The Methodist Hospital
REGIONAL HEALTH CARE SYSTEM

RECEIVED BY LFMB
Date ... 11/23/83
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... CAP
... To ...
Action Compl. 1/4/84

November 25, 1983

030-11234

U.S. Nuclear Regulatory Commission
Materials Licensing Section
Region III
799 Roosevelt Road
Glen Ellyn, Illinois 60137

RE: NRC License #13-16558-01 - Physician's Use of Radioactive Drugs

Gentlemen:

This is in request of an exemption to 10 CFR 35.14 (b) (6) for the use of Technetium-99m pertechnetate, and technetium-99m sulfur colloid for the evaluation of ventriculo-peritoneal shunts, ventriculo-atrial, and LeVeen Shunts, respectively. As indicated in the February 4, 1983 Federal Register, the authorization to perform such procedures at an institution such as ours may be obtained by the NRC rather than the FDA when the following information is submitted for your review:

1. Please refer to the enclosed article from Neuroradiology (July, 1974) which details the ventriculo-atrial, ventriculo-peritoneal shunt studies using Tc99m pertechnetate. In summary, this procedure involves an intra-catheter injection of 1-5 millicuries of Tc99m pertechnetate into the shunt system to demonstrate obstruction of cerebrospinal fluid for patients with hydrocephalus.

2. The purpose of this study is to localize (visualize) shunt blockage prior to any operative procedure.

3. The 1-5 millicuries injected into the catheter to evaluate the shunt patency does not pose any radiation hazard regardless of the age of the patient involved. We confirm the technetium-99m pertechnetate will be obtained from either an FDA approved Mo99/Tc99m generator or from a central radiopharmacy on a unit dose basis. Evaluation of Mo99 contamination of the pertechnetate product will be made by our department or supplier to ensure levels are consistent with those listed in 10 CFR 35.14 (b) (4) (iii).

4. Please refer to the attached Mo99/Tc99m generator package insert for analysis of radiation dose. We confirm the maximum dose to the patient will be 5.0 millicuries for adults and dosage to pediatric patients will be based on weight.

   For LeVeen Shunt studies, please refer to the attached protocol. We confirm the Tc99m pertechnetate will be eluted from an FDA approved Mo99/Tc99m generator. It will then be used to label sulfur colloid from an NRC/FDA approved kit.

Applicant ...
Check No. 30725
Amount, Fee Category $40 - 7B
Type of Fee Amendment
Date Check Rec'd. 1/9/84
Received By Jackson

Control No. 75950

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Since the Tc99m pertechnetate and sulfur colloid are already FDA approved drugs, radiation dosimetry analysis is already on file with that agency or available in the manufacturer's package inserts for each.

5. We confirm the routine radiation safety precautions listed in our current license application, which are observed by our nuclear medicine personnel during other imaging procedures, will be followed for this procedure.

We trust this information is sufficient to grant our exemption and look forward to your positive response.

Sincerely,

Ivan Chermel, M.D.
Radiology

:KRF

Enclosures

cc: Darryl Wiedeman
Inspection and Enforcement Division
U.S. Nuclear Regulatory Commission
Region III
799 Roosevelt Road
Glen Ellyn, IL 60137

Control No. 75950

PROTOCOL

LeVeen Shunt Study

A. Application:

To determine the patency of peritoneal jugular vein diversionary shunt and to quantitate the flow rate of ascitic fluid.

B. Preparation:

Patient is asked to void completely prior to the examination. Abdominal skin in either lower quadrant is prepped with aseptic technique.

C. Radioisotope and Dose:

5 mCi of Tc99m-sulfur colloid to be injected into the peritoneal cavity.

D. Technique:

The patient is placed supine on imaging table. Ascitic fluid-intestinal air interface in lateral flank and lower quadrant is determined by percussion. The skin is prepped with aseptic technique and anesthetized with 10% xylocaine intradermally.

The polyethylene (LeVeen) shunt, which is palpable subcutaneously in patient's thoracic wall and lateral side of the neck, is positioned under the camera. Two cobalt or technetium source markers are placed at 10 cms apart at uppermost portion of shunt.

A 20 gauge needle is passed through the anesthetized area of the abdominal wall until ascitic fluid is obtained. Five mCi of Tc99m sulfur colloid is injected intraperitoneally. The needle is withdrawn and the puncture site is treated with pressure and colloidon. The patient's abdomen is balloted to facilitate mixing with ascitic fluid. [illegible] pyroxylin [illegible]

Imaging is started as soon as activity is noticed in lower portion of the tube. Imaging is done in continuous dynamic mode; each frame is of two seconds. Images are stored on a magnetic disc.

E. Interpretation:

Diagnosis of complete obstruction is made if no colloid enters in LeVeen shunt.

A liver and spleen scan is attempted at the end of one hour. Visualization of liver and spleen in standing position is indirect evidence of patency of LeVeen shunt.

Quantification of shunt flow is calculated by noting the time needed by the radioactive bolus to traverse a known distance and diameter of the shunt tube.

$$cc/min = \frac{X\ (cm)\ \pi\ (D/2)^2}{t\ (min)}$$

X = distance traveled (cm)

D = tube diameter (cm)

t = time to travel distance X

π = pi = 3.14

F. References:

Nancy Kirchmer, Umbert Hart
Radionuclide Assessment of LeVeen Shunt Patency
Ann. Surg., February 1977

G. ADVERSE REACTIONS

Any adverse reaction to the patient from the procedure will be noted and recorded.

Neuroradiology 7, 145–152 (1974)
© by Springer-Verlag 1974

Functional Evaluation of Ventriculo-atrial and Ventriculo-peritoneal Shunts with ^{99m}Tc-pertechnetate

M. Frick, H. Rösler, and J. Kinser
Dept. of Nuclear Medicine, Central Radiology Institute, University of Berne, Switzerland

Received: November 13, 1973

Summary. More and more ventriculo-atrial shunt operations are being carried out on every type of hydrocephalus and in every age group. Thus, the need for a simple, repeatable and atraumatic examination of the shunt function is increasing. The examination method of Bueno, in which ^{99m}Tc-pertechnetate is injected into the shunt system, has been adapted for our use. Here, the isotope is introduced into the reservoir of a Rickham valve. In this way visualization of the proximal and distal catheters, as well as of the ventricles, is possible. By using sequence scintigraphy it is possible to demonstrate obstruction of the CSF flow in the proximal, i.e. the intracranial, and/or in the distal, i.e. the extracranial, catheter. Localization of the block is necessary before an operative procedure can be performed. The method presented here is simple, quick, without risk to the patient, and can be repeated at will. In addition to examples of normally functioning shunts, characteristic disturbances are also described.

Evaluation fonctionnelle des valves ventriculoatriales et ventriculo-péritonéales a l'aide du ^{99m}Tc-pertechnetate

Résumé. La mise en place de valves ventriculo-atriales est de plus en plus fréquente dans tous les cas d'hydrocéphalie et dans toutes les catégories d'âge. Par conséquent il devient nécessaire de disposer d'un examen simple, reproductible et non traumatique vérifiant le bon fonctionnement de la valve. Les auteurs ont adopté la méthode de Bueno qui utilise le ^{99m}Tc-pertechnetate injecté dans la valve. Chez eux, le radio-élément est injecté dans le réservoir d'une valve de Rickham. De cette façon il est possible de visualiser la fois le cathéter proximal et distal et les ventricules. L'utilisation de la scintigraphie séquentielle permet de démontrer un blocage de la circulation du liquide céphalorachidien dans le cathéter proximal, c'est-à-dire le cathéter intra-crânien et/ou dans le cathéter distal, c'est-à-dire le cathéter extra-crânien. Il est nécessaire de localiser le blocage avant de procéder à l'intervention. La méthode présentée est simple, rapide, sans risque pour le patient et peut être répétée à volonté. Outre les exemples de valves fonctionnant normalement, les auteurs rapportent quelques dysfonctionnements caractéristiques.

