

Is Your Technetium Generator Eluate Sterile?

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Objective: This study was performed to assess the sterility of multidose ^{99m}Tc generator eluate vials at the end of a working day.

Methods: Expired ^{99m}Tc generator eluate vials were collected over a period of 10 wk and stored until the activity reached background. Four batches of 10 vials each were selected randomly and sent to an independent microbiology laboratory for sterility testing.

Results: No eluate showed any microbial growth after 14 d incubation in growth media.

Conclusion: Retrospective sterility testing of ^{99m}Tc generator eluate confirmed the validity of our departmental protocol for radiopharmaceutical preparation. Sterility testing has become part of our quality control program.

Key Words: technetium-99m generator eluate; sterility; multidose vial

J Nucl Med Technol 2000; 28:94–95

The preparation of ^{99m}Tc cold kits often requires using a portable ^{99m}Tc generator. The daily elution of this generator provides a source of ^{99m}Tc -sodium pertechnetate in a vial that requires multiple sampling. Up to 50 septal penetrations of a ^{99m}Tc eluate vial have been recorded during a workday. Even with good aseptic technique there remains a possibility of microbial contamination of the eluate vial and radiopharmaceutical kits formulated with its contents.

Studies on intravenous anaesthetics, contrast agents and dextrose have shown that microbiological contamination of multidose vials is possible (1–3). Therefore, we had retrospective microbiological testing performed on the eluate of our multidose vials.

MATERIALS AND METHODS

Elution of the Technetium-99 Generator

A portable ^{99m}Tc generator (100 GBq) was delivered routinely to our nuclear medicine department each Sunday before commencement of work on Monday morning. The ^{99m}Tc

generator was eluted according to the manufacturer's directions, which included swabbing the empty elution vial with a skin cleansing swab (Alcwipe®, Promedica, Pymble, NSW, Australia) containing 70% isopropyl alcohol. The septum was allowed to dry before septal penetration with a 21-G needle.

A new needle was attached to the generator elution port and the elution procedure was performed Monday through Friday. The volumes of eluate varied from 6 ml to 10 ml, depending on the required specific activity. A new needle was used each time the generator was eluted.

Radiopharmaceutical Preparation

Radiopharmaceutical kits were prepared routinely with ^{99m}Tc drawn from the elution vial according to the manufacturer's directions. The rubber septa of each radiopharmaceutical cold kit and elution vial were swabbed with an Alcwipe before needle penetration and a new needle was used each time the eluate vial was sampled. Septal penetration of the eluate vial with 21-G needles occurred 30–50 times per day for radiopharmaceutical kit preparation and for drawing ^{99m}Tc for direct injection.

Microbiological Testing

The near-empty eluate vials, containing 1–2 ml of solution, were collected at the end of the work day for a period of 10 wk and stored behind lead shielding until the activity had reached the background level. Four groups of 10 vials each were selected randomly and sent to an independent microbiology laboratory for sterility testing. Each group of 10 vials was aseptically pooled and incubated for 14 d in fluid thioglycollate USP + 0.5% tween 80 at $32.5 \pm 2.5^\circ\text{C}$ and tryptone soya broth + 0.5% tween 80 at $22.5 \pm 2.5^\circ\text{C}$ to assess microbial contamination, as described in the BP/EP 1998 (4) for sterility testing.

RESULTS

The results of the study are given in Table 1. No microbial growth was observed in the 4 groups of pooled eluate vials tested over the 10-wk sampling period.

DISCUSSION

Recent reports in the literature and the popular press have led hospitals to review their policies regarding the use of multidose

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TABLE 1
Results of Sterility Testing of Technetium-99m Generator Eluate

Media/Incubation	Observation Growth/No growth			
	Batch 1*	Batch 2*	Batch 3*	Batch 4*
Fluid thioglycollate USP + 0.5% tween 80 at 32.5 ± 2.5°C for 14 d	No growth	No growth	No growth	No growth
Tryptone soya broth + 0.5% tween 80 at 22.5 ± 2.5°C for 14 d	No growth	No growth	No growth	No growth

*Each batch consisted of the pooled contents of 10 vials of expired ^{99m}Tc in 0.9% sodium chloride BP of variable volumes from separate days.

vials. In nuclear medicine there is no choice but to use multidose vials, especially for ^{99m}Tc generator eluate. As well as observing the principles of best practice, we also must demonstrate to others that our operating procedures are safe.

Preparation of radiopharmaceuticals in our nuclear medicine department is performed in a room identified as our “hot lab,” which is not fed with 0.22-μ filtered air. Consequently syringe transfers are performed in an uncontrolled environment. The room is clean but not aseptic, as is required in some countries. When handling radioisotopes, personnel are required to wear protective gowns and nonsterile rubber gloves for radiation safety as well as infection control.

CONCLUSION

Our current practice has not resulted in any breaches in sterility of our eluate vials. We have ensured hygienic technique by swabbing all rubber septa with isopropyl alcohol before needle penetration and by frequent changing of syringe needles before penetration of the eluate vial. We are confident that our standard operating procedures for preparing radiopharmaceutical kits will produce a sterile product.

We plan to implement retrospective sterility testing of eluate vials as part of our ongoing quality control program. This will ensure that staff radiopharmaceutical kit preparation techniques consistently produce a sterile product.

ACKNOWLEDGMENTS

I wish to thank Boris Shuter for his advice and the technologists of the Department of Nuclear Medicine, Royal North Shore Hospital for their assistance on this project.

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