

Study of microbial spread when using multiple-use nasal anaesthetic spray*

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SUMMARY

Background: Current economic constraints have led to the emergence of reusable anaesthetic sprays with replacement nozzles (Xylocaine) as an alternative to disposable anaesthetic solutions (Co-phenylcaine) for rhinological procedures. The former costs £ 191 per year versus £ 10,761 for the latter, at equivocal doses. However, research regarding the sterility of such instruments is limited. The aim of this *in vitro* study was to determine whether bottles of Xylocaine could pose a risk of cross-infection to patients. **Methods:** Two techniques were used. The first was to introduce nozzles into methylene blue and fluorescein dyes, and then analysing the anaesthetic solutions using spectrophotometry for assessment of colour change indicating retrograde contamination. The second method involved spraying Xylocaine into cultures of *Staphylococcus aureus* with concurrent nozzle changes. This was repeated over a 36-day-period. Sterility checks were performed on the Xylocaine before and after inoculation into the culture. **Results:** None of the anaesthetic solutions showed the presence of dyed saline following spectrophotometric analysis. No *S. aureus* was isolated from any of the 30 spray bottles cultures over the 36-day trial period. **Conclusion:** It was demonstrated that using the Xylocaine spray with disposable nozzles for each patient should not pose a cross infection risk to patients.

Key words: nasal spray, anaesthetic, cross infection, sterility

BACKGROUND

Lidocaine and Phenylephrine Spray (LPS) is supplied as a single patient nasal preparation, which is effective on mucous membranes and dominates current practice as the choice for topical nasal anaesthesia for common rhinological procedures. Each pump dispenser is reported to deliver 6.5 mg lidocaine and 0.65 mg phenylephrine per spray⁽¹⁾. More recently, Xylocaine Spray (XS) has been developed by manufacturers as a multi-use bottle, which can be used with disposable nozzles for multiple patients. It is a prepackaged, commercial solution. Each dose of XS contains Lidocaine and Phenylephrine, Eur 10 mg, ethanol, Macrogol 400, essence of banana, menthol natural, saccharin and purified water⁽²⁾. A disposable plastic nozzle is attached to the anaesthetic bottle, the spray is administered nasally to patients and the nozzle is discarded. These steps are repeated for each patient. LPS comes as a 2.5 ml preparation at a cost of £ 10.02 per bottle whilst XS at 50mls costs £ 3.68 per bottle; in other words the latter is potentially capable of yielding 20 times the dose of the former⁽³⁾. In our department in a busy district general hospital, 1074 bottles of

LPS were ordered by the pharmacy department at a cost of £ 10,761 for the year. The equivalent cost of XS was £ 191. The fiscal incentive for adopting a multi-use regime is thus eminently apparent. However, the potential risk of patient cross-contamination with multiple uses is less clear and there are no prior studies to our knowledge that has addressed this significant issue. The sterility of ophthalmic drugs dispensed from spray bottles has previously been assessed with the authors of one study concluding that there appears to be minimal risk of instilling contaminated diagnostic drugs using the spray method when a single drug is stored in a spray bottle⁽⁴⁾. Our paper sets out not only to ascertain the sterility of anaesthetic solutions over a time period, but also to assess the potential contamination risk of anaesthetic fluid from the backflow of sprayed solution from the patient into the anaesthetic solution container.

The aim of the study was to determine whether using a nasal Xylocaine spray with replacement nozzles presents a cross infection risk to patients.

MATERIAL AND METHODS

Two techniques were used to assess microbial spread.

Method 1. Spectrophotometer analysis

Spectrophotometric analysis of the Xylocaine took place prior to application of nozzles dipped in the dyed solutions to establish baseline colour (Figure 1). Subsequently nozzles were inserted into containers with methylene blue and fluorescein dyes separately with the Xylocaine solution re-analysed for any colour change (Figure 2). The containers were kept away from light prior to the experiment to ensure uniformity of baseline colours.

Method 2. Culture analysis

A standard inoculating culture was prepared using one colony of *S. aureus* into a 10 ml nutrient broth, which was then incubated aerobically at 37°C for 24 hours. A 100 ml bottle of sterile water was used combined with 100 µl of overnight culture to prepare a 1:1000 dilution to give an organism count of 10⁸/L or greater.

