STEREOTACTIC BODY RADIOTHERAPY OF PRIMARY AND SECONDARY LUNG TUMORS USING CYBERKNIFE AND LINEAR ACCELERATOR: ANALYSIS OF CLINICAL RESULTS, PROGNOSTIC FACTORS AND TOXICITY

PhD thesis-book

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1. Introduction

Lung cancer is one of the most frequent types of cancer, with high mortality rates, correlated to approximately 25 % of all cancer deaths. The estimated worldwide incidence is approximately 2.4 million new cases annually, worldwide, and the proportion of early diagnosis (lymph node negative stage) is around 16-23 %. Unfortunately, Hungary presents particularly high incidences of lung cancer in European comparison, with approximately 9500 newly diagnosed cases, annually. The gold standard treatment for early-stage non-small cell lung cancer is surgical removal, however, approximately 25% of early-stage lung cancer will not undergo surgery because of severe comorbidities or more rarely of patient refusal.

Nowadays, modern stereotactic body radiotherapy (SBRT) is a widely used, precise and successful non-surgical alternative in medically inoperable early-stage lung cancer and in patients with lung oligometastases originated from various primary tumors.

Provided that 18-FDG-PET/CT supports a strong suspicion of malignancy, actually patients with high risk for invasive biopsy are also considered eligible for SBRT in many centers, in the absence of other alternative, effective therapy.

Currently, there are different devices available to perform thoracic SBRT such as gantry-based linear accelerators (LINAC) and the robotic CyberKnife system: both produce rapid dose fall-off in the target region, sparing surrounding healthy tissues.

In contrast to conventional radiotherapy-which is given in 25-35 fractions-, stereotactic treatments are performed in an extremely hypofractionated way. Results from the study of Lagerwaard et al. underlined the importance of differentiation of dose schemes during lung SBRT in function of the localization of the target lesion, with more caution, and more modest biological doses on central lesions. In their study, 3 dose regimens were used (3 x 20 Gy, 5 x 12 Gy, and 8 x7.5 Gy), and authors emphasised the need for risk-adapted fractionation in lung SBRT. Over time, several dose and fractionation schemes has been tested by different workgroups using 1-8 fractions of SBRT with wide ranges of biological effective doses, reported high local control rates of 76-96 %. However, the

results concerning optimal lung SBRT doses are controversial and individualized treatment strategy is needed, in function of the size and the location of the target lesions.

This thesis is based on two clinical studies with focus on optimal dose, clinical results, predictive factors and toxicities. Both benchmarking researches investigated the implementation of a special technique, being novelty in the given institutions. Question was raised whether clinical results of a large cohort of the first consecutive patients would reflect high rate of success, as had been shown in the literature. Furthermore, our results make contribution in defining the optimal, individualized dose/ fraction regimens in lung SBRT.

2. Objectives

1. Evaluation of clinical results of primary and recurrent lung tumors and lung metastases treated with CyberKnife stereotactic radiotherapy (SBRT) .

2. Evaluation of long-term clinical results focusing on a large-cale, consecutive patient cohort of early-stage primary lung cancer treated with gantry-based linear accelerator (LINAC) or CyberKnife SBRT.

3. Analysis of predictive factors influencing local control (LC), local progression free survival (LPFS), progression free survival (PFS) and overall survival (OS) in patients treated with lung SBRT.

4. Validation of use of SBRT in patients of high risk of invasive biopsy (unknown histology)

5. Investigation of early-, and late toxicities after pulmonary SBRT.

6. Validation of use of risk-adapted SBRT dose-schemes in real life cohort.

3. Methods

The thesis is principally based on two large-cohort, retrospective studies. The first one was based on patients treated for either primary, recurrent or metastatic lung tumors in the University Hospital of Liège, Belgium between 2010 and 2012, using Cyberknife robotic fractionated SBRT (results published in 2017, in Radiology and Oncology). The second study was conducted in the National Institute of Oncology, Budapest between 2015-2023, on a larger, and more homogenous patient cohort of exclusively early-stage primary lung cancer treated predominantly with linear accelerator or with CyberKnife to a lesser extent (results published in 2025, in Strahlentherapie und Onkologie).

