



Original Research Article

An economic model to assess the value of triclosan-coated sutures in reducing the risk of surgical site infection in orthopedic surgeries in India

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ABSTRACT

Background: The incidence of surgical site infections is higher in India compared to the rest of the world. In orthopedic surgeries, the risk is even higher. Surgical site infections following orthopedics are associated with an additional length of stay resulting in additional costs thus causing a significant economic burden on patients and society. We aimed to determine the additional costs and length of stay and evaluate the efficacy of triclosan-coated sutures in reducing surgical site infections rate.

Materials and Methods: A systematic literature search of available evidence for both epidemiologic and economic data pertaining to the incidence of surgical site infections and efficacy of triclosan-coated sutures, from 1998-2018 and 2000-2018 respectively, were gathered. We compared 100 surgeries from private and public hospitals from orthopedics and calculated cost-effectiveness of triclosan-coated sutures in comparison to conventional non-coated sutures using a decision-tree cost model.

Results: Two studies were analysed for analysis of surgical site infections' incidence and for the efficacy of triclosan-coated sutures vs non-coated sutures, 3 studies were included. We performed a one-way sensitivity analysis to calculate the impact of % efficacy and surgical site infections' incidences %, cost of non-coated and triclosan-coated sutures on cost savings depicted by Tornado charts. Sensitivity analysis on the comparison of triclosan-coated sutures with non-coated sutures, a base cost saving of orthopedic surgeries for a private hospital was is INR -5573 and public hospital INR -1410.

Conclusion: The use of triclosan-coated sutures reduced surgical site infections incidence and cost savings for orthopedic surgeries in both public and private sectors in India.

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1. Introduction

Surgical site infection (SSI) is defined as microbial contamination of the surgical wound within 30 days of operation or within 1 year after surgery if an implant is placed in a patient.¹ After implant surgery, SSI is the most common nosocomial infection in the patient in orthopedics. These surgeries call for a disaster for both patients and surgeons.²

An SSI infection pertaining to the orthopedic surgical procedures can increase the patient's hospitalization time by up to two weeks and care costs by more than 300%.³ They can double the re-hospitalization rates and they can

cause some substantial physical limitations which can alter patients' life after the surgery. SSIs in orthopedic procedures present a stark and catastrophic complication for patients, surgeons, and hospital institutions.³ Incidence levels of orthopedic SSIs can range between 0.8 and 71%.²

The main reason behind infection in implants is due to the formation of biofilm by microorganisms and which is more resistant to the antibiotic regimen and therefore its annihilation is difficult.⁴ *Staphylococcus aureus* (*S. aureus*) is found to be the most common infecting organism in orthopedic infection.⁵ These infections are classified according to the duration of infection into 3 stages i.e., early (less than two weeks), delayed (2 to 10 weeks) and late (more than 10 weeks).⁶ In 1896, Brewer reported the

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infection rates of 39% in postoperative patients that was reduced to 0.2% with proper aseptic measures in recent times. At the beginning of the 19th century, the rate of infection was reduced due to basic aseptic measures and antibiotic use. Moreover, with an increase in age and other comorbidities the risk for infection increases in patients above 60 years of age. It may be because of low immunity, increasing catabolism, increasing co-morbidities and low wound healing rates in old age patients.⁷

WHO Guidelines (2018) have recommended the use of triclosan-coated sutures (TCS) irrespective of the type of surgery for minimizing SSI related to these surgical techniques.⁸ Triclosan is a broad-spectrum antimicrobial agent active against both gram-positive and gram-negative bacteria. TCS acts by creating an active zone around it in vitro and inhibits *S. aureus*, *Staphylococcus epidermidis* (*S. epidermidis*) and methicillin-resistant strains of *Staphylococcus* (MRSA and MRSE).⁹ There are contrasting opinions regarding the use of TCS. Recent studies involving several thousand patients showed that TCS or triclosan impregnated sutures can efficiently and significantly reduce SSIs when compared to non-antimicrobial coated sutures (NCS)¹⁰ whereas in contrast to the study by Sprowson et al involving 2546 patients suggests that use of TCS is insignificant in reducing SSI in total knee arthroplasty (TKA).⁹ In this retrospective study, we accessed the incidences of SSI and the efficacy and cost-effectiveness of TCS based on a decision-tree analytical model for an orthopedic surgical procedures in India.

