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THE ISRAELI STUDY OF SURGICAL INFECTION OF DRAINS AND THE RISK OF WOUND INFECTION IN OPERATIONS FOR HERNIA

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In a prospective follow-up study of 5,571 general surgical patients at 11 hospitals (23 departments) in Israel, 1,487 patients underwent operations for hernia (all types) and were screened daily for the development of postsurgical wound infection. Infection developed in 68 (4.6 per cent) at the site of the incision.

Fourteen factors were analyzed for the presumed effect on the risk of infection; only four were significant in a multivariate model. Of these factors (old age, incarcerated or recurrent hernia, coexistent infection and drains), the introduction of drains had the strongest effect (relative risk equaled 4.1; $p<0.001$). Drains increased the risk in all the participating hospitals and in any category of patient. They prolonged the period a wound was susceptible to bacterial infection from nine to 16 days. The risk increased linearly with the duration of the drainage.

The over-all proportion of patients who had a drain inserted was 19 per cent, with hospitals varying from 9 to 40 per cent of patients operated upon ($p<0.001$). Our findings suggest that the risk of an infection associated with drains may outweigh their worth. Furthermore, there is no concensus among surgeons on the need for drains. Some surgeons use drains indiscriminately and others, rarely.

THE PROPHYLACTIC USE of drains in general surgical procedures, especially ones of the open system type, has been a focus of controversy in the surgical literature (1–7). Even in such operations as cholecystectomy and intestinal anastomosis, results from experimental studies suggest that "draining is of doubtful benefit" (2–6). However, although closed system drains "consistently reveal less wound infection, less wound margin necrosis and reduced hospital stay," they still "serve as portal of entry for bacteria, and there is less resistance of drained tissue to bacterial challenge" (1). In certain clean operations, such as mastectomies, there is evidence for the benefit of closed system draining. By contrast, no such evidence is provided from either observational studies or clinical trials to support the recommendation (1) of using closed system drainage in dissection of the groin and ventral hernias. The use of drains in various types of operations for the repair of hernias and its role in predisposing patients to infection is the subject of this report.

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MATERIAL AND METHODS

A total of 1,487 patients underwent operations for hernia as part of the Israeli Study of Surgical Infection (ISSI), which is an ongoing prospective study involving hospitals throughout Israel. The part of the study investigating general surgical patients involved 11 hospitals (23 departments). In every hospital, the resident nurse epidemiologist kept daily records of every patient admitted to the service during the period that it took to complete the sample of 500 patients. To ensure meaningful comparisons between hospitals, the collection of data was done using identical study questionnaires. In addition, a standardized method of collecting the information was supervised by two Central Team Nurses who rotated between the hospitals throughout the study period. The diagnosis of an infection was uniformly made, regardless of the hospital, by a central panel of four physicians, who trained themselves to achieve a high degree of concordance in their decision on the presence or absence of an infection. Details concerning the methods of this study were reported in a previous article (8).

The definition of wound infection used in this study was evidence of a purulent discharge observed by the nurse or recorded in the patient report, with or without bacteriologic findings. If there was no mention of pus, the definition required a continuous discharge (on two days or more), together with two of these stipulations—either the clinicians initiated systemic antibacterial therapy or treated the wound locally with drainage, or there was a bacteriologic report of

