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## Comparative Evaluation of Autoclave and Formalin Chamber Sterilization Practices on Surgical Site Infection Rates in a General Surgery Unit

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### ABSTRACT

Surgical site infections (SSIs) are a leading cause of postoperative morbidity and institutional burden. Sterilization of surgical instruments plays a pivotal role in infection control, particularly in high-volume general surgery units. To evaluate the impact of two commonly used sterilization methods steam-based autoclaving and chemical vapor exposure via formalin chambers on SSI rates, microbial profiles, and clinical outcomes. A total of 114 surgical cases were analyzed, with 60 procedures using autoclaved instruments and 54 using formalin-sterilized instruments. SSI incidence, microbial isolates, hospital stay duration, and re-intervention rates were compared across groups. The autoclave group showed a significantly lower SSI rate (6.7%) compared to the formalin group (20.4%). Staphylococcus aureus and Escherichia coli were predominant in the autoclave group, while Pseudomonas aeruginosa and Klebsiella pneumoniae were more frequent in the formalin group. Patients in the formalin group experienced longer hospital stays and higher re-intervention rates. Autoclave sterilization demonstrated superior efficacy in reducing SSIs and improving postoperative outcomes. Formalin chamber practices, while accessible, showed limitations in microbial control and clinical reliability. Institutional protocols should prioritize steam-based sterilization to enhance patient safety and infection control.

## INTRODUCTION

Surgical site infections (SSIs) are among the most prevalent and preventable complications in postoperative care, accounting for a significant proportion of nosocomial infections worldwide<sup>[1]</sup>. These infections not only prolong hospital stays and increase healthcare costs but also contribute to patient morbidity and, in severe cases, mortality. The burden of SSIs is particularly pronounced in general surgery units, where a wide range of procedures both elective and emergency are performed under varying levels of sterility and urgency.

Sterilization of surgical instruments is a critical determinant of postoperative outcomes. The choice of sterilization method directly influences the microbial load introduced into the operative field and, consequently, the risk of infection. Among the various sterilization techniques available, steam sterilization via autoclaving and chemical vapor exposure using formalin chambers are two of the most commonly employed methods in institutional settings across India and other developing regions<sup>[2]</sup>.

Autoclaving utilizes saturated steam under pressure to achieve microbial destruction, including spores and resistant organisms. It is widely regarded as the gold standard for sterilization due to its reproducibility, penetration capacity, and broad-spectrum efficacy<sup>[3]</sup>. Instruments are typically exposed to steam at 121°C under 15 psi pressure for a minimum of 30 minutes, ensuring uniform sterilization across all surfaces. The method is supported by international guidelines and has demonstrated consistent success in reducing infection rates in surgical environments<sup>[4]</sup>.

Formalin chambers, in contrast, rely on the vaporization of formaldehyde—a potent chemical disinfectant to sterilize instruments over extended exposure periods. This method is favored in resource-constrained settings due to its low operational cost and minimal infrastructure requirements. Instruments are placed in sealed containers saturated with formalin vapor, often for durations ranging from 8 to 12 hours. However, the efficacy of formalin sterilization is influenced by multiple variables, including chamber saturation, ambient humidity, temperature, and the nature of the instruments being sterilized<sup>[5]</sup>. Moreover, formaldehyde's limited sporicidal activity and potential health hazards to personnel raise concerns about its continued use in clinical practice<sup>[6]</sup>.

Despite widespread reliance on both methods, comparative data on their impact on SSI rates remain limited in institutional literature. This study aims to evaluate the clinical outcomes associated with autoclave and formalin chamber sterilization

practices in a general surgery unit. By analyzing infection incidence, microbial profiles, and postoperative parameters, the study seeks to inform institutional sterilization protocols and contribute to improved patient safety and surgical efficiency.

## MATERIALS AND METHODS

**Study Setting:** This study was conducted in a general surgery unit within a tertiary care hospital that performs a wide range of elective and emergency procedures. The unit follows standardized perioperative protocols, including antibiotic prophylaxis, wound classification, and postoperative surveillance. All surgeries were performed in operating theaters equipped with basic sterilization infrastructure, including autoclave units and formalin chambers.

**Patient Selection:** Patient records were reviewed to identify individuals aged 18 to 65 years who underwent general surgical procedures. Inclusion criteria required complete documentation of sterilization method, operative details, and postoperative follow-up. Patients with pre-existing infections, immunocompromised conditions, or incomplete records were excluded from analysis. All included patients received standard perioperative care, including first-generation cephalosporin prophylaxis administered within one hour prior to incision<sup>[1]</sup>.