3.1. Methods of Study I.: Cyberknife SBRT of primary, recurrent, and secondary lung tumors (Belgium)

A CyberKnife robotic stereotactic system was installed in the University Hospital of Liège, Belgium in 2010, enabling the implementation of intra-, and extracranial SRT treatments. This retrospective analysis focused on clinical results and toxicities of patients treated for intrapulmonary malignancies. In total we identified 130 patients treated between April 2010 and June 2012, including medically inoperable patients presenting 62% primary (n=81), 18% (n=23) recurrent lung cancer, and cases (20 %, n=26) with solitary or oligometastatic lung lesions from other primary malignancies. Altogether, 160 lesions were treated, with 53% (n=86) primary, 22% (n=35) recurrent tumor/intrapulmonary metastasis of an earlier lung tumor and 25% (n=39) of metastatic origin. Median age was 71 years (range 40–93), and treatment decisions were made in multidisciplinary tumor boards. In case of contraindication for invasive biopsy, patients with clinical diagnosis based on high FDG^{18} uptake on PET-CT were also accepted for SBRT. For the 86 metastases the primary cancer was colorectal in 49% (n = 19), salivary gland in 13% (n = 5), breast in 10% (n = 4), melanoma and kidney in 5-5% (n = 2-2), neuroendocrine tumor in 3% (n = 1), multiple primaries in 13% (n = 5), and unknown in 2% (n = 1). In the primary cancer subgroup, there were 62 cases with histology proven disease, with 47% adenocarcinoma, 33% squamous cell carcinoma, 15% NSCLC and 5% undifferentiated cancer. In the whole study group, the rate of histological confirmation was 62% (n=81) in terms of patients, and 54% (n=86) in terms of lesions. The distribution

of peripheral vs central location of the target lesions was 71% vs 29%. Lesions were classified central, if located within 2 cm from great vessels, heart, hilar structures, oesophagus or trachea. T3 tumors and T1N1, lymph node positive cases were also represented in smaller numbers.

SBRT treatments were performed with the CyberKnife VSI robotic radiosurgery unit - generation 5- (Accuray, Madison, WI, USA), using Iris collimator of 15-60 mm apertures, 6 MV FFF photon beams, 600 min/MU dose rate. Real-time position verification was ensured by the orthogonal kilovoltage imaging of CK system. 3-fraction treatments were delivered every other day, and 5-fraction treatments on consecutive working days.

We used 3 or 5 fraction dose schemes, to a total dose of 40 to 60 Gy, with respect to nearby OAR (organ at risk) dose limits. The dose was prescribed to 75-82 % PTV-encompassing isodoses. Mean GTV and PTV volumes were 11.5 cc (range 0.6-86.5) and 33.2 cc (range 5.8-118.1). Dose was prescribed on 80 % (range 75-82 %) isodose line covering the PTV.

Descriptive analysis was applied for patient and treatment characteristics, acute and late toxicities. Analysis of LC, OS and CSS (cause specific survival) was performed using Kaplan-Meier method. Uni-, and multivariate Cox-regression analysis was used for investigation of prognostic factors influencing local control. P-values ≤ 0.05 were considered statistically significant. Software: SAS ver.9.3.