TABLE I.—POTENTIAL RISK FACTORS FOR POSTOPERATIVE WOUND INFECTION IN OPERATIONS FOR HERNIA

Categories of risk	*N*	*Infection rate*	*Crude relative risk*	*Adjusted relative risk*
Females	340	7.3	2.1 p=0.008	1.4 p=0.4
Males	1,147	3.7	1.0	
Age ≥70 yrs.	359	6.4	1.6 p=0.06	1.6 p=0.07
<70 yrs.	1,107	4.0	1.0	
Incarcerated	179	7.8 }		
Recurrent	195	10.8 }a	3.2 p<0.001	1.7 p=0.05
+ other diagnosis	671	3.4 }		
None of the above	442	2.3 }b	1.0	
Incisional/ventral	282	9.2		
Femoral hernia	52	7.7 }a	2.4 p=0.02	1.3 p=0.3
Inguinal hernia	1,138	3.3b	1.0	
Blood transfusion				
Yes	5	(40.0)	9.1 p<0.001	—
No	1,482	4.4	1.0	
Yes other infection	13	38.5	8.9 p<0.001	9.5 p=0.002
No	1,474	4.3	1.0	
Spring season	363	5.2 }		
Summer	200	7.5 }a	1.6 p=0.04	1.2 p=0.5
Autumn	359	3.3 }		
Winter	565	3.9 }b	1.0	
Duration ≥91 mins.	269	99a		
61-90	346	2.9 }	2.6 p<0.002	1.4 p=0.3
31-60	484	3.9 }b		
≤30	147	2.7	1.0	
Yes drains introduced	292	13.7	5.3 p<0.001	4.1 p=0.001
No	1,195	2.5	1.0	
Juniors residents	432	4.9 }		
Juniors and seniors	889	4.5 }a	1.2 p=0.06	1.8 p=0.34
Seniors alone	77	3.9b	1.0	
Two separate operations	8	12.5		
One + added procedure	126	7.9	1.9 p=0.06	1.4 p=0.3
One operation	1,353	4.2b	1.0	
General anesthesia	709	4.4 }		
Epidural	651	5.5 }a	3.0 p=0.24	—*
Local	60	1.7b	1.0	
Yes given prophylaxis	184	5.4	1.1 p=0.9	1.6 p=0.4
No	303	4.4	1.0	

*Number of patients or infections, or both, was too small to allow the inclusion of the factor in the model.

Total less than 1,489 patients indicates patients with specific information unknown.

Crude relative risk is ratio of the rates of infection among patients in the risk category (a) and those in the "other" categories (b). Statistical significance was tested by the two tail Mantel Haenszel.

Adjusted relative risk is represented by the odds ratio derived as the beta coefficient of the logistic model. It is adjusted for all 12 risk factors that entered the regression equation. Statistical significance based on the standard error of the coefficient.

a pure culture of one pathogen on more than one occasion.

Putative risk factors for operations for hernia were chosen according to the findings from previous studies by ourselves and others (9–17) and in consultation with the surgeons on the team (Table I). For patients who acquired an infection, only the risk factors present before the appearance of an infection were considered.

The analysis of data involved an estimation of the crude effect of every potential risk factor on infection, followed by an adjustment in a multivariate model for the simultaneous effect of many risk factors. The crude risk was expressed as a relative risk, that is, the ratio of the infection rates among patients with and without the risk factor. Statistical significance was tested by the two-tailed Mantel Haenszel χ (18). The adjusted risk for each of the variables under study (controlled for the effect of other risk factors) was derived from the beta coefficient of the logistic multivariate model (19, 20). The antinormal logarithm of the coefficient is an approximation of the relative risk. Statistical significance for this estimate was based on the standard error of the coefficient.

Details of the effect of drains on wound infection were analyzed by comparing the proportions of infected patients among those with and without drains within various hospitals and different categories of risk. Statistical tests for differences between proportions were used. The effect of the duration of drainage on the risk of infection was expressed as the ratio of the rates of wound infection or each additional day of drainage relative to those without drains.

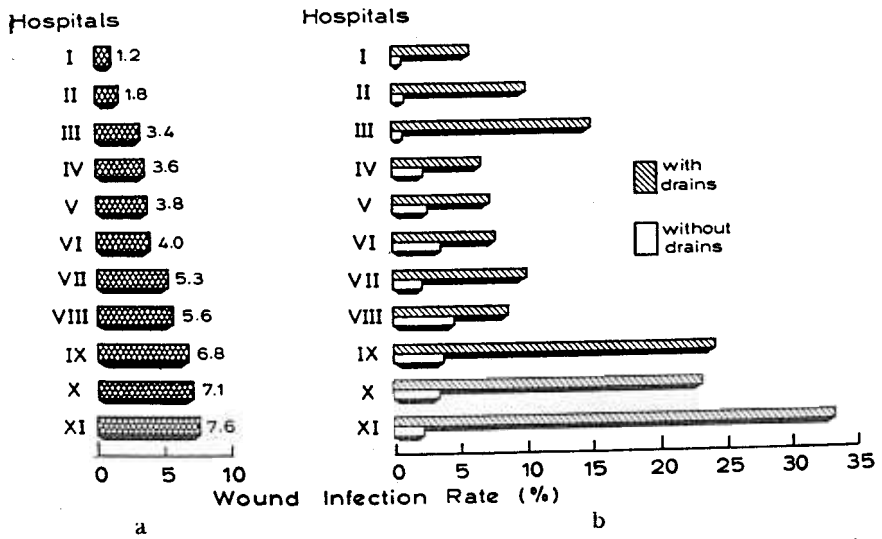

FIG. 1. a, Total infection rates shown for all hospitals. b, Infection rates for patients with drains, cross-hatched columns, and patients without drains, open columns, shown. $p<0.05$ For hospitals VI-XI.

