The American Journal of Surgery 217 (2019) 17–23

Contents lists available at ScienceDirect

The American Journal of Surgery

journal homepage: www.americanjournalofsurgery.com

The association of surgical drains with surgical site infections – A prospective observational study

Edin Mujagic [a,*,1], Jasmin Zeindler [a,1], Michael Coslovsky [b], Henry Hoffmann [a], Savas D. Soysal [a], Robert Mechera [a], Marco von Strauss [a], Tarik Delko [a], Franziska Saxer [c], Richard Glaab [d], Rebecca Kraus [d], Alexandra Mueller [d], Gaudenz Curti [d], Lorenz Gurke [a], Marcel Jakob [c], Walter R. Marti [d,2], Walter P. Weber [a,2]

[a] Department of Surgery, University of Basel and University Hospital Basel, Spitalstrasse 21, 4031, Basel, Switzerland
[b] Clinical Trial Unit, University of Basel and University Hospital Basel, Spitalstrasse 12, 4031, Basel, Switzerland
[c] Department of Orthopedic Trauma Surgery, University of Basel and University Hospital Basel, Spitalstrasse 21, 4031, Basel, Switzerland
[d] Department of Surgery, Kantonsspital Aarau, Tellstrasse 25, 5001, Aarau, Switzerland

ARTICLE INFO

Article history:
Received 15 May 2018
Received in revised form
6 June 2018
Accepted 14 June 2018

Keywords:
Surgical drains
Surgical site infection
Prospective observational study

ABSTRACT

Background: Surgical drains are widely used despite limited evidence in their favor. This study describes the associations between drains and surgical site infections (SSI).
Methods: This prospective observational double center study was performed in Switzerland between February 2013 and August 2015.
Results: The odds of SSI in the presence of drains were increased in general (OR 2.41, 95%CI 1.32–4.30, $p = 0.004$), but less in vascular and not in orthopedic trauma surgery. In addition to the surgical division, the association between drains and SSI depended significantly on the duration of surgery ($p = 0.01$) and wound class ($p = 0.034$). Furthermore, the duration of drainage (OR 1.24, 95%CI 1.15–1.35, $p < 0.001$), the number (OR 1.74, 95%CI 1.09–2.74, $p = 0.019$) and type of drains (open versus closed: OR 3.68, 95%CI 1.88, 6.89, $p < 0.001$) as well as their location (overall $p = 0.002$) were significantly associated with SSI.
Conclusions: The general use of drains is discouraged. However, drains may be beneficial in specific surgical procedures.

Introduction

Surgical site infections (SSI) represent the most common type of nosocomial infection amongst surgical patients.[1,2] In spite of several measures to prevent SSI, as many as 5% of patients experience SSI. They cause morbidity and mortality[3–5] as well as prolonged hospital stays and increased costs.[6–8]

Different types of drains are available. They are commonly inserted at the end of many surgical procedures. In clean and clean-contaminated surgeries, for example, they are intended to allow drainage of liquids such as blood or lymphatic fluid from the surgical dead space to improve wound healing and potentially prevent SSI.[9] In addition, they serve as indicators of anastomotic leakage.[10,11] In contaminated or dirty surgeries, they are primarily intended to drain infected fluids and help treat a pre-existing infection. In contrast to these potential benefits, however, drains are also thought to potentially serve as a conduit of bacteria into the wound and hence may increase the risk of SSI.[12–14]

Patterns of use of drains vary widely across surgical disciplines and individual practices. There are no uniform guidelines and standards are often rather based on tradition than on evidence. In orthopedic surgery, for example, there is an abundant body of literature on outcomes in relation to the insertion of closed suction drains. They are still commonly used in spite of repeat failure to

* Corresponding author.
E-mail addresses: edin.mujagic@usb.ch (E. Mujagic), jasmin.zeindler@usb.ch (J. Zeindler), michael.coslovsky@usb.ch (M. Coslovsky), henry.hoffmann@usb.ch (H. Hoffmann), savas.soysal@usb.ch (S.D. Soysal), robert.mechera@usb.ch (R. Mechera), marco.vonstrauss@usb.ch (M. von Strauss), tarik.delko@usb.ch (T. Delko), franziska.saxer@usb.ch (F. Saxer), richard.glaab@ksa.ch (R. Glaab), rebecca_kraus@bluewin.ch (R. Kraus), alexandracharlotte.mueller@insel.ch (A. Mueller), curti@chirurgieaarau.ch (G. Curti), lorenz.guerke@usb.ch (L. Gurke), marcel.jakob@usb.ch (M. Jakob), martiwr@bluewin.ch (W.R. Marti), walter.weber@usb.ch (W.P. Weber).
[1] The first two authors contributed equally to this work.
[2] The last two authors contributed equally to this work.

https://doi.org/10.1016/j.amjsurg.2018.06.015
0002-9610/

demonstrate a clear benefit.[15–17] In abdominal surgery, there are conflicting results in the literature concerning the impact of drains on the risk of SSI in different types of procedures. Data from randomized trials suggests that drains may not reduce infectious complications in hepatic and lower gastrointestinal surgery and even increase the risk in some patients undergoing hepatectomy. In upper gastrointestinal surgery such as oesophagectomy and gastrectomy, drainage is recommended, but this is based on very limited evidence.[18] In superficial and clean surgical procedures, such as breast cancer and thyroid surgery, the routine use of drains has been questioned.[19–21] Although drains are commonly used in peripheral vascular surgery, there is a striking lack of high level evidence supporting or discouraging their use.[22]

The objective of this large prospective study was to examine the association of presence, duration, type, number and location of drains with the risk of SSI in a contemporary and multicentric cohort of general, orthopedic trauma and vascular surgery procedures.