Funktionelle Untersuchungen der ventrikulo-atrialen und ventrikulo-peritonealen Shunts mit Technetium ^{99m}-pertechnetat

Zusammenfassung. Die ventrikulo-atrialen Shunt-Operationen werden bei verschiedenen Typen des Hydrocephalus durchgeführt. Es ist daher eine wiederholbare, einfache und atraumatische Untersuchung der Shunt-Funktion erforderlich. Technetium-^{99m} kann in das Rickham-Reservoir injiziert werden. Es wird damit der proximale und der distale Katheter und auch das Ventrikelsystem in allen Abschnitten nachweisbar. Die Untersuchungsmethode ist einfach und ohne Risiko für den Patienten, sie kann beliebig wiederholt werden.

More and more cerebro-spinal fluid (CSF) shunt operations are being performed in patients with hydrocephalus, regardless of the etiology of the hydrocephalus or the age of the patient. This attemps, in effect, to restore the CSF circulation, as far as its transfer into the venous system is concerned, whereby the normal CSF pathways and the physiological resorption areas are partially circumvented (Fig. 1) [3, 5, 7, 9, 10, 14].

For those patients in whom the function of the shunt is in doubt, an objective method of examining the freedom of CSF flow is needed in order to discover an obstruction in time and, when necessary, to be able to undertake a revision of the system. The method presented here, which is based on the previously reported method of Bueno and coworkers [1], has proven itself in routine use. It can demonstrate the function of the shunt, as well as the morphology of both shunt and ventricular systems. Theoretically there is no possibility of damaging the shunt system or endangering the patient; we have seen no complications from this examination in our patients. There is no contraindication for repeated examinations. In Berne, the Rickham valve system is implanted routinely to facilitate later functional examination.

Method

Theoretically each radioisotope which is nontoxic for intrathecal application, and has a scintigraphically detectable gamma energy, can be used as long as the half-life is short and the radiation exposure small. This is especially important in children and infants. We use ^{99m}Tc-pertechnetate which has a short half-life (6 h), a gamma quantum well suited for scintigraphy (140 KeV), and, last but not least, is relatively inexpensive. Its rapid diffusion into the brain, as well as into the rest of the body, after intrathecal application is of no importance because of the short duration of the usual examination (5–10 min). The examinations are performed with the Anger camera[1] using the high resolu-

1 Nuclear Chicago Pho/Gamma III HP.

tion collimator and Polaroid scintiphotos made 150000 to 200000 counts.

The silastic cap of the Rickham ventriculost reservoir is punctured with a fine needle. After as tion of a small amount of CSF, 1–5 mCi ^{99m}Tc-technetate in less than 1 ml physiological saline i jected. The first picture is taken immediately and second after an interval of about 2–5 min. Then, a pumping of the valve, more pictures are made follow the activity flow. The persistence scope offe great advantage in positioning the patient and foll ing the activity flow. In the case of an occlusion pr mal or distal to the valve, an attempt is made to block the catheter by flushing with physiological N The result is checked with a repeat examination in 2

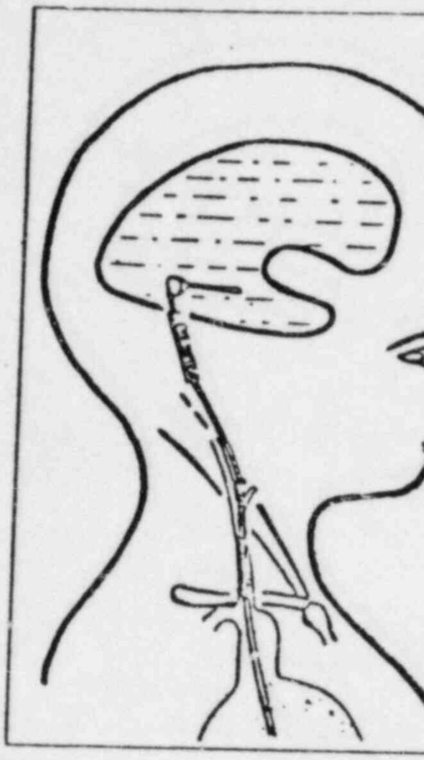

Fig. 1. Schematic illustration of the Rickham shunt s tem. This consists of a straight ventricular (proxin catheter with a cup-shaped reservoir on the outer end Spitz-Holter valve is connected between this reservoir the venous (distal) catheter. The distal end of the ven catheter lies in the right atrium

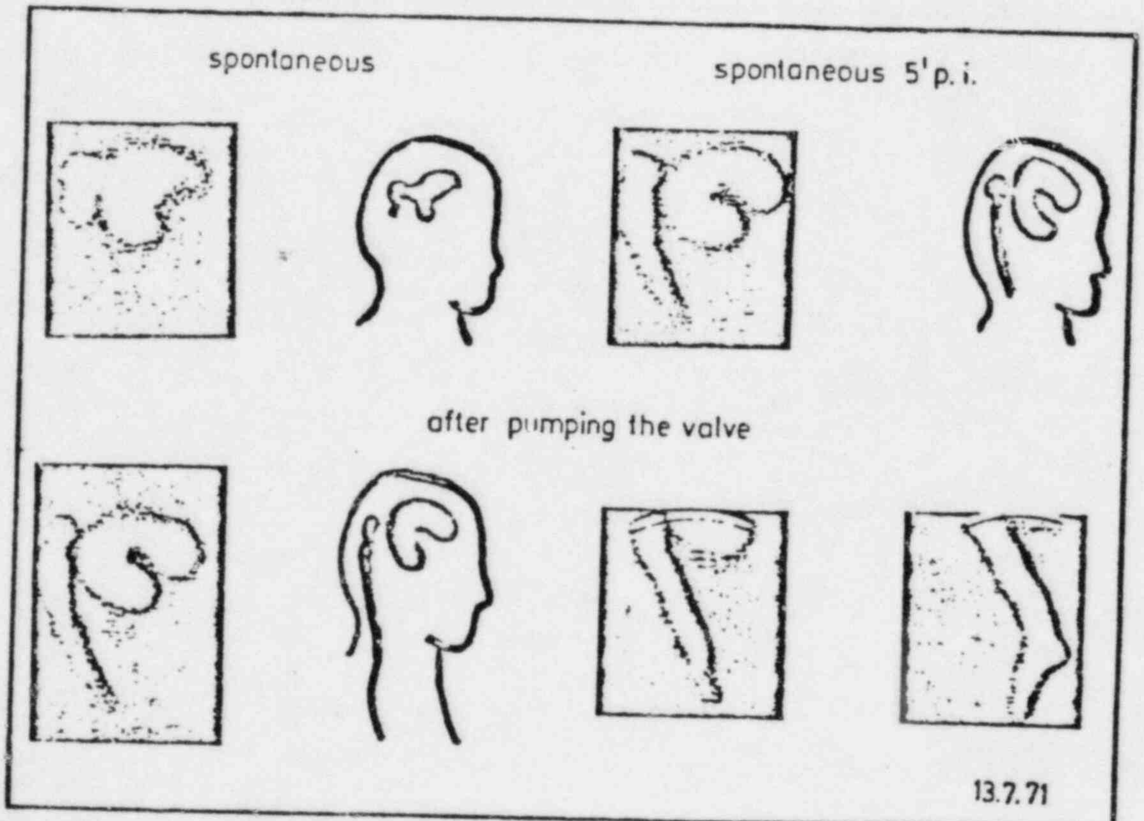

Fig. 2. Normally functioning V-A shunt. Here there is a good spontaneous flow which increases after pumping th valve

Comm

Case Histories

Case 1

(M.C. ♂ (1906) 8296) (Fig. 2) This patient serves as an example of a normally functioning shunt. In this 65 year old man with a massive aresorptive hydrocephalus there is a spontaneous flow of the activity in the proximal catheter and into the lateral ventricle after the injection of 5 mCi ^{99m}Tc-pertechnetate in the Rickham reservoir (upper left hand side of the figure). Somewhat later (about 5 min after the injection) there is also activity seen in the distal catheter (upper right hand side of the figure). After pumping the valve (lower row of pictures) there is a prompt flow of activity out of the lower end of the distal catheter.

