



Original Research Article

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

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ABSTRACT

Objectives: The present study demonstrates the efficacy and economic outcome of triclosan-coated sutures (TCS) Vs conventional non-antimicrobial-coated sutures (NCS) for surgical site infections (SSIs) in obstetrics and gynecology (Ob/Gyn) in India.

Materials and Methods: 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 both Laparoscopic hysterectomy (L-hysterectomy) and Cesarean-section (C-section). Cost-effectiveness of TCS in comparison to the conventional NCS was calculated using a decision-tree deterministic model.

Results: We performed one-way sensitivity analysis to compare TCS with NCS. We found a base cost - saving for C-section at private hospital, INR 5513 and public hospital INR 791 whereas for L-hysterectomy it was INR 4924 at private hospital and INR 999 at public hospital. For C-section, at private hospital, the cost-saving for SSIs per 100 surgeries at SSI incidence rates (3.77%, 7.94%, and 24.2% at low efficacy (41%) (INR 2,05,508, INR 4,41,668, and INR 13,62,526,) and high efficacy (61%) were (INR 3,09,657, INR 6,61,018, and INR 20,31,075). For L-hysterectomy, at private hospital, the cost- saving for SSIs per 100 surgeries for SSI incidence rates (2.28%, 6.51%, and 11.7%) at low efficacy (41%) were (INR 1,32,902; INR 3,94,313; and INR 7,15,052, and high efficacy (61%) were (INR 2,01,635; INR 5,90,564; and INR 10,67,760).

Conclusion: Decision tree modeling showed that the use of TCS resulted in cost savings for Ob/Gyn surgeries in India.

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1. Introduction

Surgical site infection (SSI) is one of the leading infection among healthcare-associated infections (HAIs), especially prevalent in low and middle-income countries (LMICs).¹ The incidence rates of SSIs in India are comparatively higher varying between 23-38%. In Telangana, the estimated SSIs for each condition (n=100) were 5% for clean, 58.3% for clean-contaminated, 85% for contaminated, and 66.6% for dirty wounds.² In a cohort study among obstetrics and gynecology patients, out of 1173 patients, 92 were affected with SSI. Thus, the

cumulative incidence rate of SSI was 7.84% (95% CI, 6.30 – 9.38). The SSI rates were lower for obstetric surgeries compared to gynecological surgeries; 1.23% (95% CI 0.02 – 2.4) versus 10.37% (95% CI 8.32 – 12.43), respectively.³ Another study reported out of 285 gynecological patients, 46% had SSI.⁴

Although there is a fewer incidence of SSI with obstetrics and gynecology surgery, patients suffering from SSI not only have to bear the additional cost due to extended hospital stay but also have to undergo pain and suffering due to delayed wound healing that increases the economic burden of a patient. In addition affects a nation's economy.⁵ A case-control study reported that from hospital-acquired

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bacteremia the maximum hospital stay was 22.9 days, significant intensive care unit stay was 11.3 days while mortality rate was 54%, and these costs may exceed INR 6,71,255 (US \$14,818, cost converted from US dollars to INR using exchange rate of INR 45.30/USD as per the publication) for treatment.⁶ Forty to sixty percent of SSI are manageable risk or non-manageable risk because bacterial adherence and biofilm formation on implanted sutures and suture materials become a nidus of infection causing acute exacerbations or dissemination.⁷ Hence, suture materials coated with an antibacterial or antimicrobial agent such as triclosan have the potential to reduce the risk of SSIs or HAIs.⁶

Triclosan is a broad-spectrum antimicrobial agent active against both gram-positive and gram-negative bacteria. There are contrasting opinions regarding the use of triclosan-coated sutures (TCS). Recent studies involving several thousand patients showed that TCS or triclosan impregnated sutures can efficiently reduce SSIs^{8–12} whereas, in contrast, a study involving 2546 patients suggests that TCS is inefficient in reducing SSI.¹³ Furthermore, another study demonstrated higher incidences of SSI on the use of TCS (bioactive sutures).¹⁴ However, WHO Guidelines (2018) have recommended the use of TCS irrespective of the type of surgery.¹⁵ In this retrospective study, we accessed the incidences of SSI and the efficacy and cost-effectiveness of TCS based on decision-tree analytical model for obstetrics and gynecology (Ob/Gyn) practices for two surgical procedures, L-hysterectomy and C-section, in India.

