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## An economic model to assess the value of triclosan-coated sutures in reducing the risk of surgical site infection in general surgery in India

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### Abstract

Surgical site infections (SSIs) are increasing worldwide. The present study demonstrates the efficacy and economic outcome of triclosan-coated sutures (TCS) vs conventional non-antimicrobial-coated sutures (NCS) for SSIs in general surgery in India. A systematic literature search of available evidence for both SSI incidences and TCS efficacy data in India from 1998-2018 and 2000-2018, respectively, were gathered. We collected cost data from a private and public hospital, respectively for hernia and cholecystectomy procedures. The cost-effectiveness of TCS in comparison to the conventional NCS was calculated using a decision-tree deterministic model. We performed a one-way sensitivity analysis to compare TCS vs NCS. We found a base cost saving of INR 9621 (private hospital) and INR 1900 (public hospital). Whereas, for cholecystectomy, it was INR 14450 (private hospital) and INR 2643 (public hospital). The use of TCS resulted in reduced SSI incidence and cost savings for general surgeries in India.

**Keywords:** Cost savings, general surgery, non-antimicrobial-coated sutures, general surgery, sensitivity analysis, surgical site infection, triclosan-coated sutures

### 1. Introduction

Triclosan is a broad-spectrum antibiotic that inhibits the activity of Gram-positive and Gram-negative bacteria, common pathogens that are responsible for Surgical Site Infection (SSI). Several experimental *invitro* and *invivo* studies [1] have reported the efficacy of triclosan coated-sutures (TCS) when incorporated with polydioxanone, polyglactin 910, and poliglecaprone 25 [2]. The maximum concentration of triclosan required to produce an antimicrobial effect in impregnated absorbable sutures polydioxanone and poliglecaprone 25 is 2360 mcg/m and 472 mcg/m for polyglactin 910 [3].

Ford *et al.* and Storch *et al.* suggested that TCS cannot be differentiated from conventional sutures thus making it feasible to conduct randomized clinical trials (RCTs) [2, 4]. Several recent, systematic reviews and meta-analysis that included several thousand patients have demonstrated the efficacy of TCS in ameliorating the incidence of SSI in comparison to non-antimicrobial sutures [5]. Similarly, several retrospective analysis has also corroborated the efficacy of TCS [6].

The burden of SSI after general surgery in India is increasing, this may be due to poor adaption of guidelines or therapeutic interventions [7]. A prospective study conducted in India reported an overall incidence of 12% of SSI, the significant average length of hospital stay 17.2 days ( $P<0.001$ ), the significant average ICU stay 8.6 days ( $P<0.001$ ), significant excess total expenses of Rs. 29,000 ( $P<0.001$ ), and mortality rate of 12.8% [8]. Another retrospective case-control study reported significant hospital stay (mean: 22.9 days;  $P<0.0001$ ), significantly prolonged ICU stay (mean: 11.3 days;  $P<0.0001$ ), significantly higher mortality (mean: 54%;  $P<0.0001$ ) and cost significantly more (mean: US \$14,818;  $P<0.0001$ ) as compared to controls. It is not feasible to calculate the direct SSI-attributable cost from systematic reviews and meta-analysis. Smith and colleagues conducted an economic study using a decision analytical model suggesting that using TCS significantly reduced hospital stay, conditional when SSI rate was reduced to 10% [9]. In this study, we accessed the incidences of SSI and the efficacy and cost-effectiveness of TCS based on a decision-tree analytical model in two surgical procedures, hernia and cholecystectomy, in India.

## 2. Methods

### 2.1 Literature Search and Data Extraction

For both, economic burden analysis of SSI in India and the efficacy of TCS vs NCS, we conducted a systematic literature review (SLR) of available evidence to gather epidemiologic and economic data pertaining to the occurrence of SSI from 1998-2018 (Fig. 1) and the efficacy of TCS vs NCS from 2000-2018 (Fig. 2). The evidence was gathered from prospective Randomized Controlled Trials (RCT) and comparative cohort studies and high-quality systemic reviews where available. PubMed Medline and EMBASE indexed articles were searched using Mesh terms or Emtree, respectively, and free text terms such as SSIs, the incidence of SSI, and efficacy of TCS. Search criteria were defined by the total number of patients undergoing surgery (N), the number of patients developing SSI (n), and type of health care institute (private and public hospital). In this study, data extracted was from Indian studies for general surgery

that included two surgical procedures hernia and cholecystectomy. For the majority of the publications, the SSI or surgery wounds were recorded as defined by the Centers for Disease Control and Prevention (CDC) as clean, clean-contaminated, contaminated, and dirty. In other studies, either the CDC criteria were not specified or were clinical observations.

