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COMPARATIVE ANALYSIS OF MEDICAL EQUIPMENT USED IN DIAGNOSTIC IMAGING IN BULGARIA AND COUNTRIES WORLDWIDE AND OPTIMIZATION AIMED AT IMPROVING THE HEALTH CARE SYSTEM MANAGEMENT.

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ABSTRACT

Purpose: to reveal the current condition of medical equipment in Bulgaria related to those major groups of socially significant diseases and to make an attempt to define guidelines for its optimization in view of improving the functioning and management of the healthcare system in this field.

Material and methods: The following research methods have been applied:

1. Document review method – research, processing and analysis of medical statistical information taken from data from WHO and annual reports of NRA. The study includes data from 2009 - 2015.

2. Graphical method – summarizing data in relevant tables and diagram presentations.

Results: The article analyzes the condition of medical equipment in the field of oncologic and cardiologic medical aid in Bulgaria based on data taken from WHO (World Health Organization) and annual reports of NRA (Nuclear Regulatory Agency). Six types of diagnostic imaging and radiation therapy devices have been studied: Magnetic Resonance Imaging units (MRI); Computed Tomography Scanners (CT), Positron Emission Tomography Scanners, Mammographs, Linear accelerators and Telecobalt units (Cobalt-60). The condition of medical equipment since 2009 has been analyzed, results have been reported and trends – studied.

Conclusion: The oncologic and cardiologic medical equipment in Bulgaria has been gradually improving in the last seven years, but quantitative indicators regarding the devices studied are still far away from the figures recommended by WHO with one single exception, i.e. Computed Tomography Scanners

Key words: Oncologic medical aid, cardiologic medical aid, Magnetic Resonance Imaging units (MRI), Computed Tomography Scanners (CT), Positron Emission Tomography Scanners, Mammographs, Linear accelerators, Telecobalt units (Cobalt-60),

INTRODUCTION

The greatest challenge that medicine and healthcare face in XXI century is the increasing costs for socially significant diseases. The most specific feature of those diseases is their large scale distribution. They are the result of a number of reasons, endogenic andexogenic forces acting throughout one's life. Those diseases mostly affect middle-aged people, which threatens the social and economic welfare of individuals, their families and on a more general level – the welfare of the entire population of a country. A positive affect regarding those groups of diseases can be achieved through: limiting major risk factors and taking advantage of the advance in medical science and practice [1].

RESULTS AND DISCUSSION:

The analysis includes data taken from 58 countries regarding 6 types of medical devices: Magnetic Resonance Imaging units (MRI); Computed Tomography Scanners (CT), Positron Emission Tomography Scanners, Mammographs, Linear accelerators and Telecobalt units (Cobalt-60). The source of information is WHO (World Health Organization) and part of the data for Bulgaria is provided by NCRRP (National Center of Radiobiology and Radiation Protection) and taken from annual reports of NRA [2, 3]. Countries from five continents take part in the research as follows: Europe – 25 countries; Asia - 13 countries; North and South America – 10 countries; Africa- 10 countries. The costs of medical equipment are related to 1 million inhabitants with the purpose of possible comparison and therefore most of them are not whole numbers. The research presents data from 2009 and in the graphs Bulgaria is marked in red so that it could be quickly and easily seen. Finally, average values are presented in tables and graphs for the six types of devices.

1. Magnetic Resonance Imaging units (MRI)

The first Magnetic Resonance Imaging unit in Bulgaria was delivered back in 1966 – MRI spectrometer (JEOL – Japan 60 MHz) [4]. As seen from the graph, Japan is leading in terms of quantitative indicators with 45.94 MRI units per 1 million people, the difference with the other countries being significant. (Fig.1.) Japan also leads in early diagno-

sis and effective treatment of oncology diseases. Despite using cutting edge technologies, treatment in Japan is less expensive than, for example, Germany or Greece. Latest trends in Japanese medicine, serving as standard for other countries, are as follows: minimal invasiveness, efficiency and individual approach to patients. An evidence of the highly efficient Japanese healthcare system is their record-breaking life expectancy, directly related to the promotion of healthy lifestyle, use of cutting edge technical and scientific achievements and the availability of competent medical experts. In 2015 Japan manufactured and commissioned the most powerful so far MRI unit with operating frequency of 1020 MHz. Before that the most powerful and ensuring the most precise diagnostics device was in Germany, with a frequency of 1000 MHz and functioning since 2009. Second among the countries studied is Belgium, having 24.89 MRI units per 1 million people, followed by Iceland with 21.69 MRI units per 1 million people, etc. Bulgaria in 2009 had 4.02 devices per 1 million people. This means that Bulgaria, with its population of 7.25 million, had in 2009 30 MRI units registered and functioning according to data. The majority of them are not brand new, but second hand. The main reason is the high price of brand new equipment and that is why second hand devices are most often purchased in a relatively good condition at prices about 800 000 - 1 000 000 BGN. Other reasons include high cost of maintenance, high operating costs and low return on investment. Profitability is ensured by a patient flow depending on the regulatory standards set by NHIF (National Health Insurance Fund) and on the patients' solvency. NHIF covers 180 BGN, and the rest is paid by patients. Financial estimates show that at such prices it takes 140-145 patients per month so that such kind of apparatus can be profitable for the medical institution. The average price of an MRI in Bulgaria in 2015 was 550 BGN with contrast agents and 350 BGN w/o contrast agents.

