

## ABDOMINAL CLOSURE WITH ANTI BACTERIAL COATED SUTURE MATERIALS AND ITS RELATION TO THE INCIDENCE OF POST OPERATIVE SUPERFICIAL SURGICAL SITE INFECTION RATES

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### ABSTRACT

#### BACKGROUND

Surgical site infection (SSI) is an immense burden on healthcare resources even in the modern era of immaculate sterilization approaches and highly effective antibiotics. An estimated 234 million various surgical procedures, involving skin incisions requiring various types of wound closure techniques, are performed in the world, with the majority resulting in a wound healing by primary intention. Triclosan (5-chloro-2-(2, 4-dichlorophenoxy) phenol) is a broad-spectrum bactericidal agent that has been used for more than 40 years in various products, such as toothpaste and soaps. Higher concentrations of Triclosan work as a bactericide by attacking different structures in the bacterial cytoplasm and cell membrane. Use of Triclosan-coated sutures should theoretically result in the reduction of SSI.

The aim of the study is to assess the abdominal closure with antibacterial coated suture materials and its relation to the incidence of post-operative superficial surgical site infection rates.

#### MATERIALS AND METHODS

The data will be collected from hospital records of surgery performed, post-operative daily progress notes and outpatient folders and telephonic conversations with patients after discharge. All patients undergoing laparotomy procedure for any cause. 100 patients divided as 50 in each group.

#### RESULTS

The positive outcome of infection (21.5%) in patients using ordinary sutures was significantly differed with the positive outcome of infection (11.4%) of Triclosan coated sutures.

#### CONCLUSION

In conclusion since there was a definite advantage inferred to the patients by using Triclosan coated polyglactin 910, it is the opinion of the researcher that Triclosan coated sutures has a role to play in reducing SSI in clean wounds and its use should be confined to areas where its application has proven benefits. However more studies should be done to clearly define its role and indications in surgery.

#### KEYWORDS

Surgical Site Infection, Triclosan, Polyglactin 910.

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#### BACKGROUND

Surgical site infection (SSI) is an immense burden on healthcare resources even in the modern era of immaculate sterilization approaches and highly effective antibiotics. An estimated 234 million various surgical procedures, involving skin incisions requiring various types of wound closure

techniques, are performed in the world, with the majority resulting in a wound healing by primary intention.<sup>1-3</sup>

The most widely recognized definition of infection, which is used throughout the United States and Europe, is that devised and adopted by the Centre for Disease Control and Prevention.<sup>4</sup> An SSI is defined as an infection occurring within 30 days of surgery that meets the following criteria: (1) the diagnosis consists of the infection of an anatomic plane by one of the following manifestations: collection, inflammatory signs (pain, oedema, tenderness, redness), dehiscence, or positive culture; and (2) classification according to the anatomic plane as follows: superficial incisional SSI, infection of the skin and subcutaneous tissue; deep incisional SSI, infection of the deep soft tissue (fascia and muscles); and organ/space SSI, infection of the organ/space. These classifications are defined as follows:

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- Superficial incisional SSI- Infection involves only skin and subcutaneous tissue of incision.
- Deep incisional SSI- Infection involves deep tissues, such as fascial and muscle layers; this also includes infection involving both superficial and deep incision sites and organ/space SSI draining through incision.
- Organ/space SSI - Infection involves any part of the anatomy in organs and spaces other than the incision, which was opened or manipulated during operation.

In this study, SSIs were categorized by the above classifications.<sup>5</sup>

A system of classification for surgical wounds that is based on the degree of microbial contamination was developed by the US National Research Council group in 1964. Four wound classes with an increasing risk of SSI were described: clean, clean-contaminated, contaminated, and dirty. In this study, SSIs were researched based on each of the wound classes.