Full papers were retrieved from accepted articles. Manual checking of references for relevant articles was performed. Data extraction was conducted by one reviewer and re-examined by others. The inclusion criteria for the literature search were confirmed cases of SSI after abdominal surgery irrespective of age. The exclusion criteria included preclinical studies, infection occurring within 30 days from surgery, skin infection at the surgical site, prior abdominal surgery, stitch abscess cases, and infection of episiotomy.

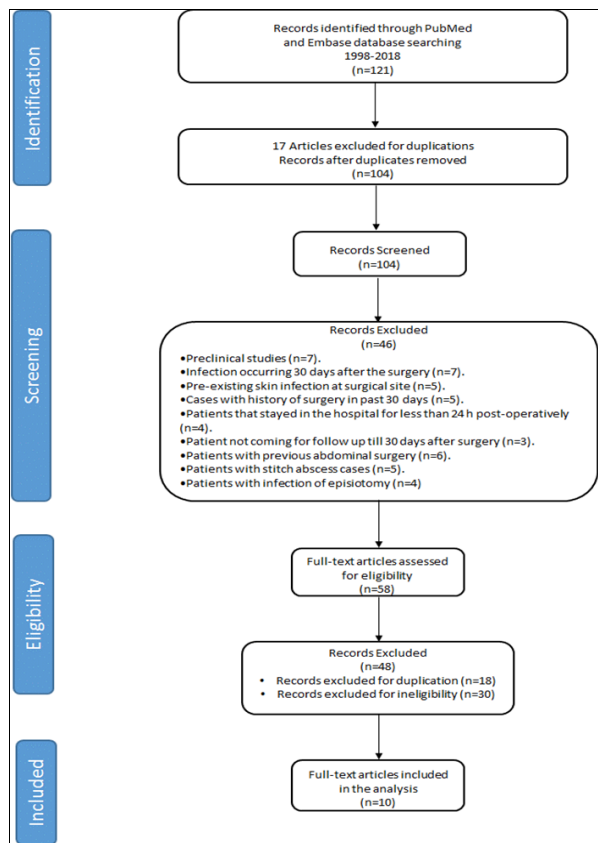


Fig 1: PRISMA Flow chart for the review

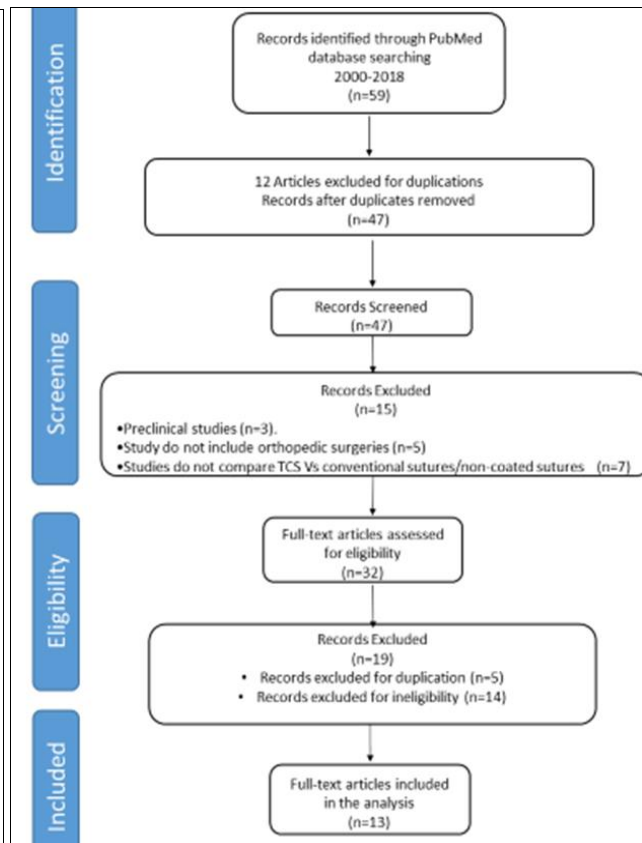


Fig 2: PRISMA Flow chart for the review

### 2.2 Cost Study

The cost study is conducted to assess the costs associated with SSI. We determined the package cost of 1 hernia and 1 cholecystectomy procedure from 2 tertiary care hospitals (private and public hospital) in India. We also determined the cost associated with treating patients with SSI and without SSI by obtaining and calculating cost information (refer section: cost analysis model for SSI). Further, we also calculated the difference in the cost of TCS vs NCS using a decision-tree model for the efficacy of TCS in SSI (refer section: cost analysis model for TCS vs NCS).

