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# COMPARISON OF SURGICAL SITE INFECTION RATE BETWEEN ANTIBACTERIAL COATED SURGICAL SUTURE AND CONVENTIONAL SUTURE: A RANDOMIZED CONTROLLED SINGLE CENTRE STUDY FOR PREVENTIVE MEASURE OF POSTOPERATIVE INFECTION

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**Keywords:**

Infection prevention, *In-vitro* testing surgical sutures, Sutures for Infection, SSI, TC versus SSI

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**ABSTRACT:** The main objective of this study is to compare the reduction rate of surgical site infection (SSI) between Triclosan coated (TC) and conventional surgical (CS) suture postoperatively. Surgical site infection (SSI) can be presented as a major challenge for people in the sense of mortality and morbidity mostly in developing countries. The result of SSI with antibacterial suture in developed countries have been already reported; however, these interventions have been studied very little in those developing and underdeveloped countries where lifestyle and the hospital facility plays a major role in infection. A single-center randomized controlled trial was conducted at Civil Hospital Aizawl, Mizoram, India. A total of 110 patients were recruited for the study with a 1:1 ratio in both TC and CS. Superficial SSI was assessed as primary outcomes according to the Centre for Disease Control (CDC) guidelines until 30 days. Secondary outcomes also measured for 1st and 3rd days of surgery. Sutures were tested in laboratory condition for their antibacterial activity before use in surgery. Zone of inhibition (mm), 5.67 ± 0.2, 5.25 ± 0.25 and 4.75 ± 0.25 (Mean ± SEM) against *E. coli*, *B. Subtilis*, and *P. aeruginosa* with TC and no inhibition were observed with CS respectively. The clinical study shows 5 infections in CS and zeroes infection in TC after 1st, 3rd, and 30 days observations. The studies confirm the antibacterial efficacy of TC and also reduce the infection rate in the patient.

**INTRODUCTION:** SSI is one of the most familiar healthcare-associated infections worldwide in modern era [1]. At least a 5% patient develops surgical site infection (SSI) undergoing surgery [2].

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In the early of the middle of the 19th century, patient undergone surgery generally developed "irritative fever," followed by a purulent discharge from the incisions, irresistible sepsis and often death. In the present scenario, although infection control practices such as room ventilation, sterilization methods, barriers, surgical procedure, and availability of antimicrobial prophylaxis are performed, SSI remains the biggest challenge for health care professionals among the hospitalized patients.

This may be due to the antimicrobial resistant pathogen or patients who are elderly and have a chronic disease, or immune-compromising disease [3]. Numerous risk factors have been identified which are responsible for delayed wound healing. Sex, age, body mass index, lifestyles, surgical procedure, etc. are the risk factors which are difficult to control, however by standard surgical techniques, skin antisepsis, proper antibiotic prophylaxis and finding the strategies that are most important factors which can aid in decreasing the risk of SSIs [3, 4, 5]. Most of the SSI's are mainly caused by the patient's endogenous flora. *S. aureus*, coagulase-negative *Enterococcus species*, and *E. coli* are mainly found in the infected wound of the patients when cultured [6, 7]. Many investigators experimentally and clinically reported the frequency of wound infectivity and found wound infection incidents more in the case of multifilament sutures than monofilament sutures [8].

Despite the other risk factors for SSI, surgical sutures can contribute to developing the wound infections especially in developing countries due to their lifestyle and inadequate facilities and have major impact on human health. It has been reported that bacteria can adhere on the suture especially in multifilament braided sutures [9]. The presence of Pathogenic bacteria on the surgical suture increases the threat of infection. The bacterial species can move from the skin to the wound through capillary [10]. To prevent wound contamination, suture has been developed with antibacterial activity. Various pharmaceutical industries have developed surgical suture with different types of antimicrobial agents such as triclosan, chlorhexidine, *etc*. which claims that the coated sutures drastically reduce SSI. Bacterial species isolated from the infected wound has been tested against antimicrobial coated surgical sutures and confirmed their efficacy [11, 12]. In our study surgical suture coated with triclosan compared with CS for their efficacy. This paper mainly focused on the antimicrobial efficacy of the surgical sutures along with efficacy testing on surgical wounds in patients.

