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CLINICAL STUDY OF ADAPTIVE PROSTATE BRACHYTHERAPY WITH I-125 IMPLANTS BASED ON RADIOLOGICAL FINDINGS. RESULTS ON EARLY AND LATE TOXICITY AND ONGOING CHALLENGES

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Key words: LDR prostate brachytherapy, I-125 seeds, adaptive prostate brachytherapy, early radiation toxicity, late radiation toxicity.

Summary

Introduction. It's about three decades when prostate brachytherapy with radioactive implants has been performed in cancer treatment practice. The transrectal ultrasound guidance let this method to develop and to become more and more usable. According ESTRO/EAU/EORTC recommendations – dose to the target (prostate) must be 145 Gy or higher . It is essencial condition to reach good treatment results. Consolidation of various MRI regimes (T2, MRI diffusion, perfusion, spectroscopy) can give us this information ,which nor other method can. Because of this we can use multiparametrical MRI not for only diagnostic but also brachytherapy planning purposes. We define adaptive radiotherapy or brachytherapy as radiation tumour treatment, when radiation dose is delivered to the exact tumour (focal therapy) or when there are several volumes with different radiation doses. According to the literature – prostate brachytherapy with I-125 implant is not part of adaptive prostate treatment protocols, but technically is possible and could be an ideal method of adaptive prostate cancer treatment.

Objectives. In 2010 in Vilnius University Institute of Oncology (VUOI) we initialized clinical study called "Adaptive prostate cancer treatment with I-125 implants, safety and efficacy study". It is open prospective non-randomized study. In this review we will concentrate on giving the early and late radiation toxicity results of our study and shortly deliver some our experience about impact of US and MRI in prostate tumour diagnosis and treatment with adaptive I-125 brachytherapy.

Methods and materials. From July 2011 until December 2013 52 (50 planned) patients who had favorable risk cancer took part in this study. The age of the patients was 49 – 75 years. Patients' T were from cT1c to cT2c. PSA level 3,13 – 14,6 ng/ml. Gleason score of all patients – 6. All these low and intermediate risk prostate cancer patients undergone the procedure of real time planned low dose rate (LDR) brachytherapy with I-125 prostate implants. During the adaptive prostate low dose rate (LDR) brachytherapy (BT) with I-125 implants we have done dose escalation 200 Gy or more to the prostate malignant lessions defined with biopsy, MRI and/or US and the dose to the other prostate area were homogeneous and reached not less than 160 Gy (from 167 Gy – to 194 Gy).

Results. This is a table with incidence and degree of early (until 6 mths. after treatment) and late (after 6 mths. after treatment) genitourinary (GU) and gastrointestinal (GI) toxicity of adaptive prostate LDR BT study (Table).

Conclusions. Acute GU toxicity is presenting in all patients, but there are very low count of III toxicity. Late grade II GI toxicity manifested with blood traces in faeces, which were managed with medicines. Late toxicity rates of our study is similar to those demonstrated by other authors. Still

Degree of toxicity	Incidence of GU toxicity, percent (n)		Incidence of GI toxicity, percent (n)	
	Early	Late	Early	Late
I	76 (40)	30 (16)	15 (8)	not observed
II	13 (7)	13 (7)	13 (7)	11 (5)
III	11 (5)	not observed	not observed	not observed

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our adaptive brachytherapy methodic is very new ground in brachytherapy and the count of patients either follow up period is very short, so we should keep on doing this technique and keep on going with follow up of these patients to get more confident results on toxicity.

PSA dynamics, quality of life and benefits of MRI and US for our method remains the main questions to answer in our early future articles.

Introduction

It's about three decades when prostate brachytherapy with radioactive implants has been performed in cancer treatment practice (1). The transrectal ultrasound guidance let this method to develop and to become more and more usable. For now, we can find some reliable, even long term, data about results of prostate brachytherapy with so called seed's (I-125 implants). By the data given in articles of the leading radiotherapy sources the survival without biochemical progression (BFFS – biochemical failure free survival) reaches 80% – 90% in 8 – 10 years period for low risk prostate cancer patients treated with I-125 seeds (2), (3), (4). According these results, brachytherapy is equal to the radical prostatectomy. 5 – 10 years BFFS for intermediate risk cancer patients treated with I-125 seeds is above 80% (5), (6), (7), (8). These investigations also demonstrates direct correlation between D_p 90 (dose devired to the 90% of the prostate volume) and BFFS (6), (7), (9). Prostate brachytherapy with I-125 implants has ESTRO/EAU/EORTC recommendations (10). According these recommendations – dose to the target (prostate) must be 145 Gy or higher . It is essential condition to reach good treatment results.

