Protocol

Effectiveness in Preventing Surgical Site Infection by Using Prophylactic Occlusive Ionic Silver-containing Dressing in Abdominal Colorectal Surgery Patients – Randomized Controlled Trial

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Abstract

Background: Ionic silver-containing dressing has been proven as a broad spectrum antimicrobial agent to reduce inflammation of wounds and promote healing. However, surgical incisions are usually dressed with conventional gauze dressing in colorectal surgery.

Objective: To compare the effectiveness in preventing surgical site infection (SSI) by using conventional gauze dressing and occlusive ionic silver-containing dressing.

Methods: This is a single-blind two-arm parallel randomized controlled trial on occlusive ionic silver-containing dressing conducted in Surgery Department of Princess Margaret Hospital. Two hundred patients who undergo emergency or elective abdominal colorectal surgery will be recruited and randomly assigned to have the surgical incisional wound dressed with conventional gauze dressing or occlusive ionic silver-containing dressing. Subjects will be assessed for SSI on day 3, 15 and 30 after operation in a clinical visit followed by phone interviews.

Background

Surgical site infections

According to a Clean Care is safer programme by World Health Organization(WHO), the second most frequent and surveyed health care-associated infections in high-income countries is surgical site infections (SSI). The highest SSI is the colorectal surgery with 9.5% interlude per operations [1]. SSI develop negative influence on patient outcome, such as burden the morbidity, mortality and extra expenses to health care system. The length of stay increased 9.7 days due to SSI in 2005 in USA, and more expenses spend on the antibiotics and the advanced dressing materials [1]. Patient suffered from SSI will double the mortality rate in USA with increased cost and readmission for the treatment.

Modern dressing

There are many different treatment and dressing options for health care providers for wound care. The dressings with advanced technology become more popular in recent days. Many studies show the importance of moist wound dressing to enhance the wound healing process. It can provide a moist wound environment, absorb the excess exudate, move away the microorganism and prevent their replication, and provide a barrier from the external environment than the conventional gauze dressing [2-4]. Besides, a recommendation from the UK's National Institution for Health and Clinical Excellence (NICE) suggest that all surgical incision wound should be dressed with low-adhesive dressing for at least 3-5 days after operation [5]. And a journal published in CINAHL Information

System stated that the use of dressing with moist wound healing effects can help to reduce the SSI rate by 50% that the conventional gauze [6]. On the other hand, there are studies commended that there are no significant different in prevention of SSI with the use of moist wound dressing [7-10]. Therefore, it is a controversial issue on the effectiveness of preventing SSI by using moist wound dressing versus conventional gauze dressing.

Ionic silver-containing dressing

Ionic silver (Ag+), is an active state silver oxidized biologically, is proved as a broad spectrum antimicrobial agent that is effective against aerobic, anaerobic, Gram-negative and Gram-positive bacteria, as well as fungi, viruses, and yeast with minimal development of bacterial resistance [7,8,11-13]. Silver is used commonly in many dressings for the antimicrobial effect. Silver containing dressing can reduce the inflammation of wounds and promotes healing, since silver cations in the dressing can destroy microorganism by inactivating bacterial enzymes, disrupting the functions of cell membrane and binding the bacterial DNA/RNA to cause cell death and inhibiting cell replication [12, 14-15].

Abdominal Colorectal surgery and ionic silver-containing dressing in Hong Kong

In Hong Kong, colorectal cancer is the commonest cancer, there were around 5000 new cases in 2014. And it is the second leading cause of cancer deaths, in 2015, around colorectal cancer caused 2000 deaths [16]. An unpublished internal audit carried out in surgical department in Princess Margaret Hospital (PMH) in 2015 found that the day 30 post-operation SSI incidence among patients with colorectal surgery using occlusive ionic silver-containing dressing (20%; 19/95) was statistically lower than those using conventional gauze dressing (52.9%; 9/17) with p=0.012 (Table 1). Although the effect of using silver dressing to reduce SSI rate is controversial, there are no formal study has been published locally. Therefore, it is meaningful to carry out a randomized controlled trial (RCT) to prove the significance of silver dressing in reduce SSI rate.

Table 1. Findings of unpublished internal audit in PMH on SSI among patients with colorectal surgery in 2015

	Conventional gauze dressing (n=17)		Occlusive ionic silver-containing dressing (n=95)		p value
	SSI	Incidence (95%CI)	SSI	Incidence (95%CI)	
Day 3	1	5.9% (1.0%-27.0%)	2	2.1% (0.6%-7.4%)	0.393
Day 15	8	47.1% (26.2%-69.0%)	14	14.7% (9.0%-23.2%)	0.005
Day 30	9	52.9% (31.0%-73.8%)	19	20% (13.2%-29.1%)	0.012

Objective

To compare the SSI incidence among patients with abdominal colorectal surgery patients using prophylactic occlusive ionic silver-containing dressing and conventional gauze dressing.

