Radiochemical Purity and Stability of Commercial ^{99m}Tc-Stannous DTPA Kits Using a New Chromatography Technique

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The radiochemical purity and stability of four commercial ^{99m}Tc-stannous diethylenetriaminepentaacetic acid (^{99m}Tc-Sn-DTPA) kits were evaluated. A chromatographic technique involving Gelman instant thin layer chromatography was utilized to distinguish between ^{99m}Tc-Sn-DTPA, ^{99m}Tc-pertechnetate ($^{99m}TcO_4^-$), and hydrolyzed reduced ^{99m}Tc (^{99m}Tc-HR). The radiochemical purity of the kits was consistently greater than 99.0% on the two consecutive days evaluated. The stability of the commercial kits was greater than 99.0% at 4 hr after preparation. However, breakdown of two commercial kits was observed 6 hr after radiopharmaceutical preparation. These kits had radiochemical purities of 85.7 and 86.6% at 6 hr after preparation.

A number of radiochemical impurities are produced in the preparation of ^{99m}Tc-tin radiopharmaceuticals (^{99m}Tc-Sn-RRX). Major impurities include ^{99m}Tc-pertechnetate ($^{99m}TcO_4^-$) and reduced ^{99m}Tc that is not bound to the radiopharmaceutical, also referred to as hydrolyzed reduced ^{99m}Tc (^{99m}Tc-HR) (*1,2*). These radiochemical impurities can degrade the quality of radioisotope images and also increase the radiation dose to patients.

Many nuclear medicine quality control procedures for ^{99m}Tc-Sn-RRX involve the use of chromatography systems such as paper chromatography and 85% methanol. With this system, $^{99m}TcO_4^-$ migrates with an R_f value of 0.5, while ^{99m}Tc-Sn-RRX and ^{99m}Tc-HR remain at the origin. Therefore, if ^{99m}Tc-HR makes up a significant part of the radiopharmaceutical preparation, a false high estimate of radiochemical purity or tagging efficiency is obtained (*1,3*). For example, if 25% of a radiopharmaceutical preparation consisted of ^{99m}Tc-HR and the remainder was ^{99m}Tc-Sn-RRX, the above chromatography system would give a 100% tagging efficiency, whereas the actual tagging efficiency would only be 75%.

A chromatographic technique developed in our laboratory distinguishes between these radiochemical components for specific radiopharmaceuticals, including ^{99m}Tc-stannous diethylenetriaminepentaacetic acid (^{99m}Tc-Sn-DTPA) (*4*). The technique involved spotting the radiopharmaceutical on Gelman instant thin layer chromatography using silica gel (ITLC—SG) and consecutive strip development in acetone followed by normal saline. A chromatographic scan for ^{99m}Tc-Sn-DTPA using this chromatographic technique is shown in Fig. 1. Technetium-99m-pertechnate migrated with the acetone solvent front, ^{99m}Tc-Sn-DTPA migrated with the normal saline solvent front, and ^{99m}Tc-HR remained at the origin. As illustrated on the scan, distinct separation was achieved between the various radiochemical components. The purpose of the study was to determine the radiochemical purity and stability of commercial ^{99m}Tc-Sn-DTPA kits by utilizing the chromatographic technique.

Materials and Methods

Four commercial ^{99m}Tc-Sn-DTPA kits were evaluated for radiochemical purity. The kits were manufac-

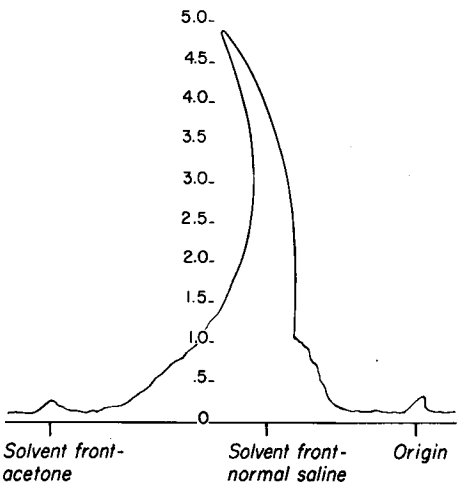

FIG. 1. Chromatograph scan for ^{99m}Tc-Sn-DTPA.