2. Materials and 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 (Figure 1) and the efficacy of TCS vs NCS from 2000-2018 (Figure 2). Evidence was gathered from prospective randomized controlled trials (RCTs), comparative cohort studies, and high-quality systemic review. PubMed Medline and EMBASE indexed articles were searched using Mesh terms or Emtree, respectively, and free test terms such as SSIs, the incidence of SSI, efficacy and cost-effectiveness of TCS. Search criteria were defined by total number of patients undergoing surgery (N), 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 Ob/Gyn surgery that included two surgical procedures L-hysterectomy and C-section. For all publications, the SSI or surgery wounds were recorded as defined by Centers for Disease Control and Prevention

(CDC) as clean, clean-contaminated, contaminated, and dirty.

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.

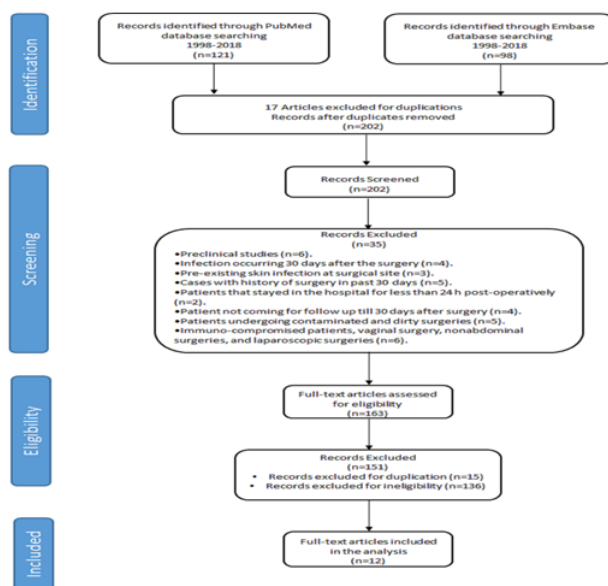


Fig. 1: PRISMA Flow chart for the Economic Burden of SSI in India

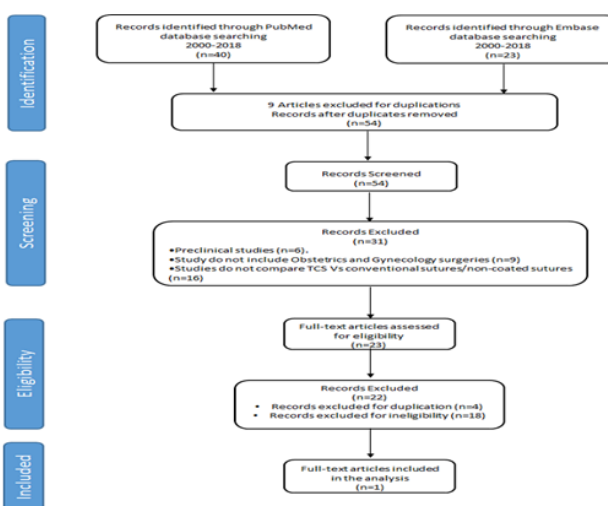


Fig. 2: PRISMA Flow chart for the TCS vs NCS Efficacy

2.2. Cost Study

We conducted a cost study to assess costs associated with SSI. We determined the package cost of 1 C-Section and

1 L-hysterectomy procedure from 2 tertiary care hospitals (private and public hospital) in Mumbai, India. We also determined the cost associated in treating patients with 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) (Figure 3).

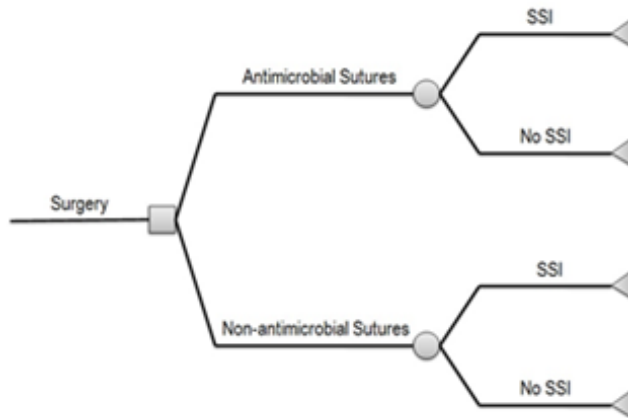


Fig. 3: Basic structure of the decision tree cost model.*SSI-surgical site infection

2.3. Statistical Analysis

2.4. Cost analysis model

2.5. SSI

In the economic burden study, the SSI incidence (number of patients with SSI/total number of patients undergoing surgery expressed as the median, the range was calculated to determine incidence (expressed as a %) of SSI. This was supported with a cost study to obtain costs associated with SSI. The cost associated with treating patients with or without SSI was obtained from 2 tertiary care hospitals (one private and one public hospital) in Mumbai, India. In addition, the standard SSI treatment protocol for that hospital was obtained for analysis. To analyze, the cost of treatments of patients developing SSI with those without SSI following parameters were considered such as total cost of hospital stay for patients, total cost of surgical bundle (including surgeons, Operation Theater (OT), anesthetists, and bed charges), average total cost of antibiotic treatment, cost of procedures for management, pathology service costs, medical staff costs, and cost of 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 setting was calculated by combining the SSI incidence (%) with the total cost incurred by the patients with or without SSI. This helped us for

the calculation of extra cost due to SSI per 100 surgeries performed that were specific to private and public hospital settings in India.