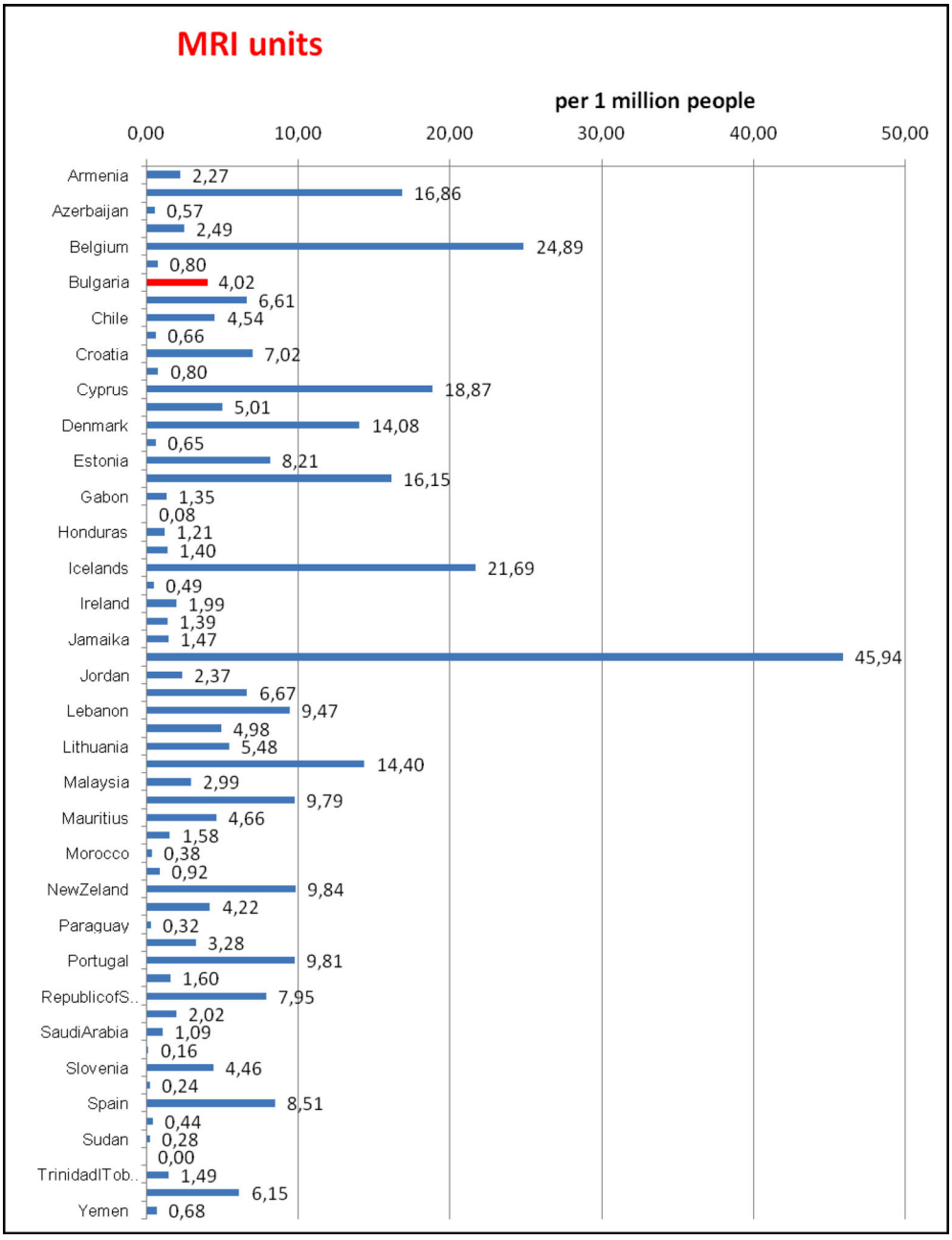

Fig. 1. MRI units worldwide in 2009

After 1998 the world of oncologic surgery welcomed a technical revolution thanks to robot-assisted surgery and proton therapy**. Gamma knife was also introduced in 1998 to perform** safe and minimal invasive operations through gamma ray radiation and with no cuts and bleeding. The device operates with the expensive radioactive cobalt and is mainly used in cases of malignant tumors in the head [5, 6, 7].

