How can we perform endovascular brachytherapy in a standard catheterization laboratory?

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Abstract. Endovascular brachytherapy is a radiation treatment modality for reducing the risk of restenosis after percutaneous coronary interventions. Several devices using different nuclides and source geometries have been introduced into clinical practice. In general treatments are performed in the standard catheterization laboratories of cardiology departments, which are not dedicated for radiotherapy. Radiation safety regulations and shielding constructions are normally adjusted for conventional x-ray angiography.

In order to establish guidelines for radiation safety several measurements and calculations of the dose rates during typical procedures and at different locations in and outside of a cath lab were performed. In addition an incoming check including leakage radiation, missing catheter interlock, positioning test, timer check, interrupt button check, power-off test and verification of the manual retraction facility was established. Emergency equipment was tested for practical usefulness.

Our results show that doses to personnel are low compared to the exposure due to X-ray angiography. Gamma devices showed a significantly higher dose rate compared to beta radiation. However, by leaving the cath lab during treatment and limiting the number of procedures, the maximum dose levels can be maintained below accepted dose limits without any further shielding. Based on calculated and measured data recommendations can be given in order to minimize the exposure to the personnel involved. For beta sources a safety distance from the unshielded part of the delivery catheter during source delivery should be planned in order to avoid doses of up to 50 µSv per treatment at 1 meter distance. Handling of the catheter during source travel is a radiation risk for the operator. Emergency situations should be handled by using appropriate equipment.

Endovascular brachytherapy can be performed in standard cath labs without additional exposure exceeding the level of a normal X-ray angiography, when the personnel works in compliance with basic safety instructions.

1. Introduction

Endovascular brachytherapy is an established treatment to reduce the restenosis rate after percutaneous coronary interventions [1-3]. Clinical trials using various beta- or gamma-radiation emitting sources showed a significant improvement in the treatment outcome, even at long-term follow-up. Especially the treatment of in-stent restenosis is a FDA (U.S. Food and Drug Administration) approved method, which is performed worldwide for several thousand cases per year. The procedure is highly interdisciplinary between an interventionist (e.g. cardiologist, angiologist, radiologist, surgeon), a radiation oncologist and a physicist.

To deliver such treatments different new brachytherapy devices have been developed during the last years and are available commercially. Nowadays mostly the beta nuclides Strontium-90/Yttrium-90 and Phosphorus-32 are applied with afterloaders. The initially extensively used gamma nuclide Iridium-192 is by now not further available commercially.

Endovascular brachytherapy is usually performed directly after the cardiologic intervention using the same treatment set-up with the patient positioned on a table in a coronary catheterization laboratory. These rooms were initially designed for the use of X-rays from angiography. The wall thickness of the room and available shielding facilities are initially not adapted to handle radioactive material. For beta sources the existing configuration may often be sufficient, whereas gamma sources may only be used with additional requirements.

Radiation safety issues and quality assurance aspects are discussed in different guidelines as by the American Association of Physicists in Medicine (AAPM) Task Group 60 [4], the Report 16 of the
Deutsche Gesellschaft für Medizinische Physik (DGMP) [5] and the recommendations of the Endovascular working group of the Groupe Européen de Curiethérapie / European Society for Therapeutic Radiology (EVA GEC ESTRO) [6]. However, in neither of these documents detailed instructions and dose rate values for clinical routine are given. This paper provides a summary of measured dose rates, recommendations to minimize the dose to the staff and methods to perform quality assurance based on international recommendations. Standard equipment for peripheral endovascular brachytherapy, the application of radioactive stents and our experience with radioactive filled balloons are not addressed.

2. Materials and Methods

2.1. Radiation Devices

2.1.1. Gamma Emitting Seed Ribbon

The gamma emitting source investigated is a seed ribbon consisting of individual radioactive Iridium-192 seeds (Best Industries, Inc) and is part of the Cordis Checkmate™ Intravascular Radiation Therapy system (Cordis, Johnson and Johnson company, USA). The nominal length of a single seed is 3 mm and the maximum activity for treatment is 1.2 GBq per seed. With a spacing of 1 mm these single seeds are arranged to seed ribbons of 23 mm to 55 mm length fixed in a nylon tube, which is connected to a steel cable. The delivery device provides a mechanic to deploy and retract the source ribbon inside a closed tip radiation delivery catheter. A shielded housing is used to store the source ribbon inside the device. During storage and transportation the device is additionally located in a dedicated storage container.

