**The single use Lidocaine Hydrochloride 5 per cent w/v and Phenylephrine Hydrochloride 0.5 per cent w/v topical spray, can it now be employed as a multi-use atomiser?**

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## Abstract

**Objective**

Our aim was to investigate the risk of contamination of lidocaine hydrochloride 5 per cent w/v and phenylephrine hydrochloride 0.5 per cent w/v topical solution after modification of its application technique.

**Methods**

This paper reports a prospective basic sciences study involving 22 samples and one control sample of the lidocaine hydrochloride and phenylephrine hydrochloride topical anaesthetic spray. The samples were assessed for microbiological contamination after a single use on patients after modifying technique of its application. Our modification involves keeping the nozzle (actuator) pressed down while withdrawing the spray from patient for at least 30 cm (one foot) before releasing the nozzle (actuator) and reapplying the spray.

**Results**

Three out of 23 samples confirmed bacterial growth in the contents of the bottles but there was no growth in any of the samples from the pump. We considered that these bacteria are contaminants.

**Conclusions**

There is a potential to use the lidocaine hydrochloride 5 per cent w/v and phenylephrine hydrochloride 0.5 per cent w/v topical solution as a multi-use spray by changing the actuator between patients. This would have significant beneficial cost implications without the attendant infection control risk.

**Key words**

Anaesthetics, Local; Cross Infection; Lidocaine; Phenylephrine; Endoscopy; Drug contamination

## Introduction

Lidocaine hydrochloride 5 per cent weight/volume (w/v) and phenylephrine hydrochloride 0.5 per cent w/v topical solution is a frequently used anaesthetic preparation in ENT practice. The manufacturer, Aurum Pharmaceuticals1 currently recommends its use as a single-use disposable pack.

In our previous paper- “Risk of contamination of lidocaine hydrochloride and phenylephrine hydrochloride topical solution: in vivo and in vitro analyses”2- we evaluated the potential for cross-contamination of the lidocaine hydrochloride 5 per cent w/v and phenylephrine hydrochloride 0.5 per cent w/v topical solution delivery system if used as a multidose vial in clinical practice and in laboratory settings. We demonstrated that the solution was contaminated in 2 out of 10 patients following a single use. This was further confirmed during in-vitro settings. We, therefore, recommended complying with the manufacturer’s advice of using the solution as a single-use disposable unit.

However, empirical observation suggests that this advice is not stringently followed in clinical practice. The common practices include changing the actuator between different patients but using the same bottle and solution, or alternatively, combining the contents of two or more bottles in one single bottle and then using it as a multi-use spray, changing the actuator between patients. When challenged the common reasons cited for such practices are significant cost reduction and conflicting evidence in the medical literature regarding possible cross-contamination from the multiple use of the nasal sprays.3-7

We have developed a practical easy-to-use technique for application of the spray in day-to-day practice. We kept the nozzle (actuator) pressed down whilst withdrawing the spray from patient for at least 30 cm (one foot) before releasing the nozzle (actuator) and reapplying the spray. A thorough literature review suggests that this methodology has not been evaluated for contamination.

The aim of this study was to determine whether the pump and contents of the bottle were contaminated following a single use in patients after modifying method of application of the spray.

**Materials and Methods**

This study was conducted by the ENT and microbiology departments of a tertiary referral university hospital (University Hospital Southampton NHS Foundation Trust). The study did not require ethical approval because it was a quality improvement project. As such it was registered as an audit (Audit registration number 6559).

The study involved the single application of lidocaine hydrochloride 5 per cent w/v and phenylephrine hydrochloride 0.5 per cent w/v topical solution as a single-use spray on 22 random patients attending ENT clinic, prior to undergoing nasal pharyngolaryngoscopy, as part of their routine clinical care. We believe that this sample size of 22 represents cohort of routine ENT outpatients. In addition, one control sample was collected to quality control the containers, applicators, and the laboratory process. Thus, in total, 23 samples were analysed.

Aseptic precautions were taken to reduce any contamination whilst handling the bottle and nozzle (actuator). The manufacturer’s recommendations1 were followed in assembling the pump spray. Immediately before use, the screw cap and rubber stopper were removed from the bottle. The pump was screwed onto the bottle. The nozzle (actuator) was pushed onto the top of the pump. The pump was primed by pressing down on the pump-nozzle (pump-actuator) three times before use. The solution was sprayed once in the patient’s nose or nose and then throat. The pump spray was withdrawn from the patient with the nozzle (actuator) pressed down to avoid the suck-back Venturi effect. The nozzle was released at least 30 cm (approximately one foot) away from the patient. The pump spray was reapplied in above manner if necessary. In this manner, one or two doses of spray per nostril or throat were squirted, keeping the total dose well below maximal permissible dose of 8 sprays in total, in adults, and children over 12 years1 . The pump spray assembly (i.e., the nozzle/actuator, the pump, and the bottle with the remaining solution) was transferred to the microbiology laboratory for bacteriological analysis.