Cybeknife is a newer generation of equipment and is a robot-assisted radiosurgery set. It combines a radiation device attached to a mobile arm of a super precise robot and a special navigation system. The first European Cyberknife was made in Germany. Cyberknife operations are used in much more types and locations of malignant tumors and the apparatus also successfully treats some kinds of metastasis. The average duration of a Cyberknife surgery is approximately 1 hour. Cyberknife is famous for its absolute precision and the therapy itself spares healthy tissues to the maximum possible extent [8, 9, 10].

Even newer generation of equipment used for non-operative treatment of cancer is the so called **Trilogy linear accelerator** (Trilogy linac). The apparatus was introduced by a hi-tech American company and, in contrast to the two devices described above, operates directly through the electricity network so the cost of surgery is many times lower and the treatment become much less expensive [11, 12].

In Bulgaria, before 2016, Cyberknives were commissioned for radiosurgery and radiation treatment in Sv. Ivan Rilski Hospital in Sofia, Tokuda Hospital in Sofia and Sv. Georgi University Hospital in Plovdiv.

2. Computed Tomography Scanners (CT)

Bulgaria has a quite high number of CT devices – 27.19 per 1 million people. (Fig. 2) Such figures are close to the ones reported for well-developed countries such as Austria, Portugal, etc. Japan is the world leader, having 101.75 devices per 1 million people. The total number of CT sets functioning in Bulgaria in 2009 amounted to 198. According to their type they are single-slice and multi-slice. The latter can be subdivided further into 2-slice, 4-slice, 16-slice and 64-slice. In Bulgaria the majority of CT devices are manufactured by Siemens. Tests are usually made in four areas: head, chest, abdomen and pelvis [13, 14]. Their number has been gradually increasing: 235 in 2010; 237 in 2011; 241 in 2012; 266 in 2013 and 287 in 2014.

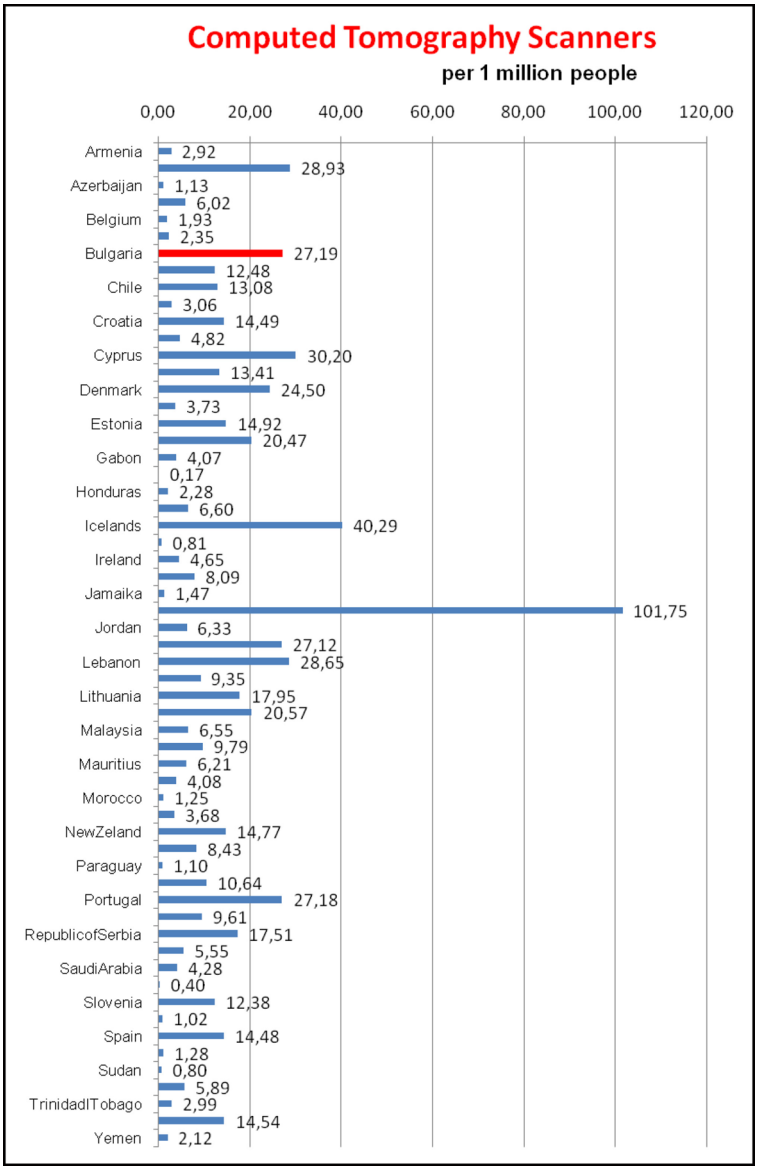

Fig. 2. Computed Tomography Scanners worldwide in 2009.