In nova days we have modern methods for the visualization of prostate cancer. We use transrectal ultrasound regimes – dopler, sonoelastography, CEUS (14), (15), (16). The main method that gives information about tumour localization, stage (tumour relation with prostate capsule) and even level of tumour malignancy (PI-RADS) is multiparametrical MRI. Consolidation of various MRI regimes (T2, MRI diffusion, perfusion, spectroscopy) (17), (18), (19), (20) can give us this information ,which nor other method can. Because of this we can use multiparametrical MRI not for only diagnostic but also brachytherapy planning purposes (as we will demonstrate below).

Adaptive radiotherapy or brachytherapy – radiation tumour treatment, when radiation dose is delivered to the exact tumour (focal therapy) or when there are several volumes with different radiation doses (dose painting). Both - focal therapy and dose painting has the same main objectives. First is dose escalation to the tumour and second – preservation organs at risk as much as possible. For both these options of treatment, precise radiological visualization of the tumour is crucial for better results. Dose escalation, dose painting is often used in external beam radiotherapy (IMRT – intense modulated RT, IGRT – image guided RT) (11). There's poor data about dose escalation in the radiologically visualized tumour using I-125 prostate implants (adaptive brachytherapy). Dose escalation in the tumour with I-125 seeds should improve treatment results as seen in dose escalating using EBRT (11, 12). According to the literature – prostate brachytherapy with I-125 implant is not part of adaptive prostate treatment protocols yet, but technically is possible and could be an ideal method of adaptive prostate cancer treatment (12).

In 2010 in Vilnius University Institute of Oncology (VUOI) we initialized clinical study called "Adaptive prostate cancer treatment with I-125 implants, safety and efficacy study". It is open prospective non-randomized study. The main aim of the study is:

- Evaluate BFFS rate for patients after adaptive prostate brachytherapy with I-125 implants, which was performed in accordance with Radiological US and MRI findings. These data we hope to present in later reviews, because short follow up at present.

Other goals is:

- Evaluate early and late radiation toxicity. This is the question, that we will discuss in this article,
- Evaluate life quality after treatment,
- Evaluate the meaning and contribution of US and MRI findings in defining the tumour and planing adaptive brachytherapy with I-125.

In this review we will concentrate on giving the early and late radiation toxicity results and shortly deliver our experience about impact of US and MRI in prostate tumour diagnosis and treatment with adaptive I-125 brachytherapy.

Methods and materials

We planned to involved about 50 prostate cancer patients in this study.

Inclusion criteria of the study:

- First time diagnosed low (T1c – T2a + Gleason <=6) or intermediate (T2b – 2c + Gleason 7 + PSA 10–20) risk prostate cancer patients.
- Age – 40–75 years.

Exclusion criteria of the study:

- Anamnesis of the other malignant disease and previous radiation therapy or chemotherapy.
- ECOG > 2 or other serious diseases or conditions which could cause worsening of patients status during

brachytherapy procedure.

- Volume of the prostate > 60 ml.
- Metastatic prostate cancer.
- Previous antiandogen or other hormonotherapy.
- Anamnesis of prostate invasive procedure.
- An indication to irradiate pelvic lymph nodes.

From July 2011 until December 2013 52 (50 planned) patients who had favorable risk cancer took part in this study. The age of the patients was 49 – 75 years. Patients' T were from cT1c to cT2c. PSA level 3,13 – 14,6 ng/ml. Gleason score of all patients – 6. All these low and intermediate risk prostate cancer patients undergone the procedure of real time planning low dose rate (LDR) brachytherapy with I-125 prostate implants.

Low dose rate (LDR) brachytherapy procedure was performed according ESTRO/EAU/EORTC recommendations (10). In addition all 52 patients, according to the study protocol, had diagnostic procedures which included pelvic MRI various regimes (T2, MRI diffusion, perfusion) and transrectal ultrasound regimes – dopler, sonoelastography. On the basis of MRI and US radiological findings also according previous prostate biopsy results we judged about places of suspected malignant lesions in prostate. Dose escalation was performed into the suspected malignant lesions – adaptive prostate brachytherapy.

