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Impact of intraoperative behavior on surgical site infections

Guido Beldi, M.D.[a,*], Sonja Bisch-Knaden, Ph.D.[a], Vanessa Banz, M.D.[a], Kathrin Mühlemann, M.D., Ph.D.[b], Daniel Candinas, M.D.[a]

[a]Department of Visceral and Transplant Surgery, Bern, Switzerland; [b]Institute of Infectious Diseases, Bern, Switzerland

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Behavior

Abstract

BACKGROUND: The aim of this study was to identify intraoperative risk factors for surgical site infections (SSIs), which are accessible to interventions. We evaluated the effect of extensive intraoperative antiseptic measures and the impact of the behavior of members of the surgical team on SSIs.

METHODS: Standard versus extensive antiseptic measures were randomly assigned in 1,032 surgical patients. The adherence to principles of asepsis by members of the surgical team was assessed prospectively.

RESULTS: The rate of SSI was 14% with standard antiseptic measures and 15% with extensive measures ($P = .581$). Multivariate analysis identified following independent risk factors: lapses in discipline (odds ratio [OR] 2.02, confidence interval [CI] 1.05–3.88), intestinal anastomosis (OR 6.74, CI 3.42–13.30), duration of operation more than 3 hours (OR 3.34, CI 1.82–6.14), and body mass index >30 kg/m^2 (OR 1.98, CI 1.22–3.20).

CONCLUSION: Extensive measures of antisepsis did not reduce the incidence of SSI. A lapse to adhere to principles of asepsis was identified as an independent risk factor for the development of SSI (ClinicalTrials.gov number, NCT00555815).

Surgical site infections (SSIs) are the third most frequently reported nosocomial infections, accounting for 14% to 16% of nosocomial infections overall, and for 38% of nosocomial infections among surgical patients.[1] SSIs increase hospital stay on average by 7 to 13 days and average cost by 2.6 to 3 times per case.[2–4]

Risk factors for SSI are dependent on patient traits or surgical characteristics. Risk factors associated with the surgical environment such as duration of operation, blood loss, and type of surgery have a greater influence on SSI than do patient characteristics such as age, diabetes, and use of nicotine or steroids.[1,5,6] The investigation of risk factors associated with intraoperative characteristics has most often been limited to individual factors of the surgical environment such as room ventilation, skin shaving, skin disinfection, and use of specific drapes.[5,6] In the present study, we focused on factors that were globally associated with intraoperative antiseptic measures implemented by surgical team members. This was done based on 2 hypotheses: (1) extensive antiseptic measures reduce the incidence of SSI; and (2) the discipline to adhere to principles of asepsis by surgical team members affects the incidence of SSI. A prospective randomized trial was conducted to compare standard versus extensive antiseptic measures. The discipline of surgical team members was assessed prospectively in the same trial.

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* Corresponding author. Tel.: +41-31-632-8275; fax: +41-382-4772.
E-mail address: guido.beldi@insel.ch

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Methods

Study design

The protocol for this prospective cohort study trial was reviewed by the institutional ethics review board of Bern (Switzerland). All patients requiring general surgical procedures in Bern University Hospital were eligible to enter the study and were consented to clinical follow-up and data collection. Operative rooms were randomly assigned to one of the 2 groups (extensive antiseptic measures and standard antiseptic measures as an independent concurrent control) for an entire day; randomization was performed starting at 7 AM and ending at 7 AM on the following day. Random numbers were calculated online in blocks of 20 subjects (http://www.randomization.com). The treatment was not blinded to all persons involved.

Primary study end points

Primary outcome measure was the rate of SSI 30 days after surgery.[7] SSIs were assessed by the surgeon according to the criteria developed by the Centers for Disease Control and Prevention.[1,5,8] Infections were categorized as incisional (superficial or deep) infections or organ-space infections. Superficial incisional infections involved only skin and subcutaneous tissue and excluded stitch abscesses. Deep incisional infections involved deeper soft tissues at the site of incision. Organ-space infections were defined as infections in any organ or space other than the incised layer of body wall that was opened or manipulated during the initial surgical procedure. Patients were examined regularly during their postoperative stay, in keeping with the clinical routine. In addition, an independent observer contacted each patient 30 days postoperatively.