3. Positron Emission Tomography Scanners (PET scanners)

Positron Emission Tomography Scanners (or positron emission tomography) are diagnostic imaging devices that display biochemical and physiological changes and diagnose a disease at a very early stage before any morphological changes have occurred. This makes them different from MRI and CT devices that register structural anatomical changes that have already appeared in organs [15, 16]. In addition, they are used to monitor the effects of antitumor therapy. A disadvantage is their high price when compared to other diagnostic imaging tests: 2800 BGN, now entirely covered by NHIF, registration being subject to approval by a special medical committee. The first PET scanner was introduced in Bulgaria in 2009 at Sv. Marina University Hospital in Varna. Gradually their number increased and by 2016 there were 3 hospitals operating PET scanners: Sv. Marina University Hospital in Varna, Sv. Georgi University Hospital in Plovdiv and Aleksandrovska University Hospital in Sofia.

As seen from the graph the countries covered by the study that have the greatest number of PET scanners per capita are Belgium – 26.76 devices per 1 million people, Denmark – 6.03, Japan – 4.34, etc. (Fig.3.)

To operate, PET scanners need a specific radioactive isotope consumable called radionuclide fluorine-18. In 2016 Bulgaria had 2 cyclotron sets for their manufacturing: in Sv. Marina University Hospital in Varna and Aleksandrovska University Hospital in Sofia. A third set is to be constructed in INRNE (Institute for Nuclear Research and Nuclear Energy) at BAS (Bulgarian Academy of Sciences) – Sofia by the end of 2017. *A* cyclotron set consists of a *mini cyclotron device producing individual doses of radioactive isotopes for about 180–200 patients a month. It guarantees constant availability of the PET scanner consumable. Until then isotopes for PET scanners will be delivered by air due to their short period of decay* [17, 18].

The radiopharmaceutical most applied is 18F Fludeoxyglucose (F18 FDG). It is a substance analogous to glucose used in PET and suitable for testing metabolism of glucose in the heart, lungs and brain. It is also applied when monitoring treatment of Hodgkin's disease, non-Hodgkin's lymphoma, colorectal cancer, breast cancer, melanoma, lung cancer, etc. [19, 20].