Case 2

(M.S. ♂ (1968) 3917) (Fig. 3) This patient had fallen on his head at 11 months of age, sustaining a parietal fracture which was first diagnosed 2 months later in the presence of a large subdural hematoma, fever and apathy which progressed to coma. After operative removal of the hematoma, the cavity persisted as the brain was unable to

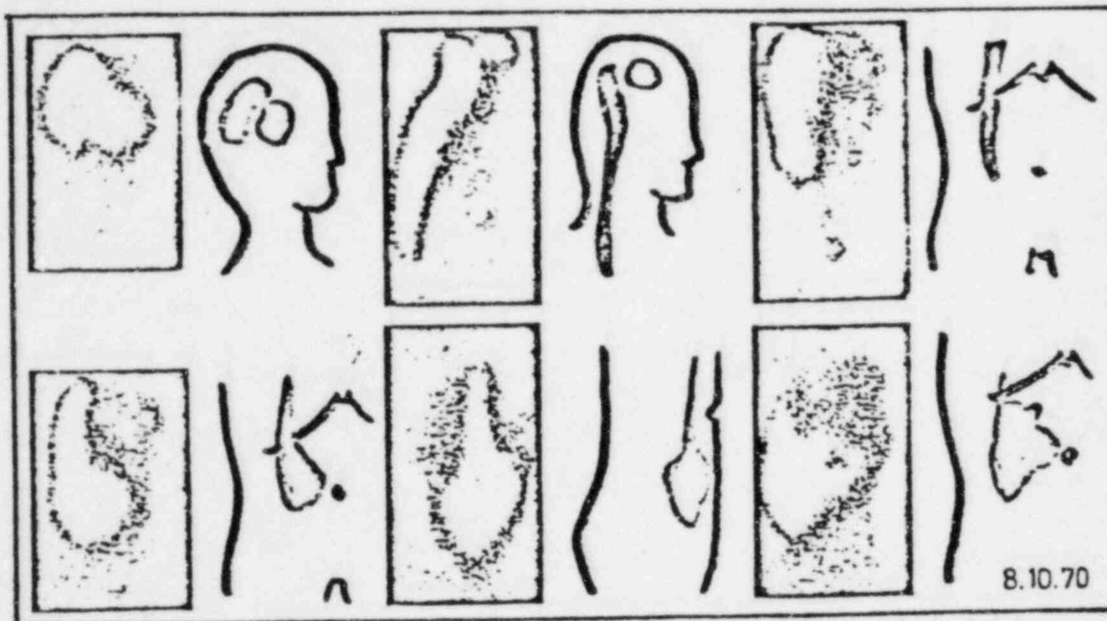

Fig. 3. Normally functioning V-P shunt. This series demonstrates the spontaneous flow of activity in the shunt from the enlarged ventricular system to a spread of activity within the peritoneal cavity

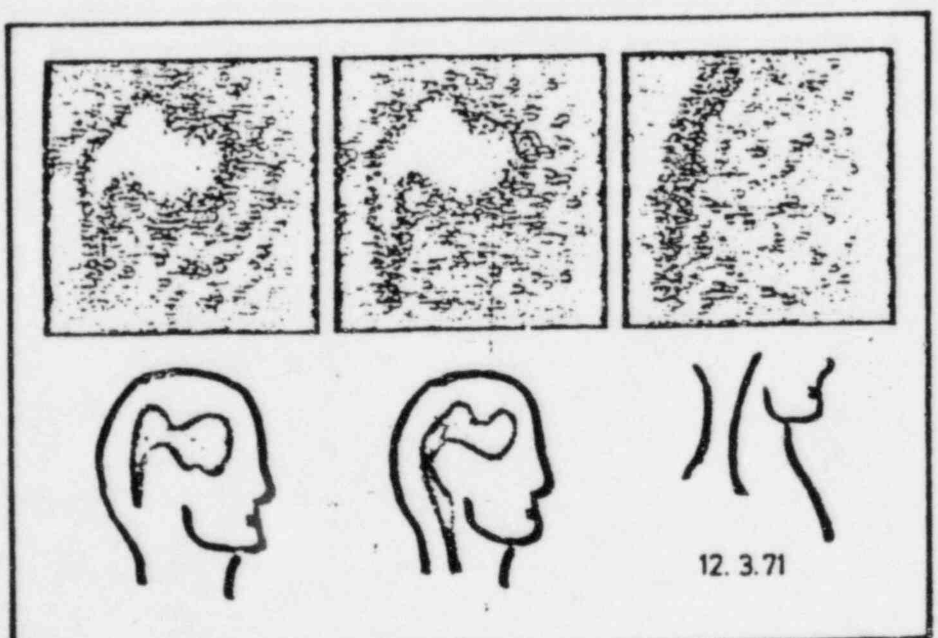

Fig. 4. False negative: scintigraphically a normally functioning shunt. This sequence of scintiphotos shows the enlarged ventricular system with spontaneous flow in the proximal and distal catheters

re-expand after such a long period of compression. Three months later, because of hygroma formation and an increase in the circumference of the head, a Pudenz-Heyer ventriculo-abdominal CSF shunt was performed. Seven months later the child underwent an emergency appendectomy because of acute appendicitis with localized peritonitis. At this time the distal end of the catheter was obstructed by a fibrin clot. This was revised, but no CSF flow was observed during the operation. Fig. 3 shows the shunt examination carried out three weeks after operation with spontaneous isotope flow into the peritoneal space. Appendicitis is rare in this age group (16 months), perhaps to be regarded here as a complication of the ventriculo-peritoneal shunt operation.

Case 3

(B.M. ♂ (1927) 7687) (Fig. 4) This 44 year old man with low-pressure hydrocephalus, a sequel of chronic arachnoiditis 10 years previously, serves as an example of a scintigraphically normally functioning shunt. He was sent to us with signs and symptoms of increased intracranial pressure. After injection the activity passed freely through the proximal as well as the distal catheter. However, because spontaneous emptying through the valve required a higher pressure than that present in the low-pressure hydrocephalus, new signs of increased intracranial pressure had appeared. To avoid such false negative results it is necessary to register the CSF pressure simultaneously with the isotope application. Thanks to the low-pressure valve used today in such patients, which practically rules out such complications, this is no longer necessary.

Case 4

(H.H. ♀ (1944) 14230) (Fig. 5) This 29 year old woman was examined because of increasing somnolence. The first examination (upper row of pictures) revealed an obstruction of the distal catheter, seen as a pooling of the activity in the neck. There was good visualization of the enlarged ventricles. The system was revised and the patient did well for about six weeks. At this time she became somnolent again and was referred for re-examination. This second examination (second, third and fourth rows of pictures) proved the patency of the proximal and distal catheters, with flow of the activity seen both spontaneously and after pumping the valve. Three months later the patient again developed the same clinical picture and was examined for the third time. This examination (last row of pictures) revealed an occlusion of the proximal catheter, seen scintigraphically as a failure to visualize the ventricular system. There was free passage of the activity through the distal catheter. This patient, seen three times with the same clinical syndrome, twice with an obstruction in the shunt system and once without, demonstrates the problems involved in diagnosing the function of the shunt on the basis of the clinical picture alone.