Twenty-two samples and a negative control (lidocaine hydrochloride 5 per cent w/v and phenylephrine hydrochloride 0.5 per cent w/v topical solution in its sealed container), [total of 23 samples], were collected and delivered to the microbiology department at University of Southampton NHS Hospital Foundation Trust.

Each sample was divided into three parts: A – nozzle (actuator), B – pump content, C – bottle content. Samples were treated as sterile and processed using aseptic techniques in Class II biosafety cabinet (the air circulates upwards and is filtered out by HEPA filters in order to protect the sample from outside contamination). The nozzle (actuator) was cut off with sterile scissors, placed into FAB (Fastidious Anaerobe Broth) to extract possible bacterial growth and vortexed in order to distribute it evenly throughout the broth. Three drops of FAB broth, two drops of lidocaine from the pump (solution was collected by blocking and pressing the top of the dispenser pump and collecting the lidocaine hydrochloride in a sterile universal container) and three drops of bottle content were inoculated on corresponding set of plates. All samples were inoculated on CHOC (Columbia agar with chocolate horse blood), CBA (Columbia agar with horse blood) and CLED (Cystine-lactose-electrolyte-deficient agar with andrades indicator) agar plates. All growth was examined and identified using Matrix-assisted laser desorption/ionization mass spectrometer by biomedical scientist and interpreted by a consultant microbiologist.

**Results**

The results are tabulated in table I.

The control sample did not demonstrate any growth in nozzle (actuator), pump or bottle. Twelve nozzles (actuators) have shown bacterial growth, but these bacteria are part of normal nasal flora. There was no growth from any of 22 pump samples from patients but three samples from contents of bottles from patients had bacterial growth; two had Staphylococcus hominis and one grew Rothia mucilaginosa. The bottle contaminants varied from the nozzles (actuators) in each positive contaminant case.

**Discussion**

This study demonstrates that by modifying technique of application of the spray contamination of the pump and remaining solution in the bottle can be avoided.

In this study, three samples from contents of bottles had bacterial growth, two had Staphylococcus hominis and one grew Rothia mucilaginosa. These bacteria are likely to be contaminants as they do not match isolates from their respective nozzles (actuators), and, secondly, retrieving fluid from the pump bottle assembly and applying on culture is a challenging process which, we believe, may have led to contamination.

Furthermore, this study showed that, twelve nozzles (actuators) had grown bacteria. Though these bacteria are part of normal nasal flora we advise change of nozzles between patients if the spray were to be used on more than one patient.

The modification in application technique of the spray may have avoided the suck-back Venturi effect. However, it is user dependent, but this study has shown that by a simple modification in application technique there is a possibility that the lidocaine hydrochloride 5 per cent w/v and phenylephrine hydrochloride 0.5 per cent w/v topical solution can be used on more than one patient without risk of spreading infection.

Current clinical evidence questions the routine use of topical anaesthetic spray in flexible laryngoscopy.8 However, it is often required when rigid nasal endoscopy or flexible nasal pharyngolaryngoscopy is used for minor interventions in out-patient settings or when the patient has a preference2.

Thus, the lidocaine hydrochloride 5 per cent w/v and phenylephrine hydrochloride 0.5 per cent w/v topical solution makes up a substantial part of any otolaryngology department’s pharmaceutical budget2.

Therefore, these findings have a potential to make savings which could be quite considerable over time.

The Venturi principle atomisers and positive displacement pumps have a long history of usage to deliver ENT medication. It should be realised that the Venturi effect may theoretically also occur on release of the pump through a suction effect. This is supported by many studies which have also have demonstrated the potential for contamination of the venturi principle atomisers delivery systems due to the ‘suck-back’ Venturi effect.6,7,9 This has led to the development of positive displacement atomisers to deliver drugs into the nasal cavity.3,7 Wolfe et al. compared the risk of contamination between Venturi type devices and positive displacement pumps, and found that positive displacement atomisers never became internally contaminated.7 In addition, Rashid and Karagama found no evidence of contamination with a multi-use xylocaine spray using spectrophotometer and culture analysis.10

This is contrary to the findings of our previous study2 where it was demonstrated that the lidocaine hydrochloride 5 per cent w/v and phenylephrine hydrochloride 0.5 per cent w/v topical solution was contaminated in in-vivo and in-vitro settings even after single use.