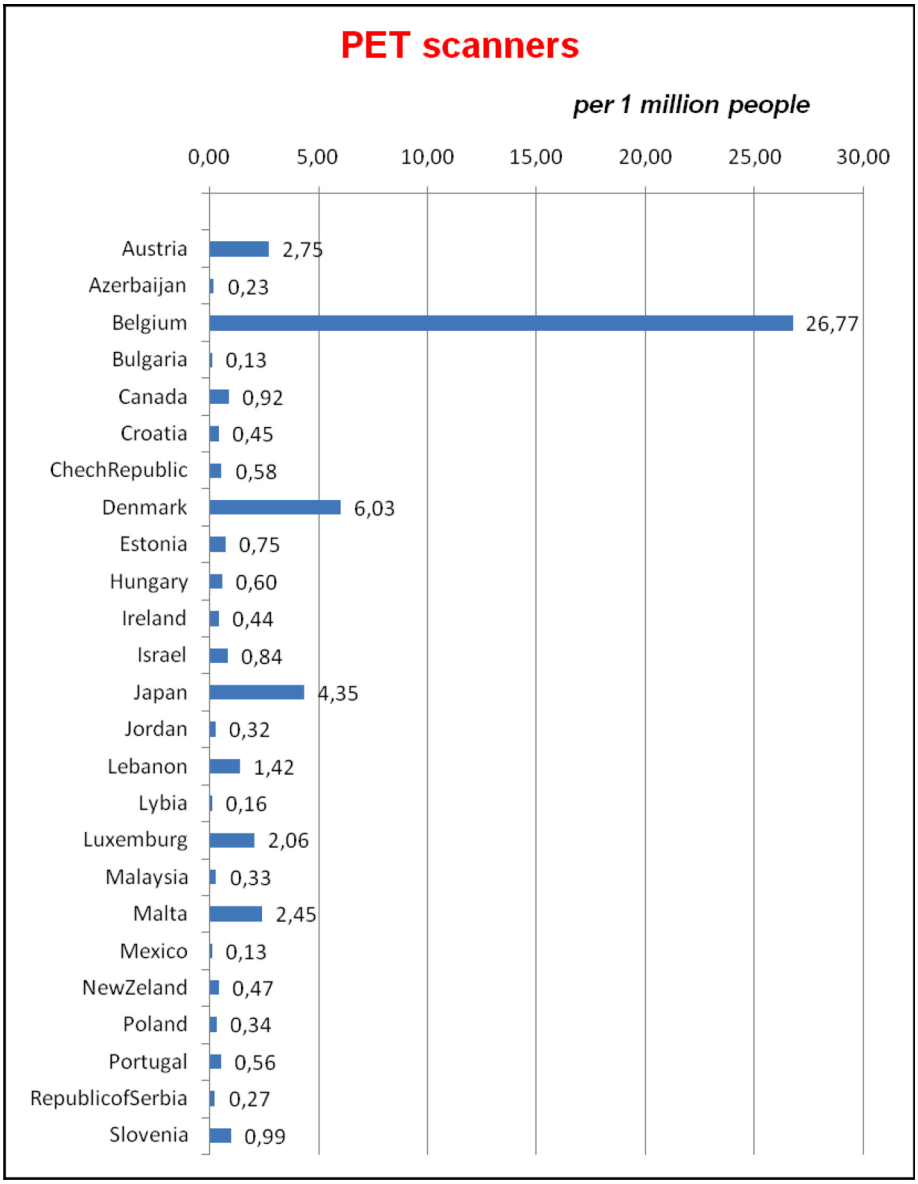

Fig. 3. PET scanners worldwide in 2009.

4. Mammographs

Each year more than 3500 women are diagnosed with breast cancer in Bulgaria. The most efficient method of prevention are the regular check-ups involving X-ray mammography (X-ray of the mammary glands). Mammography is a specific imaging method during which the structures forming the mammary gland are visualized using a relatively low amount of X-ray radiation [21, 22]. Routine preventive check-ups are meant for women, and those who do not have a family history should have their first mammography after they become 35-year old. Those who do have a family history should have their first mammography at about 30. Females up to 35-year old with no complaints and family history are recommended to have a echomammography (mammary gland ultrasound), where no X-rays are used [23, 24]. During mammography the mammary gland is placed between two planes and a slight controlled pressure is applied for several seconds. The X-ray mammography takes two views of the mammary gland. Bulgaria is well supplied with such equipment, the leading position being taken by Serbia with 210.18 devices per 1 million people, followed by Lebanon, Portugal, Finland, etc. (Fig.4.) The price of a mammography test (mammography and consultation) in Bulgaria is about 50 BGN and after the GP issues a medical referral, it is paid by NHIF. By 2009 the number of mammographs in Bulgaria was 199. In 2010 their number dropped down to 181. In 2011 they were 180, in 2012-213, in 2013 - 231 and in 2014 their number reached 255.

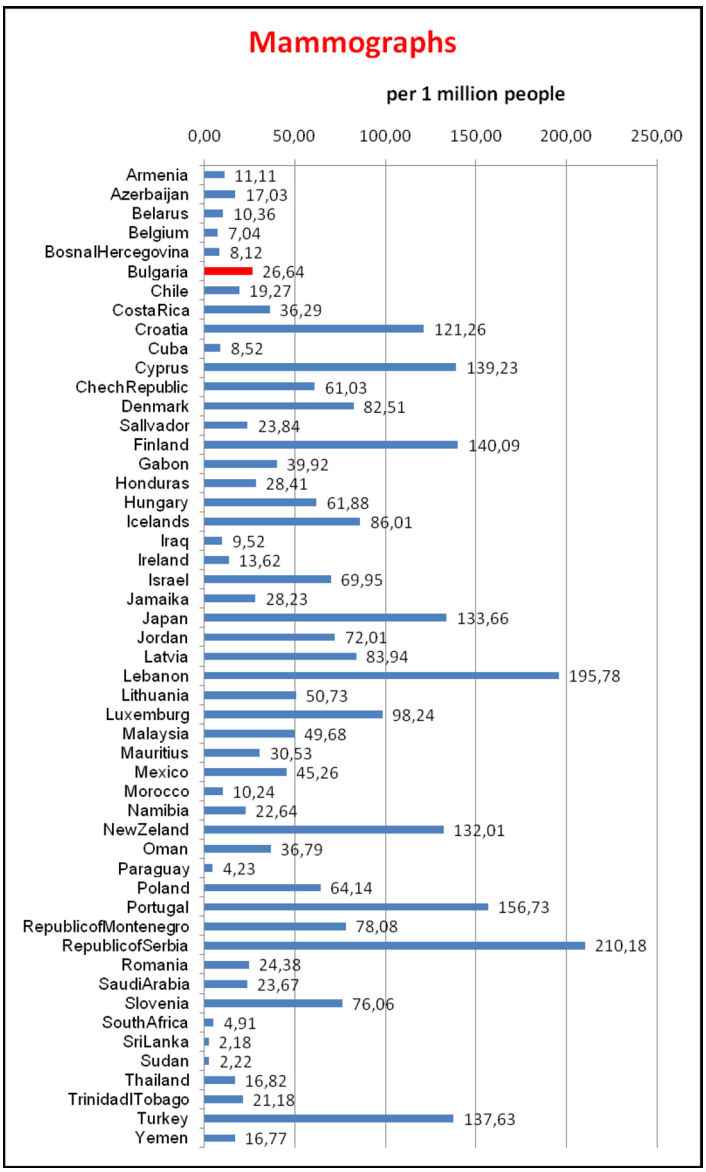

Fig. 4. Mammographs worldwide in 2009.

