Radiation Safety

A Remote Reservoir Injection Accessory for Reducing Exposure

Jacklyn S. Hopkins and Irwin L. Jasper

Riverside Hospital, North Hollywood, California

We evaluate a new accessory for reducing personnel radiation exposure. The disposable accessory, a "bypass device," couples a conventional hypodermic needle and syringe. As saline from the syringe is expelled, the radionuclide dose, which is stored in a remote shielded reservoir resting on a surface adjacent to the injection site, is driven out through the hypodermic needle. Dosimetry studies in conjunction with the most frequently used technetium compounds indicate that the use of the bypass device reduces the exposure rate to the fingertips by factors of approximately 6,700 and 670 compared to unshielded and shielded syringes, respectively. In addition to the substantial reductions in exposure, the manipulative ability when administering injections provided by the bypass device was judged to be very nearly equivalent to that with unshielded syringes. The bypass device was also highly effective in such special applications as bolus injections.

The continuing increase in the number of millicurie-level dose administrations has prompted a number of studies (*1–5*) measuring the exposure levels to nuclear medicine personnel. Although these studies investigated dosimetry for diverse procedural activities, they do offer a common basis of comparison with regard to the assessment of finger exposure from a syringe loaded with Tc-99m. The relative reduction in exposure through the use of syringe shields has also been measured by several investigators (*3, 6, 7*).

This study examines the efficacy of a new injection accessory, a "bypass device" (proprietary development), which provides an alternative means for reducing exposure. Samples of this device were made available to us for evaluation. The device, shown in Fig. 1, bypasses normal flow between the syringe and hypodermic needle by using an intermediate fluid shunt. A pair of thin flexible tubes extends from the shunt to a shielded coil reservoir where the radionuclide is retained prior to injection. In this study the loading and injection procedures for the device will be described and the maximum exposure rate to the fingertips will be measured. Specific clinical applications of the bypass device will be examined.

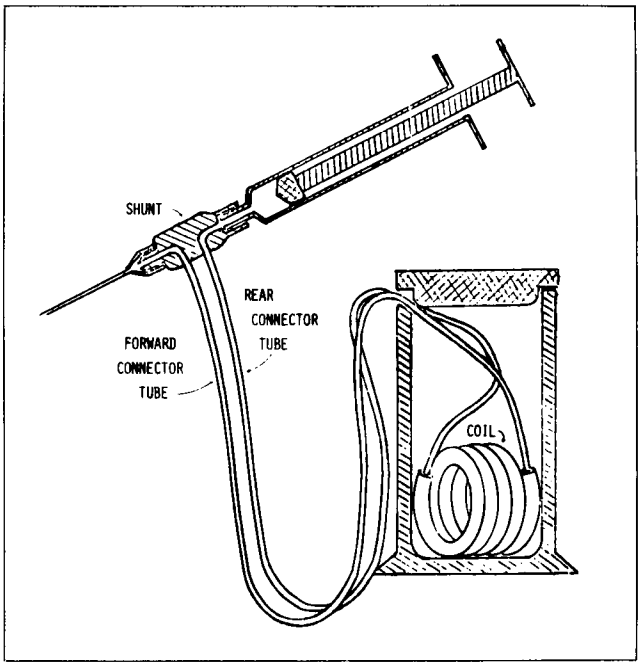

FIG. 1. Bypass device coupled to hypodermic needle and syringe shown in partial cross-section view. Shielded radionuclide dose is displaced from coil and through hypodermic needle by expelling saline in syringe.

Materials and Methods

Apparatus description and operation: The plastic bypass device is a sterilized, disposable single-use accessory consisting of a fluid shunt, flexible connector tubes, and either a 1- or 2-cc capacity coil. An assembled injector set, as shown in Fig. 1, is normally comprised of a hypodermic needle together with either a 1-cc bypass de-

For reprints contact: Jacklyn S. Hopkins, Dept. of Radiology, Riverside Hospital, 12629 Riverside Drive, North Hollywood, CA 91607.

vice coupled to a 3-cc syringe, or a 2-cc bypass device coupled to a 5- or 6-cc syringe. Once assembled, the same syringe would normally remain coupled throughout the loading and injection procedures.

The injector set is prepared for use by filling the needle, shunt, connector tubes, and syringes with saline and filling the coil with the appropriate dose of radionuclide. To accomplish this, the assembled injector set is first preloaded with saline by pumping the syringe plunger 2 or 3 times while the hypodermic needle is inserted in a saline vial to void all air from the set. The plunger is then partially drawn back so that the syringe is left half-full of saline.

