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Assessment of Multi-dose Lidocaine Vials use for Microbial Contamination in Ophthalmic Regional Anesthesia in Ocular Surgeries

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ABSTRACT

Background: Lidocaine is a commonly used local anesthetic in various medical procedures, including ocular surgeries. However, there are important considerations when lidocaine is used in conjunction with microbial pathogens or in the presence of infection, particularly during ocular procedures. Microbial contamination could potentially increase the risk of endophthalmitis, a serious complication following eye surgery. The choice of anesthetic should not interfere with the effectiveness of antimicrobial agents used during surgery. It is essential to follow strict infection control practices, and should always be used in conjunction with proper antimicrobial treatment to reduce the risk of ocular infections.

Objective: This study aimed to evaluate the risk of microbial contamination of multiple-dose lidocaine vials after opening, and the associated risk factors in ocular surgeries.

Materials and methods: This study includes 360 lidocaine vials and 1 control multi-dose vials (MDV) from the same patch used in the assessment at the Research Institute of Ophthalmology's Ocular Operating Rooms between May and September 2024. Samples were taken from MDV Lidocaine under sterile precaution and underwent microbial analysis to inspect bacterial contamination related.

Results: A total number of 9 vials containing microorganisms were identified from the 360 administered lidocaine solution vials used in the microbiology investigation, the overall prevalence of contamination was 2.5%. Gram negative bacteria were more common than Gram positive bacteria and no mixed contamination was found in any of the MDVs, microbial species were identified from the total number of bacterial isolates as follows: 2 (37%) and 7 (63%) of the contaminations were caused by Gram-positive and Gram-negative bacteria respectively. P. aeruginosa and K. pneumoniae were the most prevalent Gram-negative bacteria and accounts for 5 (71.4%) and 2 (28.6%) isolates respectively. The only Gram positive bacteria that were isolated were coagulase negative staphylococci (CoNS).

Conclusion: The demonstrated data in this study showed the possible risk of microbial contamination after opening and repeatedly using the lidocaine multidose vials. Adhering to aseptic protocols can minimize the risk of infection and ensure optimal outcomes for the patient.

Keywords: Vial contamination, Multiple-dose vial, Bacterial contamination, Aseptic procedures.

INTRODUCTION

There is a raising of awareness that safe medical practice should be addressed systematically and learned firmly [(1)]. Safe handling of medications applies to multiple different professional groups and clinical areas. The catastrophic medication error avoidance is basically dependent on both the physician and the system applied in each department of the hospital [(2)].

Bacterial contamination of injection vials in a multi-dose is a significant concern in healthcare settings, as it can lead to severe infections, particularly if the contaminated vials are delivered to patients [(3)]. The contamination often occurs during handling, storage, or preparation of the vials, and the risk is higher with multi-dose vials due to repeated access to the vial, which increases the potential for introducing microorganisms [(4)]. Bacterial contamination of vials includes contamination during medications production, vial opening technique, improper handling along with environmental factors including improper storage conditions. Also, the duration of use as in multi-dose vials that are in use over long periods, especially if stored incorrectly [(5)].

Ocular surgeries, particularly those involving the use of vials (such as medications or anesthetics), can be at risk for bacterial contamination, which is a significant concern due to the sensitive nature of eye tissues and the potential for serious infections [(6)]. Many studies reported the possibility of existence of harmful microbes, like Staphylococcus epidermidis, that may live and sometimes grow in multi-dose vials with other common microbial agents that could contaminate vials, which include Pseudomonas aeruginosa, and Escherichia coli[(7)]. These pathogens can lead to infections if they come into contact with ocular tissues. Potential infections from contaminated anesthesia could lead to post-operative endophthalmitis [(8)].

Lidocaine was first manufactured under the name Xylocaine® by Nils Löfgren in 1942 and was not used in the market until 1948. In addition to its use as a local anesthetic and anti-arrhythmic drug, i.v. lidocaine was soon reported in 1960s to exhibit analgesic properties in numerous pain conditions [(9)].

Generally injectable medication used in the peribulbar and retobulbar spaces for ophthalmic regional anesthesia must be sterile and safe to decrease the risk of infection [(10)]. Administration safety depends on strict compliance with protocols and guidelines

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recommended by the Centers for Disease Control and Prevention (CDC) [11]. The CDC stated that injection safety is considered a major issue of public health concern recognized, in low- and middle-income countries [12]. Unsafe injections resulted in millions of new hepatitis B virus infections, hepatitis C virus infections, and human immunodeficiency virus infections with the global burden associated with the illness following the infections. Reported outbreaks are due to unsafe injection procedures that increased globally because of the mishandling of injectable medical items. Most invasive bloodstream infections were bacterial in origin [13].