Methods

Setting

This observational cohort study was nested in a multicenter randomized controlled trial (RCT)[23] that was designed to evaluate the optimal timing of surgical antimicrobial prophylaxis (SAP) in a general, orthopedic trauma and vascular surgery population. The term “general surgery” refers to gastrointestinal, oncologic breast, endocrine and hernia surgery and includes laparoscopic procedures. All patients from the RCT were included in this analysis. The current study question was defined a priori, and pre-specified data were prospectively collected between February 22nd, 2013 and August 31st, 2015 at the University Hospital of Basel and the hospital of Aarau, two tertiary referral centers in Switzerland.

The study was approved by the local ethics committees and informed consent was obtained from all patients. This study has been registered on clinicaltrials.gov under the identifier NCT03408782. The underlying RCT was registered on clinicaltrials.gov under the identifier NCT01790529.

Patients

The full study protocol of the underlying RCT has been published.[24] Briefly, all inpatients aged 18 years or older undergoing general, orthopedic trauma and vascular procedures with an indication for surgical antimicrobial prophylaxis according to clinical standards (cefuroxime, combined with metronidazole in colorectal surgery) were eligible. These standards were based on center for disease control (CDC) definitions for surgical wound classification and corresponding guidelines for SSI prevention.[2] Because the diagnosis of wound class 4 can only be made intraoperatively in some cases, few patients with wound class 4 were still included in the RCT and remained in the analysis according to intention to treat principles. Therefore, these patients remained in the analysis set of the present study as well.

Exclusion criteria included outpatient surgery, contraindication for cefuroxime and/or metronidazole, preexisting antibiotic therapy within 14 days prior to surgery, cognitive impairment, combined operations including other than the above specified surgical subspecialties and emergency procedures with planned incision within 2 h after indicating the procedure.

Predictors

The pre-specified variables that were prospectively collected for this analysis included:

- the presence of a surgical drain versus none
- the number of drains
- the types of drains for each drain (open vs. closed suction)
- the location of drains for each drain (organ space, fascia level, subcutaneous)
- the time until removal of each drain in days

These variables were collected from the electronic and paper charts including surgical reports, clinicians' and nurses' charts by trained study nurses and entered into an electronic source document specifically designed for the RCT underlying this study.

The decision whether or not, how many, what type and where to insert drains was at the discretion of the operating surgeon in charge and the reasons those decisions were based on were not recorded. However, some institutional standards apply: In elective intraabdominal surgery, open drains are generally placed only in hepatobiliary and pancreatic surgery. In urgent surgery, open drains are placed in severely dirty wounds like in perforated colon surgery. In oncologic breast surgery, drains are not commonly used except in axillary dissections. In thyroid surgery, no drains are placed and in hernia surgery, drains are not commonly used except for closed drains in major abdominal wall reconstructions. In elective orthopedic trauma surgery, drains are used rather restrictively except for knee and hip replacement surgery, arthroscopic joint surgery and contaminated surgery. In urgent orthopedic trauma surgery, drains are mainly used in contaminated wounds. In vascular surgery, closed suction drains are used in all carotid and lower limb arterial surgery.

Endpoints

The endpoint of this study is the occurrence of SSI within 30 days of the index procedure, as defined by the CDC.[2] In order to detect SSI, inpatients were seen daily by the ward residents, ward physicians and operating surgeons. In addition, ward rounds were joined by members of the study team. Diagnoses of SSI made by the surgical team could not be overruled by members of the study team. Post discharge follow up at 30 days after surgery was performed by trained nurses and physicians at each study site by contacting patients via telephone. To assess the past or present occurrence of SSI, a standardized questionnaire was used. Where the telephone interview suggested possible SSI, the general practitioners who performed post-discharge care were contacted for further information and hospital charts were again reviewed. A maximum of 5 attempts was made to contact patients within 4 weeks after the due 30-day follow-up date, after which hospital charts were screened for possible readmissions and outpatient visits. Those patients that could not be contacted and for whom no other sources of information were available were considered lost to follow-up. All diagnoses of SSI were validated by a board certified infectious diseases specialist at each study site.

Statistical analysis

Patient baseline characteristics and demographics were summarized using descriptive statistics and stratified according to drainage (drains vs. no drains placed). Continuous variables are reported as the mean and standard deviation (SD) and compared between patients with and without drainage using Welch t-tests, unless highly skewed. Highly skewed variables are summarized as the median, the first and the third quartile (interquartile range; IQR) and compared using the Wilcoxon's non-parametric test. The frequency distribution and proportion are reported for categorical variables, and a Fisher exact test used to compare the distribution among the two patient groups.

Analyses are based on logistic regression. The focal variable is the presence of a drainage, a binary variable. The primary model included only the presence of a drainage as predictor for SSI as outcome. Variables of interest (potential confounders, potential effect modifiers) and their interaction with drainage were included, in turn, in a model to examine their effects. Prespecified potential confounders were diabetes, wound class, ASA class, incomplete skin closure, body mass index (BMI), steroid therapy, other immunosuppressive therapy and duration of surgery while prespecified potential effect modifiers were the surgical division, implant surgery and urgent surgery. Interactions were tested using likelihood ratio tests and were removed from the model if not significant ($p < 0.05$). For potential confounders showing no significant interaction, the magnitude of confounding was calculated as the percent change in the effect size (odds ratio; OR) associated with drainage (see below). Subgroup analyses followed for the different levels of effect modifiers. Drainage characteristics were either included in the model alongside the drainage identifier in order to estimate their effect independent from the effect of drainage per se, or they were analyzed in the set including only patients who had exactly one drain placed ($n = 784$) which was defined to examine specific drain characteristics such as drain type, duration and location.