Secondary study end points

Intraoperative adherence to principles of asepsis was measured with the use of a standardized protocol. Experienced members of the nurses of the operative room observed surgical team members. Assessment included 10 items, each of which was subjectively rated as correct (0 points) or incorrect (1 point), according to the following scale: (1) general impression (repetitive violations present, no: 0 points, yes: 1 point); (2) preparation of the patient in the operating room, including skin disinfection and surgical draping (correct/incorrect); (3) hand scrub (correct/incorrect); (4) cap/mask worn correctly/incorrectly; (5) distance of 50 cm to surgical tables maintained by nonsterile persons (yes/no); (6) exchange of surgical team members (no: 0 points, one or more: 1 point); (7) movement in the operating room (normal: 0 points, hectic: 1 point); (8) noise in the operating room (calm: 0 points, loud: 1 point); (9) visitors (none: 0 points, one or more: 1 point); and (10) intraoperative changing of patient position (no: 0 points, yes: 1

Table 1 Patient baseline characteristics

	Extended hygiene measures (n = 538)	Standard hygiene measures (n = 494)	*P* value
Age, y, median (range)	59 (5–94)	60 (19–91)	.58
Sex			.95
Female	278/538 (51.7)	254/494 (51.4)	
Male	260/538 (48.3)	240/494 (48.6)	
Diabetes, no. (%)	53/507 (11)	62/466 (13)	.20
Nicotine, no. (%)	139/489 (28)	131/451 (29)	.89
COPD, no. (%)	43/505 (9)	52/458 (11)	.16
Immunosuppression, no. (%)	45/497 (9)	36/464 (8)	.49
BMI >30 kg/m^2, median (range)	25.5 (14.2–69.6)	25.5 (15.2–64.3)	.51
Consultant surgeon, no. (%)	218/536 (41)	217/491 (44)	.26
Duration of surgery, min, median (range)	180 (15–780)	190 (15–660)	.12
Length of hospital stay, d, median (range)	8 (1–105)	10 (1–97)	.047
Type of operation, no. (%)			.77
Hernia, laparoscopy	115 (21)	87 (18)	
Endocrine	91 (17)	82 (17)	
Upper gastrointestinal surgery	41 (8)	42 (9)	
Hepatobiliary surgery	114 (21)	105 (21)	
Colorectal surgery	115 (21)	120 (24)	
Transplant surgery	8 (2)	9 (2)	
Other	54 (10)	49 (10)	
Discipline score, no. (%)			.08
Score 0	172/464 (37)	115/386 (30)	
Score 1 or 2	180/464 (39)	170/386 (44)	
Score ≥ 3	112/464 (24)	101/386 (26)	

COPD = chronic obstructive pulmonary disease; BMI = body mass index.

Table 2 Rates of surgical site infections

	Extended hygiene measures (n = 538)	Standard hygiene measures (n = 494)	*P* value
Infections, total, no. (%)	74/492 (15)	64/469 (14)	.58
Type of infection, no. (%)			.43
Superficial	54/492 (11)	45/469 (12)	
Deep	2/492 (.4)	1/469 (.2)	
Organ-space	18/492 (4)	18/469 (4)	

point). A lapse in discipline was defined as the presence of 1 or more points.

Definition of study groups

In both study groups (extensive and standard antiseptic measures), patients underwent bowel preparation for colorectal surgery. As detailed by Dellinger et al, established methods for the prevention of SSI were applied in all patients, including correct timing and duration of antibiotic prophylaxis.[9–11] Hairs were removed using clippers immediately before the operation.[12,13] Skin disinfection was applied 3 times using povidone-iodine–based disinfectant. Single-use sterile drapes were used in all patients.[14] All members of the surgical team wore surgical caps and masks.[15,16] Room temperature was measured and, at the discretion of the surgeon and the anesthetist, was set to maintain patient body temperature between 36.5°C and 37°C.[17] Skin incision (with scalpel or electrocautery), intra-abdominal drainage, and skin closure were in accordance with the surgeon's preferences.[18] No subcutaneous sutures were placed.

Extensive antiseptic measures

All surgeons wore 2 pairs of gloves. The top pair of gloves was changed after each anastomosis, every 2 hours, and after closure of the abdominal fascia.[19] In addition to sterile drapes, an iodine-impregnated transparent foil was used to cover any nondraped body surface within the operating site.[20] All surgeons wore caps that covered their ears and neck. Surgical instruments (eg, needle holders, scissors, swabs, and forceps) were replaced after every anastomosis. At the end of the operation, the abdomen was rinsed with a minimum of 5 L Ringer's solution. Prior to abdominal closure, the operative field was covered again with new sterile drapes, and the subcutaneous tissue was rinsed with 1 L Ringer's solution.

Standard antiseptic measures

Surgeons wore 1 or 2 pairs of gloves, depending on their preference, and did not change them regularly. Surgeons wore caps the way they chose to, and surgical instruments were not changed during the operation. At the end of the operation, the abdomen and the subcutaneous tissue were rinsed at the discretion of the surgeon. No second draping was performed before abdominal closure.