2. Materials and Methods

We conducted the systemic literature review (SLR) to gather epidemiologic and economic data about SSI incidence in the span of 1998-2018 and efficacies of TCS from 2000-2018 (Figures 1 and 2). Studies included are randomized controlled trials (RCT) and comparative cohort studies and systemic review. Mesh terms (PubMed Medline) and Emtree (EMBASE) indexed articles were searched using terms such as SSIs, the incidence of SSI, or TCS and NCS. Full papers were retrieved from accepted articles. Manual checking for references of relevant review articles was performed.

2.1. Cost study analysis

We conducted a cost study to assess costs associated with SSI. We determined the cost associated with treating patients with SSI and without SSI by obtaining and calculating cost information from 2 tertiary care hospitals (private and public hospital) in Mumbai, India. The efficacy rates of TCS were calculated from global studies.

Patients with SSI had extended hospital stay and requires additional medical and surgical care. So, SSI management consisted of IV antibiotics, pathology cost, wound care, and

surgical care for SSI management.

The total SSI cost included SSI management, additional hospitalization cost, and cost of each admission loss due to bed occupancy which is called an opportunity cost.

The total cost for treating a patient who developed SSI was calculated as the sum of the surgical package cost (the cost of NCS), opportunity cost and SSI management cost.

2.2. Data extraction

The study type, number of patients undergoing surgery in TCS and NCS group, the number of patients who developed SSI, type of health care institute, wound class data was collated and arranged for this economic burden study.

2.3. Analysis

The SSI incidence was calculated as the number of patients with SSI/total number of patients undergoing surgery. It was expressed as the median and range were calculated to determine incidence (expressed as a %) of SSI for orthopedic.

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 in public and private hospitals respectively 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.

In the TCS/NCS efficacy study, decision tree analysis was used to compare the costs of using TCS and NCS in orthopedic surgeries. Sensitivity analysis was performed for key inputs: probability for developing SSI (or SSI risk), the efficacy of TCS and the cost of sutures.

Calculation of cost savings using the decision tree model was with the following assumptions:

1. The cost of TCS and NCS was the same in private and public hospitals and the MRP was used for each suture.
2. SSI incidences were assumed the same for private and public hospitals.
3. The efficacy of TCS was obtained from literature studies of the surgical specialty.
4. SSI incidences from literature sources for each surgical procedure represented the SSI incidences for the NCS arm of the decision tree model.

3. Results

3.1. Study identification

A total of 87 citations were screened manually for SSI and studies those did not include rates of SSI were excluded. After final review, 2 studies were included for analysis of SSI however for TCS vs NCS efficacy, 3 studies were included.