3.2. Methods of Study II.: LINAC and Cyberknife SBRT of early-stage primary lung tumors (Hungary)

Gantry-based LINAC lung SBRT was implemented in the National Institute of Oncology in 2015. CyberKnife lung SBRT has become available from 2018. In this retrospective study we focused on a homogenous patient population of early-stage (T1-2 N0 M0) primary lung cancer with or without histological confirmation treated with either SBRT technique. The overwhelming reason for selection of SBRT was medical / functional inoperability. All cases were discussed in multidisciplinary tumor boards, and for patients with high risk for invasive biopsy, 18-FDG-PET/CT was obligatory for SBRT decision. Local recurrences, tumors with satellites, metastatic lesions and patients with previous

lung irradiation were excluded. Altogether we identified 401 patients, 53% males, 47% females. Median age was 70 years (range 44-90). Classification by tumor size was T1a (≤1 cm) in 8 % (n=32), T1b (>1cm to ≤2 cm) in 44.6% (n=179), T1c (> 2cm ≤ 3cm) in 27.9% (n=112), T2a (>3cm to ≤4 cm) in 16.7% (n=67) and T2b (>4cm to ≤5 cm) in 2.7% (n=11). Histology was adenocarcinoma in 23% (n=92), Squamous cell carcinoma in 12% (n=48), other in 2.5 % and unknown in 62.5%. The clinical diagnoses were supported with 18-FDG-PT/CT positivity in all cases without proven histology and the rate of PET/CT was high in the total cohort (96.3%) as well.

SBRT treatments were performed with two techniques:

- Gantry-based LINAC treatments (90%) were performed with VMAT (volumetric modulated arc therapy), 6MV, FFF foton beams on either Varian VitalBeam or TrueBeam linear accelerators (Varian, Palo Alto, CA, USA) Image verification was carried out with kilovoltage built-in cone-beam CT (CBCT) of the LINAC before each treatment fraction.

- Cyberknife treatments (10%) were performed with Cyberknife M6 generation device using the novel MLC (multileaf collimator) for beam shaping. Step-and-shoot IMRT was carried out using 6MV, FFF photon beams, with real-time tumor tracking ensured by the orthogonal 2D kilovoltage imaging system and the Synchrony camera.

Institutional protocol defined 3 preferred dose levels for both LINAC and CK SBRT treatments: 3x18 Gy (BED_{10}=151.2 Gy), 5x12 Gy (BED_{10}=132.2 Gy) and 8x7,5 Gy (BED_{10}=105 Gy) in function of tumor location, with lower BED doses forseen for tumors adjacent to the chest wall, or more particularly to mediastinal organs or pulmonary hilum. Further dose reduction was allowed in case of conflict with organs at risk constraints. Mean GTV and PTV volumes were 7.4 cc (range 0.3-85.1) and 34.7 cc (range 5-195.9). The maximum dose criteria inside the PTV was 120-130 % of the prescribed dose. Dose prescription for PTV for both techniques were identical: *95% of the prescribed dose should cover the 99% of PTV (=V95%>90)* and *100% of the prescribed dose should cover the 90% of PTV (`V100%>90%)*

Descriptive analysis was applied for patient and treatment characteristics, acute and late toxicities. Analysis of LC, LPFS, PFS and OS was performed using Kaplan-Meier method. Univariate (Cox-Mantel test)-, and multivariate (Cox regression test) analysis

were performed in order to identify prognostic factors influencing local control, local pregression free survival, progression free survival and overall survival. P-values < 0.05 were considered statistically significant. Software: Statistica (ver10).

4. Results

4.1 Results of Study I. (Jánváry, 2017)

After 21 months of median FUP, we observed promising results showing local control rates of 86%, 75% and 62% **(Figure 1.)**, and overall survival rates of 85%, 74% and 62%, at 1-, 2- and 3 years, respectively **(Figure 2.)**. Our results are fully consistent with those of other published series, where 2-year LC rates range between 59,7 - 96%, and 2-year OS rates are reported between 47-87%

