



Research article

The impact of needle size and angle on rubber coring after multiple puncturing of multi-dose propofol vial rubber stoppers

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ABSTRACT

Background: Multiple puncturing of the rubber stoppers of multi-doses vials can produce a rubber core. Propofol is one of the multi-dose anesthesia frequently used for sedation and induction of general anesthesia, and a previous study reported a high incidence of rubber coring in propofol vials but no study has yet reported the factors that affect rubber coring.

Objective: To investigate the variables which have an impact on rubber core contamination after the puncturing of rubber stoppers of multi-dose propofol vials using various sizes of needles and different angles of piercing.

Materials and methods: An experimental study which involved puncturing the rubber stoppers of 50 ml propofol vials with needles of various sizes (18G, 20G, 21G) and at different angles of puncture (45° and 90°). The particles occurred in the vials in each situation were evaluated under the microscope, including the number, width and length. Sizes of the needle and degrees of puncture were evaluated to determine the cause of coring.

Results: Rubber coring occurred in 26 out of a total of 150 samples (17.33%). Comparing the incidence of coring by needle size, the 18G needle produced the highest number (38%, P-value < 0.01). Especially, puncturing with 18 gauge needle at 45° (56%, P-value 0.01).

Conclusion: Large-bore needle was the factor that impacted rubber coring after puncturing through the rubber stopper of the multi-dose vial, regardless of the angle of puncture.

1. Introduction

Anesthesia requires a variety of intravenous medications that are housed in ampules or vials. Multiple puncturing of the rubber stoppers of multi-doses vials can produce a rubber core, a small foreign object floating in the liquid medication (Figure 1). The incidence of coring of rubber stoppers has been estimated to range overall from 0-40%, depending on the study methods and the medical devices used to pierce the rubber stopper [1, 2]. A previous study reported that particles larger than 6–8 μm in diameter are able to enter the patient's vessels. These particles can obstruct and diminish blood flow to specific organs, causing a pulmonary embolism (PE) [3] or stroke, may reduce tissue capillary perfusion, and possibly cause vascular inflammation resulting in infection and allergic reactions. These complications adversely affect the patients' health, the cost of their treatment, and their length of hospitalization.

Propofol is one of the multi-dose anesthesia frequently used for sedation and induction of general anesthesia, and a previous study reported a high incidence of rubber coring in propofol vials [4]. No study

has yet reported the factors that affect rubber coring of multi-dose propofol vials; therefore, we aimed to investigate the variables which have an impact on rubber core contamination after the puncturing of rubber stoppers of multi-dose propofol vials using various sizes of needles and different angles of piercing.

2. Materials and methods

2.1. Methodology

This was an experimental study which involved puncturing the rubber stoppers of 50 ml propofol vials which contained 25 ml of sterile water (propofol emptied out of the vials, then filled again with sterile water before conducting the punctures) with needles of various sizes (18G, 20G, 21G) and at different angles (45° and 90°). The bevel was set to be an up position for all tests. The compression force for each puncture was set at 10 N, regulated by the tensile strength tester in order to standardize each puncture [5]. The rubber stoppers were punctured 3 times at different

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Figure 1. A small particle of rubber stopper floating in propofol.

sites for one set, 25 sets for each of 6 settings: 18G and 45°; 18G and 90°; 20G and 45°; 20G and 90°; 21G and 45°; and 21G and 90°.

After the third puncturing of each stopper, 1 ml of sterile water was flushed through the needle into a propofol vial using a 3ml-syringe connected to the needle. The fluid in the vial was then filtrated by a 0.8-micron pore size vacuum filter unit. The evaluation was done under a stereomicroscope at 100x magnification (picture 2).