5. Linear accelerators

Linear accelerators for medical purposes (LINAC) ensure the opportunity to apply one of the most modern methods of external radiation therapy. It destroys cancer cells with minimal effect on healthy tissues surrounding a tumor. It is followed by a chemotherapy treatment varying in duration from 5 to 6 months and sometimes such chemotherapy has to be repeated. LINAC can be used for all radiation sensitive tumors such as breast, cervix, oral cavity, larynx, nose and testicles carcinomas; lung, prostate, bladder, stomach and pancreas cancer, etc. [25, 26, 27].

According to the graph, the country best supplied with such equipment is Denmark, having 9.87 devices per 1 million people, followed by Finland with 7.51, New Zea-

land with 6.56, etc. (Fig.5.)

By the end of 2009 Bulgaria had 3 linear accelerators used for radiation treatment of oncology diseases in Sv. Georgi University Hospital in Plovdiv, the Specialized Hospital for Active Treatment in Oncology in Sofia and the new one located in Tokuda Hospital in Sofia.

In 2014 the total number of linear accelerators used for medical purposes was 10: 3 in Sofia, 2 in Plovdiv and 2 in the town of Shumen, while 6 were being installed and tested: two new ones in Sofia, 2 in Varna, 1 in Plovdiv and 1 in the town of Vratsa.

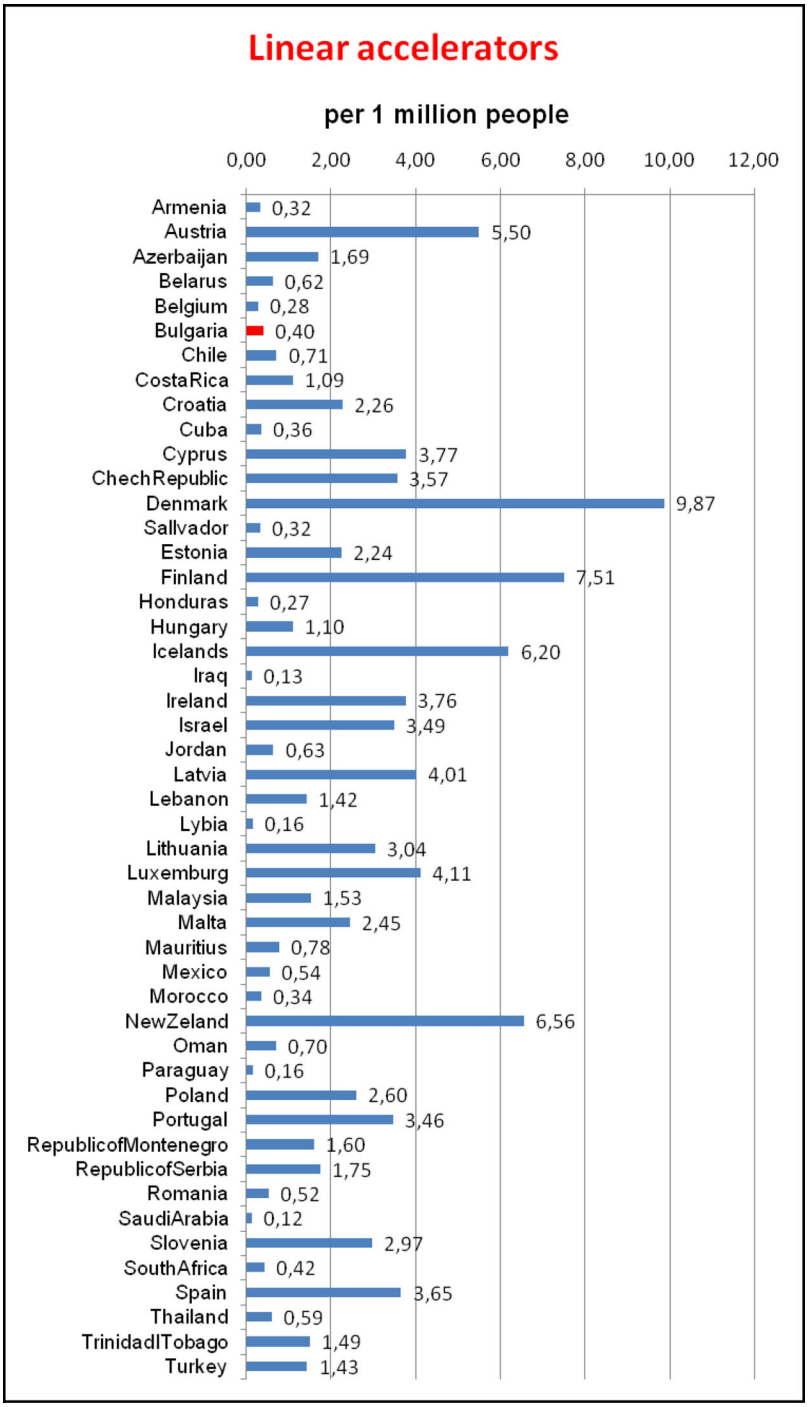

Fig. 5. Linear accelerators worldwide in 2009.

