A COMPARATIVE STUDY OF THE EFFICACY OF ANTIMICROBIAL COATED POLYGLACTIN 910 SUTURE VERSUS TRADITIONAL POLYGLACTIN 910 SUTURE IN SUBCUTICULAR SKIN SUTURING IN ELECTIVE INGUINAL HERNIA SURGERIES

Sharanabasappa S. Karbhari, Prachi M. Pujari, Umeshchandra D. G

1 Professor, Department of General Surgery, M. R. Medical College, Kalaburagi, Karnataka, India.
2 Postgraduate Student, Department of General Surgery, M. R. Medical College, Kalaburagi, Karnataka, India.
3 Professor and HOD, Department of General Surgery, M. R. Medical College, Kalaburagi, Karnataka, India.

ABSTRACT

BACKGROUND
Surgical site infection (SSI) remains a pervasive problem in the surgical community. SSI leads to significant morbidity and mortality, also to longer hospital stays and greater health-care costs. Although several risk factors have been associated with SSI, contamination of suture material appears to be one of the most frequent causes. In view of the above, the present study is undertaken to evaluate the efficacy of new antibacterial coated Polyglactin 910 suture (Vicryl Plus) compared with a traditional Polyglactin 910 suture (Vicryl) in reducing surgical site infection.

MATERIALS AND METHODS
A total of 150 Patients undergoing elective inguinal hernia surgeries were studied during the study period from November 2016 to August 2018 at Basaveshwar Teaching and General Hospital attached to Dept of Surgery, Mahadevappa Rampure Medical College, Kalaburagi, Karnataka. Antimicrobial Coated Polyglactin 910 (Vicryl Plus) suture was used on 75 patients and Traditional Coated Polyglactin 910 (Vicryl) suture was used on 75 patients. The results of the study were tabulated and compared by using Chi square test and Fischer’s Exact test to calculate P value. The sample size estimation was also done at conveniences.

RESULTS
In our study, statistically significant differences in reducing surgical site infection were noted on day 3, day 5, day 7 and day 14 between the two groups with p value of 0.03, 0.04, 0.02 and 0.028 respectively.

CONCLUSION
In the present study, Antimicrobial Coated Polyglactin 910 suture (Vicryl Plus) showed better results in reducing surgical site infection compared with the Traditional Coated Polyglactin 910 (Vicryl) suture.

KEY WORDS
Antibacterial Suture; Inguinal Hernia Repair; Surgical Site Infection.


BACKGROUND
Surgical site infection (SSI) remains an imminent problem in the surgical community. The definition of surgical site infections (SSIs) according to the criteria developed by the Centers for Disease Control and Prevention include every SSI up to 30 days after the operation.(1)

According to the US Centers for Disease Control (CDC) National Nosocomial Infections Surveillance System, SSI is the third most frequent nosocomial infection in United States, accounting for 14-16% of infections among hospitalized patients and 38% of infections in surgical patients.(1,2)

SSI leads to substantial morbidity, mortality and also adds to longer hospital stays and greater health-care costs.(3-4)

Although several risk factors have been associated with SSI,(1,2,5) bacterial contamination of suture material appears to be one of the most frequent causes.(6-8)

To reduce the risk of suture contamination, antimicrobial Polyglactin 910 suture coated with triclosan (Vicryl Plus) has been introduced. Triclosan is a broad spectrum antiseptic that has been widely used in humans for over 30 years.(9)

Surgical site infections after clean elective surgeries like inguinal hernia repair would increase the morbidity and also result in high cost of treatment.

Hence the present study is undertaken to evaluate the efficacy of new antibacterial coated Polyglactin 910 (Vicryl plus) suture compared with traditional coated Polyglactin 910 (Vicryl) suture in reducing surgical site infections in elective inguinal hernia surgery so as to reduce the use of antibiotics post operatively.

Aims and Objectives
1. To evaluate the efficacy of antibacterial coated Polyglactin 910 suture (Vicryl Plus) compared with a traditional Polyglactin 910 suture (Vicryl) in reducing surgical site infection.
2. Reducing antibiotic use postoperatively.
MATERIALS AND METHODS

Study Design
It is a prospective, randomized, comparative, single-centre study.

The present study was carried out at Department of General Surgery, Basaveshwar Teaching and General Hospital attached to Mahadevappa Rampure Medical College, Kalaburagi, Karnataka from November 2016 to June 2018.

A total of 150 patients aged above 18 yrs. undergoing elective inguinal hernia repair were divided into two groups of 75 each. Antimicrobial Coated Polyglaftin 910 (Vicryl Plus) was used on 75 patients and Traditional Coated Polyglaftin 910 (Vicryl) suture was used on 75 patients. The sample size estimation was also done at conveniences.

Inclusion Criteria
1. Patients undergoing elective inguinal hernia repair.
2. Patients aged above 18 years.