The nozzles were placed into the Xylocaine bottle and an application of one spray onto a blood plate was used to assess pre-sterility. The attached nozzle was then submerged directly into the 100 ml culture bottle with the open neck sealed with parafilm and then 1 spray of Xylocaine was applied into the culture. After discarding the first nozzle and applying a second nozzle, a further single spray was applied to a blood plate to assess post-sterility. The blood agar plates were then incubated for 48 hours and bacterial growth was checked using a CLED dip strip plate. This was repeated at daily intervals over a 36-day period. The same steps were also repeated using 30 spray applications to determine if multiple sprays yielded any difference in bacterial growth. After completing the 36-day testing protocol described above, the procedure was also repeated several times over the course of 1 day for both the 1 and 30 spray bottles. The procedure was repeated 6 times over a 5.5 hour period.

Table 1. Spectrophotometer analysis – Methylene Blue.

Batch No.*	Pre –Dye Reading	Post – Dye Reading
1	0.002	0.005
2	0.004	0.002
3	0.007	0.004
4	0.004	0.006
5	0.005	0.008

*Note each batch is comprised of 10 samples with the reading recorded as the mean result of each set.

RESULTS

Results (1) spectrophotometer analysis

The results are presented in Table 1 and 2.

Results (2) culture analysis

1 spray inoculation

Daily inoculation: In the pre-sterility cultures, over the 36-day period, in all the sterility cultures, no growth was seen. On the other hand, in the post sterility cultures, on day 9, the sterility culture contained 8 colonies of *S. aureus*. All of the remaining cultures did no grow (Table 3).

Multiple inoculation over a one day period

The procedure was repeated 6 times over 5.5 hours. Each procedure consisted of 30 sprays. In both the pre sterility cultures and the post sterility cultures, no growth was visible.

Diluting an overnight culture of *S. aureus* gave a bacterial count of 10⁸.

Nozzle sterility checks

No pathogenic micro-organisms including *S. aureus* were isolated from any of the nozzle sterility checks, but some low numbers of bacteria normally associated with skin carriage were isolated.

30 spray inoculation

Daily inoculation: in the pre-sterility cultures, over the 36-day period, in all of the sterility checks, no growth was seen. This was also the case with the post-sterility cultures (Table 4).

DISCUSSION

Changes in the way the anaesthetic spray Xylocaine is administered has raised concerns regarding cross infection of nasal flora between patients. The condition in which the Xylocaine is administered was recreated in the laboratory using a 10⁸ culture of *S. aureus*, as this is the organism most commonly carried in the nasal passages of patients⁽⁵⁾. Inoculating the Xylocaine directly into the *S. aureus* culture daily over a

Table 2. Spectrophotometer analysis – Fluorescein.

Batch No.*	Pre – Dye Reading	Post – Dye Reading
1	0.006	0.005
2	0.005	0.002
3	0.007	0.008
4	0.004	0.004
5	0.003	0.005

*Note each batch is comprised of 10 samples with the reading recorded as the mean result of each set.

Table 3. Daily Inoculation 1 Spray into *S. aureus* Culture Bottle.

Date	Spray Sterility Check (pre inoculation) 48 hrs	Nozzle sterility Check 1 st	Nozzle Sterility Check 2 nd	Bacterial count/l	Post inoculation Spray culture 48 hrs (fresh nozzle)
Day 1	NG	SC STE/DIPS	NG	10 ⁸	NG
Day 3	NG	SC skin	NG	10 ⁸	NG
Day 9	NG	SC skin	NG	10 ⁸	8 colonies <i>S. aureus</i>
Day 17	NG	NG	SC skin	10 ⁸	NG
Day 19	NG	NG	SC skin	10 ⁸	NG
Day 24	NG	NG	NG	10 ⁸	NG
Day 34	NG	NG	NG	10 ⁸	NG
1 spray bottle multiple inoculation over a 1 day period (30 sprays)					
11.15	NG	1 col skin	NG	10 ⁸	NG
11.45	NG	NG	NG	10 ⁸	NG
12.30	NG	1 col skin	NG	10 ⁸	NG
13.00	NG	1 col skin	NG	NG	NG
14.30	NG	1 col skin	2 cols skin	NG	NG
17.00	NG	2 cols	NG	NG	NG

Bacterial count: >25 colonies = 10⁸ /L, NG = No Growth, col= colony, SC = scanty

Table 4. Daily Inoculation 34 Spray into *S. aureus* Culture Bottle.