**Antimicrobial Assay of Surgical Suture:**

**Materials:** Conventional absorbable surgical suture MITSU (PGN 910) and antibacterial coated suture MEGASORB-T+ (Polyglycolic Acid coated with Triclosan) were obtained from Meril-Endo-Surgery Pvt. Ltd., Mumbai, India. All the bacterial species were ATCC grade, chemicals and reagents were analytical grades.

The antimicrobial assay was performed by using the following test organisms-

- *Pseudomonas aeruginosa* (ATCC-10145)
- *Bacillus subtilis* (ATCC-11774)
- *Escherichia coli* (ATCC-10536)

**Preparation of Inoculum:** Pure culture of bacteria such as *Pseudomonas aeruginosa*, *Bacillus subtilis*, and *Escherichia coli* were inoculated in test tubes containing previously sterilized nutrient hiveg broth and incubated at 37 ± 0.2 ºC overnight.

**Antimicrobial Assay of Surgical Sutures:** Antimicrobial assay of surgical sutures were performed by standard protocol. Four Petri dish were taken, and in each Petri dish 0.5 ml of inoculums, adjusted to 0.5 McFarland standard, containing different species of microorganism were poured by micropipette and then sterilized sabouraud dextrose agar media were poured from the conical flask. The dish was then rotated gently or moved back and forth to ensure that the culture and medium are thoroughly mixed and medium covers the plate evenly. After solidifying the media a small portion approximately 1 inch of antimicrobial-coated surgical suture (Megasorb-T+) were cut and put into the Petri dish with the help of sterile forceps. The Petri dish was incubated for overnight and the zone of inhibition was observed. The same procedure was performed for control suture, *i.e.* Mitsu (CS).

**Antimicrobial Efficacy of Surgical Sutures in Patients:**

**Study Design:** It is a prospective, single center, randomized, single-blind comparative study of sutures which was conducted at Civil Hospital Aizawl, Mizoram, India where patients from different parts of Mizoram visit for their treatment. The study was approved by the Civil Hospital Ethical Committee, Aizawl with registration number B.12018/1/13-CH (A)/IEC/48.

**Participants:** The eligibility criteria of the patients recruited for the study were ≥18. The different surgery involved in the study were appendectomy, GI surgery, gall bladder surgery and Thyroid

surgery with proper informed consent which was written in bilingual (Regional) and English. Exclusion criteria for the patient were with that uncontrolled diabetes mellitus, uncontrolled hypertension, patients with an allergic reaction to triclosan and lost in follow up.

**Recruitment:** Total of 110 patients were enrolled for the study. The Subjects were explained briefly the significance of the study and also the risk and benefit of the study. To the selected patients, written informed consent with the selected subject's language was taken for their voluntary participation. Baseline data were collected from the patient profile from the hospital.

**Randomization:** Subjects were randomized in a 1: 1 ratio to each treatment group using the statistical determination of the sample size. The study included sufficient numbers of patients according to the sample size calculation to omit randomization error.

**Study Treatment and Assessment of the Subject:** All the patients were assessed for their eligibility criteria mentioned above, medical history record, and physical examination before surgery. Demographic information, laboratory data, vital sign, and current medications were recorded.

**Blinding:** The study was single-blinded where the type of sutures used was not disclosed to the patient. The surgeons were aware of the type of suture.

**Interventions:** All the surgery and wound closure were performed by surgeons. For primary wound closure, it was immediately closed soon after operation using non-absorbable monofilament sutures or stapler.

**Co-interventions:** The use of antibiotics, pain killer, wound dressing, and closed suction drain was standardized. All the patients received intravenous antibiotic and painkiller for the first 24/48 h, followed by oral antibiotic and painkiller for one to two weeks. The entire antibiotic prescribed was broad spectrum.

**Study Outcomes:** Superficial SSI was assessed as primary outcomes, defined by CDC (Centre for Disease Control) [14] within 30 days of surgery, involves only skin and subcutaneous tissue along with one of the following purulent discharge, organism isolated from culture of fluid or tissue or at least one of the sign or symptoms: pain / tenderness, localized swelling, redness or heat generation, or superficial incision deliberately opened by surgeon with culture positive or not cultured. Superficial SSI was assessed by the on-duty physician before discharge with 1 week and 1 month follow up. When patients did not visit the outpatient department, the phone call was made to confirm wound swelling, pain, and discharge. Secondary outcomes were measured as a postoperative pain on day 1 and 3. The dosage of analgesic drugs administered to patients was also recorded.

