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SURGICAL SITE INFECTIONS IN CLEAN AND CLEAN CONTAMINATED WOUNDS A PROSPECTIVE STUDY

General Surgery

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ABSTRACT

Background – clean wounds include those in which no infection is present; only skin microflora potentially contaminate the wound. Clean contaminated wounds Include those in which a hollow viscus such as respiratory, alimentary or genitourinary tracts with indigenous bacterial flora is opened under controlled circumstances without significant spillage of contents. This study hopes to compare surgical site infection in two types of wounds as well as most common organism causing surgical site infection. **Methodology-** After explaining the patients regarding the study design, patients giving informed consent were enrolled for the study. All the patients were assessed pre-operatively by taking relevant detailed clinical history, examination and all investigations and work-up required prior to surgery. At the end of surgery, standard closure protocol was followed. Cleaning the open wound with normal saline followed by skin suturing, followed by application of spirit - normal saline - dry gauze; followed by occlusive type of dressing. Wound was opened for dressing on the 3rd post-operative day, unless there are local/systemic signs of inflammation or soakage. Sterile cotton swabs will be obtained from the depth of wounds showing signs and symptoms of SSI and were sent for culture and sensitivity and antibiotics were started accordingly. **Results-** Presence of diabetes mellitus is a significant risk factor for causing surgical site infection in clean contaminated wounds ($p<0.05$) whereas presence of diabetes mellitus is not a significant risk factor for causing surgical site infection in clean wound ($p>0.05$). Presence of drain/implant is a significant causative factor for both clean and clean contaminated wounds ($p<0.05$). Presence of hypertension is not a significant causative factor for clean wound ($p>0.05$) as well as clean contaminated wound ($p>0.05$). **Conclusion-** According to this study the rate if surgical site infection in clean wounds is 6.66% and in clean contaminated wounds is 12%.

KEYWORDS

Clean wound, Clean contaminated wound, Surgical site infection

INTRODUCTION

Surgical site infection (SSI) is a hospital acquired infection occurs at surgical site during the post-operative periods[1]. It is ranked as the third most commonest healthcare associated infections These infections have a major impact on both morbidity and mortality as it doubled the risk of patient's death after surgery Infection is defined as 'invasion and colonization of microorganisms in the body tissues, which may be clinically unobvious which occurs due to competitive metabolisms, intracellular replication, toxins or antigen-antibody responses in body. It is difficult to predict which wounds will become infected.

Surgical site infections (SSIs) are infections that occur at or near surgical incision within 30 days of operation or after 1 year if an implant is placed. The risk of developing an SSI will depend upon the patient's health status, age, gender, nutrition, smoking, alcoholism, co-morbidities, length of the surgical procedure, type of surgery, length of hospital stay, amount and type of local skin bacteria, preoperative glucose levels, core body temperature fluctuations, and incorrect or lack of antibiotic prophylaxis. Even with improvements made within operating room practices, instrument sterilization methods and the prevention strategies, SSIs continue as a major cause of nosocomial infection and the rates are increasing worldwide even in hospitals having modern facilities and with standard protocols for the pre-operative preparations and antibiotic prophylaxis. Though SSIs are among the most preventable healthcare-associated infections. However, according to the available global evidence, SSIs impose significant burden to the patient and health care system in terms of prolonged hospital stays, spend time in an intensive care unit, readmission to hospital, long-term disability, contribute to spread of antibiotic resistance, increase treatment intensity, substantial financial burden to health care systems, high costs for patients and families, deterioration in the quality of life, and unnecessary deaths. A cut or incision made by scalpel in the skin during surgery and sometimes drain place during surgery is also known as surgical wound. Based on degree of contamination surgical wounds are classified into 4 types

Clean wound (class I) –
include those in which no infection is present; only skin microflora potentially contaminate the wound, and no hollow viscus that contains microbes is entered Elective, Not emergency, Non-traumatic, Primarily closed, No signs of acute inflammation, No break in technique, Respiratory, gastrointestinal, biliary and genitourinary tracts not entered

Class ID –
wounds are similar except that a prosthetic device (e.g – mesh or valve) is inserted. Expected infection rate is 1-2%
E.g – Hernia repair
Breast biopsy