Classification	Criteria
Clean	Elective, not emergency, Non-traumatic, Primarily closed; No acute inflammation; No break in technique; Respiratory, Gastrointestinal, Biliary and Genitourinary tracts not entered.
Clean-contaminated	Urgent or emergency case that is otherwise clean; Elective opening of respiratory, gastrointestinal, biliary or genitourinary tract with minimal spillage Not encountering infected urine or bile; Minor technique break.
Contaminated	Non-purulent inflammation; Gross spillage from gastrointestinal tract; Entry into biliary or genitourinary tract in the presence of infected bile or urine; Major break in technique; Penetrating trauma <4 hours old; Chronic open wounds to be grafted or covered.
Dirty	Purulent inflammation (e.g. abscess); Preoperative perforation of respiratory, gastrointestinal, biliary or genitourinary tract; Penetrating trauma >4 hours old.

Skin wounds are at risk of SSI and therefore may lead to increased morbidity, delayed recovery and prolonged hospital stay. The prevalence of SSI in the developed world is variable but reported figures are estimated at around 5%.<sup>2,3</sup> The development of SSI is a multifactorial phenomenon, which requires a multimodal approach to prevent and treat it in a timely manner to avoid financial, psychological and health-related quality of life consequences. Various predisposing aetiopathological factors for SSI include immunosuppression, nutritional deficiencies, hypoproteinemias, congestive cardiac failure, and hepatic failure, and renal failure, use of steroids, chemotherapy agents, steroids and diabetes mellitus.<sup>6</sup> In additions to these factors, wound contamination, contaminated instruments, surgical technique and sutures used to close skin have also been reported to be responsible for SSI and cosmetic outcomes. The prevention of the SSI by various invasive and non-invasive interventions is the most common measure surgeons and other healthcare professional advocate to tackle the problem of SSI. This includes use of prophylactic antibiotics and various other multimodal approaches already reported in the medical literature.<sup>6</sup>

Triclosan (5-chloro-2-(2, 4-dichlorophenoxy) phenol) is a broad-spectrum bactericidal agent that has been used for more than 40 years in various products, such as toothpaste and soaps.<sup>7</sup> Higher concentrations of Triclosan work as a bactericide by attacking different structures in the bacterial cytoplasm and cell membrane.<sup>8</sup> At lower concentrations,

Triclosan acts as bacteriostatic agent, binding to enol-acyl reductase (ENR), a product of the Fab I gene and thus inhibiting fatty acid synthesis.<sup>7,8,9</sup> Use of Triclosan-coated sutures should theoretically result in the reduction of SSI. Several studies have shown a reduction in the number of bacteria in vitro and also of wound infections in animals.

**Aim and Objectives of the Study**

**Aim of the Study-** To assess abdominal closure with antibacterial coated suture materials and its relation to the incidence of post-operative superficial surgical site infection rates.

**Objectives of the Study**

1. To compare the incidence of superficial SSI in laparotomy incisions closed with coated polyglactin 910 suture with Triclosan versus incisions closed with coated polyglactin 910 suture without Triclosan
2. To study the time frame between surgery and development of SSI
3. To determine which bacteria is commonly associated with SSI after laparotomy closure

**MATERIALS AND METHODS**

**Source of Data-**

1. The data will be collected from hospital records of surgery performed, post-operative daily progress notes and outpatient folders and telephonic conversations with patients after discharge.

2. Type of subject: all patients undergoing laparotomy procedure for any cause.
3. Choosing subjects: number to be studied: 100-divided as 50 in each group. This number was chosen keeping in mind the time restrictions of the study, the feasibility and ease of calculations.

**Inclusion Criteria**

1. All patients above the age of 18 yrs. requiring a laparotomy.
2. All superficial SSI (skin and subcutaneous layer only) developing within a 30-day period post-surgery, as per the traditional definition.

**Exclusion Criteria**

1. Patients <18 yrs. of age
2. Deep SSI or Organ space SSI
3. Wound infections occurring beyond the 30-day time period post-surgery.

**Method of Collection of Data**

1. The pre-operative data collected will include the patient’s demographics, co-morbidities, laparotomy indication, setting (emergency/elective) and class of wound. Intra-operative data will include the method of painting and draping, duration of the surgery, antibiotics received during surgery, intra-operative findings which will help in classifying the wound (e.g.: biliary contamination).