The misuse of MDVs causes harms that are very difficult to trace and considered a challenge to determine the frequency of such incidence. On the other hand, single used local anesthetic ampules in ocular surgeries are considered safer and carries very low risk of infections and high cost compared to MDVs [14]. Many studies searched the MDV contamination of various drugs thoroughly. However, only few studies addressed the potential MDV contamination of local anesthetic solution during use in the ocular regional anesthesia for ocular surgeries. Therefore, the scope of this study was to evaluate the risk of microbial contamination of multiple-dose lidocaine vials after opening, and the associated risk factors in ocular surgeries. Assessment of the anesthetic drugs is mandatory in cases of the unfortunate endophthalmitis outbreak that might occur after ocular surgeries and also when investigating isolated cases of endophthalmitis.

MATERIALS AND METHODS

This study includes 360 vials of Lidocaine 2% in 50 ml and 1 control MDV from the same patch used in the assessment at the Research Institute of Ophthalmology (RIO), Anesthesia Department and microbiology laboratory between May and September 2024.

Sample collection: prior to sampling, all open and in use MDV injectable lidocaine vials were thoroughly mixed and 70% isopropyl alcohol was used by swabbing to disinfectant the rubber stoppers.

The vials were inverted using sterile procedures, the MDVs were marked externally with a level at which three fourths of the medicine would have been consumed to serve as a marker to maintain a fluid level for investigation. One vial per batch was used to draw 2 ml of the medication by inserting a sterile needle within the stopper before use. This served as the batch's control sample. After the medicine was utilized for the study group, another 2 mL sample was taken and microbiological analysis was performed on both the first and the second samples. The sample was then promptly taken by a specialized microbiologist and transported in a closed labeled container to the microbiology Laboratory. The batch number and the MDV lidocaine vials' opening date were recorded.

Microbial analysis: Samples from the MDV lidocaine were inoculated into 15 mL Brian heart infusion broth and incubated at 37°C for 24-72 hours and further for 7 days. The broth was visually inspected every other day and subcultured using the streak plate technique onto blood, MacConkey, Wilkins and chocolate agars (oxoid, UK). It was then incubated for 24 hours at 37 °C for inspection and for up to 48 hours [15]. Growth outside of the lines was rejected and reported as contamination. Only growth on the streaks was reported significant. Following positive growth, the colonial morphology, Gram staining, hemolysis type, blood agar pigmentation, and standard confirmatory identification tests were performed in accordance with the Clinical and Laboratory Standards Institute's (CLSI) criteria [16]. Gram positive bacteria were identified using standard biochemical assays such coagulase and catalase tests. Conventional biochemical tests, such as oxidase and indole tests (Oxoid, UK), were used to identify Gram-negative bacteria [17].

Ethical approval:
This study was conducted at the Research Institute of Ophthalmology without involving any human or animal participants.

Statistical analysis

IBM Inc., Chicago, implemented statistical analysis using SPSS version 24.0. The variables were represented by their mean values and standard deviations. The Chi-square test determined the frequency and percentage distribution of qualitative variables. A P value ≤ 0.05 in a two-tailed test signifies a statistically significant result.

RESULTS

Prevalence of isolated bacteria: Nine vials contain microorganisms were identified from the 360 utilized lidocaine vials used in the microbiology investigation and 351 vials were clean.
In this study, the overall prevalence of contamination was 2.5 percent (Table 1). Gram negative bacteria were more common than Grampositive bacte ria and no mixed contamination was found in any of t he MDVs (Figure 4). Microbial species were identified from the total number of bacterial isolates as follows: 37% (2 vials) and 63% (7 vials) of the contaminations were caused by Gram-positive and Gram-negative bacteria, respectively (Figure 5). P. aeruginosa accounts for 5 vials (71.4%) and K. pneumoniae for 2 vials (28.6%) of the isolated Gram-negative bacteria, which was the most prevalent (Figures 1 and 2). The only Gram-positive bacteria that were isolated were coagulase-negative staphylococci (CoNS) (Figure 3).

Figure (1): Pseudomonas aeruginosa

Figure (2): Klebsiella pneumoniae

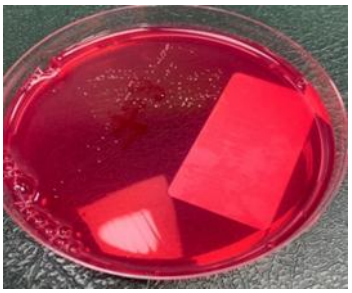

Figure (3): Staphylococcus (CoNS)

Table (1): Microbial analysis

Vial No.	Gram negative bacteria 7 (63%)		Gram positive bacteria	Total Frequency of microbial contamination
	P. aeruginosa	K. pneumoniae	Coagulase negative staphylococci	9 2.5%
360	5 (71.4%)	2 (28.6%)	2 (37%)	

