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Research Article

Comparative study of chlorhexidine dressings versus simple gauze dressings in midline laparotomy wound

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ABSTRACT

Background: Wound infections are the most common complication of surgery that adds significantly to the morbidity of the patient and the cost of the treatment. Most of the surgical site infections are preventable. Dressing is an active element of wound management, designed to control infection and promote healing. This study was done to compare clinical efficacy of normal gauze dressings versus chlorhexidine dressings in midline laparotomy wounds.
Methods: Patients with midline laparotomy incision were randomized to receive either gauze or chlorhexidine dressings. Bacterial colonization, post- operative fever, frequency of infection, change of dressings, hospital stay and postoperative pain were assessed at the start of treatment and at weekly intervals until full healing occurred.
Results: A total of 128 patients were enrolled in the study and divided into 2 groups viz chlorhexidine group (Group A) and Simple gauze group (Group B) with 64 patients each. Wound cultures, change of antibiotics, post-operative soakage, median hospital stay duration, postoperative pain, post- operative wound infection, and follow up visits for wound healing were compared between two groups A and B and statistical significance established.
Conclusions: The analysis of wound culture, fever incidence and frequency of infection on Chlorhexidine dressings showed decreasing trends compared to traditional dressings.

Keywords: Chlorhexidine dressings, Simple gauze dressings, Bacterial infection/ colonization, Healing, Pain

INTRODUCTION

Dressing is an active element of wound management, designed to control infection and promote healing. The practice of using dressings dates back thousands of years. The use of fabrics such as linen on wounds continued for at least 4000 years until woven absorbent cotton gauze was introduced in 1871.The Edwin Smith Surgical Papyrus, which is one of the earliest medical treatises (dating back to 1615 B C), describes the use of linen strips and plaster to dress wounds, stating that closed wounds heal more quickly than open wounds.[1]

Treatment of wound has evolved from the usage of traditional gauze, bandages to implementation of modern dressing techniques that promote a moist environment in order to accelerate the process of healing.[2]

Gauze dressings

Gauze dressings continue to be the most readily available wound dressings in use today. Gauze is highly permeable and relatively non-occlusive. Therefore gauze dressings may provide desiccation in wounds with minimal exudate unless used in combination with another dressing or topical agent.

Gauze may be used as primary or secondary wound dressing. Gauze dressings are inexpensive for one-time or short term use. Gauze dressings come in many forms:

squares, sheets, rolls, and packing strips. Gauze dressings are made of woven or non-woven materials and come in a wide variety of shapes and sizes.

Advantages

1. Usually readily available may be cheaper than other dressing types.
2. Can be virtually used in any type of wound.

Disadvantages

1. Dressing must be changed frequently ,which may add to overall cost
2. May adhere to the wound bed
3. Must often be combined with another dressing type
4. Often not effective for moist wound healing

Chlorhexidine dressing

Description

Chlorhexidine acetate is a white to pale cream microcrystalline powder, odorless or almost odorless. It is soluble (at 20 deg c) in 55 parts of water and 15 parts of alcohol.

Composition of dressing

Chlorhexidine acetate BP 0.5% in white soft paraffin BP.

The action of chlorhexidine acetate is both bacteriostatic and bactericidal. Chlorhexidine acetate has been shown to be active, in vitro, against a wide range of gram-positive and gram-negative bacteria at concentrations of 10-50 ug/ml including: *Bacillus subtilis*, *Salmonella pullorum*, *Streptococcus lactilis*, *V. choleroe*, *Streptococcus pyogenes* (4 strains), Streptococcus Faecalis, *Corynebacterium diphtheria*, *Salmonella Dublin*, Streptococcus Pneumonia, Salmonella Typhimurium, Staphylococcus aureus (20 strains), Aaerogenes, Proteus vulgaris, *Eschericia coli* and *Pseudomonas aeruginosa*. Chlorhexidine has been found to be ineffective against heat resistant spores and acid-fast bacilli.[3]

Wound assessment

For surgical wound assessment several scoring systems are employed especially:

1. ASEPSIS Scoring system
2. Southampton wound assessment scale

ASEPSIS scoring system

ASEPSIS is an acronym of seven wound assessment parameters. It is a quantitative scoring method that provides a numerical score related to the severity of wound infection using objective criteria based on wound appearance and the clinical consequences of the infection.[4]

Table 1: Asepsis scoring system.