The magnitude of confounding (percent change in OR)[25] is calculated, where relevant, as $100*((OR_{unadjusted} - OR_{adjusted})/OR_{unadjusted})$, where $OR_{unadjusted}$ is the odds ratio associated with drainage as calculated from the primary model, and $OR_{adjusted}$ is estimated in the model including the potential confounder. The percent change in effect size is a descriptive measurement and not a precise test. In addition, it can be biased in logistic regression models.[26] Despite the bias, it is useful for identifying variables which cause strong effects on the focal effect.

After all potential confounders were examined singularly, a multiple logistic regression model was fit. Confounders and effect modifiers were included in the model if their interaction with drainage was significant or if they had a large magnitude of confounding (>10%).

At a following step, we fitted a model including all the potential confounders and effect modifiers, with their interaction with drainage (the “full model”). As a sensitivity analysis, the full model was reduced using backward variable selection based on Akaike's information criterion (AIC).

The assumption of a linear association between continuous variables and outcome was assessed and proved reasonable in all cases.

All analyses were done using R version 3.4.0.[27]

Results

A total of 5175 patients were analyzed in the underlying RCT, 579 of whom were lost to follow up after hospital discharge and therefore, the SSI status 30 days after surgery was known for 4596 patients. In 12 patients, data on the use of surgical drainage was missing and therefore, 4584 patients were analyzed for this study. Table 1 presents baseline characteristics by use of drainage. It shows that patients with drain were significantly older, more likely to be male, had higher ASA scores, lower wound classes, more additional diagnoses, longer surgeries, were less likely to have incomplete skin closure and to have undergone vascular surgery (46.5% of patients with drainage vs. 16.2% in general and 24.5% in orthopedic trauma surgery).

On the primary, univariate logistic regression model, 1065 patients with drains experienced 86 (8.1%) SSI compared to 145 SSI in 3519 patients (4.1%) without drains (OR 2.04, 95%CI 1.55–2.69, $p < 0.001$).

Pathogen profiles were ordered in 73 out of 234 SSI (31%). The most commonly isolated pathogens were *Staphylococcus aureus*, coagulase-negative staphylococci, *Escherichia coli* and Enterobacter species. In total, only eight multidrug-resistant pathogens were isolated. There were no relevant differences between those patients with SSI who had drains and those who did not have drains in terms of pathogens isolated.

The analysis of all predefined potential confounders, each added individually to the primary model, is summarized in Table 2. It demonstrates that only the interaction terms between the presence

Table 1
Patient and procedure characteristics by the presence of drains.

	No drainage	Drainage	p
Number of patients	3519	1065	
SSI[a] n (%)	145 (4.1)	86 (8.1)	
Age (mean (sd))	56.2 (18.8)	60.5 (17.2)	<0.001
Female sex n (%)	1651 (46.9)	454 (42.6)	0.014
BMI[b] (mean (sd))	27.0 (6.4)	27.4 (6.3)	0.135
ASA[c] classification n (%)			<0.001
1	664 (18.9)	154 (14.5)	
2	1906 (54.2)	525 (49.3)	
3	913 (25.9)	372 (34.9)	
4	36 (1.0)	14 (1.3)	
Surgical division n (%)			<0.001
General surgery	1900 (54.0)	368 (34.6)	
Orthopedic trauma surgery	1304 (37.1)	424 (39.8)	
Vascular surgery	315 (9.0)	273 (25.6)	
Wound class n (%)			<0.001
1	2649 (75.3)	927 (87.0)	
2	628 (17.8)	110 (10.3)	
3	197 (5.6)	18 (1.7)	
4	45 (1.3)	10 (0.9)	
Elective surgery n (%)	2860 (81.3)	875 (82.2)	0.529
Nr of additional diagnoses (mean (sd))	2.8 (2.4)	3.9 (2.5)	<0.001
Dialysis n (%)			0.066
No dialysis	3468 (98.6)	1057 (99.2)	
Hemodialysis	47 (1.3)	6 (0.6)	
CAPD[d]	2 (0.1)	0 (0.0)	
Unknown	2 (0.1)	2 (0.2)	
Duration of surgery (h) (median [IQR[e]])	1.3 [0.9, 2.0]	2.2 [1.4, 3.3]	<0.001
Incomplete skin closure (%)	168 (4.8)	13 (1.2)	<0.001
Steroid treatment n (%)	74 (2.1)	33 (3.1)	0.064
Other immunosuppressive drugs n (%)	37 (1.1)	17 (1.6)	0.147
Duration of drainage (d) (median [IQR])	n/a	3 [2, 4]	n/a
Number of drains (%)			
1	n/a	784 (73.6)	n/a
2	n/a	224 (21.0)	n/a
3	n/a	44 (4.1)	n/a
4	n/a	11 (1.0)	n/a
5	n/a	2 (0.2)	n/a
Type of drains (%)[f]			
Closed suction drains	n/a	699 (89.2)	n/a
Open drains	n/a	84 (10.7)	n/a
Unknown	n/a	1 (0.1)	n/a
Localization of drains (%)[f]			
Subcutaneous	n/a	341 (43.5)	n/a
Fascia level	n/a	211 (26.9)	n/a
Organ space	n/a	122 (15.6)	n/a
Unknown	n/a	110 (14.0)	n/a

Percentages may not total 100% due to rounding.
Comparison of continuous variables by Welch t-tests or Wilcoxon's non-parametric test when highly skewed. Comparisons of frequency distributions and proportions by Fisher's exact test.
[a] SSI: Surgical site infection.
[b] BMI: Body mass index in kg/m^2.
[c] ASA: American Society of Anesthesiologists.
[d] CAPD: Continuous ambulatory peritoneal dialysis.
[e] IQR: Interquartile range.
[f] For type and localization of drains, the analysis sets consisted of those 784 patients that had only one drain.