## 3. Statistical analysis

### 3.1 Cost Analysis Model

#### 3.1.1 SSI

In the economic burden study, the SSI incidence (number of patients with SSI/total number of patients undergoing surgery

expressed as the median and range were calculated to determine incidence (expressed as a %) of SSI. This was supported by a cost study to obtain costs associated with SSI. The cost associated with treating patients with and without SSI was obtained from 2 tertiary care hospitals (one private and one public hospital) in India. The current management for SSI is the collective process evolved/developed during the practices called the surgical care bundle (SCB). The aim of SCB is to reduce the risk of SSI.

The standard SSI treatment protocol for that hospital was obtained for analysis. To analyze, the costs of treatment of patients developing SSI with those without SSI following parameters were considered such as total cost of hospital stay for patients, the total cost of the surgical bundle (including surgeons, operation theater (OT), anesthetists, and bed charges), the average total cost of antibiotic treatment, cost of procedures for management, pathology service costs, medical staff costs,

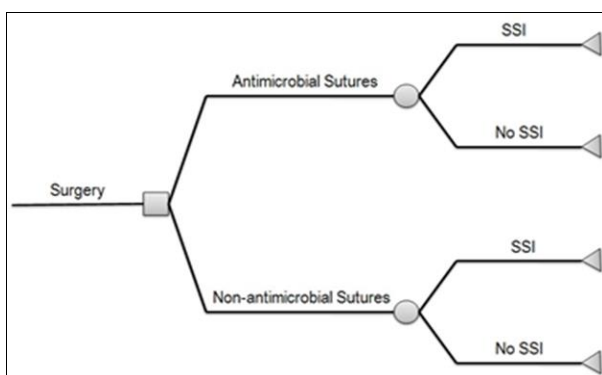
and cost of the intervention.

The SSI incidence data was combined with cost data to calculate the extra cost due to SSI. The cost difference in public and private hospital settings was calculated by combining the SSI incidence (%) with total costs incurred in patients with and without SSI. This helped us with the calculation of extra cost due to SSI per 100 surgeries performed that were specific to private and public hospital settings in India.

### 3.1.2 TCS vs NCS

In the TCS/NCS efficacy study, the decision tree analysis model (Fig. 3) was designed to compare the costs associated with the use of TCS and NCS in surgical procedures. The decision tree analysis is the most widely used model which provides a framework for the calculation of the expected value of each available alternative. In the current study SSI incidence expressed as the proportion of patients developing SSI by the total number of patients was determined from SLR for the TCS and NCS group for general surgeries; hernia and cholecystectomy. Cost data for treating patients with and without SSI obtained from the cost study. These costs were assigned as the payoff to different branches of the decision tree that enabled calculation of total costs associated with the use of TCS and NCS. Sensitivity analysis was performed to check the quality and reliability of the given model and its prediction provides an understanding of how model variables react to input changes. In this study the key inputs considered are the probability for developing SSI (or SSI risk), the efficacy of TCS, and the cost of sutures. The calculation of cost savings using the decision tree model was based on the following assumptions:

- The cost of TCS and NCS was the same in private and public hospitals and the maximum retail price (MRP) was used for each suture;
- SSI incidences were assumed the same for private and public hospitals;
- Efficacy of TCS was obtained from a literature study of general surgery;
- SSI incidences from literature sources for each surgical procedure (hernia and cholecystectomy) represented the SSI incidences for the NCS arm of the decision tree model.



\*SSI-surgical site infection

**Fig 3:** Basic structure of decision tree cost model.

## 4. Results

### 4.1 Study identification

A total of 121 citations was screened manually for SSI. Those

studies that did not include rates of SSI were excluded. After the final review, 10 studies were included for analysis of SSI. For TCS vs NCS efficacy study, 59 articles were screened and 13 studies were included.

