DOI: https://doi.org/10.53350/pjmhs02024181102

**ORIGINAL ARTICLE**

# Infection Rate in Cholecystectomy using Cidex Sterilized Versus Autoclaved Sterilized Instruments

MUHAMMAD AZHAR[1], SADIA[2], SYED ARIF HUSSAIN[3], KUMAIL HAIDER[4], MALAKA FATIMA[5], AYESHA FAROOQ[6]
*[1]Associate Professor, [2]Assistant Professor, Department of Surgery, Wah Medical College Wah Cantt*
*[3]Consutlant Surgeon, Department of Surgery, Bahria International Hospital, Safari*
*[4-6]Final Year MBBS Students, Wah Medical College, Wah Cantt*
*Correspondence to: Dr. Muhammad Azhar, E-mail: azharmuhammad84@gmail.com, Cell: 0300-9540964*

## ABSTRACT

**Background:** Cholecystectomy is a common procedure for removal of the gall bladder which is preferred to be conducted laparoscopically. The infection of cholecystectomy varies on several factors. one important factor is sterilization of laparoscopic ports and instruments. By opting for a better sterilization method of the instrument, the surgical site infections can be prevented up to a great extent.

**Objective:** To determine and compare the rate of infection through cidex sterilized versus autoclave sterilized instruments in patients undergoing laparoscopic cholecystectomy

**Study design:** Comparative analytical study

**Place and duration of study:** Department of Surgery, Muhammad Aslam Chaudary Hospital, Wah Cantt from 1st March 2023 to 31st August 2023.

**Methodology:** One hundred and five patient undergoing cholecystectomy were enrolled in the study between the age 10-55 years. These patients were randomly divided into two groups as Group A (n=55) and Group B (n=50) through double blinding mechanism. The groups were assigned according to the opted sterilization procedure for the instruments. In group A cases the instruments were sterilized by Cidex while in group B autoclaving sterilization was applied. All the relevant clinical data and study findings were entered in a well structured questionnaire. The data was analyzed and compared within groups and results were interpreted.

**Result:** The mean age group was 42.3±3.5 years and 47.2 ±2.5 years in Group A and Group B respectively. Majority of the patients had surgery duration of 51-60 minutes followed by 41-50 minutes. There was an overall increase in infection cases with the increasing time of surgery however there was significantly higher number of port site infections in Group A (14.5%) them Group B (2%). A total of 8.5% of the cases who underwent laparoscopic cholecystectomy developed port site infections.

**Conclusion:** The autoclave sterilization method is a better option of instrument sterilization than CIDAX sterilization technique.

**Keywords:** Infection, Cholecystectomy, Cidexsterilized, Instrument

## INTRODUCTION

Cholecystectomy is a surgical procedure applied for the removal of the gallbladder. The gall bladder may be affected by various conditions including gall stones, cholecystitis, carcinoma or bile duct blockage.[1-3] The prevalence of cholecystectomy varies within regions and can depend on various geographical, gender, age or ethnicity-based factors. In unites states around 700 thousand cholecystectomies are performed each year. The global estimate details that around 10-20% of the adult population have the risk of development of gall stones with 1-2% adults who undergo the cholecystectomy procedure.[4-6]

Research has investigated the complications related with cholecystectomy and it has been elaborated that the infection of cholecystectomy varies on several factors, such as the type of surgery (open or laparoscopic), patient health, and surgical site infections (SSIs) prevention measures. Studies has demonstrated that laparoscopic cholecystectomy has lower infection rate (0.5-2.5%) compared to open cholecystectomy (3-5%).[7]