**Determination of Sample Size:** Assuming 80% response rate, confidence interval 95%, the margin of error 5%, and the total sample size was obtained as 110 including both the group in the present study, whereas 137 patients were set as a target. By considering 55 patients in each group, the margin of error was set to be 4.84%.

**Statistical Analysis:** For the statistical analysis Graph pad prism 7.01 software was used. Epidemiological data between the two groups of patients were analyzed by using the Chi-Square test. The differences between the infected and non-infected groups were analyzed using student t-test. The statistical significance between the groups was taken at 5% significance.

## RESULTS:

***In-vitro* Antimicrobial Assay:** Comparative zone inhibition assay between the two sutures and zone of inhibition were calculated by a transparent scale. TC sutures have shown prominent zone of inhibition against tested bacterial species whereas CS did not show inhibition (mm) **Fig. 1** and **Fig. 2**. TC coated sutures had shown the antibacterial efficacy against both Gram-negative as well as Gram-positive bacteria. The maximum zone of inhibition produced by TC sutures and CS are given in **Table 1**.

**Antimicrobial Efficacy of Surgical Sutures on Patients:** In total 110 patients were enrolled for the study which was then randomized 55 patients each control and study group **Fig. 3**.


**FIG. 1: ZONE OF INHIBITION PRODUCED BY TC SUTURES AGAINST A) *E. COLI* B) *P. AERUGINOSA* AND C) *B. SUBTILIS***

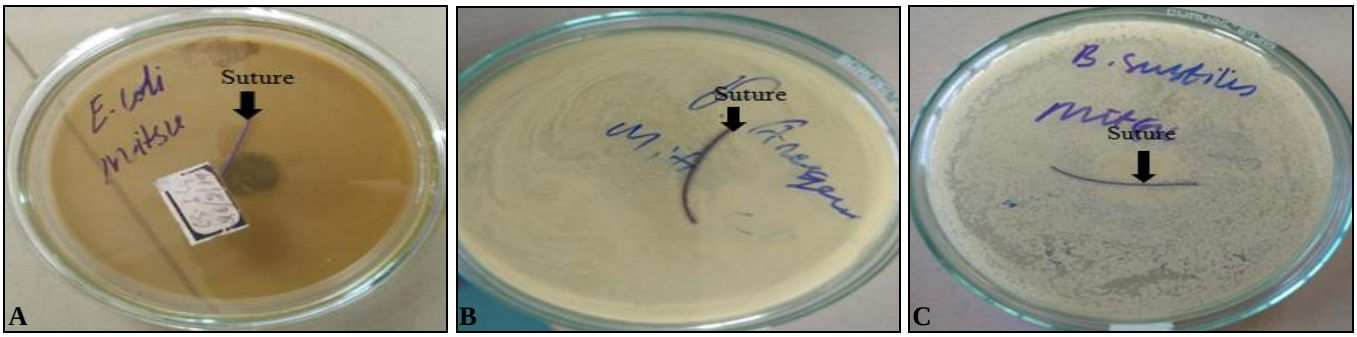


**FIG. 2: ZONE OF INHIBITION PRODUCED BY CONVENTIONAL SUTURES (CS) A) *E. COLI* B) *P. AERUGINOSA* AND C) *B. SUBTILIS***

**TABLE 1: SUMMARY OF ZONE OF INHIBITION PRODUCED BY MEGASORB-T$^{+}$ AND MITSU AGAINST *B. SUBTILIS, E. COLI,* AND *P. AERUGINOSA* ALL THE VALUES ARE MEAN ± SEM OF TRIPLICATE DETERMINANTS**

| Surgical suture | Test organisms | Zone of inhibition (SEM) (mm) |
|---|---|---|
| (Triclosan coated) | *Bacillus subtilis* (ATCC-11774) | 5.25 ± 0.25 |
| | *Escherichia coli (*ATCC-10536) | 5.67 ± 0.25 |
| | *Pseudomonas aeruginosa* (ATCC-10145) | 4.75 ± 0.25 |
| MITSU (Control) | *Bacillus subtilis* (ATCC-11774) | 0 ± 0 |
| | *Escherichia coli (*ATCC-10536) | 0 ± 0 |
| | *Pseudomonas aeruginosa* (ATCC-10145) | 0 ± 0 |

