RESEARCH ARTICLE

Irrigation suction therapy reduces post-hysterectomy surgical site infection in middle-aged and older diabetic women: A randomized prospective study

Shazia Saaqib[1], Munazza Naheed[2]

Abstract

Objective: To determine whether or not closed wound irrigation and suction therapy can reduce post-hysterectomy surgical site infections in middle-aged diabetic women without increasing pain, causing complications or lowering patient satisfaction.

Method: The prospective randomised controlled study was conducted from April 2017 to March 2022 at Lady Willingdon Hospital, Lahore, Pakistan, and comprised women aged >40 years with body mass index >25kg/m^2 who were scheduled for hysterectomy. The subjects were randomised into intervention group A and control group B. In the irrigation and suction group A, subcutaneous drains were inserted for daily closed wound saline irrigation followed by full-day suction for 3 days. In control group B, wound closure was done without drains and irrigation and suction. Wounds were assessed daily during hospitalisation and at 4, 8 and 12 weeks postoperatively. Primary outcome was surgical site infection rate, fever, white blood cell count, pain score and length of hospital stay. Secondary outcomes were readmission rate, wound pain during follow-up other complications and patient satisfaction. Data was analysed using SPSS 20.

Results: Of the 334 patients, 300(89.8%) were included; 150(50%) in group A with mean age 56.66±9.264 years, and 150(50%) in group B with mean age 55.77±9.394 years. However, the study was completed by 274(91.3%) subjects; 138(50.4%) in group A and 136(49.6%) in group B. Group A had significantly fewer surgical site infections (p<0.0001), lower white blood cell count (p<0.0001), fever (p<0.001) and pain scores (p<.0001), shorter hospital stay (p<.0001) and higher patient satisfaction (p<.0001) compared to group B. Follow-up pain scores and other complications did not differ significantly between the groups (p>0.05).

Conclusion: Irrigation and suction strategy reduced surgical site infection rates without increasing pain, causing complication or compromising patient satisfaction.

Keywords: Surgical site infection, Elderly, Diabetic women, Abdominal hysterectomy, Suction, Irrigation, Satisfaction.

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Introduction

Surgical site infection (SSI) accounts for 20% of all healthcare-associated infections[1] and is a significant complication of surgery in middle-aged and elderly diabetic patients.[2,3] Wound infections are a known risk factor for incisional hernias as well as a source of pain, prolonged hospitalisation and increased costs.[4] The wound infection rate in the general population in the United States is 7.1% but can approach 50% in certain vulnerable groups.[5] According to a recent research conducted in Pakistan, the incidence of surgical site infections (SSIs) was 9.86% across the study population as a whole; 7.19% among nondiabetic individuals and 11.9% among those with increased glycosylated haemoglobin (HbA1c).[6]

SSI is mainly determined by the pathogens, wound environment and immune response of the patients.[7] Old age and diabetes are considered independent risk factors for SSIs.[7,8] With advancing age, skin function deteriorates due to an age-related decline in microcirculation, reduced collagen production, decreased skin lipid, loss of rete ridges, and epidermal atrophy.[9] In diabetics, host defences are further impaired by circulatory failure, hypoxia, neuropathy and altered neuropeptide signalling.[10] Therefore, the prevention of SSIs in geriatric diabetic patients is a focus of study in all surgical fields. In a meta-analysis of SSIs, diabetic women after gynaecological surgery had an estimated 1.61 times higher risk of than those without diabetes (1.15-2.24).[11]

Irrigation and suction (I&S) is a novel bedside primary wound care that may reduce SSIs in closed abdominal wounds by lowering infectious organisms and increasing collagen synthesis and fibroblast proliferation. Although a few studies have linked I&S to increased pain and a risk of wound dehiscence[12,13] other studies have found anecdotally beneficial results.[14-18]

The current study was planned to determine the effectiveness of closed wound I&S by using surgical drains in preventing SSIs in middle-aged and elderly diabetic

[1]Department of Obstetrics and Gynecology, Allama Iqbal Medical College and Jinnah Hospital, Lahore, Pakistan; [2]Lady Willington Hospital, Lahore, Pakistan.
Correspondence: Shazia Saaqib. e-mail: roohi_123@hotmail.com
ORCID ID. 0000-0003-4667-3350

women undergoing hysterectomy.