Table 2
Analysis of potential confounders for the association of drainage with SSI.

Variable	Coef. (SE)	OR [95% CI]	p	% change
Diabetes				
Interaction	–	–	0.468	
Diabetes	0.45 (0.20)	1.56 [1.05, 2.26]	0.023	1.8
Drainage	0.70 (0.14)	2.01 [1.52, 2.64]	<0.001	
Wound Class				
Interaction	–	–	0.004	
Wound class 2	0.86 (0.19)	2.36 [1.61, 3.42]	<0.001	
Wound class 3	0.87 (0.30)	2.39 [1.28, 4.17]	0.004	
Wound class 4	1.36 (0.49)	3.91 [1.32, 9.31]	0.005	
Drainage	0.70 (0.18)	2.01 [1.41, 2.84]	<0.001	
Wound class 2: Drainage	0.19 (0.35)	1.21 [0.59, 2.39]	0.598	
Wound class 3: Drainage	2.09 (0.58)	8.12 [2.65, 25.97]	<0.001	
Wound class 4: Drainage	0.53 (0.86)	1.70 [0.29, 9.08]	0.534	
ASA[a] Classification				
Interaction	–	–	0.020	
ASA 2	0.19 (0.30)	1.21 [0.70, 2.25]	0.514	
ASA 3	1.34 (0.29)	3.82 [2.23, 6.96]	<0.001	
ASA 4	1.69 (0.59)	5.41 [1.48, 15.92]	0.004	
Drainage	−1.26 (1.04)	0.28 [0.02, 1.41]	0.223	
ASA 2: Drainage	2.29 (1.06)	9.84 [1.84, 182.61]	0.031	
ASA 3: Drainage	1.71 (1.06)	5.52 [1.04, 102.03]	0.106	
ASA 4: Drainage	1.55 (1.39)	4.71 [0.33, 125.57]	0.265	
Skin Closure				
Interaction	–	–	0.185	
Incomplete skin closure	−0.31 (0.42)	0.74 [0.29, 1.54]	0.466	1.0
Drainage	0.71 (0.14)	2.02 [1.53, 2.66]	<0.001	
Body Mass Index				
Interaction	–	–	0.410	
Body Mass Index	0.02 (0.01)	1.02 [1.01, 1.04]	0.011	0.6
Drainage	0.71 (0.14)	2.03 [1.54, 2.67]	<0.001	
Steroid Treatment				
Interaction	–	–	0.545	
Steroid treatment	0.22 (0.40)	1.25 [0.52, 2.54]	0.575	0.2
Drainage	0.71 (0.14)	2.04 [1.54, 2.68]	<0.001	
Other Immunosuppressive Drugs				
Interaction	–	–	0.100	
Immunosuppressive treatment	0.60 (0.48)	1.83 [0.63, 4.24]	0.206	0.4
Drainage	0.71 (0.14)	2.04 [1.54, 2.68]	<0.001	
Duration of Surgery				
Duration of surgery	0.64 (0.06)	1.89 [1.68, 2.13]	<0.001	
Drainage	0.42 (0.19)	1.52 [1.04, 2.20]	0.027	
Duration of surgery: Drainage	−0.27 (0.08)	0.76 [0.65, 0.89]	<0.001	

Each confounder was added as predictor to a logistic regression model including drainage as a fixed predictor. Effect sizes are given as coefficients and standard errors (SE) on the logit scale as well as odds ratios (OR) with their 95% confidence interval (CI). The percent change in the effect of drainage compared to an unadjusted estimate is provided for variables showing no significant interaction with drainage.

[a] ASA: American Society of Anesthesiologists.

of drains and wound class, ASA class and duration of surgery, respectively, were significant. Therefore, only these parameters were treated as potential confounders. The drivers of their significant interaction terms with the presence of a drainage become apparent in Figs. 1 and 2. Fig. 1 demonstrates that the effect of drainage on the risk of SSI was much more pronounced in wound class 3 than wound classes 1, 2 and 4. Furthermore, the presence of drainage seemed protective against SSI in ASA class 1 while the opposite was found in ASA classes 2, 3 and 4. Fig. 2 shows that in shorter surgical procedures, including the median duration of 1.5 h, the probability of SSI was higher when a drainage was inserted, while in longer operations, the opposite was found. Irrespective of the presence of drainage, the odds of SSI increased with increasing duration of surgery.

In addition to potential confounders, potential effect modifiers including their interactions with the presence of a drainage were considered and are reported in Table 3 including a subgroup analysis. The only significant interaction term was between the surgical division and the presence of drains ($p < 0.001$). The subgroup analysis demonstrates the driver for the highly significant interaction term: In general surgery, the presence of drains was strongly and significantly associated with increased odds of SSI (OR 3.23, 95% CI 2.26–4.57). In vascular surgery, the odds of SSI were still increased in the presence of drains, but this association was less strong (OR 1.80, 95% CI 0.94–3.53) while there was a trend for decreased odds of SSI with drains in orthopedic trauma surgery (OR 0.69, 95%CI 0.28–1.49) (Fig. 1 and Table 3). The interaction terms between surgical wound class, duration of surgery and the surgical division on one hand and the presence of drains on the other hand remained significant in the multiple logistic regression model. The only non significant likelihood ratio was for the interaction term between ASA classification and drainage (likelihood ratio test $p = 0.385$) and was therefore removed from the model (Supplementary Table 1).