Assembling and preloading the injector set with saline is straightforward and takes approximately 1 min. In clinical practice, several injector sets have been assembled and preloaded in advance so that radionuclide doses may be added during the course of the day with virtually no increase in preparation time. Then, as needed, a dose is quickly and easily drawn up from a radionuclide vial into one of the assembled saline preloaded injector sets with the coil in the coil shield. As the radionuclide is drawn into the coil, an equal volume of saline is automatically displaced into the syringe. Apparently, the tubular construction of the coil reservoir effectively eliminates significant intermixing of the dose and the saline during the loading process. This has been verified by the absence of any measurable trace of activity in the rear connector tube and syringe. Details of these measurements are discussed below with regard to dosimetry.

The activity drawn up is verified by briefly removing the coil from its reusable lead shield and suspending it in a dose calibrator. During the loading procedure, the withdrawn activity is immediately shunted away from the hand and into the coil. Even the exposure rate from the fractional activity temporarily present in the forward connector tube can be effectively eliminated either by storing most of the connector tubing in the coil shield or by drawing up the radionuclide while the connector tubing and coil are suspended in the calibrator. The latter technique has the added advantage of providing a simultaneous readout of the activity that has been drawn into the coil. In any case, a final volume of 0.3 cc of saline is subsequently drawn up to clear the forward connector tube of radionuclide. This completes the loading procedure and effectively isolates the dose inside the coil shield. No subsequent intermixing of the dose with the connector tube saline has been observed—even with loaded injector sets left standing for 1 hr. However, it might be advisable to apply a small pinch clamp to the connector tubing just outside the coil shield if an unusually long delay between final loading and injection is anticipated.

For the injection procedure, the coil shield is placed on a surface adjacent to the injection site as shown in Fig. 2. Intravenous penetration is readily verified by a reflux of blood into the shunt and forward connector tube. The activity is confined within the coil shield during this procedure. When the saline in the syringe is expelled, the radionuclide is driven out of the coil and through the hypodermic needle.

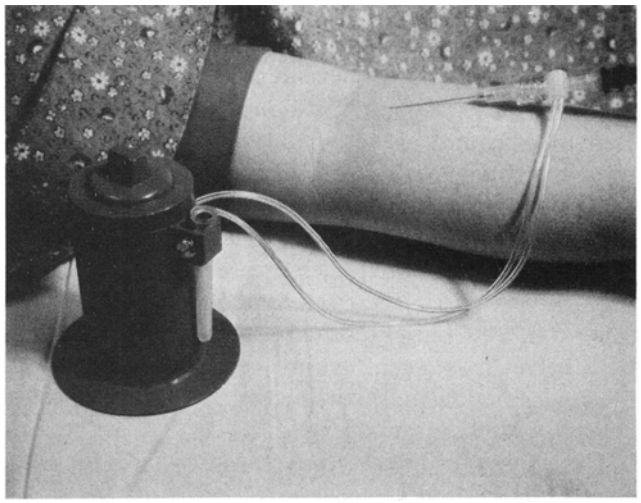

FIG. 2. Placement of coil shield and bypass device injector set during injection procedure.

Dosimetry: For the exposure measurements, a series of 12 injector sets using the 1-cc version of the bypass device was loaded with saline and radionuclide. All radionuclide volumes were 0.8 cc, with 3 sets each of 20-mCi technetium pertechnetate (TcO_4), 20-mCi technetium medronate sodium (TcMDP), 5-mCi technetium macroaggregated albumin (TcMAA), and 4-mCi technetium sulfur colloid (TcSC). Thermoluminescent dosimeters (TLDs) were placed at the fingertip locations on the syringes 4 cm from the center of the fluid shunt. The coil was kept in its shield and the connector tubing was extended to simulate injection geometry. The TLDs were left in place for one day, which provided a decay-corrected time exposure of 487 min. For example, the cumulative TLD exposure for a 20-mCi dose would be equivalent to 1,948 exposures of 15 sec each to injector sets filled with 20-mCi doses. In addition to the 12 TLDs, a series of 3 control TLDs was subjected to known exposures of 0, 5, and 25 mrem.

A repeat series of the 12 loaded injector sets was prepared. Each connector tube along with its fluid contents was severed into halves and counted separately in a dose calibrator that had been checked for counting linearity by a set of dilution standards. Additionally, the hypodermic needles, the fluid shunts, and the syringes were each counted with their fluid contents. Finally, the coil shield with the filled coil inside was counted for each dose.