Date	Spray sterility check (pre inoc) 48 hrs inc	Nozzle sterility check 1 st	Nozzle sterility check 2 nd	Bacterial count	Post inoculation spray culture 48 hrs (fresh nozzle)
Day 1	NG	2 cols skin	3 cols skin	10 ⁸	NG
Day 3	NG	1 col skin	3 cols-asp fu	10 ⁸	NG
Day 9	NG	1col skin	NG	10 ⁸	NG
Day 17	NG	1 col skin	NG	10 ⁸	NG
Day 19	NG	NG	3 cols skin	10 ⁸	NG
Day 24	NG	SC skin	SC skin	10 ⁸	NG
Day 34	NG	NG	NG	10 ⁸	NG
30 spray bottle multiple inoculation over a one day period (30 sprays)					
11.15	NG	SC skin	SC skin	10 ⁸	NG
11.45	NG	SC skin	SC skin	10 ⁸	NG
12.30	NG	SC skin	SC skin	10 ⁸	NG
13.00	NG	SC skin	SC skin	10 ⁸	NG
14.30	NG	SC skin	SC skin	10 ⁸	NG
17.00	NG	SC skin	SC skin	10 ⁸	NG

36-day period using 1 or 30 sprays gave negative cultures with the exception of day 9 - one spray post inoculation sterility check. Subsequent pre- and post inoculation sterility did not show any growth. This isolated result may be a result of laboratory contamination via aerosol production. Repeating the procedure 6 times over a 5.5 hour period also yielded no culture growth. Patients are sprayed once with the Xylocaine, repeating the procedure with 30 sprays demonstrated that the procedure was not a risk to patients in doses far in excess of those administered.

The Xylocaine and the disposable tips are stored at room temperature prior to use. All of the pre inoculation sterility checks did not show any growth, the medium therefore can be stored at room temperature without presenting a cross infection risk to patients.

The nozzles are not sterile. Nozzle sterility checks did not show any growth or only scanty skin flora and therefore do not appear to pose a cross infection risk. The dye experiment also did not demonstrate any evidence of contamination.

CONCLUSION

Using multiple use anaesthetic spray with disposable nozzles for each patient should not pose a cross infection risk through backflow to the bottles.

ACKNOWLEDGEMENTS

Cathy Hatch, Senior Microbiology Technician, Tameside Hospital and Tony Sivner, Chief Pharmacist, Tameside Hospital.

AUTHORSHIP CONTRIBUTIONS

Both authors have played a significant contribution to the paper. Mr Karagama designed the study including methodology and analysis, Mr Rashid was involved in developing the methodology, was involved in data collection, and both were involved in the drafting and analysis aspects of the paper.

CONFLICTS OF INTEREST

None declared.



Figure 1. Image of the spectrophotometer together with Xylocaine spray and dyes.



Figure 2. Image of the dyes close up.



Figure 3. Image of nozzle into staph solution set up.

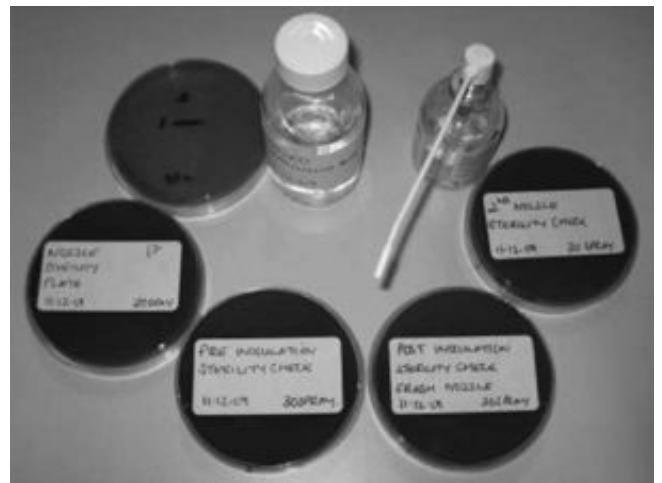


Figure 4. Image of blood agar plates at various check points.

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Corrected Proof