBM Corporation, Somers, NY, USA). The threshold of statistical significance was  $p < 0.05$ .

### Results

All groin wounds were considered clean, with a mean wound length of  $4.1 \pm 0.5$  cm. SSIs occurred in 6 (0.4%) of



**Figure 1.** (A) The 3- to 6-cm oblique incision was made in the groin along the Langer line. (B) A saline-soaked gauze was inserted to prevent airborne bacteria from contaminating the wound throughout the procedure. (C) The incision was irrigated carefully with saline prior to wound closure. (D) Absorbable suture was used to close each layer.

1604 patients (Table 1), but only 1 (0.06%) arose within 30 days after surgery. In addition, lymphocele was suggested in 45 (1.6%) patients and hematoma in 6 (0.4%).

The single superficial SSI patient had a deep infection. While the hospital course was uneventful, wound infection was found at follow-up in the outpatient department. In this patient, drainage of the abscess was successfully performed under local anesthesia. Methicillin-resistant *Staphylococcus aureus* (MRSA) and *Streptococcus g* group were isolated as causal bacteria. The open wound was washed with saline in a shower after drainage, and appropriate antibiotics were administered for 5 days by infusion followed by oral antibiotics for an additional 14 days. The wound was completely healed at 30 days after occurrence.

Space/organ SSIs occurred in 5 (0.3%) patients within 1 year after surgery. All cases were late-onset prosthetic graft infections. Pyrexia developed in all cases, while blood culture was negative for bacteria despite repeated examinations. Fluid accumulation was observed on CT, as well as abnormal accumulation of gallium (Figure 2). Stent-graft removal was considered a radical treatment for graft infections, and conservative treatment with antibiotic administration was

feasible because the patients were elderly and/or did not want to undergo invasive treatment. One patient died secondary to septic shock, while infection subsided in the others without recurrence during a mean follow-up of 36 months (range 1–85).

All the patients with infections had undergone additional procedures, such as coil embolization. On univariate analysis, the need for additional procedures was identified as a risk factor of SSI (Table 2).

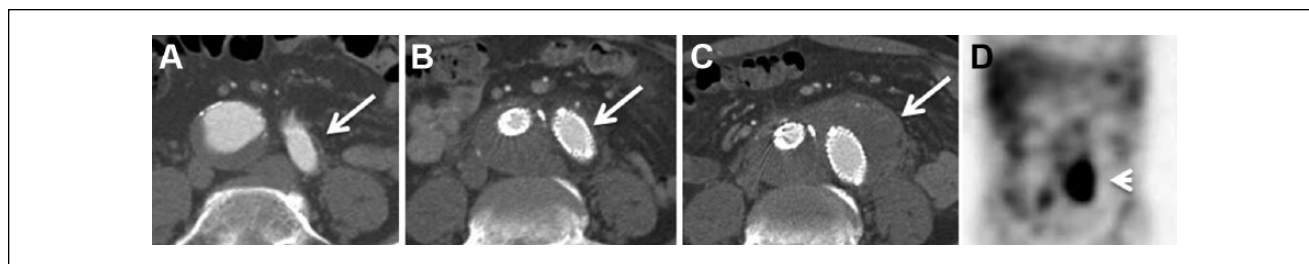
## Discussion

Surgical site infections are one of the major causes of morbidity and mortality in vascular surgery, and they increase the cost of hospitalization. According to previous reports, the incidence of SSI in cardiovascular surgery ranged from 0.5% to 15%.<sup>5-14</sup> Among the procedures for lower limb bypass, the incidence of SSIs is particularly high.<sup>15</sup> SSI also occurs in aneurysm repair, and graft infection in particular can be fatal. The incidence of SSI after endovascular surgery varies (0.5%–5%),<sup>16-23</sup> suggesting that SSI rates can be reduced when preventive methods are optimized. The

**Table 1.** All Cases of Surgical Site Infection.

Sex/Age, y	Comorbidities	Type of SSI	Procedure	Device	Time to SSI, d	LOS, d	Follow-up, mo	Outcome
1. M/80	HT, HL, BMI>25, smoking history	Deep	EVAR+ IIA coil	Excluder	14	4	63	Alive
2. M/84	HT, CKD, smoking history	Organ/space	EVAR+ IIA coil	Zenith	214	4	10	Alive
3. M/85	HT, smoking history	Organ/space	EVAR+ IIA coil	Zenith	241	2	8	Death from sepsis
4. M/75	HT, CVD, smoking history	Organ/space	EVAR+ IIA coil	Excluder	176	2	24	Alive
5. M/83	HT, CAD, CKD, smoking history	Organ/space	EVAR+ IIA coil	Excluder	70	2	15	Alive
6. M/67	HT, CAD, smoking history	Organ/space	TEVAR+ SCA coil	TX2	243	6	8	Alive