Patients and Methods

The prospective randomised controlled trial (RCT) was conducted from April 2017 to March 2022 at Lady Willingdon Hospital, Lahore, Pakistan, which is a tertiary care hospital associated with King Edward Medical University (KEMU), Lahore. The study was conducted in line with the Consolidated Standards of Reporting Trials (CONSORT) 2010 statement[19] after approval by the KEMU ethics review board, and was registered retrospectively with the International Clinical Trials Registry Platform (NCT#05611944). However, since it was a single-centered study, it did not fulfill the criteria of a full trial and was instead conducted as a pilot study.

The sample size was determined using G Power 3.1 calculator.[20] The SSI rate for diabetic women undergoing hysterectomy at the study site is 25%. As such, the sample size was calculated to detect a 50% decline in SSIs with 0.05 margin of error, 80% power, and a dropout rate of 10%. The subjects were enrolled from April 2017 to December 2021, with the last follow-up on March 31, 2022. We recruited 300 women who satisfied the study criteria as subjects by purposive sampling.

The inclusion criteria for subjects of this study were age over 40 years, a body mass index (BMI) greater than 25kg/m^2, scheduled to undergo hysterectomy and a haemoglobin (Hb) level of 10 gm/dl or higher, and adequate fitness for anaesthesia. Patients with preoperative haemoglobin levels of less than 10 gm/dl and a BMI of less than 25 kg/m^2 were excluded from the study. This was because drains in thin patients with subcutaneous fat of less than 4 cm could lead to tension in stitches, and the preferable method in such cases was direct wound closure.

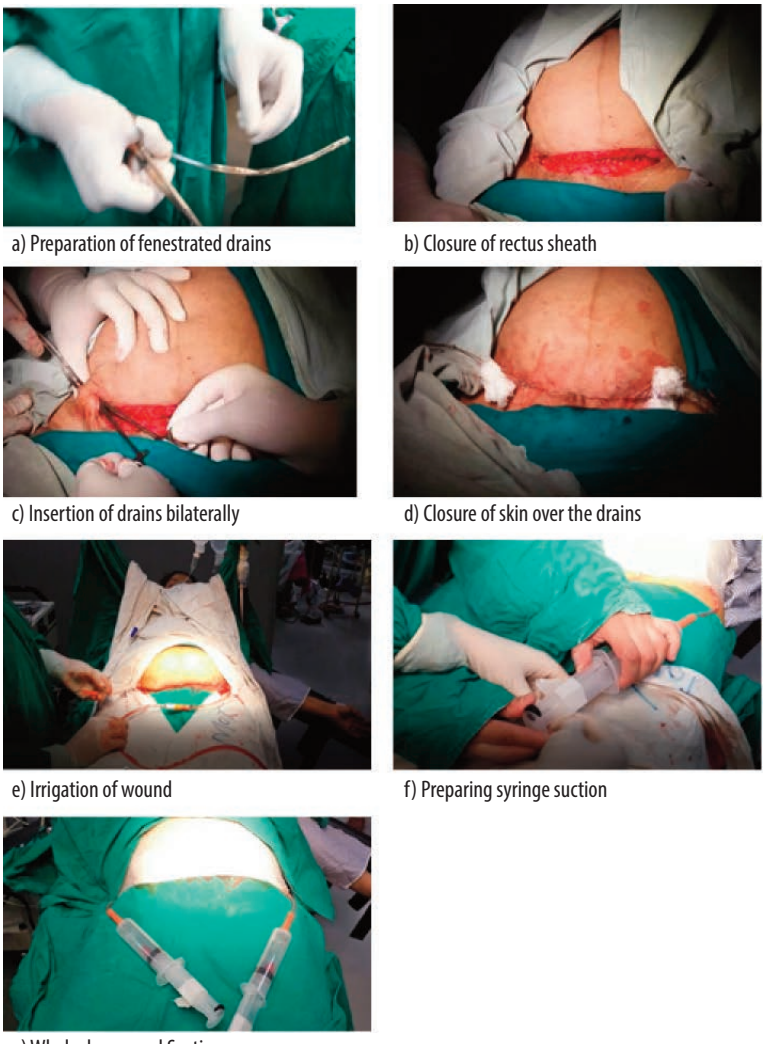

Figure-1: Steps of the irrigation and suction (I&S) technique.

