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Original Research Article

INVESTIGATION OF GLASS PARTICLES REMAINING IN BROKEN AMPOULES WITH OR WITHOUT THE USE OF AUXILLIARY EQUIPMENTS

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Abstract:

The injection of drugs in ampoules, which is one of the methods of drug administration, is one of the most frequently used treatment methods by nurses. The frequency of use of this method may be higher depending on the type and duration of the disease. In our research, the specialist nurse broke the same type of medicine ampoule, paying attention to the same speed and time, using the recommended appropriate breaking method and the ampoule breaker. Microscopic methods were then used to examine the presence and shape of the glass remaining in the ampoule. The drug content was examined using a measuring slide and a microscope. It was observed that the use of the ampoule breaker resulted in the formation of more, but smaller, pinewood particles in the medicine, whereas manual crushing resulted in the formation of a small number of larger mm sized pieces. It was observed that there was an average of 6 differently shaped glass pieces of 0.034 mm in 10 ml of the medicine used in this study when the ampoule breaker was used. It was also observed that the ampoule broken by the nurse contained an average of 4 pieces of glass 0.2075 mm in size. The qualitative and quantitative detection of glass fragments using the method applied in this study is scientifically valuable and makes a valuable contribution to the literature in terms of the health of both drug users and practitioners.

Keywords: Ampoule breaker, Injection, Microparticles, Occupational health and safety.

1. INTRODUCTION

Medication administration, which is one of the statutory duties of nurses, is carried out in many ways. One of these ways is parenteral administration. This route, which is often used in practice, allows the drug to be delivered directly or indirectly to the cardiovascular system[1]. For parenteral drug administration, glass containers called ampoules, invented by a French pharmacist in the 19th century, are used to keep liquid drugs sterile for single use. Ampoules are often preferred in areas where drug use is common, such as intensive care units, emergency departments, and operating theatres, for reasons such as the ability to prepare drugs according to dose, durability, and sterility. In addition to the advantages, the fact that the vials are made of glass and need to be broken by a nurse to use the medication inside also poses some risks [2]. A significant proportion of sharps injuries to nurses are caused by glass fragments from breaking an ampoule. Cuts on the hands and fingers of nurses due to the failure to break the ampoule neck properly cause the disruption of skin integrity and create an entry point for microorganisms [3]. In a review of studies conducted with nurses, Erkoc et al. found that all participants were injured at least once when breaking an ampoule [4]. In the study of Omac et al. [5], the percentage of those who reported breaking glass ampoules as a cause of stabbing injuries was 12.8%, and in the study of Ozlu et al.[6], it was 32.5%. In the study by Kahriman et al.[7], 20.8% of the participants reported that they were injured while breaking the ampoule, diluting the medicine, and withdrawing the medicine from the ampoule. In the study by Raza et al.[8], 75.3% reported that breaking the ampoule was the cause of injury. Saad and Hussein[9] found in their study that glass, such as ampoules, caused 25% of cutting tool injuries. According to Belachew et al.[10], 41.7% of the reported cutting injuries occurred during ampoule breakage. Glass particles formed when the ampoule is broken are a serious problem not only for nurses but also for patients. If broken macroparticles are visible, they are removed without applying the medication. However, micro glass particles, which are invisible to the naked eye, fall into the ampoule and cause contamination of the medication. This puts patients at risk of infection. In addition, intravenous administration of glass particles into the patient's cardiovascular system can lead to complications such as pulmonary thrombus, micro embolism, and infusion phlebitis. Intramuscular administration may result in complications such as pain, bleeding, or hematoma formation [11,12]. This risk is increased in patients receiving long-term parenteral therapy and in vulnerable groups such as children and the elderly[2]. In a study where ampoules of different sizes were examined by breaking them in different directions and using different manual techniques, glass contamination was found in 449 out of 672 ampoules. According to this study, although the method used by nurses to break ampoules affects the number of glass particles, contamination cannot be completely prevented[13]. The use of a filter is recommended to prevent complications when administering medication to patients in glass ampoules. However, the cost of these filters is high[14], and a study found that the syringe filter used could not completely prevent glass particle contamination[12]. To prevent these problems caused by glass particles formed during ampoule breaking, ampoule breakers have been produced by some companies[3].

This study aimed to compare the glass particles remaining in the drug by breaking the ampoule form of a drug frequently used in the clinic with and without the ampoule breaker, and thus to investigate the usability of the ampoule breaker.

2. MATERIAL and METHOD

2.1 Institution and Location

This study was conducted at Sakarya University of Applied Sciences, located in Sakarya, Turkey.