The pattern the day of the appearance of the infection among those patients with and without drains was analyzed using survival without infection curves: the cumulative proportion of patients without a wound infection was calculated for each postsurgical day and was contrasted for patients with and without a drain. The statistical significance between the two curves was estimated using the log rank test (21).

RESULTS

The crude association of 14 hypothetic risk factors with an infection in operations for hernia is presented in Table I. Of these variables, ten were associated with a significantly increased risk of wound infection ($p<0.05$). However, when each of these variables was adjusted for the effect of the others, in a multivariate analysis (Table I), only four were found to have an independent association with an infection. In descending order of significance, these variables were introduction of drains ($p<0.001$), a coexistent infection at another site ($p=0.002$), a diagnosis of an incarceration or recurrence ($p=0.05$) and old age ($p=0.07$). Drains seemed to increase the risk of infection in all of the hospitals, but the magnitude of the effect varied (Fig. 1). For example, in hospital XI, the relative risk of drains was 17.6, while in hospital VI, it was barely 2.0.

The risk associated with drains was also obvious in all categories of patients tested (Fig. 2). The relative risk ranged from 2.0 to 9.0. The effect of combinations of drains plus other factors could be observed. The combined effect of old age (greater than 70 years) and drains produced an infection rate of 23.4 per cent, while among patients with neither risks, the rate was only 1.6 per cent. Similar interactions were observed for combinations of other risk factors and drains.

There was a different pattern observed in the day of appearance of wound infection among patients with and without drains (Fig. 3). For the former group, infections continued to occur

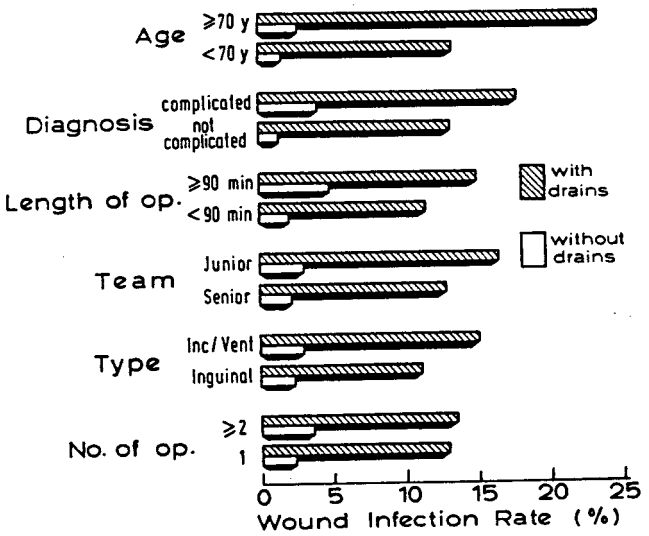

FIG. 2. The effect of drains within different categories of patients ($p<0.05$ in all categories). The height of the crossed columns represents the rates of wound infection in patients with drains; the open columns represent the rates among patients without drains in the specific risk category. Thus, four columns are formed for each risk variable and the effect of combination of drains plus other factors can be observed.