*Significance at $p<0.05$

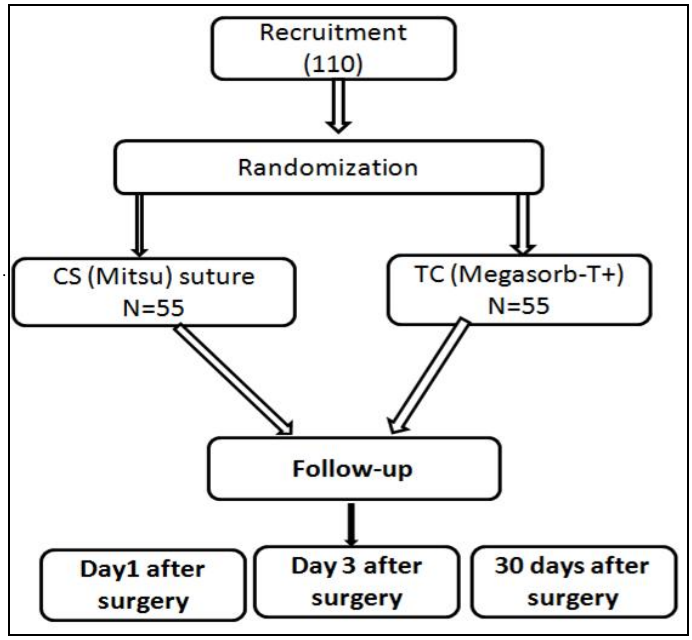


**FIG. 3: FLOW CHART OF THE STUDY WITH FOLLOW UP VISIT**

In the CS group, 5 (infection rate 9.09%) patients were found to be superficial SSI. However, TC sutures did not have any patients related to wound infection. Secondary outcomes of SSI of 5 infected wound were 2 patients with swelling wounds, 2 patients with pain, 1 patient with discharge from wound were observed. However, no culture was made for the infected wound. All the patients with SSI were treated by open dressings with/without re-suture and cured within 30 days. Patients were given an extra 7 days of broad-spectrum antibiotics compared with non-infected patients. There was no loss in follow up.

**DISCUSSION:** Surgical site infection is being one of the most challenging problems among the hospitalized patients affecting at least 5% of the hospitalized population postoperatively [2]. Despite the different measurement to prevent infection,

SSIs still major threat causing financial burden as well as quality living of the patients. Multifilament sutures may enhance the chance of wound infection as bacteria can adhere to the suture [9]. Coating of suture with antibacterial agents can be one strategy to reduce SSIs. Studies revealed that bacterial isolates from the infected wound had been tested against antibacterial sutures and the result was compared to CS. Antibacterial coated sutures were found to inhibit those bacterial isolates [11]. TC sutures are developed to produce the suture with antibacterial activity against those bacterial species which mostly causes surgical site infection [14]. Bacterial strains which are responsible for most of the SSIs are *P. aeruginosa*, *E. coli* and *Staphylococcus aureus* [15]. TC suture (Megasorb-T+) have shown good *in-vitro* antibacterial efficacy against Gram-positive as well as Gram-negative bacteria compared with CS **Fig. 1** & **2**. The utility of the antibacterial coated suture may get a better result in terms of postoperative infection and also improve the quality of the postoperative life. The clear zone around the suture encourages the effectiveness of the sutures in patients. Zone of inhibition produced by antibacterial sutures compared with conventional sutures is given in **Table 1** which agrees with previous findings [11, 12, 16].