In the next paragraph we will describe the methodic of adaptive LDR BT procedure we performed for our study patients. LDR prostate brachytherapy is based on transperineal implantation (implantation of the needle applicators through the perineum), guided by transperineal ultrasound [9]. Brachytherapy planning methods can be planning before the procedure (preplaning) or planning during the procedure (real time planning). Real-time scheduling technique we use is far superior, because the correction of the contours during the implantation procedure is necessary to ensure the quality of the implant. The prostate volume determines the quantity and activity of J-125 implants required for the patient. One implant activity ranging from 0.3 to 0.5 mCi.

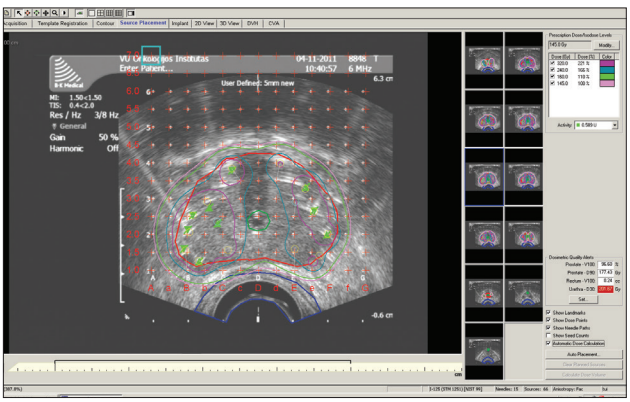

Fig.1. Dose escalation area to the suspected malignant lesions contoured in pink

Prostate brachytherapy with J-125 implants are performed under general anesthesia. Before the procedure patient undergoes intestine cleaning procedure including enema etc. Patient lies on the brachytherapy table in extended lithotomy position (supine, legs are bent 90 degrees over hip joints). A special locking system is mounted on the operating table a on which the transrectal USG detector is placed. It is inserted into the rectum. Bladder catheter is inserted into the urinary bladder. Prostate scanned in transversal plane (every 5 mm) and images are transferred to the planning system. Defined target (prostate) and critical structures (rectal wall, urethra). Planning system are scheduled for optimal needle penetrating and implant positions. When the peripheral needles (applicators) are inserted, the prostate contour is adjusted again, depending on the contour changes of target and critical structures. After peripheral implants, inner needles and implants inserted to ensure a homogeneous dose distribution and the adequate doses to target and critical structures. The framework outlines during the procedure can be adjusted as many times as necessary to ensure the quality of implantation procedure. We use loose I-125 implants for implantation.

As mentioned earlier at first we perform prostate LDR BT according to ESTRO/EAU/EORTC [1] recommendations on permanent seed implantation for localized prostate cancer. D 90 (dose covering 90 per cent. of prostate volume) - 145 Gy, V 100 (prostate volume, which receives a 100 per cent. of prescribed dose) - 95 - 100 percent., D_u30 (dose which receives 30 per cent. of urethra) ≤ 200 Gy, V_R 100 (rectal volume, which receives a 100 per cent. of prescribed dose) ≤ 0.5 cm 3. During the adaptive prostate LDR BT with I-125 implants we have done dose escalation 200 Gy or more to the prostate malignant lessions defined with biopsy, MRI and/or US (Fig. 1), and the dose to the other prostate area were homogeneous and reached not less than 160 Gy (from 167 Gy – to 194 Gy).

The follow up of the patients was performed after the procedure. Follow up included - as was mentioned earlier - PSA level, late and early radiation toxicity, quality of life of the patients.

Results

With this article we want to report the results of the early and late toxicity observed after adaptive prostate brachytherapy using I-125 implants. Treatment toxicity as-

Table 1. Incidence and degree of early (until 6 mths. after treatment) and late (after 6 mths. after treatment) genitourinary and gastrointestinal toxicity of adative prostate LDR BT study

Degree of toxicity	Incidence of GU toxicity, percent (n)		Incidence of GI toxicity, percent (n)	
	Early	Late	Early	Late
I	76 (40)	30 (16)	15 (8)	not observed
II	13 (7)	13 (7)	13 (7)	11 (5)
III	11 (5)	not observed	not observed	not observed

Table. 2. Late toxicity after LDR prostate BT

Author	Patient n	Median follow up (moths)	GU toxicity II*, %	GI toxicity (max. II*), %
Zelefsky et al. (21)	367	63	23	9
Zelefsky et al. (22)	562	40	21	7
Eade et al. (23)	158	48	14	8
Martin et al. (24)	396	60	31	0
Gaudet et al. (25)	190	36	30	1
Zilly et. al. (26)	130	34	21	0
Lawton et al. (27)	93	63	23	5

sessment was performed every 3 moths on the first year after treatment and then every 6 moths. Toxicity was graded according to the Radiation Therapy Oncology Group/European Organization for Research and Treatment of Cancer radiation morbidity scoring system. Table 1.

