ALARM SYSTEM FOR SURVEILLANCE OF PATIENTS RECEIVING HIGH DOSES OF RADIOIODINE (^{131}I) THERAPY IN THE CASE OF UNAUTHORISED ABANDONING OF A CONTROLLED AREA

by

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After receiving high doses of radioiodine the patients have to remain isolated within the "restricted area", until the radioactivity of the body drops below a certain level. The aim of this paper was to present our alarming system designed to discover patients who attempt to abandon the "restricted area" and inform medical staff about the event. The system consists of a survey-meter with a pancake probe directed towards the corridor. The survey-meter is connected to a trigger circuit which gives a signal in the case when the measured count rate exceeds a pre-set value. This signal sets "on" the alarm device, blinking light, programmable siren and IP camera, in order to warn the patient and inform the personnel when such a case occurs. In order to test the consistency and sensitivity of our system we measured ten times the ambient dose equivalent, $H^*(10)$, from the source of 925 MBq (25 mCi) ^{131}I, kept at a distance of 1 m. The average ambient dose equivalent was 77.73 31.57 (0.084 Svh^{-1} per MBq, or 3.1 Svh^{-1} per mCi). We measured ten times the same source at various distances (1-2.25 m) from the probe. In each position, the system was triggered. Also we tested the system on 40 patients treated with radioiodine instructed to pass through the corridor. Each of their attempts triggered the system. According to our experience gained over the past few years, this alarm system intended for patients receiving radionuclide therapy ensures a high level of safety for both the patients and medical staff.

Key words: radioiodine, alarm system, patient behavior

INTRODUCTION

Radioiodine ^{131}I was used in diagnosis and treatment of thyroid disorders for the first time in 1942 by Hertz and Roberts [1]. Shortly after this, the radionuclide was introduced into clinical practice for treatment of differentiated thyroid cancers [2, 3]. Thanks to its biophysical characteristics ^{131}I remained the principal therapeutic means of treatment of differentiated thyroid cancer with an aim to ablate thyroid remnants or tumor tissue.

In general, activities of ^{131}I which are used in the treatment of differentiated thyroid cancer are relatively high and depends on the estimate of risk, on the uptake of radioiodine in thyroid/tumor tissue and on the volume of the thyroid tissue remnant/tumor. Activities of ^{131}I used for postoperative ablation of thyroid remnants in the gland's bed range from 1.11 to 3.7 GBq (30-100 mCi), while for treatment of local or remote metastases are within the range of 5.55-7.4 GBq (150-200 mCi) [4-6]. However, some of the authors used either lower [7] or higher [8] ^{131}I activities for the treatment of differentiated thyroid cancers.

After receiving high activity of radioiodine the patients have to remain isolated within the "restricted access premises" or "restricted area"), until the radioactivity of the body drops below a certain level, usually defined by legal acts. Unfortunately, international recommendations are lacking, and this level varies from country to country. In the Republic of Serbia the level of radioactivity defined by this law is rather high, and a patient could be discharged only after the radioactivity of the body due to ^{131}I drops below 400 MBq (10.8 mCi) [9]. The patients are usually hospitalized

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for 2-5 days [10], but during the hospitalization medical personnel can be faced with certain challenges and surprises. One of the frequent challenges is a phenomenon that some patients from time to time try to abandon the "restricted area", despite strict instructions and warnings given before administration of the radionuclide. Such patients could be dangerous to others, including medical personnel, because of the high ambient dose equivalent, $H^*(10)$, originating from their bodies. Since locking the doors is not suitable and legally allowed, there is a need for a special alarm system in order to warn the personnel promptly when such a case occurs, and help them to undertake appropriate action(s) in due time.

Based on our previous experience [11, 12], we have decided to use a telemedicine approach as a solution for this challenge. The aim of this paper was to present key features of our innovative alarming system.

MATERIALS AND METHODS

We have developed our own system which continuously monitors the corridor which a patient must use in case of an attempt to abandon the special "restricted area" (fig. 1).