#### Included studies

Out of 10 studies, 9 were prospective [7, 8, 10–16] and 1 study was retrospective [17]. The total number of patients included in the SSI analysis was 8,488. For TCS vs NCS efficacy study, out of 13 studies, 7 were randomized clinical trials [18–24], 4 were prospective studies [25–28], 1 was controlled [29], and 1 was contrast observation [30] study. The total number of patients included in the TCS vs NCS efficacy study was 9,556. All studies included compared triclosan-coated polyglactin 910 suture (VICRYL Plus, Ethicon, Deutschland, Norderstedt, Germany) or triclosan impregnated 2-0 polydioxanone loop (PDS II, Ethicon GmbH) with either polyglactin 910 suture or polydioxanone (PDS II, Ethicon, Deutschland, Norderstedt, Germany) or 2-0 polydioxanone loop (PDS Plus, Ethicon GmbH) or reabsorbable standard sutures. Out of 10 studies, 7 studies followed CDC guidelines of wound infection and within a 30-day time frame following surgery, 1 study followed the Southampton wound scoring system, and data was not available for 2 studies.

### 4.2 SSI rate analysis

We calculated the SSI incidence rate from Indian studies for 2 general surgical procedures (hernia and cholecystectomy). The results state that the median SSI incidence rates were 13.17% (1.75% - 60%) and 13.41% (1.71% - 25.58%) for hernia and cholecystectomy surgery respectively.

### 4.3 Efficacy Rate Analysis

Efficacy rates of TCS were calculated for two surgical procedures (hernia and cholecystectomy). The median for the efficacy of TCS vs NCS for general surgery was found to be 53% (8% - 100%).

### 4.4 Cost Analysis

Cost data were obtained for 2 general surgical procedures; hernia and cholecystectomy, from both private and public hospitals. We have considered opportunity cost as loss of surgical package based on bed occupancy.

The decision tree analysis model was used to calculate the costs associated with the use of TCS and NCS. The difference in total costs for each suture type was represented as the model output. SSI incidences obtained from SLR were assigned as probabilities for developing SSI in the non-antimicrobial suture arm of the decision tree. The efficacy of TCS obtained from literature data was applied and used to calculate the probability of developing SSI in the antimicrobial suture arm of the decision tree. Cost data were obtained from the treatment with or without SSI development assigned as a payoff to the branches of the decision tree. SSI incidence (high, median, and low end) and efficacy of TCS were varied and the cost savings per 100 surgeries were calculated. Cost savings represented by negative values were observed across all SSI incidence and efficacy values in both private and public hospital settings (Table 1).

**Table 1:** Costs savings (in INR) per SSI for varied efficacies of TCS to prevent SSI and risk of developing SSI among hernia and cholecystectomy surgeries in a private and public hospital

		SSI incidences (%)					
		Hernia			Cholecystectomy		
Efficacy of TCS (%)		1.75	13.17	60	1.71	13.41	25.58
Private Hospital	8	-173.38	-1435.34	-6610.24	-256.57	-2162.54	-4145.08
	53	-1261.16	-9621.61	-43905.3	-1823.5	-14450.6	-27584.9
	100	-2397.27	-18171.7	-82858	-3460.07	-27284.8	-52066.6
Public Hospital	8	-18.51	-269.85	-1300.48	-29.31	-380.41	-745.61
	53	-235.16	-1900.23	-8728.18	-317.95	-2643.95	-5063.38
	100	-461.43	-3603.07	-16486	-619.42	-5008.09	-9573.06

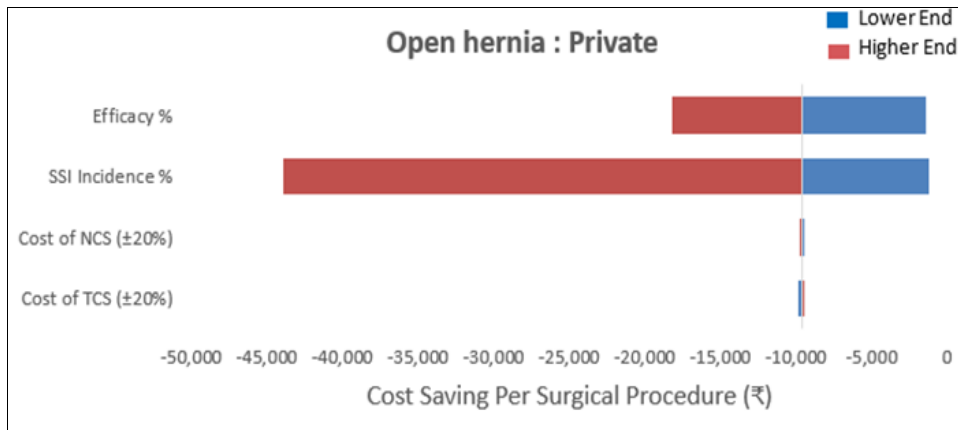
\*Negative values represent cost saving

The incremental cost increased on the use of TCS vs NCS as compared to cost savings. The incremental cost for hernia was 0.1% and 0.89% for a private and public hospital, respectively whereas for cholecystectomy surgery the incremental cost was 0.01% for both private and public hospitals. These results showed that the cost savings generated using TCS was greater than the cost increase in using TCS across all SSI incidences and efficacy values.