It is noticeable, that all 52 patients experienced early toxicity, but mostly grade I. Also, no III late toxicity was observed. GI toxicity rate was low, late grade II GI toxicity manifested with blood traces in faeces, which were managed with medicines. 1 patient had to undergo transurethral resection TUR) because of chronic urine retention, caused by urethral stricture.

If talking about PSA results, which shows treatment efficacy – no cases of biochemical failure were observed during follow up period (min. 4 months, max. 32 months). Details about PSA dynamics would be presented in upcoming articles.

Discussion

There are a lot of papers considering low dose rate prostate brachytherapy toxicity. Focus of attention in most of them is on the late toxicity. That is because acute toxicity is typical to almost all patients treated either with LDR brachytherapy or those with external beam radiotherapy. If talking about late toxicity – it is more objective indicator of treatment quality (26). Some results are displayed in table 2.

Conclusions

From data on toxicity that we have from adaptive low dose prostate brachytherapy we can say that:

1. Acute GU toxicity is presenting in all patients, but there are very low count of III toxicity.

2. Late grade II GI toxicity manifested with blood traces in faeces, which were managed with medicines.

3. Late toxicity rates of our study is similar to those demonstrated by other authors.

4. Still our adaptive brachytherapy methodic is very new ground in brachytherapy and the count of patients either follow up period is very short, so we should keep on doing this technique and keep on follow up to get more confident results on toxicity.

5. PSA dynamics, quality of life and benefits of MRI and US for our method remains the main questions to answer in our early future articles.

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PRITAIKOMOSIOS PROSTATOS BRACHITERAPIJOS GYDYMO I-125 IMPLANTAIS, REMIANTIS RADIOLOGINIAIS TYRIMAIS, KLINIKINIS TYRIMAS. ANKSTYVŲJŲ IR VĖLYVŲJŲ SPINDULINIŲ REAKCIJŲ REZULTATAI IR ATEITIES IŠŠŪKIAI

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Raktažodžiai: MDG prostatos brachiterapija, I-125 sėklos, pritaikomoji prostatos brachiterapija, ankstyvosios spindulinės reakcijos, vėlyvosios spindulinės reakcijos.

Santrauka

Įvadas. Jau beveik tris dešimtmečius pasaulyje atliekama prostatos brachiterapija radioaktyviais implantais transrektalinio UG kontrolėje. Įdiegus transrektalinę UG kontrolę, ši metodika pradėjo sparčiai vystytis. Prostatos brachiterapija J-125 implantais atliekama Pagal ESTRO/EAU/EORTC rekomendacijas - dozė, kuri skiriama į prostatą, turi būti ne mažesnė kaip145 Gy. Ši dozė būtina geresniems rezultatams pasiekti.

Įvairių magnetinio rezonanso režimų (T2, perfuzijos, difuzijos, spektroskopijos) derinimas gali suteikti daugiau informacijos nei bet kuris kitas tyrimo metodas. Todėl mes galime panaudoti multiparametrinio magnetinio rezonanso tomografijos duomenis ne tik diagnostiniu, tačiau ir prostatos brachiterapijos planavimo tikslu. Pritaikomąja spinduline terapija arba brachiterapija vadiname tokią metodiką, kai spindulių dozė skiriama tik į naviką (fokalinė terapija) arba, kai yra keli tūriai, gaunantys skirtingas dozes (didesnė papildoma dozė į navikinį audinį). Literatūros duomenimis, prostatos brachiterapija J-125 implantais nėra standartinis gydymo metodas, tačiau techniškai galima, ir būtų idealus metodas pritaikomajam gydymui realizuoti.

Pritaikomosios terapijos metodai, kurie yra taikomi šiuo metu yra HIFU, krioterapija, fotodinaminė terapija. Yra prospektyvinių analizių, taikant pritaikomąją krioterapiją, kurios parodė šio metodo privalumus apsaugant kritinius organus (genitourinarinės sitemos apsauga siekė 90% - HIFU, 85% - krioterapijos atveju) (13).