The central part of our system (fig. 2) is a survey-meter (model TBM-15; Technical Associates, Canoga Park, Cal., USA). This device is usually used as a survey meter in nuclear medicine institutions, including our Center for Nuclear Medicine. According to legal rules, this device was properly tested in an appropriate laboratory with ^{60}Co and ^{137}Cs sources. The device was tested with an ambient dose equivalent, $H^*(10)$, of up to 15 $mSvh^{-1}$. We have used data given by ^{137}Cs sources, because of its gamma energy peak it is closer to the gamma peak of ^{131}I than the gamma peak of ^{60}Co.

Our system uses a survey-meter with a detachable pancake probe, 2 inches in diameter (model T-1190; Technical Associates, Canoga Park, Cal., USA) directed towards the spot on the floor of the corridor where a patient has to pass if he or she tries to escape. The probe is 45 degrees inclined toward the floor, and about 30 degrees toward the vertical plane, 2.25 meters above the ground. Such a position gives an approximate distance of 1 meter between the probe and middle of the patient's torso (for patients of average height between 1.75 and 1.80 cm); such a distance was deliberately chosen as it is the usual setting for a survey-meter.

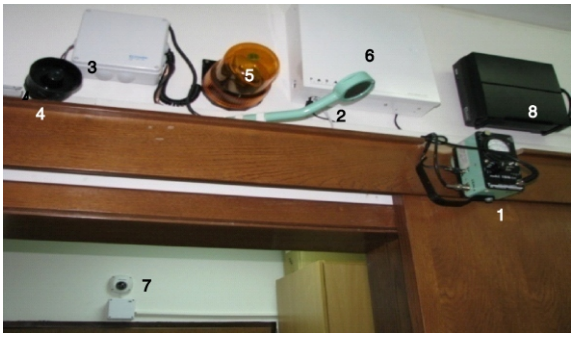

Figure 2. Our alarm system
1 – survey-meter, 2 – pancake probe, 3 – box with the trigger circuit, 4 – programmable siren, 5 – blinking light, 6 – alarm device, 7 – IP camera, 8 – UPS (uninterrupted power supply)

The survey-meter was connected to a trigger circuit (Schmitt comparator) which gives a signal in the case when the measured count rate exceeds a pre-set value, (fig. 3).

The trigger circuit was connected via a relay to a programmable siren (model WT588D, High power voice alarm horn, Waytronic Hongkong Ltd, Hong

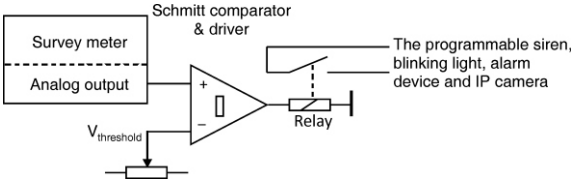

Figure 3. The trigger circuit for triggering the programmable siren, blinking light, alarm device and IP camera, which gives a signal if the ambient dose equivalent, H*(10), from the survey-meter exceeds a pre-set value

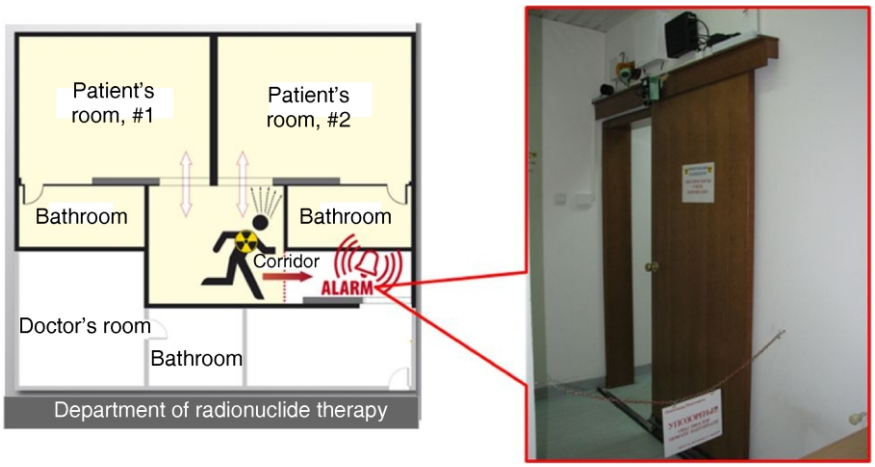

Figure 1. Schematic view of the "restricted access premises" dedicated to radionuclide therapy with the alarming system placed over the sliding door at the entrance

