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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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Main Article

Mr M Jog takes responsibility for the integrity of the content of the paper

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Abstract

Objective. This study investigated 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 the application technique.

Methods. This paper reports a prospective basic sciences study involving 22 study samples and 1 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 using a modified application technique. The modification involves keeping the nozzle (actuator) pressed down whilst withdrawing the spray to at least 30 cm (1 ft) from the patient, before releasing the nozzle (actuator) and subsequently reapplying the spray.

Results. Three of the 23 samples confirmed bacterial growth in the bottle contents, but there was no growth in any of the samples from the pump. These bacteria are considered to be contaminants.

Conclusion. 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.

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 Pharmaceuticals,[1] 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 multi-dose 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 into 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 applying the spray in day-to-day practice. We keep the nozzle (actuator) pressed down whilst withdrawing the spray to at least 30 cm (1 ft) from the patient, before releasing the nozzle (actuator) and subsequently reapplying the spray. A thorough literature review suggests that this methodology has not been evaluated for contamination.

This study aimed to determine whether the pump and contents of the bottle are contaminated following a single use in patients after modification of the spray application method.

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 the ENT clinic, prior to undergoing nasal pharyngolaryngoscopy, as part of their routine clinical care. We believe that this sample of 22 patients represents a cohort of routine ENT outpatients. In addition, one control sample (sample two) was collected to act as a quality control for the containers, applicators and 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 recommendations[1] 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 when at least 30 cm (approximately 1 ft) away from the patient. The pump spray was subsequently reapplied in the same way if necessary.

In this manner, one or two doses of spray per nostril or throat were squirted, keeping the total dose well below the maximal permissible dose (for adults and children over 12 years) of eight sprays in total.[1] 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 the University of Southampton NHS Hospital Foundation Trust.

Each sample was divided into three parts: the nozzle (actuator), the pump contents and the bottle contents. Samples were treated as sterile. The samples were processed using aseptic techniques for a class II biosafety cabinet (the air circulates upwards and is filtered out by high-efficiency particulate air ('HEPA') filters in order to protect the sample from outside contamination).

The nozzle (actuator) was cut off with sterile scissors, placed into fastidious anaerobe broth to extract possible bacterial growth, and vortexed to distribute it evenly throughout the broth. Three drops of fastidious anaerobe broth, two drops of lidocaine from the pump (the 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: Columbia agar with chocolate horse blood, and Columbia agar with horse blood and cystine–lactose–electrolyte-deficient agar, with Andrade's indicator agar plates.

All growth was examined and identified by a biomedical scientist using a matrix-assisted laser desorption/ionisation mass spectrometer, and interpreted by a consultant microbiologist.

Results

The results are tabulated in Table 1.

The control sample did not demonstrate any bacterial growth in the nozzle (actuator), pump or bottle. Twelve nozzles (actuators) showed bacterial growth, but these bacteria are part of normal nasal flora. There was no bacterial growth from any of 22 pump samples from patients, but 3 samples from the bottle contents had growth: 2 grew *Staphylococcus hominis* and 1 grew *Rothia mucilaginosa*. The bottle contaminants varied from those of the nozzles (actuators) in each positive contaminant case.

Discussion

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

In this study, three samples from the contents of bottles had bacterial growth: two grew *S hominis* and one grew *R mucilaginosa*. These bacteria are likely to be contaminants, as they do not match isolates from their respective nozzles (actuators). 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 12 nozzles (actuators) had grown bacteria. Though these bacteria are part of normal nasal flora, we advise a change of nozzles between patients if the spray is to be used on more than one patient.

The modified spray application technique may have avoided the suck-back Venturi effect. However, it is user dependent. Nevertheless, this study has shown that the simple modification in application technique means it is possible to use the lidocaine hydrochloride 5 per cent w/v and phenylephrine hydrochloride 0.5 per cent w/v topical solution on more than one patient without the 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 outpatient settings, or when the patient has a preference.[2] 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 budget.[2] Therefore, these findings could provide considerable savings over time.

- 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
- It is a single-use disposable pack, but advice regarding single-use application is not strictly followed
- This study demonstrated that modifying the method of spray application can prevent contamination
- Our modification involves keeping the nozzle (actuator) pressed down whilst withdrawing the spray to at least 30 cm from the patient, before releasing the nozzle and reapplying the spray
- This is likely to have significant cost implications for the ENT department's pharmaceutical budget

The Venturi principle atomisers and positive displacement pumps have a long history of usage in delivering ENT medication. The Venturi effect may also theoretically occur on release of the pump through a suction effect. This is supported by many studies that have demonstrated the potential for

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Table 1. Culture results

	Culture results after 48-hour incubation & matrix-assisted laser desorption/ionisation bacterial identification		
Sample number	Nozzle (actuator)	Pump	Bottle
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	*R 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

*Part of normal nasal flora. †Potential contaminants, as they do not match original growth from the nozzle (actuator) samples. S = staphylococcus; NG = no growth; R = rothia; C = corynebacterium

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 a spectrophotometer and culture analysis.[10]

This is contrary to the findings of our previous study,[2] 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 a 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 delivery system as a multi-use vial. These strategies include changing the actuator between different patients but using the same bottle and solution, or, alternatively, combining the contents of two or more bottles into one single bottle and then using it as a multi-use spray, changing the actuator between patients.[2] Other strategies followed are: the avoidance of any direct contact of equipment with nasal mucosa; use of a bacteriostatic preservative in the nasal spray; use of a nasal speculum; the application of continuous spray, for less than 1 second, to the nasal cavity; and the wiping of the atomiser nozzle with an isopropyl alcohol pad after each use.[4,11] These practices are followed to decrease the risk of infection transmission,[4,11] and, we believe, probably for cost saving purposes.[2]

We have developed a remedy, and have tested its safety and efficacy in routine ENT clinical practice. We demonstrated that our modification of the spray application technique can prevent contamination. Although the technique is user dependant, it potentially allows the lidocaine hydrochloride 5 per cent w/v and phenylephrine hydrochloride 0.5 per cent w/v topical solution assembly to be employed as a multi-use vial.

Conclusion

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

Although we advise readers to follow the manufacturer's guidance on single-use application, this does not always represent a 'real-world' situation and the procedural variance encountered in practice. We assessed the potential to use the lidocaine hydrochloride 5 per cent w/v and phenylephrine

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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.

Competing interests. None declared

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