2.1.2. Beta Emitting Wire Source

The Phosphorus-32 source is a wire source with a length of 20 mm used in the computer controlled remote afterloading device Galileo™ of Guidant (Guidant Corporation, USA). The automatic afterloader software allows stepping of the source with a maximum activity of 10 GBq. The wire is shielded within a built-in lead container. According to modern afterloading technique a non-active dummy wire is used for catheter obstruction testing and accurate positioning of the active source.

2.1.3. Beta Emitting Source Train

The Strontium-90 source used in this study is a source train with an active source length of 40 mm or 60 mm, consisting of single seeds. Each seed contains a $^{90}\text{Sr}$ ceramic core encapsulated in a stainless steel capsule of 0.64 mm diameter and 2.5 mm seed length. The source design is part of the manual hydraulic afterloading device BetaCath™ (Novoste Corporation, Norcross, USA). The seed train is located inside a transfer device. The delivery device stores the seed in a container, with an appropriate beta radiation shielding made of plastic and a glass window to look at the stored seeds. Using hydraulic pressure with a syringe connected to the device, the seed train is delivered into the delivery catheter. The delivery catheter is constructed with one lumen for the sources and a second lumen for a closed water circulation. So the seed train is retraced by switching a lever and pressing the seed trains with water from the tip of the catheter back to the delivery device. A safety lock system ensures that seed transfer is only possible with a catheter connected to the device. Electronic light indicators show the position of the source and the pressure of the water circulation. During transport and storage the transfer device is put into an additional storage container of lead.

2.2. Radiation Protection Dosimetry

Dose rate of gamma rays is measured using the Berthold LB-133-1 survey meter. Mean and maximum values are determined during 30 patient treatments. The personal dose to individual members of the intervention team was determined using a portable survey meter (Graetz EDW 150). In order to evaluate the exposure form the beta sources during storage and transport the Bremsstrahlung outside
the transfer device and storage container, respectively was measured using the LB-133-1. The directional dose equivalent \( H'(0.07) \) in case of beta radiation was measured with the Babyline 61 A device (Nardeux). The Babyline 61 A uses a ionization chamber with a wall equivalent to a tissue thickness of 7 mg/cm\(^2\). The energy correction factor for \(^{90}\text{Sr}\) of 1.05 is close to unity [7]. Further details on the measurement conditions and the experimental set-ups can be found in a recent publication [8].

2.3. Quality assurance

At acceptance test the missing catheter interlock, source positioning, irradiation timer, interrupt button, power failure and the manual retraction facilities are checked. The emergency equipment consists of a emergency container with at least 1 cm of plastic or 10 cm of lead suitable for beta or gamma source, respectively. In addition two tongues of 20 cm length, a magnification glass, magnetic tweezers and a pocket lamp are always stored in the emergency container. The presence of this equipment in the cath lab is checked before each treatment. Once per year an instruction in radiation safety procedures related to endovascular brachytherapy is given to all staff members working in the cath lab.

3. Results

3.1. Dose rates outside the cath lab

Shielding of the cath labs at the University Hospital of Vienna has not been adapted for gamma brachytherapy treatments. The walls and the window to the control room are equipped with 3 mm of lead, the doors with 2 mm lead. This thickness is appropriate for X-ray angiography, but the attenuation effect is low for \(^{192}\text{Ir}\) due to much higher half value layers. During irradiation using the gamma source the dose rates directly behind the walls surrounding the cath lab were 20 µSv/h at maximum behind the most exposed door and 2 µSv/h in the cath lab control room. The staff members present in the control room are exposed to not more than 1 µSv per treatment.

The bremsstrahlung of beta devices located close to the angiography table in the centre of the room could not be detected behind the cath lab walls.

3.2. Dose rates during storage and transport of sources

The maximum dose rates at the most exposed location from the storage container normalized to an activity of 20 GBq is 40 µSv/h on the surface and 1.2 µSv/h at 1 meter distance. Dose rates from the storage container of a 2.3 GBq \(^{90}\text{Sr}\) seed train device are between 130 µSv/h on the surface to 1 µSv/h at 1 meter distance. The dose at 1 meter distance from the \(^{32}\text{P}\) source located inside the built-in lead container of the automatic afterloader is below the measured background values and 0.4 µSv/h directly on the surface of the device.

3.3. Dose and dose rates inside the cath lab during patient treatment

In case of the gamma emitting source measured values at a distance of 1 meter from the patient are in the order of 500 to 1000 µSv/h. Therefore all staff members leave the room after positioning the source inside the target vessel, limiting high dose rates to the personnel to a few seconds for deploying and retracting the source. Using personnel dosimetry with the Graetz dosemeter the mean value was 6 µSv for the radiation oncologist and 3 µSv for the physicist per procedure. In any case the personnel exposure did not exceed 8 µSv in 20 procedures.

