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Surgical Site Infections in Relation to the Timing of Shaving among the Gastrointestinal Emergency Patients through the Midline Incisions- A Randomized Controlled Clinical Trial

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Abstract

This Randomized Controlled Clinical Trial (RCT) was conducted among the indoor patients of general surgery wards in a tertiary level hospital in Bangladesh to assess the possible link between the surgical site infections among the gastrointestinal emergency patients of surgery through midline incisions and timing of preoperative shaving. Follow up of at least 30 days period after surgery was done in each patient and has been found that 31.7% patients in control group (received razor shaving 24 hrs prior to surgery) and 27.5% (received razor shaving at OT table) patients in experimental group has developed surgical site infections (SSIs) and the overall infection rate was found to be 29.6%. SSIs were found to be only 1.2 fold higher in case of the patients who received razor shaving at least 24 hour prior to surgery in contrast to the patients received razor shaving at OT table. Grade IIId (18.4% and 27.3% respectively) and grade IVb (21.1% and 21.2% respectively) were found to be the most common types of surgical site infections among the gastrointestinal emergency post-surgical patients.

Introduction

"Surgical sites infections" is a very important chapter in our day to day common surgical practice. The "Guideline for Prevention of Surgical Site Infection, 1999" presents the Centers for Disease Control and Prevention (CDC)'s recommendations for the prevention of surgical site infections (SSIs), formerly called surgical wound infections [1-3]. Surgical Site Infection (SSI) may be defined as the infection of the wound characterized by the invasion of organism through tissues following a breakdown of local and systemic host defenses [4]. Or, SSI is infection at the site of surgical procedure within 30 days of operation but may be within one year if prosthetic or implant surgery is performed [1]. Sources of infection may be Primary: acquired from a community or endogenous source (such as that following a perforated peptic ulcer) or secondary or exogenous (Health care associated infection): acquired from the operating theatre (such as inadequate air filtration) or the ward (e.g. poor hand-washing compliance) or from contamination at or after surgery (such as an anastomotic leak). Secondary or Health care associated infections include Respiratory infection (ventilator associated pneumonia), Urinary tract infections (urinary catheter associated infection), Bacteraemia (associated with vascular catheter) and surgical site infections. SSIs again classified into superficial surgical site infection (When infection involves skin and subcutaneous tissue of the incision within 30 days of operation), deep surgical site infection (infection in the deeper musculo-fascial layers) and organ space infection (such as an abdominal abscess after an anastomotic leak) [4-9].

In the United States alone, an estimated 27 million surgical procedures are performed each year [10]. The CDC's National Nosocomial Infections Surveillance (NNIS) system, established in 1970, monitors reported trends in nosocomial infections in U.S. acute-care hospitals. Based on NNIS system reports, SSIs are the third most frequently reported nosocomial infection, accounting for 14% to 16% of all nosocomial infections among hospitalized patients [11]. Among surgical patients, SSIs were the most common nosocomial infection, accounting for 38% of all such infections. Of these SSIs, two thirds were confined to the incision, and one third involved organs or spaces accessed during the operation [12-14]. When surgical patients with nosocomial SSI died, 77% of the deaths were reported to be related to the infection, and the majority (93%) was serious infections involving organs or spaces accessed during the operation [15,16]. In 1980, Cruse estimated that an SSI increased a patient's hospital stay by approximately 10 days and cost an additional $2,000 [17-19]. A 1992 analysis showed that each SSI resulted in 7.3 additional postoperative hospital days, adding $3,152 in extra charges [20]. Other studies corroborate that increased length of hospital stay and cost are associated with SSIs [21-23]. Deep SSIs involving organs or spaces, as compared to SSIs confined to the incision, are associated with even greater increases in hospital stays and costs [24-26].

Preoperative Issues

Preoperative antiseptic showering

In a study of >700 patients who received two preoperative antiseptic showers, chlorhexidine reduced bacterial colony counts nine fold, while povidone-iodine or triclocarbanmedicated soap reduced colony counts by 1.3- and 1.9-fold, respectively [27]. Other studies corroborate these findings [28,29]. Chlorhexidine gluconate-containing products require several applications to attain maximum antimicrobial benefit, so repeated antiseptic showers are usually indicated [30]. Even though preoperative showers reduce the skin's microbial colony counts, they have not definitively been shown to reduce SSI rates [31,32].

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Preoperative hair removal

Preoperative shaving of the surgical site the night before an operation is associated with a significantly higher SSI risk than either the use of depilatory agents or no hair removal [16,33-44]. In one study, SSI rates were 5.6% in patients who had hair removed by razor shave compared to a 0.6% rate among those who had hair removed by depilatory or who had no hair removed [45].

- Patient skin preparation in the operating room
- Preoperative hand/forearm antisepsis
- Management of infected or colonized surgical personnel

Antimicrobial prophylaxis

Preoperative preparation is another very important part of management for the patients who require surgery especially in case of emergency as well as critical. It is a vital aspect for prevention of developing postoperative complications. In case of surgically ill patients, according to the availability of time for preoperative optimization, there are five basic preoperative windows [46-49].

1) The 4- minutes window
2) The 4- hours window
3) The 4- days window
4) The 4- weeks window
5) The 4- months window

By definition of US CDC, Southampton wound grading system with 30 days follow-up period is an effective and accurate surveillance clinical tool for assessing and categorizing the SSIs [4].