Post-operative data include development of superficial SSI as per the standardized means of detecting and diagnosing superficial surgical site infections, and if they did, what organism did the wound swab grow, and how many days after laparotomy did they develop the SSI.

2. The study planned is an observational study. All individuals admitted in one surgical unit undergoing laparotomy will have closure of subcutaneous layer with coated polyglactin 910 with Triclosan. All individuals

undergoing laparotomy in other surgical units will have closure of subcutaneous closure with coated polyglactin 910 without Triclosan. These patients will be followed up for a period of one month post-surgery and the above-mentioned data will be collected.

3. The superficial SSI rates will be reported as percentages within each group and compared between the groups using t-test for proportion.

The time frame between surgery and development of superficial SSI will be summarized as mean and standard deviation. This will be compared between the two groups using independent sample t-test, if the data is normally distributed.

The commonly observed bacteria in the 2 groups will be listed as number and percentage.

All statistical tests will be considered significant at  $p < 0.05$  level of significance.

**OBSERVATION AND RESULT**

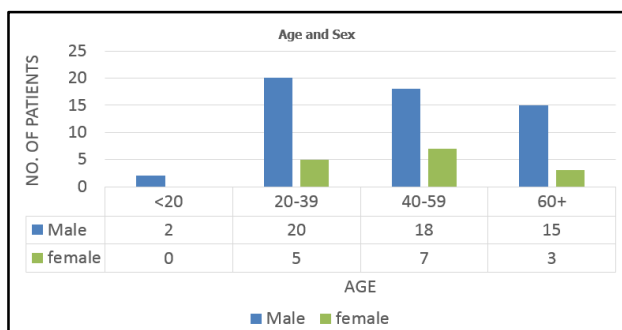
**Statistical Analysis and Interpretations-** The study subjects were described according to the type variables. The continuous variables were described by averages and the categorical variables were described by percentages. The descriptions of continuous variables were interpreted by student “t” tests and the descriptions of categorical variables were interpreted by  $\chi^2$  tests of goodness of fits. The relationships were analysed and interpreted by  $\chi^2$  tests of independence. The above statistical procedures were performed with the help of the statistical packages namely IBM SPSS statistics-20. The P- values less than or equal to 0.05 ( $P < 0.05$ ) were treated as statistically significant.

**RESULTS**

**Description of the study subjects-** The study subjects namely abdominal surgical cases were described according to their age and gender, type of diagnosis and surgical procedure performed.

Age Group (Years)	Male		Female		Total	
	Frequency	Percentage	Frequency	Percentage	Frequency	Percentage
<20	2	2.9	0	0.0	2	2.9
20-39	20	28.6	5	7.1	25	35.7
40-59	18	25.7	7	10.0	25	35.7
60+	15	21.4	3	4.3	18	25.7
<b>Total</b>	<b>55</b>	<b>78.6</b>	<b>15</b>	<b>21.4</b>	<b>70</b>	<b>100.0</b>

**Table 1. Percentage Distribution of Gender Wise Age Group**



**Figure 1. Age and Sex**

The above Table-1 states the age distribution according to the gender of the subjects. The males were 78.6% and females were 21.4%. The mean age of the males was  $44.8 \pm 17.6$  and females were  $50.1 \pm 14.2$  years. The difference between the mean ages were not statistically significant ( $p > 0.05$ ). The total subjects mean age was  $45.9 \pm 17.0$  years with a range of 18-86 years.

Sl. No.	Diagnosis	Frequency	Percentage
1	Appendicular abscess	1	1.4
2	Colonic perforation	2	2.9
3	Gastric perforation	2	2.9
4	Ileal perforation	5	7.1
5	Intestinal obstruction	25	35.7
6	Jejunal perforation	1	1.4

7	Liver laceration	3	4.3
8	Obstructed hernia	5	7.1
9	Perforative peritonitis	23	32.9
10	Retroperitoneal hematoma	1	1.4
<b>Total</b>		<b>70</b>	<b>100.0</b>