During preparation of the \(^{90}\text{Sr}\) source, the transfer device is taken out from the lead storage container, increasing the dose rate to 4 µSv/h at 1 meter and 35 µSv/h at 30 cm distance. For a typical procedure of 20 mins the dose to a person at 1 meter distance would be 1.3 µSv. Dose to the hands can reach maximum values up to 27 µSv per procedure. After sending the source into the patient’s artery these values are decreased due to the increased shielding ability of the human body. The dose from direct beta rays is limited to the time period when the source is travelling from the transfer device into the patient. The \( H'(0.07) \) values measured with the Babyline device are 18 mSv/h.
at 1 meter to 260 µSv/h at 4 meter distance from a 2.3 GBq $^{90}$Sr seed train. The period of source travelling is limited to 2 seconds per treatment. This corresponds to a dose of 10 µSv for a person located at 1 meter distance and 0.2 µSv at 4 meter distance. For the $^{32}$P source dose rates are comparable to $^{90}$Sr. However, based on the higher activity used for this device the dose reaches a maximum of 50 µSv to a person located at 1 meter distance to the radiation catheter.

4. Discussion and conclusion

4.1. Dose rates outside the cath lab

According to the findings of different groups the implementation of endovascular brachytherapy with gamma sources can be done without additional shielding of the cath lab walls by using appropriate workload, use and occupancy factors [8, 9]. For beta sources even no additional requirements are necessary.

4.2. Dose rates during storage and transport of sources

Due to the increased dose rates around the storage containers all devices have to be stored in dedicated safe rooms, which are usually available in radiotherapy departments. During transport from this safe room to the cath lab care should be taken to avoid public hallways and elevators.

4.3. Dose and dose rates inside the cath lab during patient treatment

The dose rate in case of gamma sources is limiting the presence of the intervention team inside the cath-lab if not using additional shielding. Therefore all personnel except the radiation oncologist and physicist is leaving the room after positioning of the delivery catheter. After deploying the radioactive source into the delivery catheter all personnel is at the control room outside the cath lab. By doing so the dose to staff members is kept to a maximum value below 10 µSv per treatment [10,11].

For beta sources the dose values are low compared to the effective dose limits for exposed workers (20 mSv/year). The equivalent dose for the skin, hands and lens of the eye should be taken into account, but is still low compared to the dose limits of 500 mSv, 500 mSv and 150 mSv, respectively. However, following the ALARA principle a distance of 4 meters to the catheter should be maintained during source travel. This should be considered for all personnel not directly involved in the handling of the device, e.g. cardiologist, nurses, technicians. In case of the $^{32}$P device higher doses at 1 meter distance can be expected. However, the Guidant system uses an automatic afterloading technique, allowing the user to maintain at larger distances and shortening the time close to the source travelling through the catheter.

Dose rate measurements before and after the treatment are performed for each patient to detect unnoticed loss of the source or parts of it and to detect unforeseen contamination. The measurement before the treatment is of high importance in case of patients, who received a nuclear medicine examination, which is quite often in cardiology. The increased background dose rates around such patient have to be recorded and compared to the dose rate after radiotherapy.

4.4. Tasks to be performed at each treatment

Based on the previously presented dose values and existing international recommendations following task are proposed. This procedure was successfully performed in more than 400 coronary brachytherapy treatments at the Medical University of Vienna.

- Transportation of the radiation device into the cath lab
  - Limiting the contact of members of the public with the radiation devices
- In the cath lab
  - Inspection of the emergency equipment
Radiation survey of the patient, the room and the delivery catheter with appropriate measurement instruments

- **During device preparation**
  - All staff members wear lead aprons *(which is usual in case of angiography anyway)*

- **During sending of the source**
  - Staff members should maintain a safety distance to the radiation catheter *(especially take care of the cardiologists which are often holding the catheter with their hands!)*

- **During irradiation**
  - Leave the room in case of gamma sources *(no requirements for beta sources)*

- **During retraction of the source**
  - Same as for the send procedure

- **After the treatment**
  - Inspection if the sources are send back and radiation survey of the patient, the room and the delivery catheter

Following basic guidelines the dose to the staff can be kept well below the dose of angiography alone and therefore within the occupational dose limits proposed by EC regulations.

**References**