2.2 Chemical and Reagents

In our study, drug ampoules (50 pcs) made of brown glass from a randomly selected company and belonging to the group of nootropic drugs commonly used in the clinic were used.

2.3 Equipment and Devices

A plastic ampoule breaker collar, compatible with 5-10 mL ampoules supplied by Millipore, was used as an ampoule breaker. Additionally, a Thoma device, a drying oven for sterilization, and a 10 mL 21-gauge sterile syringe were utilized.

2.4 Study Design

This study was designed as an experimental study to investigate glass particles remaining in broken ampoules with or without the use of auxiliary equipment.

2.5 Study Parameters

Twenty-five ampoules were broken using the breaker device (Figure 1) by an experienced nurse (with at least 5 years of experience in the field) and twenty-five ampoules were broken without using the device, according to clinical practice procedures [15], from the part marked in the opening direction. The broken versions of the ampoules are shown in Figure 2.

The Thoma slides were cleaned with 70% alcohol and sterilized in an oven, and the Thoma slides were photographed before and with the sample before dropping the sample to eliminate errors due to scratches on the slide and incorrect sterilization. The entire contents of the ampoule were then drawn into a 10 ml 21-gauge sterile syringe, which is commonly used in the clinic. Randomly, 250 µl of the syringe contents of each ampoule were dropped separately onto standard striped Thoma slides (Figure 3).

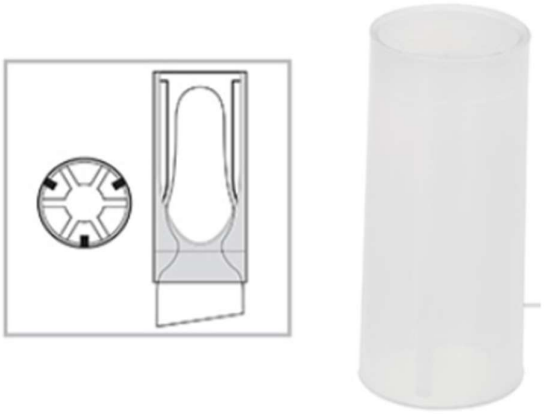

Fig. 1. Plastic ampoule breaker

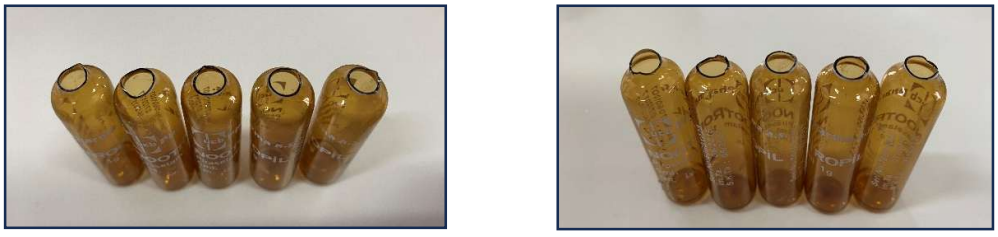

Fig. 2. Broken states of the ampoules, a; without using apparatus, b; using the apparatus

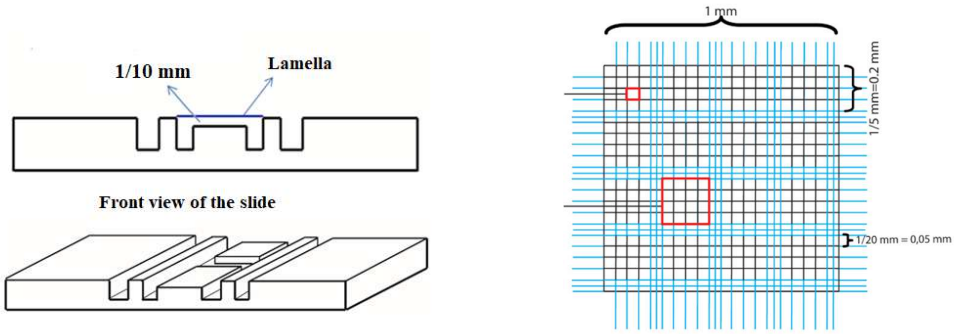

Fig. 3. Standard striped Thoma slide and dimensions

2.6 Statistical Analysis

The samples were examined under a microscope at 10 x magnifications using the field scanning method. The number of glass particles observed was recorded.

3. RESULTS

As a result of our study, the ampoule contents of a total of 50 samples, 25 samples broken with the apparatus and 25 samples broken without the apparatus, were examined. While an average of 6±1 glass particles were observed in the 25 ampoule samples broken with the apparatus, a total of 4±1 glass particles were observed in the samples broken without the apparatus.