Statistical analysis

This study was designed to test the noninferiority of standard measures versus extensive antiseptic measures in

Table 3 Univariate analysis of patient and surgical risk factors

	Absent	Present	Relative risk (95% CI)	*P* value
Patient risk factors, no. (%)				
Diabetes	114/806 (14)	15/111 (14)	.96 (.58–1.58)	1.00
Nicotine	89/633 (14)	37/254 (15)	1.04 (.73–1.48)	.83
COPD	116/818 (14)	15/89 (17)	1.19 (.73–1.94)	.53
Immunosuppression	121/838 (14)	8/68 (12)	.82 (.42–1.60)	.72
BMI > 30 kg/m^2	85/686 (12)	42/214 (20)	1.58 (1.13–2.22)	.01
Age >60 y	67/514 (13)	71/447 (16)	1.22 (.90–1.66)	.23
Male sex	72/497 (15)	66/464 (14)	1.02 (.75–1.39)	.93
Surgical risk factors, no. (%)				
Extended hygiene measures	64/469 (14)	74/492 (15)	1.10 (.81–1.50)	.58
Missing adherence to principles of asepsis (discipline score) ≥ 1	14/258 (5)	103/536 (19)	3.54 (2.07–6.07)	<.001
Duration of operation > 180 min	23/482 (5)	113/467 (24)	5.07 (3.30–7.80)	<.001
Consultant surgeon	59/539 (11)	79/417 (19)	1.73 (1.27–2.37)	.001
Intestinal anastomosis	16/457 (4)	122/504 (24)	6.91 (4.17–11.46)	<.001

COPD = chronic obstructive pulmonary disease; BMI = body mass index; CI = confidence interval.

Table 4 Multivariate analysis of risk factors

	Odds ratio (95% CI)	*P* value
BMI ($\leq$30 kg/m^2 $\rightarrow$ $>$30 kg/m^2)	2.00 (1.22–3.20)	.006
Surgeon (consultant$\rightarrow$ fellow)	1.27 (.80–2.03)	.32
Duration of surgery ($\leq$3 h $\rightarrow$ $>$3 h)	3.34 (1.82–6.14)	$<$.001
Discipline score (0 $\rightarrow$ $\geq$1)	2.02 (1.05–3.88)	.04
Intestinal anastomosis	6.74 (3.42–13.30)	$<$.001

BMI = body mass index; CI = confidence interval.

the prophylaxis of surgical site infection. An incidence of SSIs of 13% and a maximal increase of 5% were assumed to be noninferior. The significance level was set at .05. To achieve a power of 90%, 455 patients had to be enrolled per group. For analysis of proportional data, Fisher exact test and the chi-square test were applied; the Mann–Whitney *U* test was used for continuous data. Two-sided 95% confidence intervals (CIs) were determined, and for multivariate analysis of risk factors, logistic regression analysis was conducted.

Results

Between July 2005 and January 2007, a total of 1,032 patients were enrolled in the study and were randomly assigned to undergo surgery with the use of standard or extensive antiseptic measures. Patient's baseline characteristics are shown in Table 1. Of these 1,032 patients, 961 (93%) were available for follow-up 30 days after surgery.

The rate of SSI was not different between the 2 groups (Table 2). Most infections were superficial, whereas deep incisional and intra-abdominal infections were observed less frequently. Univariate analysis revealed that among investigated patient characteristics, only a high body mass index $>$30 kg/m^2 had a significant influence on the rate of SSI. Among surgical risk factors, realization of an intestinal anastomosis, operations lasting longer than 3 hours and lapses in adherence to principles of asepsis were independently associated with an increased incidence of SSI (Tables 3 and 4).

Factors that contributed to the discipline score were change within the surgical team members (odds ratio [OR] 2.84; CI 1.97–4.08; $P < .001$), hectic movement (OR 1.82; CI 1.10–3.01; $P = .04$), loud noise in the operating room (OR 1.87; CI 1.34–2.60; $P < .001$), and the presence of 1 or more visitors during surgery (OR 1.79; CI 1.26–2.53; $P = .002$), were strongly associated with the occurrence of SSI (Figure 1 and Table 5).

Comments

This prospective study focused on the influence of 2 intraoperative factors on SSI: extensive antiseptic measures and discipline by the surgical team members. Results show that extensive antiseptic measures did not decrease the rate of SSI. On the other hand, lapses in discipline by surgical team members as well as intestinal anastomosis, operations longer than 3 hours, and body mass index $>$30 kg/m^2 were significant independent risk factors for SSI.

Extensive antiseptic measures are associated with increased cost and in the light of the results of the study; such additional expenses seem to be unnecessary.