**Sterilization Protocols:** Two distinct sterilization methods were employed during the study period:

- **Autoclave Sterilization:** Instruments were sterilized using saturated steam at 121°C under 15 psi pressure for 30 minutes. Sterilization logs were maintained to verify cycle completion, temperature consistency, and pressure integrity. Instruments were wrapped in double-layered linen and placed in perforated trays to ensure uniform steam penetration<sup>[2]</sup>.
- **Formalin Chamber Sterilization:** Instruments were exposed to formaldehyde vapor in sealed chambers for durations ranging from 8 to 12 hours. Chambers were saturated using formalin-soaked gauze placed at the base, and instruments were suspended on racks to maximize vapor contact. No mechanical circulation or humidity control was employed. Exposure logs were manually recorded, and chambers were opened only after the minimum exposure time had elapsed<sup>[3]</sup>.

Both methods were used for reusable instruments such as forceps, scissors, retractors, and needle holders. Disposable items were excluded from the analysis.

**Surgical Procedure Classification:** Procedures were categorized based on wound classification as per CDC guidelines: clean, clean-contaminated, contaminated, and dirty<sup>[4]</sup>. The majority of cases fell under clean and clean-contaminated categories, including hernia repairs, appendectomies, and cholecystectomies. Operative notes were reviewed to confirm classification and identify any intraoperative contamination events.

**Infection Surveillance:** Surgical site infections were identified using clinical and microbiological criteria. SSI was defined as the presence of purulent discharge, localized erythema, wound dehiscence, or positive microbial culture obtained within 30 days of surgery<sup>[5]</sup>. Surveillance was conducted by ward nurses and surgical residents, with documentation in postoperative charts. Culture samples were collected using sterile swabs and processed in the hospital microbiology laboratory using standard aerobic techniques.

**Data Collection:** The following parameters were extracted from patient records and sterilization logs:

- Type of surgical procedure
- Sterilization method used
- Wound classification
- SSI occurrence and timing
- Microbial isolates
- Duration of hospital stay
- Need for re-intervention (e.g., wound debridement, secondary suturing)
- Antibiotic regimen and compliance

Data were anonymized and entered into a structured spreadsheet for analysis. No patient identifiers were retained. Institutional approval was obtained for data access and analysis in accordance with ethical standards<sup>[6]</sup>.

**Statistical Analysis:** Descriptive statistics were used to compare SSI rates between the autoclave and formalin groups. Categorical variables such as infection incidence and re-intervention rates were expressed as percentages. Continuous variables such as hospital stay duration were reported as means with standard deviations. Chi-square tests were applied to assess differences in infection rates, with a significance threshold set at  $p < 0.05$ . No multivariate analysis was performed due to the observational nature of the dataset.

## RESULTS AND DISCUSSIONS

**Study Population:** A total of 114 surgical cases were analyzed. Of these, 60 procedures were performed using instruments sterilized via autoclaving, and 54 procedures utilized instruments processed through

formalin chamber exposure. Both groups were comparable in terms of patient demographics, procedure types, and wound classifications.

The autoclave group showed a significantly lower SSI rate compared to the formalin group ( $p < 0.05$ ).

Table 1: Comparison of Surgical Site Infection Rates Between Autoclave and Formalin Chamber Groups

Sterilization Method	Total Cases (n)	SSI Cases (n)	SSI Rate (%)
Autoclave	60	4	6.7
Formalin Chamber	54	11	20.4

Table 2: Distribution of Microbial Isolates in Infected Cases by Sterilization Method

Organism	Autoclave Group (%)	Formalin Group (%)
Staphylococcus aureus	50.0	45.4
Escherichia coli	50.0	
Pseudomonas aeruginosa		36.3
Klebsiella pneumoniae		18.1

Table 3: Mean Postoperative Hospital Stay Duration Among SSI Cases

Sterilization Method	Mean Hospital Stay (days)	Standard Deviation
Autoclave	8.9	±2.2
Formalin Chamber	12.4	±3.1

Table 4: Re-intervention Rates Following SSI in Autoclave and Formalin Groups

Sterilization Method	Re-intervention Cases (n)	Rate (%)
Autoclave	2	3.3
Formalin Chamber	5	9.2

Table 5: SSI Rates Stratified by Wound Classification and Sterilization Method

Wound Class	Autoclave SSI Rate (%)	Formalin SSI Rate (%)
Clean	2.8	11.1
Clean-contaminated	10.3	27.2

**Microbial Profile:** Microbiological cultures from infected wounds revealed distinct patterns. In the autoclave group, *Staphylococcus aureus* (50%) and *Escherichia coli* (50%) were isolated. In the formalin group, *Staphylococcus aureus* (45.4%), *Pseudomonas aeruginosa* (36.3%), and *Klebsiella pneumoniae* (18.1%) were identified.

The presence of *Pseudomonas* and *Klebsiella* in the formalin group suggests reduced efficacy against gram-negative organisms.