Case 5

(W.R. ♀ (1918) 7118) (Fig. 6) This 52 year old patient had undergone two operations for an aneurysm of the middle cerebral artery with resulting hydrocephalus and a severe organic mental syndrome. In spite of the implantation of a shunt as a palliative measure, the patient developed signs of increased intracranial pressure. At the first examination (first and second rows of pictures) there was no retrograde spread of the activity in the proximal catheter or the ventricular system. The distal flow was seen only to the level of the carotid bifurcation. After pumping the valve six times (picture upper right) there is only a pooling of the activity at this level. After 120 min (middle row of pictures) there is uptake of the isotope in the thyroid and salivary glands as a sign of an incomplete CSF obstruction distally. At the time of the second examination, one day later, and after flushing the system with aspirated CSF (lowest row of pictures), there was prompt demonstration of the proximal catheter and, as before, a partly obstructed flow distally. This block was then cleared by flushing with physiological saline. This patient illustrates the fact that with a proximal obstruction, the appearance of a distal obstruction is only a question of time.

Case 6

(B.B. ♂ (1972) 15597) (Fig. 7) In this 7 month old infant a bilateral ventriculo-atrial shunt operation had been performed because of a massive hydrocephalus of uncertain etiology. At the time of examination there were no signs of increased intracranial pressure although there was a decubitus ulcer caused by the venous catheter in the left side of the neck. After fontanelle puncture and application of the isotope only a very wide ventricular system was seen. Because of the dilution effect it was not possible to diagnose the functional state of the shunt systems. On the next day the isotope was applied directly in the Rickham reservoir on the right side (second row of pictures) and later also on the left side (third and fourth row of pictures). On the right side there was a spontaneous spread of the activity through the proximal catheter although only a partial demonstration of the CSF space in comparison to the previous examination (compare the second with the first row of pictures). Thus, although the ventricular catheter was functioning, the end was not in an optimal position and an operative revision was indicated. The ^{99m}Tc application on the left side showed heavy activity within a 3 × 7 cm area on the left side, as well as less activity within the atypically configured, markedly dilated 11.5 × 10 × 10 cm ventricular system. Even after repeated pumping of the valve, a distal flow could not be registered. The left venous catheter had become obstructed, apparently as a result of the decubitus ulcer. The complete shunt system on the left side was removed and the proximal end of the right-sided shunt system placed in a better position. After removal of the "foreign body", the ulcer healed rapidly, and there was no increase in the intracranial pressure. Here, with this shunt examination, it was also possible to diagnose the size and form of the apparently multichambered ventricular system.

Results

Between January 1970 and May 1973 23 shunt examinations were carried out in 17 patients. The oldest patient was 67 years, the youngest 7 months.

In 9 examinations the shunt system functioned completely normally. The clinical symptomatology was then relegated to other causes and the patient spared the operative shunt revision. In contrast are the 14 instances in which an obstruction in the shunt system could be proven. A proximal obstruction was seen 10 times, associated with a complete distal obstruction in one case, a partial distal obstruction in 3 patients, and an undisturbed flow in the venous catheter in the remaining 6. A distal obstruction was seen 8 times, in which half were possibly induced through a simultaneously existing proximal occlusion.

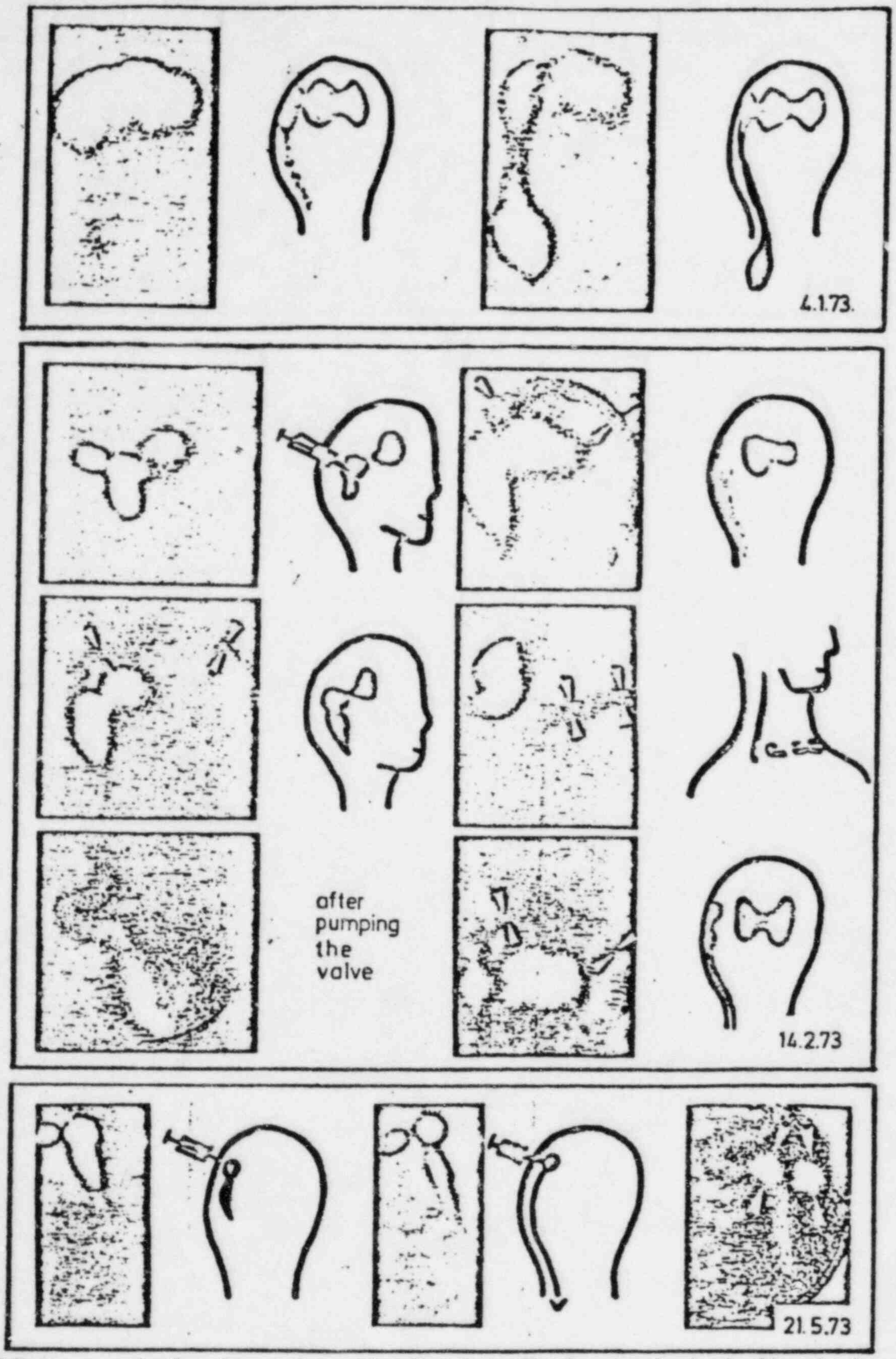

Fig. 5. Follow-up examinations in a patient with a V-A shunt. The first examination in this series demonstrates the patency of the ventricular catheter and a block of the venous catheter (seen as a pooling of the activity) in the neck. The second examination, six weeks later, shows a normally functioning shunt with good visualization of the enlarged ventricules, the proximal and the distal catheters. Three months later the patient developed an obstruction of the ventricular catheter, seen in the last examination as a failure to visualize the ventricles. (The "activity depots" seen here are markers in the neck or head: ►◄)