After taking written informed consent from the patients, they were randomised into intervention group A and control group B. A random number container was prepared by downloading the numbers from the internet, and it was handed over to one of the medical officers who was taking care of the enrolment process for random selection of the participants by Lottery method. On surgery day, each patient received a weight-based intravenous (IV) dose of Inj ceftriaxone. The surgeons performed hysterectomy through the abdominal route. They were blinded to group allocation before rectus sheath closure, and could use either a Pfannenstiel or a midline incision on the patient as they deemed appropriate, and performed the operation. The assigned medical officer informed the surgeons about the allocated group after closure of the rectus sheath.

In the intervention group, for each patient a staff nurse prepared two fenestrated Nelaton drains (#16) by making 5-6 fenestrations of about 0.4 cm in size from the tip of the drain to a length of 6 cm. After closing the rectus sheath, the same surgeon created a skin hole on both sides of the wound, using long artery forceps, and implanted drains into the subcutaneous tissue from either side, putting all fenestrations perfectly within the incision and fixing the drains with silk#1. The surgeon closed the subcutaneous tissue over the drains with catgut 2/0 and approximated skin margins with interrupted mattress sutures spaced 2cm apart. Hydrodynamic effects of irrigation and suction have been shown to ensure better

penetration with more fluid used at a higher flow rate of 240 drops per minute compared to slow infusion at 80 drops/minute.[21] Therefore, 1000cc saline was poured at a running rate for irrigation via drip set in one of the drains; the fluid penetrated the skin and soft tissue down to the rectus sheath, and emptied via drain on other side of the wound. Any fluid that leaked through the incision during the irrigation process was wiped off. After irrigation, the wound and external portion of the drains were covered with an airtight dressing, except for the ports.

To begin syringe suction, the plungers were pushed all the way forward to expel all air, and syringes were attached to the drains via the ports. Negative pressure was generated by retracting the pistons and securing them in the retracted position with a piston of 20 cc syringe and surgical tape. Suction was applied for a full day after the wound was irrigated. The procedure was repeated for three days in a row. The drains were retrieved on the fourth postoperative day (Figure2).

In the control group, the subcutaneous tissue was closed with catgut #2 without the insertion of subcutaneous drains, and the abdominal wall was closed with interrupted mattress stitches.

On the fourth day, culture and sensitivity of the tips of the removed drains in group A, and wound swabs in group B were tested. Whenever signs of an SSI appeared in either group, the procedure was repeated. In both groups, wounds were cleansed with spirit and dressings were changed daily by the ward medical officers. Postoperatively, the duty medical officers performed daily monitoring of the subjects for temperature, white blood cell (WBC) count and pain, and assessed the wound for symptoms of SSIs, like presence of oedema, erythema, serous discharge, purulent exudate and separation of wound margins.

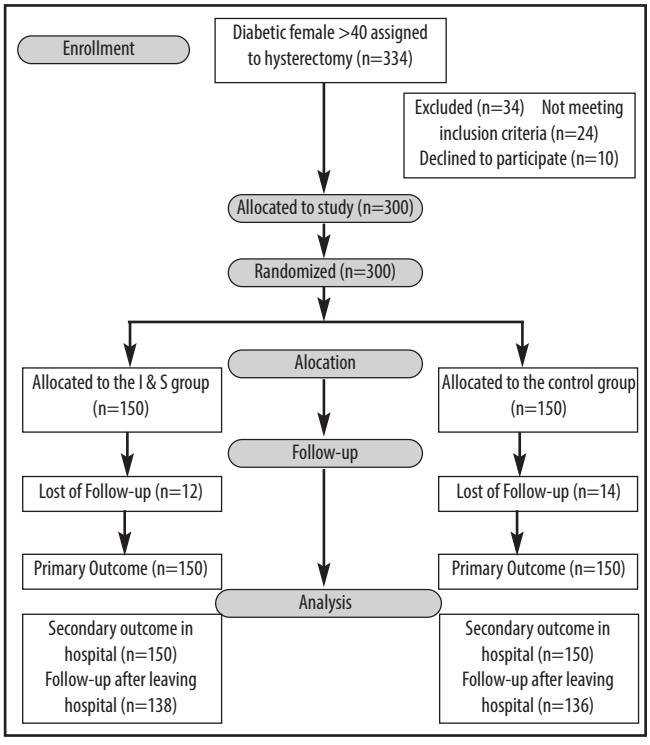

Figure-2: Consolidated standards of reporting trials (CONSORT) flowchart.