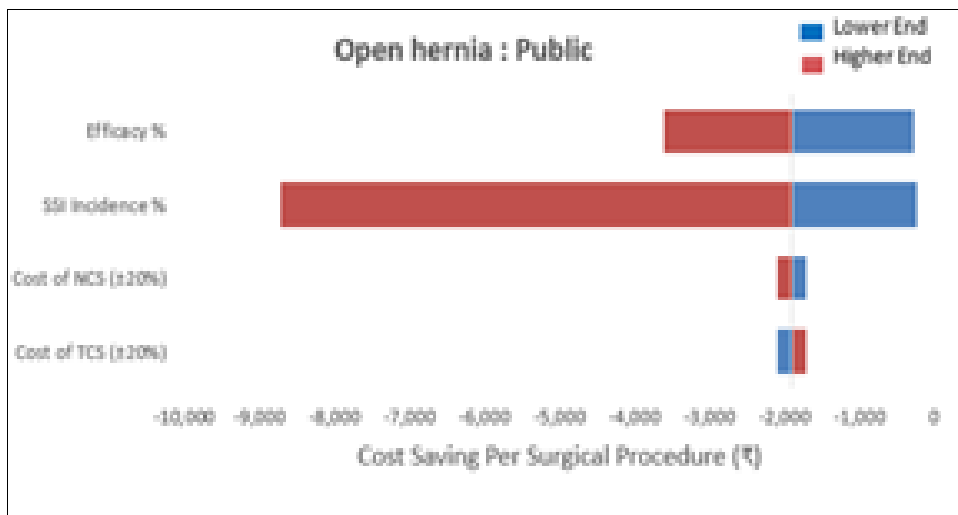
(Fig. 6 and 7) showing sensitivity analysis of four variables, efficacy%, SSI incidences%, Cost of NCS ( $\pm 20\%$ ), and cost of TCS ( $\pm 20\%$ ) for a private and public hospital. On comparison of TCS with NCS, a base value cost savings for hernia surgery for the private hospital is INR -9621 (Fig. 4) and the public hospital is INR -1900 (Fig. 5). Whereas, for cholecystectomy, a base value cost savings for the private hospital is INR -14450 (Fig. 6) and the public hospital is INR -2643 (Fig. 7). SSI incidence had the greatest impact on total cost saving.

**4.5 Sensitivity Analysis**

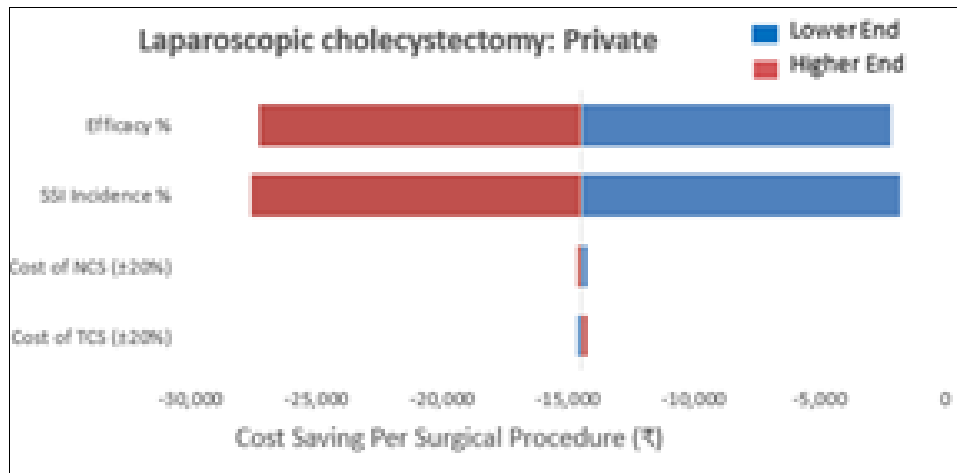
Tornado plots for hernia (Fig. 4 and 5) and cholecystectomy