2.2. Materials

- 1) 4mm thick propofol rubber stopper (B. Braun, Germany)
- 2) 50 ml propofol vials (B. Braun, Germany)
- 3) Needles [5]: 18-gauge x 1 inch metallic beveled sterile hypodermic needles (Nipro Corporation, Japan. Product code AH+1825-1M) 20-gauge x 1 inch metallic beveled sterile hypodermic needles (Nipro Corporation, Japan. Product code AH+2025-1M) 21-gauge x 1 inch metallic beveled sterile hypodermic needles (Nipro Corporation, Japan. Product code AH+2125-1M)
- 4) 3 ml syringe
- 5) 0.8-micrometer pore size cellulose nitrate white gridded filter
- 6) Vacuum filter unit
- 7) Texture analyzer model CTX with software Texture Pro (Figure 2)
- 8) Tensile strength tester: 45 and 90-degree stand (Figure 3)
- 9) 25 ml cylinders
- 10) 250 ml beakers
- 11) Distilled water
- 12) Stereo microscope (Olympus SZH10) with Axiocam

2.3. Statistical analysis

The primary outcome was to determine the incidence of rubber coring, and the secondary aim was to establish the factors which caused it. Data were analyzed using SPSS version 20.0 statistical software.



Figure 2. The particles of rubber stopper were evaluated under the stereo microscope.

Quantitative variables were reported as mean and range while categorical variables were given as count (percentage). Statistical analysis was performed with a non-parametric test (Mann-Whitney, Kruskal-Wallis test) for quantitative variables and Fisher's test for categorical variables, and a value of $P < 0.05$ was considered significant. All analyses were performed with SPSS version 20.0 statistical software.

3. Results

Rubber coring occurred in 26 out of a total of 150 samples (17.33%). The particles of rubber coring were shown in Figure 4. Table 1 reveals the number and size of the coring by needle size and angle of puncturing.



Figure 3. Tensile strength tester: 45-degree stand.

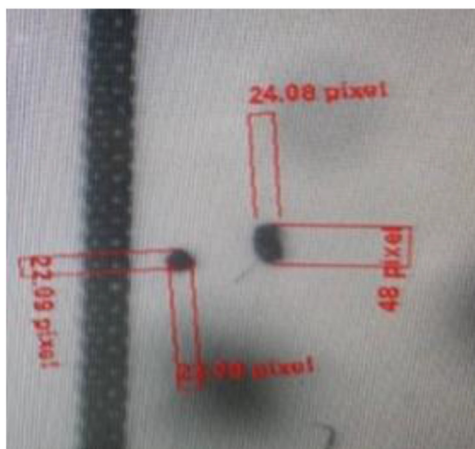


Figure 4. Texture analyzer model CTX with software Texture Pro.

Comparing the incidence of coring by needle size, the 18G needle produced the highest number as shown in Table 2.

The numbers of coring at different angles of puncture are shown in Table 3.

There was no difference in the number of coring in 20G and 21G needles when punctured at angles of 45 and 90°. There was the highest incidence of rubber coring when punctured with 18 gauge needle at 45°.

The correlation between needle size, angle of puncture, and size of coring is shown in Table 4. There was no difference in the size of the coring that occurred while using the 18G, 20G, and 21G needle to puncture at 45 and 90°.

4. Discussion

Propofol (Bromobutyl rubber stopper) is an anesthesia commonly used in practice which is housed in a multi-dose vial. Multiple puncturing through the rubber stoppers of the vial can produce a rubber core which is a small foreign object floating in the liquid medication [1, 2].

Wani et al. [4] studied the incidence of coring with blunt and sharp hypodermic needles and found that more coring occurred when using a blunt needle. The study also reported the incidence of rubber coring in various anesthesia: 58% for propofol, 17.8% for rocuronium, and 11% for succinylcholine. We studied the puncturing of a bromobutyl rubber stopper (Propofol) with a sharp needle.

Chennell et al [1] reported that thicker rubber stoppers (4mm) had a higher incidence of coring compared to thinner ones (2mm). They also stated that using an angle of needle insertion of 45° reduced particle formation.

Table 1. Number and size of particles in different situations.

Situation No.	Needle	Degree	Particle n (%)	Width (millimeters) Mean ± SD	Length (millimeters) Mean ± SD
1	18	45	14/25 (56%)	0.049 ± 0.020	0.080 ± 0.039
2	18	90	5/25 (20%)	0.044 ± 0.022	0.051 ± 0.018
3	20	45	2/25 (8%)	0.051 ± 0.011	0.082 ± 0.036
4	20	90	2/25 (8%)	0.028 ± 0.044	0.040 ± 0.088
5	21	45	0/25 (0%)	-	-
6	21	90	3/25 (12%)	0.042 ± 0.031	0.055 ± 0.030

Table 2. The incidence of coring according to the needle size. The data were considered significant when P-value < 0.05.