**Table 2. Percentage Distribution of Diagnosis**

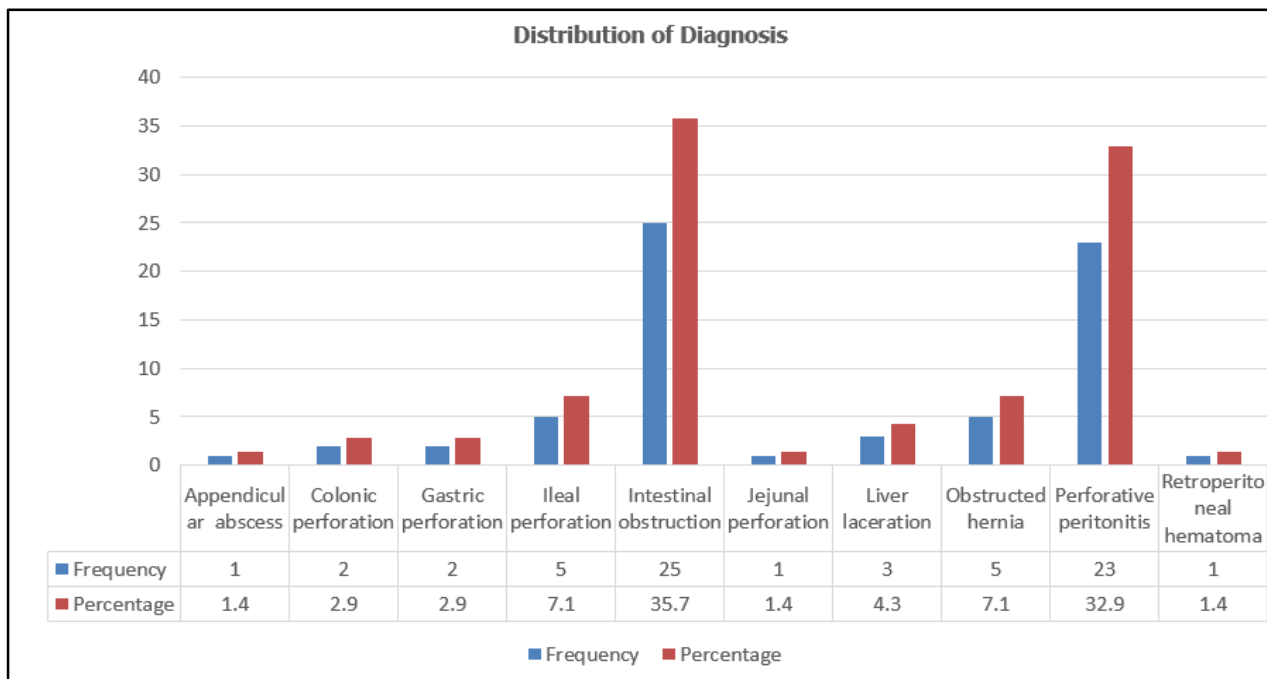


Figure 2. Distribution of Diagnosis

The diagnosis of study subjects were posted in the above Table 2. The Intestinal obstruction was the major (35.7%) diagnosis and next was the Perforative peritonitis (32.7%). Both of Appendice abscess (1.4%) and retroperitoneal hematoma (1.4%) was the least diagnosed symptoms.

undergone the procedure Resection anastomosis as second most procedures. The Gastrojejunostomy, Ileostomy and Obstruction release were the least scored procedure with 1.4% each. The differences between them were statistically very highly significant (P<0.001).

Sl. No.	Procedures	Frequency	Percentage
1	Adhesiolysis	10	14.3
2	Colostomy	5	7.1
3	Gastrojejunostomy	1	1.4
4	Ileostomy	1	1.4
5	Lavage and drainage	6	8.6
6	Obstruction release	1	1.4
7	Omental patch	23	32.9
8	Primary closure	6	8.6
9	Resection anastomosis	17	24.3
<b>Total</b>		<b>70</b>	<b>100.0</b>

**Table 3. Percentage Distribution of Procedures**

The Table 3 states the procedures adopted among the study subjects. The Omental patch (32.9%) was the leading procedures of the subjects. The 24.3% persons had

Sl. No.	Diabetic Status	Frequency	Percentage
1	Diabetic	17	24.3
2	Non-Diabetic	53	75.7
<b>Total</b>		<b>70</b>	<b>100.0</b>

**Table 4. Percentage Distribution of Diabetics**

The above Table 4 classifies the diabetic status of the study subjects as diabetic and non-diabetic. The diabetic subjects were 24.3% and non-diabetics were 75.7%. The difference was statistically very highly significant (P<0.001).