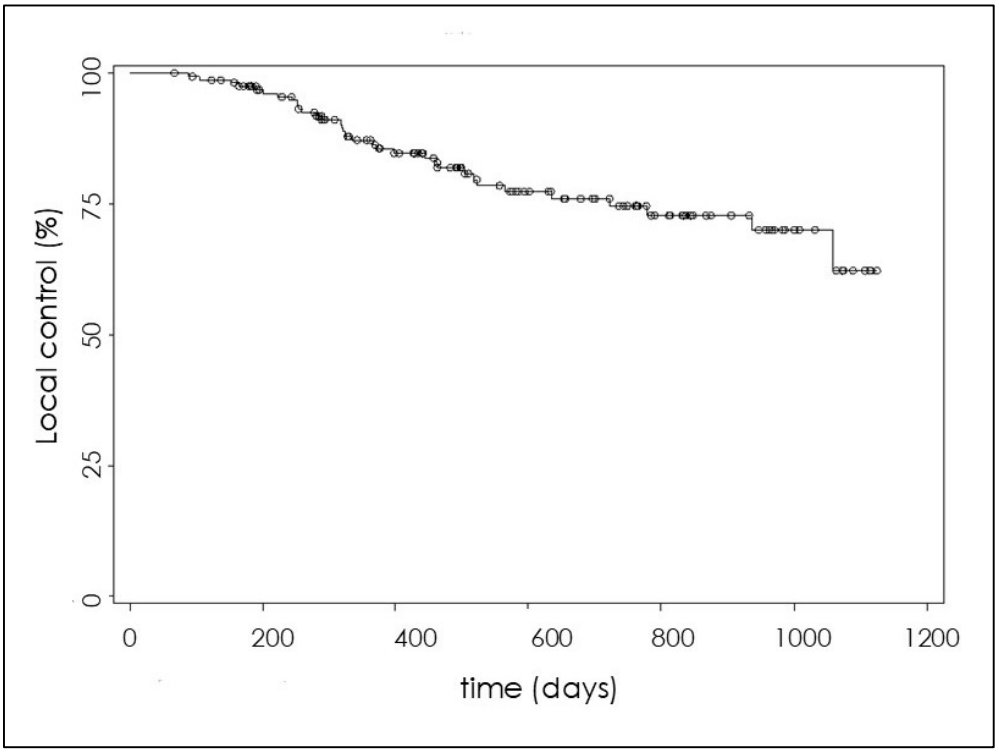

Figure 1. Probability of actuarial local control for the total cohort of Study I.