In the final multiple logistic regression model (Table 4), the presence of a drainage remained significantly associated with increased odds of SSI in the reference division of general surgery (OR 2.41, 95%CI 1.32–4.30, $p = 0.004$). When assuming the other surgical divisions as reference levels, the odds of SSI with drains versus no drains remained increased in vascular surgery (OR 1.95, 95% CI 0.98–3.98, $p = 0.061$) and decreased in orthopedic trauma surgery (OR 0.56, 95% CI 0.22–1.22, $p = 0.173$).

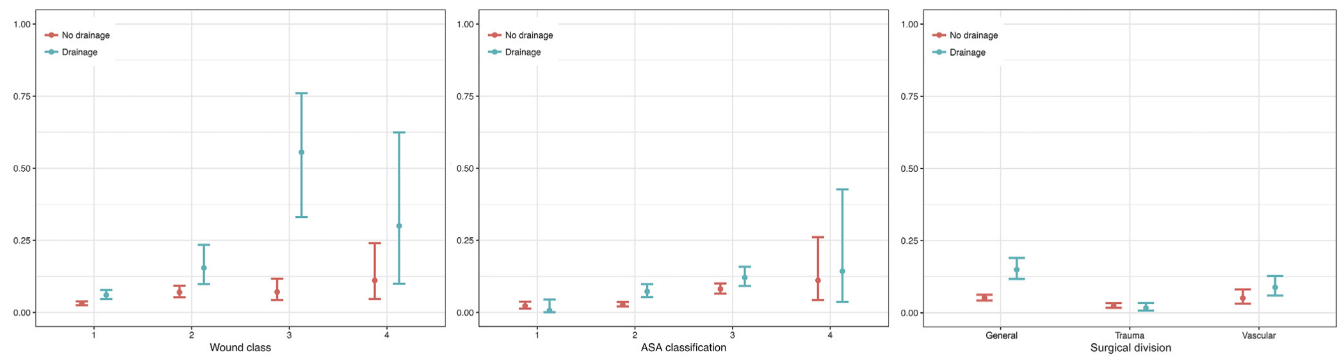

Fig. 1. Probability of SSI by wound class, ASA classification and surgical division, stratified by the presence of drains. The figure shows predicted Wald 95% confidence intervals.

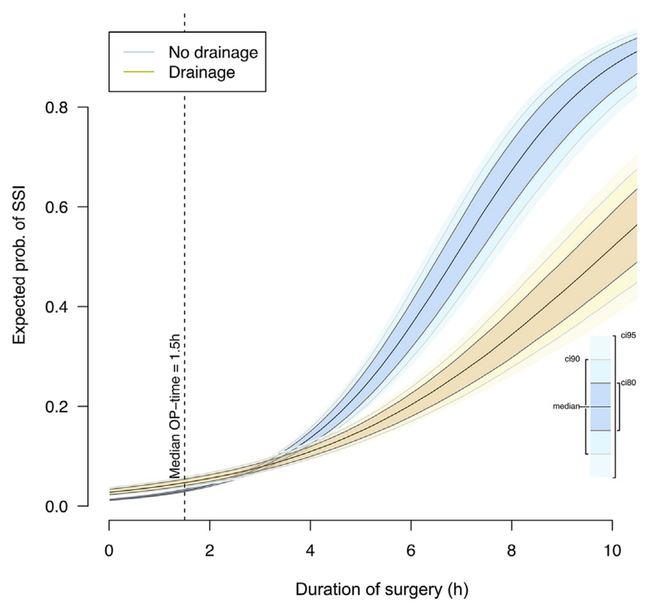

Fig. 2. Probability of SSI by duration of surgery stratified by the presence of drains.

Table 3
Analysis of potential effect modifiers for the association of drainage and SSI including interaction tests and sub-group analyses.

Subgroup	Level	Events	OR [95% CI]	p
Surgical division				
Interaction	–	–	–	<0.001
General	No drainage	98/1900		
	Drainage	55/368	3.23 [2.26, 4.57]	
Orthopedic trauma	No drainage	31/1304		
	Drainage	7/424	0.69 [0.28, 1.49]	
Vascular	No drainage	16/315		
	Drainage	24/273	1.80 [0.94, 3.53]	
Implant vs. non-implant surgery				
Interaction	–	–	–	0.178
No implant	No drainage	99/1938		
	Drainage	56/458	2.59 [1.82, 3.64]	
Implant	No drainage	46/1581		
	Drainage	30/607	1.73 [1.07, 2.76]	
Elective vs. urgent surgery				
Interaction	–	–	–	0.508
Elective	No drainage	123/2860		
	Drainage	76/875	2.12 [1.57, 2.84]	
Emergency/urgent	No drainage	22/659		
	Drainage	10/190	1.61 [0.72, 3.37]	

Results of the two sensitivity analyses (the full model and the backward selection model) including the respective likelihood ratio tests are shown in Supplementary Tables 2–5. There were no relevant differences between the main model and the sensitivity analyses.

Secondary analyses included the effect of duration, number, type and location of drains on SSI. Table 5 demonstrates that the odds of experiencing SSI were significantly associated with the duration, the number, the type (open vs. closed) and the location of drains, each analyzed in a separate univariate logistic regression model.