Clean contaminated wound (class II) –
Include those in which a hollow viscus such as respiratory, alimentary, or genitourinary tracts with indigenous bacterial flora is opened under controlled circumstances without significant spillage of contents

Emergency case that is otherwise clean Elective opening of respiratory, gastrointestinal, biliary or genitourinary tract with minimal spillage (e.g. appendectomy) not encountering infected urine or bile Minor break in technique Expected infection rate is 2.1-9.5% for GI surgery other than colon surgery 4-14% for colorectal surgery[9]
E.g – Cholecystectomy
Elective GI surgery

Contaminated wound (class III) –
Include open accidental wounds encountered early after injury, those with extensive introduction of bacteria into a normally sterile area of the body due to major breaks in sterile technique.

Dirty or Infected wound (class IV)

AIMS AND OBJECTIVES

- To study the rate of SSI in clean wounnds
- To study rate of SSI in clean contaminated wounds

- To study rate of different levels of SSI according to CDC classification.
- To identify most common organism isolated

Secondary Aims

1 To study rate of surgical site infection in different genders
2 To study rate of surgical site infection in hypertensive patients
3 To study rate of surgical site infection in diabetic patients
4 To study rate of SSI in patients with implants and drains

Litreature Survey

Surgical site infection has always been a major complication of surgery and trauma and has been documented for 4000 – 5000 years

The Hippocratic teachings described the use of wine and vinegar, which were widely used to irrigate open and infected wounds before delayed primary and secondary wound closure

Galen recognized that this location of infection (suppuration) in wounds inflicted in the gladiatorial arena often heralded recovery, particularly after drainage (pus bonum et laudabile)

MATERIALAND METHODS

Inclusion Criteria :

Patients who underwent clean or clean-contaminated surgery including emergency and elective open and laproscopic surgeries in the Department of General Surgery, SSG Hospital Vadodara. Patients who gave consent for the study

Exclusion Criteria :

Patients who were on steroids and immunosuppressive therapy. Patients having HIV , Hepatitis B and Hepatitis C Patients requiring re-exploration from previous same incision site. Patients who do not give consent for the study Patients who are lost to followup Patients having uncontrolled diabetes

METHODOLOGY

After explaining the patients regarding the study design, patients giving informed consent were enrolled for the study.

All the patients were assessed pre-operatively by taking relevant detailed clinical history, examination and all investigations and work-up required prior to surgery.

All patients posted for surgery underwent bathing with antiseptic soap prior to surgery.

Hair removal was done on table prior to surgery.

Injectable antibiotic – injection ceftriaxone 1gram intravenously was given to all patients on table prior to surgery.

Painting and draping was done by using betadine solution followed by spirit application.

At the end of surgery, standard closure protocol was followed:
Cleaning the open wound with normal saline followed by skin suturing, followed by application of spirit - normal saline - dry gauze; followed by occlusive type of dressing. Wound was opened for dressing on the 3rd post-operative day, unless there are local/systemic signs of inflammation or soakage.

Dressings were done on 5th 7th and 10th day and suture removal was done accordingly

Injectable amoxicillin + clavulinic acid 1.2 gram intravenously 12 hourly was given to all types of surgery, followed by shift to Tablet augmentin 625mg one BD in both cases.

For all bowel surgeries injectable metronidazole 400 mg intravenously 8 hourly was added additionally followed by Tablet metronidazole 400mg one TDS.

In case of development of SSI: daily dressing with non-occlusive dressing were done for purulent discharges, and alternate-day dressing with occlusive dressing in case of serous discharges.

Sterile cotton swabs will be obtained from the depth of wounds showing signs and symptoms of SSI and were sent for culture and sensitivity and antibiotics were started accordingly.

If pus culture is positive injectable antibiotics were given for 5 days depending on sensitivity.

Follow-up of the patients to check for development of SSI was done for 30 days for all, except for surgeries with prosthesis placement, in which case, follow-up was done till 90 days.

Sample Size :

Total-150 patients [Through open epi software with CI of 95% and power 80%]

Ratio of clean : clean contaminated = 1 : 1
Assuming % of unexposed (clean) to the outcome (SSI) was 5%
Assuming % of exposed (clean contaminated) to the outcome (SSI) was 20%.Statistical analysis was done using Chi square and Independent T test.