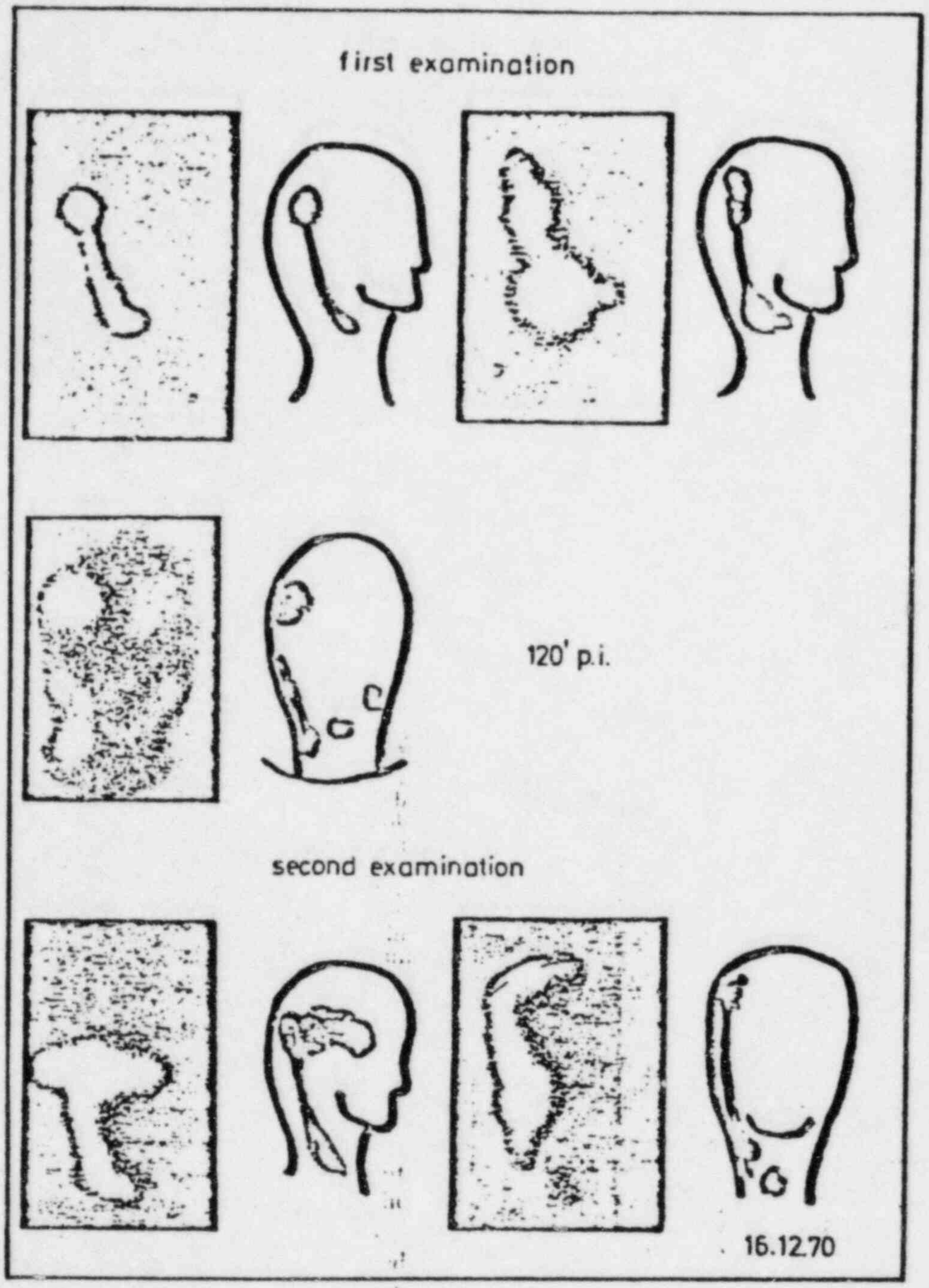

Fig. 6. Obstruction of the proximal and distal catheters. The first examination shows flow of activity only to the level of the carotid bifurcation; there is no visualization of the ventricular catheter. In the scintiphoto taken 120 min after injection there is uptake of the radioactivity in the thyroid and salivary glands as proof of a partial patency of the distal catheter. The second examination, performed after flushing the system with aspirated CSF, shows good visualization of the proximal catheter and an incomplete block in the distal catheter

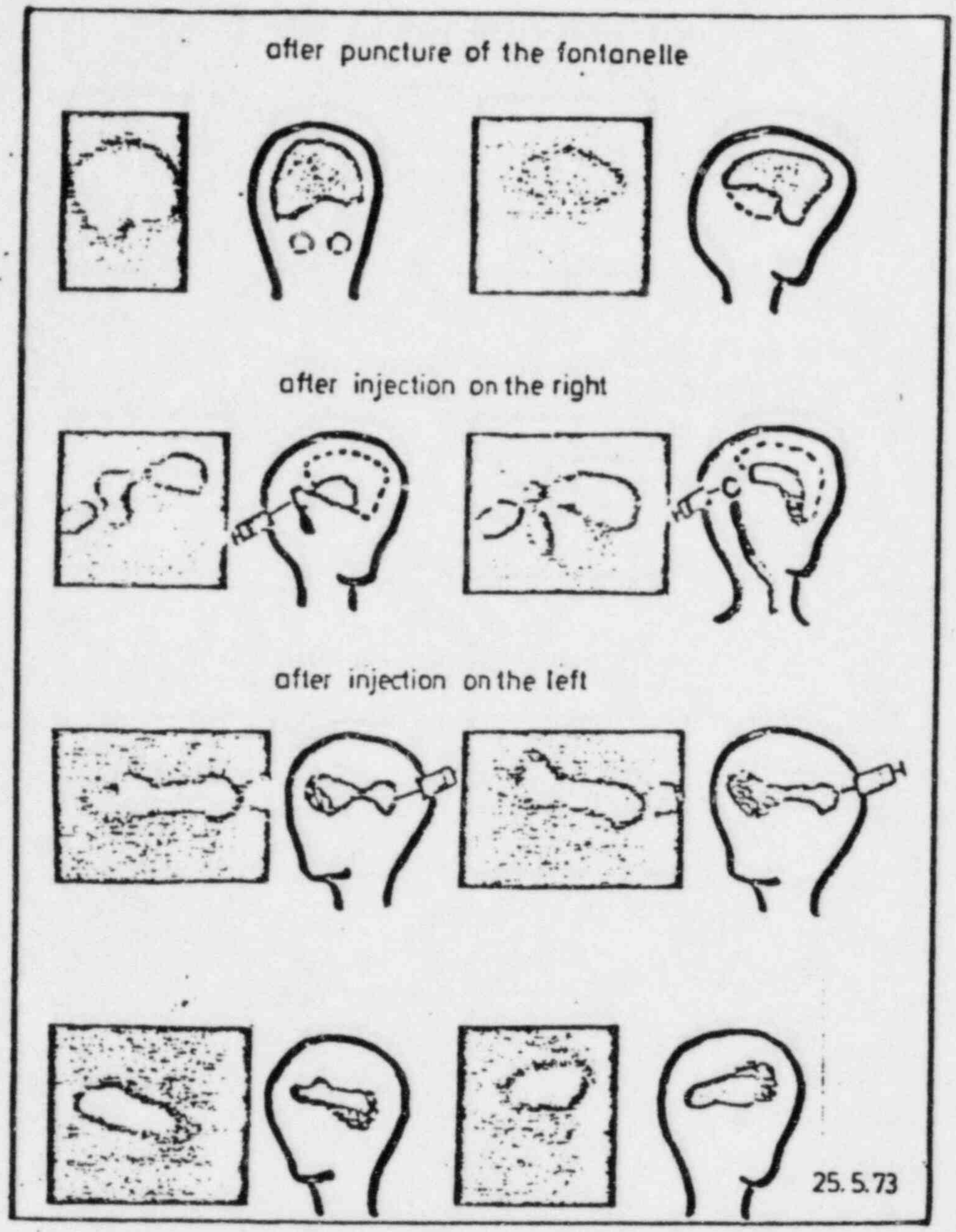

Fig. 7. Bilateral V-A shunt. The first row of pictures shows the extremely dilated ventricular system (after fontanelle puncture and direct injection of the activity). The second row of pictures comes from the examination after injection of the isotope into the Rickham reservoir on the right side: here there is spontaneous flow in the distal catheter but demonstration of only a small part of the ventricular system. The third and fourth rows of pictures show the injection on the left side with partial demonstration of the ventricle and no visualization of the venous catheter

