Nuclear Medicine Community Urged to Continue Reporting

Reported Adverse Reactions to Radiopharmaceuticals Remain Low in 1984

A review of the adverse reactions experience in The Society of Nuclear Medicine (SNM) during 1984 in the United States indicates fewer reports than in previous years. This result may reflect the use of improved radiopharmaceuticals, but is more likely a consequence of a decreased awareness within the nuclear medicine community and a tendency toward not reporting reactions or drug defects.

From an estimated 7 million radiopharmaceutical administrations, 21 adverse reactions were reported in 1984. There has been a consistent decline over the past decade, with 60 reports in 1976, 52 in 1977, 47 in 1978, 35 in 1979, 45 in 1980, 39 in 1981, 36 in 1982, and 20 in 1983.

The minimum rate (number per 100,000 administrations) was less than 1.0 for most radiopharmaceuticals (see table), but it should be noted that a more likely estimate is 2–10 times the reported incidence because of noncompliance with reporting requirements (*1*).

The minimum rate of adverse reactions for diagnostic radiopharmaceuticals has been consistently lower than that for contrast media and therapeutic drugs. [The high minimum rate for technetium-99m dimercapto succinic acid (DMSA) of 20.6 is not statistically meaningful because only one reaction was reported.]

Although radiopharmaceuticals have shown to be clinically safe, the reporting of adverse reactions or drug defects is of great importance to detect any patterns that may emerge with an agent. In addition, a high rate of compliance with adverse reaction reporting requirements will add more validity to the data in the SNM registry. Even though members of the nuclear medicine community recognize the minimal level of risk in using radiopharmaceuticals, it is imperative to compile accurate data as evidence.

The SNM Adverse Reactions Committee has worked with the US Food and Drug Administration (FDA) and the US Pharmacopoeia Convention (USP) since 1976 to gather and analyze adverse reaction data in the SNM registry. The USP mails reporting forms to SNM members about three times a year. Individual members file reports with the USP, which obtains additional verification data by telephone before sending the reports to the Adverse Reactions Committee and to the FDA for review. The FDA maintains this data in a computerized file.

The White House Office of Budget and Management (OMB) has made an effort to reduce the overall number of government forms in current use. As a result, the SNM Drug Problem Report form will no longer be used, and the USP is providing SNM members with a slightly modified version of the standard form used for nonradioactive drugs, and a separate form for drug defects.

I would urge the SNM membership to be vigilant and conscientious in reporting any adverse reactions and drug defects. (When no report forms are available, members may telephone the report to the USP at (800) 638-6725.)

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Chairman
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References

1. Rhodes BA, Cordova MA: Adverse reactions to radiopharmaceuticals: Incidence in 1978, and associated symptoms. *J Nucl Med* 21:1107-1110, 1980

Reported Adverse Reactions to Radiopharmaceuticals in 1984

Radiopharmaceutical	Number of Reactions	Minimum Rate*
Technetium-99m methylene diphosphonate (MDP)	7	0.5
Technetium-99m diethylenetriaminepentaacetic acid (DTPA)	3	0.9
Technetium-99m human albumin microspheres (HAM)	3	3.8
Technetium-99m sulfur colloid	3	0.2
Technetium-99m dimercapto succinic acid (DMSA)	1	20.6
Technetium-99m glucoheptonate	1	0.3
Technetium-99m red blood cells (RBC)	1	3.6
Pyrophosphate (nonradioactive)	1	0.2
Iodine-131 sodium iodide	1	0.4
Total	21	0.3

*Number per 100,000 administrations