Abbreviations: BMI, body mass index; CAD, coronary artery disease; CKD, chronic kidney disease; CVD, cerebrovascular disease; EVAR, endovascular aneurysm repair; HL, hyperlipidemia; HT, hypertension; IIA, internal iliac artery; LOS, length of stay; TEVAR, thoracic endovascular aneurysm repair; SCA, subclavian artery; SSI, surgical site infection.



**Figure 2.** Computed tomography (CT) scans of the (A) preoperative common iliac artery (arrow), (B) same site (arrow) after insertion of an endograft, and (C) the abscess (arrow) circumference on postoperative day 14. (D) Gallium scintigraphy of the same site as the CT scans. The infection site was improved with administration of antibiotics for 10 months.

endograft is a foreign substance, which is susceptible to bacterial inoculation. When prosthetic grafts are infected, it is quite difficult to eradicate bacteria without graft removal.

The rules for preventing wound SSI that we applied resulted in only one wound-related (superficial or deep) SSI, which is better than those of previous reports. The risk factors of SSI identified in clinical reports include age, gender, obesity, diabetes, COPD, CKD, high ASA class, emergency operation, history of smoking, use of steroids, and longer procedure time. As a result, additional therapies, such as coil embolization preceding the stent-graft procedure, were a predictor for SSI, which was consistent with previous studies.<sup>18</sup> Several studies have reported that patients in whom MRSA was detected in the nasal cavity had 2 to 9 times the risk of SSIs.<sup>24,25</sup> We did not routinely examine the nasal cavity for MRSA but achieved a favorable result in terms of a very low incidence of vascular SSIs.

Randomized controlled trials have been performed comparing the effects of povidone iodine and chlorhexidine, with an advantage for chlorhexidine found.<sup>26,27</sup> Nevertheless,

we continue to use povidone iodine due to the difficulty in observing the sterilization region and leaks associated with the use of chlorhexidine. According to the CDC guidelines<sup>3</sup> and the study of Harbarth et al,<sup>28</sup> when antibiotics are delivered 1 hour before the start of skin incision, effective blood concentrations are maintained during the surgical procedure. We followed the CDC guidelines that recommend additional infusions of antibiotics administered every 3 hours during the procedures.

Previous studies suggest that oblique groin incision is superior to longitudinal incision to reduce groin infections.<sup>29,30</sup> Therefore, we adopted the oblique incision as one of our basic rules. Oblique incisions are performed with the skin secant (Langer line) and may prevent keloid formation and SSI. Furthermore, we attempted to reduce the risk of SSI by using absorbable sutures.

Although the operating room must be clean, operative field infections have occurred due to airborne bacteria.<sup>31</sup> Given such findings, the endograft was exposed just prior to insertion, and the saline-soaked gauze was used to protect the wound to prevent infection by airborne bacteria during

