

## P1-5

**MICROBIOLOGICAL TESTING OF ASEPTIC EXTEMPORANEOUS PREPARATION OF GALLIUM-68-PEPTIDE CONJUGATES WITH MEDI-MEDIA-FILL KIT IN NUCLEAR MEDICINE LABORATORIES**Klára Németh<sup>1</sup>, Gergely Jánoki<sup>1</sup>, Zsolt Mike<sup>2</sup>, Győző Jánoki<sup>2</sup><sup>1</sup>Radiopharmacy Laboratory Ltd., Budaörs<sup>2</sup>Medi-Radiopharma Co.Ltd., Érd

**INTRODUCTION:** The nuclear medicine laboratory should guarantee the sterility and low bacterial endotoxin content of parenteral radiopharmaceuticals according to the current good practice for radiopharmaceuticals production. The microbiological purity can only be assessed after the administration of radioactive material, so exact knowledge of the aseptic preparation and its microbiological monitoring is of key importance. It can predict the microbiological purity of the radiopharmaceuticals prospectively. Our aim was to examine the aseptic preparation of the Ga-68-DOTA-TOC conjugate by previously developed microbiological quality control kit, MEDI-MEDIA-FILL kit.

**METHODS:** Before starting the preparation the aseptic environment must be ensured by sanitation (cleaning and disinfection). The microbiological contamination was checked by solid microbiological culture media TSA contact plates. During the aseptic preparation the media-fill method was applied, the aseptic process was carried out by a general microbial broth, TSB solution. The Ge-68/Ga-68 generator elution, the radiolabelling, the dilution and the sterile filtration were simulated. At each step samples were taken from TSB solution and incubated at 23 °C and 32 °C for 14 days as prescribed. The working surfaces and the operator were also sampled by contact plates at the end of the preparation, and the test plates were incubated at 23 °C to 32 °C for 5 days.

**RESULTS:** The sanitation was considered adequate if there was no visible colonies on agar plates (< 1 CFU/sample) after the incubation. The aseptic procedure was appropriate if TSB solution was a clear fluid indicating sterility. Turbidity of TSB solution observed by necked eyes, and the colonies grown on agar plates indicated some microbial contamination because of incorrect aseptic preparation, insufficient sanitation procedure, or inadequate personnel hygiene. The microbiological tests were performed in three independent repeats in accordance with the validation requirements.

**CONCLUSION:** Application of the media-fill method in nuclear medicine laboratory can ensure the safe preparation of parenteral products, because it can help to estimate the microbiological risks and troubleshoot the hygiene risks. The method can be also applied for the professional staff's regular education, job training and checks required to work well. Documented good results obtained with MEDI-MEDIA-FILL kit and its supply kits in these studies can demonstrate the proper operation of the laboratory for the authorities, and the existence of safety standards in healthcare.

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## P1-6

**XOFIGO THERAPY NEEDS INTERDISCIPLINARY COOPERATION**

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**INTRODUCTION:** 223Radium dichloride (Xofigo) is an effective therapeutic tool for patients with symptomatic multiple bone metastasis of castration-resistant prostate cancer (mCRPC) without soft-tissue metastasis. Several clinical trials are going on to define optimal pretreatment clinical criteria for the most effective („personalized”) use of Xofigo in the dynamically changing therapeutic stage.

**PATIENTS:** Various clinical data of our first 21 patients with mCRPC were analysed before, during and after Xofigo treatment. 7 patients had previous chemotherapy (docetaxel). Treatment had to be finished after one to three injections in 4 patients because severe granulocytopenia and/or thrombocytopenia. In 3 patients Xofigo therapy was temporarily suspended due to reversible cytopenia (but continued 6–8 weeks later). Xofigo treatment was finished in two patients (due to newly developed brain metastasis and relapsed peptic ulcer respectively) and in other two patients with suspected radical nerve compression. These two patients presented severe ischialgia and neurological symptoms. Both patients had the same symptoms in their history long years before. We indicated MRI examination, and in both cases radical nerve compression was found. 13 patients had the full course of Xofigo treatment. The average number of injections was 4.53 per patient. The median follow-up period was 4.54 ± 3 months. No death occurred during the treatment and the follow-up.

**METHODS:** Bone pain was monitored by a subjective scoring system. Hemoglobin, absolute number of granulocytes and thrombocytes were measured not in every four, but in every second week during the Xofigo treatment. The serum level of prostate-specific antigen (PSA) and alkaline phosphatase (SAP) were measured before and in every eight weeks during and after the treatment. In all 13 patients with full cycle of treatment bone scintigraphy was performed before and 6–8 weeks after the last injection of Xofigo.

**RESULTS:** Xofigo-induced critical cytopenia occurred more frequently in patients with previous chemotherapy. In 18 out of 21 patients (and in all 13 with full course) bone pain has significantly decreased. Serum PSA level was slightly increased during the treatment period with exception of 2 patients. SAP level tended to be decreasing continuously, however, it started to rise again in the follow-up period. Bone scintigraphy demonstrated diminishing of abnormally increased focal osteoblastic activity.

**CONCLUSIONS:** Our first experience with Xofigo treatment underlines the importance of detailed knowledge of the history of patients before the planned Xofigo therapy. Close interdisciplinary cooperation is important not only with the uro-oncologists. In patients with previous low back pain and neurological symptoms in the history, neurological examination and MRI have to be performed. Previous chemotherapy seems to be increase the risk of interrupting Xofigo treatment. In patients with well-tolerated Xofigo treatment a second course of Xofigo might be indicated to increase the quality of life and possibly overall survival.