Discussion

To our knowledge, this is the first prospective study investigating the association between the use of surgical drains and the odds of SSI in a large cohort of various surgical procedures. Our data suggest that the association between the use of surgical drains and SSI depend on several factors. Furthermore, the duration, type, location and number of drains were significantly associated with the odds of SSI. This is clinically relevant, since a wide variety of surgeons continue to use surgical drains at their discretion.

We found several significant interactions between drains and potential confounders and effect modifiers that may have implications on clinical practice recommendations for subgroups of procedures. First, the surgical division acted as an effect modifier in terms of the association between drains and SSI. While the presence of drains in vascular and even more so in general surgery procedures was associated with increased odds of SSI, this was not true for orthopedic trauma surgery where the odds of SSI tended to be reduced in the presence of drains. This interaction term between the surgical division and the presence of drains remained significant in the multiple logistic regression model. One possible explanation may be that, considering the institutional standards as described in the methods, within the orthopedic trauma division, drains were mainly used in procedures that are per se associated with low SSI rates such as knee and hip replacement surgery and arthroscopies. On the other hand, however, other common procedures with typically low SSI rates such as other joint replacement or osteosynthetic procedures do not typically include the insertion of drains. In addition, in contaminated procedures with higher expected SSI rates, drains are regularly used as well. Therefore, it remains unclear whether or not our data are biased towards lower baseline SSI rates in procedures that include the placement of drains in orthopedic trauma surgery. Furthermore, in the typical relatively healthy patient undergoing clean orthopedic trauma surgery, the prevention of a fluid collection by means of drainage may suffice to relevantly decrease the risk of SSI. It must be kept in mind that the orthopedic trauma patients represent a subgroup of this study and that within this subgroup, the 95% confidence

Table 4
Multiple logistic regression model for the association of drainage with odds of SSI.

Variable	Coef. (SE)	OR [95% CI]	p
Wound class 2	0.32 (0.23)	1.38 [0.87, 2.17]	0.164
Wound class 3	0.59 (0.34)	1.80 [0.89, 3.42]	0.083
Wound class 4	1.46 (0.52)	4.30 [1.39, 10.93]	0.005
ASA[a] class 2	0.11 (0.29)	1.12 [0.66, 2.02]	0.695
ASA class 3	0.97 (0.29)	2.64 [1.54, 4.80]	<0.001
ASA class 4	1.57 (0.53)	4.79 [1.59, 12.87]	0.003
Duration of surgery	0.53 (0.07)	1.70 [1.50, 1.94]	<0.001
Orthopedic trauma division	−0.21 (0.24)	0.81 [0.50, 1.30]	0.381
Vascular surgery division	−0.25 (0.31)	0.78 [0.41, 1.40]	0.414
Drainage	**0.88 (0.30)**	**2.41 [1.32, 4.30]**	**0.004**
Wound class 2: Drainage	−0.49 (0.44)	0.61 [0.26, 1.42]	0.257
Wound class 3: Drainage	1.51 (0.66)	4.52 [1.26, 16.92]	0.022
Wound class 4: Drainage	0.03 (0.91)	1.03 [0.16, 6.08]	0.976
Duration of surgery: Drainage	−0.24 (0.09)	0.79 [0.66, 0.94]	0.010
Orthopedic trauma division: Drainage	−1.46 (0.50)	0.23 [0.08, 0.60]	0.004
Vascular surgery division: Drainage	−0.21 (0.43)	0.81 [0.35, 1.90]	0.624

The interaction term between ASA-classification and drainage was removed for missing significance (likelihood ratio test p = 0.385). The table reports coefficients and standard errors (SE) on the logit scale alongside the odds ratios (OR) and their 95% confidence intervals. ":" refers to the interaction term. Akaike's information criterion (AIC) for this model is 1596.52.
[a] ASA: American Society of Anesthesiologists.

Table 5
Effect of duration, number, type and duration of drains in terms of odds of SSI.

Predictor	n	OR [95% CI]	p
Duration of drainage	784		
Per additional day		1.24 [1.15, 1.35]	<0.001
Number of drains	4584		
1 drain vs. none		1.72 [1.24, 2.36]	<0.001
>1 drain vs. 1 drain		1.74 [1.09, 2.74]	0.019
Type of drain	783		
Open vs. closed		3.68 [1.88, 6.89]	<0.001
Location of drain	674		0.002
Fascia level vs. subcutaneous		1.43 [0.67, 3.06]	0.632
Organ space vs. subcutaneous		3.76 [1.83, 7.73]	<0.001
Organ space vs. fascia level		2.64 [1.24, 5.59]	0.031

Analyses of separate logistic regression models for each of the potential predictors are shown.

interval of the odds ratio of experiencing SSI with a drain versus none is wide and crosses one. In abdominal surgery, drains are only inserted in non-clean wounds, where the placement of a foreign body may have a deleterious impact on the risk of SSI. Similarly, in the typical vascular patient, the higher baseline risk of SSI caused by the complexity of the procedure, duration of surgery, as well as vascular and other morbidities, the drain seems to have an adverse impact on SSI risk.

