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Evaluation of Quality Assurance Procedures and Radiation Safety in Ruthenium-106 (Ru -106) based Ophthalmic Plaque (Manual) Brachytherapy

Ashish Binjola[1], V. Subramani[1], S. Megha Singh[1], Seema Sharma[1], S. Pathy[1], N. Lomi[2]

[1]Department of Radiotherapy, Dr. B.R.A. IRCH, AIIMS, New Delhi – 110029

[2]RPC, AIIMS, New Delhi - 110029

Abstract:

Title: To Evaluate the effectiveness of Quality Assurance and Radiation Safety procedures in Ophthalmic Plaque Brachytherapy.

Introduction: Plaque Brachytherapy can be an effective vision preserving treatment for many malignant (Uveal melanoma, retinoblastoma, etc) and benign eye conditions. Plaque brachytherapy with Ru – 106 beta source (*Half-life: 373.6 days and maximum beta energy 3.54 MeV*) poses minimal risk to the patient, personnel, public, and the environment if proper QA and radiation safety practices are adopted. This study intended to evaluate the effectiveness of QA and Radiation safety procedures adopted for the treatment process.

Materials and Methods: Efficacy of shielding during storage, procedure and in treatment was evaluated. Safety of the radioactive sources is an important aspect of radiation safety as loss of radioactive sources can cause undue exposure. Radiation levels around the facility were measured using pressurized ion chamber based survey meter in various locations (during storage, procedure, and treatment). Radiation levels near the wrist and at the level of eyes was measured.

Results: The maximum leakage level measured from a calibrated contamination monitor at a distance of 5 cm is found to be 5 μGy/hr which is well below the prescribed limits by the regulatory authority. Radiation levels around the facility are just slightly above the background level. Dose rate to the wrist of the surgeon is 3.5 mR/hr and at the level of eyes, it is 55 μR/h.

Keywords: Quality Assurance, Radiation safety, Ru – 106, Ophthalmic Plaque Brachytherapy, ICRP – 103.

Objective: Evaluation of Quality Assurance Procedures and Radiation Safety in Ruthenium-106 (Ru -106) based Ophthalmic Plaque (Manual) Brachytherapy.

Introduction: Ophthalmic brachytherapy is done using radioactive plaques emitting either low energy photon (^{125}I, ^{103}Pd or ^{131}Cs, etc.) or beta (^{106}Ru or ^{90}Sr) sources[1]. During the procedure, the plaque is surgically placed on the sclera surface over the intraocular tumor so that localized radiation dose can be administrated to the target volume. Dose prescription is done to the base of the tumor. For the retinoblastoma in children and uveal melanoma in adults, ophthalmic brachytherapy provides results that are comparable with enucleation[2] (removal of the eye). Ophthalmic brachytherapy is also an effective treatment of nonmalignant disorders of eye e.g. choroidal hemangioma[3].

^{106}Ru is a beta emitter (in secular equilibrium with its daughter ^{106}Rh, having half-life approximately 30 sec) with maximum energy 3.54 MeV and Mean Energy 1.42 MeV; ^{106}Ru radionuclide has a half-life of 373.6 days[4].

We have procured four different types of ^{106}Ru plaques depending upon clinical needs, (supplied by Eckert & Ziegler BEBIG India Branch) in our Institute. Details of the sources are tabulated in table1.

Make and Model	Eckert & Ziegler BEBIG GmbH Ru-106 eye applicator			
Sr. No.	Radio-Isotope	Diameter	Radius of Curvature	Activity (On Calibration Date)
CCX0289	Ru-106	11.6 mm	12.0 mm	7.1 MBq
CCB2569	Ru-106	20.2 mm	12.0 mm	23.6 MBq
CCZ0099	Ru-106	11.6 mm	12.0 mm	7.5 MBq
COB1172	Ru-106	19.8 mm	12.0 mm	17.5 MBq

Table 1. Details of Eye Applicators

The form of these applicators is a spherically concave silver bowl with an inner radius of curvature between 12 and 14 mm, and a total shell thickness of 1 mm[3]. We have sources with diameters from ranging from 11.6 to 20.2 mm[5].

The objective for this study is to evaluate the efficacy of quality assurance and radiation safety procedures followed before, during and after the surgical insertion of the plaque. The quality assurance is important for the radiation safety of the patient, attendants, and involved personnel.