The dimensions of these pieces of glass were calculated in 2 dimensions using the standard lines of the Thoma slide. As a result of this calculation, the glass particles observed in the ampoules broken by the apparatus are of sizes 0.150, 0.025, 0.025, 0.002, 0.002 and 0.002, and their average size is 0.0344 mm (Figure 4). The glass particles in the ampoules that were not broken by the apparatus were 0.430, 0.350, 0.025, and 0.025 in size, and their average size was 0.2075 (Figure 5). The dimensions of the total glass particles are given in Table 1.

Table 1. Sizes of glass particles in broken ampoules

	Total number of glass particles	**Average sizes of glass particles**
Ampoules broken by device 25pcs/10ml	6 ± 1 pcs	0,0344 mm
Ampoules broken by hand 25pcs/10ml	4 ± 1 pcs	0,2075 mm

Fig. 4. Glass particles in ampoules broken with the apparatus

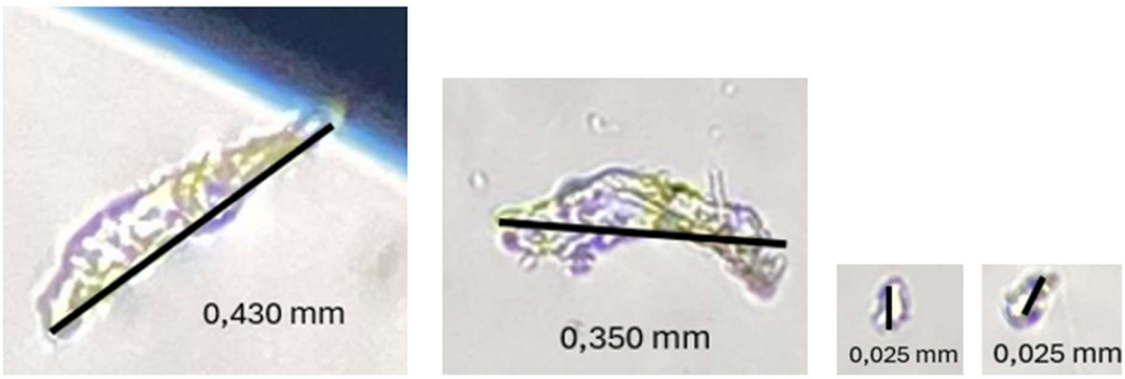

Fig. 5. Glass particles in ampoules broken without using the apparatus

4. DISCUSSION

In the study, the data obtained by breaking the ampoules of a drug commonly administered in the clinic, using an ampoule-breaking device or by a specialist nurse, and comparing the glass particles remaining in the drug drawn into the syringe, were discussed in the light of the literature. During the preparation of ampoule-form drugs used in the clinic, micro and macro glass particles are formed when the ampoules are broken at the neck. These glass particles cause both contamination of the drug and administration of glass particles to the patient via the parental route. Injected glass particles cause a severe inflammatory response and systemic complications such as thrombus, embolism, tissue necrosis, sepsis, and end-organ damage [11, 16-17]. For these reasons, it is very important to determine whether there is a piece of glass in the medicine.

As a result of the literature review, it was understood that there were not many studies in this area and that the regulations to be made in this area would lead to significant health improvements in terms of protecting the health of both patients and healthcare workers. As both studies involved sampling and counting with a needle tip, it was clear that the number of glass fragments observed could be given to the patient with the medication. As a result of the study, it was determined under a microscope that there was glass particle contamination due to the breaking of the drug in ampoule form. It was found that there were fewer glass particles in the ampoules broken by hand by the nurse than in the ampoules broken by the machine. However, when these glass particles were examined for size and shape, they were both larger and in shapes that could cause more damage to the cell wall when used intravenously.

In addition, although the number of jars in the medicine was increased by 50% in applications using the device, it was found that the average size of these jars was 6 times smaller and they were spherical in shape. Another negative aspect is that glass particles cause cuts and injuries to the hands of healthcare professionals who prepare the medicine[13]. Among healthcare professionals, nurses are the most frequent victims of stab wounds, and it is known that most of these injuries occur during drug administration[16,18]. To prevent these injuries, devices of different sizes have been developed from many different raw materials. In our study, fewer glass particles were formed in the ampoules broken by the manual method using a cotton ball in an outward direction than in those broken by the ampoule-breaking apparatus. Like our study, Chiannilkulchai and Kejkornkaew's study of 56 nurses working in a university hospital found that breaking ampoule medicines outwards with a cotton ball, rather than manual breaking methods, resulted in the least amount of glass particles [13].