Methods

Study design and setting

This is a single-blind two-arm parallel randomized controlled trial on occlusive ionic silver-containing dressing conducted in Princess Margaret Hospital (PMH). PMH is a major acute general hospital in Kowloon West Cluster in Hong Kong, providing 1,542 beds to maintain a wide range of specialist care. There are around 150 abdominal colorectal surgery provided every year in our department. Both the subjects, data collectors and outcome assessors will be blinded to the type of dressing being used. Eligible inpatients receiving colorectal surgery from the department of surgery will be consecutively recruited in each surgical ward (namely, A4 ward, B4 ward and CD4 ward).

Subjects

Patient aged 18 years or above will be included if they undergo abdominal colorectal operation including colorectal cancer case and non-colorectal cancer case such as perforated diverticulitis, trauma, and so on. Patients with cognitive impairment and/or with known allergic reactions to silver, hydrofibre or hydrocolloid and/or with non-closed wound immediate after operation will be excluded.

Subjects will be randomly assigned to use occlusive ionic silver-containing dressing (experimental group) or conventional gauze dressing (control group) with equal probability. Blocked randomization will be carried out by an independent party using computer-generated random number sequences (www.randomization.com) in random blocks of two, four, six and eight, allocated in sequentially numbered, sealed opaque envelopes. Those envelopes would be prepared and placed in each surgical ward.

Data collection procedure

On the day of admission, or an emergency operation is offered, written informed consent will be obtained from all eligible patients. Patients will be arranged by an independent primary nurse in two groups, the experimental and control group, according to the designed block randomized sequence. Relevant dressing materials will be prepared by the primary nurse and bring to the operation theatre. In order to blind the subject, the incisional wound will be covered by ionic silver containing and hydrocolloid dressing with gauze covered on the top for the experimental group, whereas only gauze dressing will be applied for the control group.

Patient's case doctor will be responsible to document in date collection form, if there are surgical site infection occur. A research team is responsible for the data collection. Data obtained includes age, gender, pre-operative albumin level, pre- and post-operative sepsis status, operation class (elective or emergency), operation duration, number of operation, wound classification (clean, clean-contaminated, contaminated, and dirty), types of stoma raised (colostomy or ileostomy), the use and length of duration of antibiotics (pre op and post op). Subjects will be assessed for SSI on Day 3, 15 and 30 after operation in clinical area and followed by phone interviews. During hospitalization, patient's case doctor, who are independent to the study, will be responsible for outcome assessment. After patient discharge, patient will be provide the information of SSI status. Data will be collection by

research team via phone contact, patient will be blind to the study as well. Carers of the patient, who are blind to the study, will be interviewed if the patient is unable to describe their surgical site condition.

Outcomes

Primary outcome is the SSI on day 30 after operation, whereas secondary outcomes are day 3 and 15 SSI after operation. In view of updating patient's condition after the operation and removal of stitches, the secondary outcomes are decided on day 3 and 15 after operation. Assessment of SSI will adopt the basis of criteria developed by the Centers for Disease Control and Prevention (CDC) [17].

Statistical analysis

SSI incidence and relative risk with 95% confidence interval will be computed for the experimental and control groups. Differences in distribution of the clinical data and the development of an SSI in control and experimental groups were evaluated using Pearson's chi-square test, Fisher's exact test, independent t-test or Mann-Whitney U test, where appropriate. Statistical analyses will be performed using SPSS 22.0 for Windows (IBM Corp., Armonk, New York). A p value <0.05 will be regarded as statistically significant.

Sample size estimation

With reference to our previous internal audit, we might assume the day 30 SSI incidence in the experimental group and control group as 20% and 40%, respectively. Using PASS 13 for sample size calculation, the number of subjects needed in both groups will be 80 with a power of 0.8 and a significance level of 0.05. Assuming the response rate to be 80%, the total sample size required will be 200. It is estimated that the ratio of eligible patients in A4 ward, B4 ward and CD4 ward will be around 1:2:3, therefore the number of subjects needed will be 34, 66 and 100, respectively.

Ethical consideration

The protocol of this study will be submitted to KWC Research Ethics Committee for ethical approval and will be registered in ClinicalTrials.gov. Patients who meet the inclusion criteria will be given a comprehensive explanation of the wound dressing selection, including the experimental and control group, and the process of treatment allocation before the start of operation as well. Patient will be reassured the participation is voluntary and they may withdraw at any time during the study with no obligations. They will also be reminded that all detected SSIs are treated immediately and appropriately. Patients who developed an SSI will not be withdrawn from the study and will record as part of the data.

Data handling and record keeping

All data are for research purposes only. The data in paper form will be kept in a locked cupboard inside a locked room and the electronic data will be saved in encrypted file during the study. The hard copies of personal data will be discarded by shredding as confidential waste and all encrypted files with electronic personal data will be saved in CD-Rom for storage which will be destroyed at five

years after completion of the study. Principal investigator will be responsible for safekeeping of personal data during and after the study.

Publication

The research is for internal review and quality improvement but the publication right is still reserved.

Tentative time table

Protocol development	July 2017
Application of Ethical Approval	Aug 2017
Start of subject recruitment and data collection	Sep 2017
Interim analysis	Apr 2018
End of subject recruitment	Dec 2018
End of data collection	Jan 2019
Data cleaning and analysis	Feb - Mar 2019
Report writing	Apr - May 2019

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