	No.18G	No.20G	No.21G	P-value
Number of particles	19 (38%)	4 (8%)	3 (6%)	< 0.01

Table 3. The correlation between needle size and angle of puncture. The data were considered significant when P-value < 0.05.

	45°	90°	P-value
No. 18G	14 (56%)	5 (20%)	0.01
No. 20G	2 (8%)	2 (8%)	0.64
No. 21G	0 (0%)	3 (12%)	0.07

Roth et al [6] suggested puncturing at an angle of 45–60° while using a large-bore needle to reduce the size of the particle that resulted. The risk of coring may be reduced by using the smaller needle compared to the larger one, however, seeing this small particle is more difficult [7]. Another important factor is the bevel position, Rase et al [8] reported the bevel up position resulted in fewer particles than the bevel down position. To date, there has been no study to compare needle size with the occurrence of particles.

In our study, we hypothesized that needle size and angle of puncture were the factors that affected the occurrence of particles. We compared 18G, 20G, and 21G needles, which are the most commonly used in practice as they can achieve a good flow of fluid. We found that large-bore needles were the main cause of particle occurrence. The 18G needle yielded a significantly higher number of particles than the 20G and 21G ones (p-value < 0.01).

Comparing the angles of puncture at 45 and 90°, there was no difference in the coring that occurred while utilizing similar-size needles. This differed from the findings of previous studies by Chennell and Roth who reported that puncturing at 45 degrees of angle can reduce the coring, while completely eliminating was found by using a blunt metal needle [1]. Basically, 90 degrees of puncture should result in the least damage to the stopper because it has the shortest length as well as the least cut surface diameter when traveling through the rubber stopper. In practice, however, the difference is too small to be statistically significant.

The needle size and angle of puncture did not affect the size of the coring. The coring that occurred from all needle size was small enough to pass through even the 21G which was the smallest in this study in which we mocked up the puncturing using just one puncture for each rubber stopper. In real-life practice, there may be more than one puncture for each stopper, which means that there is a higher chance of coring occurring in the needle lumen or the container. Therefore, we would suggest using a small size needle to puncture through the rubber stopper only once in order to decrease the incidence of coring. Furthermore, it should be noticed that this study used the propofol which manufactured by B. Braun facilities in Germany, however, propofol was distributed from several manufacturers, thus the rubber stopper can be different in material and property that can affect the different incidence of the coring. Apart from the rubber stopper itself, there are several factors that can affect the coring including the type of needle, bevel position, and puncture method. There were several studies that reported the occurring of coring, the incidences were different according to the medication vials or containers, methods of puncture, and the needle types [9, 10, 11, 12].

Table 4. The correlation among needle size, angle of puncture, and size of coring.

Angle of puncture	Needle size	Coring; width (mm) Mean ± SD	Coring; length (mm) Mean ± SD
45°	18G (1.2 mm × 25 mm)	0.049 ± 0.020	0.080 ± 0.039
	20G (0.9 mm × 25 mm)	0.051 ± 0.011	0.082 ± 0.036
	21G (0.8 mm × 25 mm)	0	0
	P-value	0.90	0.95
90°	18G (1.2 mm × 25 mm)	0.044 ± 0.022	0.051 ± 0.018
	20G (0.9 mm × 25 mm)	0.028 ± 0.044	0.040 ± 0.088
	21G (0.8 mm × 25 mm)	0.042 ± 0.031	0.055 ± 0.030
	P-value	0.73	0.65

5. Conclusion

Large-bore needle was the factor that induced a higher rubber coring rate after puncturing through the rubber stopper of the propofol multi-dose vial that were tested in this study, regardless of the angle of puncture.

Declarations

Author contribution statement

Thanyarat Chotikawanich: Conceived and designed the experiments; Analyzed and interpreted the data; Contributed reagents, materials, analysis tools or data; Wrote the paper.

Thipaporn Kamme, Sirikarn Khantee: Performed the experiments; Analyzed and interpreted the data; Wrote the paper.

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Data availability statement

Data included in article/supplementary material/referenced in article.

Declaration of interests statement

The authors declare no conflict of interest.

Additional information

No additional information is available for this paper.

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