However, in practice, clinicians follow various strategies and use the lidocaine hydrochloride 5 per cent w/v and phenylephrine hydrochloride 0.5 per cent w/v topical solution as multi-use vial. These strategies includechanging the actuator between different patients but using the same bottle and solution, or alternatively, combining the contents of two or more bottles in one single bottle and then using it as a multi-use spray, changing the actuator between patients2. Other strategies followed are avoidance of any direct contact of equipment with nasal mucosa; use of a bacteriostatic preservative in the nasal spray; use of a nasal speculum; application of continuous, less than 1 second spray to the nasal cavity; and wiping the nozzle of the atomisers with an isopropyl alcohol pad after each use4,11.

These practices are followed to decrease the risk of infection transmission.4,11 and, we believe, probably for cost savings purposes2.

Therefore, we developed a remedy and have tested its safety and efficacy in routine ENT clinical practice. We have demonstrated that by modification of technique of application of the spray contamination can be avoided. Though the technique is user dependant it has created prospect of using lidocaine hydrochloride 5 per cent w/v and phenylephrine hydrochloride 0.5 per cent w/v topical solution assembly as a multi-use vial.

**Conclusions**

This study has revealed that by modification of application technique of the lidocaine hydrochloride 5 per cent w/v and phenylephrine hydrochloride 0.5 per cent w/v topical solution spray contamination can be avoided.

Although we advise readers to follow the manufacturer’s guidance on single use, this does not always represent a ‘real-world’ situation and the variance of procedure which is encountered in practice. We assessed the potential to use the lidocaine hydrochloride 5 per cent w/v and phenylephrine hydrochloride 0.5 per cent w/v topical solution as a multi-use spray, by simply changing the actuator between patients.

This has a significant cost savings implication for the pharmaceutical budget of an ENT department without the attendant risk of infection.

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## Tables and Charts

TABLE I

TitleCulture results

|  |  |  |  |
| --- | --- | --- | --- |
| Sample  number | Culture results after 48 hour incubation and MALDI ID | | |
| Nozzle/ Actuator (A) | Pump (B) | Bottle (C) |
| 1 | \*S. capitis  \*S. epidermidis | NG | NG |
| 2/ control | NG | NG | NG |
| 3 | NG | NG | NG |
| 4 | NG | NG | NG |
| 5 | NG | NG | NG |
| 6 | \*S. epidermidis | NG | S. hominis\*\* |
| 7 | NG | NG | NG |
| 8 | NG | NG | NG |
| 9 | \*S. epidermidis | NG | NG |
| 10 | NG | NG | NG |
| 11 | \* S. epidermidis | NG | Rothia mucilaginosa\*\* |
| 12 | \* S*.* epidermidis | NG | NG |
| 13 | \*S. epidermidis \*Enterococcus faecalis | NG | NG |
| 14 | \*S. epidermidis \*C. propinquum | NG | NG |
| 15 | \*S. epidermidis  \*C. propinquum | NG | NG |
| 16 | \*C. pseudodiptheriticum  \*C. accolens | NG | NG |
| 17 | NG | NG | NG |
| 18 | NG | NG | NG |
| 19 | \*S. epidermidis | NG | S. hominis\*\* |
| 20 | \*C. pseudodiptheriticum | NG | NG |
| 21 | NG | NG | NG |
| 22 | NG | NG | NG |
| 23 | \*S. aureus, \*S. capitis \*S. epidermidis | NG | NG |

S= Staphylococcus C= Corynebacterium. NG= No growth.

\*Part of normal nasal flora.

\*\* Potential contaminants as they do not match original growth from the nozzle/actuator samples.

## Bullet Point Summary

* Lidocaine hydrochloride 5 per cent w/v and phenylephrine hydrochloride 0.5 per cent w/v topical solution is a frequently used anaesthetic preparation in ENT practice.
* It is a single use disposable pack, but advice regarding its single use is not strictly followed.
* This study demonstrated that by modifying method of application of the spray contamination can avoided. Our modification involves keeping the nozzle (actuator) pressed down while withdrawing the spray from patient for at least 30 cm (one foot) before releasing the nozzle (actuator) and reapplying the spray.
* This is likely to have significant cost implications for the ENT department’s pharmaceutical budget.