2.6. TCS vs NCS

In the TCS/NCS efficacy study, decision tree analysis model was designed, as shown in the Figure. 3 to compare the costs of TCS and NCS in surgical procedures. The decision tree analysis is the most widely used model which provide a framework for the calculation of the expected value of each available alternative.¹⁶ In 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 across Ob/Gyn (L-hysterectomy and C-section). Cost data for treating patients with or without SSI were calculated 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 given model and its prediction provides the understanding of how model variables react to input changes.¹⁷ In this study the key inputs considered are the probability for developing SSI (or SSI risk), the efficacy of TCS, and cost of sutures. The calculation of cost savings using the decision tree model were 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 Ob/Gyn surgery; and SSI incidences from literature sources for each surgical procedure (L-hysterectomy and C-section) represented the SSI incidences for the NCS arm of the decision tree model.

3. Results

3.1. Study identification

A total of 219 citations were screened manually for SSI and studies those did not include rates of SSI were excluded. After final review, 12 studies were included for analysis of SSI however for TCS vs NCS efficacy, only 1 study was included.

3.2. Included studies

Twelve out of 10 studies were prospective and 2 studies were descriptive (Table 1). The total number of patients included for SSI analysis were 13,847 (Table 1). For TCS vs NCS efficacy, only 1 study was available (Table 1). The total number of patients (n=284) were 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 12 studies,

Table 1: Studies included for analysis of SSI Incidence, and efficacy and cost-effectiveness of TCS

First author	Year	Study Design	Setting	Category
Bangal <i>et al.</i> ¹	2014	Prospective observational	Tertiary care hospital in the rural area of central India	L-hysterectomy
Pathak <i>et al.</i> ³	2017	Prospective	Chandrikaben Rashmikant Gardi Hospital, Madhya Pradesh	L-hysterectomy C-section
De <i>et al.</i> ¹⁸	2013	Prospective	Lady Hardinge Medical College and Smt. Sucheta Kriplani Hospital, New Delhi	C-section
Priya K <i>et al.</i> ¹⁹	2016	Prospective	Meenakshi Medical College and Research Institute, Kanchipuram, Chennai	C-section
Dahiya <i>et al.</i> ²⁰	2016	Prospective observational	Dr Baba Saheb Ambedkar Hospital, Rohini, New Delhi	C-section
Shah <i>et al.</i> ²⁰	2015	Prospective observational	Kokilaben Dhirubhai Ambani Hospital and Medical Research Institute, Mumbai	L-hysterectomy
Chada <i>et al.</i> ²¹	2017	Prospective cross-sectional	Narayana Medical College and Hospital	C-section
Naphade and Patole ²²	2017	Prospective longitudinal	Dr. Vasantrao Podar Medical College Hospital and Research Center, Nashik	L-hysterectomy
Sujatha and Sasikumari ²³	2017	Descriptive	Sree Avittam Thirunal Hospital, Thiruvananthapuram	C-section
Swain ²⁴	2014	Prospective descriptive	A tertiary teaching hospital in Odisha, SUM hospital	C-section
Vijayan <i>et al.</i> ²⁵	2016	Descriptive	Tertiary care and teaching center, Dept of Ob/Gyn Government MCH, Kottayam, Kerala	C-section
Singh <i>et al.</i> ²⁶	2014	Cohort prospective surveillance	12 hospitals in 6 Indian cities	L-hysterectomy
Hara <i>et al.</i> ²⁷	2017	Retrospective	-	TCS Vs NCS

11 studies followed CDC guidelines of wound infection and within a 30-day time frame following surgery. Wound infection guidelines were not available for 1 study.

3.3. SSI Rate Analysis

We calculated the SSI incidence rate from Indian studies for 2 Ob/Gyn surgical procedures (C-section and L-hysterectomy). We used SSI incidence ranges (lowest to highest) (Table 2).

3.4. Efficacy Rate Analysis

Due to limitation of the number of studies, the analysis of efficacy rates of TCS (median and ranges) were calculated from 1 global study for Ob/Gyn surgical category and included in our study analysis (Table 3).