Materials and Methods

Type and period of study

This study was a randomized controlled clinical trail from 12.05.2009 to 03.04.2011

Study population

Indoor patients of general surgery wards (Unit 1 and 2, Ward no 9+10 and 11+12), Khulna Medical College Hospital, Bangladesh

Sample size

The sample size was selected by using the formula Z2pq×D, where, Z= given confidence level. (Z=1.96 for 95% confidence level), p=Probability =20%=0.20, q=1.0-p=0.8 (C1-p) Degree of error limit (the accuracy desired).

Sampling method

Random allocation (random assignment) was the method of choice to select the sample from the hospital admitted patients during the earlier mentioned period of study. A total number of first 1200 patients (on the basis of admission serial to hospital who fulfilled the inclusion criteria) were included here initially from which 240 patients were taken as study population at an interval of 5 by using a simple random table.

Control group: The patients who received razor shaving of skin at least 24 hours before the surgery were the control of this RCT which were selected on random basis. Every alternate patient, as for instance, number 1, 3, 5, 7 …….... (and so on) out of 240 (that is number 3, 13, 23, 33, 43…… out of 1200) were included here as controlled group.

Experimental group: The patients who received razor shaving of skin at the operation table just before operation were the experimental group of this RCT which were selected on random basis. Every alternate patient as for instance number 2, 4, 6, 8 …….... (and so on) out of 240 (that is number 8, 18, 28, 38, 48…… out of 1200) were included here as experimental group.

Confounding variables

- Age and sex
- Nutritional status: BMI (Body mass index)
- Different types and modalities of surgery through midline incisions
- Difference in preoperative preparation and antibiotics prophylaxis regimens as well as variation in postoperative care and dressings
- Selection bias, as no blinding of the study was done

Inclusion criteria

- Patients of gastrointestinal emergency (through 4 day preoperative window) surgery (46-49) through midline incisions were included here who received optimal preoperative prophylactic antibiotic coverage
- All the patients of both control and experimental group had same type of preoperative skin preparation by povidone iodine
- Proposed patients had a skin closure by a monofilament suture material (PDS) were included as study population
- Patients with an age between 20 to 50 years of both sexes were included as the study population
- Patients having a BMI (Body mass index) of 20 to 30 were included here only
- Respective patients with no congenital disability or disorder or disease were selected as population.
- Only the patients found to have a surgical management based upon the basic principle of 4 days windows (46-49) were included here

Exclusion criteria

- In certain kinds of operations, patient characteristics possibly associated with an increased risk of an SSI include coincident remote site infections or colonization, diabetes, cigarette smoking, systemic steroid use, obesity, extremes of age, poor nutritional status and perioperative transfusion of certain blood products. This sort of patients were excluded from this study design
- Patients receiving skin closure with a suture material other than a monofilament were not included in this (RCT)
- Patients with ASA 5 (American Society of Anaesthesiologists) were not included as study population
- Patients with past history of any surgery through abdominal incision were excluded from study population

Diagnosis of SSIs in study population: Diagnosis of SSIs was done in the both study groups on the basis of clinical presentations and examination and categorized by using Southampton wound grading system, but it was not confirmed by culture and sensitivity of wound swabs

Procedure of data analysis of interpretation: In this clinical study, both manual and computer based statistical analysis of the data were done. Data were analyzed manually and then rechecked with SPSS. The survey data will usually be analyzed using both analytic as well as descriptive statistic.

Results and Discussion

This randomized controlled clinical trial was aimed to assess the possible link between the surgical site infections among the gastrointestinal emergency [46-49] patients of surgery through midline incisions and the contributing role of razor shaving of skin at least 24 hours preoperatively in contrast to shaving at operation table. Age, sex and the nutritional status of both controlled and experimental groups are given in Table 1.

According to the "Guideline for Prevention of Surgical Site Infection, 1999" and also by the definition of "The US Centers for Disease Control and Prevention" (CDC)'s, follow up of at least 30 days period after surgery was done in each patient and has been found that 31.7% (38 patients out of total 120 patients of control group) patients in control group and 27.5% (33 patients out of total 120 patients of experimental group) patients in experimental group (Table 2) has developed surgical site infections (SSIs) in different extent and the overall infection rate was found to be 29.6% in case of the total study population (total 240 patients of gastrointestinal emergency surgical patients through midline incisions). In comparison to other studies [1,4], the overall rate of infection was found to be very high in this study (different studies suggest that in case of clean contaminated gastrointestinal surgery with open viscus and minimal spillage, SSIs rate should be less than 10% with prophylaxis and up to 30% before prophylaxis, in case of contaminated gastrointestinal surgery it should be 15-20% and up to 60% respectively). Here, the P value was found >0.4.

Diagnosis of SSIs was done in the both study groups on the basis of clinical observations and categorized by using Southampton wound grading system4, but it was not confirmed by any investigation based microbiological assessments.

This RCT points that SSIs were found to be only 1.2 fold higher in case of the patients who received razor shaving at least 24 hour prior to surgery in contrast to the patients received razor shaving at OT table. By using the Southampton wound grading system4, in Table 3, the infectious site of the study population is tried to be categorized based on this study results in case of both control and experimental group. "The ASEPSIS wound score" was not taken in consideration for interpretation of the study results 4.

Table 3 suggests that grade IIId which reflects SSIs with clear or haemoserous discharge for prolong time at least for more than 3 days (18.4% and 27.3% respectively) was the most common type of surgical site infections followed by grade IVb (SSIs with major complication along wound more than at least 2 cm) (21.1% and 21.2% respectively) among the gastrointestinal emergency surgical patients.

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