Materials and Methods:

In our institute, Ophthalmic plaque brachytherapy was started after taking due authorization from the Atomic Energy Regulatory Board, Mumbai. Site approval, the nomination of RSO and other regulatory formalities were done before procuring the ^{106}Ru radioisotopes. For the safety and security of radioisotopes, two safe lockers were installed in a separate source storage room in which entry is highly restricted for unauthorized persons. Sources are secured in four layers of gates, and there is 24 x7 CCTV surveillance and security personnel is present. Appropriate radiation symbol was pasted in storage room main door and other required places. After the receipt of sources, all the sources were unpacked inside the source room (controlled area) and visually checked for any kind of physical distortion. Leakage test was performed for all four sources using GM based contamination monitor of valid calibration (table.2) and radiation survey was performed by calibrated pressurized ion chamber-based survey meter for each source in source room, operation theatre, autoclaves and patient ward in which patient shall be kept after insertion of radioactive eye applicator till the removal of source (table 3). Treatment time calculation software was validated with the help of source calibration certificates provided by the manufacturer for all the four sources and comparison with manual calculations was done with the help of source data (table 4).

Clinical application of the plaque brachytherapy was started only after proper clinical, physics and radiation safety training of all associated personnel. All the involved personnel were provided TLD badges and educated about its proper use before the inception of the facility. It's a customary practice that before planning the procedure, each time, selection of the source (depending upon the dimensions of the

ophthalmic tumor measured in US and MR imaging) for insertion is done and the treatment time is calculated in advance. Ru-106 sources can be used for the ocular tumors having apical height 5-6 mm and sclera dose needs to be less than 2000 Gy[6].

During the procedure first, dummy applicator (same as a source in design and geometry but not radioactive) was inserted. Correct dummy applicator can be identified by matching the code written over the dummy with a treatment chart. This is an important step as choosing the wrong dummy applicator can delay the procedure. First, cleaning of dummy eye applicator is done as per manufacturer guidelines and then it is sterilized in an autoclave at temperature up to 400 C for 20 minutes.

Figure 1 One of the dummy Sources (CCX 029)

After the sterilization of the dummy eye applicator is about to complete in the first autoclave, the medical physicist posted for the procedure takes the active source (after recognizing the intended source) which is inside the source shield to the autoclave room. Source shield is designed in two layers. The first layer is of a low Z material that absorbs most of the beta radiation and the second layer is of lead alloy to attenuate bremsstrahlung radiation produced by betas and a small amount of gamma (less than 1%) emitted by the source. Source sterilization is done before the physicist and radiation monitoring is done with the help of survey meter. Every month, Swab test is performed to know whether there is any contamination in the

source before putting it to the autoclave. For easy recognition, each source shield is marked by a permanent marker with source name and source code.

After the dummy eye applicator is placed on the desired place over the sclera, ultrasound imaging is done to see the placement of eye applicator, if it is satisfactory to the ophthalmic surgeon, the dummy is removed and returned to the physicist after cleaning. The source (active eye applicator/plaque) is brought to the designated OT in a bowl filled with minimum 5 cm of water to cut down the betas and insertion is done over the target. During the insertion, radiation monitoring is done using a survey meter. Doses near the wrist and eye level of the surgeon is recorded.

Contamination monitoring of equipment used to hold or keep the source is done using contamination monitor. After that, the patient is transferred to the recovery ward. Room survey is done and the attendant is properly educated to try to maintain a suitable distance (approx. 2 meters) from the patient when not caring. The patient stays in this room until the removal of the source.

Once treatment time is over the source is removed from the patient and handed over to medical physicist after cleaning immediately. The Presence of the source inside is shield is ensured by survey meter readings. The source is then transferred to the source room inside the source container. The source is then kept in the respective locker in the presence of radiological safety officer (RSO) and locked. Source room is then locked and keys are handed over to the RSO.

Results:

Radiotherapy Plaque facility fulfills all the regulatory requirements of manual plaque brachytherapy regarding sitting, layout and shielding design. Security plan for the radioactive sources is in place along with the written emergency procedures. Mock drills for different emergencies are practiced from time to time. Results of leakage test, at the time of receipt of the sources, are shown in the table below:

Source	5 cm from the surface in µGy/h	100 cm from the surface in µGy/h	Limit
CCX0289	2.0	0.1	For manual brachytherapy 500 µ Gy/h at 5 cm from the surface And 20 µGy/h at 100 cm from the surface
CCB2569	3.0	0.2	
CCZ0099	2.0	0.2	
COB1172	4.0	0.3	

Table 2. Leakage Radiation level

Radiation survey for the assessment of radiation safety of the facility is shown in the table below:

1	Source Type	CCZ0099	CCX0289	COB1172	CCB2569
2	Source Activity during the measurement	4.8 MBq	5.7 MBq	14.3 MBq	15.7 MBq
3	Unit of Radiation Measurement	µR/h			
4.	Make & Model of Radiation Survey meter used:	Fluke 451P/S N:5570			

Source	Wall-1 (W1)	Wall-2 (W2)	Wall-3 (W3)	Wall-4 (W4)	Wall-5 (W5)	Ceiling	Floor	Door location	Door location	Door location	Door location	Console (C)	Nursing station/changing room)
	(Record Room)	(source storage room)	Corridor	Wide corridor	Corridor	Toilet	Earth	D	D1	D3	D4	(TPS)	N
CCZ0099	12	22	17	19	14	9	-	15	20	20	16	13	16
CCX0289	14	26	20	23	17	11	-	18	24	24	19	15	19
COB1172	13	20	25	25	19	10	-	20	26	29	25	14	19
CCB2569	14	22	27	27	21	11	-	22	29	32	27	15	21

Table 3. Radiation survey of the facility

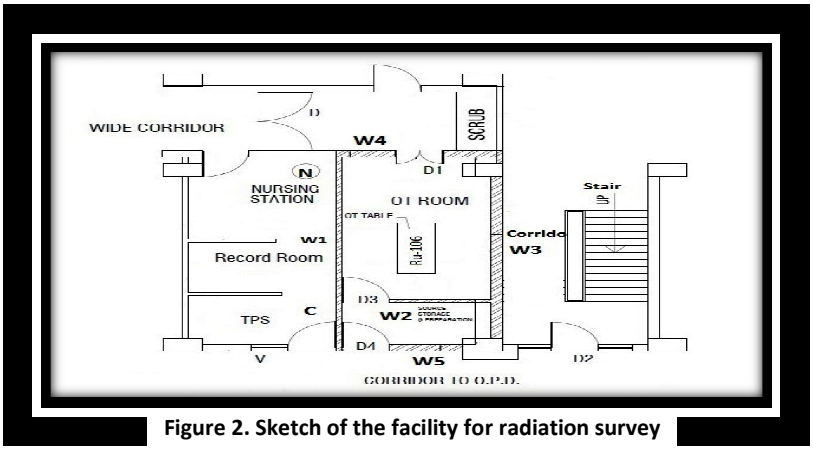

Figure 2. Sketch of the facility for radiation survey

Dose rates at various depths to water for all four sources provided by the manufacturer, for the purpose of treatment time calculations are shown in table 4. The Absolute calibration of the source dose rate to water was done using plastic scintillation detector on the reference date. The calibration of the detector is based on National Institute of standard and technology, USA. These data are double verified by the physicist from the source certificate before the clinical application in the treatment time calculation software as well as for manual calculations.

Applicator	CCX 0289	COB 1172	CCB 2569	CCZ 0099
Reference Date	**24-xxx-xx**	**24-xxx-xx**	**24-xxx-xx**	**24-xxx-xx**
Depth / mm				
0.48	153.90	140.70	149.10	181.20
1	131.00	122.40	131.50	154.90

2	92.90	91.50	101.80	109.20
3	62.60	67.40	76.80	74.10
4	39.70	47.40	56.20	46.80
5	24.80	33.00	40.40	28.80
6	14.80	22.00	27.70	17.50
7	8.67	14.10	18.40	10.20
8	4.78	8.74	11.90	5.56
9	2.60	5.08	6.90	2.99
10	1.33	2.86	4.12	1.57

Table. 4 Source Data used for validation of treatment time calculations

The maximum dose rate near the surface of autoclave, during source sterilization, is found to be approx. 400 µR/h and 80 µR/h at a distance of 5 cm and 1 metre respectively. Dose rate to the wrist of the surgeon is 3.5 mR/hr and at the level of eyes, it is 55 µR/h.

When the patient is present in the recovery ward with eye applicator, maximum radiation levels at different points inside and outside the isolation ward are shown in figure 3.