**Table 2.** Univariate Analysis to Identify Risk Factors for SSI in Stent-Graft Procedures.

	All Cases <sup>a</sup>	– SSI <sup>a</sup>	+ SSI <sup>a</sup>	p	95% CI
Age, y	75.2±9.5	75.3±9.5	79.0±6.8	0.334	–11.4 to 3.7
Male gender	1282	1276	6	0.608	–0.22 to –0.18
Hypertension	1310	1304	6	0.600	–0.20 to –0.16
Hyperlipidemia	646	645	1	0.411	–0.06 to –0.54
Diabetes	227	227	0	1.000	0.12 to 0.16
CAD	438	436	2	0.667	–0.44 to 0.32
CKD stage ≥4	79	78	1	0.263	–0.42 to 0.18
CKD stage ≥1–3	208	207	1	0.567	–0.33 to 0.26
COPD	239	239	0	0.600	0.13 to 0.17
BMI >25 kg/m <sup>2</sup>	261	259	2	0.254	–0.55 to 0.21
Smoking history	1205	1199	6	0.346	–0.27 to –0.23
Use of steroids	29	29	0	1.000	–0.01 to 0.02
Aneurysm diameter, cm	5.9±1.3±	5.8±2.9	6.1±8.1	0.633	–12.9 to 7.8
Rupture	54	54	0	1.000	0.02 to 0.04
ASA classification ≥3	256	255	1	1.000	–0.31 to 0.29
Wound classification	1	1	1		
Length of incision, cm	4.1±0.5	4.1±0.5	4.5±0.8	0.304	–1.30 to 0.49
Procedure time, min	201±99	200±99	218±66	0.649	–97.9 to 61.0
Blood loss, mL	433±809	437±826	497±316	0.858	–722.5 to 601.7
Contrast use, mL	205±116	203±114	200±103	0.947	–88.9 to 95.2
Fluoroscopy time, min	47±35	47±35	56±37	0.503	–37.3 to 18.3
Additional therapy <sup>b</sup>	778	772	6	0.013	–0.54 to –0.49
Coil embolization <sup>c</sup>	477	471	6	0.001	–0.72 to –0.68
Preoperative LOS, d	3.6±4.0	3.6±4.1	3.3±1.6	0.885	–3.00 to 3.50
Postoperative LOS, d	7.8±15	7.9±15.5	6.8±6.4	0.870	–11.40 to 13.50
Scrub ≥20 seconds	350	348	2	0.617	–0.49 to 0.26
Modular stent-grafts	952	949	3	0.692	–0.31 to 0.49
Persistent endoleaks	215	214	1	0.584	–0.33 to 0.27
Reintervention <sup>d</sup>	73	72	1	0.244	–0.42 to 0.18

Abbreviations: ASA, American Society of Anesthesiologists; BMI, body mass index; CAD, coronary artery disease; CI, confidence interval; CKD, chronic kidney disease; COPD, chronic obstructive pulmonary disease; SSI, surgical site infection.

<sup>a</sup>Continuous data are presented as the means ± standard deviation; categorical data are given as the counts (percentage).

<sup>b</sup>Includes femorofemoral bypass.

<sup>c</sup>Coil embolization simultaneously with endovascular aneurysm repair.

<sup>d</sup>Reoperation with endovascular aneurysm repair or thoracic endovascular aortic repair.

the procedures. Wound irrigation was copious and retractors were moved to avoid missing any area. We believe that these precautions allowed us to significantly limit the occurrence of wound infections. Importantly, any facility can easily and quickly implement these precautionary procedures; no special medication or devices are required.

Recent reports regarding the efficacy of percutaneous EVAR found that the access-related complication rates were almost equal between cutdown and the percutaneous approach.<sup>32,33</sup> Nevertheless, we believe that cutdown appears to be safer than the current percutaneous approach in terms of decreased risk for perioperative hemorrhage or open conversion.

Organ/space SSIs, including graft infections, are intractable complications that can be life-threatening. Setacci et al<sup>18</sup>

described an overall mortality rate of 17.5% in 102 cases of abdominal stent-graft infections. According to the type of treatment, the mortality was 38.8% for conservative treatment, 14.6% for stent-graft removal and extra-anatomical bypass, and 7.4% for in situ reconstruction.<sup>17–21</sup> Conservative treatment appears to result in worse outcomes, but patients who receive conservative therapy are more frail than those undergoing reoperation.<sup>17–21</sup> The most common causative pathogen appears to be *S aureus*, including MRSA, and other organisms implicated in endograft infection including *Escherichia coli*, *Klebsiella* sp, and other aerobic gram-negative bacilli.<sup>17–23</sup> We conservatively and successfully treated all but one of the patients with graft infections. It should be noted that the risk of aortoenteric fistulas increases with time after initial disappearance of the infections.<sup>18–23</sup>

## Limitations

This was a retrospective study, with its attendant likelihood of selection bias. Second, multivariate analysis could not be performed, but additional therapy including coil embolization was defined as a risk factor in the univariate analysis. Third, this study was based on the 1999 CDC guidelines,<sup>5</sup> but the definition of organ/space SSI has changed on the current CDC guidelines.<sup>3</sup>

## Conclusion

Appropriate antibiotic administration, oblique groin incision, meticulous operative technique, protection against airborne infection during the operation, and closed dressings may avert vascular wound SSI. Further efforts are needed to decrease endograft-related infection and obviate the serious risks of reintervention and death.

## Declaration of Conflicting Interests

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