Exclusion Criteria
1. Immunocompromised individuals (diabetics, human immunodeficiency virus, bleeding disorders, patients on steroid therapy).
2. Pregnancy.
3. Known hypersensitivity to suture or its components based on past history.
4. Pre-existing surgical site infection.
5. Other surgeries like appendicectomy, exploratory laparotomy etc.

Randomization
Computer generated blocked random numbers will be used to assign the type of suture material used, that is,
2. Group B – Traditional Coated Polyglaftin 910 (Vicryl) suture.

Procedure
In both the groups patients received same antibiotic dose that is Injection Taxim 1g prior to surgery and same Inj. Taxim 1 gm IV BD was given for two days post operatively in all the patients. However, antibiotics were changed based on the severity of SSI, culture and sensitivity.

Patients in group A had wound closure using Vicryl plus and in group B, traditional Vicryl was used. The Post-Operative care was similar for both the groups. Lichtenstein repair was done using prolene mesh followed by subcuticular skin suturing.

Statistical Analysis
The data obtained was entered in Microsoft Excel Spreadsheet. The categorical data was expressed in terms of rates, ratios and percentages. Continuous data was expressed as mean ± standard deviation. The comparison of categorical data was carried out using chi-square test, Fisher’s exact test. The comparison of continuous data was done using independent sample t test. A ‘p’ value of less than or equal to 0.05 was considered as statistically significant.

The database setup software was Oracle Clinical Version 4.1. All statistical analyses and summaries were performed using SAS® for Windows Version 9.1.3 on Enterprise Guide 4.1 (USA).

Outcome
The assessment of wound was carried out based on Southampton wound scoring system on post operative day three, five seven and fourteen.

Assessment of wound using Southampton Wound Scoring System

<table>
<thead>
<tr>
<th>Grades</th>
<th>Appearance</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>Normal Healing</td>
</tr>
<tr>
<td>I</td>
<td>Normal Healing with Mild Bruising or Erythema</td>
</tr>
<tr>
<td></td>
<td>A</td>
</tr>
<tr>
<td></td>
<td>B</td>
</tr>
<tr>
<td></td>
<td>C</td>
</tr>
<tr>
<td>II</td>
<td>Erythema plus other Signs of Inflammation</td>
</tr>
<tr>
<td></td>
<td>A</td>
</tr>
<tr>
<td></td>
<td>B</td>
</tr>
<tr>
<td></td>
<td>C</td>
</tr>
<tr>
<td></td>
<td>D</td>
</tr>
<tr>
<td>III</td>
<td>Clear or Haemo-Serous Discharge</td>
</tr>
<tr>
<td></td>
<td>A</td>
</tr>
<tr>
<td></td>
<td>B</td>
</tr>
<tr>
<td></td>
<td>C</td>
</tr>
<tr>
<td></td>
<td>D</td>
</tr>
<tr>
<td>IV</td>
<td>Major Complications</td>
</tr>
<tr>
<td></td>
<td>A</td>
</tr>
<tr>
<td></td>
<td>B</td>
</tr>
<tr>
<td>V</td>
<td>Deep Severe Wound Infection with or without Tissue Breakdown; Haematoma requiring Aspiration</td>
</tr>
</tbody>
</table>

RESULTS
The data obtained was tabulated and analysed. The final results and observations were tabulated as below.

<table>
<thead>
<tr>
<th>Age Group (Years)</th>
<th>Group A (n=75)</th>
<th>Group B (n=75)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Number</td>
<td>Percentage</td>
</tr>
<tr>
<td>30 or less</td>
<td>12</td>
<td>16</td>
</tr>
<tr>
<td>31 to 45</td>
<td>18</td>
<td>24</td>
</tr>
<tr>
<td>46 to 60</td>
<td>22</td>
<td>29.33</td>
</tr>
<tr>
<td>&gt; 60</td>
<td>23</td>
<td>30.66</td>
</tr>
<tr>
<td>Total</td>
<td>75</td>
<td>100.00</td>
</tr>
</tbody>
</table>

Table 1. Age Distribution

<table>
<thead>
<tr>
<th>Variables</th>
<th>Group A (n=75)</th>
<th>Group B (n=75)</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (Years)</td>
<td>Mean</td>
<td>SD</td>
<td>Mean</td>
</tr>
<tr>
<td>50.33 ± 16.44</td>
<td>52.68</td>
<td>16.85</td>
<td></td>
</tr>
</tbody>
</table>

Table 2. Mean Age

In the present study most of the patients in group A were aged be > 60 years (30.66%) compared to 36% each between 46-60 years and >60 years in group B. However, the difference was statistically not significant (p=0.12).

In this study the mean age in group A was 50.33 ± 16.44 years compared to 52.68 ± 16.85 years in group B but the difference was statistically not significant (p=0.38).
In this study, on postoperative day five, among the patients with group A, grade IA (2.66%) and IC (1.33%) SSI was noted while in group B grade IA (6.66%), IC (5.33%), IIC (4%) and IIIB (2.66%) and IIIC (1.33%) were present. A statistically significant difference was noted, (p= 0.042).