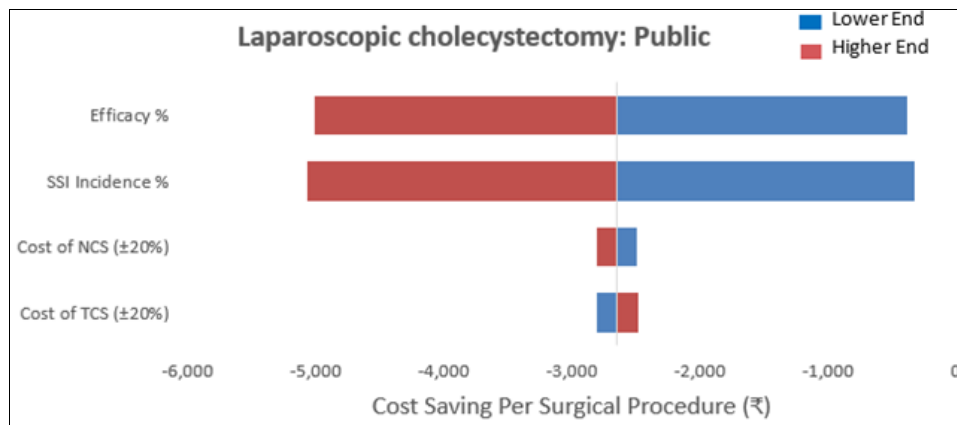
**Fig 4:** One-way sensitivity analysis. Tornado graph showing cost saving per surgical procedure of hernia for private hospital



**Fig 5:** One-way sensitivity analysis. Tornado graph showing cost saving per surgical procedure of hernia for public hospital



**Fig 6:** One-way sensitivity analysis. Tornado graph showing cost saving per surgical procedure of cholecystectomy for private hospital



**Fig 7:** One-way sensitivity analysis. Tornado graph showing cost saving per surgical procedure of cholecystectomy for public hospital

## 5.0 Discussion

This retrospective study included RCTs and prospective studies from private and public hospitals that provided a comprehensive overview of the SSI incidence in India and efficacy of TCS for the prevention of SSI. In addition, the finding also concentrated on recent cost data to evaluate the efficacy of TCS on the total cost of care in private and public hospitals. The evidence of efficacy for general surgery for two surgical procedures (hernia and cholecystectomy) from prospective, RCTs, and another study design [18–26, 29, 30], and the healthcare resources were included in this study which was based on decision tree cost model. Thus, suggesting that TCS should be used for surgeries since it not only reduces the risk of SSI but also the economic burden.

Even though TCS sutures are minimally expensive than NCS, the cost-saving for general surgery for two surgical procedures by the use of TCS in preventing SSI in private and public hospitals outweighs the additional cost of hospital stay, antibiotic treatment, surgical procedures for SSI management, pathology services, and medical staff.

Our analyses showed consistent findings for hernia and cholecystectomy surgical procedures, wherein cost-savings were obtained using TCS. The cost savings obtained using TCS varied primarily with the SSI incidence (%) and TCS efficacy rate where low savings were obtained at lower ends of these two parameters. The cost of either suture, TCS, or NCS ( $\pm 20\%$  of the base cost) did not have a major impact on cost savings based on sensitivity analysis. In addition to cost savings, reduction in SSI would lead to better patient outcomes and also make beds available for the treatment of newer patients especially in public

settings in India. It is also necessary to consider the indirect costs such as productivity loss associated with SSI that we have not calculated in this model which is an important consideration for policymakers in making informed and well-rounded decisions.

## 6. Conclusion

The study concluded that the use of TCS offers efficacy and total cost savings in both private and public hospitals in India. The findings of analysis showed the risk of SSI reduced due to the use of TCS and also it outweighs the additional cost of lengthy hospital stay, antibiotic treatment, surgical procedure for the management of SSI, and pathological services. In addition to cost-saving, the use of TCS leads to better patient outcomes with minimal or no SSI.

## 7. Limitations of the study

This analyses was sensitive to the efficacy of TCS and did not differentiate superficial from deep incisional SSI, or wound classification but from a societal perspective, it was cost-effective as it improved patient outcomes included both direct cost (hospital stay, treatment) and cost savings were greater at greater risk of SSI. Also, another limitation of our study was that we used SSI risk from literature studies across both private and public hospitals that may actually vary in reality.

**8. Scope for further research:** Future prospective studies are required to be conducted to calculate actual SSI risk in both private and public settings in India and also consider SSI classification when evaluating the sutures, to allow comparisons

across studies and across SSI types and gain more insight in the efficacy of sutures.

## 9. Acknowledgements: NIL

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