The association of SSIs with lapses in discipline to adhere to principles of asepsis may be due to repetitive minor violations rather than due to gross contamination, which would have been noticed by other personnel. Factors particularly found to be significantly associated with SSI include a change of members within the surgical team during the operation, visitors in the operating room, hectic movements, and loud noise. The perception of the last 2 factors and therefore was dependent on subjective judgment. Further, as direct causal relationships of these factors seem unlikely we propose that such individual factors as well as the overall score reflects decreased concentration within the operating room, possibly due to a difficult or long operation but also due to decreased attentiveness by members of the surgical team. This by its nature could account for reduced accuracy during surgery. Multivariate analysis identified discipline and duration of an operation as independent risk factors; however, an interrelation between these 2 factors cannot be excluded.

Duration of surgery greater than 3 hours (median duration of all operations) was associated with a 7.5-fold increased risk of SSI in our study. This result supports previous studies showing that a duration above the 75th percentile was an independent risk factor for SSI in major operations (ie, 3 hours for gastric and colorectal surgery and 5 hours for hepatobiliary surgery).[5,6,21] The impact of duration on SSI reveals the importance of modifying intraoperative measures to decrease SSIs.

Potential risk factors as determined by the patient's comorbidities such as diabetes, chronic obstructive pulmonary disease, and immunosuppression were not associated with SSI. However, obesity seems to have a significant influence as shown previously.[22] Expanded large-scale studies involving administrative databases have investigated the effects of

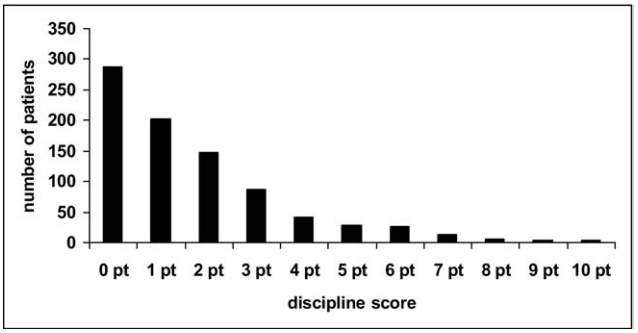

Figure 1 Distribution of lapses in discipline in the study population.

Table 5 Univariate analysis of the factors assessed to evaluate the adherence to principles of asepsis (discipline) of surgical team members

	Correct/factor absent no. (%)	Not correct/factor present no. (%)	Relative risk	95% CI	*P*
General impression	115/767 (15.0)	2/26 (7.7)	.513	.134–1.964	.407
Preparation of patient	108/752 (14.4)	9/41 (22.0)	1.528	.836–2.794	.178
Hand scrub	111/768 (14.5)	6/25 (24.0)	1.661	.809–3.407	.244
Type of cap/mask	100/702 (14.2)	17/91 (18.7)	1.311	.823–2.089	.272
Distance to surgical tables maintained	104/722 (14.4)	13/71 (18.3)	1.271	.754–2.144	.381
Exchange of surgical team members	37/450 (8.2)	80/343 (23.3)	2.837	1.972–4.080	<.001
Movement in operative room	104/742 (14.0)	13/51 (25.5)	1.819	1.101–3.005	.039
Noise	57/507 (11.2)	60/286 (21.0)	1.866	1.338–2.602	<.001
Visitors	79/625 (12.6)	38/168 (22.6)	1.789	1.264–2.533	.002
Change of patient's position	110/761 (14.5)	7/32 (21.9)	1.513	.769–2.979	.304

CI = confidence interval.

patient characteristics such as age, diabetes, nicotine and alcohol consumption, and intake of steroids.[6,23–25] In these studies, significant but weak associations were noted, with an OR not exceeding 1.8. In our prospective study, we found that intraoperative factors are associated with a higher relative risk than patient-related risk factors.

Provided the results are confirmed by other studies, lapses of discipline by the intervening physician may not only determine the incidence of SSIs but also many other types of complications in other medical specialties. Future studies are now required to develop tools to objectively assess soft factors such as attentiveness, technical accuracy, and concentration of members of the surgical team. A very recent report underscores the finding of this study. Haynes and coauthors show that complications are significantly decreased by the implementation of a checklist into surgical routine.[26]

Conclusions

The present study reveals that the discipline to adhere to principles of asepsis by surgical team members is a significant intraoperative risk factor, which could be accessible to interventions. Additional antiseptic measures, however, do not reduce the incidence of SSI.