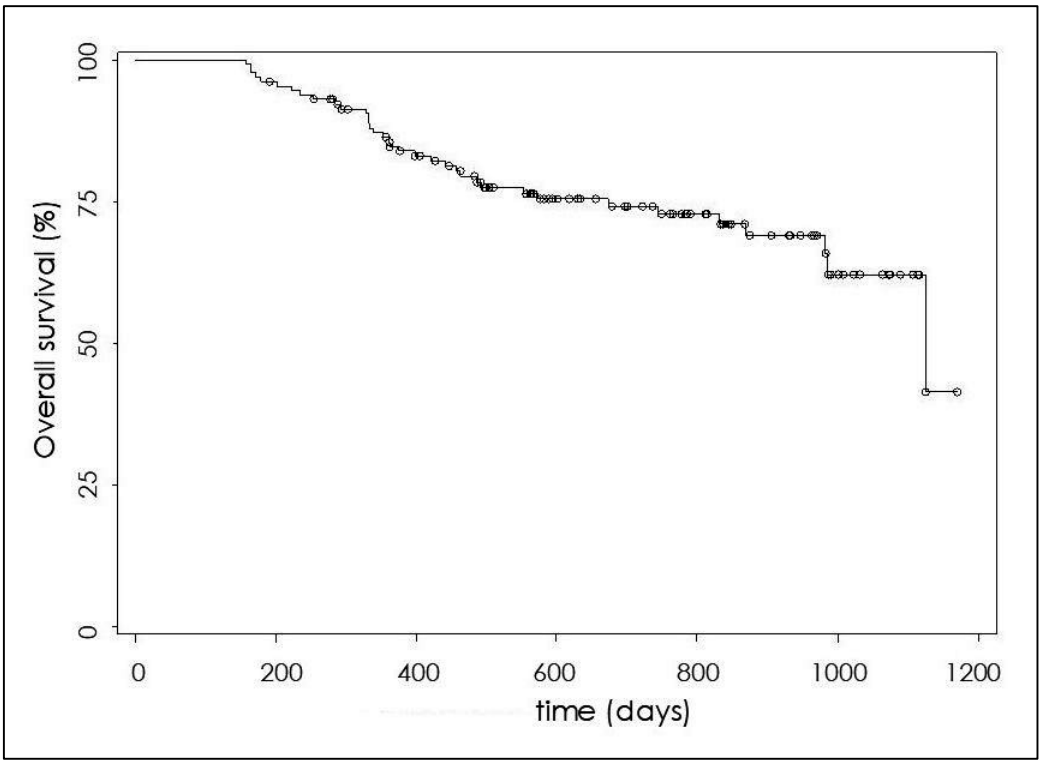

Figure 2. Probability of overall survival for the total cohort of Study I.

Multivariate analysis of Study I. cohort revealed predictive factors associated with significantly lower local control rates after SBRT: *metastatic origin* (HR=7.3, p<0.0001), *proven histology* (HR=4.1, p=0.0052 and *larger PTV* (HR=1.03, p<0001).

4.2. Results of Study II. (Jánváry, 2025)

After a median follow-up of 32 months, our retrospective analysis of 401 patients revealed important findings. We observed outstanding local effect, with only 9% (n=36/401) of local failure and 94%, 90% and 87% of actuarial 2-, 3-and 4-year local control rates. 2-, 3-and 4-year OS rates were 79%, 68% and 56% **Figure 3. a**–**d**. When compared to results of series reporting experiences with more than 100 patients, our findings are coherent with the relevant literature.

Multivariate analysis of Study II. cohort revealed predictive factors associated with significantly better overall survival rates after SBRT: *smaller tumor size* (T1a, b vs

T1c, T2a,b) (p= 0.002), *lower ECOG score* (better ECOG status) (p= 0.002). *Prescribed dose ≥BED_{10}132* was predictive for better LPFS (p<0.0001)

We observed significant 3-year overall survival advantage (73 vs 61%) for smaller tumors (T1a, b vs T1c, T2a,b)**.** In terms of median values this advantage was 23 months (69 vs 46 months). (**Figure 4.a.)**

Significant OS benefit was observed in favor of better performance status, with 83%, 68%, and 37% at 3 years, regarding EGOG 0,1 and 2 subgroups (p= 0.0005). (**Figure 4b.)**

Application of doses of BED≥ 132Gy was associated with an advantage of more than 12 months median, and 6 % of 3-year local progression free survival, compared to lower doses-group: 55 vs. 42.4 months (95% CI: 42.8–67.2 and 35.8–49) and 63 vs. 57% (p= 0.0046) respectively. (**Figure 5.)**