Another study in the literature evaluated nurses' breaking of ampoules using a manual technique and found that 73 of 672 gloves worn by nurses were damaged (glove tears) and the lowest injury rates were obtained using the method of breaking the ampoule outwards using the syringe package[19]. In the study by Rahayu et al. [20], which involved 100 nurses and compared the wooden 'ampoule breaker' with the manual breaking technique, it was found that the ampoules were easier to break with the developed breaker, that the use of the breaker reduced hand injuries and that it was safer for nurses.

Erkoc Hut and Yazici reported that 0.94-90.70 µm glass particles were found in 94% of samples taken from ampoules of medicines broken by nurses using filtered syringes and unfiltered 21 or 22 G needles and that the use of syringe filters prevented the removal of glass particles parenterally[12]. This was found to reduce the risk of exposure. These particle sizes are like the sizes we measured. In the meta-analysis study, it was found that glass particles were generated by ampoule breakage in most articles reviewed, and that the use of syringe filters resulted in an 83% reduction in the total number of particles (>10 µm).

Zhang et al. [21] showed that breaking the ampoule form of lidocaine, an anesthetic used for minor dermatological surgery, by nurses was safe and beneficial in reducing injury when broken with the assistance of the tube part of the syringe compared with the manual method. In our study, the reason why fewer glass particles were found in ampoules broken by hand than in those broken with a device may depend on the nurse's breaking technique, the structure of the ampoule, and the raw material of the device used. The European Parenteral Medicines Association (PDA) organizes training for healthcare professionals to share up-to-date information on the potential harmful effects of particles on patients and to actively participate in research activities. One such innovation is the practice of preventing exposure to microparticles by filtering along the intravenous infusion line. While the 5.0 µm in-line filter reduces coarse particles (glass, rubber, plastic), the finer 0.2 and 1.2 µm in-line filters prevent contamination from airborne particles and 1-3 µm microorganisms[23]. In their study, Villa et al. (22) applied filtration along the infusion line to prevent glass particles from being administered intravenously to patients. It was found that patients in the postoperative period receiving intravenous treatment with the in-line filtration method have lower rates of phlebitis development than patients with standard venous cannulae, and the life of the cannula is extended. In the study by Schmitt et al.[23], it was found that 0.2 and 1.2 µm in-line filtration applied to patients receiving parenteral drug therapy in the intensive care unit could be associated with less organ dysfunction and less inflammation. These studies in the literature provide evidence that different filtering techniques can prevent glass particles from being delivered to the patient, even after the vial has been broken.

As a result of our research, it was clear that an assessment should be made in terms of patient safety and occupational health during the use of ampoules. Literature studies have shown that the use of an ampoule breaker can prevent many practitioners from being injured when breaking ampoules. However, it is also known that the fragments formed when the ampoule is broken can be removed by using a needle filter. When these two measures are taken together, an important step is taken in terms of

health. As a result, it was understood that if the ampoule were to break during drug administration, the glass would remain in the drug content in both methods. It is therefore important to use packaging such as bottles or vials instead of ampoules for appropriate drug formulations, to use a filter device in the ampoule or needle, or to manufacture ampoule packaging that leaves fewer glass fragments in the drug content when broken. The use of a vial breaker is of great importance to the health of the practitioner.

Glass particles delivered to the patient because of parenteral drug administration can cause life-threatening complications. To prevent these complications, the level of knowledge of healthcare professionals should be increased and innovative intervention strategies should be developed to improve the awareness of healthcare professionals. Although the development of ampoule breakers and the use of syringe filters and infusion filters are partially effective in preventing exposure to glass particles, further research is needed to completely remove the particles.