The surgical site infection (SSI) contributes to increased duration of hospitalization as well as cost on the healthcare.[8] The incidence of SSI is reported higher in cases where open cholecystectomy procedure has been opted while it is lower in laparoscopic cholecystectomy. Various studies have reported different incidences ranging from 1.1% to 8.4% in open cholecystectomy while 0.3% to 3.4% post laparoscopic cholecystectomy.[8,9] Surgical site infections (SSIs) are significant risk of morbidity and mortality which account for 20% of all the hospital-based infections.[10] The surgical site infection can be caused in cases where the instrument sterilization is improper. Cidex is a brand name for a high-level disinfectant and sterilant solution containing glutaraldehyde (2% or 3.4%). It is used to sterilize and disinfect medical instruments, equipment, and surfaces. An autoclave is a device used for sterilization by subjecting materials to high-pressure steam. The standard method of sterilization has been identified as autoclave, while the some equipment as telescope and ports used during cholecystectomy cannot be autoclaved and overheated for sterilization.[10]

The present study was designed for comparing the CIDEX sterilization chemical method with autoclave sterilization technique. These results of the study provided a deep insight into the most appropriate instrument sterilization choice leading to reducing the incidence of infections during the cholecystectomy procedure and consequently benefiting the overall health and well being of the patients.

Received on 02-09-2023
Accepted on 27-12-2023

## MATERIALS AND METHODS

The study was designed as comparative analytical and was performed at Department of Surgery, Muhammad Aslam Chaudary Hospital, Wah Cantt from 1st March 2023 to 31st August 2023. A total of 105 patients undergoing laparoscopic cholecystectomy were enrolled between the age of 10-55 years. These patients were randomly divided into two groups as Group A (n=55) and Group B (n=50) through double blinding mechanism. The groups were assigned according to the opted sterilization procedure for the instruments. In group A cases the instruments were sterilized by Cidex while in group B autoclaving sterilization was applied. The sample size was generated by suing WHO sample size calculator using 80% power of test, 95% CI and 5% margin of error. All surgeries were planed after the preoperative sterilization procedure with administration of prophylactic antibiotics during introduction of general anaesthesia or at pre-operative time. Surgery was performed through standard 4 port technique. In Group A all laparoscopic instruments were sterilized by 2% glutaraldehyde (CIDEX)/OPA/paracetic acid solution with a contact time of approximately 30 minutes. Before surgery all the instruments were washed with warm saline. While in Group B the autoclaving of instruments was done.

All patients who underwent laparoscopic cholecystectoy due to acute gall bladder infection were excluded from the study. Also

the patients who had uncontrolled diabetes, communicable infective disease, who were taking steroids/immunosuppressant and or those with superficial skin infections were all excluded. Pneumo-peritoneum was formed in few patients via verses needle while in other patients it was conducted through open process by infra umbilical-incision. Through the same incision, a 10 mm safety trocar (primary trocar) introduced in to the abdominal cavity. The time duration from abdominal incision to primary trocar entry was calculated. Gall bladder specimens were retrieved. The 10 mm port closure was conducted through hand sutures. The patients were followed up postoperatively for a time period of 30 days and observed for any sign of infection at port sites. All the relevant clinical data and study findings were entered in a well structured questionnaire. The data was analyzed using SPSS version 25.0 wherein Chi square test was applied for comparative data analysis. P value <0.05 was considered as significant.

## RESULTS

The mean age group was 42.3±3.5 years and 47.2±2.5 years in Group A and Group B respectively. Majority of the cases were females and were within the age group of 41-50 and above years. There was no significant difference within males and females of the two groups (Table 1).

Table 1: Frequency of age according to gender among both groups (n=110)

| Age (years) | Group A (n= 55) | | Group B (n= 50) | |
|---|---|---|---|---|
| | Male | Female | Male | Female |
| 11-20 | - | 2 | 2 | 2 |
| 21-30 | 4 | 3 | 2 | 4 |
| 31-40 | 6 | 7 | 4 | 4 |
| 41-50 | 6 | 9 | 6 | 8 |
| >55 | 8 | 10 | 10 | 8 |

Table 2 Comparison within gender and groups of study of port infection

| Gender | Epigastric Port | | Umbilical Port | | P value |
|---|---|---|---|---|---|
| | Group A | Group B | Group A | Group B | |
| Male | 1 | 0 | 2 | 0 | 0.856 |
| Female | 2 | 0 | 3 | 1 | 0.045 |
| Total | 3 | 0 | 5 | 1 | 0.041 |

