الهيئة العامة للغذاء والدواء
Saudi Food & Drug Authority

Post-market clinical evaluation for the Safety and the Current Local Practices of Ultrasound Gel Products

Study Category:

☑ Post-market evaluation study (دراسة تقييم سريري)

☐ Risk analysis study (دراسة تحليل مخاطر)

BACKGROUND

Ultrasound gel is a conductive medium that creates a bond between the skin and the ultrasound probe [1]. Because ultrasound sound waves have a hard time traveling through the air, the gel prevents any extra air space between the probe and the skin to produce a clear image. Ultrasound gel utilizes a basic physics principle where sound waves tend to carry very well through an aqueous or watery medium. Furthermore, ultrasound gel works as a lubricant and improves the acoustic transmission of sound waves [2].

Recently, several reports showed some safety issues and adverse events related to the ultrasound gel. Also, the ultrasound gel was one of the most safety alerts that affected Saudi Arabia in 2021. According to the Public Health England guidance, contaminated ultrasound gel has been associated with infection outbreaks in various settings and identified as a potential vector for infection [3]. Additionally, ultrasound gel is one of the most commonly reported sources of Burkholderia cepacia complex (Bcc) outbreaks; several studies reported hospital outbreaks due to contaminated ultrasound gel [4]. This study aims to evaluate the safety and current local practice of ultrasound gel products in Saudi healthcare providers**.**

EVALUATION OUTCOMES

Part I: Methodology

This is a survey-based study, an online survey was prepared in order to evaluate the safety and current local practice of ultrasound gel, and it was distributed to 24 Saudi healthcare providers. Furthermore, the incidents related to the ultrasound gel were reviewed, considering the local (NCMDR) and international databases.

Part II: Results

A- Feedback of Saudi users

Feedback from the Saudi users were obtained through an online survey; a number of 18 responses were received from Saudi healthcare providers out of 24 healthcare providers. The major findings of this study indicate that the awareness level of healthcare providers regarding the ultrasound gel is high and compliant with the requirements of SFDA, which represents in the following findings:

- 94% of Saudi users don't use the refilled ultrasound gel.
- 89% of Saudi users check the expiration date on ultrasound gel bottle before using it.
- 50% of Saudi users report any safety issues regarding ultrasound gel to SFDA and supplier/manufacturer.

On the other hand, 56 % of healthcare providers do not have a specific policy and procedure for safety issues related to ultrasound gel to apply any corrective actions to reduce or avoid the appearance of these issues. Moreover, 22% of healthcare providers stated that patients experienced safety issues after using ultrasound gel; most cases were bacterial contamination.

The healthcare providers suggest some recommendations in order to ensure patient safety, which represents in the following points:

- It must be clear that this gel is intended for the ultrasound device only.
- Following the good infection prevention practice.
- Gel should be stored according to the manufacturer's instructions in an area that is dry and away from potential sources of contamination, and dispose of the container if it appears soiled, is damaged, or is out of date.

B- NCMDR data of ultrasound gel products

At the end of 2021, Saudi Food and Drug Authority (SFDA) issued a safety alert due to the risk of bacterial contamination in the affected lots with Burkholderia cepacian complex (Bcc).

Part III: Conclusion

The awareness of the importance of reporting the complication of the ultrasound gel to the Saudi FDA is very essential, 50% of healthcare providers report the complications or other incidents or adverse events of ultrasound gel. However, 73% of healthcare providers do not apply any corrective actions to reduce or avoid the appearance of safety issues regarding the ultrasound gel. Moreover, 22% of healthcare providers stated that patients experienced safety issues after using ultrasound gel; most of these cases were bacterial contamination. Therefore, healthcare providers should have a policy and procedure for good infection prevention practice of ultrasound gel products.

SFDA RECOMMENDATIONS

Based on the study findings, the following actions are recommended:

Recommendations for SFDA:

- Issuing a safety communication which includes recommendations for healthcare providers, as follows:
  - Healthcare providers must follow the intended uses of ultrasound gel according to the manufacturer's recommendations.
  - Healthcare providers must store the ultrasound gel according to the manufacturer's recommendations in an area that is dry and away from potential sources of contamination and dispose of the container if it appears soiled, damaged, or is out of date.
  - Healthcare providers must report the incidents or complications of the ultrasound gel to the Saudi Food and Drug Authority (SFDA).
  - Healthcare providers must have a policy and procedure for good infection prevention practice of ultrasound gel products.
  - Healthcare providers must ensure that healthcare workers carry out hand hygiene before and after the use of ultrasound gel.
  - Healthcare providers must check the expiration date on ultrasound gel bottles before using them.

ACKNOWLEDGMENT

This study is authored by Eng. Ali Masmali, who designed the survey, collected, and analyzed data, and wrote up the manuscript of the study. Eng. Abdulmohsen Al-Hajlan verified the study methodology and supervised the study progress. With the appreciation to the post-market clinical evaluation team for their efforts in conducting this work.

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