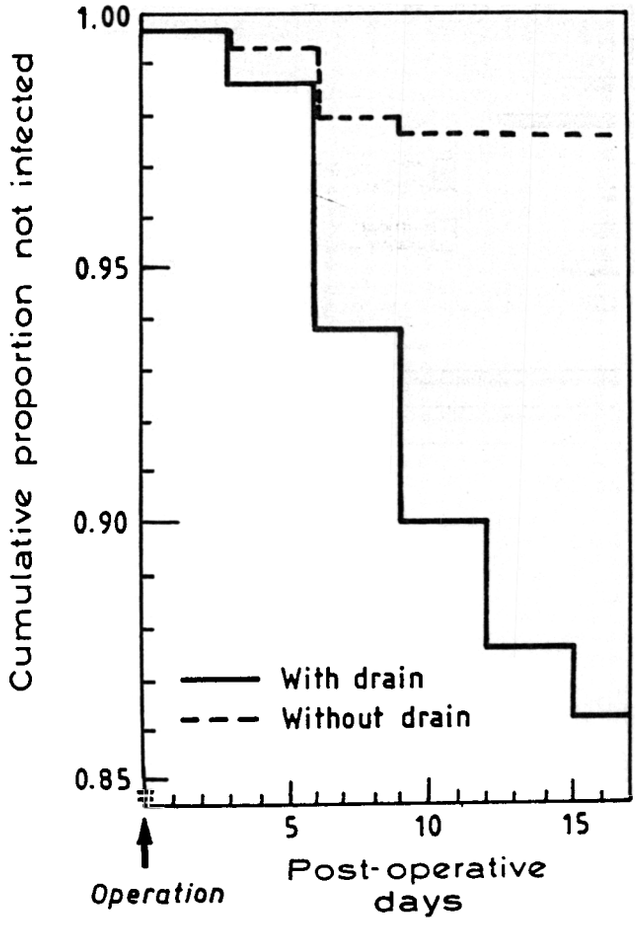

FIG. 3. The cumulative proportion of noninfected patients in the days after the operation is shown for patients with (solid line) and without (broken line) drains.

until the 15th postoperative day, while none occurred in the latter group after the ninth day (log rank test, $p<0.001$).

A linear increase in the risk of infection was observed with each additional day of drainage. Patients with drains left in situ for four days or more had 13 times more infections than those without drains and four times more than those with drains introduced and withdrawn within 24 hours (Fig. 4). Patients with open drains had an infection rate of 15.7 per cent compared with 10.1 per cent among those with closed drains (chi-square, 1.2; $p=0.115$).

Use of drains varied both within the hospital (among different types of patients) and between the participating hospitals (Table II). While the over-all proportion of patients with drains was 19 per cent, drains were introduced in 68 per cent of those with an incarcerated incisional or ventral hernia, in 46 per cent of those with simple incisional and ventral hernia, in 22 per cent with incarcerated inguinal and femoral hernia and in 8 per cent with simple inguinal and femoral hernia. However, even within these types of hernias, the variability among the hospitals was impressive. For example, in the group with incarcerated incisional and ventral hernias among whom drains were introduced most often, the proportion ranged from 33 to 90 per cent ($p=0.02$). In the group with nonincarcerated incisional and ventral hernias, the proportion ranged from 21 to 90 per cent ($p=0.003$), and in the group with simple inguinal and femoral hernias, from 2.8 to 23.0 per cent ($p=0.001$).

The stated reasons for introducing drains in two of the hospitals are given in Table III. Except for agreement on the need for drains in incisional and ventral hernias, other indications were different between the two hospitals.

TABLE II.—VARIABILITY AMONG ISSI HOSPITALS IN USE OF DRAINS

	Hospital No.												
	I	*II*	*III*	*IV*	*V*	*VI*	*VII*	*VIII*	*IX*	*X*	*XI*	*Total*	*p*
ALL PATIENTS													
Number of pts.	165	108	146	56	157	125	152	143	20	70	158	1,487	
Per cent with drains	11.0	9.0	18.0	27.0	26.0	10.0	40.0	24.0	12.0	19.0	17.0	19.0	0.001
PATIENTS WITH INCARCERATED OR RECURRENT INCISIONAL OR VENTRAL HERNIAS													
Number of pts.	5	12	30	4	14	7	15	7	20	10	14	138	
Per cent with drains	100.0	58.0	33.0	75.0	78.6	71.0	93.0	85.0	75.0	60.0	78.6	68.1	0.002
PATIENTS WITH NONINCARCERATED INCISIONAL OR VENTRAL HERNIAS													
Number of pts.	15	4	16	11	20	9	10	17	24	8	10	144	
Per cent with drains	53.0	25.0	56.0	36.4	75.0	55.6	90.0	35.0	21.0	25.0	30.0	46.5	0.003
PATIENTS WITH NONINCARCERATED INCISIONAL OR VENTRAL HERNIAS													
Number of pts.	30	25	27	9	26	17	22	26	19	16	19	236	
Per cent with drains	3.3	0	11.0	33.3	38.5	0	63.6	50.0	5.3	25.0	21.0	22.4	0.001
PATIENTS WITH NEITHER INCARCERATED RECURRENT NOR INCISIONAL HERNIAS													
Number of pts.	115	67	73	32	97	92	105	93	144	36	115	969	
Per cent with drains	3.5	3.0	5.5	18.7	7.2	3.3	23.0	11.8	2.8	2.8	10.4	8.0	0.001

p Determined by chi-square, 10 degrees of freedom.
ISSI, Israeli Study of Surgical Infection.