	Proportion of wound affected
Wound characteristic	0 <20 20-39 40-59 60-79
Serous exudate	>80
Erythema	0 1 2 3 4 5
Purulent exudate	0 1 2 3 4 5
Separation of deep tissues	0 1 2 3 4 5
	0 1 2 3 4 5
Points are scored for daily wound infection	
Criterion	Points
Additional treatment	
- Antibiotics	10
- Drainage of pus under local anesthesia	5
- Debridement of wound (General anesthesia)	10
- Serous discharge*	Daily 0-5
- Erythema*	Daily 0-5
- Purulent exudate*	Daily 0-10
- Separation of deep tissues*	10
- Isolation of bacteria	5
- Stay as inpatient over 14 days	

*Given score only on five of seven days. Highest weekly score used

Table 2: Southampton wound assessment scale.

Grade	Appearance	
0	Normal healing	
I	Normal healing with mild bruising or erythema	
	I a	Some bruising
	I b	Considerable bruising
	I c	Mild erythema
II	Erythema plus other signs of inflammation	
	II a	At one point
	II b	Around sutures
	II c	Along wound
	II d	Around wound
III	Clear or haemoserous discharge	
	III a	At one point only (≤ 2cm)
	III b	Along wound (>2 cm)
	III c	Large volume
	III d	Prolonged (> 3 days)
IV	Pus	
	IV a	At one point only (≤ 2cm)
	IV b	Along wound (>2 cm)
V	Deep or severe wound infection with or without tissue breakdown; hematoma requiring aspiration	

Category of infection

Total score 0-10=satisfactory healing; 11-20= disturbance of healing; 20-30= minor wound infection; 31-40=moderate wound infection

Southampton wound grading system

The Southampton system is much simpler than the ASEPSIS system, with wounds being categorized according to complications, if any, and their extent.[5]

Southampton scale

By using the worst wound score recorded and information about any treatment instituted either in hospital or the community, wounds were regarded in four categories:

a. Normal healing
b. Minor complication
c. Wound infection
d. Major hematoma.

METHODS

This was a prospective analytical study of 128 opted cases of midline laparotomies which were treated as surgical emergencies (clean contaminated and contaminated laparotomies) at our tertiary care Centre, Mumbai, Maharashtra.

Sample size calculation

A previous study by Ruschulte h, Franke m, et al reported incident of infection in chlorhexidine impregnated wound dressing to be 6.3%. another study by Conley JM, Grieves K et al reported an incidence of wound infection in gauze dressing to be 24%.

Using an estimate from these 2 studies ,with an alpha= 0.05 and power=80%, we applied the sample size estimation for the 2 groups. The ratio in both the groups was 1;1. Using state version 13, the sample size estimated in each group was 64. Thus, a total sample size for our study's 64 in gauze ground 64 in the chlorhexidine group. The total was 128 patients.

Inclusion criteria

All patients with age >18 years operated in the emergency (clean contaminated and contaminated) with midline laparotomy incision.

Exclusion criteria

All patients with age <18 years and >60 years and elective surgery.

Study procedure

Patients were recruited in casualty and randomized according to randomization table. Since patients were in distress in emergency, relatives were consented. Post - operatively, patients were consented once he/she was in condition to give consent. Patient's demographic, clinical, and past history was noted.

Patients were operated as per their disease and allocated to: Group A - Plain gauze dressing; Group B - Chlorhexidine dressing

Both these were used as standard of care at the institute. Plain gauze means dry gauze with betadine and BACTIGRAS which is chlorhexidine gauze. Both these were available on schedule at our institution and were provided free of cost. Post-op, as per randomization, plain gauze/BACTIGRAS was applied. Patients were observed till discharge / death. Every day, patients were checked for wound soakage/infection, if anything found, wound swab/discharge was sent for culture and sensitivity as per routine protocol.