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References

1. Mangram AJ, Horan TC, Pearson ML, et al. Guideline for prevention of surgical site infection, 1999. Hospital Infection Control Practices Advisory Committee. Infect Control Hosp Epidemiol 1999;20:250–78.
2. Coello R, Charlett A, Wilson J, et al. Adverse impact of surgical site infections in English hospitals. J Hosp Infect 2005;60:93–103.
3. Leaper DJ, van Goor H, Reilly J, et al. Surgical site infection—a European perspective of incidence and economic burden. Int Wound J 2004;1:247–73.
4. Plowman R, Graves N, Griffin MA, et al. The rate and cost of hospital-acquired infections occurring in patients admitted to selected specialties of a district general hospital in England and the national burden imposed. J Hosp Infect 2001;47:198–209.
5. National nosocomial infections surveillance (NNIS) system report, data summary from January 1992 through June 2004, issued October 2004. Am J Infect Control 2004;32:470–85.
6. Neumayer L, Hosokawa P, Itani K, et al. Multivariable predictors of postoperative surgical site infection after general and vascular surgery: results from the patient safety in surgery study. J Am Coll Surg 2007;204:1178–87.
7. Oliveira AC, Lima ED, Lima Ade P. Post-discharge surgical site infection surveillance in a hospital in Brazil. Am J Surg 2007;193:266–8.
8. Horan TC, Gaynes RP, Martone WJ, et al. CDC definitions of nosocomial surgical site infections, 1992: a modification of CDC definitions of surgical wound infections. Infect Control Hosp Epidemiol 1992;13:606–8.
9. Dellinger EP, Hausmann SM, Bratzler DW, et al. Hospitals collaborate to decrease surgical site infections. Am J Surg 2005;190:9–15.
10. Wenzel RP. Preoperative antibiotic prophylaxis. N Engl J Med 1992; 326:337–9.
11. Classen DC, Evans RS, Pestotnik SL, et al. The timing of prophylactic administration of antibiotics and the risk of surgical-wound infection. N Engl J Med 1992;326:281–6.
12. Alexander JW, Fischer JE, Boyajian M, et al. The influence of hair-removal methods on wound infections. Arch Surg 1983;118:347–52.
13. Tanner J, Woodings D, Moncaster K. Preoperative hair removal to reduce surgical site infection. Cochrane Database Syst Rev 2006;2: CD004122.
14. Segers P, de Jong AP, Spanjaard L, et al. Randomized clinical trial comparing two options for postoperative incisional care to prevent post-sternotomy surgical site infections. Wound Repair Regen 2007;15:192–6.
15. Copp G, Mailhot CB, Zalar M, et al. Covergowns and the control of operating room contamination. Nurs Rev 1986;35:263–8.
16. Tunevall TG, Jorbeck H. Influence of wearing masks on the density of airborne bacteria in the vicinity of the surgical wound. Eur J Surg 1992;158:263–6.
17. Kurz A, Sessler DI, Lenhardt R. Perioperative normothermia to reduce the incidence of surgical-wound infection and shorten hospitalization. Study of Wound Infection and Temperature Group. N Engl J Med 1996;334:1209–15.

18. Kearns SR, Connolly EM, McNally S, et al. Randomized clinical trial of diathermy versus scalpel incision in elective midline laparotomy. Br J Surg 2001;88:41–4.
19. Tanner J, Parkinson H. Double gloving to reduce surgical cross-infection. Cochrane Database Syst Rev 2006;3:CD003087.
20. Webster J, Alghamdi AA. Use of plastic adhesive drapes during surgery for preventing surgical site infection. Cochrane Database Syst Rev 2007;4:CD006353.
21. Leong G, Wilson J, Charlett A. Duration of operation as a risk factor for surgical site infection: comparison of English and US data. J Hosp Infect 2006;63:255–62.
22. Smith RL, Bohl JK, McElearney ST, et al. Wound infection after elective colorectal resection. Ann Surg 2004;239:599–605.
23. Sorensen LT, Hemmingsen U, Kallehave F, et al. Risk factors for tissue and wound complications in gastrointestinal surgery. Ann Surg 2005;241:654–8.
24. Tang R, Chen HH, Wang YL, et al. Risk factors for surgical site infection after elective resection of the colon and rectum: a single-center prospective study of 2,809 consecutive patients. Ann Surg 2001;234:181–9.
25. Konishi T, Watanabe T, Kishimoto J, et al. Elective colon and rectal surgery differ in risk factors for wound infection: results of prospective surveillance. Ann Surg 2006;244:758–63.
26. Haynes AB, Weiser TG, Berry WR et al. A Surgical Safety Checklist to Reduce Morbidity and Mortality in a Global Population. N Engl J Med 2009 Jan 14. [Epub ahead of print].