In case of SSIs, the incisions of patients in both groups were opened, cleaned and repacked with antiseptic-soaked gauze twice a day, only re-stitching the rectus sheath if found open. On the 8th postoperative day, sutures were removed and patients were discharged if there was no other reason for them to remain in the hospital. The characteristics of participants and primary and secondary outcomes were recorded on the study proforma. Demographic features included age, parity, socioeconomic status (SES), height, weight, cause of hysterectomy, and blood sugar levels. The primary outcomes were the proportion of patients with SSI and the length and depth of wound disruptions, and additional indicators of wound infection, such as pain in the wound, fever, infected culture and elevated WBC count, as well as length of hospital stay (LOS). The secondary outcomes recorded were wound pain after discharge, readmission due to SSIs, wound complications and patient satisfaction.

Subjects with SSIs were confirmed by modifying the original asepsis score.[22] Points were given for the need for additional treatment, the presence of serous discharge, erythema, purulent exudate, and separation of the deep tissues, the isolation of bacteria, and the duration of inpatient stay. Nonetheless, initial 5 criteria of the original asepsis scoring method (oedema, erythema, serous discharge, purulent discharge, wound dehiscence) could be used to assess the sepsis in previously uninfected wound, and, therefore, it was referred to as the sepsis score (Table 1).

Patients having sepsis score 20 or above, or those who met the Centers for Disease Control and Prevention (CDC 2023) criterion for detecting nosocomial SSIs,[23] were diagnosed with SSI, and a wound was considered infected if it was oozing pus even if the sepsis score was <20.10

Fever was recorded by a standard mercury thermometer.

Table-1: Sepsis score criteria.

Wound Affected	0-20%	21-40%	41-60%	61-80%	81-100%
Oedema	1	2	3	4	5
Erythema	1	2	3	4	5
Serous discharge	1	2	3	4	5
Purulent discharge	2	4	6	8	10
Wound dehiscence	2	4	6	8	10

The level of discomfort experienced by the patient was quantified using a numeric rating scale (NRS); ICCS (Intraclass correlation coefficients for relative reliability)= 0.673-0.825, r (reliability coefficient)=0.7-0.99.

Subjects self-reported their rating of pain, while medical officers assessed all other features. All SSI findings from the beginning of the hospital stay until the time of the patient's stitch removal on the 8th postoperative day were documented. The subjects were called for follow-up in outpatient clinics at 4 weeks, 8 weeks and 12 weeks after surgery. For the purpose, the subjects were counselled on the symptoms of SSIs, like discharge, redness, swelling and pain. Satisfaction of the subjects with the surgical result was recorded on a three-point scale (very satisfied, satisfied, or not satisfied) at the end of 12 weeks.

Data was analysed using SPSS 20. Data normality was checked with the Shapiro-Wilks test. For numerical data, mean and standard deviation or median and range were calculated, whereas frequency and percentage were calculated for qualitative data. Mann-Whitney U test, mixed method analysis of variance (ANOVA), and chi-square test were used to compare the variables. The two groups were compared using regression analysis. P<0.05 was considered significant.

Results

Of the 334 patients, 300(89.8%) were included; 150(50%) in each of the two groups (Figure 2). There were 12(%) patients in group A and 14(%) in group B who did not come for follow-up. Their characteristics were taken into account for assessing the main outcome, but they were left out of the analysis related to secondary results. The study was completed by 274 (91.3%) subjects; 138 (50.4%) in group A and 136(49.6%) in group B.

The mean age in group A was 56.66±9.264 years, and it was 55.77±9.394 years in group B. There were no significant differences between the groups for age, parity, SES and metabolic index, while the duration of surgery was significantly longer in group A (p<0.0001) (Table 2).

Group A had significantly fewer SSIs (p<0.0001), lower WBC count (p<0.0001), fever (p<0.001) and pain scores (p<.0001), shorter hospital stay (p<.0001) compared to group B (Table 3). Follow-up pain scores and other

Table-2: Patient's characteristics.