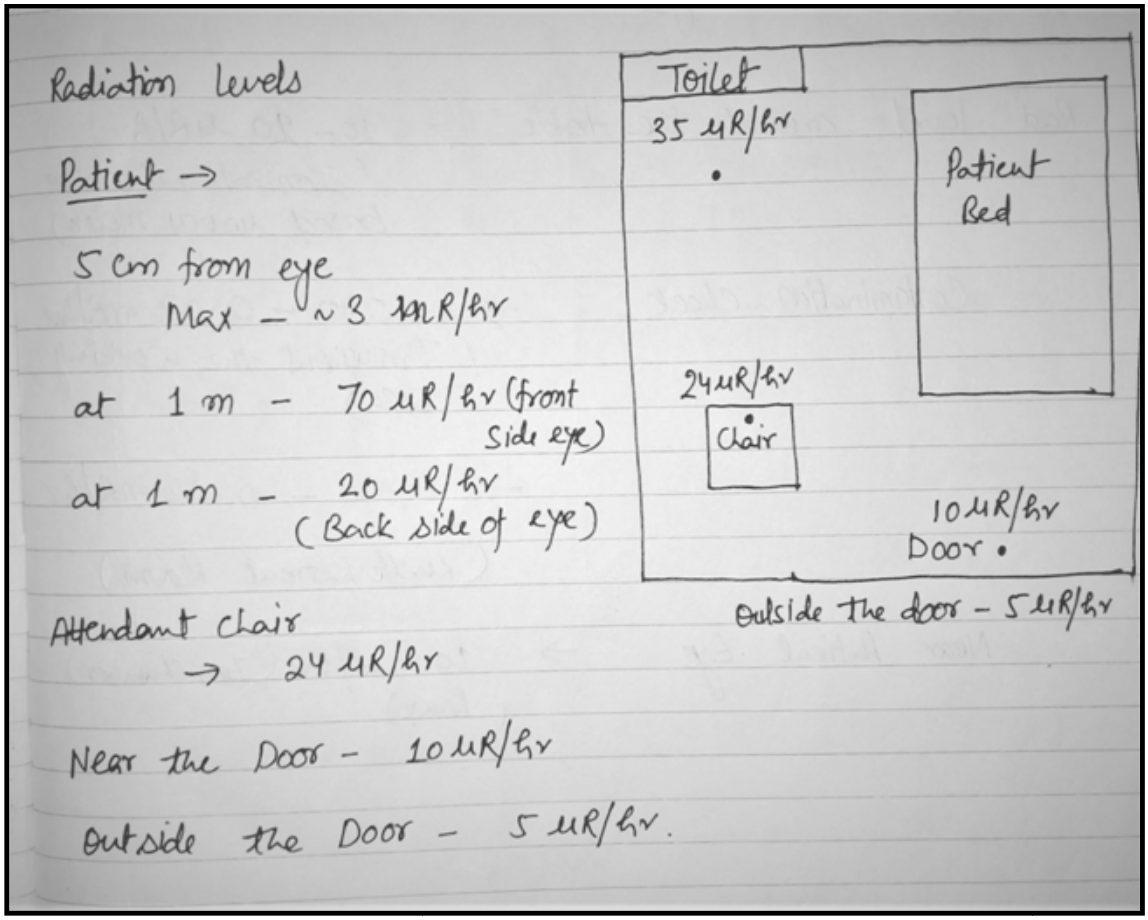

Figure 3 Radiation levels in isolation ward

Discussion: Quality assurance of equipment and the treatment process is essential for safe and effective medical care. But when it comes to radiotherapy, in any form, a stringent quality assurance program is essential not only for the safety and effectiveness of the treatment but for the protection of personnel involved, member of public as well as the environment[7]. Our study demonstrates that the quality assurance process what we have adopted from the treatment preparation to the removal of the radioactive eye applicator minimizes the chances of error. The facility fulfills shielding and source safety requirements as per the latest AERB safety codes[8].

For minimizing the harmful radiation effects, doses to the personnel shall be as low as reasonably achievable. ICRP (in the year 2011) has reduced equivalent dose limit for eye lens for radiation professional from 150 mSv to 20 mSv[9]. Measurement of the doses at eye level can be an important indirect parameter for the estimation of lens dose.

In their report task group number 56[10], Americal Association of physicists in medicine (AAPM) recommends following quality assurance tests with different frequencies, for manual brachytherapy (only relevant tests pertaining to plaque brachytherapy discussed here):-

1. Evaluation of source dimensions and serial number
2. Source Leak Test (Source Integrity)
3. Source Strength Calibration
4. Source Inventory
5. Source Preparation area survey, etc

Our quality assurance program not only conforms the national and international standard for plaque brachytherapy, but we perform additional tests which ensure safety and prevent errors.

Conclusion: Quality assurance and radiation safety and security procedures as prescribed by regulatory authority are important to minimize human errors, fulfills the clinical goals to achieve favorable outcomes and to protect public, personnel and environment. The quality assurance during the entire treatment process for the ophthalmic plaque brachytherapy ensures the safe delivery of the treatment without any undue hazard.

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