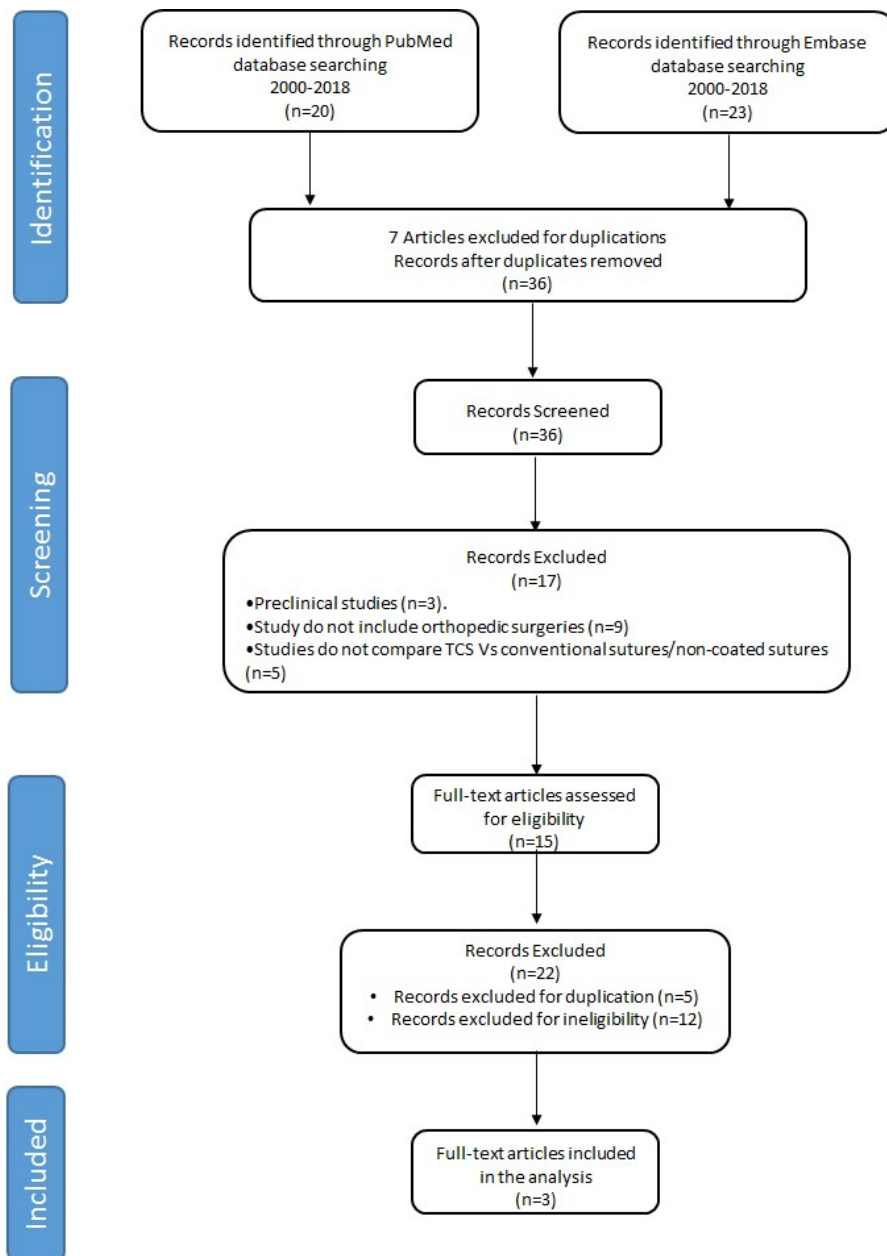


Fig. 1: PRISMA flow chart for the review

3.2. Included studies

One study was prospective and 2 studies were retrospective while one was randomized controlled trial and one was two-arm, double-blind study (Table 1). The total number of patients included in SSI analysis was 5908. For TCS vs NCS efficacy, 3 studies were available (Table 1). The total number of patients (n=5321) was included in the TCS vs NCS efficacy study. The study compared Polyglactin 910 suture without triclosan coat (VICRYL) Vs Polyglactin 910 suture with triclosan coat (VICRYL Plus). Out of 5 studies, 3 studies followed CDC guidelines of wound infection.

Wound infection guidelines were not available for 1 study while for 1 study, the use of CDC guidelines is not known.

SSI incidences and TCS vs NCS analysis was calculated from Indian and global studies respectively for TKR surgery (Table 1). Characteristics of studies that were screened and selected for this study are mentioned in Table 1.

3.3. SSI Rate analysis

We calculated the SSI incidence rate from 2 Indian studies for orthopedic surgical procedures. SSI incidence ranges from 1.74% (lower end) to 12.5% (upper end). The median