Results

In the dosimetry studies using TLDs, the following readings were obtained. The 12 TLDs placed on the sy-

ringes of the loaded injector sets and the first two controls were all reported as zero—i.e., at background levels below the threshold of measurability. The last control was reported as 20 mrem. Although these results would seem to indicate an exceptionally low exposure rate when using the bypass device, the inherent insensitivity of the TLD in the range of several mrem would preclude any accurate quantification.

For the dosimetry studies measuring the radiation from the various injector set components using a dose calibrator, a μCi-level residual activity was detected on both halves from each forward connector tube. All of the other components including the rear connector tubes registered at background levels.

The activity for the halves averaged 17.5 μCi for TcO_4 and TcMDP, 4.4 μCi for TcMAA, and 7.8 μCi for TcSC. The half closer to the shunt consistently measured about 33% less activity than the half closer to the coil because of the somewhat greater rinsing action on the former when drawing in the final 0.3 cc of saline during the loading procedure.

Because the forward connector tube represented the only measurable radiation source on a loaded injector set, the exposure rate to the fingertips was calculated based upon this source. The geometric configuration shown in Fig. 3 was used to facilitate this calculation. The horizontal line represents the extended forward connector tube tube (27 cm long) with the fingertip location taken to be a target point on the syringe barrel 4 cm below this line. The calculation is then reduced to solving the exposure rate from a linear gamma-emitter source, a problem that has been treated in the literature (*8*).

The solutions were divided by the corresponding total coil activity in each instance, which expressed the final exposure rates in terms of per mCi of the dose, consistent with the practice of other investigators (*2, 3, 5*). The result was $1.5 \pm 0.5 \times 10^{-4}$ mrem/min – mCi for TcO_4, TcMDP, and TcMAA (and $3.2 \pm 1.0 \times 10^{-4}$ mrem/min – mCi for TcSC).

This corroborates the negative results of the TLD devices since the cumulative exposure over one day computed from the above figures is about 1.5 mrem for 20-mCi doses of either TcO_4 or TcMDP. This exposure is below the sensitive range of the TLD.

Clinical Studies

The bypass injector set was used in a series of 25 routine clinical radionuclide injections in order to assess the functional characteristics of the device and to examine possible applications.

Residual activity: For the entire course of 25 clinical studies (all Tc-99m), the postinjection residual activity was measured by resuspending the coil in the dose calibrator. An equal number of hypodermic needles and syringes used for conventionally administered radionuclides was also counted postinjection for comparison.

The average residual activity with respect to the original injected activity was $0.8 \pm 0.4\%$ and $3.8 \pm 1.0\%$ with and without the bypass device, respectively.

The latter figure is in general agreement with Rotman's measurement of 4.5% for postinjection residual of Tc-99m in syringes (*9*).

Administration through a small vein infusion set: We felt that if the saline in the 3-cc syringe was sufficient to flush the bypass device, then it might also adequately flush a small vein infusion set added to the bypass injector set in place of the hypodermic needle. The infusion set coupled directly to a syringe is frequently used in such applications as pediatric injections, but this configuration necessitates some means of clearing the radionuclide in the infusion set tubing.

Accordingly, the postinjection residual was measured for six assemblies of a (18 cm) small vein infusion set and a 3-cc syringe coupled by a 1-cc bypass device. The total average residual was $1.2 \pm 0.5\%$, which is slightly higher than the previous result for the bypass device when coupled to a hypodermic needle. However, the residual is still lower than that for the conventional syringe–hypodermic needle combination.

Bolus injection: The bypass device was also examined with regard to application in rapid bolus delivery for dynamic vascular studies. Lane et al. (*10*) described a technique using an assembly of an extension tube and a 3-way stopcock. A similar assembly is also available commer-

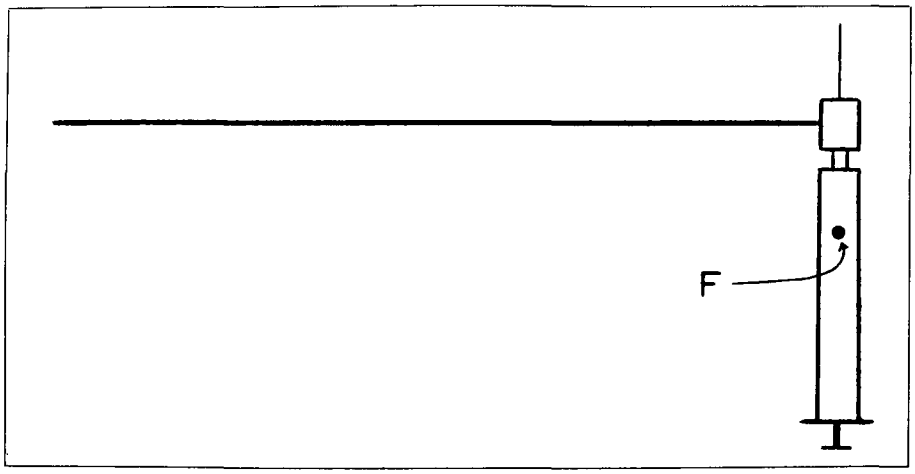

FIG. 3. Geometric configuration used for dosimetry calculation with horizontal line representing extended forward connector tube and point F simulating fingertip location on syringe barrel.

