KIT FOR CARRIER-FREE ^{123}I-SODIUM IODIDE. VIII

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A kit preparation for high-purity carrier-free ^{123}I-sodium iodide from the ^{123}Xe→^{123}I generator is described. The optimum dissolution procedure, the characteristics of the Na^{123}I from the suggested kit preparation, and the features of the kit are discussed.

Iodine-123 is an ideal radioiodine for use in radiopharmaceuticals. The desirability of ^{123}I from the point of view of its physical properties and radiation dosimetry is well known. The prospects for general availability of ^{123}I are good; thus, the need for the development of convenient methods of preparation of carrier-free ^{123}I are apparent. The preparation of carrier-free ^{123}ICl as an iodination reagent for the synthesis of radiopharmaceuticals has recently been described (*1*).

In this paper we report on a kit method for the fast, dependable preparation of carrier-free Na^{123}I. The radiochemical purity and chemical forms of ^{123}I that are formed following the ^{123}Xe(β^+,EC)^{123}I nuclear transformation under selected experimental and preparative conditions are discussed. A ^{123}Xe→^{123}I kit that could be supplied to hospitals is described.

Sodd, et al (*2–7*) have provided an exhaustive evaluation of the accelerator production of ^{123}I. Further exploratory studies by Lambrecht, et al (*1,8*) have verified the suggestion that the production of ^{123}I by the ^{123}Xe generator coupled with rigorous chemical scrubbing (*1,8*) results in ≧99.8% radionuclidic purity as ^{123}I. The only radiohalogen contaminant is ≦0.2% ^{125}I. The ^{123}Xe decays by positron emission and electron capture with a 2.1-hr half-life to ^{123}I ($T_{1/2}$ = 13.3 hr). The ^{125}I ($T_{1/2}$ = 60 days) contaminant results from the decay of ^{125}Xe ($T_{1/2}$ = 16.8 hr) which is produced simultaneously with the ^{123}Xe. For the cyclotron production of ^{123}I we recommend the ^{122}Te(^{4}He,3n)^{123}Xe and ^{123}Xe(β^+,EC)^{123}I nuclear reactions with $E_{^4He}$ ~ 45–36 MeV. The alternate but as yet unexplored possibilities are the ^{122}Te(d,n)^{123}I and ^{124}Te(p,2n)^{123}I nuclear reactions which might be feasible if ultra-high purity ^{122}Te or ^{124}Te were commercially available. Extensive calculations (*9,10*) reported in 1969 and preliminary (*11*) experiments have indicated that multicurie quantities of ^{123}Xe can be produced in high yield and purity with the ^{127}I(p,5n)^{123}Xe nuclear reaction. Subsequently, Fusco, et al (*12*) have verified the radiochemical purity and yield obtainable with the spallation reaction. The production of ^{123}Xe is presently the most promising route from which to obtain high-purity carrier-free ^{123}I. The preparation of carrier-free Na^{123}I is independent of the method of ^{123}Xe production.

EXPERIMENTAL MATERIALS AND METHODS

The cyclotron parameters and the gas-collection traps and purification procedures used to obtain high-purity carrier-free ^{123}Xe free of radiohalogen contamination are discussed elsewhere (*1,8*). The ^{123}Xe was purged from the irradiated ^{122}Te target and was collected on-stream in Pyrex traps immersed in liquid nitrogen. The ^{123}Xe + ^{123}I were either used directly or vacuum transferred to the holding vessel that is shown in Fig. 1 and stored in liquid nitrogen (77°K) or a dry-ice Dewar (−78°C) for 6.5–7.5 hr. When ~90% of the ^{123}Xe had decayed to ^{123}I, the ^{123}I-radionuclidic purity and yield was optimum. The apparatus was fabricated with O ring seals so that the unit containing the O ring seated glass stopcock was vacuum tight even at 77°K. The volume of the vessel was 100 ml. The cap was easily removed after the vacuum was released and provided an easy access for removal of the aqueous iodide solution after the dissolution reagents were added.

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FIG. 1. Holding vessel for ^{123}Xe ^{123}I generator.

Analytical methods. Descending paper chromatography was used for the quantitative analysis and identification of the chemical forms of ^{123}I. Whatman No. 1 chromatographic grade paper was used and the eluant chosen was butanol saturated with 3 *M* NH_4OH. The chromatograms were developed for 6–8 hr and were protected from open exposure to air and light as much as possible. Losses of carrier-free iodide from the chromatographic paper under these conditions did not appear to be serious but have been observed previously (*13*). If the chromatographic paper containing microgram amounts of iodide is left exposed to light and air, iodide is lost. We observed a 10% loss in 3 hr, 30% in 6.5 hr, and 70% in 24 hr. Note, however, that even under conditions in which iodide is not lost, some forms of iodine may be volatile.