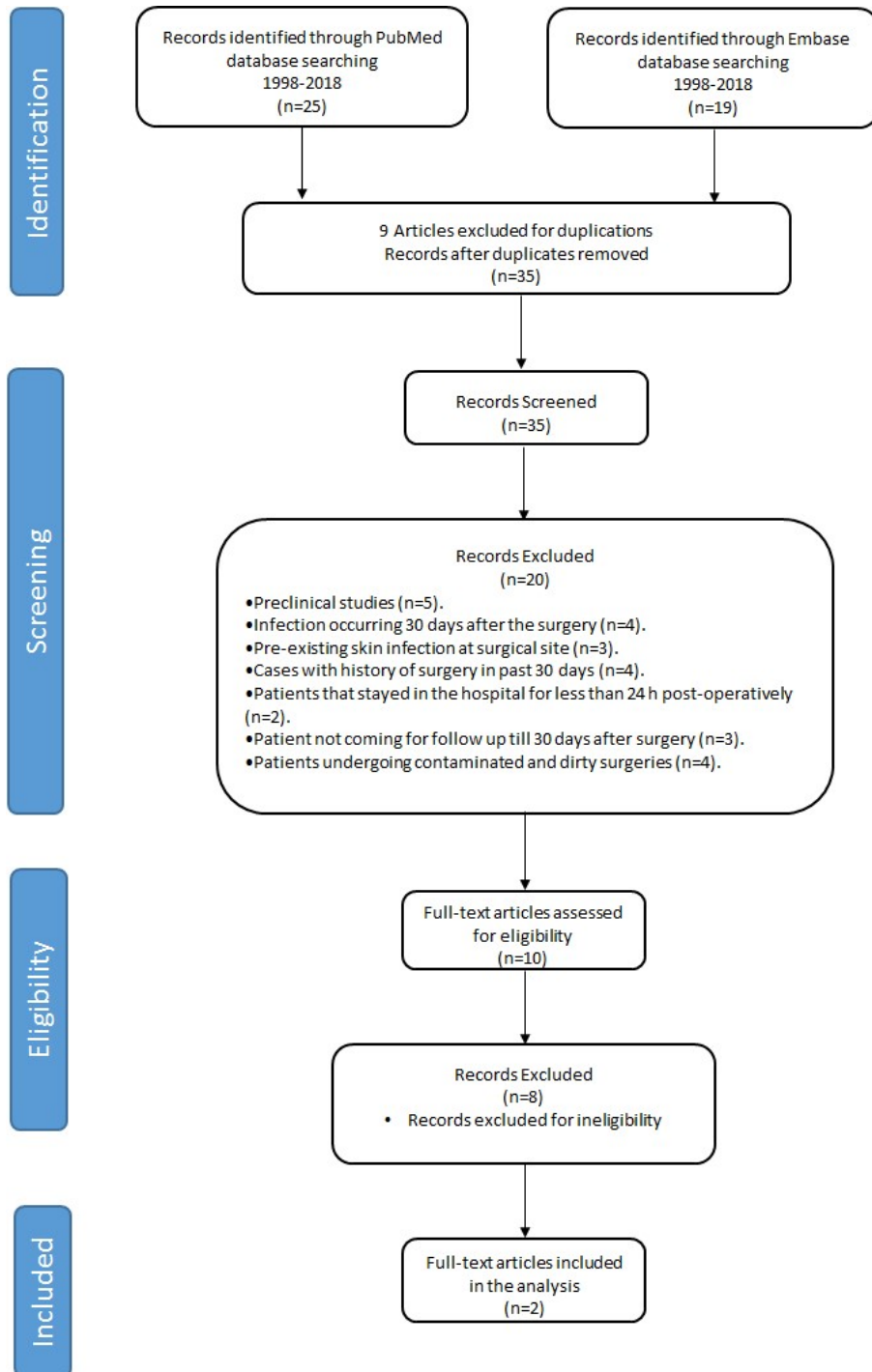


Fig. 2: RISMA flow chart for the review

Table 1: Studies included for analysis of SSI incidence and TCS vs NCS efficacy

Author	Year	Study Design	Setting	Category
Roy et al ¹¹	2018	Retrospective	Murshidabad Medical College	SSI incidence analysis
Singh et al ¹²	2014	Cohort prospective surveillance	12 hospitals in 6 Indian cities	SSI incidence analysis
Jensen et al ¹³	2014	RCT	-	TCS vs NCS efficacy analysis
Sprowson et al ⁹	2018	Three-centre, two-arm, parallel, double-blind	Three hospitals in UK	TCS vs NCS efficacy analysis
Ueno et al ¹⁰	2013	Retrospective, non-randomized clinical study	Department of Orthopaedic Surgery of University Hospitals, Japan	TCS vs NCS efficacy analysis

*SSI- Surgical site infection, TCS-Triclosan-coated suture, NCS-Non-coated suture

of SSI incidence is 7.12%.

3.4. Efficacy rate analysis

The analysis of efficacy rates of TCS (median and ranges) were calculated from 3 global studies. The efficacy rate for TCS vs NCS varies from 18% (lower end) to 88% (upper end) while the median is 28%.

3.5. Cost analysis

Cost data were obtained for orthopedics 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 presented in Figure 3 was used to calculate the costs associated with the use of TCS and NCS. The decision tree model provides a framework for the calculation of the expected value of each available alternative.¹⁴ In current study, the difference in total cost for each suture type was represented as the model output. In a private hospital, by using TCS the cost-saving is 26.62% and in a public hospital, by using TCS the cost saving is 23.44% (Table 2).

For TKR surgeries with TCS at a private hospital, at risk of SSI (1.74%, 7.12%, and 12.5%), cost savings were observed at all efficacy values. Cost savings increased with an increase in SSI incidence and an increase in efficacy (Table 3).