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Discussion

Without exaggeration it may be stated that the ventriculo-atrial shunt raised the therapy of hydrocephalus into a new, hopeful state [4]. As a practical addition Rickham constructed a ventriculostomy reservoir (Fig. 1). By puncturing this reservoir CSF can be removed for examination, pressure can be measured, antibiotics may be injected [8, 11]. In order to evaluate the function of a ventriculo-venous drainage ^{99m}Tc-pertechnetate can be injected into the reservoir repeatedly and without any risk. There is a broad spectrum for these ^{99m}Tc-pertechnetate function tests, as was demonstrated with the above mentioned cases. Table 1 gives a survey on the problems [2, 6, 12, 13, 15] which might be within the scope of this technique. There is no other method similarily useful in giving data on functional disturbances as well as on anatomical structures.

Table 1. *Complications seen with V-A shunts*

1. Obstruction
   - Thrombosis of the catheter[a]
   - Kinking of the catheter[a]
   - Separation of the valve from the catheter[a]
   - Leaking of the catheter caused by damage sustained during operation[a]
   - Narrowing of the catheter by scar tissue[b]
   - Thrombosis of the internal jugular vein or the superior vena cava[b]
2. Delayed wound healing[c]
3. Slipping of the catheter out of the atrium and into the superior vena cava or internal jugular vein[a]
4. Other less frequent complications
   - Damage to the right atrium[c]
   - Endocarditis (usually as a result of septicemia)[c]
   - Postoperative subdural hygroma or hematoma[c]

[a] These complications well demonstrated by this method.
[b] These less well demonstrated by this method.
[c] These not demonstrated by this method.

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CH-3010 Berne
Switzerland

FORM NRC-313M (8-78) 10 CFR 35	U.S. NUCLEAR REGULATORY COMMISSION APPLICATION FOR MATERIALS LICENSE – MEDICAL	Approved: GAO R0557

INSTRUCTIONS – *Complete Items 1 through 26 if this is an initial application or an application for renewal of a license. Use supplemental sheets where necessary. Item 26 must be completed on all applications and signed. Retain one copy. Submit original and one copy of entire application to: Director, Office of Nuclear Materials Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555. Upon approval of this application, the applicant will receive a Materials License. An NRC Materials License is issued in accordance with the general requirements contained in Title 10, Code of Federal Regulations, Part 30, and the Licensee is subject to Title 10, Code of Federal Regulations, Parts 19, 20 and 35 and the license fee provision of Title 10, Code of Federal Regulations, Part 170. The license fee category should be stated in Item 26 and the appropriate fee enclosed.*

1.a. NAME AND MAILING ADDRESS OF APPLICANT *(institution, firm, clinic, physician, etc.)* INCLUDE ZIP CODE

Alexian Bros. Medical Center
800 Biesterfield Rd.
Elk Grove Village, IL 60007

TELEPHONE NO.: AREA CODE (312) 437- 5500

1.b. STREET ADDRESS(ES) AT WHICH RADIOACTIVE MATERIAL WILL BE USED *(If different from 1.a.)* INCLUDE ZIP CODE

(Same)

2. PERSON TO CONTACT REGARDING THIS APPLICATION

James Peterson

TELEPHONE NO.: AREA CODE (312) 282 1689

3. THIS IS AN APPLICATION FOR: *(Check appropriate item)*

- a. ☐ NEW LICENSE
- b. ☐ AMENDMENT TO LICENSE NO.
- c. ☒ RENEWAL OF LICENSE NO. 12-12979-01

4. INDIVIDUAL USERS *(Name individuals who will use or directly supervise use of radioactive material. Complete Supplements A and B for each individual.)*

See attached

5. RADIATION SAFETY OFFICER (RSO) *(Name of person designated as radiation safety officer. If other than individual user, complete resume of training and experience as in Supplement A.)*

Medhi Behinfar, M.D.

6.a. RADIOACTIVE MATERIAL FOR MEDICAL USE

RADIOACTIVE MATERIAL LISTED IN:	ITEMS DESIRED "X"	MAXIMUM POSSESSION LIMITS (In millicuries)
10 CFR 31.11 FOR IN VITRO STUDIES	X	0.240
10 CFR 35.100, SCHEDULE A, GROUP I	X	AS NEEDED
10 CFR 35.100, SCHEDULE A, GROUP II	X	AS NEEDED
10 CFR 35.100, SCHEDULE A, GROUP III	X	2,000
10 CFR 35.100, SCHEDULE A, GROUP IV	X	AS NEEDED
10 CFR 35.100, SCHEDULE A, GROUP V	X	AS NEEDED
10 CFR 35.100, SCHEDULE A, GROUP VI		

ADDITIONAL ITEMS:	MARK ITEMS DESIRED "X"	MAXIMUM POSSESSION LIMITS (In millicuries)
IODINE-131 AS IODIDE FOR TREATMENT OF HYPERTHYROIDISM	X	200
PHOSPHORUS-32 AS SOLUBLE PHOSPHATE FOR TREATMENT OF POLYCYTHEMIA VERA, LEUKEMIA AND BONE METASTASES		
PHOSPHORUS-32 AS COLLOIDAL CHROMIC PHOSPHATE FOR INTRACAVITARY TREATMENT OF MALIGNANT EFFUSIONS.		
GOLD-198 AS COLLOID FOR INTRACAVITARY TREATMENT OF MALIGNANT EFFUSIONS.		
IODINE-131 AS IODIDE FOR TREATMENT OF THYROID CARCINOMA	X	200
XENON-133 AS GAS OR GAS IN SALINE FOR BLOOD FLOW STUDIES AND PULMONARY FUNCTION STUDIES.	X	500

6.b. RADIOACTIVE MATERIAL FOR USES NOT LISTED IN ITEM 6.a. *(Sealed sources up to 3 mCi used for calibration and reference standards are authorized under Section 35.14(d), 10 CFR Part 35, and NEED NOT BE LISTED.)*

ELEMENT AND MASS NUMBER	CHEMICAL AND/OR PHYSICAL FORM	MAXIMUM NUMBER OF MILLICURIES OF EACH FORM	DESCRIBE PURPOSE OF USE
^{99m}Tc	MAA	As needed	LaVeen Shunt Patency
^{99m}Tc	Pertechnetate	As needed	Radionuclide Cystography
see range	— — ——		

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23. Under the Taplin exception, Alexian Brothers Medical Center also wishes to apply for permission to use ^{99m}Tc-MAA for LaVeen Shunt Patency Test and ^{99m}Tc-pertechnetate for radionuclide cystography. In support of this request, we submit the following support data.

<u>LaVeen Shunt Patency Test</u>

- Description of the procedures:

  5-10mC of ^{99m}Tc-MAA is injected into the peritoneal cavity. Using a large field of view gamma camera, multiple images are taken at 10, 20, 30, 40, 50 and 60 minutes after injection. Delayed images taken 1½ or 2 hours post-injection may also be taken.

Purpose and benefits:

A LaVeen Shunt is surgically inserted in patients with intractable ascites. It runs from the peritoneal cavity along the chest wall and into the jugular vein. When functioning properly, it provides drainage of ascitic fluid into the venous system that has otherwise been blocked by disease process. When there is reaccumulation of fluid after a successful initial implant, it has been demonstrated that in 5 to 8% of the cases, it is due to shunt malfunction. The remaining majority of the cases are managed dietatically. The test allows for evaluation of the shunt without resorting to another surgery.