Outcomes

1. Primary outcome

Incidence of surgical site infections

2. Secondary outcomes

- Pain
- postoperative fever
- any discharge through wound
- requirement of change of antibiotic (culture and sensitivity)
- duration of hospital stay
- condition of wound on follow up

We could measure efficacy of dressing in terms of above outcome associated with particular dressing.

Statistical analysis

For continuous variables, means and standard deviations were calculated. We calculated proportions for categorical variables. Means were compared using the "t" test and proportions were compared using the "chi square "test or "Fischer's exact test for low expected cell count.

We also proposed logistic regression models for multivariate analysis; as there are useful for adjusting potential confounder in data. A "P" value <0.05 was considered statistically significant.

RESULTS

A total of 128 patients were enrolled in this study and divided into 2 groups, viz chlorhexidine group (Group A) and simple gauze group (Group B) with 64 patients each.

1) Age

Table 3: Mean age.

Age	Group A	Group B
Mean±SD	44.72±16.78	41.73±16.54

The mean age of patients in the chlorhexidine treated group was 44.72±16.78 years and in the simple gauze group was 41.73±16.54 years. The two groups were analyzed using the unpaired t-test and showed no statistical difference.

2) Gender

Table 4: Gender.

Gender	Group A	Group B
Males	40	48
Females	24	16
Total	64	64

The distribution of males and females in both the groups where almost similar with 40 (62.5%) males & 24 (37.5%) females in chlorhexidine group and 48 (75.0%) males & 16 (25%) females in simple gauze group. Analysis using Fischer's exact test indicated no statistical difference in the gender-wise distribution of patients between the two groups.

3) Wound culture

Table 5: Wound culture.

Wound culture	Group A	Group B
Positive	3	11
Negative	61	53
Total	64	64

Wound culture in 3 of 64 (4.7%) patients in Group A was found to be positive compared to 11 out of 64 (17.2%) in Group B which was calculated to be statistically significant using Fisher's exact test, indicating that a significantly greater proportion of patients with simple gauze dressing had positive wound culture.

4) Change of antibiotic

Table 6: Change of antibiotic.

Change of antibiotic	group A	Group B
Yes	12	18
No	52	46
Total	64	64

12 out of 64 (18.8%) patients in group A and 18 out of 64 (28.1%) patients in group B required change of antibiotics. A p-value of 0.5280, using the Fisher's exact test was calculated, indicating no significant difference in the proportion of patients who required change of antibiotic, between the two groups.

5) Post-operative fever

Table 7: Post-operative fever.

postoperative fever	group A	group B
Yes	19	35
No	45	29
Total	64	64

19 of 64 (29.75) patients in Group A and 35 of 64 (54.7%) patients Group B developed post-operative fever. Using the Fisher's exact test, p value was 0.0070, indicating that post-operative fever was present in significantly greater proportion of patients with simple gauze dressing.

6) Post-operative soakage

Table 8: Post-operative soakage.

Post - operative soakage	Group A	Group B
Yes	7	26
No	57	38
Total	64	64

7 of 64 (10.9%) patients in Group A and 26 of 64 (40.6%) patients in Group B had post-operative soakage with a statistical significant difference detected between the two groups using Fisher's exact test. Lower number of patients with postoperative soakage was seen in chlorhexidine group compared to simple gauze group.

7) Duration of hospital stay

Table 9: Duration of hospital stay.

Duration of hospital stay	Group A	Group B
Median (Range)	8 (4 to 28)	12 (5 to 30)

The median hospital stay duration for patients in Group A was 8 (4-28) days and 12 (5-30) days for patients in Group B. The difference between the two groups was statistically tested using Mann-Whitney test. The p value was 0.0006 indicating that the duration of hospital stay was significantly greater in patients with simple gauze dressing.