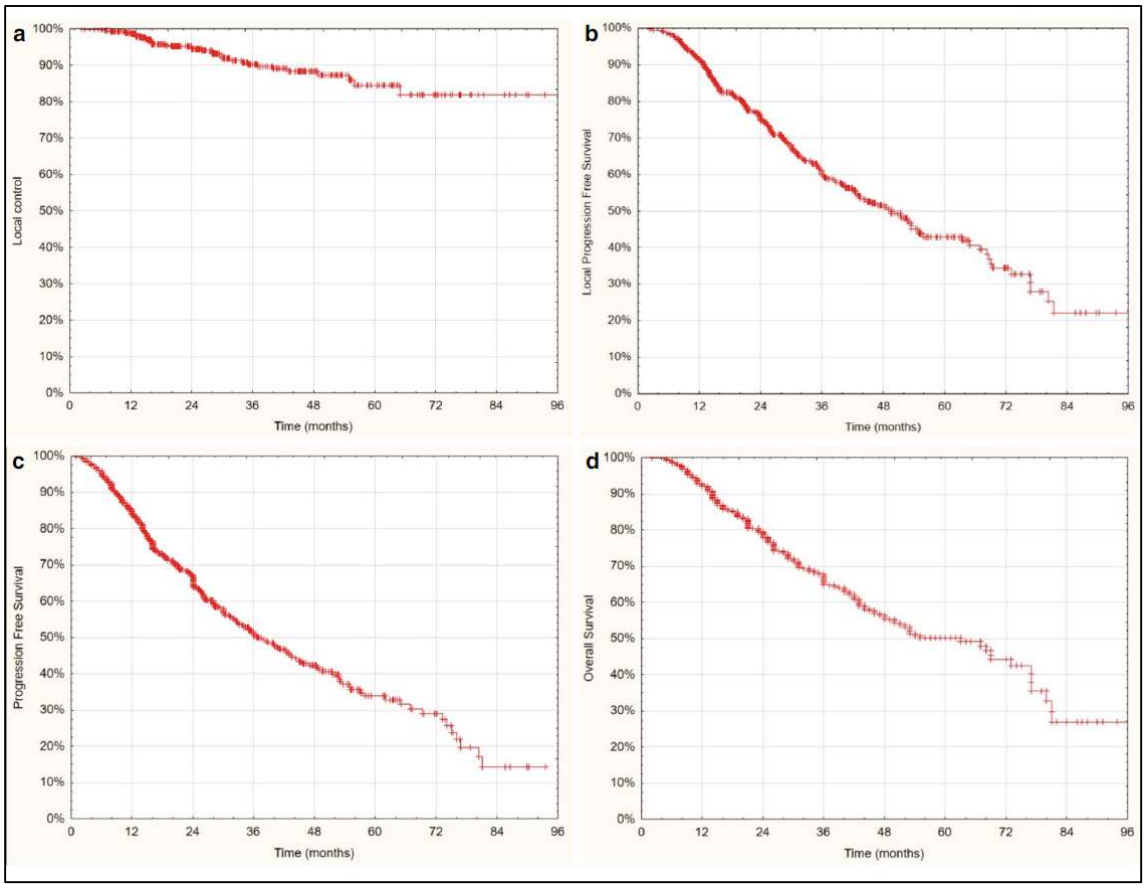

Figure 3. a–d Kaplan–Meier curves of the entire cohort of Study II. (*n*= 401 patients)

treated with stereotactic body radiotherapy. **a** Local control, **b** local progression-free survival, **c** progression-free survival, **d** overall survival