Second, ASA and wound classes interacted significantly with the presence of drains. The increase in the odds of SSI with higher wound classes was more pronounced in the presence of a drain, especially in wound class 3. This interaction between the presence of drains and wound class 3 remained significant in the multiple logistic regression model. This could be translated into a recommendation to refrain from inserting drains in higher wound classes, particularly in wound class 3. Wound class 4 represents an exception as it is per definition a preexisting infection at the surgical site. Therefore, the results for this subgroup have to be interpreted with caution. However, there were only very few cases of wound class 4 in our cohort which also explains the very wide 95% confidence intervals for both wound class 4 and its interaction with the presence of drains. In terms of ASA class, the significant interaction with the presence of drains stems mainly from the fact that in ASA class I, patients with drainage had a slightly lower probability of experiencing SSI while in ASA classes II, III and IV, the opposite was true. However, the effect of drains on SSI does not differ strongly across ASA classes and herefore does not seem to be clinically relevant. This is also supported by the loss of significance of the interaction term in the multiple logistic regression model.

Third, duration of surgery interacted significantly with the presence of drains in terms of risk of SSI. Interestingly, while in shorter surgeries including those with the median duration of 1.5 h, the presence of drains was associated with increased odds of experiencing SSI, drains were protective in longer lasting surgical procedures. This interaction remained significant in the multiple logistic regression model. The duration of surgery is a well-known surrogate for the complexity of the procedure and its underlying condition. Furthermore, its association with SSI rates has been previously described.[28] Therefore, it could be argued that the negative impact of drains by potentially serving as a conduit for bacteria into the wound is shifted towards a protective effect in longer procedures where the bacterial contamination at the end of the procedure is increased compared to shorter procedures.

This study has several strengths: First, data were collected in a strictly prospective manner within a RCT to address a pre-specified question in routine surgical practice. This allowed the inclusion of a variety of parameters in the field of drain usage, such as different types, localizations and numbers of drains. The fact that open drains, organ space drains and the presence of more than one drain were all associated with significantly increased odds of SSI allows a nuanced interpretation of our results. Second, the sample size of over 5000 patients allowed the investigation of a wide variety of general, orthopedic trauma and vascular surgery procedures which supports the generalizability of our data. Third, known risk factors for SSI such as duration of surgery, higher ASA classes and higher wound classes remained significant confounders in all of our models. Furthermore, known or suspected risk factors for SSI such as diabetes, higher BMI and immunosuppressive therapy were associated with increased odds of SSI, thereby highlighting the validity of our data.

We acknowledge the limitations of this study. First, the observational nature of this study allows the potential presence of selection bias. While multivariable analyses can control for baseline differences between those patients with and without drains and for SSI risk factors, individual reasons for drain insertion was mostly at the discretion of the surgeon and therefore, we cannot rule out residual confounding by the selection of patients considered to require drainage.

Second, only patients who received surgical antimicrobial prophylaxis (SAP) were included due to the design of the underlying RCT. It cannot be ruled out that the association between the presence of drains and SSI is different in procedures without SAP, thereby limiting the generalizability of our findings. However, such procedures are associated neither with high rates of SSI, nor with a frequent use of drains and therefore, this limitation may not be relevant.

In conclusion, our data suggest that in general, surgical drains are associated with increased odds of SSI and therefore, their general use is discouraged. However, it seems that drains may be effective in reducing the risk of SSI in specific subgroups such as longer procedures and clean orthopedic trauma surgery. Corroboration of our findings by means of additional RCTs including predefined numbers, types and localizations as well as duration of drains in specific procedures is recommended.

Summary

This prospective observational study describes the associations between surgical drains and surgical site infections (SSI) in a general, vascular and orthopedic trauma surgery cohort. The odds of SSI in the presence of drains were significantly increased in general surgery, but less so in vascular and not in orthopedic trauma surgery. Furthermore, the duration of drainage and the number, type and location of drains were significantly associated with SSI.

Funding

This work was supported by the Swiss National Foundation (32003B_138467/1); the "Kantonsspital Aarau"; the "Gottfried und Julia Bangerter-Rhyner-Stiftung"; the University of Basel (DMS2226); the "Freiwillige Akademische Gesellschaft Basel"; and the "Nora van Meeuwen-Haefliger-Stiftung".

Conflicts of interest

The authors have no conflicts of interest to disclose.

Appendix A. Supplementary data

Supplementary data related to this article can be found at https://doi.org/10.1016/j.amjsurg.2018.06.015.