		I&S group n (%)	Control group n (%)	*p*-value
Mean Age (years)		56.66±9.264(43-72)	55.77±9.394	0.408
Parity	Nullipara	3(1)	2 (0.7)	0.725
	Primipara	7 (2.3)	7 (2.3)	
	Multipara	140 (46.7)	141 (47)	
Socio-economic status	Low	39(13)	52 (17.3)	0.129
	Medium	108 (36)	95 (31.7)	
	High	3 (1)	3(1)	
Mean BMI		30.13±2.62	30.55±2.35	0.141
Quetelet index	Overweight	77 (55.8)	61 (44.2)	0.054
	Obese	73 (45.1)	89 (54.9)	
Previous scars on the abdomen		33 (11)	31 (10.3)	0.779
Indications of hysterectomy	Endometrial hyperplasia	81 (27)	79 (26.3)	1.00
	Fibroids	17 (5.7)	21 (7)	
	Ovarian cysts	21 (7)	20 (6.7)	
	Gynaecological Cancer	15 (5)	13 (4.3)	
	Chronic PID	10 (3.3)	11 (3.7)	
	Adenomyosis	6 (2)	6 (2)	
Incision type	Pfannenstiel	105 (35)	110 (36.7)	0.523
	Midline infra-umbilical	45 (15)	40 (13.3)	
Duration of surgery		95 (60-145)	85 (45-130)	<0.0001
Hepatitis		29 (9.7)	31 (10.3)	0.774
Hypertension		103 (34.3)	105 (35)	0.803
BSL Mean Composite		131.49±6.227	131.53±5.928	0.953

Values are Mean±Standard deviation, Number (%), Median (range). Significant p-value of Mann Whitney U test, Chisquare test, and mixed method ANOVA is <0.05.I&S: Irrigation and suction, BMI: Body mass index, PID: Pelvic inflammatory disease, BSL (Blood sugar level).

Table-3: Inter-group comparison of primary outcome measures.

Outcome variables		I&S group (n=150)	Control group (n=150)	Odds ratio (confidence interval)	*p*-value
Subjects with SSI during the hospital stay		5 (3.3)	58 (38.7)	-0.434(0.437--0.270)	<0.0001
Subjects not falling into SSI during the hospital stay		145 (96.7)	92 (61.3)	0.428(0.258-.0422)	<0.0001
The depth of wound disruption	Skin margins	1 (0.7)	4 (2.7)	-0.428(-1.050--0.643)	<0.0001
	Subcutaneous tissue	4(2.7)	33 (22)		
	Rectus sheath	Nil	18 (12)		
	Peritoneum	Nil	3 (2)		
The length of wound disruption	≤20%	9 (6)	Nil	-0.441(-3.367-2.099)	<0.0001
	21-40%	4 (2.7)	4 (2.7)		
	41-60%	Nil	23 (15.3)		
	61-80%	1 (0.7)	15 (10)		
	81-100%	Nil	16 (10.7)		
Pain score (average pain during hospital stay)		4.11±.483	4.72±1.284	-300(-0.830--0.389)?	<0.0001
Fever		6 (4)	22(14.7)	-0.183(-0.172--0.041)	<0.001
WBC count (composite mean)		6500(5000-16750)	7000(5000-17000	-0.261(-0.2445.89-994.11)?	<0.0001
Growth of organisms		4 (2.7)	55(36.7)	-0.428(-0.422--0.258)	<0.0001
Hospital stay duration		7.24±1.464	10.49±4.96	-0.407(-4.08-2.42)	<0.0001

I&S: Irrigation and suction, SSI: Surgical site infections, WBC: White blood cell.

Table-4: Intergroup comparison of secondary outcome measures.

Outcome variables		I&S group (n=138)	control group (n=136)	Odds ratio (confidence interval)	*p* value
Readmission for wound disruption during follow-up		2(1.3)	3(2.7)	-0.028(-.040--.024)	0.641
Pain score after discharge (composite mean)		.256±.492	.29±.395	0.083(-.035-.221)	0.152
Other complications	Holes in stitches	2(1.4)	3(2.2)	-0.033(-.266-.146)	0.557
	Thick scar	10(7.2)	16(11.8)		
	Thinning beneath the wound	1(.9)	Nil		
Satisfaction score	Not satisfied	4(2.9)	13(9.6)	0.324(0.245-0.508)	<0.0001
	Satisfied	9(6.5)	42(30.9)		
	Very satisfied	125(90.6)	81(59.6)		

Values are Means±SD, median (range), and number (proportions). Significant p-value of the regression analysis is <0.05. I&S: Irrigation and suction.

complications did not differ significantly between the groups (p>0.05). Level of patient satisfaction was significantly high in group A (Table 4).