Permission Of Ethics Committee

Institutional Ethics Committee for Biomedical and Health Research (IECBHR)

Medical College & SSG Hospital, Baroda

Chairperson — Dr. Rashmin Sompura
Member Secretary — Dr. Sandeep Nanda
Dr. Sheila Ajwer — Dr. Neeta Bose — Dr. Chirag Mistry
Dr. Ramantarram — Dr. Purvi Patel — Dr. Kavita Sindhav
Dr. Minal Shastri — Dr. Anand Patel — Mr. Rasesh Shah
Dr. Samir Kachariwala — Dr. Vikas Doshi — Mr. B. B. Gaekwad

No. IEC BHR/187-2020 Date: 21/01/2021

To,

Dr. Annem Naga Bindu Madhavi, Dr. D. B. Choksi,
Department of Surgery
Medical College & SSG Hospital, Baroda

Subject:- Ethics Committee Approval of the study.

Reference:"Surgical site infections in clean and clean contaminated wound"

Dear Doctor,

Your application to conduct the above mentioned study was received by IECBHR, Medical College & SSG Hospital Baroda.

Your proposal was reviewed and discussed on both scientific and ethical aspects by the Ethics Committee while its meeting held on 12/03/2020. Neither you nor any of your study team members were present during the decision making process and did not vote for the approval of the study.

We approve the trial to be conducted in its presented form. Any changes in the protocol, study design and informed consent documents can be done after obtaining approval from ethics committee.

The Ethics committee expects to be informed about the progress of the study, any SAE occurring in the course of the study. You are asked to submit a copy of final report of analysis of the study.

Dr. Sandeep Nanda
Member Secretary,
IECBHR, Research,
Medical College,
Baroda.

RESULTS AND DISCUSSION

Age Distribution Of Patients Studied

Table 1A – age distribution of patients studies (clean)

Age (in years)	Number of patients	Percentage of patients	Number of patients with SSI
0 – 10	3	4%	0
11 – 20	9	12%	0
21 – 30	12	16%	0
31 – 40	15	20%	1
41 – 50	14	18.66%	2
51 – 60	13	17.33%	1
61 – 70	9	12%	1
71 – 80	0	0%	0

Majority of the patients who underwent clean wounds in our study were concentrated in the age group of 31 – 40 years followed by age group of 41 – 50 years

Most of the SSI in clean surgeries were found in the age group of 41 – 50 years in our study.

Table 1B – age distribution of patients studied (clean contaminated)

Age (in years)	Number of patients	Percentage of patients	Number of patients with SSI
0 – 10	7	9.33%	0
11 – 20	11	14.66%	0
21 – 30	15	20%	1
31 – 40	6	8%	2

41 – 50	14	18.66%	2
51 – 60	13	17.33%	1
61 – 70	6	8%	2
61 – 70	3	4%	0

Majority of the patients who underwent clean contaminated surgeries in our study were concentrated in the age group of 21 – 30 years followed by the age group of 41 – 50 years.

Most of the patients with SSI in clean contaminated studies were found in the age groups of 31 – 40, 41 – 50, 61 – 70 years in our study.

Types Of Surgery

Table 2 A – types of surgeries (clean)

TYPES OF SURGERIES	NUMBER OF CASES	CASES WITH SSI
Mastectomy	4	2
Inguinal hernia	23	2
Ventral hernia	13	0
Hydrocele	10	0
Orchidectomy	2	0
Orchidopexy	3	0
Varicose veins surgery	1	0
Excision	19	1
Total	75	5

Majority of the clean surgeries in our study were of inguinal hernia (31%) followed by excisions (25%) of fibroadenoma and other swellings.

Most of the SSI in clean surgeries in our study occurred in mastectomies and inguinal hernias.

Type 2 B – types of surgeries (clean contaminated)

TYPES OF SURGERIES	NUMBER OF CASES	CASES WITH SSI
Cholecystectomy	13	3
Appendicectomy	12	0
Spleenectomy	2	0
Feeding jejunostomy	5	1
Stoma closure	7	2
Urosurgical procedures	5	1
Other bowel surgeries	21	1
Circumsicion	5	0
Miscellaneous	5	1
Total	75	9

Miscellaneous surgeries include 1 excision of sebaceous cyst, 2 stump closures, 1 secondary suturing of scrotal ulcer, 1 marsupilisation of hydatid cyst of liver.