Kong), equipped with a 1GB micro SD memory card; to the blinking yellow-amber light device; to the alarm device unit with an integrated phone communicator (Paradox Magellan 5000) and to the IP surveillance camera (HikVision DS-2CD2512F-IS) placed on the wall against the sliding door. The resolution of the camera is 1.3 MP, sensitivity is less than 0.01 lux and it has additional IR illumination. The shooting rate of the camera is 25 frames/s, and it has also a micro SD memory card of 16 GB. The siren has a previously recorded verbal warning: "Attention, attention, you must not leave these premises! Please return, immediately". After the system is triggered by a patient leaving the premises, he or she will hear this message and see a blinking light. When the alarm device is triggered, it will also call the on call physician and nurse on a mobile phone (fig. 4) via a phone communicator. The IP camera simultaneously records this event (fig. 5) and the system sends via e-mail the respective data (fig. 6).

RESULTS – SYSTEM TESTING

In order to test the consistency and sensitivity of our system, we measured ten times the ambient dose

Figure 4. A call in progress on the responsible on call physician's mobile phone after the alarm system has been triggered

Figure 5. Live video from an IP camera on the on call physician's mobile phone after the alarm was initiated

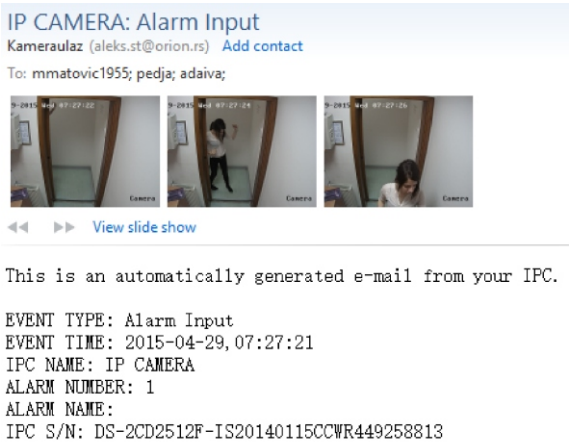

Figure 6. An e-mail message with data about an event sent after the alarm system has been triggered.

equivalent, $H^*(10)$, from the shielded and collimated point source of 925 MBq (25 mCi) ^{131}I, kept at a distance of 1 m. The average ambient dose equivalent, $H^*(10)$, was 77.73 31.57 (0.084 μSvh^{-1} per MBq of activity).

To estimate measurement uncertainty (MU) we have used the calibration coefficient N_k = 11.01 0.55 μSv/mR, which has been estimated for the ambient dose equivalent, $H^*(10)$, of 70 μSvh^{-1} in a specialized laboratory during routine device testing. We used this value because it covers all measurement ranges in our experiment.

Next we tested the sensitivity of the system by measuring (ten times) the same source at various distances from the probe. At each position of measurement, the system was triggered, i. *e*., we received a positive response of the system. The results of the tests are shown in tab. 1.

Finally, we conducted real-life testing of the system on a sample of 40 patients treated with radioiodine, on the first, the second and the third day of their stay in the restricted area. Using our previously developed system [12] we measured residual activity in the patients' bodies. The measured activity ranged from 177 MBq (4.8 mCi) to 3680 MBq (99.5 mCi). The patients were then instructed to pass through the corridor where the alarm system was installed, and each of their attempts triggered the system.

Table 1. Results of the system testing using a source of radioactivity with 925 MBq (25 mCi) ^{131}I

Distance [m]	Exposure rate (mRh^{-1}) 2SD	Ambient dose equivalent, $H^*(10)$ (Svh^{-1}) MU	System response
1.00	7.06 0.32	77.73 31.57	+
1.25	4.44 0.34	48.88 20.45	+
1.50	3.23 0.30	35.56 14.00	+
1.75	2.51 0.22	27.63 9.37	+
2.00	1.78 0.26	19.60 7.20	+
2.25	1.41 0.22	15.52 5.26	+

We measured ten times the same source at various distances (1-2.25 m) from the probe. At each position, the system was triggered. Also we tested the system on 40 patients treated with radioiodine instructed to pass through the corridor. Each of their attempts triggered the system.