The R_f values for the chemical forms of iodine as IO_3^-, IO_4^-, and I^- were established by x-ray fluorescence detection on chromatograms developed with 10 μg of the respective sodium salts. An R_f value of 0.00 ± 0.05 was assigned to iodate and periodate, whereas an R_f value of 0.24 ± 0.05 was identified as iodide. In addition, one to four unidentified chemical forms of ^{123}I were found in the carrier-free solutions*. Iodine as $^{123}I_2$ was not found in the preparations.

The paper chromatograms were qualitatively evaluated by exposing the developed chromatogram to Dupont Cronex 4 film for several hours. For the quantitative assay of the ^{123}I, the chromatogram was subsequently cut into segments and counted in a NaI(Tl) scintillation counter of known efficiency. The radiochemical yields were determined by the ratio of the activity in the respective bands to the total activity on the chromatograph. Unless otherwise indicated, 100 ± 5% of the activity applied to the chromatogram was recovered. Results of duplicate chromatograms of the same sample were within ±2% a.d.

Iodine-123 dissolution procedures. Two approaches from which to obtain carrier-free $Na^{123}I$ were investigated. The $^{123}Xe \rightarrow ^{123}I$ nuclear transformation can be allowed to occur directly in solution. Unfortunately, the limited solubility of xenon in aqueous solutions negates the usefulness of this method on a preparative scale unless the dead volume is very small and the ^{123}Xe is continuously mixing with the solvent. The latter point could be a source of difficulty if the $Na^{123}I$ kit were to be shipped while the $^{123}Xe \rightarrow ^{123}I$ decay-process was occurring. The second approach was the dissolution of ^{123}I from a Pyrex surface on which the ^{123}Xe had been condensed and allowed to decay to ^{123}I.

Table 1 summarizes data on the identity and yield of the chemical forms of ^{123}I that are in solution. The final chemical forms of ^{123}I in solution are quite sensitive to the dissolution reagents, reducing agents, and neutralization procedures used to give a final product of pH ~ 7. Typically, >95% of the ^{123}I in the trap was removed from the walls with the dissolution procedure. See Table 1 (1.3–1.9). The optimal yield of ^{123}I was obtained when the activity was dissolved in sodium hydroxide and sodium thiosulfate was added before the solution was neutralized with hydrochloric acid (1.6B, 1.7 and 1.8). Sodium bisulfite was more effective at reducing the oxidized forms of iodine to iodide (1.6D) than sodium thiosulfate. An 0.1 *M* solution of sodium bisulfite is not acceptable in a pharmaceutical product.

In addition to IO_3^-, IO_4^-, and I^-, the $Na^{123}I$ preparations contained from one to four unidentified forms with their R_f values at 0.48, 0.67, 0.77, and 0.94. The best dissolution procedures tested resulted

* The solutions are carrier-free in the context that the ^{123}I is removed from the collection vessel without the addition of a natural iodine carrier. However, we have not attempted to remove the iodine that may be present in the starting reagents. The unidentified ^{123}I bands may be related to the reaction of the ^{123}I species with impurities present in the dissolution media.

in the elimination of all but a single form that is typically found in a ~3% yield at an R_f value of 0.94. The fact that this fraction does indeed correspond to a chemical form of ^{123}I and not to a radioimpurity in the preparation was verified by gamma spectrometry.

The anomalous bands are not peculiar to the $^{123}Xe \rightarrow {}^{123}I$ generator since others have observed unidentified fractions in carrier-free preparations of $Na^{131}I$ formed by the (n,γ) activation of ^{130}Te (*14–23*).

SUGGESTED METHOD FOR THE $^{123}I^-$ KIT

A suggested $^{123}Xe \rightarrow {}^{123}I$ generator kit is shown in Fig. 1. The characteristics of a typical carrier-free $Na^{123}I$ preparation are summarized in Table 2. The total solids in the preparation are sodium chloride (2.5 mg/ml) resulting from the pH adjustment and the reducing agent (0.2 mg/ml). The tellurium carryover from the irradiation target is below the limits of detection by atomic absorption, i.e., <1 μg/ml. The final preparation contains 0.02% sodium thiosulfate as a stabilizing reagent to prevent the oxidation of iodide to iodine, iodate, and periodate. Sodium thiosulfate is itself oxidized at a rate proportional to the radioactive concentration (*24*). However, the shelf-life of $Na^{123}I$ is long relative to the 13.3-hr physical half-life of ^{123}I. Hence, 0.02% sodium thiosulfate is adequate for preserving the quality of the $Na^{123}I$.