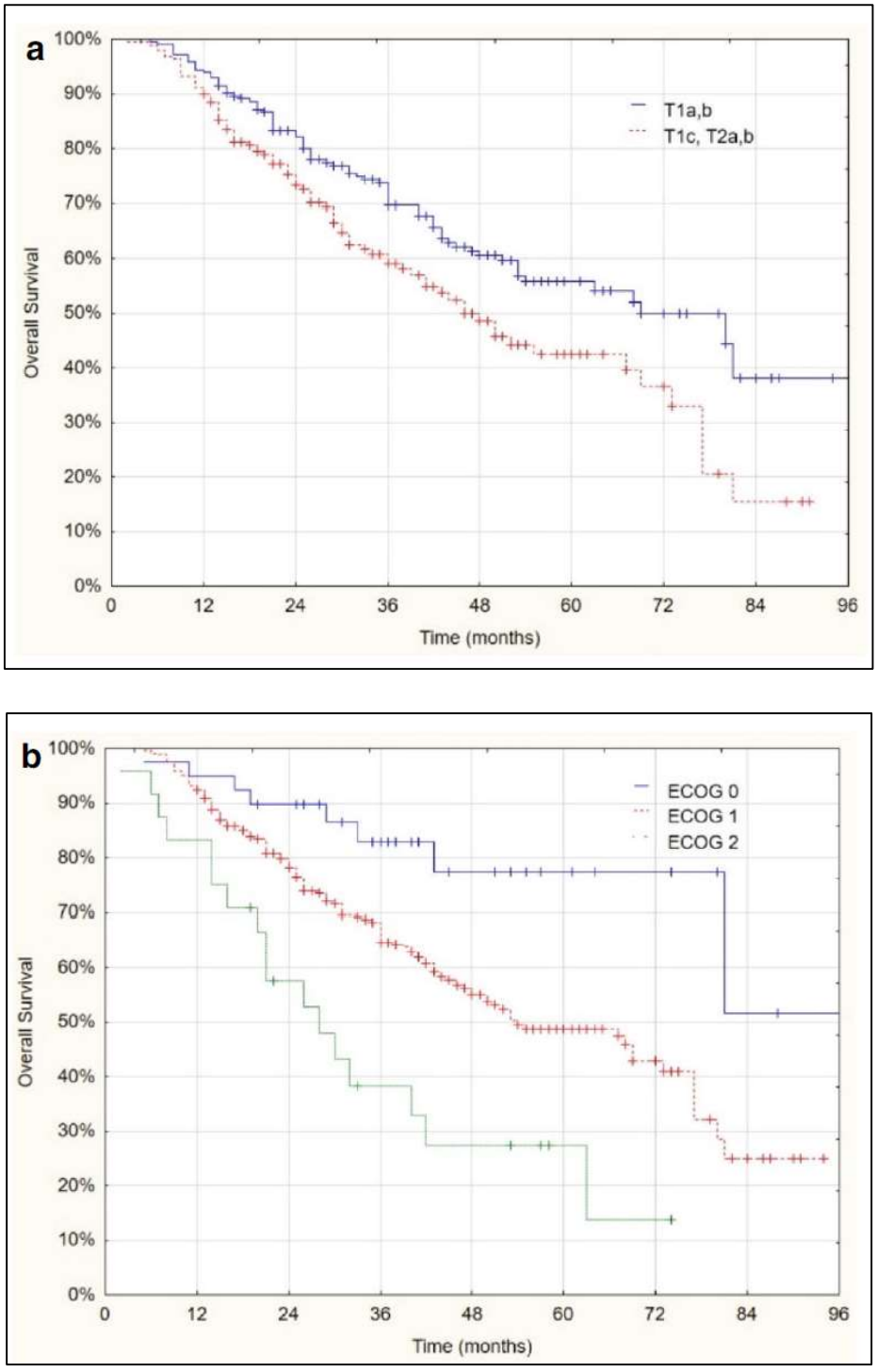

Figure 4. Study II., Kaplan–Meier curves of overall survival, **a)** T stage 1a,b vs. T1c, T2a,b (p= 0.0044) and **b)** ECOG performance status (p= 0.0005)