We calculated the incremental cost of TCS suture (Cost of TCS-Cost of NCS)/surgical package cost*100) for TKR surgery. In a private hospital, it was 0.03% whereas in a public hospital, it was 0.09%. The cost savings (%) generated using TCS was greater than the incremental cost increase across all SSI incidences and TCS efficacy rates.

3.6. Sensitivity analysis

The sensitivity analysis is performed to check the quality and reliability of a given model and its prediction provides an understanding of how model variables react to input

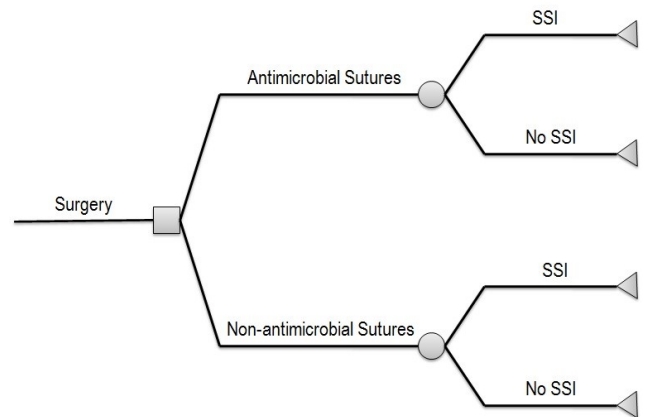


Fig. 3: Basic structure of decision tree cost model

changes.¹⁵ The results of one-way sensitivity analysis was further detailed using tornado plots, for orthopedic surgery (Figures 4 and 5), showed the impact of four independent variables; efficacy %, SSI incidences %, cost of NCS ($\pm 20\%$), and cost of TCS ($\pm 20\%$) on cost-saving per surgical procedure in private and public hospitals. The most sensitive factor was SSI incidences followed by efficacy, the cost of NCS, and the cost of TCS. Among the individual variables, the least sensitive factor was the cost of TCS. In comparison of TCS with NCS, a base value cost savings for the private hospital was INR -5573 (Figure 4) and public hospital INR -1410 (Figure 5). SSI incidence had the greatest impact on total cost saving. However, the literature study did not differentiate wound type as clean, clean-contaminated, contaminated, and dirty with respect to SSI.

The sensitivity analysis for four variables is shown in the Tornado graph below (Figures 4 and 5). The base value cost savings for TKR surgery for the private hospital is INR -5573. The base value cost savings for TKR surgery for the public hospital is INR -1410. The Efficacy of the suture had the greatest impact on total cost saving.

Table 2: Cost savings (INR) for 7.12% SSI risk at median TCS efficacy per 100 TKR surgeries in both private and public hospitals

	Private		Public	
	TCS	NCS	TCS	NCS
No of patients undergoing surgery per year	100	100	100	100
Suture cost per year	165,100	159,700	165,100	159,700
Total Cost per TKR with SSI	486683	486683	131853	131853
No of SSI	5.1264	7.12	5.1264	7.12
Total cost due to SSI	2494931.731	3465182.96	675931.2	938793.36
Total cost using suture	2,660,032	3,624,883	841,031	1,098,493
Difference	-	-964,851	-	-257,462
% (TCS - NCS/ NCS)	-	-26.62%	-	-23.44%

* Negative values indicate savings; (SSI- Surgical site infection, TCS-Triclosan-coated suture, TKR-Total knee replacement)

Table 3: Costs savings (in INR) per 100 surgeries for varied efficacies of TCS to prevent SSI and risk of developing SSI among TKR surgeries in private hospital and public hospital

SSI Incidence (%)	Private Hospital			Public Hospital		
	Efficacy of TCS (%)			Efficacy of TCS (%)		
	18	28	88	18	28	88
1.74	-83010.1	-132126.816	-426827	-17604.5	-30384.84	-107067
7.12	-356370	-557353.408	-1763254	-88733.5	-141029.92	-454808
12.5	-629730	-982580	-3099680	-159863	-251675	-802550

*Negative values represent cost savings; SSI- Surgical site infection, TCS-Triclosan-coated suture, TKR-Total knee replacement