The effect of drains in ventral and incisional hernias at the point of more or less routine introduction is given in Table IV. As with other types of hernias, the introduction of drains was associated with an increased observed infection rate.

DISCUSSION

The infection rate (4.6 per cent; 68 of 1,487) in this series seems to be higher than those reported in the literature (12–14). Three possible explanations could account for this: 1, our data collection system was based on daily follow-up study and observations of the patients and not on self-reporting or chart review; 2, our definition of infection included patients with continuous discharge other than pus, and 3, infection rates in this country (Israel) are higher than elsewhere. Support for the third explanation is the fact that, within ISSI, some hospitals had very low infection rates, not unlike those in other reports.

Crude and adjusted risk for wound infection in operations for hernia. When considered individually, ten of the 14 variables screened were found to have a significant association with wound infection. Many of these variables have been previously described as risk factors for surgical infection (not necessarily for procedures for hernia): long operations (11, 13, 16), more than one operation during admission (10, 22), the insertion of drains (10, 17), coexistent infection at another site (13, 15), old age (16, 17) and incisional hernias (12). However, in most of the aforementioned studies, these variables were not controlled for the effect of other factors. In this data set, when controlling for the simultaneous effect of many risk variables, only four of the original risk factors maintained an independent association with infection. These, in descending order of significance, were introduction of drains during the operation, coexistent infection at another site, incarceration or recurrent hernia and old age. Of those that were not included among the significant risk factors, the duration of the operation does merit some discussion.

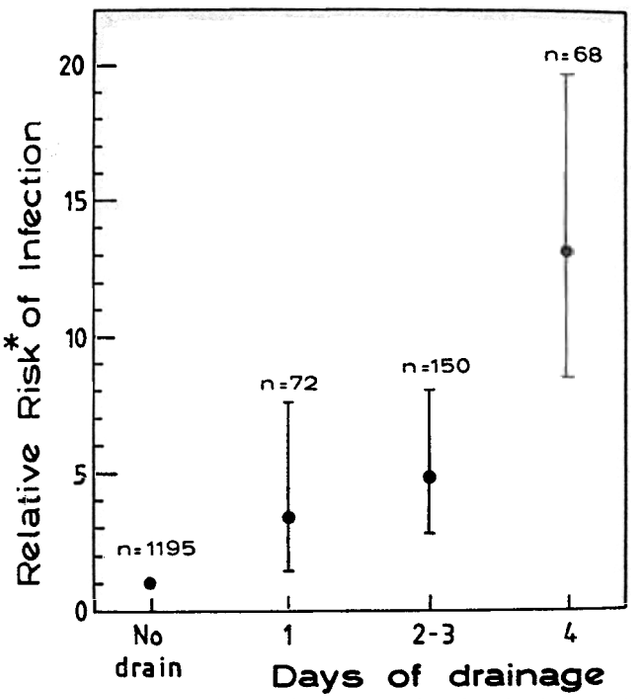

FIG. 4. The association between risk of infection and duration of drainage is shown. *, Relative risk, each category of duration is compared with the category of "no drain."

In studies that reported the importance of duration of operation, there was a pooling of data from many types of surgical procedures (13, 16). Under these circumstances, the length of the operation would serve as a marker to differentiate between the simple and the more complicated operations. In homogeneous groups of patient (12, 22), in which other characteristics of the patients were included in the analysis, the duration of the operation was usually not significant (with the exception of cardiac procedures). This may mean that the risk of exposure of the tissues to bacteria during a prolonged procedure was overwhelmed by other problems. This is also true with operations for hernia in which a prolonged