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tured by E.R. Squibb and Sons, Inc., Union Carbide Corporation, General Radioisotope Products, and Diagnostic Isotopes, Inc. Each kit was prepared by adding between 20 and 40 mCi of $^{99m}TcO_4^-$ eluate from a Mallinckrodt Ultra-TechneKow generator on two successive days. After pertechnetate addition, each kit preparation was allowed to stand for approximately 30 min with frequent agitation. The radiochemical purity of each preparation was then determined by spotting the radiopharmaceutical on Gelman ITLC-SG, developing the strip in acetone (solvent front migrated approximately 14 cm from origin), air drying the chromatography strip for 4 min, and redeveloping the strip in normal saline (solvent front migrated approximately 7 cm from origin). The chromatography strip was then scanned using a mechanized strip mover, a 2 × 2 in. NaI(Tl) crystal attached to a pulse height spectrometer, and a strip chart recorder that quantified the ^{99m}Tc radioactivity.

In addition, the stability of the ^{99m}Tc-Sn-DTPA kits was evaluated by preparing each kit as previously described. At various time intervals up to 6 hr after preparation the radiochemical purity of each kit was determined using the same chromatography technique as outlined.

Results and Discussion

The radiochemical purity of the commercial ^{99m}Tc-Sn-DTPA kits is shown in Table 1. The radiochemical purity of all preparations was consistently greater than 99.0% 30 min after preparation on the two consecutive days. Technetium-99m-pertechnetate and ^{99m}Tc-HR accounted for less than 1.0% of the total radioactivity.

The stability of the various commercial ^{99m}Tc-Sn-DTPA kits is shown in Table 2. All commercial kits evaluated maintained tagging efficiencies greater than 99.0% up to 4 hr after preparation. However, the radiochemical purity of two commercial kits was reduced to 85.7 and 86.6% at 6 hr after radiopharmaceutical preparation. The remaining activity was ^{99m}Tc-HR. It is important to note that using conventional chromatographic techniques would have resulted in a false estimation (greater than 99.0%) of the radiochemical purity of these two specific kits.

Quality control procedures for ^{99m}Tc radiopharmaceuticals are essential in the practice of nuclear medicine. Prior to clinical use, each new radiopharmaceutical kit must be thoroughly evaluated for radiochemical purity and stability. The chromatographic technique outlined is relatively easy to perform and yields maximum information on the radiochemical purity of a ^{99m}Tc radiopharmaceutical. As such, the technique should be incorporated as a routine quality control procedure for the specific radiopharmaceuticals.

TABLE 1. Radiochemical Purity of Commercial ^{99m}Tc-Sn-DTPA Kits

Kit manufacturer	Radiochemical component	Day 1 (%)	Day 2 (%)
E. R. Squibb	Tc-Sn-RRX	99.0+	99.0+
	TcO_4^-	–	–
	Tc-HR	–	–
Union Carbide	Tc-Sn-RRX	99.0+	99.0+
	TcO_4^-	–	–
	Tc-HR	–	–
General Radio Isotope Prod.	Tc-Sn-RRX	99.0+	99.0+
	TcO_4^-	–	–
	Tc-HR	–	–
Diagnostic Isotopes	Tc-Sn-RRX	99.0+	99.0+
	TcO_4^-	–	–
	Tc-HR	–	–

Dash indicates radiochemical purity of less than 1.0%.

TABLE 2. Stability of Commercial ^{99m}Tc-Sn-DTPA Kits

Kit manufacturer	Radiochemical component	Time after preparation (hr) 1.0 (%)	2.0 (%)	4.0 (%)	6.0 (%)
E. R. Squibb	Tc-Sn-RRX	99.0+	99.0+	99.0+	99.0+
	TcO_4^-	–	–	–	–
	Tc-HR	–	–	–	–
Union Carbide	Tc-Sn-RRX	99.0+	99.0+	99.0+	85.7
	TcO_4^-	–	–	–	0.0
	Tc-HR	–	–	–	14.3
General Radio Isotope Prod.	Tc-Sn-RRX	99.0+	99.0+	99.0+	99.0+
	TcO_4^-	–	–	–	–
	Tc-HR	–	–	–	–
Diagnostic Isotopes	Tc-Sn-RRX	99.0+	99.0+	99.0+	86.6
	TcO_4^-	–	–	–	0.0
	Tc-HR	–	–	–	13.4

Dash indicates radiochemical purity of less than 1.0%.

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