According to our experience gained over the past few years, this alarm system intended for patients receiving radionuclide therapy ensures a high level of safety for both the patients and medical staff.

DISCUSSION

As we already mentioned, due to its beneficial biophysical characteristics ^{131}I has been used for more than 70 years in the treatment of differentiated thyroid cancer. This radionuclide disintegrates and emits beta minus particles with an average energy of 182 keV, followed by gamma rays with a main energy peak of 364 keV. Beta particles are mostly responsible for its effect on thyroid tissue and tissue of the thyroid cancer. Gamma rays are less important in the therapeutic sense, but they carry a major risk for persons in the vicinity of the patients treated with radioiodine (other patients, medical staff, family members, *etc*.).

After ^{131}I enters the human body its radioactivity is decreased exponentially and relatively slowly, due to its long half-life (8.04 days). However, if one takes into account its pharmacokinetics, the effective half-life of ^{131}I in patients with differentiated thyroid cancer is much shorter, about 10.5 to 15.7 h, depending on the methods of preparation for radioiodine therapy [13].

Because of the relatively high value of the gamma constant for photons coming out of ^{131}I (7.647E-5 mSvh^{-1} per MBq *i*. *e*. 0.22 mRh^{-1} per mCi, at a distance of 1.0 meter) [14], large doses of ^{131}I used for treatment of differentiated thyroid cancers result in significant residual radioactivity which is a real threat for the surrounding persons. The threat is the greatest immediately after administration of radioiodine, and then gradually decreases. It is of utmost importance to estimate the level of residual radioactivity which is of not further risk to persons who come into contact with the patient, so the patient could be discharged or even treated as an outpatient. As mentioned previously, this regulation varies from country to country, and may be either non-obligatory or very restrictive. In certain countries the estimated quantity of residual radioactivity is taken into account, in others it is the TEDE (Total Effective Dose Equivalent), and some countries set standards for both. In the USA, according to the update made by the US Nuclear Regulatory Commission (NRC) in May 1997, a patient treated with radioiodine could be discharged from hospital if the TEDE (Total Effective Dose Equivalent) transferred to surrounding persons is below 5 mSv, which is equivalent to radioactivity of 1.11 GBq (about 30 mCi) within the patient's body [15, 16]. In other words, in this country the patients could be discharged from the hospital with relatively high residual radioactivity. On the other hand, the regulations in Germany are more restrictive, so the maximum level of radioactivity after treatment with ^{131}I which is allowed at discharge from the "restricted area" is only 75 MBq (about 2 mCi). Values in Great Britain, France, Belgium and The Netherlands are much higher, and the maximum permitted radioactivity for outpatient treatment with ^{131}I ranges from 370 MBq (100 mCi) to 740 MBq (200 mCi) [17].

The Republic of Serbia could be classified in the group of countries with restrictive regulations. The patients could be discharged from the "restricted area" in a hospital only after residual radioactivity of ^{131}I drops below 400 MBq (10.8 mCi) [9]. It is clear that after administration of high doses of radioiodine (>1850 MBq, *i*. *e*. >50 mCi) in Serbia and other countries with similar regulations the patient has to be hospitalized for quite some time. The hospitalization usually lasts for 2-5 days, but it could be prolonged, depending on the volume of thyroid and tumor tissues, and on many factors which affect the pharmacokinetics of radioiodine (binding affinity of target tissues for ^{131}I, renal function, drug-drug interactions, *etc*.). At our facility (Center for Nuclear Medicine, Clinical Center Kragujevac, Serbia), residual radioactivity in a patient's body is measured by an in-house online tele-monitoring system, previously described [12].