3.5. Cost analysis

Cost data were obtained for L-hysterectomy and C-section from both private and public hospitals. We have considered opportunity cost as loss of surgical package based on bed occupancy.

Decision tree analysis model presented in Figure 3 was used to calculate the costs associated with the use of TCS

and NCS. The difference in total cost for each suture type was represented as the model output.

For L-hysterectomy and C-section surgeries with TCS at private and public hospitals, at risk of SSI (41%, 51%, and 61%), cost savings were observed at all efficacy values. Cost savings were increased with an increase in SSI incidence and efficacy with the use of TCS (Table 4). Considering the introduction of Ayushman Bharat scheme for L-hysterectomy and C-section (surgical package cost of INR 9000), cost savings were observed across all SSI risk and efficacy levels.

We calculated the incremental cost of TCS suture (Cost of TCS-Cost of NCS)/Surgical package cost*100) for cesarean surgery. A private hospital the incremental cost was 0.1% and public hospital -0.89%. The incremental cost for L-hysterectomy surgery at private hospital was 0.1% whereas at public hospital was 0.4%. 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 results of one-way sensitivity analysis was further detailed using tornado plots, for C-section (Figure 4) and L-hysterectomy (Fig.5) Showing the impact of four

Table 2: SSI Incidence rates in India

Specialty	Surgical procedure	Low SSI Incidence (%)	Median SSI Incidence (%)	High SSI Incidence (%)
Ob/Gyn	C- Section	3.77	7.94	24.2
	L-hysterectomy	2.28	6.51	11.7

Table 3: Efficacy of TCS vs NCS (ranges) for Ob/Gyn

Surgical Specialty	No. of studies	Efficacy of TCS vs NCS (median)	Upper end	Lower end
Ob/Gyn	1	51%	61%*	41%*

*These values are ±20% of the median efficacy for Ob/Gyn category

Table 4: Cost savings (INR) per 100 surgeries for varied efficacies of TCS to prevent SSI and risk of developing SSI among L-hysterectomy and C-section surgeries in private and public hospitals

	SSI incidences (%)	L-hysterectomies			C-section			
		Efficacy of TCS (%)	2.28	6.51	11.7	3.77	7.94	24.2
Private Hospital	41		-132902	-394313	-715052	-205508	-441668	-1362526
	51		-167269	-492439	-891406	-257583	-551344	-1696800
	61		-201635	-590564	-1067760	-309658	-661019	-2031075
Public Hospital	41		-22390.3	-78772.4	-147950	-25248	-62023.7	-205422
	51		-29802.6	-99936.5	-185987	-33357.3	-79102.6	-257476
	61		-37214.9	-121100	-224024	-41466.5	-96181.5	-309531

*Negative values represent cost savings

independent variables; efficacy%, SSI incidences%, cost of NCS (±20%), and cost of TCS (±20%) on cost - saving per surgical procedure in private and public hospital. The most sensitive factor was SSI incidences followed by efficacy, cost of NCS, and cost of TCS. Among the individual variables, the least sensitive factor was cost of TCS.

On comparison of TCS with NCS, a base value cost savings for C-section for the private hospital was INR - 5513 (Figure 4 A) and public hospital INR -791 (Figure 4B). For L-hysterectomy, a base value cost savings for a private hospital was INR -4924 (Figure 5 A) and public hospital was INR -999 (Figure 5B). 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.

4. Discussion

SSIs is a growing concern in developed and developing countries. In India, higher incidence of SSIs have been reported and the cost of treatment may exceed INR 6,71,255.¹¹ There are contrasting views on the use of TCS for SSI. A study, that included 7 RCTs encompassing 836 patients reported that the use of TCS is not beneficial.²⁸ whereas another study that included 17 RCTs involving 3720 individuals reported that the use of TCS is beneficial.²⁹ Furthermore, among three studies evaluating the effect of TCS on abdominal