Justification for exception:

We believe that the fact that the procedure is not included on the product labeling is 1) The procedure is new, and 2) it is a simply executed but rarely used procedure that it has been overlooked.

Radiation Dose:

In one hour, assuming a functioning shunt, the activity should accumulate in the lung, otherwise we assume its staying in the peritoneal cavity. We assume a 10 mC dose. From the MIRD Pamphlet No. 11, S [rads/µC-hr] are:

Source organs / Target organs	Peritoneal cavity	Lung
Total body	2.2×10^{-5}	2.0×10^{-6}
Gonads	1.0×10^{-5}	8.2×10^{-8}
Lung	5.6×10^{-7}	5.2×10^{-5}
Peritoneal cavity	3.8×10^{-5}	5.7×10^{-7}

Note: Gonadal values refers to ovaries (testes would be less)

Peritoneal cavity values are average of stomach, SI, ULI and LLI values.

Multiplying these values times 10^4 µC x 6.03 hrs. 1.44 yields dose in rads

	Activity in Cavity	in Lung
Total body	1.9 rads	0.17 rads
Gonads	0.9 rads	0.007 rads
Lung	0.05 rads	4.5 rads
Peritoneal cavity	3.3 rads	.049 rads

23. (Cont'd)

These doses are comparable to those delivered in other studies and are clinically justifiable.

Protection:

Our staff will observe routine clinical procedures assuring their own safety.

Radionuclide Cystography

Description of Procedures:

A Foley catheter is inserted in the bladder and a sample of urine is collected for urinalysis. The catheter is then connected to a bottle of normal saline with a rubber hose and as a free flow of saline is established, 1 mC of ^{99m}Tc pertechnetate is injected through the rubber hose. Various images are taken during filling and voiding of the bladder, and stored on computer for analysis of vesicoureteral reflux parameters. Collection of urine to allow calculation of residual volume during the voiding sequence is necessary.

Purpose and Benefits:

This test allows the quantitation of functional reflex parameters, bladder volume at which reflux occurs, measurement of actual amount of reflux into the upper tracts, calculation of drainage time of reflux after voiding, and residual urine volume.

Justification and Exception:

We believe that the fact that the procedure is not included on the product labeling is because 1) the procedure is new, and 2) it is a simply executed, but rarely used procedure that has been overlooked. Significant reduction in radiation dose to the patient over conventional x-ray examinations (which deliver m rads to even rads) is achieved using this test.

Radiation Dose:

1 mC of ^{99m}Tc pertechnetate in the bladder is assumed. S [rads/μC-hr] for the total body is 1.9×10^{-6}, for the gonads is 6×10^{-6} and bladder is 1.6×10^{-4}. This calculates (multiplying by 10^{3} μC) to a dose of 2 mR/hr rads to the total body, 6 mR/hr to gonads, and 160 mR/hr to the bladder when the bladder is filled. Average times that the bladder is filled has been reported in the literature and total dose to the bladder has been estimated at 5 to 30 mR. These doses are comparable to other nuclear diagnostic studies and we feel are justifiable.

Protection:

Since this procedure involves the transfer of radioactive saline and collection of radioactive urine, technologists will be instructed to place disposable covers on the floor and cart around the patient. They will wear lab coats and gloves. After the study, the area will be surveyed for contamination and decontaminated if necessary. Contaminated gowns will be stored

23. (Cont'd)

in our Hot Lab for 10 half lives before being sent to the laundry. Contaminated trash will similarly be stored for decay before disposal, as is our policy concerning radioactive waste.

CRC Manual of Nuclear Medicine Procedures

4th Edition

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DACRYOCYSTOGRAPHY

John W. Keyes, Jr.

Principle

Blockage of the normal pathway of drainage of tears from the eye into the nasopharynx and resultant epiphora is a fairly common opthalmologic problem. Due to the small size of the nasolacrimal drainage apparatus, determination of the exact site of blockage is difficult. Nevertheless, determination of the site of obstruction is important as this determines the type of therapy which will be implemented. It is possible to image the flow of tears through the nasolacrimal drainage system by placing a drop of radioactive fluid in the eye and taking a series of sequential images of the resulting radioactivity distribution using a gamma camera and a high-resolution, pinhole collimator. The technique is simple, safe, and much more physiologic than other techniques for studying the patency of the nasolacrimal drainage system.

Indications

The test is indicated in any patient with epiphora and suspected obstruction of the nasolacrimal drainage system. It is also useful in evaluating patients who have had prior surgical procedures to relieve obstruction without success.

Limitations

The test has no significant limitations. The amount of radioactivity used is so small that even the usual relative contraindications of pregnancy and lactation need not be considered. The test does require a gamma camera with a special, high-resolution, pinhole collimator.

Radiopharmaceutical and Absorbed Dose

Technetium-99m pertechnetate
100 to 200 μCi instilled into the eye
Emissions: *140 keV gamma*
Dosimetry: Lens 0.02 rad/100 uCi (unobstructed flow)
0.5 rad/100 uCi (obstructed flow)

Patient Preparation

None.

Procedure

1. The Technetium-99m pertechnetate should be diluted in sterile, pyrogenfree, buffered physiologic saline solution to a concentration of 4 to 6 mCi/ml. One drop of this diluted solution is placed in the eye (on the conjunctiva near lateral canthus) with a 23-gauge needle. Imaging begins immediately.
2. This study requires a gamma camera with a special, high-resolution, micropinhole collimator. A pinhole insert with an aperture size of approximately 1 mm is required

to successfully perform the study. Such inserts are commercially available from a number of sources and are interchangeable with the standard 4- to 5-mm aperture insert found in the conventional gamma camera, pinhole collimator.

3. Use a gamma camera with a high-resolution, pinhole collimator (see step 2 above) and a 20% window centered at 140 keV.
4. The patient should be positioned sitting with the collimator between 1 and 1½ in. from the lacrimal sac.
5. Beginning immediately after instillation of the radiopharmaceutical, obtain sequential 2- to 4-sec images of the inner canthus of the eye for 40 sec and then a series of three to five 40-sec images. More delayed images may be necessary in some patients with slow filling of the nasolacrimal drainage apparatus.

Interpretation

In the normal individual, radioactivity collects along the palpebral fissures and drains medially into the lacrimal sac within 5 to 10 sec. Over the next 30 to 40 sec good filling of the canaliculi, the nasolacrimal sac, and the nasolacrimal duct to its outlet in the nasal cavity occurs. The canaliculi, the nasolacrimal sac, and the nasolacrimal duct are usually well-defined on the longer-duration, later images. Abnormalities consist of obvious obstruction and lack of filling in any of these structures and/or prolongation of clearance time through the nasolacrimal drainage apparatus beyond 5 min.

LE VEEN SHUNT PATENCY

Roger P. Bowers

Principle

The Le Veen peritoneo-venous shunt consists of a subcutaneous tube running from the peritoneal cavity to a large central vein such as the internal or external jugular. A one-way valve allows flow of ascites from the peritoneal cavity to the venous system only when intraperitoneal pressure exceeds intrathoracic venous pressure by 1 to 3 cm of H_2O. When Technetium-99m sulfur colloid is injected into the peritoneal cavity it is absorbed very slowly and it can be used to trace the flow of ascites through the shunt. If there is any flow of ascites into the venous system, the Technetium-99m sulfur colloid will be taken up by the reticuloendothelial system and will be detected as activity in the liver.

Indications

This procedure will diagnose shunt malfunction such as blockage by clot or valve failure. Thus, other causes of intractibility can be considered when shunt is shown to be patent or surgical revision planned when shunt is nonfunctional.

Limitations

The tracer must distribute through the peritoneal cavity and not be restricted from shunt inlet by being localized in a loculation. Patient cooperation is important since performance of breathing techniques affects pumping action.