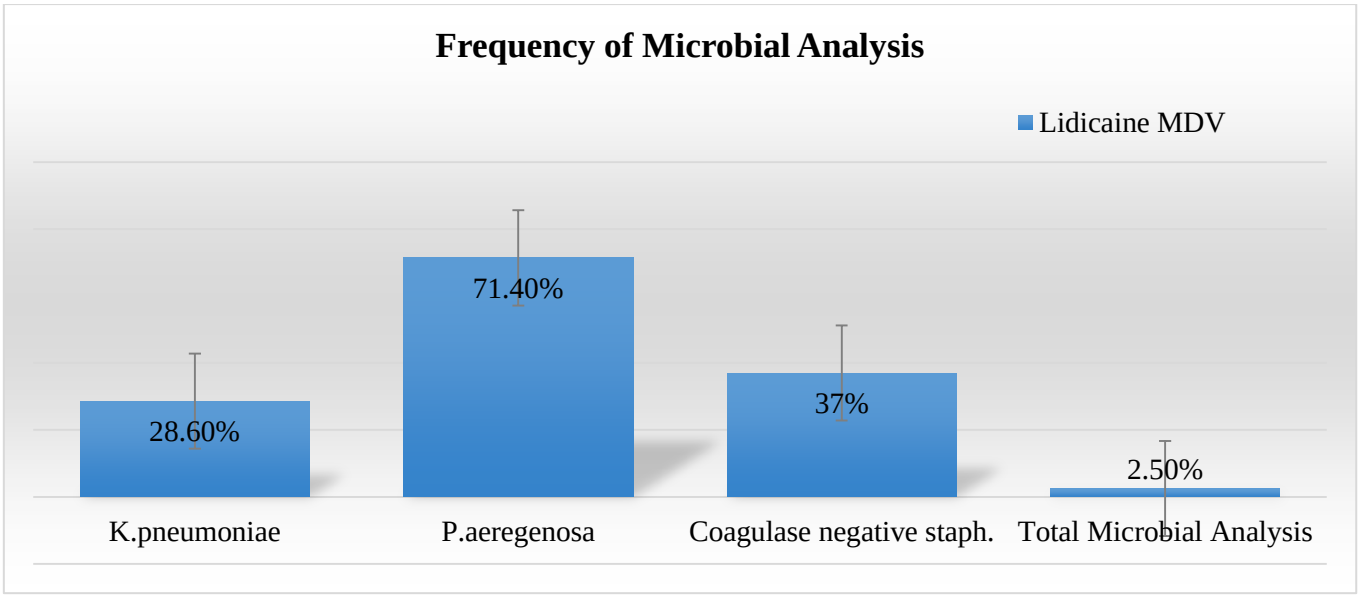

Figure (3): Frequency of microbial analysis (*P<0.005, significant).

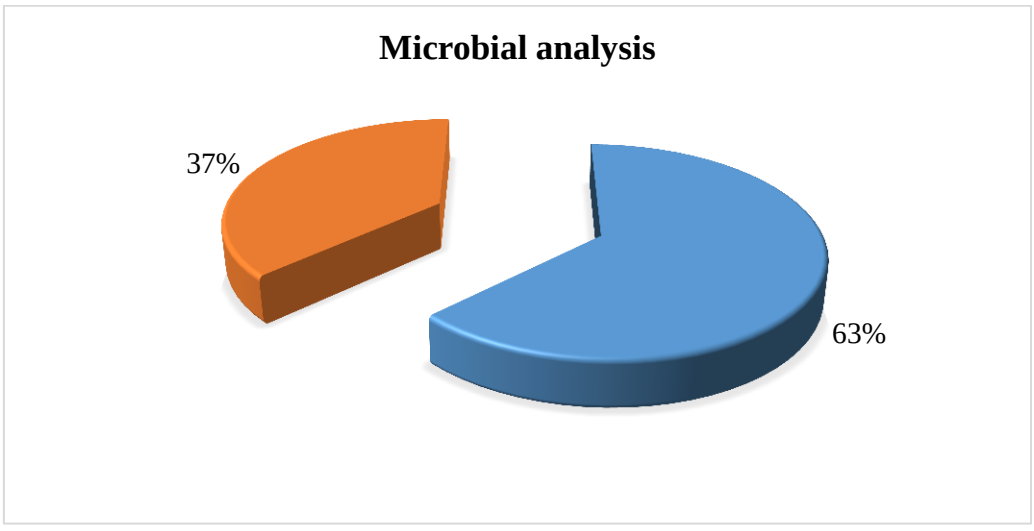

Figure (4): Gram-negative 63% and Gram-positive bacteria.