Sl. No.	Wound Class	Frequency	Percentage
1	2	16	22.9
2	3	24	34.3
3	4	30	42.8
<b>Total</b>		<b>70</b>	<b>100.0</b>

**Table 5. Percentage Distribution of Wound Class**

The type of wound was stated in the above table 5. The types 2, 3, and 4 were 22.9%, 34.3% and 42.8% respectively. The difference between the wound classes was not statistically significant ( $P>0.05$ ).

Relationships between abdominal closures with suture materials-

The relationships between wound class, 3<sup>rd</sup> day, 7<sup>th</sup> day and total suture infection were studied. The relationship of suture infection was associated with type of culture positive.

Suture Materials	-		+		Total		x <sup>2</sup>	df	Sig.
	No	%	No	%	No	%			
V	24	34.3	10	14.3	34	48.6	.945	1	P>0.05
V+	29	41.4	7	10.0	36	51.4			
<b>Total</b>	<b>53</b>	<b>75.7</b>	<b>17</b>	<b>24.3</b>	<b>70</b>	<b>100.0</b>			

**Table 6. Association between the Suture Materials used and Infections on 3<sup>rd</sup> Day of Surgery**

The association of suture materials with the outcome of infections on 3<sup>rd</sup> were showed in the above table 6. There was no statistically significant association between the suture materials with outcome of infections on the third day of surgery ( $P>0.05$ ).

Suture Materials	-		+		Total		x <sup>2</sup>	df	Sig.
	No	%	No	%	No	%			
V	28	40.0	6	8.6	34	48.6	4.296	1	P<0.05
V+	35	50.0	1	1.4	36	51.4			
<b>Total</b>	<b>63</b>	<b>90.0</b>	<b>7</b>	<b>10.0</b>	<b>70</b>	<b>100.0</b>			

**Table 7. Association between the suture materials used and infections on 7<sup>th</sup> Day of Surgery**

In the above Table 7, the relationship between the suture materials with the outcome of infections was stated on the seventh day of operations. The results revealed that there was statistically significant relationship between them ( $P<0.05$ ). The positive outcome of infection (8.6%) of V was significantly differed with the positive outcome of infection (1.4%) of V+. Similarly the negative outcome of infections (40%) was associated with V.

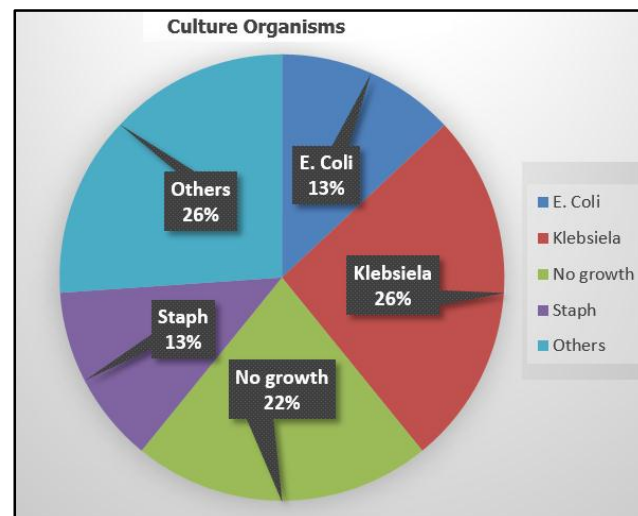
Suture Materials	-		+		Total		x <sup>2</sup>	df	Sig.
	No	%	No	%	No	%			
V	19	27.1	15	21.5	34	48.6	3.842	1	P<0.05
V+	28	40.0	8	11.4	36	51.4			
<b>Total</b>	<b>47</b>	<b>67.1</b>	<b>23</b>	<b>32.9</b>	<b>70</b>	<b>100.0</b>			

**Table 8. Association between the Suture Materials used and total Infections of Surgery**

The above Table 8 states the relationship between the suture materials and the total outcome of infections. The results revealed that there was statistically significant relationship between them ( $P<0.05$ ). The positive outcome of infection (21.5%) of V was significantly differed with the positive outcome of infection (11.4%) of V+. Similarly the negative outcome of infections (27.1%) was associated with V and negative outcome of infections (40.0%) was associated with V+ materials.