6. 6. Telecobalt units (Cobalt-60)

Cobalt therapy is the use for medical purposes of gamma rays from cobalt-60 isotope in cases of malignant tumors. After World War II, cobalt radiation therapy equipment revolutionized oncology and such devices were widespread in the 1950s and 1960s. After the introduction of the medical linear accelerator in the 1970s their role was partially replaced by linear accelerators. Advantages: medically efficient, having simple design, less expensive in terms of purchase price and maintenance costs as compared to modern linear accelerators. Disadvantages: radioactive waste related problems; cobalt-60 radioisotope has a half-life of 5.3 years and so it has to be periodically replaced [28, 29].

The modern cobalt therapy is also known as Gamma Knife therapy and can be applied in oncology for all body parts and organs. It is extremely precise and so it is used for

patients having brain tumors [30, 31, 32].

As seen from the graph from the countries covered by the study Malta has 2.44 devices, Belarus has 2.33, Mauritania – 1.55, etc. It is obvious that in countries with well-developed economies linear accelerators prevail instead of Telecobalt units. (Fig. 6)

In 2009 the old devices were replaced by new gamma radiation therapy equipment in the Specialized Hospital for Active Treatment in Oncology in Sofia and the district oncology clinics in the towns of Stara Zagora and Ruse. NRA issued installation and testing permits for the new devices, approval committees were set up and operation licenses were granted. In 2010 the medical gamma radiation equipment in the Oncology Center in the town of Plovdiv was uninstalled and decommissioned.