Table 3: Comparison of surgery duration with the rate of infection within groups

| Duration of Surgery (minutes) | Number of Surgeries | Group A | Group B | P value |
|---|---|---|---|---|
| 31-40 | 18 | - | - | -- |
| 41-50 | 26 | - | - | -- |
| 51-60 | 31 | 2 | - | 0.056 |
| 61-70 | 15 | 3 | - | 0.660 |
| 71-80 | 10 | 3 | 1 | 0.053 |
| 81-90 | 5 | - | - | -- |

Fig. 1: Comparison of surgical site infection in both groups and duration of surgery

13.3% of the cases admitted cases undergoing laparoscopic cholecystectomy developed port site infections with 18.18% cases developing infection were operated through CIDAX sterilized instruments while 8% cases were operated with autoclaved and sterilized instruments. The number of males who developed port infection was same for epigastric port as well as that of umbilical port (Table 2).

Majority of the patients had surgery duration of 51-60 minutes followed by 41-50 minutes. There was an overall increase in infection cases with the increasing time of surgery. The increase in number of the cases was much higher in the group A in comparison with group B (Table 3). The present study shows that there was a significantly high number of cases in superficial port site infection with increased duration of surgery, however the number was subsequently increased in Group A than Group B (Fig. 1).

## DISCUSSION

The present study has reported a 8.5% of the cases admitted and enrolled for laparoscopic cholecystectomy developed port site infections. However this frequency can be decreased by improving the instrument sterilization method as there were 14.5% cases where CIDAX sterilization was used leading to surgical site infection in them. Only 2% cases with autoclave sterilization were also reported to surgical site infection. Surgical instruments, either disposable or reusable, are most crucial part of any surgical procedure.[11,12] The highest used surgical instruments need sterilization before any procedure. Owusu et al[13] detailed that sterilization is highly important for avoiding any kind of nosocomial pathogen in cases undergoing laparoscopic-tubectomies. Although instrument sterilization is a primary focus of any surgical procedure which can lead to infections however the port site infection is not only due to instrument sterilization but may be reported due to other reasons as improper surgical methods. This was totally avoided in the current study by ensuring non biasness and professional surgical teams.

All of the infections in current study were observed in umbilical and epigastric ports. In an international study 88.2%infection are due to epigastric port site infection and 11.7% are from umbilical port site infections. Mubarak et al[14] stated that the reason of port site infection can be gross spillage of infected bile as well as other reasons including obesity and umbilical stitch sinus.

In the present study two surgical sterilization methods were compared to assess the most appropriate method in use during surgery. It was analytically assessed that autoclave sterilization is the most appropriate method of sterilization for instruments. Mustafa et al elaborated in their study that autoclave being a low-cost and most effective method is the most appropriate method of sterilization than any other available.[14]

It is effective against bacteria (including Mycobacterium tuberculosis), viruses (including HIV, HBV, and HCV), and other microbial infections which can be found in a hospital setting. The surgical instruments such as and equipment's can be sterilized by its application.[15-18] Autoclaves are a crucial tool for ensuring the sterilization of materials in various industries and require steam-based sterilization method which last longer than any other sterilization protocol.[19,20]

## CONCLUSION

14.5% of the cases admitted cases undergoing laparoscopic cholecystectomy developed port site infections with 14.5% cases developing infection were operated through CIDAX sterilized instruments while 2% cases were operated with autoclaved and sterilized instruments. The autoclave sterilization method is a better option of instrument sterilization than CIDAX sterilization technique.

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**This article may be cited as:** Azhar M, Sadia, Hussain SA, Haider K, Fatima M, Farooq A: Infection Rate in Cholecystectomy using Cidex Sterilized Versus Autoclaved Sterilized Instruments. Pak J Med Health Sci, 2024; 18(1): 102-.