Culture Positive	Frequency	Percentage
E. Coli	3	13
Klebsiella	6	26
No growth	5	22
Staph	6	26
Others	3	13
<b>Total</b>	<b>23</b>	<b>100</b>

**Table 9. Percentage Distribution of Type of Culture Positive**



The above table 9 states the culture types of total SSI. Among them E.Coli was 4.3%, Klebsiella 8.6%, no growth 7.1%, Staph 8.6% and others 4.3%.

## DISCUSSION

Surgical site infection remains a major burden in healthcare and so it is imperative that more research is done to find new innovative ways of reducing it. The purpose of this study was to evaluate the effectiveness of antimicrobial coated suture vicryl plus from Ethicon (Triclosan coated polyglactin 910 suture) in reducing superficial surgical site infection in clean wounds.

The contaminated and dirty wound infection rate is mainly associated with incidence of postoperative wound infections. It is for this reason that we also decided to study wound infection rates in the emergency setup so as to assess the quality of surgical care we give to our patients. From the study we found the infection rate for clean-contaminated wound to be 21%, which was considerably higher than the expected rate for clean wound which is less than 10%. For contaminated cases it was 33% while the expected rate was 20%, which is also high. But for dirty cases the incidence was 35% which was within the expected range of <40%. (8a, 10a) Therefore, there is certainly need to do more in prevention and management of SSI at our facility.

The age of the patient was not found to be a contributing risk factor in the development of SSI. There was no age group associated with an increased risk of developing SSI (P value 0.761). Our study population had a median age for males was 44.8 and females was 50.1.

From this study we demonstrated a reduction of superficial SSI when Triclosan coated polyglactin 910 (vicryl plus) was used as compared to plain vicryl. There was a significant statistically difference (P-value <0.05) demonstrated between the two sutures. This is in line with some previous studies that also demonstrated significant difference between the two sutures.<sup>10,11,12,,13,14,15,16</sup> It is important to note that the mechanisms leading to surgical site infections are not fully understood, however the presence of a foreign material like a suture is known to lower the size of bacterial inoculum necessary to develop infection hence creating an antibacterial environment within the wound is supposed to reduce the risk of SSI,. This was the thinking behind the creation of antimicrobial coated suture.<sup>17,18</sup>

Although vicryl plus has been demonstrated to reduce SSI in some areas like abdominal surgery, it has not been found to be effective in others.

One possibility is that, like all good innovations it may be overused and misused. The widespread use of Triclosan for many years in topically personal hygiene products like toothpaste, soap etc may lead to diminished antimicrobial activity. This inevitable can lead to the development of drug resistance, this has been demonstrated in some studies.<sup>19</sup>

The other issue of concern is safety when using Triclosan coated sutures, although several studies have demonstrated Triclosan to be relatively safe in classic toxicological terms.

Currently in the United States, the Food and Drug Administration (FDA) is reviewing the safety and efficacy of Triclosan. And so it would be prudent to exercise caution when using Triclosan coated sutures.

## CONCLUSION

In conclusion since there was a definite advantage inferred to the patients by using Triclosan coated polyglactin 910, it is the opinion of the researcher that Triclosan coated sutures has a role to play in reducing SSI in clean wounds and its use should be confined to areas where its application has proven benefits. However more studies should be done to clearly define its role and indications in surgery. Microbiological culture and sensitivity should be done, for all the patients who developed SSI so as to elucidate local causative agents and the most effective drugs. Microbiological testing for local patterns of resistance to Triclosan should also be done. Prudent use of antimicrobial so as to reduce the development of drug resistance.

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