Since the patients treated with radioiodine are mostly without hormonal substitution for 4-6 weeks prior to radioiodine administration, they are actually hypothyreotic, and sometimes with weakened cognition [18, 19]. Some of the patients have difficulty in understanding and following instructions about proper behavior in the "restricted access premises" after receiving therapeutic doses of radioiodine. Others may disobey due to cultural or personal specificities, so sudden abandoning the "restricted area" and endangerment of surrounding persons is not a rare event. It is therefore very important for medical staff to be warned on time when such an event happens, as according to ALARA [20] principles no human being should be unnecessarily exposed to even minimal radiation.

An alarm system is the best solution, as locking up the patients is a kind of human rights violation [21], not to mention the dangers in the case of accidents (like earthquake, fire, floods, *etc*.). The system should alert both medical staff and patients about the event, so adequate actions to prevent further harm could be undertaken on time.

Although many systems for tele-monitoring were developed and used in various areas (measuring isotopes of some pollutants, alarms in nuclear facilities, *etc*.) [22-25], there are no published data about such systems used in the field of radionuclide therapy. Our alarm system satisfies both requirements, *i*. *e*., it

instantaneously warns both medical staff and the patient, and visualizes the event.

The survey-meter which we used could register both beta particles and gamma-rays, and it has high sensitivity within a wide area with little background detection. It is equipped with an anti-saturation circuit, which provides for efficient measurement of a high-rate of the ambient dose equivalent, $H^*(10)$. The survey-meter we used had five pre-set detection areas, as 0-0.2, 0-2, 0-20, 0-200, and 0-2000 mRh^{-1} (0-0.002, 0-0.02, 0-0.2, 0-2, and 0-20 $mSvh^{-1}$, respectively), but it was also tested for measurement of rates of the ambient dose equivalent $H^*(10)$ up to 2000 $mSvh^{-1}$ (200 R^{h-1}) [26], which is far above the levels that could be expected in patients treated with radioiodine. The device was originally supplied with a 9 V battery, but we switched the battery with an appropriate stabilized 9 V supply, in order to avoid failures in the functioning of the device due to power loss.

Through measurement of the source with known radioactivity by a survey-meter at a 1 meter distance, we found that the average value of the ambient dose equivalent, $H^*(10)$, was 77.73 31.57 μSvh^{-1}, or 0.084 μSvh^{-1} per MBq. This value was somewhat higher than the value of the gamma constant of ^{131}I (0.059 μSvh^{-1} per MBq). The difference between the literature value and our measured value is more likely to arise due to the measurement uncertainty.

The trigger circuit (Schmitt's comparator), was set to turn on when the device registered an ambient dose equivalent, $H^*(10)$, higher than 13.76 μSvh^{-1}, which corresponds to radioactivity of about 4.3 mCi (159.1 MBq), measured at a 1m distance from the body. This is significantly below the maximum permitted level of radioactivity after radioiodine treatment determined by law, with which a patient could be discharged from hospital. In such a way we ensured that regardless of the height and body mass of a patient and distribution of ^{131}I within the body, the alarm system is always activated if the patient tries to leave the "restricted access premises". The trigger circuit was made as a classic Schmitt's comparator which turns on the relay and through it starts the programmable siren, blinking light, the alarm device unit and IP camera. The response time of the whole device is measured in tens of milliseconds, which could be considered as an almost instantaneous response in comparison to the velocity of the patients' movements through the corridor.

Auditory warning of the patients is conveyed by a programmable siren with a recorded voice message, stored on a SD card. This device has a signal to noise ratio 82 db [27] which is loud enough to be heard by a patient in a relatively narrow corridor. The blinking yellow-orange light was also used for warning the patients, produced by a yellow-orange lamp with a rotating reflector with a frequency of 1 turn per second. According to the studies in the field of physiology, yellow and orange colors are the most visible and the first to be spotted and understood as a warning [28, 29], while blinking gives a subjective feeling of urgency, much more than constant light [30].

The device unit Paradox Magellan 5000 with a built-in phone communicator was used to inform the medical staff that a patient has attempted to leave the "restricted area". This is a reliable device which after receiving a signal from the relay automatically calls the phone numbers of the on call physician and nurse; it happens just a few seconds after the attempt of a patient to pass through the corridor. In order to secure evidence of the event and to identify the perpetrator, we used the IP camera to send the report and photographs to e-mails of the on call physician and nurse. The camera we used was relatively simple and inexpensive, but its technical characteristics (resolution 1.3 MP, sensitivity 0.01 lx, additional IR illumination, 25 frames/s) were sufficient for the purpose, as suitable photographs could be made even in darkness.