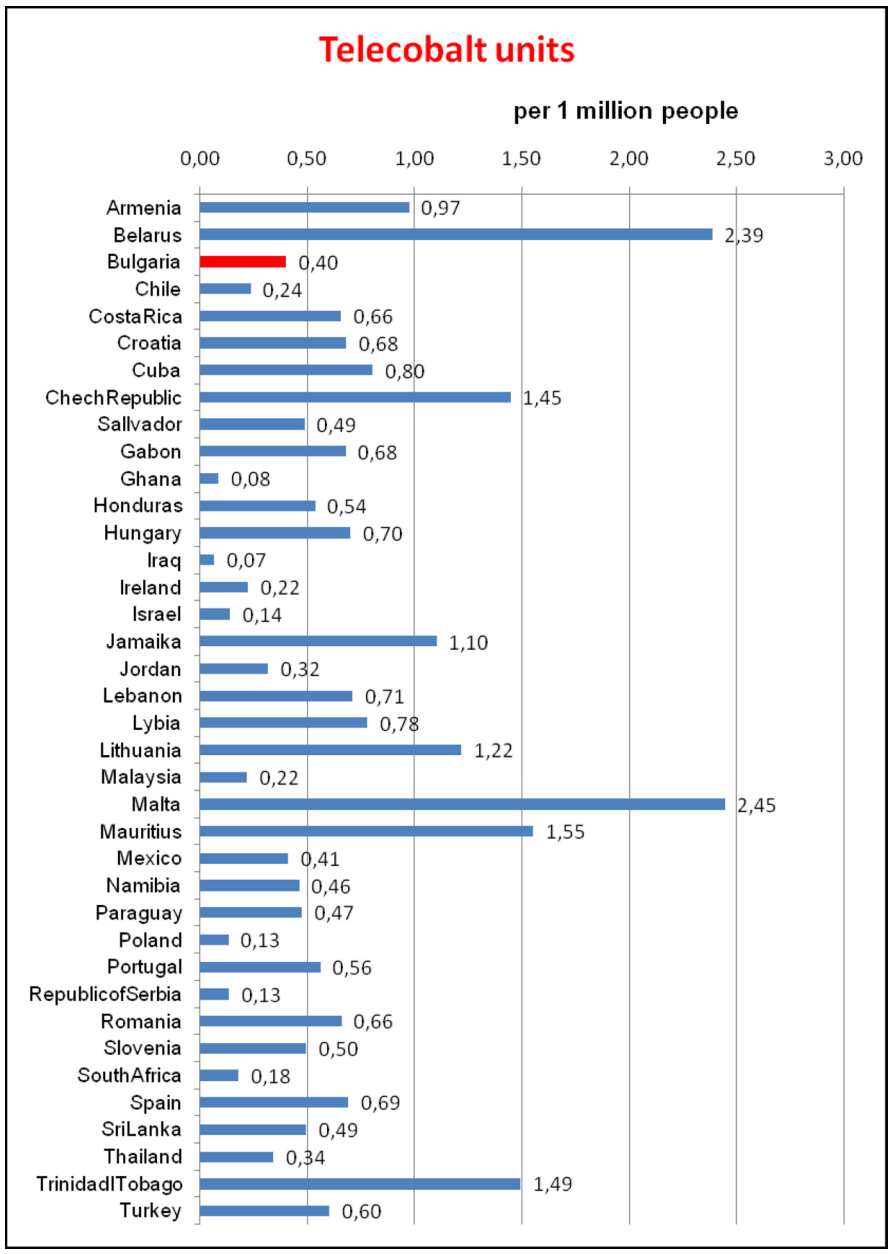

Fig. 6. Telecobalt units (Cobalt-60) worldwide in 2009.

Comparative data of the 6 types of studied diagnostic imaging and radiation therapy devices used in Bulgaria is presented, comparing the average figures on the continents taken into account with the purpose of displaying the general condition of the infrastructure studied in different countries worldwide. For better data illustration North and South America are presented together under a single name, i.e. America. (Table 1 and Fig.7)

Table 1. Average number of the 6 types of medical equipment (per 1 million people) per continents and Bulgaria in 2009.

	MRI units	CT	PET scanners	Mammographs	Linear accelerators	Telecobalt units
EUROPE	8.78	15.84	2.09	81.49	3.13	0.61
ASIA	5.99	13.71	0.58	50.38	0.89	0.3
AMERICA	1.93	4.9	0.116	23.91	0.61	0.69
AFRICA	2.29	4.17	0.08	34.6	0.92	0.397
Bulgaria	*4.02*	*27.19*	*0.13*	*26.64*	*0.4*	*0.4*

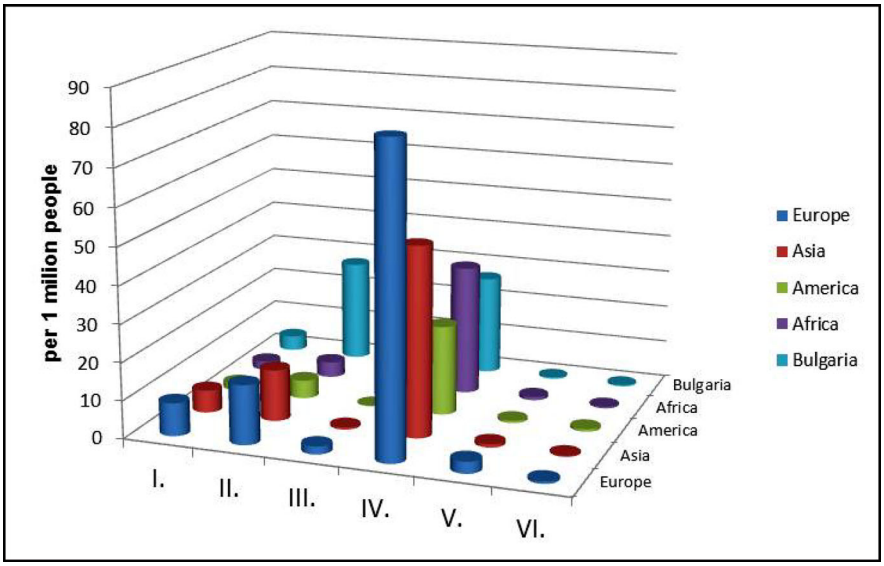

Fig. 7. Average number of the 6 types of medical equipment (per 1 million people) per continents and Bulgaria in 2009.

Key:
I. MRI units;
II. CT
III. PET scanners
IV. Mammographs
V. Linear accelerators
VI. Telecobalt units

CONCLUSIONS:

1. As seen from the study, the oncologic and cardiologic medical equipment in Bulgaria has been gradually improving in the last seven years, but quantitative indicators regarding the devices studied are still far away from the figures recommended by WHO with one single exception, i.e. CT. For example, WHO recommends a standard of 1 linear accelerator per 250 000-300 000 people, which means that our country by 2016 has approximately half of the numbers required for achieving this standard.

2. There is a considerable difference in those indicators between Bulgaria and the countries with well-developed economies. However, it has to be emphasized that the results do show a significant modernization and fast reduction of those differences, especially during the last three years.

3. The use of modern technologies by medical experts is directly related to improving the results in terms of diagnostics and treatment. Therefore, the recent year trend of increasing material resource has to be continued together with a steady improvement of medical specialists' qualification with the purpose of their adequate adjustment to new technologies.

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