The advantages of the $^{123}I^-$ kit are that the short-lived parent, ^{123}Xe, can be collected at the accelerator and transported to hospitals while the $^{123}Xe(\beta^+,EC)^{123}I$ nuclear transformation is occur-

TABLE 1. EFFECT OF VARIOUS DISSOLUTION PROCEDURES ON THE FINAL CHEMICAL FORMS OF ^{123}I

	Dissolution procedure	Typical radiochemical yield, % $^{123}IO_3^- + {}^{123}IO_4^-$	$^{123}I^-$	^{123}I-others	Comments* †
1.1	$^{123}Xe \rightarrow {}^{123}I$ decay in 0.1 M NaOH	1.3	96	2.7	Low solubility of Xe in aqueous solution negates routine use as kit.
1.2	$^{123}Xe \rightarrow {}^{123}I$ decay in H_2O	3.9	86	8.9	
1.3	^{123}I dissolution from trap with distilled H_2O	5.9	76	16.4	95% recovery, paper streaked 1 min after dissolution.
		3.4	80	15.6	82% recovery, paper streaked 5 min after dissolution.
		6.0	86	7.1	Paper streaked 1 hr after dissolution.
		3.5	84	12.0	75% recovery, paper streaked 1.5 hr after dissolution.
1.4	^{123}I dissolution from trap with 0.1 M NaOH, neutralize with 0.1 M HCl,				
	(A) no reducing agent	6.1	85	6.4	
	(B) add 10^{-2} to 10^{-3} M $Na_2S_2O_3$	6.1	88	5.5	
1.5	^{123}I dissolution from trap with 1.0 M NaOH	11.0	86	2.5	
	+ H_2O, neutralize with 0.1 M HCl,	7.7	87	5.1	
	add 2×10^{-3} M $Na_2S_2O_3$				
1.6	^{123}I dissolution from trap with 1 M NaOH				
	(A) neutralize with 0.1 M HCl, add 2×10^{-3} M $Na_2S_2O_3$	13.9	82	3.8	
	(B) add 2×10^{-3} M $Na_2S_2O_3$, neutralize with 0.1 M HCl	1.1	95	3.2	
	(C) Mixture of equal volumes of (A) & (B)	7.1	89	3.2	
	(D) Solution (C) + 0.1 M $NaHSO_3$	0.2	98	1.8	
1.7	^{123}I dissolution from trap with NaOH, add 2×10^{-3} M $Na_2S_2O_3$, neutralize with 0.1 M HCl	1.4	95	3.4	
1.8	^{123}I dissolution from vessel with 0.1 M NaOH, add 2×10^{-3} $Na_2S_2O_3$, neutralize with 0.1 M HCl	0.2	96	2.8	96% recovery.
1.9	^{123}I dissolution with 0.1 M NaCl containing 0.2% $Na_2S_2O_3$ pH = 7	0.3	93	6.6	82% recovery from chromatograms ~ ¼ of ^{123}I not in final solution.

* Recovery balance is ratio of % activity recovered on the chromatogram vs the activity applied. Radiochemical yields are relative to activity recovered on the paper chromatogram.

† Most experiments reported are the average of two or more duplicate chromatograms, experimental error < ±2% a.d.

TABLE 2. CHARACTERISTICS OF $Na^{123}I$ FROM THE SUGGESTED KIT PREPARATION PROCEDURES

Chemical form	Carrier-free $Na^{123}I$
Chemical composition	95% iodide, <1.5% iodate + periodate, balance unidentified iodides
Radioiodine purity	≥99.8% as ^{123}I, balance as ^{125}I
Total solids	2.5 mg, ml NaCl
Reducing agent	0.2 mg/ml or 0.02% $Na_2S_2O_3$
pH of final solution	6.8–7.8
Tellurium content	<1 μg/ml

ring. At the appropriate time after receipt of the kit, the dissolution reagents are added to the vessel. The product is ready for dispensing with less than 20 min of workup at the clinic. A disadvantage, although not serious, is that the generator, which is not a generator in the true sense, can be used only once for each $^{123}Xe \rightarrow {}^{123}I$ shipment. One limitation necessitates that the dissolution be performed in an area which has adequate ventillation to dispose of the radioxenons that are insoluble in the aqueous solution and volatilize during the dissolution process. The principal advantage of the $^{123}Xe \rightarrow {}^{123}I$ kit is that carrier-free $^{123}I^-$ is now available in a radionuclidic purity heretofore unavailable.

While the virtues of ^{123}I in radiopharmaceuticals have been noted in the literature for some time now (*25,26*), ^{123}I with acceptably low quantities of other radioiodine, especially ^{124}I and ^{125}I, has not been readily available. It must be stressed that the preparation described in this paper contains no ^{124}I and less than 0.2% ^{125}I. Presently, the production of "economical quantities" of ^{123}I by this method are being explored at BNL. The same method we have described can be used to convert the multicurie quantities of ^{123}Xe which will be produced by BLIP (*27*) when it eventually comes on stream. Although the production method differs, the products in both cases are characterized by high radionuclidic purity. Clinical evaluation of ^{123}I prepared by this method has been in progress for some time now and has been reported (*28,29*).

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