DISCUSSION

Lidocaine is a local anesthetic commonly used during ocular surgeries to provide anesthesia for various procedures. It works by blocking voltage-gated sodium channels (VGSCs) leading to a reversible block of action potential propagation, preventing pain during the surgery. However, like any medical procedure, the use of lidocaine in ocular surgeries comes with risks, including the possibility of bacterial contamination [(18)].

According to the study, the overall contamination rate of MDV lidocaine was 2.5%, which is more or less consistent with a previous study from Austria that showed contamination rates (4%) [(19)]. And in contrast with two previous studies from Ethiopia and Iran that showed higher contamination rates of 5.6% and 5.36%, respectively [(3, 20)]. Also, in contrast with a study from Germany, which stated that the contamination rate was less than that in our study of 0.9% [(19)]. The difference in the current study might be due to the duration period of the study, which was longer than that of the other studies along with different sample size collected, kinds of wards included, aseptic policies undertaken, the reuse of needles, the durability of the rubber closure and storage policies, direct or indirect contact with contaminated environmental surfaces during multiple uses of vials [(21)].

Our study was conducted on MDVs supplemented with preservatives due to the possibility of external contamination. Methylhydroxybenzoate (E218) is the preservative utilized in MDVs of lidocaine. However, it is not predicted that preservatives added to MDVs will completely cast out any microbial agents that may be interpolate during re-use but other studies showed that preservative free medications are more susceptible to contamination [(22)]. On the other hand, few previous studies reported that local anesthetics like lidocaine vials can prevent bacterial growth that have injected into the soft tissue during the injection procedure and that might aid elimination of microorganisms that are introduced into the tissues or blood vessels by inhibiting effect on bacterial growth, which results when the bacterial cell wall or cytoplasmic membrane is disrupted, cellular components are disrupted and cause cell lysis, which is why local anesthetics have antibacterial effect according to reports, the electrostatic binding of anesthetic molecules to polar groups associated with the hydrophobic nature of the anesthetic on the membrane surface causes penetration of bacterial membranes [(23)].

In this current study, the prevalence of bacterial isolates was reported as Gram-negative bacteria that accounted for 63%, which were more frequent than Gram-positive bacteria (37%). This was in consistence with a study from Ethiopia, which stated that Gram-negative bacteria (85.7%) were more frequent than Gram-positive bacteria (14.3%) [(16)].

P. aeruginosa and K. pneumoniae were the most p revalent Gram-negative bacteria and accounted for 71.4% and 28.6% isolates respectively. This is in contrast to a similar investigation conducted in the USA who reported that the most frequently isolated bacterium was Gram negative bacteria and P. aeruginosa (28.5%), followed by K. pneumoniae (23.8%) [(24)]. However, this finding is different from other researches done in Iran, which reported that 88.9% prevalence of Gram-positive bacteria [(25)]. This outcome may indicate the local pattern of hospital-acquired infections caused by Gram-negative bacteria.

The inappropriate storage of MDVs has been identified as one of key factors in previous epidemics by prolonging the persistence of microorganisms. According to earlier studies based on a study of MDVs without preservatives, refrigeration was advised following initial use to stop bacterial development. According to recent studies, refrigeration may actually increase bacterial viability by decreasing the effect of certain preservatives at lower temperatures. After reviewing the manufacturer's instructions, the Centers for Disease Control and Prevention advises that MDVs be stored at particular temperatures based on the product [(26)].

Repeated poor aseptic practices are favored when using MDVs that induce of serious and life-threatening infections in hospital settings. The following list of guidelines for healthcare workers on how to handle MDVs includes using a new needle and syringe for each injection and hands should be kept clean. Clean the medication vial's diaphragm with a disinfectant. MDVs should only be accessed and stored in a clean, designated area for drug preparation, away from patient treatment areas. The vial should be dated after an MDV has been opened or accessed, and it should be discarded within 28 days unless the manufacturer specifies a different (shorter or longer) date. This study reported minimal microbial contamination of multiple-dose lidocaine vials after operational use in ocular surgeries. These reported results followed by strengthen given to the heath-care personnel regarding the aseptic protocol for MDVs.

LIMITATIONS

Limitations in this study was that we did not assess the possibility of additional contamination, like viral contamination or fungal agents and anaerobic bacteria, which can also cause vial contamination during the investigation process.

CONCLUSION

Despite the antimicrobial properties that makes lidocaine generally safe when used as local anesthetic in ocular surgeries, careful attention to sterility and hygiene is essential to prevent bacterial contamination.

The demonstrated data in this study showed the possible risk of microbial contamination after opening and repeatedly using the lidocaine multidose vials. Adhering to aseptic protocols and following guidelines can minimize the risk of infection and ensure optimal outcomes for the patient.

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