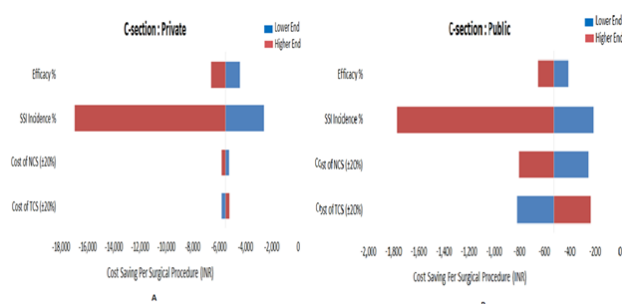


Fig. 4: One-way sensitivity analysis for C-section. Tornado graph showing independent variables which have the largest effect on cost-saving per surgical procedures for (A) private hospital and (B)Public hospital *TCS=Triclosan-coated sutures, NCS=Non-coated sutures

procedures.(20–22) Two studies showed no effect^{30,31} whereas one showed a substantial reduction in SSIs (35%–65%).³² Due to contrasting opinion on the use of TCS for SSI, to our knowledge, we for the first time evaluated the efficacy and cost -effectiveness of TCS in obstetrics and gynecology patients, in India. This systematic review included a prospective,^{3,18,19} prospective observational,^{1,20,33} prospective cross-sectional,²¹ prospective longitudinal,²² descriptive,^{23–25} and cohort prospective surveillance²⁶ studies for SSI, and a retrospective (double-glove)²⁷ study for TCS vs Non-TCS efficacy.

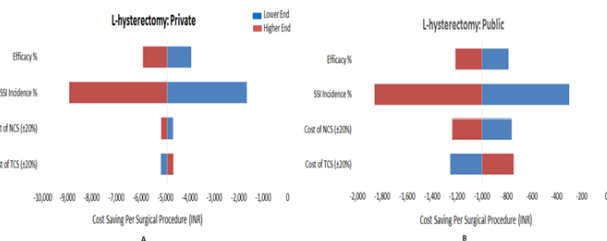


Fig. 5: One-way sensitivity analysis for L-hysterectomy. Tornado graph showing independent variables which have the largest effect on cost-saving per surgical procedures for (A) private hospital and (B) Public hospital, *TCS=Triclosan-coated sutures, NCS=Non-coated sutures

Our analysis showed a trend in cost-saving by the use of TCS which was directly proportional to efficacy. The cost savings generated for C-section for SSIs per 100 surgeries for similar incidences (3.77%, 7.94%, and 24.2%) at private hospital at low efficacy (41%) were INR 2,05,508; INR 4,41,668; and INR 13,62,526, and high efficacy (61%) were INR 3,09,657; INR 6,61,018; and INR 20,31,075, whereas at public hospital the cost savings at low efficacy (41%) were INR 25,248; INR 62,023; and INR 2,05,422, and high efficacy (61%) were INR 41,466; INR 96,181; and INR 3,09,530, respectively. Similarly, the cost-saving for L-hysterectomy for SSIs per 100 surgeries for similar incidences (2.28%, 6.51%, and 11.7%) at private hospital at low efficacy (41%) were INR 1,32,902; INR 3,94,313; and INR 7,15,052, and high efficacy (61%) were INR 2,01,635; INR 5,90,564; and INR 10,67,760 whereas at public hospital the cost-saving at low efficacy (41%) were INR 22,390; INR 78,772; and INR 1,47,950 and high efficacy (61%) were INR 37,214; INR 1,21,100; and INR 2,24,024. Depending on their efficacy, TCS may, in fact, save more costs per SSI prevented than many other interventions.

Several studies have reported the efficacy of TCS in different SSIs.³⁴ In addition, Hara *et al.*, 2017 reported the efficacy of TCS using double-glove specifically in abdominal hysterectomy implicating that use of TCS in combination with double gloving were able to alleviate SSIs.²⁷ 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.

The cost-saving generated by the use of TCS in private hospitals for both L-hysterectomy surgery and cesarean surgery was 47% whereas in public hospital the cost-saving was 35.84% for L-hysterectomy and 29.72% for cesarean surgery. A lower cost of coated-suture can generate even more cost savings, leading to an additional saving; the

costs savings per C-section and L-hysterectomy increased linearly with increasing efficacy and with increasing SSI Incidence. Cost savings would decrease proportionately with higher-priced coated-sutures. The reasons for such a wide range in results are unclear and design limitations are to blame, for instance, small sample size and limited controls, varied incision closure methods, SSI definitions, incomplete data, or reporting biases.²⁶ To conclude, the results from our analysis are sensitive to the efficacy of TCS, however, additional studies are needed to establish the efficacy of such sutures and evaluate their benefits for surgeries with varied SSI rates.

5. Conclusion

The current study concludes the triclosan-coated suture was effective in reducing the risk for postoperative SSIs in a broad population of patients undergoing L-hysterectomy and C-section surgery. Our analysis showed a trend in cost-saving by the use of TCS was directly proportional to efficacy and it outweighs additional cost of lengthy hospital stay, antibiotic treatment and surgical procedure for management of SSI. The use of TCS leads to better patient outcome with minimal or no SSI.

6. Source of funding

None.

7. Conflict of interest

None.

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