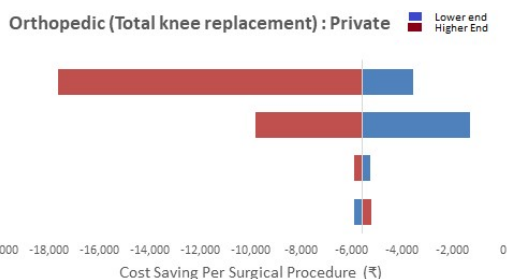


Fig. 4: Orthopedic (TKR): Private hospital, Tornado chart showing mean cost savings per surgical procedure based on model assumptions

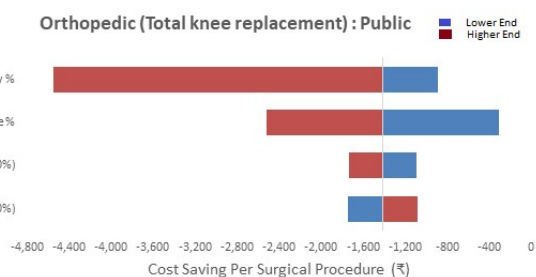


Fig. 5: Orthopedic (TKR): Public hospital, Tornado chart showing mean cost savings per surgical procedure based on model assumptions

4. Discussion

SSIs are a growing concern in developed and developing countries. In India, higher incidence of SSIs has been reported, ranging from 23% to 38%.¹⁶ SSIs increase the total cost for the patients due to prolonged hospitalization, additional diagnostic tests, therapeutic antibiotic treatment, and rarely, additional surgery.¹⁷ The use of antibiotic suture such as TCS has been proven beneficial according to the literature and study by Fleck et al.¹⁸ and Ruiz et al.¹⁹ However, there are studies which oppose these views. Chang et al. claimed in a study that use of TCS is not beneficial.²⁰ Due to contrasting opinions on the use of TCS for SSI, to our knowledge, we for the first time evaluated the efficacy and cost-effectiveness of TCS in orthopedic patients, in India.

The study consists of 1 retrospective transectional study,¹¹ one multicentre surveillance study,¹² one 3 centred patient accessor blinded quasi-randomised controlled trial,⁹ one RCT,¹³ and one retrospective nonrandomized study.¹⁰

Our analysis showed a trend in cost saving by the use of TCS which was directly proportional to efficacy. The cost savings generated for SSIs per 100 surgeries for similar incidences (1.74%, 7.12% and 12.5%) at the public hospital at low efficacy (18%) were INR 17,604.5; INR 88,733.5; and INR 1,59,863, and high efficacy (88%) were INR 1,07,067; INR 4,54,808; and INR 8,02,550, whereas at the private hospital the cost savings at low efficacy (18%) were INR 17,604.5; INR 88,733.5; and INR 1,59,863, and high efficacy (88%) were INR 1,07,067; INR 4,54,808; and INR 8,02,550, respectively.

Cost-saving at public and private hospitals is more than incremental cost. Though the cost of TCS is more than NCS, the cost-effectiveness produced by TCS is significant as SSI incidence is higher among patients with NCS and total cost for patients treated with NCS increases. Cost-saving increases as the cost of suture decreases. Also, cost saving is higher in a private hospital than a public hospital while the incremental cost is higher in the public hospital than the private hospital.

Our analysis showed that cost-saving generated at both public and private hospitals concluded the use of TCS is beneficial. Therefore, healthcare resources savings predicted by the decision-tree deterministic and stochastic cost model used in this study, suggest that antimicrobial sutures could be included in SSI surgical care bundles, which have been shown to reduce the risk of SSI.

Even though our analysis was sensitive to efficacy however it did not discriminate between incisional SSI and superficial to deep SSI. However, the other way at looking at it was economical as it improved patient outcomes such as direct cost; hospital stay and treatment. The limitation of our study was that the literature we used consisted of data on the risk of SSI across both private and public hospital which may differ in reality. Perhaps future prospective studies are required that should take into consideration of SSI wound classification while evaluating sutures. This will allow comparing different studies and different types of SSI to gain more insights about the efficacy of the sutures.

5. Conclusion

The antimicrobial suture is found effective in decreasing the incidence of SSIs in a broad population of patients undergoing orthopedic surgery. The results from this analysis showed that the use of TCS is cost-effective and directly proportional to efficacy in orthopedic surgeries where the incidence of SSI infections is high. This analysis is sensitive to the efficacy of TCS and the risk of SSI. However, additional studies on different populations needed to be performed to establish the effectiveness of antibiotic sutures and evaluate their benefits for orthopedic surgeries with varied SSI rates.

6. Source of Funding

None.

7. Conflict of Interest

None.

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