CONCLUSIONS

The testing of the system confirmed the consistency, sensitivity and reliability; it constantly achieved both goals – to warn a patient and to warn the medical staff that the "restricted area" has been abandoned. The system was set to be turned on when the ambient dose equivalent, $H^*(10)$, surpasses 13.76 μSvh^{-1}. This value was much lower than that in the case of residual activity with 400 MBq in the body, because the system should be always activated, regardless of the body size and distribution of radioactivity. The high sensitivity of the system could hardly be a problem, because it just detects a patient trying to escape, and remains without influence on the decision of the physician when to discharge the patient. Such a decision is based on online measuring of the ambient dose equivalent, $H^*(10)$, and on the calculation of the radioactivity load within the body, using some other system [12].

According to our experience gained over the past few years, the tele-monitoring system dedicated for to patients receiving radionuclide therapy ensures a high level of safety for both the patients and medical staff.

Besides radioiodine ^{131}I, our system could be a usefull tool also in case of the use of PRRT (Peptide Receptor Radionuclide Therapy) with ^{177}Lu or/and ^{90}Y labelled radiopeptides. We will improve our system with the option of on-line adjustment and setting of a trigger's cut-off value, for use with different radionuclides.

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AUTHORS' CONTRIBUTIONS

The idea was carried out by M. D. Matović and M. Ž. Jeremić, the practical solution of the system was carried out by M. D. Ravlić and M. D. Matović. The testing of the system has been provided by M. D. Matović, M. Ž. Jeremić and M. Ž. Vlajković. The manuscript was written and the figures were prepared by all authors.

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АЛАРМНИ СИСТЕМ ЗА НАДЗОР ПАЦИЈЕНАТА КОЈИ СУ ПРИМИЛИ ВИСОКЕ ДОЗЕ РАДИОЈОДНЕ ТЕРАПИЈЕ (^{131}I) ЗА СЛУЧАЈ НЕОВЛАШЋЕНОГ НАПУШТАЊА КОНТРОЛИСАНЕ ЗОНЕ

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После примања високих доза радиојода пацијенти морају да остану изоловани у контролисаној зони, док радиоактивност у њиховом телу не падне испод одређеног нивоа. Циљ овог рада је да представи наш алармни систем, који је дизајниран да открије пацијенте који покушавају да напусте контролисану зону и информише медицинско особље да се такав покушај догодио. Систем се састоји од монитора зрачења са "pancake" сондом која је усмерена у правцу ходника којим пацијент мора проћи. Монитор зрачења је повезан са прекидачким колом које даје сигнал у случају да је измерена брзина експозиционе дозе већа од раније постављене вредности. Овај сигнал укључује алармини уређај, трепћуће светло, програмабилну сирену и IP камеру, са циљем да упозори пацијента и обавести персонал када се такав случај догоди. Са циљем да тестирамо конзистентност нашег система, мерили смо десет пута амбијентални дозни еквивалент, H*(10), од извора са 925 MBq (25 mCi) ^{131}I, постављеног на одстојању од 1 m. Средња вредност јачине амбијенталног дозног еквивалента, H*(10), је била 77.73 31.57 Svh^{-1} (0.084 μSvh^{-1} по MBq, или 3.1 μSvh^{-1} по mCi активности). Ми смо овај извор мерили по десет пута и на различитим одстојањима од 1-2.25 m од сонде. У свакој позицији систем се укључивао. Такође смо тестирали систем и на 40 пацијената лечених радиојодом, којима је речено да прођу кроз ходник. Сваки покушај проласка је укључивао систем. У складу са нашим искуством током последњих неколико година, овај алармни систем намењен пацијентима који су примили радионуклидну терапију осигурава висок ниво безбедности и пацијената и медицинског особља.

Кључне речи: радиојод, алармни систем, понашање пацијента