There was no death, but an unusual complication occurred in 1(0.66%) patient in group A. She presented with a cord-like thickening beneath the scar line that was slightly tender, but it cleared on its own within 8 weeks.

Discussion

To the best of our knowledge, the current study is the first to study SSIs in post-hysterectomy, middle-aged and elderly diabetic women.

The risk of wound infection due to ageing and age-related disorders like diabetes has increased in recent years, mirroring the worldwide trend toward an ageing population.[24] Despite numerous experiments conducted by researchers, no fool-proof method of preventing wound infections has yet been identified.

Examples of preventive wound therapy include antibiotics, wound protectors and antibacterial sutures, wound probing and debridement, preoperative warming, supplemental perioperative oxygenation, subcutaneous drain placement, and delayed primary closure.[10,25-27] Closed-wound suction and open-wound irrigation are two separate well-established surgical procedures used in trauma surgery to create a more favourable environment for wound healing.[14-16,18,28] Treatment of SSIs has been shown to benefit from the application of negative pressure wound therapy (NPWT) in the US and other countries by inserting a non-collapsible tube attached with sterile foam placed into the wound subjected to suction.[14-17] Other studies have supported the use of wound irrigation with normal saline or antiseptic solutions to decrease open wound infection.[18,29]

Since irrigation and suction methods both use drains, the current study omitted foam insertion and put drains directly into the wound for I&S, and achieved encouraging outcomes. However, syringe suction drains used in abdominal surgery in a small trial showed that both the drains and the additional time needed to complete the procedure caused significant discomfort to the participants, a rise in SSIs and readmissions.[13] The study method revealed the absence of suction application and wound irrigation with only passive drains. The findings of that study suggested that putting a passive drain in a closed wound increased the risk of wound infection. In another study, the surgeons used radon drains for negative pressure, but did not get a significant reduction in SSIs.[12] That intervention was a lot like the current trial as closed wound system could not be maintained during drain charging in both the studies. The only exception was wound irrigation in the present study, which indicates usefulness of the combined technique.

An important observation of the present study was the drainage of tissue fluid from drain sites following the removal of drains which has also been reported by an earlier study.[13] This can be explained by the persistence of a subcutaneous tunnel at drain sites for a few days following drain removal, preventing excess fluid from penetrating and separating the wound edges. The closing of the tunnel by mildly painful granulation tissue suggests that both primary and secondary healing processes are involved in I&S. In only 1 patient, tunnel filling by firm granulation tissue was apparent and felt like a cord. It was recorded as a complication, although it resolved by itself within 8 weeks.

In the current study, other methods of prevention of SSIs, like antibiotic cover and control of blood sugar levels, were kept similar in both groups.[30] A wound-closure review suggested removing dressings after 48 hours,[31] but all subjects in the current study underwent dressing for 7 days. The dressings were used in I&S group to create a seal for continuous suction and to approximate the stitched abdominal wall closer to the rectus sheath after removal of the drains. In the current study, patients were scheduled to stay in hospital for a minimum of 8 days so that researchers could monitor the daily SSI scores of both groups until the removal of stitches. In standard hospital care, non-I&S patients with well-controlled blood sugar levels and no other complications that could need an extended hospital stay are often discharged 4 days following surgery. While I&S drains are removed on the 4th postoperative day and

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wound care thereafter is comparable to non-I&S group, the same approach can be applied to I&S patients.

The current study also included patients with additional risk factors for SSIs in addition to diabetes and age, such as hypertension, malignancy, midline incision, and prolonged operations, in both groups. Larger studies are warranted to show significant effects of I&S on wound healing in different medical and surgical risk factors in the light of the current results.

The limitations of the current study include the fact that it was conducted at a single centre. As it is a novel method in gynaecology, there is no national or global research in the same discipline to compare the results against. Due to the drains and procedure involved, it was not possible to blind both the patients and the surgeons. Therefore, the possibility of bias could not be ruled out. Suction irrigation is an inconvenient and time-consuming approach for medical professionals. Costs are somewhat higher than with the conventional method of wound closure. Consequently, it is only applicable to high-risk patients.

To prove the effectiveness and patient acceptance of I&S, the strategy needs more extensive multi-centre trials.

Conclusion

I&S was found to be a simple technique that could be applied in the hysterectomy of diabetic patients with or without other chronic medical disorders to significantly reduce SSIs.

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