cially. With this technique, the radionuclide is first injected into the extension tube and subsequently propelled into the patient using 10 cc or more of saline.

For this application, the only necessary modification to the bypass device injection set is the replacement of the 3-cc syringe with a larger volume unit to provide a substantial saline flush.

The clinical dynamic studies using the bypass device were judged to be technically superior to those studies obtained by bolus injections with a conventional hypodermic needle and a 3-cc syringe. In a series of approximately 30 bolus injections for brain perfusion studies, eight were randomly selected by one of us to be administered with the bypass device. In conjunction with routine diagnostic evaluation of the perfusion images by the other author, nine studies were noted as exhibiting technical superiority. Subsequent correlation showed that seven of these nine studies had been administered with the bypass device.

Discussion

The subject of exposure to the fingers when handling millicurie quantities of Tc-99m in unshielded syringes has been examined by Clayton et al. (*1*), Husak (*2*), Lombardi et al. (*3*), McEwan (*4*), and Neil (*5*). Their results for Tc-99m, expressed in units of mrem/min – mCi, are 14.7, 13, 10, 12, and 9.3, respectively. Lombardi et al. (*3*) observed that their own results and those of other investigators (*1,2,4,5*) were in reasonable agreement and suggested that the intermediate value of 10 mrem/min – mCi would probably serve as an adequate standard for purposes of radiation protection.

The relative reduction factor for syringe shields in clinical use with Tc-99m-filled syringes has been reported by Lombardi et al. (*3*), Grove et al. (*6*), and Branson et al. (*7*). Their results indicated maximum relative reduction factors of 10, 7, and 8.2, respectively, in comparing shielded to unshielded syringes.

It is interesting to note that the substantially higher relative reduction factors of 50 to 300, which are often quoted for syringe shields in the commercial literature, are nevertheless ostensibly correct. Investigators (*3*) have shown that the results for TLD devices placed directly over the radionuclide fluid (1 cc in volume) on the surface of the syringe shield and on the syringe barrel can easily differ by a factor of 300. However, at a location halfway down the barrel, this factor drops by an order of magnitude to approximately 10, which is more in keeping with the previously referenced clinical results (*3,6,7*).

By a similar argument, an order of magnitude reduction of the reported unshielded syringe exposure rate is presumed in the interests of conservatively evaluating the relative reduction factor for the bypass device. The previously suggested standard of 10 mrem/min – mCi (*3*) for the exposure rate directly over the dose on an unshielded syringe would then be approximately 1 mrem/min – mCi halfway down the barrel on an unshielded syringe. In comparing shielded syringes to unshielded syringes, Lombardi et al. (*3*) measured a reduction factor of 10. Applying this reduction factor to 1 mrem/min – mCi yields 0.1 mrem/min – mCi as the corresponding exposure rate on a shielded syringe.

By comparison, the exposure rate measured for the loaded bypass device injector sets was given as 1.5×10^{-4} mrem/min – mCi for TcO_4, TcMDP, and TcMAA (and 3.2×10^{-4} mrem/min – mCi for TcSC). Using this value, the relative reduction factor in exposure for the bypass device with respect to unshielded syringes would then be 1 mrem/min – mCi $\div$ 1.5×10^{-4} mrem/min – mCi or approximately 6,700 for TcO_4, TcMDP, and TcMAA (and 3,000 for TcSC). The reduction factor for the bypass device compared to shielded syringes would be 0.1 mrem/min – mCi $\div$ 1.5×10^{-4} mrem/min – mCi or approximately 670 for TcO_4, TcMDP, and TcMAA (and 300 for TcSC). These figures indicate quite a substantial reduction in radiation exposure in conjunction with the use of the bypass device.

Finally, in a more subjective context, the ease of venipuncture when using the bypass device was judged to be very nearly equivalent to that with an unshielded syringe; the bypass device did not require any additional expertise. The flexible connector tubing was found to be unobtrusive and visibility was excellent. The bypass device was used successfully in a variety of clinical applications without encountering any difficulties.

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