References

1. Lewis SS, Moehring RW, Chen LF, et al. Assessing the relative burden of hospital-acquired infections in a network of community hospitals. *Infect Control Hosp Epidemiol*. 2013 Nov;34(11):1229–1230. PubMed PMID: 24113613. Pubmed Central PMCID: PMC3977691.
2. 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 Apr;20(4):250–278. quiz 79-80. PubMed PMID: 10219875.
3. Coskun D, Aytac J, Aydinli A, Bayer A. Mortality rate, length of stay and extra cost of sternal surgical site infections following coronary artery bypass grafting in a private medical centre in Turkey. *J Hosp Infect*. 2005 Jun;60(2):176–179. PubMed PMID: 15866018.
4. Coello R, Charlett A, Wilson J, et al. Adverse impact of surgical site infections in English hospitals. *J Hosp Infect*. 2005 Jun;60(2):93–103. PubMed PMID: 15866006.
5. Kirkland KB, Briggs JP, Trivette SL, et al. The impact of surgical-site infections in the 1990s: attributable mortality, excess length of hospitalization, and extra costs. *Infect Control Hosp Epidemiol*. 1999 Nov;20(11):725–730. PubMed PMID: 10580621.
6. Poulsen KB, Bremmelgaard A, Sorensen AI, et al. Estimated costs of postoperative wound infections. A case-control study of marginal hospital and social security costs. *Epidemiol Infect*. 1994 Oct;113(2):283–295. PubMed PMID: 7925666. Pubmed Central PMCID: PMC2271539.
7. Vegas AA, Jodra VM, Garcia ML. Nosocomial infection in surgery wards: a controlled study of increased duration of hospital stays and direct cost of hospitalization. *Eur J Epidemiol*. 1993 Sep;9(5):504–510. PubMed PMID: 8307135.
8. Boyce JM, Potter-Bynoe G, Dziobek L. Hospital reimbursement patterns among patients with surgical wound infections following open heart surgery. *Infect Control Hosp Epidemiol*. 1990 Feb;11(2):89–93. PubMed PMID: 2107250.
9. Scevola S, Youssef A, Kroll SS, Langstein H. Drains and seromas in TRAM flap breast reconstruction. *Ann Plast Surg*. 2002 May;48(5):511–514. PubMed PMID: 11981192.
10. Giovinazzo F, Butturini G, Salvia R, et al. Drain management after pancreatic resection: state of the art. *J Hepato-Biliary-Pancreatic Sci*. 2011 Nov;18(6): 779–784. PubMed PMID: 21861143.
11. Levy M. Intraperitoneal drainage. *Am J Surg*. 1984 Mar;147(3):309–314. PubMed PMID: 6367505.
12. Willett KM, Simmons CD, Bentley G. The effect of suction drains after total hip replacement. *J Bone Joint Surg Br*. 1988 Aug;70(4):607–610. PubMed PMID: 3403607.
13. Dougherty SH, Simmons RL. The biology and practice of surgical drains. Part 1. *Curr Probl Surg*. 1992 Aug;29(8):559–623. PubMed PMID: 1499329.
14. Dougherty SH, Simmons RL. The biology and practice of surgical drains. Part II. *Curr Probl Surg*. 1992 Sep;29(9):633–730. PubMed PMID: 1424760.
15. Kelly EG, Cashman JP, Imran FH, et al. Systematic review and meta-analysis of closed suction drainage versus non-drainage in primary hip arthroplasty. *Surg Technol Int*. 2014 Mar;24:295–301. PubMed PMID: 24574017. Epub 2014/02/28. eng.
16. Parker MJ, Livingstone V, Clifton R, McKee A. Closed suction surgical wound drainage after orthopaedic surgery. *Cochrane Database Syst Rev*. 2007 Jul;18(3), Cd001825. PubMed PMID: 17636687. Epub 2007/07/20. eng.
17. Clifton R, Haleem S, McKee A, Parker MJ. Closed suction surgical wound drainage after hip fracture surgery: a systematic review and meta-analysis of randomised controlled trials. *Int Orthop*. 2008 Dec;32(6):723–727. PubMed PMID: 17687554. Pubmed Central PMCID: PMC2898962. Epub 2007/08/10. eng.
18. Petrowsky H, Demartines N, Rousson V, Clavien PA. Evidence-based value of prophylactic drainage in gastrointestinal surgery: a systematic review and meta-analyses. *Ann Surg*. 2004 Dec;240(6):1074–1084. discussion 84-5. PubMed PMID: 15570212. Pubmed Central PMCID: PMC1356522.
19. Woods RS, Woods JF, Duignan ES, Timon C. Systematic review and meta-analysis of wound drains after thyroid surgery. *Br J Surg*. 2014 Apr;101(5): 446–456. PubMed PMID: 24633830. Epub 2014/03/19. eng.
20. Taylor JC, Rai S, Hoar F, et al. Breast cancer surgery without suction drainage: the impact of adopting a 'no drains' policy on symptomatic seroma formation rates. *Eur J Surg Oncol*. 2013 Apr;39(4):334–338. PubMed PMID: 23380200. Epub 2013/02/06. eng.
21. Thomson DR, Sadideen H, Furniss D. Wound drainage after axillary dissection for carcinoma of the breast. *Cochrane Database Syst Rev*. 2013 Oct;20(10), CD006823. PubMed PMID: 24158902.
22. Healy D, Clarke-Moloney M, Hannigan A, Walsh S. Wound drainage for lower limb arterial surgery. *Cochrane Database Syst Rev*. 2016 Nov 11;11, Cd011111. PubMed PMID: 27841438. Epub 2016/11/15. eng.
23. Weber WP, Mujagic E, Zwahlen M, et al. Timing of surgical antimicrobial prophylaxis: a phase 3 randomised controlled trial. *Lancet Infect Dis*. 2017 Jun;17(6):605–614. PubMed PMID: 28385346.
24. Mujagic E, Zwimpfer T, Marti WR, et al. Evaluating the optimal timing of surgical antimicrobial prophylaxis: study protocol for a randomized controlled trial. *Trials*. 2014;15:188. PubMed PMID: 24885132. Pubmed Central PMCID: Pmc4040488. Epub 2014/06/03. eng.
25. Rothman KJ, Greenland S, Lash TL. *Modern Epidemiology*. 3 ed. Lippincott Williams & Wilkins; 2008.
26. Janes H, Dominici F, Zeger S. On quantifying the magnitude of confounding. *Biostatistics*. 2010 Jul;11(3):572–582. PubMed PMID: 20203259. Pubmed Central PMCID: PMC2883302.
27. Team RC. *R: A Language and Environment for Statistical Computing*. Vienna, Austria: R Foundation for Statistical Computing; 2017.
28. Cheng H, Chen BP, Soleas IM, et al. Prolonged operative duration increases risk of surgical site infections: a systematic review. *Surg Infect (Larchmt)*. 2017 Aug/Sep;18(6):722–735. PubMed PMID: 28832271. Pubmed Central PMCID: PMC5685201.