Triclosan is a broad spectrum antiseptic agent which has been used as a safe, non-toxic and efficacious against a variety range of bacterial species with least chances of bacterial resistance [17]. WHO has reported that SSIs rate worldwide population is 2.5 to 41.9%, where the higher rate of SSIs is reported in developing countries [18]. The main reasons behind the higher rate of SSIs undoubtedly reveal the typical condition of inadequate resource hospitals [19], also the lifestyle such as the hygienic environment. Postoperative infection is a serious consequence in the patient's life as it can disable the patient permanently. Use of antibacterial coated suture may be one of the ways to reduce the SSIs in hospitalized patients. Suture coated with the antibacterial agent has been studied widely in many developed countries; however, very few studies have been conducted in developing countries. Therefore, the study demonstrates the actual efficacy of the antibacterial coated sutures in the typical condition where limited hospital facilities, post operative care along with lifestyle management which is considered as a risk factor for SSI.

The present study indicates that there were 9.09% SSI in CS and 0% in TC. The differences between the groups were analyzed by the Chi-square test. The epidemiological data such as sex ratio, age, height, weight, TLC count, temperature and platelet count were not significantly different between the group with p-value 0.689, 0.339, 0.318, 0.448, 0.986, 0.708 and 0.588 with a 5% level of significance respectively **Table 2**. Comparative data between the infected and non-infected populations were not statistically significant at 5% statistical significance **Table 3**. Data between TC and CS groups shows that the population enrolled for the study does not produce any bias in terms of demographic data.

Similarly, infected and non-infected patients data shows no significant difference. These means the antibacterial agent coated with the sutures may prevent the infection in the treated group. The study assumes that there might be some factors which contribute wound infectivity in the CS group. TC sutures which is an antibacterial suture, clearly demonstrated the efficacy. The main reason for reducing SSIs in the TC group may be the antibacterial agent that blocks the probable risk factor which has been the contributor of infection. The drastic change in the infection rate by TC suture may be applied widely in developing countries to reduce the risk of SSIs postoperatively.

**TABLE 2: EPIDEMIOLOGY OF TWO GROUPS OF PATIENTS**

| S. no. | Specification | MITSU (n=55) | Megasorb-T$^+$ (n=55) | P-value |
|---|---|---|---|---|
| 1 | Sex (M:F) | 27:23 | 24:26 | 0.689 |
| 2 | Age (years) | 45.29 | 41.50 | 0.339 |
| 3 | Height (cm) | 158.8 | 160.1 | 0.318 |
| 4 | Weight (kg) | 56.86 | 58.14 | 0.448 |
| 5 | TLC (/cmm) | 8079 | 8088 | 0.986 |
| 6 | Temperature (°C) | 37.12±0.04 | 37.1±0.04 | 0.708 |
| 7 | Platelet Count (/cmm) | 2.41 | 2.49 | 0.588 |

*Significance at $p<0.05$

**TABLE 3: COMPARATIVE ANALYSIS OF PATIENT'S DATA BETWEEN INFECTED AND NON-INFECTED GROUP**

| S. no. | Parameter | Non-infected (n=105) | Infected (n=5) | P-value |
|---|---|---|---|---|
| 1 | Age (year) | 43.56 ± 2.02 | 46 ± 5.59 | 0.763 |
| 2 | Skin Temperature (°C) | 37.12 ± 0.033 | 37.02 ± 0.337 | 0.459 |
| 3 | TLC(/cmm) | 8083 | 7420 | 0.538 |
| 4 | Sex (M:F) | 30:47 | 2:3 | 0.462 |
| 5 | Pulse rate | 78.87 | 75.2 | 0.324 |

*Significance at $p<0.05$

**CONCLUSION:** In conclusion, the antibacterial assay and patients data reveal the efficacy of TC sutures. The reduction of SSIs with antibacterial coated suture gives a hope to use antibacterial suture during surgery as a preventive measure for SSIs, especially in developing countries. However, for promising results, large numbers of patients are required to ensure the effectiveness and efficacy of TC suture compared with CS.

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**CONFLICT OF INTEREST:** The authors declare there is no conflict of interest.