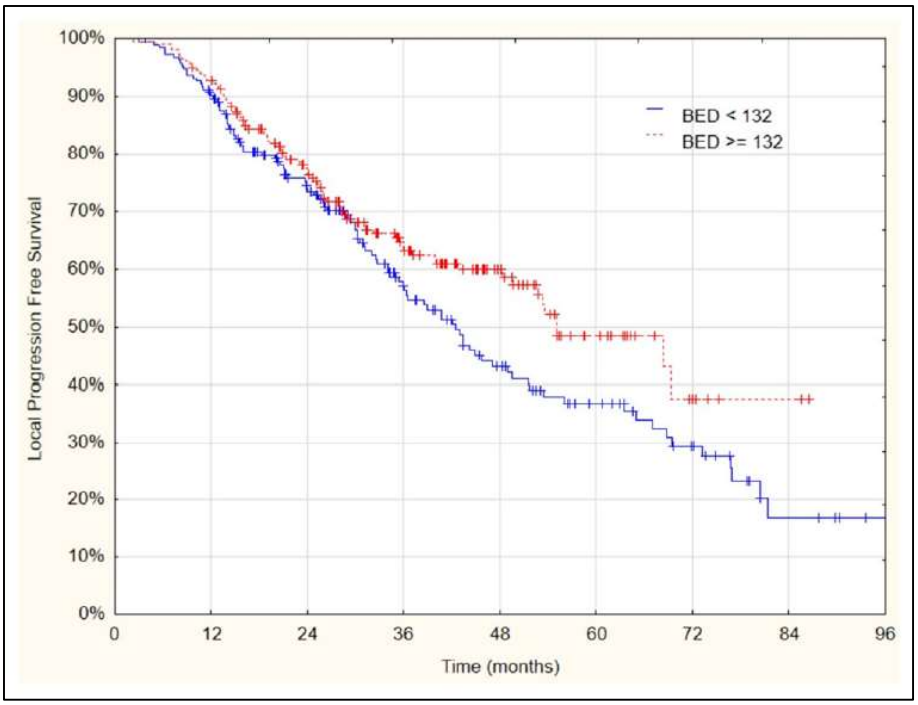

Figure 5. Study II. Kaplan–Meier curves of local progression-free survival as a function of biologically effective dose (*BED*) <132Gy vs. ≥132Gy (p= 0.046)

Analysis of Study II. did not show any significant difference between biopsy proven group, and that with unknown histology with regard to LC, LPFS, PFS and OS.

4.3. Evaluation of toxicities of Study I. and II.

Both studies confirmed low rates of severe adverse events after lung SBRT with 0-2 % of acute-, and 4-5% of late toxicities ≥ Grade 3. Among mild-moderate toxicities, pulmonary fibrosis was the most common late side effect (10.8 and 32%).

6. Conclusions

Based on two large-scale retrospective studies, with a total of 531 patients and 561 tumors, our results confirm the clinical effectiveness and safety of stereotactic

radiotherapy in primary and secondary lung malignancies. To our best knowledge, Study II. represents the largest cohort analysis on SBRT of early-stage primary lung cancer in Hungary, and also amongst the largest series reported so far in Europe.

1. In Study I. we analysed the clinical effectiveness CyberKnife-based robotic SBRT on 130 patients with 160 lung lesions, representing a mixed population of primary, recurrent or metastatic origin, with focus was on the investigation of local effectiveness. Promising LC and OS rates were in line with corresponding literature.

2. In Study II. we investigated clinical results of 401 patients of T1-2 N0 M0, early-stage primary lung tumors treated with either LINAC or CyberKnife. During our analysis we observed outstanding local control rates, and good LPFS, PFS and OS rates. Our results were coherent with findings of other workgroups in international comparison.

3. Analysis of data of Study I. showed negative predictive value of metastatic origin, proven histology and larger planning target volume (PTV) on local control.

Analysis of data of Study 2. revealed positive predictive value of smaller tumor size (T1a, b vs T1c, T2a,b) and better (lower) ECOG performance status score on overall survival and applied dose of ≥132 Gy BED_{10} on local progression-free survival. Application of doses of BED≥ 132Gy was associated with an advantage of more than 12 months median, and 6 % of 3-year local progression free survival, compared to lower doses-group.

4. Our results were controversial between Study I. and II. concerning the potential effect of proven vs unknown histology on LC. Nevertheless, the significantly larger and more homogenous cohort-based analysis of Study II. did not show difference between the two groups neither in terms of LC, nor of LPFS, PFS and OS, supporting the continuation of SBRT in patients without pathological confirmation.

5. Both Study confirmed lung SBRT to be a well tolerable treatment method, with low rates of severe acute and late toxicities.

6. In both studies, but especially in Study II. diversified dose levels were applied, with 3 major regimens of 3x18 Gy, 5x12 Gy and 8x7.5 Gy, with further possibility of slight dose-reduction, individually, in case of conflict with nearby organs at risk. Our globally high rates of clinical effectiveness alongside with low rates of severe adverse event in a real-life cohort of a large, consecutive patient cohort of more than 400 patients, validating the safe and effective application of risk-adapted SBRT approach.

6. Bibliography of the candidate's publications

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