TABLE III.—STATED REASONS FOR USING DRAINS IN OPERATION FOR HERNIA

	Hospital I, N=25 drains		*Hospital II, N=61 drains*	
	N	*Per cent*	*N*	*Per cent*
Incisional or ventral hernia	8	32.0	16	26.2
Indirect inguinal hernia		—	14	22.9
Adhesions at site of operation		—	6	9.8
Incarcerated inguinal hernia		—	12	19.6
Bleeding at the site	4	16.0	4	6.5
Excessive obesity	5	20.0		—
Wide dissection	4	16.0	7	14.5
Introducing a graft		—	2	3.3
Large space	3	12.0		—

TABLE IV.—WOUND INFECTION RATES BY PRESENCE OF DRAINS AND INCARCERATION OR RECURRENCE

	Ventral or incisional				*Inguinal or femoral*			
	Drains		*No drains*		*Drains*		*No drains*	
	Per cent	*N*	*Per cent*	*N*	*Per cent*	*N*	*Per cent*	*N*
Incarceration or recurrence	17.9	95*	2.3	43	15.0	53*	5.5	182
None of the above	10.1	69	2.7	75	7.8	77*	1.9	891

*p (Mantel Haenszel χ^2 for differences between rates of infection with and without drains is <0.05; the over-all Mantel Haenszel χ^2 (for the effect of drains controlling for incarceration and types of hernia) is 4.6, p<0.0001.

operation was no longer a significant factor after controlling for other risk factors, such as the introduction of drains. Because drains were more frequently introduced in long (40 per cent) rather than short (14 per cent) operations, the crude effect of the length of operation must have been caused by the increased proportion of drains among the longer operations.

Drains in operations for hernia. Of the significant risk factors, introduction of drains had the strongest and most consistent association with infection. Although the risk of their use is well documented (1–7), there was total unawareness among surgeons and infection-control teams that drains were introduced often enough in procedures for hernia to cause concern. In practice, 19 per cent of the patients treated for hernia had a drain inserted. While there seemed to be concensus that incisional or ventral hernias (particularly when associated with an incarceration) warranted the use of drains, surgeons were adamant that other types of operations for hernia did not. In spite of this, in 22 per cent of operations for other incarcerated hernias and in 8 per cent of operations for seemingly simple hernias, a drain was inserted. Stated reasons included excessive obesity, bleeding and indirect inguinal hernias. Furthermore, the increased risk of an infection associated with drains was as evident for incisional and ventral hernias as for other groups (Table IV). The arbitrariness of using drains was demonstrated by the vast differences among the hospitals in the proportion of patients with drains. Some hospitals seemed to use drains sparingly, while others introduced them indiscriminately.

Open drains were used in 60 per cent of the 292 patients who had a drain inserted. Reasons for this practice included the high price of closed systems and the convenience of a soft Penrose drain. We expected larger differences in the infection rates between these types of drainage. We checked the possibility that closed system drains were left in situ longer because of the false sense of security they gave, but we found the duration of the drainage to be similar between the two groups. Mismanagement, such as emptying the bags of the closed system drains, may account for the lack of a larger protective effect.

The period at risk for acquiring an infection seemed also affected by drains. Patients with drains were at risk for development of infection for 15 days, while patients without drains were at risk for only nine days (Fig. 3). This is consistent with our understanding of the healing of surgical wounds (23); beyond the first few hours, a closed wound is resistant to the invasion of bacteria unless it is not properly closed. Drains delay the early sealing of the operative site.

Are drains causing wound infection in patients treated for hernia or is it the inherent susceptibility of the patient who required drainage that increased the risk? Our data suggest a causal association; however, the final answer will come from randomized clinical trials. Only under the special circumstances of a trial will it be possible to separate conclusively the biologic effect of drains from host factors predisposing patients to infection.

SUMMARY

Findings from the ISSI revealed an unsuspected frequent use of drains in operations for hernia, with a concomitant, significant increase in the risk of wound infection. This risk was present in all types of operations for hernia, including ventral and incisional hernias. While surgeons are aware of the danger associated with drains, there is still a prevailing opinion that the collection fluid at the site of the incision predisposes patients to infection to an even greater extent than drains. In light of the causal association between drains and wound infection suggested by our data, and in the absence of a clinical trial to support the use of drains in this type of operation, the careful weighing of the benefit and danger associated with drains and the restriction of drains to a minimum of unavoidable instances is probably feasible and beneficial.

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