References

1. Korkmaz E, Karagozoglu S. Site selection in intramuscular injection, a nursing intervention: Current knowledge and approaches. Anadolu Academy Journal of Social Sciences.2021;3(2):350-357.
2. Sogut NN, Hut AE. The hidden threat in parenteral drugs: Glass particle contamination. Gumushane University Journal of Health Sciences. 2022;11(3):1265-1273. https://doi.org/10.37989/gumussagbil.1003849
3. Hut AE. An innovative study in nursing: Medical ampoule opener. Journal of Research and Development in Nursing. 2018;20(1):57-61.
4. Erkoc A, Tan M, Yurugen B, et al. Nurses' opinions about the frequency of injuries while breaking medication ampoules and ampoule breakers. Gumushane University Journal of Health Sciences. 2015;4(3): 412-420.
5. Omac M, Egri M, Karaoglu L. Occupational sharps injuries and hepatitis B immunization status in nurses working in Malatya central hospitals. Journal of Turgut Ozal Medical Center. 2010;17(1):19-25.
6. Ozlu ZK, Yayla AC, Gumus K et al. The safe use of sharps and needlestick among nurses working in surgical clinics, Turkey. Eurasian Journal of Emergency Medicine. 2016; 15(4):187-193. https://link.gale.com/apps/doc/A486319631/AONE?u=anon~a70aed2&sid=googleScholar&xid=d19fac28
7. Kahriman I, Polat S, Ede G, et al. Injury experiences and precautions taken by nurses working in pediatric wards towards penetrative/incisive tools. International Journal of Caring Sciences. 2016;9(2): 569-578.
8. Raza V, Parel JT, Kale P. Occupational exposure to blood and body fluids and their knowledge regarding post exposure prophylaxis among nurses in a tertiary care hospital at national capital of India. International Journal of Advance Research in Medical Surgical Nursing. 2022:4(1):36-42. http://dx.doi.org/10.33545/surgicalnursing.2022.v4.i1a.86
9. Saad WI, Hussein D A. Prevalence of sharps injuries among nursing staff at hospitals in Kirkuk city. Kufa Journal for Nursing Sciences.2020;10(2):25–30. https://doi.org/10.36321/kjns.vi20202.2240
10. Belachew YB, Lema TB, Germossa GN. Et al. Blood/body fluid exposure and needle stick/sharp injury among nurses working in public hospitals; Southwest Ethiopia. Frontiers in Public Health. 2017; 5:299. https://doi.org/10.3389/fpubh.2017.00299
11. Unahalekhaka A, Nuthong P. Glass particulate adulterated in single dose ampoules: A patient safety concern. Journal of Clinical Nursing. 2023; 32(7-8): 1135-1139. https://doi.org/10.1111/jocn.16336
12. Erkoc H A, Yazici ZA. Glass particle contamination threat in nursing practice: A pilot study. Journal of Advanced Nursing, 2021;77(7):3189-3191. https://doi.org/10.1111/jan.14847

13. Chiannilkulchai N, Kejkornkaew S. Safety concerns with glass particle contamination: Improving the standard guidelines for preparing medication injections. International Journal for Quality in Health Care. 2021;33(2): https://doi.org/10.1093/intqhc/mzab091
14. Fry L. Glass micro-particulate contamination of intravenous drugs–should we be using filter needles. Australian Medical Student Journal. 2015; 6(1): 20-22.
15. Sabuncu N, Alpar SE, Karabacak U. et al. Fundamentals of nursing: A guide to essential skills (2nd ed.). Istanbul Medical Bookstore. 2015.
16. Sun J, Qin W, Jia L, et al. Investigation and analysis of sharp injuries among health care workers from 36 hospitals in Shandong Province, China. BioMed Research International. 2021: 5698483. https://doi.org/10.1155/2021/5698483
17. Joo GE, Sohng KY, Park MY. The effect of different methods of intravenous injection on glass particle contamination from ampules. Springer Plus, 2016; 5(1): 1-8. https://doi.org/10.1186/s40064-015-1632-0
18. Calikoglu EO, Bedir B, Akcay HB. et al. Needlestick and sharps injuries among nurses at Ataturk University Research Hospital and their practices after injury. The European Research Journal. 2019; 5(1): 128-133. https://doi.org/10.18621/eurj.404827
19. Chiannilkulchai N, Kejkornkaew S. A comparative study of ampoule breaking and resultant injury among registered nurses. Pacific Rim International Journal of Nursing Research. 2020; 24(1): 89-101.
20. Rahayu PT, Asmiati D, Santosa A. Technique to open an ampoule with an Ampoule opener tool. Medisains. 2020; 18(3): 110-112. http://dx.doi.org/10.30595/medisains.v18i3.8371
21. Zhang W, Gu L, Zhang Y. et al. Syringe tube as ampoule opener: A safe, simple, and effective tool in dermatologic surgery. Journal of the American Academy of Dermatology. 2022;86(3): 101–102. https://doi.org/10.1016/j.jaad.2020.05.009
22. Villa G, Chelazzi C, Giua R, et al. In-line filtration reduces postoperative venous peripheral phlebitis associated with cannulation: a randomized clinical trial. Anesthesia & Analgesia. 2018; 127(6): 1367-1374. https://doi.org/10.1213/ANE.0000000000003393
23. Schmitt E, Meybohm P, Herrmann E, et al. HIn-line filtration of intravenous infusion may reduce organ dysfunction of adult critical patients. Critical Care. 2019; 23:1-11. https://doi.org/10.1186/s13054-019-2618-z