SSI Grade | Group A (n=75) | Group B (n=75)  
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Number</td>
<td>Percentage</td>
<td>Number</td>
</tr>
<tr>
<td>IA</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>IC</td>
<td>0</td>
<td>2.66</td>
</tr>
<tr>
<td>IIIC</td>
<td>0</td>
<td>4</td>
</tr>
<tr>
<td>IIIB</td>
<td>1</td>
<td>5.33</td>
</tr>
<tr>
<td>IIIB</td>
<td>2</td>
<td>4</td>
</tr>
<tr>
<td>IIIC</td>
<td>2</td>
<td>5.33</td>
</tr>
<tr>
<td>Absent</td>
<td>75</td>
<td>100.00</td>
</tr>
<tr>
<td>Total</td>
<td>75</td>
<td>100.00</td>
</tr>
</tbody>
</table>

Table 6. Surgical Site Infection on Post Operative Day 7

p value = 0.028.

Graph 7. SSI on Post Operative Day 14

In this study, no SSI were noted in group A patients while, grade IIC (2.66%) and grade IIIB (5.33%) of patients in group B were noted with statistically significant (p value = 0.028).
In the present study the mean duration of antibiotic administration in group A and B was comparable (2.01 ± 0.11 compared to 2.18 ± 0.56 days; with statistically significant difference between the two groups p value = 0.01.

**DISCUSSION**

Surgical site infections (SSI) continue to be a major problem, despite the advances made in asepsis, antimicrobial drugs, and sterilization and operative techniques. SSIs can progress from local to systemic infection, increasing mortality and morbidity risk associated with longer hospital stay and higher healthcare costs.

The most widely recognized definition of infection is devised and adopted by the Center for Disease Control and Prevention. 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.

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.

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.

According to the National Nosocomial Infections Surveillance System, the most frequently isolated pathogens from SSI are Staphylococcus aureus (20%) and coagulase-negative staphylococci. Multiple risk factors for the development of poor wound healing have been identified. Although patient-related factors such as sex, age, body mass index (BMI), complications, prior surgical procedure and lifestyle-related factors are difficult to modify, the identification of strategies for reducing wound contamination can help decrease the risk of SSIs. In addition to above factors the presence of suture material in wounds increases the susceptibility of the tissue to infection.

A suture is a biomaterial device, natural or synthetic, used to approximate tissues together following separation by surgery or trauma. Different methods for mechanical wound closure are sutures, staples, tape and adhesives of which sutures are the most widely used materials in wound closure.

As a result of capillary action of suture materials, they can serve as vehicles for mechanical transport of bacteria into the surgical incision. Sutures can lead to surgical wound contamination due to bacterial colonization and adherence. Only 100 colony-forming units (CFU)/mg are necessary to produce infection in presence of suture materials. Thus in an attempt to reduce surgical site infection, sutures impregnated with antibacterial agents have been developed.

The most common organisms responsible for SSI include Staphylococcus aureus, Staphylococcus epidermidis, methicillin-resistant S. aureus (MRSA), and methicillin-resistant S. epidermidis (MRSE).

Potential antiseptics for coating surfaces include chlorhexidine, polyhexamethylene biguanide (PHMB), octenidine and triclosan. Compared to antibiotics, antiseptics have multiple targets and true ‘resistance’ is rare. The only substance being used to impregnate suture is Triclosan.

Vicryl Plus was approved for clinical used by the US Food and Drug Administration (US FDA) since 2002. Triclosan has been widely used as a safe and effective antimicrobial agent for more than 30 years in consumer and health-care products, including toothpaste, soap, hand hygiene products, and surgical scrubs.

Coated polyglactin 910 suture with triclosan (Vicryl Plus) was impregnated in suture material with antibacterial activity against the most common putative pathogens that cause SSI. It has been proved to be effective against both methicillin-sensitive and methicillin-resistant S. aureus ( MSSA, MRSA); furthermore, triclosan-resistant populations have not been encountered.

Furthermore, triclosan has been proved to be nontoxic and does not have effect on tissue reaction, healing response or the absorption profile of coated polyglactin 910 suture with triclosan (Vicryl Plus), compared to the traditional polyglactin 910 suture (Vicryl).

Galal and El-Hindawy reported a prospective, randomized, double-blind study that showed that triclosan-coated polyglactin 910 reduced the incidence of SSIs from 15% to 7%. In a sternal wound closure study, the rate of SSI after the use of VICRYL Plus was found to be 0 of 103 (0%) versus 24 of 376 (6%) after the use of conventional Vicryl.

Surgical site infection following elective hernia repair which is classified under clean surgery increases the morbidity, cost and long duration of hospital stay. Hence the use of antimicrobial coated Vicryl suture significantly contributes by reducing surgical site infection.

**CONCLUSION**

Based on the findings of this study, it may be concluded that the efficacy of new antibacterial coated suture (Vicryl Plus) is better than traditional coated suture (Vicryl) in reducing surgical site infection among the patients undergoing elective inguinal hernia repair.
REFERENCES