8) Post-operative pain

42 of 64 (65.6%) patients in Group A and 59 of 64 (92.2%) patients in Group B experienced post-operative pain. Using Fisher's exact test statistically significant difference (p=0.0004) was observed between the two groups indicating that significantly greater proportion of patients with simple gauze dressing had post-operative pain.

Table 10: Post-operative pain.

Post-operative pain	Group A	Group B
Yes	42	59
No	22	5
Total	64	64

9) Wound on follow-up

Table 11: Wound on follow-up.

Wound on Follow-up	Group A	Group B
Healing	56	28
Non-Healing	8	36
Total	64	64

56 of 64 (87.5%) patients in Group A and 28 of 64 (43.75) patients in Group B showed healing of wound at following up. Using Fisher's exact test, $p<0.0001$was calculated indicating that significantly greater proportion of patients in the chlorhexidine group had a healing wound at follow-up.

10) Post-operative wound infection

Post-operative wound infection was determined on the basis of post-operative fever, post-operative soakage of dressings, and confirmed by wound culture.

Table 12: Post-operative wound infection.

Post-operative wound infection	Group A	Group B
Present	3	8
Absent	61	56
Total	64	64

3 of 64 (4.7%) patients in Group A and 8 of 64 (12.5%) patients in Group B developed post-operative wound infection. Using Fisher's exact test for statistical analysis, p-value was found was found to be 0.2058 indicating that the incidence of post-operative infection was not significantly different between the two groups.

DISCUSSION

Infections at the surgery site are a common complication of surgery that cause a significantly increase in morbidity as well as cost of treatment. As surgical site infection (SSI) are preventable, several guidelines have recommended standard practices such as skin preparation, hand antiseptics, antibiotic prophylaxis, and maintenance of sterile surgical environment during pre and preoperative phase and most importantly post-operative wound care.

Treatment of wound by using dressing of various kinds has been an ancient practice with it having evolved over time from using traditional gauze and bandages to the modern dressing practices that promotes a moist environment in order to accelerate the healing process.

The characteristics of an ideal wound dressing is that it should provide mechanical and bacterial protection, maintain a moist environment, allow gaseous and fluid exchange, be non-adherent to the wound, non-toxic, non-sensitizing, non-allergic, doesn't hinder the patient's activities, highly absorbable (for exuding wounds), absorb wound odor, maintain sterility, ease of usage, require changing less frequently, cheap and be available in suitable range of sizes.

The purpose of the current study was to compare the effectiveness of Bactigras (chlorhexidine) dressing with routinely used traditional gauze dressing. Chlorhexidine is a biguanide with lower toxicity towards tissues and possess broad spectrum anti-bacterial activity, including against some fungi and viruses.

Study was conducted in our hospital with 128 of sample size which is equally divided in 2 groups of plain gauze and chlorhexidine. The mean age of patients in the chlorhexidine treated group (group I) was 44.72±16.78 years and in the simple gauze group (group II) was 41.73±16.54 years. The two groups were compared using unpaired t-teas and showed no statistical significance. In a study by Liu Z et al regarding postoperative wound dressing in patients of inguinal hernia, the average age was 40±3.5 years in the treatment group and 41±4.2 years in control arm[6] .In another study by Kerwat K et al, For patients with catheters, the average age in treatment age in treatment arm was 56±18 years and in control group was 56±17 years.[7]

The distribution of males and females in both the groups where similar as tested using fisher's exact test with 40 (62.5) males & 24 (37.5%) females in group i and 48 (75.0%) males & 16 (25.0%) females in Group in group II. Analysis using Fisher's exact test, indicated no statistical difference in the gender-wise distribution of patients between two groups. In 2015, Liu Z et al reported a similar distribution of males and females in both the groups and showed no significant difference between both arms.[6] Kerwat k et al also showed no significant difference between both arms.