Spindulinių reakcijų laipsnis	GU reakcijų dažnumas, proc. (n)		GI reakcijų dažnumas, proc. (n)	
	Ankstyvosios	Vėlyvosios	Ankstyvosios	Vėlyvosios
I	76 (40)	30 (16)	15 (8)	nestebėta
II	13 (7)	13 (7)	13 (7)	11 (5)
III	11 (5)	nestebėta	nestebėta	nestebėta

Siekiant eskaluoti dozę vizualizuotame navike dažnai naudojami išoriniai spindulinės terapijos metodai (IMRT, IGRT) bei individualizuotas pritaikomasis planavimas (11). Yra mažai duomenų apie dozės padidinimą vizualizuotame navike taikant prostatos brachiterapiją J-125 implantais. Dozės padidinimas navike (karšto taško atsiradimas) turėtų pagerinti ir gydymo efektyvumą, kaip ir eskaluojant dozę išorinio spindulinio gydymo metu (11, 12). Dozės eskalavimas daugiau kaip 140 Gy, literatūros duomenimis, pailgina laiką iki biocheminio recidyvo. Spindulinių reakcijų, eskaluojant dozę į prostatą, nedaugėja, jei neviršijama kritinių organų dozė.

Tikslai. 2010 Vilniaus universiteto Onkologijos institute (VUOI) (dabar – Nacionalinis vėžio institutas) mes pradėjome klinikinį tyrimą "Prostatos vėžio pritaikomojo gydymo J-125 implantais saugumo ir efektyvumo tyrimas". Tai atviras prospektyvinis nerandomizuotas klinikinis tyrimas. Šiame straipsnyje apibendrinamos mūsų taikyto metodo ankstyvosios ir vėlyvosios spindulinės reakcjos. Taip pat trumpai aptariama tyrimo patirtis taikant MRT, UG tyrimus prostatos navikų diagnostikai ir gydymui, taikant pritaikomąją prostatos brachiterpiją I-125 implantais.

Tyrimo metodika ir medžiaga. Nuo 2011 metų liepos iki 2013 metų gruodžio į tyrimą įtraukti 52 minimalios ir vidutinės rizikos grupės prostatos vėžiu sergantys pacientai (planuota 50). Pacientų amžius - nuo 49 iki 75 metų. Pacientų T buvo cT1c - cT2c. PSA rodiklis 3,13 – 14,6 ng/ml. Gleason – 6. Visiems šiems minimalios ir vidutinės rizikos grupės prostatos vėžiu sergantiems pacientams buvo atlikta pritaikomoji mažos dozės galios (MDG) prostatos brachiterapija (BT) I-125 implantais, planuojant realiu laiku. Į biopsijos bei MRT ir/ar UG metu prieš procedūrą nustatytas įtariamas naviko vietas šios procedūros metu dozė padidinta (eskaluota) iki 200 Gy ar daugiau, o dozė į kitas prostatos sritis buvo homogeniška ir siekė ne mažiau 160 Gy (nuo 167 G iki 194 Gy).

Rezultatai. Lentelėje parodyta spindulinių ankstyvųjų (iki 6 mėn. po implantacijos) ir vėlyvųjų (po 6 mėn. po implantacijos) genitourinarinių (GU) ir gastrointestininių (GI) reakcijų dažnumas ir lapsnis taikant prostatos pritaikomąją MDG BT (lentelė).

Išvados. Ankstyvosios spindulinės GU reakcijos pasireiškė visiems tiriamiesiems, tačiau stebėtas labai nedidelis III laipsnio ankstyvųjų spindulinių GU reakcijų dažnis.

II laipsnio vėlyvosios GI spindulinės reakcijos pasireiškė kraujo pėdsakais išmatose. Jos buvo sanuotos vaistais.

Mūsų tyrime vėlyvųjų spindulinių reakcijų laipsnis ir dažnumas yra panašus į literatūroje pateiktus duomenis. Tačiau pritaikomoji prostatos brachiterapija yra nauja metodika, pacientų skaičius ir stebėjimo laikotarpis yra dar labai trumpi, todėl mes turime tęsti taikyti šią metodiką ir pacientų stebėjimą, kad gautume patikimesnius gydymo toksiškumo rezultatus.

PSA dinamika, pacientų gyvenimo kokybės klausimai bei MRT ir UG tyrimų reikšmė, taikant mūsų metodiką, yra pagrindiniai kitų artimoje ateityje planuojamų straipsnių klausimai.

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