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Reimbursement of radiotherapy services in Romania: Qvo vadis?

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Abstract

Despite Romania's significant quantity improvement in terms of radiotherapy infrastructure during the last 5-10 years, quality has experienced a slow upgrade, at least in the public setting. This is a pandemic eye view perspective on the current romanian radiotherapy, triggering differential incentives adjusted for quality / complexity of delivered RT.

Keywords: *radiotherapy, reimbursement, healthcare, Romania*

Viewpoint

Main text

During the last 5 years, Romania has practically doubled the number of linear accelerators, reducing the gap with Western Europe, yet still covering only half of the proportion of 1 linear accelerator / 200,000 inhabitants recommended by the European Society for Radiotherapy and Oncology (ESTRO) [1]. Disparities persist between various geographical areas, with the least deficient coverage in Transylvania. Intensity modulation radiotherapy (IMRT) has gained groundat national level, even if, as a whole, it remains a minority compared to 3D conformational radiotherapy (3DCRT) or lower level (standard RT, 2D). Complex stereotactic body radiotherapy techniques (SBRT) still remain the prerogative of private centers, although the technology would allow their approach even in public institutions. Brachytherapy (BT) is limited to a few centers and is strictly focused on gynecological cancers, except for our center currently performing interstitial brachytherapy procedures, including other cancers (prostate, breast, sarcomas, head and neck).

While trying to identify possible causes of these disparities, the natural question is: What would motivate medical institutions to expand the use of IMRT, SBRT and BT, in line with the practices of other European countries? A possible logical answer, from management point of view, would be: a **different** reimbursement, at least of the SBRT or BT techniques, according the complexity levels, similar to the current national reimbursement settlement of IMRT compared to 3DCRT.

The COVID-19 pandemic highlighted at least 2 other necessary changes in the development of RT in Romania. Some of supporting data were already published before 2020 [2 -12]:

1. Implementation/wider use of hypofractionation in the cases where there is scientific evidence, according to the recommendations of the main if not all international professional societies involved in cancer treatment. There are many examples of situations where these short protracted regimes are succesfully used such as adjuvant breast, neoadjuvant rectum, prostate, glioblastoma > 65 years, early stages of non-small lung cancer.

2. Favoring outpatient RT (ambulatory or one-day hospitalization) to the detriment of the purely hotel continuous hospitalization, in all situations where the patient's condition allows it. The RT centre needs to be as close as possible to the patient's home and fortunately the current network allows a better geographical coverage than 10 years ago. Avoidance of unnecessary continuous hospitalization decreases the risk of Covid-19 contamination between patients from the same room/ department, or between patients and the medical staff. Many patients have delayed oncological diagnosis and treatment, including RT, due to delayed presentation related to fear of SARS-Cov2 infection in hospitals, influenced also by the SARS-Cov2 outbreaks in oncology and/or RT departments reported during the last year.

A change in the settlement of RT services within the Oncology-Radiotherapy subprogram, through the National Health Insurance Authority (CNAS), could create the premises for a more efficient use of resources, for the benefit of cancer patients.

There are mathematical models of biological isoefficiency between various RT fractionation schemes, supported by radiobiology studies and validated on large groups of patients. One of the most common is the linear-quadratic model (LQ) which allows the conversion of any irradiation scheme with dose fractions between 1 and 6 Gy into a standard protocol of 2 Gy / fr - equivalent as efect on tumor control and toxicity, for various types of cancers and healthy tissues. The key factor of this equation is the alpha / beta ratio, correlated with the ability of an irradiation fraction to induce lethal (irreparable) or sublethal effect (potentially repairable between 2 irradiation fractions) on a cell (tumor or healthy). This effect on the cells is extrapolable, with certain limits,

at the tissue level. Beyond 6 Gy / fr, the LQ model is not as robust, although more and more consistent data derived from SBRT and BT support its validity [13-17]. In any case, LQ is useful to generate the cohesion of a financial model.

For each patient the therapeutic index is defined by the ratio between the beneficial effect of a treatment and its potential toxicity. For RT, this index is represented by the ratio between the tumor control within the irradiated volume and the radio-induced toxicity. From a financial point of view, the costs of assessing and treating late side effects of RT are extremely difficult to quantify in any healthcare system, but they are considered as significantly higher than the "price" of the RT itself. These costs are not included in the Oncology - Radiotherapy budget of the national reimbursement system, nor are they subsequently collected, the patients being registered in the national health system with the main urological, gynecological, gastroenterological **non-oncological** diagnosis codes for the side - effects. However, these "indirect" costs are lower for complex techniques (such as IMRT), precisely because they have a significantly lower probability of severe toxicity. In other words, a higher reimbursement for IMRT compared to 3DCRT is fully justified, because the acute and late toxicity is lower, and so the costs related to it.

I propose the analysis for settlement of RT services based on:

1. Level of complexity: the necessary expertise and time allocated to the preparation and execution of RT, corroborated with the infrastructure (equipment + related technologies).

2. Assuring and controlling the quality of the daily performance of the respective treatment (traceability of verification procedures / maneuvers actually done).

3. Resolved case, regardless of the RT method or technique (IMRT, SBRT, 3DCRT or BT), based on the previously described LQ model.

4. Curative versus Palliative.

An simplified estimation of a different reimbursement can be found below, for the most common cancers of women (breast), and respectively men (prostate).