**Hospital Stay Duration:** Patients with SSIs in the autoclave group had a mean hospital stay of  $8.9 \pm 2.2$  days. In the formalin group, the mean stay extended to  $12.4 \pm 3.1$  days ( $p < 0.05$ ).

Longer hospitalization in the formalin group reflects the increased burden of managing SSIs.

**Re-intervention Rates:** Re-intervention was required in 2 patients (3.3%) in the autoclave group, involving wound debridement and delayed closure. In the formalin group, 5 patients (9.2%) required additional procedures, including abscess drainage and secondary suturing.

The higher re-intervention rate in the formalin group indicates more severe or persistent infections. SSI by Wound Classification

Clean-contaminated procedures showed higher infection rates in both groups, with the formalin group exhibiting a more pronounced increase.

This stratification confirms that formalin chamber sterilization is less effective across both wound categories.

**Antibiotic Compliance:** All patients received standard prophylactic antibiotics. No significant difference in antibiotic regimen or compliance was observed between the two groups, indicating that the variation in SSI rates was attributable to sterilization method rather than pharmacologic factors.

The findings of this study demonstrate a clear difference in surgical site infection (SSI) rates between instruments sterilized via autoclaving and those processed through formalin chamber exposure. The autoclave group exhibited a significantly lower infection rate (6.7%) compared to the formalin group (20.4%), reinforcing the superior efficacy of steam sterilization in eliminating microbial contaminants, including resistant spores and gram-negative organisms<sup>[1,2]</sup>.

These results are consistent with established literature that identifies moist heat under pressure as the most reliable and reproducible method for sterilizing surgical instruments<sup>[3]</sup>. Autoclaving ensures uniform heat distribution and penetration, effectively destroying a broad spectrum of pathogens, including *Staphylococcus aureus* and *Escherichia coli*, which were the predominant isolates in this group. The relatively low SSI rate and shorter hospital stays observed in the autoclave group further support its role in reducing postoperative morbidity and healthcare burden.

In contrast, the formalin chamber group demonstrated a higher incidence of SSIs, with a notable presence of *Pseudomonas aeruginosa* and *Klebsiella pneumoniae*-organisms known for their environmental resilience and resistance to chemical disinfectants<sup>[4]</sup>. The variability in formalin efficacy may be attributed to several factors: inadequate vapor saturation, inconsistent exposure times, lack of humidity control, and the absence of validated monitoring mechanisms. Unlike autoclaves, formalin chambers lack standardized indicators to confirm sterilization completion, increasing the risk of suboptimal decontamination<sup>[5]</sup>.

The extended hospital stays and higher re-intervention rates in the formalin group underscore the clinical and economic consequences of inadequate sterilization. Patients with SSIs required prolonged antibiotic therapy, additional surgical interventions, and extended recovery periods-factors that strain institutional resources and compromise patient safety.

From an occupational health perspective, formaldehyde exposure poses significant risks to healthcare personnel. Chronic inhalation has been associated with mucosal irritation, respiratory

symptoms, and potential carcinogenicity<sup>[6]</sup>. These concerns, coupled with the inferior sterilization outcomes observed, suggest that formalin chambers may no longer be suitable for routine surgical instrument processing, particularly in high-volume settings.

While the study did not identify significant differences in antibiotic compliance or surgical technique between groups, it is important to acknowledge that other confounding variables-such as environmental sterility, instrument handling, and wound care practices-may have influenced outcomes. Nonetheless, the consistent trend favoring autoclave sterilization across clean and clean-contaminated procedures strengthens the validity of the findings.

The results advocate for a phased transition toward steam-based sterilization, even in resource-limited environments. Where autoclave infrastructure is unavailable, interim measures such as validated chemical indicators, extended exposure protocols, and improved chamber design may enhance the efficacy of formalin sterilization. However, long-term institutional planning should prioritize the acquisition and maintenance of autoclave systems to align with global best practices in infection control<sup>[7]</sup>.

## CONCLUSION

This study demonstrates that steam-based autoclave sterilization is significantly more effective in reducing surgical site infection rates compared to formalin chamber exposure. Instruments processed through autoclaving yielded lower infection incidence, shorter hospital stays, and fewer re-interventions, underscoring the clinical reliability of moist heat sterilization. In contrast, formalin chambers-despite their accessibility-showed limitations in microbial elimination, particularly against gram-negative organisms and environmental pathogens.

The findings support the prioritization of standardized autoclave protocols in surgical units, especially where infection control is critical to patient safety and institutional efficiency. While formalin chambers may continue to serve as interim solutions in resource-constrained settings, their use should be accompanied by validated exposure standards and enhanced monitoring practices. Long-term planning should focus on transitioning toward steam-based systems to align with global sterilization benchmarks and occupational safety standards. Strengthening sterilization infrastructure and adherence to validated protocols remains essential for improving surgical outcomes, minimizing postoperative

complications, and advancing institutional infection control practices.

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