ORIGINAL ARTICLE

Can the use of 70% Isopropyl Alcohol Swab or Aspiration using 5 µm Filter Straw® reduce Bacterial Contamination of Fentanyl Solution used for Regional Anaesthesia?

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SUMMARY

This prospective study aimed to determine the extent of contamination of fentanyl solutions used for central neuraxial injection by wiping the neck of the ampoules with 70% isopropyl alcohol swabs (Kendall®) before breaking open the ampoules and aspiration of fentanyl solutions using a 5 µm Filter Straw® (B. Braun). In Group A, fifty fentanyl ampoules were wiped with 70% isopropyl alcohol swab prior to opening and the contents were aspirated immediately using a 21G needle and a 5 µm filter straw for culture. The same steps were repeated on the remaining solutions after two hours. In Group B, all the above steps were repeated but without wiping the ampoules with 70% isopropyl alcohol swabs. None of the samples from the wiped ampoules or aspiration using filter straw grew microorganisms. Six percent of the samples from unwiped group grew microorganisms when fentanyl were aspirated using a 21G needle and the contamination increased to 16% when repeated after two hours. Wiping the outsides of the fentanyl ampoules with 70% isopropyl alcohol swabs before opening or aspirating the contents using a 5 µm filter straw has been shown to be equally effective in avoiding bacterial contamination and should be practiced routinely when performing regional anaesthesia.

KEY WORDS:
Fentanyl solution, Isopropyl alcohol swab, Filter straw, Contamination, Regional anaesthesia

INTRODUCTION

Central neuraxial blockades which include spinal, epidural or combined spinal epidural anaesthesia are common procedures performed by anaesthesiologists in the operating theatres for various operations. Infectious complications such as epidural abscess or bacterial meningitis as a result of these procedures are rare but the consequences may lead to paralysis and even death [1-3]. A retrospective study on severe neurologic complications after central neuraxial blockades in Sweden between 1990 – 1999 had estimated the overall incidence of meningitis after spinal blockade to be 1:53,000 [4]. These contaminations come from the patient's skin, the anaesthetic equipment or from the anaesthetist's hair, hand or mouth. It is therefore prudent to perform central neuraxial under aseptic technique to prevent infectious complications. These include washing of hands with an antiseptic solution, wearing a cap, mask, sterile gown and gloves as well as using skin sterilising solutions [5].

Over the last decade, the use of opioid adjuvants such as fentanyl and morphine in combination with local anaesthetic in central neuraxial blocks has increased. Usually the unsterile glass ampoule is cracked open by an assistant and the anaesthetist uses a needle to aspirate the contents. Aspiration of opioids from these non-sterile ampoules has been blamed for infectious complications after central neuraxial blockades [6]. Contamination can occur if the needle touches the non-sterile neck of the ampoule. Tiny glass shards in theory can carry bacteria and may also enter the ampoule as it is opened [7,8].

McConaghy *et al* studied bacterial contamination of non-sterile fentanyl ampoules and found a high incidence of contamination of the solutions with bacteria. The common microorganisms were *Staphylococcus* coagulase-negative, *Micrococci* and *Bacillus mycoides* [9]. Some centres have therefore recommended decontaminating the neck of the ampoule by means of swabbing with alcohol before opening, in-hospital autoclaving, ethylene oxide sterilization of ampoules and the use of anti-bacterial filters in the aspiration process. The efficacy and safety of these techniques remained unknown [7,8,10-13].

In this study, we aim to determine the extent of contamination by wiping the neck of fentanyl ampoules with 70% isopropyl alcohol swab (Kendall®) before breaking open the ampoules and the use of a 5 µm Filter Straw® (B. Braun) in aspirating the contents of the ampoules.

MATERIALS AND METHODS

This study was carried out in the operating theatres of Hospital Kuala Lumpur after approval from both the Ethical and Research Committees of Hospital Kuala Lumpur and Universiti Kebangsaan Malaysia Medical Centre.

One hundred non-sterile glass packaged ampoules of fentanyl citrate (Duopharma) were randomly divided into two groups. In Group A, the upper third of each glass ampoule was wiped with 70% isopropyl alcohol swab (Kendall®) and left to air dry. An assistant then broke open the ampoule by placing the fingers and thumb above the neck of the ampoule without

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Table I: Bacterial growth isolated from fentanyl samples aspirated immediately using needle and filter straw for both groups. Values are expressed in number and percentage in parenthesis

		Group A (Wiped)	Group B (Unwiped)	p value
Needle	Growth	0	3 (6)	0.24
	No growth	50 (100)	47 (94)	
Filter straw	Growth	0	0	1.00
	No growth	50 (100)	50 (100)	

Table II: Bacterial growth isolated from fentanyl samples aspirated 2 hours after opening using needle and filter straw for both groups. Values are expressed in number and percentage in parenthesis

		Group A (Wiped)	Group B (Unwiped)	p value
Needle	Growth	0	8 (16)	0.00*
	No Growth	50 (100)	42 (84)	
Filter straw	Growth	0	0	1.00
	No Growth	50 (100)	50 (100)	

* Significant value $p < 0.05$

gloves. The operator in a sterile gown and gloves, cap and mask then immediately aspirated 0.5 ml of the fentanyl solution by using a new sterile 21G needle attached to a sterile syringe and placed it on a blood agar plate. The above steps were repeated using a new 5 µm Filter Straw® (B. Braun) to aspirate the solution instead of the needle. The filter straw was removed before the solution was transferred to a separate agar plate. Extra precaution was taken by the operator not to touch the neck of the ampoules at any time. After two hours, the above steps were repeated with the remaining fentanyl solution in the opened ampoules.