## P1-7

**RADIOIODINE THERAPY FOR TREATMENT OF BENIGN THYROID DISEASES — A 14 YEAR RETROSPECTIVE ANALYSIS**Zsófia Patkó<sup>1</sup>, Barna Bakó<sup>2</sup>, Elvira Kócsák<sup>1</sup>, János Gombos<sup>1</sup><sup>1</sup>Department for Nuclear Diagnostics and Therapy, Borsod County University Hospital<sup>2</sup>Department for Internal Medicine, Borsod County University Hospital

**INTRODUCTION:** Over the past seven decades radioiodine has been a choice of treatment for thyroid diseases. However, dose estimation for optimal therapeutic outcome remains challenging. In our study we analyzed data from patients treated with radioiodine for benign hyperthyroidism between 2002 and 2015 at the Department for Nuclear Diagnostics and Therapy, Borsod County University Hospital. The purpose of our study was to review effectiveness of radioiodine therapies applied at our department and draw consequences for future therapeutic protocols.

**METHODS:** Altogether 160 patients (20 men and 140 women, age 54.4 ± 25) undergoing radioiodine treatment in our department between 2002 and 2015 were evaluated. Indications for therapy were Graves-Basedow (86%), Plummer's disease (5%) and autonomic adenoma (9%). Inclusion and exclusion criteria were determined according to national and EANM guidelines. The primary aim of therapy was to terminate hyperthyroidism. We used iodine uptake studies and Marinelli formula to estimate optimal dose for radioiodine therapy, the applied dose varied between 70 and 150 Gy (average: 81) in Graves disease and between 100 and 300 Gy (average: 134) in cases of toxic adenoma. Searching our clinical database and following patients we scanned treatment success at 1 year and development of hypothyroidism during the follow-up period. We evaluated correlations between uptake studies, administered doses and therapeutic outcome.

**RESULTS:** We could trace patients for ca. 2–5 years after treatment and analyzed thyroid status, additional treatments and clinical outcome. At the 1 year follow-up visit, hypothyroidism has been already diagnosed in 23%, and 35% of patients were euthyroid. One year after treatment hyperthyroidism persisted in about 30% of patients which was significantly reduced (to 5%) during the follow up period (2–5 years). Retreatment was needed in 15 cases (9%).

**CONCLUSION:** Radioiodine therapy is an effective alternative treatment for benign hyperthyroidism, with a 95% cure rate in our department. Additional laboratory data and uptake studies as well as patient history may be useful to choose the accurate dose for radioiodine therapy.

**P2. POSTERS: „IN VIVO” IMAGING**

## P2-1

**EFFECT OF CHOLESTEROL RICH DIET ON TUMOR GROWING**György Trencsényi<sup>1, 2</sup>, Adrienn Kis<sup>1</sup>, Noémi Dénes<sup>1</sup>, Judit Péliné Szabó<sup>1</sup>, Tamás Nagy<sup>1</sup>, Ildikó Garai<sup>1, 2</sup>, Dezső Szikra<sup>1, 2</sup>, István Hajdu<sup>1\*</sup><sup>1</sup>Division of Nuclear Medicine, Department of Medical Imaging, University of Debrecen<sup>2</sup>Scanomed Ltd., Debrecen

**INTRODUCTION:** In developed countries, the most common cause of death are cardiovascular disease and cancer. In our opinion the high cholesterol level increases the risk of cancer. Our research goal was to create dyslipidemic tumor bearing rat model which is suitable for investigating malignant tumors and hypercholesterolemia quickly and safely at the same time.

**METHODS:** Adult Fischer-344 and Long-Evans rats were used for the experiments. Rats were divided into control groups and Ne/De or My1/De tumor bearing groups. During the experiments two different diets were used. 1: Standard diet, 2: Cholesterol rich diet. In one part of the test, beginning of the diet was equal to the time of tumor transplantation. In the other part of the test, the diet started two weeks earlier to the time of tumor transplantation. Two weeks after transplantation whole body <sup>18</sup>F-FDG-PET/MRI scans were performed and tumor existence, size and <sup>18</sup>F-FDG enhancement were determined. After the imaging rats were sacrificed, healthy kidneys and tumor bearing kidneys were removed and weighted. Blood samples were taken and lipid profile was determined from the serum.

**RESULTS:** Using cholesterol rich diet the total cholesterol level increased eight times, the LDL level increased thirty times, the HDL level increased four times the triglycerides level increased eight times. Weight of left kidney (3.36 ± 1.05 g) showed significant difference from right kidney (1.07 ± 0.25 g) in My1/De tumor bearing rats fed with standard diet. Tumor bearing left kidney showed no difference (3.19 ± 0.62) in My1/De tumor bearing rats fed with cholesterol rich diet when beginning of the diet was equal to the time of tumor transplantation. Tumor bearing left kidney significantly increased (6.73 ± 0.69) in My1/De tumor bearing rats fed with cholesterol rich diet when beginning of the diet was two weeks earlier to the time of tumor transplantation. Weight of the right kidney did not differ (p = 0.1) using standard or cholesterol rich diet.

**CONCLUSION:** We have created a dyslipidemic tumor bearing rat model which model can be used for test of huge number of chemo preventive molecule quickly and efficiently in preclinical condition.