I. RT in breast cancer is postoperative, with extremely rare exceptions. Fundamental elements in choosing a certain RT scheme are the stage, type of surgery and age of the patient (≤ 50 vs.> 50 years). Moderate (40 Gy / 15 fr, 42.5 / 16 fr) or intensely hypofractionated (26 Gy / 5 fr) schedules provide an equivalent therapeutic index [18-20]. By comparison with patients > 50 years, the younger ones have a higher risk of local recurrence and require higher doses on the tumor bed, administered as a boost by sequential or integrated external beam RT (EBRT) or even BT. Currently, 1 fr of EBRT is settled with 640 RON / IMRT, respectively 320 RON / 3DCRT, regardless of the dose/ fr. Therefore, in a patient > 50 years old, a “British” type RT with a reduced number of fractions (5-15) would be settled much more “cheaply” (3 200-9 600 RON)

than a classic RT of 25 fr (16 000 RON). A unit price / solved case, coded by gender «C50.1 Breast carcinoma, adjuvant RT, > 50 years» settled for example with 15 000 RON would encourage the services to favor the hypofractionated regime (by RTE or even by BT, if eligible according to GEC-ESTRO criteria for partial breast irradiation (APBI), the patient would have fewer days of treatment (outpatient or not) and CNAS would pay less. On the other hand, additional technologies, such as Deep Inspiration Breathhold- which minimize the mean heart dose, with a lower risk of late cardiac toxicity- should benefit from an additional settlement, for example 250 RON / fr (using at each irradiation session, with the increase of the time allocated to a patient, respectively of the necessary maneuvers, besides the additional expensive infrastructure). Another code «50.2 Breast carcinoma, adjuvant RT < 50 years» would have a settlement of about 33% more (for example + 3 200 RON) in relation to the number of additional RT sessions required, regardless of the irradiation scheme used. This includes interstitial BT, if the hospital in question has the necessary expertise and infrastructure.

In the palliative register, one can conceive an average unit price, for example 3 200 RON (which is less than the current settlement of an IMRT 6400 RON, equivalent to a 3DCRT 30 Gy / 10 fr but higher than an RT 8Gy / 1fr equally effective in analgesics for uncomplicated bone metastases). In other words, the RT departments will be motivated to organize themselves operatively in order to carry out an RT 8Gy / 1 fr on the same day with the consultation, exempting the patient from an avoidable hospitalization and respectively from returning for multiple irradiation sessions. Overall, the settlement will be lower for the payer (CNAS) than at present, given that the palliative segment represents about 30% of RT, global average. It should be noted taht Covid-19 might increase this number, at least for 2021-2022.

II. Curative irradiation in prostate cancer can be administered with classical schemes (76-80 Gy / 38-40 fr), moderately hypofractionated (62 Gy / 30 fr) or intensely hypofractionated (36.25 Gy / 5 fr, SBRT). In the „low-risk" or „intermediary-low-risk" D'Amico risk groups, brachytherapy is equivalent to external RT or radical prostatectomy, and in the high or high-risk D'Amico risk groups, BT boost improves survival without biochemical recurrence, without distant metastases, and probably specific survival [20]. Therefore, a unit settlement per case solved, for example "exclusive curative code C61.1 RT" with 20 000 RON / IMRT, SBRT or BT (regardless of the number of fractions), respectively 10 000 / 3DCRT compared to the amount of 25 000 RON / current IMRT, 12 500 / 3CRT current, 300 - 600 RON / current BT) would motivate the RT services to favor complex hypofractionated techniques, investing in the necessary upgrading. The settlement of CNAS as a whole for such cases would be lower (**so no additional costs are generated** compared to the prices currently

settled). The use of fiducial markers or real-time intra-fractional Image Guided (IGRT) techniques or pre-rectal spacer-gel would require additional settlement, as they decrease severe radio-induced toxicity (which induces much higher subsequent costs).

Obviously, it's an exercise deliberately simplified to facilitate understanding. The LQ model can be used for a conversion between particular schemes (falling into the category of example "C50.11 RT for atypical breast cancer"), with the related justifications (intra-institutional protocol, multidisciplinary commission or decision of the attending physician, which ultimately is responsible for choosing a particular scheme) and verifiable transparency. Similarly, for example a BT 7 Gy / fr for gynecological cancers is equivalent to 10 Gy EQD2, being financially quantifiable as such, ie 3 200 RON (5 fr of 2 Gy of current IMRT) but with nuance on the level of complexity: uterovaginal = 2 000 RON, utero-vaginal + interstitial = 4 000 RON, unicateter endovaginal cylinder = 1 000 RON, multicateter = 1 500 RON. This projection does **not** generate additional costs for CNAS compared to the current ones, but only allows a better correlated value with the 4 proposed settlement criteria. Such a strategy, which globally requires a smaller budget than the current one, would allow the reimbursement of the outpatient transportation to the RT clinics, for example, within a contractually agreed amount between taxi companies and CNAS, based on travel vouchers, similar to public transport settlement practiced by most EU countries.

In conclusion, to paraphrase a former US president, YES. WE CAN and we SHALL DO IT, as we have limited financial resources within our National Health System, in obvious need of indepth reform.

Abbreviations:

3DCRT – Tridimesional Conformational Radiotherapy
APBI – Accelerated Partial Breast Irradiation
BT – Brachytherapy
CNAS – National Health Insurance Authority
COVID-19 – Corona-Virus Disease 2019
ESTRO – European Society for Radiotherapy and Oncology
fr – fraction
GEC – ESTRO – Groupe Européen de Curiethérapie and the European SocieTy for Radiotherapy & Oncology
Gy – Gray
IMRT – Intensity Modulation Radiotherapy
LQ – Linear-Quadratic model

SARS-Cov2 – Severe acute respiratory syndrome coronavirus 2

SBRT – Stereotactic Body Radiotherapy

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