In Group B, all the above steps were repeated on another fifty fentanyl glass ampoules without wiping them with alcohol swab prior to breaking open the ampoules. All the agar plates were sent to the microbiology laboratory and incubated for 48 hours. The microbiology staffs were blinded to the drawing-up methods.

In this study, α value was determined at 0.05 and the power of study at 80%. Data was analyzed using Fisher's exact test and statistical analysis was performed using SPSS Software version 17.

RESULTS

Samples of fentanyl from Group A (wiped with alcohol swab) did not grow any bacteria in both the needle and filter straw groups. The results were similar in the samples taken after two hours.

Samples of fentanyl that were drawn immediately and after two hours using filter straw from Group B (unwiped with alcohol swab) did not yield any growth. However, organisms were isolated in three samples that were drawn out immediately using the needles in Group B (Table I). Two samples grew *Staphylococcus sp* and one grew *Micrococcus sp*. In the same group after two hours, organisms were isolated from eight samples (Table II). Organisms isolated were *Bacillus sp*. (one sample), *Micrococcus sp*. (three samples) and *Staphylococcus sp*. (four samples). The difference was statistically significant between Group A and Group B in the samples drawn using needles after two hours ($p < 0.001$).

DISCUSSION

Parentally administered drugs such as fentanyl and morphine are prepared in glass ampoules to maintain sterility, but many of these ampoules are not packed in a sterile package. It would be desirable to have these ampoules supplied in sterile packaging as they are routinely used as adjuvants for central neuraxial blockade. A completely sterile-packed ampoule can be placed in the anaesthetist's sterile work area to maintain sterility during central neuraxial blockade. Opioid ampoules however are not supplied in a sterile package in most centres and the need of assistants and extra precautions must therefore be taken to prevent any potential contamination.

Hemingway CJ *et al* examined a total of 100 non-sterile packaged glass ampoules of opioids (93 diamorphine and 7 fentanyl) which were used for spinal and epidural anaesthesia. He found that nine (18%; 95% CI: 10-31%) of the unwiped ampoules grew organisms compared with none (95% CI: 0-9%) from the ampoules which were wiped with alcohol (p=0.004). Organisms grown were micrococcus in five samples, coagulase-negative staphylococcus in three samples and both organisms in one sample. In the second part of his study, he found that most contamination occurred in the unwiped ampoules were further reduced with the use of 5 µm filter straw and only the wiped and filtered group yielded no significant growth. They concluded that wiping glass ampoules with alcohol before opening and use of filter straws should be a routine part of neuraxial anaesthesia [14].

McConaghy *et al* isolated *Staphylococcus* coagulase negative, *Micrococci* and *Bacillus* from fentanyl solution supplied in non-sterile packaged glass ampoules as well as from the insides of the plastic wrapping and labels of the ampoules.

They suggested that attention should be paid to ensure aseptic techniques during regional anaesthesia when using solutions which were not presented in sterile ampoules as their study revealed a high incidence of contamination of the solutions with both skin commensals and pathogens from the non-sterile ampoules and wrappers [9].

In our study, we examined 100 glass ampoules of fentanyl with a total of 400 samples taken for bacterial culture. We found that by wiping the neck of the ampoules with 70% isopropyl alcohol swab prior to breaking open the ampoules, we were able to prevent bacterial contamination of the fentanyl solutions immediately and after being exposed for two hours in the operating room environment. Wiping the ampoules reduced the risk of contamination during accidental contact with the neck of the ampoules during aspiration of the drug and also prevented bacterial contamination of the glass particles which might have entered the ampoules. This was consistent with the findings of Hemingway CJ *et al* [14].

Hemingway CJ *et al* demonstrated bacterial contamination of solution when using a 5 µm filter straw to aspirate the contents from the ampoules which were not wiped with alcohol swab [14]. We however did not manage to isolate any bacterial growth when using this technique. Theoretically, the 5 µm filter straw is not capable of filtering the microorganisms per se as the dimension of the bacteria isolated ranges from 0.5 – 1.0 µm.15 We postulate that the filter straw probably filtered off the organisms that existed in clusters and also those that were attached to the glass particles. We did not culture the glass particles that were filtered.

In our study, 6% of fentanyl solutions aspirated immediately using a 21G needle from ampoules which were not wiped with alcohol grew microorganisms and the incidence increased to 16% from fentanyl solutions that were exposed for two hours. This was indeed not a surprising finding and was consistent with many other similar studies [8,9,14]. Many authors have therefore recommended that wiping glass ampoules with alcohol before opening should be a routine practice for neuraxial anaesthesia. Although the effectiveness of 5 µm filter straws to filter out bacteria was less certain, they were able to prevent aspiration of larger non-contaminated particles [7,16]. Many other authors have recommended the use of a 0.22 µm bacterial filter during aspiration of drugs to ensure sterility when used for regional anaesthesia [13,17,18] or double-wrapping the ampoules for sterilization with ethylene oxide [13].

CONCLUSION

We conclude that wiping the neck of the fentanyl ampoules with 70% isopropyl alcohol swab before breaking them open or aspirating the contents using a 5 µm filter straw is equally effective in preventing contamination of the fentanyl solution used for central neuraxial blockade. To reduce the possibilities of contamination, we propose that ampoules of fentanyl should be wiped with 70% isopropyl alcohol swabs before being opened and/or usage of a filter straw to aspirate the contents. Solutions should be used immediately and remaining portions should be not be used at a later time. This should be a routine practice during preparation of drugs for neuraxial injections.

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