## REFERENCES:

1. Sewlikar SA, Pillai RS, Mahajan NS and Desai AA: Triclosan coated sutures: an overview of safety and efficacy in reducing risk of surgical site infection. Int Surg J 2016; 2(1): 1-7.
2. Surgical site infections: prevention and treatment | Guidance and guidelines | NICE (Accessed May 9, 2016). Available from: https://www.nice.org.uk/guidance/cg74.
3. Anderson DJ, Podgorny K, Berrios-Torres SI, Bratzler DW, Dellinger EP, Greene L, Nyquist AC, Saiman L, Yokoe DS, Maragakis LL and Kaye KS: Strategies to prevent surgical site infections in acute care hospitals: 2014 update. Infect Control Hosp Epidemiol 2014; 35(S2): S66-88.
4. Hoshino S, Yoshida Y, Tanimura S, Yamauchi Y, Noritomi T and Yamashita Y: A study of the efficacy of antibacterial sutures for surgical site infection: a retrospective controlled trial. Int Surg 2013; 98(2): 129-32.
5. Allegranzi B, Zayed B, Bischoff P, Kubilay NZ, de Jonge S, de Vries F, Gomes SM, Gans S, Wallert ED, Wu X and Abbas M: New WHO recommendations on intraoperative and postoperative measures for surgical site infection prevention: an evidence-based global perspective. Lancet Infect Dis. 2016; 16(12): e288-03.
6. Negi V, Pal S, Juyal D, Sharma MK and Sharma N: Bacteriological profile of surgical site infections and their antibiogram: a study from resource-constrained rural setting of Uttarakhand state, India. J Clin Diagn Res 2015; 9(10): DC17-20.
7. Ban KA, Minei JP, Laronga C, Harbrecht BG, Jensen EH, Fry DE, Itani KM, Dellinger EP, Ko CY and Duane TM: American College of Surgeons and Surgical Infection Society: surgical site infection guidelines, 2016 update. J Am Coll Surg 2017; 224(1): 59-74.
8. Alexander JW, Kaplan JZ and Altemeier WA: Role of suture materials in the development of wound infection. Ann Surg 1967; 165(2): 192-99.
9. Katz S, Izhar M and Mirelman D: Bacterial adherence to surgical sutures. A possible factor in suture-induced infection. Ann Surg 1981; 194(1): 35-41.
10. Obermeier A, Schneider J and Wehner S: Novel high efficient coatings for anti-microbial surgical sutures using chlorhexidine in fatty acid slow-release carrier systems. PLoS One 2014; 9(7): e101426. doi: 10.1371/journal.pone. 0101426.
11. Sudha TR: Isolation of Multi-Drug Resistant *Staphylococcus aureus* from the soil samples of Hyderabad. Int J Sci Eng Technol Res 2016; 5(2): 487-01.
12. Ming X, Rothenburger S and Nichols MM: *In-vivo* and *in-vitro* antibacterial efficacy of pds plus (polidioxanone with triclosan) suture. Surg Infect (Larchmt) 2008; 9(4): 451-57.
13. Horan TC, Andrus M and Dudeck MA: CDC/NHSN surveillance definition of health care-associated infection and criteria for specific types of infections in the acute care setting. Am J of Infect Control 2008; 36(5): 309-32.
14. Ford HR, Jones P, Gaines B, Reblock K and Simpkins DL: Intraoperative handling and wound healing: controlled clinical trial comparing coated vicryl® plus antibacterial suture (coated polyglactin 910 suture with triclosan) with coated vicryl® suture (coated polyglactin 910 suture). Surg Infect (Larchmt) 2005; 6(3): 313-21.
15. Kaup S and Sankarankutty J: Prevalence and antimicrobial susceptibility patterns of bacteria isolated from skin and wound infections. J Microbiol Biotechnol Res 2017; 4(2): 39-45.
16. Shah NP and Shah RK: Triclosan coated suture inhibits colonization of bacteria responsible for surgical site infection-An *in-vitro* efficacy study. J Inst Med 2015; 37(3): 108-11.
17. Giuliano CA and Rybak MJ: Efficacy of triclosan as antimicrobial hand soap and its potential impact on antimicrobial resistance: a focused review. Pharmacotherapy 2015; 35(3): 328-36.
18. WHO: Report on the burden of endemic health care-associated infection worldwide. (Accessed July 9, 2016). Available from (http://apps.who.int/iris/bitstream/10665/ 80135/1/9789241501507_eng.pdf)
19. Asaad AM and Badr SA: Surgical site infections in developing countries: Current burden and future challenges. Clin Microbiol 2016; 5(6): 1-2.

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