Majority of the clean surgeries in our study were of inguinal hernia (31%) followed by excisions (25%) of fibroadenoma and other swellings.

Most of the SSI in clean surgeries in our study occurred in mastectomies and inguinal hernias.

Type 2 B – types of surgeries (clean contaminated)

TYPES OF SURGERIES	NUMBER OF CASES	CASES WITH SSI
Cholecystectomy	13	3
Appendicectomy	12	0
Spleenectomy	2	0
Feeding jejunostomy	5	1
Stoma closure	7	2
Urosurgical procedures	5	1
Other bowel surgeries	21	1
Circumsicion	5	0
Miscellaneous	5	1
Total	75	9

Miscellaneous surgeries include 1 excision of sebaceous cyst, 2 stump closures, 1 secondary suturing of scrotal ulcer, 1 marsupilisation of hydatid cyst of liver.

Majority of the patients who underwent clean contaminated surgeries underwent some kind of bowel surgeries (28%) and next are cholecystectomies (17%)

Most of the SSI in clean contaminated surgeries in our study occurred in cholecystectomies followed by stoma closure surgeries.

Patients With Comorbidities

Table 3 A – patients with comorbidities (clean wounds)

Number of patients with only DM	8
Number of patients with HTN only	10
Number of patients with both DM and HTN	0

Table 3 B – patients with comorbidities (clean contaminated)

Number of patients with only DM	16
Number of patients with only HTN	1
Number of patients with both DM and HTN	2

4. GENDER DISTRIBUTION

Table 4 A – gender distribution (clean)

Gender	Number of patients	Percentage of patients	Number of patients with SSI	Percentage of patients with SSI
Female	25	33.33%	2	2.6%
Male	50	66.66%	3	4%

33.33% patients who underwent clean surgeries in our study were females and 66.66% were males.

Table 4 B – gender distribution (clean contaminated)

Gender	Number of patients	Percentage of patients	Number of patients with SSI	Percentageof patients with SSI
Female	20	26.66%	2	2.66%
Male	55	73.33%	7	9.33%

26.66% patients who underwent clean contaminated surgeries in our study were females and 73.33% were males.

Out of total 150 patients in the study, 45 (30%) patients were females and 105 (70%) patients were males

5. Rate Of Surgical Site Infections

Table 5 A – rate of SSI (clean)

Number of patients with SSI	5	6.66%
Number of patients without SSI	70	93.33%
Total	75	100%

Out of 75 patients who underwent clean surgeries, 5 (6.66%) patients developed Surgical site infections and 70 (93.33%) patients did not develop any wound site infection

Among the 5 patients with SSI in clean surgeries, 2 (40%) patients were female and 3 (60%) patients were male

Rate of SSI in clean surgeries =

$$\frac{\text{Total number of patients with SSI in clean surgeries} \times 100}{\text{Total number of patients who underwent clean surgeries}}$$

= 5/75 * 100 = 6.6% of population who underwent clean surgeries

Rate of female patients with SSI in clean surgeries =

$$\frac{\text{Number of female patients with SSI in clean surgeries} \times 100}{\text{Total number of female patients who underwent clean surgeries}}$$

= 2/25 * 100 = 8% of female population who underwent clean surgeries

Rate of male patients with SSI in clean surgeries =

$$\frac{\text{Number of male patients with SSI in clean surgeries} \times 100}{\text{Total number of male patients who underwent clean surgeries}}$$

= 3/50 * 100 = 6% per 1000 male population who underwent clean surgeries

Table 5 B – rate of SSI (clean contaminated)

Number of patients with SSI	9	12%
Number of patients without SSI	66	88%
Total	75	100%

Out of 75 patients who underwent clean contaminated surgeries, 9 (12%) patients developed Surgical site infection and 66 (88%) patients did not develop any wound infection

ORGANISMS ISOLATED IN SSI

Table 9 A – organisms isolated in SSI (clean)

ORGANISM	NUMBER OF PATIENTS INFECTED
Klebsiella species	1
Escherichia coli	3
Combined infection by Klebsiella and Escherichia coli	1

Most common organism causing SSI in clean surgeries in our study is Escherichia coli.