Radiopharmaceutical and Absorbed Dose

Technetium-99m sulfur colloid
3 mCi administered via intraperitoneal injection

Emissions:	*140 keV gamma*	
Dosimetry:	Total body	0.019 rad/mCi
(Worse case)	Testes	0.019 rad/mCi
	Ovaries	0.023 rad/mCi
	Liver	0.34 rad/mCi
	Spleen	0.21 rad/mCi
	Marrow (red)	0.027 rad/mCi

Patient Preparation

None other than the preparation appropriate to the intraperitoneal injection.

Procedure

1. Prep the patient's abdomen with Betadine® prior to local anesthetization with lidocaine. Use a 23-gauge spinal needle to inject the dose into the peritoneal cavity. An attached three-way stopcock is used to flush the dose with normal saline.

2. Use a wide-field-of-view gamma camera with a low energy, medium-resolution, parallel-hole collimator and a 20% window centered at 140 keV.
3. Image the patient in the anterior projection in a supine position.
   a. Immediately after administration of the radiopharmaceutical monitor the right anterior chest with the gamma camera persistence scope. If activity is seen accumulate 250 K counts over the chest.
   b. Image the lower abdomen for 1000 K counts or maximum of 10 min to document distribution in peritoneal cavity.
   c. Image the upper abdomen for 1000 K counts to check accumulation in liver.
   d. Repeat at 1, 3, and 6 hr to evaluate activity in the liver. An abdominal binder may be used to increase abdominal pressure prior to imaging.
   e. If no activity is seen at 6 hr, inject 500 μCi of Technetium-99m sulfur colloid intravenously to document location of liver.

Notes

After the spinal needle is placed a small amount of ascitic fluid is aspirated to ensure intraperitoneal placement. Standard breathing exercises routinely prescribed to promote pumping action should be performed.

Interpretation

Visualization of the shunt tube and heart followed by liver activity indicates a patent shunt. Absence of activity in the liver indicates that the ascitic fluid did not reach the venous system. This absence of activity in the liver may appear as a filling defect in the peritoneal fluid. This may be verified as liver by the intravenous injection of Technetium-99m sulfur colloid at 6 hr. Sulfur colloid is absorbed slowly by the lymphatic system of the peritoneal cavity. Thus a small amount of activity may reach the liver late by this method. Accumulation of activity in abdominal lymph nodes will be a clue that this process is occurring at a sufficient rate to confuse interpretation.

Dorlands medical dictionary

d protrusion of the navel. 2. ...
tor-e) [L. *exutum*, from *exuere* to ...
) 1. drawing off. 2. an ...
ve-e) [L., pl.] (*obs.*) 1. cast-off ...
gh (def. 1).
s-u"ve-a'shun) [L. *exuere* to dive...
ing of any epithelial structure, ...
s; Gr. *ophthalmos*] the organ ...
ulus [NA]. In shape the eyeba...
f a large sphere, with the seg...
, the *cornea*, in front. It is ...
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substance containing mucin ...
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ects. **crab's e's**, concretion ...
of a crawfish. **crossed e.**, ...
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form a dorsal median eye ...
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us, the eye directed toward the ...
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n hop pickers caused by ...
airs of the hop plant. **Klieg** ...
by conjunctivitis, edema of the ...
d photophobia due to expo...
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to weak light. **median** ...
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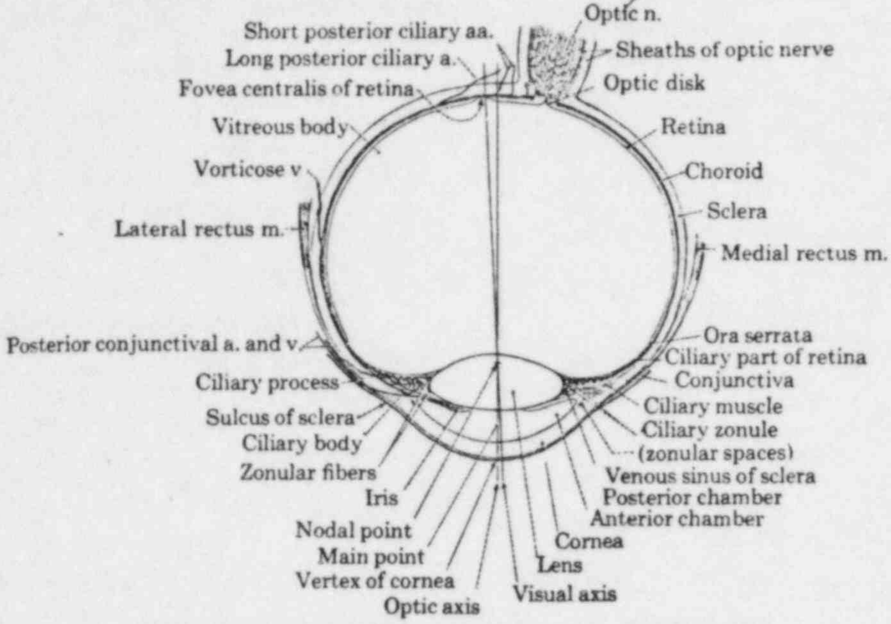
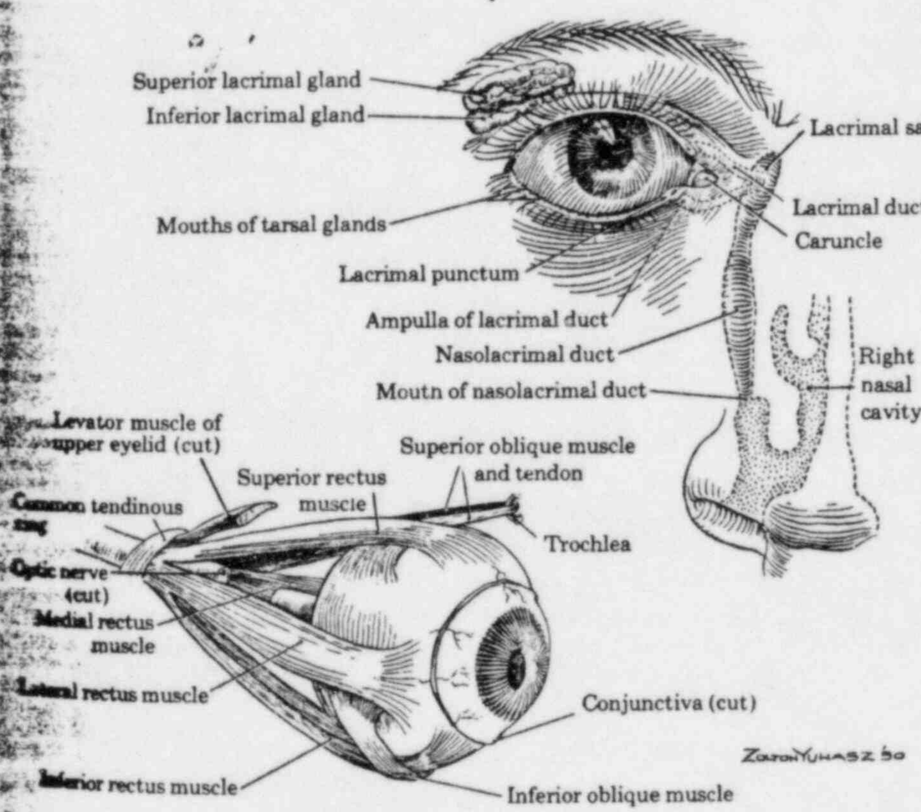
in the response to light ...
eye that can perceive ...
form of conjunctivitis ...
e juice of crushed blister ...
odification of the parieta...
es, to form a second dorsa...



HORIZONTAL SECTION THROUGH RIGHT EYE



THE EYE AND RELATED STRUCTURES