Wound culture in 3 of 64 (4.7%) patients in Group I were found to be positive compared to 11 out of 64 (17.2%) in Group II which was found to be statistically significant using the Fisher's exact test, indicating chlorhexidine to have a lower rate of positive wound cultures than simple gauze. Kerwat K et al showed that chlorhexidine gluconate impregnating wound dressing in catheter insertion sites and catheter tips showed significantly lower levels of bacterial colonization compared to conventional catheter dressing.[7]

In a study of preoperative cutaneous disinfection using chlorhexidine impregnated cloth was shown to

significantly reduce surgical site infection rates compared to control group, who did not undergo the pre-operative disinfection.[9]

12 out of 64 (18.8%) patients in Group I and 18 out of 64 (28.1%) patients Group II required change of antibiotics. No statistically significant difference was detected using Fisher's exact test between the groups for patients requiring a change of antibiotics.

19 of 64 (29.7%) patients in Group I and 35 of 64 (54.7%) patients simple gauze group developed postoperative fever. Using Fisher's exact test statistically significant difference was seen between the two groups with chlorhexidine group recording fewer numbers of patients with postoperative fever. A study by Safdar N et al indicated chlorhexidine impregnated dressings was shown to reduce catheter related blood stream infections (CRBSI) which was detected on the basis of three parameters one of which was fever.[9]

7 of 64 (10.9%) patients in Group I and 26 of 64 (40.6%) patients Group II had postoperative soakage with a statistical significant difference detected between the two groups using Fisher's exact test. Lower number of patients with postoperative soakage was seen in chlorhexidine group compared to simple gauze group.

The median hospital stay duration for patients in Group I was 8 (4-28) days and 12 (5-30) days for patients in Group II. The difference between the two groups was statistically tested using Mann-Whitney test and was found to be significant with chlorhexidine group having a shorter hospital stay period compared to simple gauze group. A clinical study by Segers P et al demonstrated that preoperative decontamination of nasopharynx and oropharynx with 0.12% chlorhexidine gluconate reduced the mean hospital stay in patients undergoing cardiac surgery by reducing the incidence of nosomial infection.[11]

42 of 64 (65.6%) patients in Group I and 59 of 64 (92.2%) patients in Group II experienced was observed between the two groups with significantly lower proportion of patients in chlorhexidine arm complaining of post-operative pain compared to simple to simple gauze group .A study conducted by Bashetty & Hegde revealed significantly lower pain in patients given irrigation for root canal treatment with 2% chlorhexidine solution after 6 hours compared to 5.25% sodium Hypochlorite solution.[12]

Contrary to this, Menakaya IN et al conducted a study, in which 0.2% chlorhexidine solution was mixed with calcium hydroxide solution for irrigation of root canal and showed higher pain levels, though not statistically significant, when compared to saline mixed with calcium hydroxide used an irrigating agent.[13] 56 of 64 (87.5%) patients in Group I and 28 of 64 (43.7%) patients in Group II showed healing of wound at following up. Using Fisher's exact test significantly greater improvement was observed in chlorhexidine arm compared to simple gauze arm. In a review by Drosou A et al, chlorhexidine treatment is seen to both promote and delay healing in various studies giving conflicting results depending on the concentration used and the site of application and may promote healing of open wounds at risk of infection.[14]

3 of 64 (4.7%) patients in Group I and 8 of 64 (12.5%) patients in Group II developed post-operative wound infection with no statistical significance, using Fisher's exact test, between the two groups for wound infection rates.

The study by Tilsit J et al also demonstrated lower levels of major catheter related infections in patients using chlorhexidine impregnated sponges compared to control.[8] Similarly, chlorhexidine impregnated dressings was shown to reduce catheter related blood stream infections (CRBSI) by Safdar N et al.[10]

CONCLUSION

This study was done to compare the effectiveness of chlorhexidine dressing against traditional gauze dressing. The analysis of wound culture, fever incidence and frequency of infection in chlorhexidine dressings showed decreasing trends compared to traditional dressings. The frequency with which the dressing had to be changed also reduced. The hospital stay period and postoperative pain experienced by the patients in whom chlorhexidine dressing was used also reduced and showed faster rates of wound healing.

The necessity to change the antibiotics given was also lower in patients with chlorhexidine dressings.

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