Table 9 B – Organism isolated in SSI (Clean contaminated)

ORGANISM	NUMBER OF PATIENTSINFECTED
Klebsiella species	4
Escherichia coli	2
Pseudomonas species	1
Combined infection by Pseudomonas species and Escherichia Coli	1
No organism isolated	1

Most common organism causing SSI in clean contaminated surgeries in our study is Klebsiella species.

8- DIABETES MIELLIETUS AND SSI

Table 10 A – DM and SSI (clean)

	Number of patients with SSI	Number of patients without SSI
Diabetic	1	7
Non diabetic	4	63

Using chi square test, P value is 0.484 which is not significant at a confidence interval of 95%

Table 10 B – DM and SSI (clean contaminated)

	PatientswithSSI	PatientswithoutSSI
Diabetic	7	11
Nondiabetic	2	55

Using chi square test p value is 0.000057 which is significant at a confidence interval of 95%

HTN AND SSI

Table 11 A – HTN and SSI (clean)

	Patients with SSI	Patients without SSI
HTN	2	8
NON HTN	3	62

Using chi square test p value is 0.06 which is not significant at a confidence interval of 95%

Table 11 B – HTN and SSI (clean contaminated)

	Patient with SSI	Patient without SSI
HTN	1	2
Non HTN	8	64

Using chi square test, p value is 0.245 which is not significant at confidence interval of 95%.

DURATION OF SURGERY AND SSI

Table 12 A – Duration of surgery (clean)

Duration of surgery	1-2hrs	2-3hrs	3-4hrs	4-5hrs
Number of patients	40	27	7	1

Table 13 A – duration of surgery and SSI (clean)

Duration of surgery	Patients with SSI	Patients without SSI
>3 Hrs	1	7
<3Hrs	4	63

Using chi square test, p value is 0.048 which is significant at a confidence interval of 95%

Table 12 B – Duration of surgery (clean contaminated)

Duration of surgery	1-2hrs	2-3hrs	3-4hrs	4-5hrs
Number of patients	18	26	28	3

Table 13 B – Duration of surgery and SSI (clean contaminated)

Duration of surgery	Patients with SSI	Patients without SSI
<3Hrs	2	42
>3Hrs	7	24

Using chi square test p value is 0.017 which is statistically significant at a confidence interval of 95%

DRAIN/ IMPLANT AND SSI

Table 14 A – Drain/implant and SSI (clean)

	With SSI	Without SSI
With drain/implant	4	32
Without drain/implant	1	38

Using chi square test p value is 0.013 which is significant at confidence interval of 95%

Drain/implant and SSI (clean contaminated)

	Patients with SSI	Patients without SSI
With drain/ implant	8	46
Without drain/implant	1	20

Using chi square test p value is 0.02 which is statistically significant at confidence interval of 95%

P value table

	Clean	Clean contaminated
DM	0.484 (>0.05)	0.000057 (<0.05)
HTN	0.06 (>0.05)	0.245 (>0.05)
Duration of surgery >3hours	0.048 (<0.05)	0.017 (<0.05)
Drain/ implant	0.013 (<0.05)	0.02 (<0.05)

From the above table we can say that duration of surgery >3hours and presence of drain/implant is a causative factor for causing SSI in our study.

Also presence of DM is a causative factor for causing SSI in clean contaminated wounds in our study.

Whereas HTN and DM in clean wounds were not significantly related for causing SSI in our study

CONCLUSION

The following study was undertaken in an effort to identify the rate of Surgical site infection in clean and clean contaminated wounds and to identify the most common organism causing SSI. This study is a prospective observational study consisting of 150 patients, conducted in government medical college, Vadodara from March 2020 to September 2021.

According to this study the rate if surgical site infection in clean wounds is 6.66% and in clean contaminated wounds is 12%.

Among the surgical site infections occurred in clean wounds 80% were superficial incisional and 20% were deep incisional whereas in clean contaminated wounds 55.55% were superficial incisional and 44.44% were deep incisional. There were no organ space infections in our study.

The most common organism causing surgical site infection in clean wounds is Escherichis Coli and in clean contaminated wounds is Klebsiella species.

Future Scope

Limitation is that this was a single center study, so multicenter study should be conducted and large scale results should be published so that confounding factors resulting from the numbers of different procedures being performed are taken care of and results are more accurate.

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